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Chemicals Management Center



Chemical substances and our lives

Products around us, such as detergents and paints, are developed using the characteristics of chemical substances in order to fulfill a function for their respective purposes. Chemical substances, which constitute foods and naturally occurring things, support our convenient and rich lives.

Chemical substances are released into the environment during synthesis, refining, processing into products, transportation, consumption, and disposal. Chemical substances are taken into our bodies from environmental media, such as air and water, and through consumption or use of foods and products processed or manufactured using the substances. If the amount of a chemical substance exceeds a certain threshold, it may affect human health and ecosystem.

What is chemicals management...

We must understand and appropriately manage chemical substances in order to use them for our convenient and rich lives while using care with human health and ecosystem and without sacrificing safety. To this end, it is necessary to anticipate that people and ecosystem will be exposed to chemical substances throughout the product life cycle from synthesis of chemical substances themselves to processing into and disposal of products, and when they are released into environment media, such as air and water. It is necessary to assess their risks based on their natures and exposures and to manage and reduce those risks appropriately considering the results in order to prevent adverse effects on human health and ecosystem.

It is also important to share information among the interested parties such as the public, business operators, and government in the process and proceed with chemicals management throughout the entire society.

Toward appropriate chemicals management

Laws related to chemicals management have been set up to prevent adverse effects of chemical substances on the environment and human health in various cases of life cycles and exposure routes. From technical aspects. NITE supports to facilitate the enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc.; the Japanese Chemical Substances Control Law (CSCL), which contains legal requirements for chemical substances that may pose risks to human health and ecosystem. NITE also provides technical supports to implement the Act on confirmation etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof: the Japanese Pollutant Release and Transfer Register (PRTR) Law, which promotes voluntary managements of chemical substances by business operators handling chemical substances.

NITE also performs on-site inspections and witnessing of international inspections based on the Act on the Prohibition of Chemical Weapons and the Regulation of Specific Chemicals (Chemical Weapons Act).

In addition, 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 arranges the technology infrastructures for "chemicals management" and plays important roles for appropriate management of chemical substances considering international cooperation through these activities.



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Roles in Act Enforcement on Chemicals Management

From technical aspects, NITE supports the enforcement of "Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL)," "Act on the Prohibition of Chemical Weapons and the Regulation of Specific Chemicals (Chemical Weapons Act)," and "Act on confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (Law concerning Pollutant Release and Transfer Register; PRTR Law)."



1. Operations Related to Chemical Substances Control Law

Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc.

Abbreviation: Chemical Substances Control Law (CSCL)

The purpose of the Chemical Substances Control Law (CSCL) is to prevent environmental pollution caused by chemical substances that may impair human health or inhabitation or development of animals and plants. It contains regulatory requirements for manufacturing, import, and the use of chemical substances according to their properties. It requires newly developed chemical substances to be reviewed in terms of properties before marketing, in conjunction with their manufacturing and importing. It also requires control measures to be continuously implemented on the chemical substances according to their properties once they are put on the market.

In 1973, the act was enacted in the wake of the environmental pollution problem caused by PCB (polychlorinated biphenyl). Initially, it regulated chemical substances similar to PCB in terms of properties (persistence, high bioaccumulation, and long-term toxicity on human). Later, however, it was extensively revised several times to cover additional chemical substances similar to tetrachloroethylene, cleaning solvent, in terms of properties (persistence, low bioaccumulation, and long-term toxicity in humans), and chemical substances similar to dichlorvos, white ant exterminating agents, in terms of properties (persistence and impairment of development/inhabitation of animals and plants). The law was revised in 2009 to implement a chemical substance control scheme where the existing chemical substances⁻¹ that had not been earlier subject to control and the substances that the government should assess in priority from the viewpoint of their risks for appropriate control were designated as "general chemical substances"² and "priority assessment chemical substances"³ respectively (for the system diagram of CSCL, see its overview on page 6).

NITE is engaged in many different activities; it provides contact service to business operators for notification of new chemical substances under CSCL, checks the reported volumes of chemical substances manufactured or imported, performs screening assessment of general chemical substances and risk assessments of priority assessment chemical substances, provides technical consulting service about CSCL requirements to manufacturers and importers, inspects laboratories for compliance with GLP guidelines (GLP⁻⁴ facilities), performs on-site inspections of manufacturers and importers, and proposes technical assessment methodologies, including risk assessment and structure-activity relationship ones.

