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 support our convenient and rich lives. Chemical substances are released into the environment during synthesis, purification, processing into products, transportation, consumption, disposal, etc. (life cycle of chemical substances).

Chemical substances are taken into our bodies via the environment such as air, water, foods and products (exposure route).

If the amount of a chemical substance exceeds a certain threshold, it may affect human health and ecosystem.

What is chemical management...

We must understand and appropriately manage chemical substances in order to use them for our convenient and rich lives without sacrificing safety. For that end, it is necessary to make efforts to manage and reduce risks appropriately considering the results of the assessment of the risks based on the natures of chemical substances and their exposure dose in order to prevent adverse effects on the environment and human health assuming various cases in the life cycles and exposure routes of chemical substances.

It is also important to proceed with chemical management throughout the entire society by sharing information among the interested parties such as the people, business operators, and government in the process (risk communication).

Toward appropriate chemical management

Laws related to chemical management have been set up to prevent adverse effects on the environment and human health in various cases of the life cycles and exposure routes of chemical substances. 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)," which assesses and reviews chemical substances used domestically from the viewpoint of their risks and regulates them based on the result, 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)," which promotes voluntary management of chemical substances by sharing information on the properties and handling among the interested parties grasping and announcing the released amounts from offices into the environment, etc. NITE also performs on-site inspections and witnessing of international inspections based on "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 "chemical management" and plays important roles for appropriate management of chemical substances considering international cooperation through these activities.
Chemical substances and our lives

Operational Overview of Chemical Management Center

Roles in Act Enforcement on Chemical Management

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Chemical Management

Field

Chemical Management

Field

Roles in Act Enforcement on Chemical Management

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1. Provision of Information on Chemical Management ................................ 11
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If the amount of a chemical substance exceeds a certain threshold, it may affect human health and ecosystem.

Organizational Chart of Chemical Management Center

Director - General

Planning Division

International/Planning Office

Data Analysis Division

Safety Assessment Division

Chemical Substance Name Office

PRTR Division

Advance Assessment Support Office

Risk Analysis Division

Safety Technology Division

Chemical Weapon Material Countermeasure Office
Roles in Act Enforcement on Chemical 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.**

The purpose of the Chemical Substances Control Law is to enforce the necessary regulations for the manufacturing, import, use, etc. of chemical substances according to their properties, etc. by continuous control measures on chemical substances after review and marketing application on the properties in advance in manufacturing and import of new chemical substances in order to prevent environmental pollution caused by chemical substances which may impair human health or inhabitation or development of animals and plants.

In 1973, this act was enacted in the wake of the environmental pollution problem caused by PCB (polychlorinated biphenyl) and regulated chemical substances with similar properties to those of PCB (persistence, high bioaccumulation, and long-term toxicity on human). After that, it has been amended significantly several times and has come to also regulate and control chemical substances with similar properties to those of tetrachloroethylene used as cleaning solvents (persistence, low bioaccumulation, and long-term toxicity on human) and those with similar properties to those of dichlorvos used as white ant exterminating agents (persistence and impairment of development/inhabitation of animals and plants).

Due to the amendment in 2009, it came to control chemical substances designating the existing chemical substances not subject to control before as "General Chemical Substances" and the substances which the state assesses in priority from the viewpoint of their risks as "Priority Assessment Chemical Substances" (For the system diagram of the Chemical Substances Control Law, see its overview on page 6).

NITE plays the roles to secure the appropriate management of the Chemical Substances Control Law, such as communication with the notifiers in preliminary review of new chemical substances, creation of materials of committees, etc., provision of the technical information required for the creation and review of public name proposals, implementation of screening assessments of General Chemical Substances and risk assessments of Priority Assessment Chemical Substances, confirmation and arrangement of notifications of annual manufacturing and import volumes, etc. of General Chemical Substances, etc., technical support for enforcement of the Chemical Substances Control Law of manufacturing/import business operators, inspections of priority test facilities (GLP*1 facility), and proposal of technical assessment methods including risk assessment methods and structure-activity relationship methods.