*1 Existing chemical substances: Chemical substances that had been already commercially available in Japan before 1973 when CSCL was enacted.

*2 General chemical substances: Chemical substances listed in the CSCL, excluding class I and II specified chemical substances, monitoring chemical substances, and priority assessment chemical substances

*3 Priority assessment chemical substances: Chemical substances for which the possibility of posing any risk to humans, animals, plants, or the living environment cannot be excluded and detailed risk assessments are estimated to be required given the findings on toxicities of general chemical substances and their manufacturing and import.

*4 GLP: Good Laboratory Practice

Operations related to the reviews of New Chemical Substances, etc.

NITE supports review operations such as preliminary consultation for notifications of new chemical substances, communication of findings of reviews, consultation/communication with notifiers, and creation of explanatory materials in committees. In addition, in order to help more efficiently review new chemical substances, NITE has in place a database (three-ministerial joint chemical substance database) containing safety test data of new chemical substances submitted according to the applicable laws, council reviews, and more. The database is used to organize information necessary for new chemical substance reviews and prepare documents for safety reviews.

Besides, in order to help consider possible improvements of CSCL processes (shortening review time, simplifying testing and evaluation methods, etc.), NITE organizes and analyzes test data on degradability, bioaccumulation and more of new and existing chemical substances as deliberated earlier. It also works with the Ministry of Economy, Trade and Industry's efforts to streamline the review processes on new chemical substances.

Inspections of GLP facilities

CSCL stipulates that the safety test data used in the reviews of new chemical substances, etc. should be obtained at a facility compliant with Good Laboratory Practice (GLP). NITE inspects these GLP test facilities to secure the quality and global harmonization of the safety test data.

On-site inspections

CSCL allows to skip notification and review by making an application in advance and having its contents confirmed if it is determined that there is no risk of environmental pollution in manufacturing, etc. of any new chemical substances. For example, manufacturing and import of such substances to be used as intermediates⁻⁵ correspond to such cases. NITE performs confirmation of the documents submitted in such applications and on-site inspections to confirm the application contents of business operators who perform manufacturing, etc.

*5 Intermediates: collectively designates intermediates, substances intended for use in closed systems, and products dedicated for export.

Support for commonality of the nomenclature between CSCL and the Industrial Safety and Health Act

To manufacture or import any new chemical substances, business operators need to make the notification of the new chemical substances as prescribed in CSCL as well as that as prescribed in the Industrial Safety and Health Act. The names of new chemical substances notified as prescribed in these laws are designated according to each of the laws. NITE proposes designations for those chemical substances. Although their designated names are given based on the IUPAC nomenclature system, 6 single chemical substances may have different regulatory designations depending on the applicable laws, which occasionally brings unnecessary inconveniences to business activities in the field. Therefore, in order to solve this problem, NITE supported the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry in creating commonality rules of the nomenclature between CSCL and the Industrial Safety and Health Act. In 2013, when the IUPAC published the Nomenclature of Organic Chemistry (2013 Recommendation) that listed PINs,^{*7} NITE supported the Chemical Society of Japan in translating the recommendation into the Japanese language. NITE also submitted recommendations for implementing the 2013 Recommendations in CSCL and the Industrial Safety and Health Act to relevant ministries, leading to the promulgation of a notification.^{*8} In this way. NITE provides technical supports in areas of identifying and naming chemical substances.

*6 IUPAC nomenclature system: Compound naming system established by the International Union of Pure and Applied Chemistry (IUPAC)

*7 PIN: Preferred IUPAC name. The name is preferentially given to a chemical structure. It is effectively a unique name.

nomenclature for new chemical substances in bulletins issued according to the Industrial Safety and Health Act and the Chemical Substances Control Law

^{*8} Notification dated July 11, 2017, by the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment, titled "Changes in

Operations related to risk assessments of chemical substances

Risk assessments under CSCL are composed of three general steps: screening assessment, primary risk assessment, and secondary risk assessment. The screening assessment step identifies the chemical substances that may not pose a sufficiently low risk. Those substances (priority assessment chemical substances) are further assessed for risk with reference to different kinds of collected data to determine whether they should be listed in the class II specified chemical substances or whether their status as priority assessment chemical substances should be canceled.

As the core institution of risk assessments under CSCL, NITE supports the regulatory authorities in implementing CSCL, checks and aggregates notification data on annual manufacturing and import volumes and more, develops emission factors for estimating the release into the environment and estimates the release, estimates exposure levels and risks to human and ecosystem, proposes risk assessment methods and provides risk assessment tools.

Operations related to notifications of annual manufacturing and import volumes, etc.

Business operators submits reports on manufacturing and import volumes of general chemical substances, priority assessment chemical substances and monitoring chemical substances. NITE links Class Reference Numbers in the Gazette List (MITI Numbers) and CAS Registry Numbers (CAS RN®)⁹ and makes the linked information publicly available as dictionary files. The files are used by the notification support software to prepare the manufacturing/import reports on the general chemical substances etc. as defined in CSCL. In addition, NITE performs technical checks on the manufacturing/import volumes and use as reported by business operators, and processes and aggregates information for screening and risk assessments.

*9 CAS Registration Numbers (CAS RN®): A unique number assigned to a chemical by the Chemical Abstracts Service, which is an organization of the American Chemical Society (For example, the CAS Registration Number (CAS RN®) for acrylonitrile is 107-13-1)

Arrangement of emission factors to estimate the released amounts into the environment and estimation of the released amounts

NITE examines and develops emission factors, which are required to estimate released amounts of chemical substances into the environment. NITE estimates the released amount into environmental media (air and water) for each chemical substance by multiplying the annual manufacturing and import volumes and use categories by these factors.

Estimation of exposure and risks to human and ecosystem

NITE estimates the exposure levels of humans to chemical substances through drinking, eating and breathing and those of flora and fauna in the human living environment (aquatic lives etc.) from their released amounts into environmental media (air and water). NITE also estimates the risks to humans and flora and fauna in the human living environment by comparing exposure levels and toxicity information using the risk assessment tool developed by itself. In addition, NITE addresses the issues related with the screening and risk assessment methods and steps for the mixtures whose components are difficult to identify and surfactants with unique properties.

Proposal of risk assessment methods and provision of risk assessment tools

NITE creates technical guidance documents which describe the risk assessment methods of CSCL and proposes them to the government.

In addition, NITE developed and published a risk assessment tool (PRAS-NITE^{*10)}, which complied with the risk assessment method described in the technical guidance documents. The assessment tool allows you to use the formula equivalent to those of Assessments I and II of primary risk assessments for calculation. The tool is useful for business operators' chemicals management activities such as



voluntary chemicals management, risk communication with local residents, and information offering to the outside

The technical guidance documents and CSCL risk assessment tool (PRAS-NITE), whose drafts were created by NITE, are available at our website.

https://www.nite.go.jp/chem/risk/kasinn.html

*10 PRAS-NITE: A tool developed by NITE to support risk assessment of priority assessment chemical substances

Overview of the Chemical Substances Control Law



Initiatives to promote use of alternative methods to animal testing (QSAR, Read-across, IATA, etc.)

Alternatives to animal testing refer to the methods of evaluating the safety of chemical substances using cell testing and computer prediction software instead of traditional animal testing. The use of alternatives to animal testing is promoted internationally and led by the OECD in order to increase the efficiency of chemical safety evaluations and animal welfare. NITE also contributes to promoting the use of alternatives to animal testing, including QSAR^{*11}, Read-across^{*12}, and IATA^{*13} to evaluate the safety of chemical substances.



*11 Quantitative Structure-Activity Relationship (QSAR): A method that uses mathematical models to estimate the toxicity of chemical substances based on their chemical structures.

*12 Read-across: A method to estimate the toxicity of chemical substances from their structural analogues with test data based on expert judgement. The Japanese translation of the term is "ruisui," which means "analogy."

*13 Integrated Approached and Testing Assessment (IATA): An approach that integrates different types of information to evaluate the hazards of chemical substances and develop testing strategies.

Use of alternatives to animal testing for CSCL processes

NITE works on the validation of the predictivity of existing QSAR models for biodegradability and bioaccumulation, and social implementation of the highly accurate biodegradability QSAR prediction system, which is driven by the state-of-the-art AI (deep learning) technology. The system was developed as a part of a service contract with the Ministry of Economy, Trade and Industry.

Support to Business Operators

Based on the knowledge gained through regulatory reviews under CSCL and OECD activities (p.14), NITE supports business operators in learning how to use alternatives to animal testing. Specifically, NITE provides the following:

- Organizes free training sessions on Read-across and other evaluation support tools, including OECD QSAR Toolbox^{*14}.
- Distributes explanatory materials on Degradation/Accumulation Evaluation Workflow, which involves use of QSAR and Read-across in evaluating degradability/accumulation potential for small volume new chemical substances and supportive Web-based tool (Detection Tool for Chemical Substances Structurally Similar to Class I Specified/Monitored Chemical Substances) and organizes the briefing sessions and operates preliminary consultation opportunities.
- Applies biodegradability prediction technology to develop cosmetic raw materials (joint project with Shiseido Co., Ltd. through the NICE program ^{*15}).
- Publishes Japanese translations of OECD guidance documents for alternatives to animal testing.
- *14 OECD QSAR Toolbox: Read-across evaluation support software application developed and released by the OECD. It is composed of a database on degradability, accumulation, and toxicity of chemical substances and capabilities for grouping chemical substances (free software).
- *15 NITE Innovative Collaboration Expert (NICE) program: A program operated by NITE to support the businesses in resolving the challenges to creating innovative products and services and to using the new technologies on a commercial basis.

Hazard Evaluation Support System Integrated Platform

NITE developed the world's first tool for supporting the evaluation of untested chemical substances for repeated-dose toxicity, the Hazard Evaluation Support System Integrated Platform (HESS) and its accompanying database system (HESS DB) under the sponsorship of the New Energy and Industrial Technology Development Organization (NEDO)/Ministry of Economy, Trade and Industry.¹¹⁶ The application is available for free on the NITE website.

https://www.nite.go.jp/en/chem/qsar/hess-e.html

HESS classifies chemical substances based on similarities in molecular structure and mechanism of toxicity and supports the read-across evaluation of untested chemical substances for repeated dose toxicity. The system is also compatible with the OECD QSAR Toolbox, which is made available by the OECD.



evaluation target substance.

*16 HESS was developed jointly with Fujitsu Limited, National Institute of Health Sciences, Burgas Prof. Assen Zlatarov University, Tohoku University, and Kwansei Gakuin University.

2. Operations Related to Chemical Weapons Act

Act on the Prohibition of Chemical Weapons and the Regulation of Specific Chemicals

Abbreviation: Chemical Weapons Act

The purpose of "Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (hereinafter called Convention)" is complete and effective prohibition and disposal of the development, manufacture, stockpiling, possession, transfer, and use of chemical weapons. Japan ratified it in September 1995. In May 1995, "Act on the Prohibition of Chemical Weapons and the Regulation of Specific Chemicals (Chemical Weapons Act)" was enacted in order to secure appropriate implementation of the Convention in Japan before ratifying the Convention. On the other hand, "The Organisation for the Prohibition of Chemical Weapons (OPCW)" was set up based on the Convention, which came into effect in April 1997, and started activities to achieve the purpose of the Convention such as international inspections.

NITE attends international inspections by OPCW, verifies the analysis results when any international inspectors perform an analysis, and performs on-site inspections for permitted (or approved) manufacturers and users of specific substances by order of the Minister of Economy, Trade and Industry based on the Chemical Weapons Act. Note that NITE analyzes the same samples as the international inspection mission to verify its inspection results when the mission collects and analyzes samples.



3. Operations Related to PRTR Law

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Abbreviation: PRTR Law

The PRTR Law was enacted in 1999 in order to promote improvements in voluntary management of chemical substances by business operators and prevent impediments to the environmental conservation. It is enforced with the PRTR^{*17} system and SDS^{*18} system as its pillars.

The PRTR system obligates business operators to confirm and report the amounts of chemical substances released into the environment or transferred to outside business as disposal associated with the business activities by themselves. 515 substances which may be hazardous to human health and ecosystem and are recognized to exist widely in the environment are specified as the object substances(as of 2021). Also, 24 industries are designated as those subject to notification. Following business operators that handle any designated chemical substances notifying the national government of the emissions into the environment, etc. through prefectural and municipalities, the national government adds the data of estimated emissions to the notified data, aggregates and publishes the result every year. Note that PRTR data notified of by business operators is internationally considered to be one of the achievement indicators for SDGs 12 (ensure sustainable consumption and production patterns).

The SDS system obligates the business operators to provide information on the properties and treatment of the chemical substances when transferring or providing any object chemical substances or products including such a substance to any other business operators.

NITE performs a series of operations from notification processing to creation of materials to be published in the PRTR system. NITE also makes efforts to ensure appropriate implementation of the PRTR Law by providing technical supports such as responses to inquiries about the PRTR system and SDS system from business operators, etc. and dispatch of instructors to municipalities, etc. Moreover, NITE provides PRTR data in a format that allows PRTR aggregate data to be displayed in an easy-to-understand manner on a map.

NITE also provides information related to the PRTR Law, including PRTR data-driven risk information for business operators and appropriate advice for calculating releases.

*17 PRTR: Pollutant Release and Transfer Register *18 SDS: Safety Data Sheet

Data aggregation and compiling of released amounts, etc.

NITE arranges and manages the notification management system for prefectural and municipalities and ministers having jurisdiction over the business or law in question to do processing from reception to record aggregation properly and the electronic notification system for business operators to make electronic notifications. To promote electronic notifications, NITE provides support tools that include instruction videos on how to operate the electronic notification system. In addition, NITE provides a notification preparation support system for business operators that have difficulty using the electronic notification system. It makes paper notification forms available to be efficiently processed by adding two-dimensional codes.

In addition, NITE plays a central role in the PRTR system by checking the contents of the notified data as well as recording the notification data, creating materials to be published.



Support tools to promote electronic notifications

Operations related to the PRTR system under the PRTR law



Analysis of PRTR data and provision of information

NITE provides downloadable PRTR data to help business operators improve their chemical substances management initiatives. The data is also intended to help the public deepen their understanding of the safety of chemical substances, and the pertinent authorities appropriately implement administrative management of chemical substances.

Once PRTR data is downloaded, analysis tools available in the market allow you to analyze the data and display the emissions map, which visualizes emissions by region, and concentration maps with a 1 or 5 km square mesh, which visualizes concentrations in the atmosphere according to notifications and estimations of emissions.

Provision of Information and Arrangement of **Technology Infrastructures on Chemicals Management**

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 information.

Provision of Information on Chemicals Management

NITE Chemical Risk Information Platform (NITE-CHRIP®)

NITE collects reliable information on the domestic and foreign laws and regulations related to chemicals management and the risks of chemical substances. NITE provides that information through the database "NITE Chemical Risk Information Platform (NITE-CHRIP®)" for compliance with the chemicals management laws and regulation as well as for appropriate assessments and voluntary management of risks by business operators, municipalities and people.

NITE-CHRIP[®] *It was renewed in March 2024.



https://www.chem-info.nite.go.jp/en/chem/chrip/chrip search/systemTop

NITE provides general information such as the names and CAS registration numbers (CAS RNs®), etc. of chemical substances, domestic and foreign laws and regulations information, hazard information, and exposure-related information. The data is regularly checked and updated to secure the reliability of the database. It also ensures that the database includes additional chemical substances quickly once they are included in the regulatory lists. It is committed to providing accurate information.

In addition, NITE aims to construct a very convenient system by considering the opinions of users through questionnaires, etc.

aws and Regulations in Japan	Description	Last Updated	List
Chemical Substances Control Law: Specified Chemical Substances	Data Description	2014-05-01	Download
Chemical Substances Control Law: Monitoring Chemical Substances, Type II Monitoring Chemical Substances (before amendment), Type II Monitoring Chemical Substances (before amendment)	Data Description	2014-05-01	Download
Chemical Substances Control Law Priority Assessment Chemical Substances	Data Description	2014-04-01	Download
Chemical Substances Control Law: Newly Announced Chemical Substances prescribed in Paragraph (4) of Article 4 of the Former Act	Data Description	2014-07-31	Download
Chemical Substances Control Law: Existing Chemical Substances	Data Description	1974-03-15	Download
Chemical Substances Control Law: Oberrical Substances exempt from notification of manufacturing/import.amount	Data Description	2014-03-24	Download
Chemical Substances Control Law: Biodegradation and Bioconcentration Results	Data Description	2014-03-25	Download
Chemical Substances Control Law : Toxicity Test Results	Qata Description	2014-03	Download
Act on Confirmation, etc., of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (Effective from October 1, 2009)	Data Description	2008-11-21	Download
Eormer Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvementa to the Management Thereof (Effective until September 30, 2009)	Data Description	2000-03-29	Deveload
Poisonova and Deleterious Substances Control Act	Data Description	2013-06-28	Download
Industrial Safety and Health Act : Prohibition of Manufacturing, etc.	Data	2006-08-02	Deveload

List of substances subject to laws and regulations

Chemical Substan	ices Control Law (Effective fi	rom April 1, 2011)	Data Description			
Classification	Priority Assessment/Existing/Type II Monitoring (before amendment)		2-6			
Registration No. of Priority Assessment Chemical Substance	3	Date of Designation in the Official Gazette	2011/04/01			
Priority Assessment Overnical Substance Name	n-Hexane					
Reason for Inclusion	Human Health	Human Health				
Existing Chemical Substance Name	Hexane					
Registration No. of Type E Monitoring Chemical Substance (before amendment)	1011	Dete of Designation in the Official Gazette	2010/04/01			
Type II Munitoring Chemical Substance Name (before amondmont)	n-Hexane					



Japan Chemicals Collaborative Knowledge Database (J-CHECK)

J-CHECK is the shared database developed by three ministries: the Ministry of Health, Labour and Welfare; the Ministry of Economy, Trade and Industry; and the Ministry of the Environment with the view of disseminating safety information on chemical substances listed under the Chemical Substances Control Law (CSCL). NITE maintains and operates this database.

You can check a wide variety of CSCL information separately accessible by chemical substances which is published by the government.

- Regulatory chemical substance classifications under CSCL
- Manufacturing/import volumes of general chemical substances and priority assessment chemical substances Screening and risk assessments (e.g. risk assessment reports) under CSCL
- Governmental safety reviews of existing chemical substances (test results, review results, etc.)

 Review information about newly announced chemical substances(Review sheets) J-CHECK also participates in OECD eChemPortal *19.

J-CHECK https://www.nite.go.jp/chem/jcheck/top.action?request locale=en

*19 eChemPortal : Portal site run by OECD in which it is possible to collectively search database information on the hazard information of the existing chemical substances of the member countries and international institutes. (eChemPortal~a Global Portal to Information on Chemical Substances~)

GHS-related information

"The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)" is the system to classify and show chemicals by an internationally recommended method in order to convey correct information on the hazards of chemicals (chemical substances and their mixtures) to all people who handle them and protect the health of people and the environment. It was issued as a United Nations Recommendation in 2003 and Japan introduced it in 2006. Domestically, business operators that handle chemical substances have obligations such as to classify the hazards of chemicals in accordance with GHS and create GHS labels and SDSs.

For the purpose of knowledge diffusion and promotion of the implementation of GHS, NITE publishes on the website the classification results conducted by the GHS-related ministries, the GHS-related information and "NITE Japan-GHS", which clarifies the classification results of each year. The classification results conducted by the GHS-related ministries and NITE Japan-GHS are searchable and available from NITE-CHRIP.

GHS-related information https://www.chem-info.nite.go.jp/chem/english/ghs/ghs_index.html

*It was renewed in March 2024.

GHS Mixture Classification and Label/SDS Creation System (NITE-Gmiccs)

NITE operates the web tool GHS Mixture Classification and Label/SDS Creation System (NITE-Gmiccs) in order to support business operators in classifying mixtures according to GHS and creating GHS labels and SDSs. This tool allows anyone to classify mixtures easily and automatically according to the GHS categories anywhere the internet is available *20.

It contains updated GHS Classification Results by the Japanese Government and EU CLP classifications as basic data. Users do not have to update the data.

NITE-Gmiccs https://www.ghs.nite.go.jp/home/en

*20 Regarding the physical hazards, except some items, test data of the mixture will be required. The main targets of this system are health hazards and environmental hazards.

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The search results screen









Information for mutual understanding of the interested parties related to chemical risks

NITE provides information on the risks of chemical substances and assessment methods through a variety of media, such as its website and pamphlets, according to the needs of the different actors, including the public, business operators and local government officials.

"Risk Assessments on Chemicals"

NITE publishes "Risk Assessments on Chemicals", which describes the risk assessments required to use chemical substances safely.

https://www.nite.go.jp/en/chem/shiryo/yoriyoku.html



Risk Assessment

The "Chemical Substances Contained in Household Products" series

NITE publishes "Cosmetics," "Paints (Household)," "Adhesives (Household)," "Detergents (Household),' "Household Control Agents," and "Clothing" as the "Chemical Substances Contained in Household Products" series in brochures and the website. These brochures are used for responses to consultations, workshops for chemical substances in products in consumer centers of municipalities, etc.



https://www.nite.go.jp/chem/shiryo/product/productinfo.html

Introduction to Chemical Substances

NITE created and published an easy-to-understand brochure considering opinions from junior high-school students, regarding the concepts of safe chemicals management. This brochure and website are used for provision of information for ordinary citizens in municipalities, etc.



Website

https://www.nite.go.jp/chem/management/kaisetsu/kaisetsu index.html

Brochure (PDF) https://www.nite.go.jp/data/000009057.pdf



International activities

NITE participates in multilateral dialogue, bilateral cooperation, etc. in order to promote international cooperation of chemicals management.

- ONITE works with the Working Party on Hazard Assessment (WPHA), the Working Party on Exposure Assessment (WPEA), the Working Party on GLP (WPGLP), the (Q)SAR Program, and the Working Party on PRTR (WPPRTR) under Environmental Health and Safety (EHS) Program in the Organization for Economic Co-operation and Development's (OECD) and exchanges information with the authorities from other countries and address international issues. As part of these activities, NITE implements the collaboration with the existing chemical portal site "eChemPortal" of OECD and provides the repeated-dose toxicity prediction tool (HESS), biodegradation and bioaccumulation data, etc. to OECD QSAR Toolbox. In addition, NITE staff are continuously seconded to the OECD Secretariat (Paris) to support its activities.
- ONITE maintains and operates "ASEAN-Japan Chemical Safety Database: AJCSD", which Japan and ASEAN countries constructed together based on the agreement made by the Working Group on Chemical Industry (WG-CI) in the ASEAN Economic Ministers and METI Economic and Industrial Cooperation Committee (AMEICC). https://www.ajcsd.org/
- NITE concluded the Statement of Intent with European Chemicals Agency (ECHA) with the Ministry of Economy, Trade and Industry, the Ministry of Health, Labour and Welfare, and the Ministry of the Environment in order to promote exchanges of information and opinions and technical cooperation between Japan and Europe.
- NITE signed cooperative agreements with the U.S. Environmental Protection Agency (EPA) to increase technological cooperation.

2. Arrangement of Technology Infrastructures on **Chemicals Management**

Risk assessments of chemical substances contained in products and arrangement of technology infrastructures

Risk Assessment for Chemicals in Consumer Products

NITE works on risk assessments of chemical substances contained in consumer products, which are present in our daily life, such as flame retardants, water repellents, and ultraviolet absorbers. Those risk assessments are utilized in governmental policies. https://www.nite.go.jp/en/chem/risk/assessment consumer product.html

Consumer Product Risk Assessment Methodology Guidance for GHS Labeling

When adding GHS labelling to any consumer products for chronic hazards on human health, it is allowed to determine the necessity for GHS labelling based on the result of the risk assessment conducted by the method recognized by the governing agency. NITE reviewed the method to assess chronic health risks of consumer products and summarized it as a guidance at the reguest of the Ministry of Economy, Trade and Industry. This guidance is published together with the estimated human exposure dose estimation software compatible with the guidance on the website. https://www.nite.go.jp/en/chem/risk/ghs consumer product.html

Information on lifestyle/behavior patterns relevant to indoor exposure (exposure coefficient)

For assessing risks of consumer products, it is necessary to estimates exposure levels via consumer products and indoor environment, requiring supposition of such as where to use (e.g., the size of the room), what kind of products to use (i.e., information on the consumer products), how to use (e.g., the duration of stay indoors, information on the use of the products and situations of ventilation).

NITE collects and analyzes information related to those lifestyle and behavior patterns through questionnaire surveys and publishes the findings on its website.

https://www.nite.go.jp/chem/risk/expofactor index.html

Provision of Information and Arrangement of Technology Infrastructures on Chemicals Management

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