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*1 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.

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

NITE confirms the combinations of Class Reference Numbers in the Gazette List (MITI Numbers) and CAS Registry Numbers *2 and publish them as dictionary files used in the notification system such as the manufacturing (import) track records, etc. of General Chemical Substances, etc. of the Chemical Substances Control Law in order to confirm the notification classes and create notifications in notifications of the annual manufacturing and import volumes, etc. of general chemical substances, Priority Assessment Chemical Substances, and Monitoring Chemical Substances by business operators.

In addition, NITE responds to inquiries on the MITI Numbers and CAS Registry Numbers as well as use category in notifications of the annual manufacturing and import volumes.

*2 CAS Registry Numbers: Also called CAS numbers. Unique numbers given to chemical substances by the Chemical Abstracts Service of the American Chemical Society (e.g. acrylonitrile 107-13-1)

**Inspections of GLP facilities**

The Chemical Substances Control Law 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**

The Chemical Substances Control Law 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 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 performs manufacturing, etc.

**Support for commonality of the nomenclature between the Industrial Safety and Health Act and the Chemical Substances Control Law**

To manufacture or import any new chemical substances, business operators need to make the notification of the new chemical substances as prescribed in the Chemical Substances Control Law 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. Though their designated names are given based on the IUPAC nomenclature system*3, there may be multiple naming conventions for the same structure, so even the same chemical substance may be designated with different names.

Therefore, NITE has been supporting the creation of the commonality rules of the nomenclature between the Industrial Safety and Health Act and the Chemical Substances Control Law proceeded with by the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry. NITE creates designated name proposals of the Chemical Substances Control Law as well as confirms designated name proposals of the Industrial Safety and Health Act created by the Ministry of Health, Labour and Welfare based on the commonality rules since 2013.

*3 IUPAC nomenclature system: Compound nomenclature determined by the International Union of Pure and Applied Chemistry (IUPAC)
Operations related to risk assessments

Risk assessments under the Chemical Substances Control Law are composed of three general steps: screening assessment, primary risk assessment, and secondary risk assessment. NITE supports operations related to risk assessments under the Chemical Substances Control Law, which require knowledge of chemical substances and assessment methods.

NITE supports the enforcement of the Chemical Substances Control Law by the state as the core institution of risk assessments under the Chemical Substances Control Law by performing "confirmation and aggregation of the notification data, etc. of annual manufacturing and import volumes according to the Chemical Substances Control Law," "arrangement of use category of chemical substances," "arrangement of emission factors to estimate the released amounts into the environment and estimation of the released amounts," "estimation of exposure doses and risks to human and ecosystem," "arrangement of use category of chemical substances," "arrangement of chemical substance property data," "creation of drafts of risk assessment documents," etc.

Confirmation and aggregation of the notification data, etc. of annual manufacturing and import volumes according to the Chemical Substances Control Law

NITE confirms the notification contents from technical viewpoint for annual manufacturing and import volumes, usage information, etc. notified from the business operators, and processes/aggregates them to use for screening assessments and risk assessments. NITE also performs responses to technical inquiries from business operators regarding notifications, update and publication of data to identify chemical substances, aggregation of annual manufacturing and import volumes published by the Ministry of Economy, Trade and Industry, etc.

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

NITE arranges emission factors required to calculate released amounts of chemical substances into the environment. NITE estimates the released amount of each chemical substance into the environment (atmosphere and water) 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 human exposure through drinking and eating, respiration and that of flora and fauna in the human living environment (aquatic lives, etc.) using the mathematical model constructed by NITE. Moreover, NITE estimates risks of chemical substances by comparing them with the information of hazards on humans and flora and fauna in the human living environment. In addition, NITE is also making new considerations for the issues with the methods and procedures of screening assessments and risk assessments for mixtures whose substances are difficult to identify, etc.

Proposal of risk assessment methods and provision of risk assessment tools

NITE creates technical guidance documents which describe the risk assessment methods of the Chemical Substances Control Law and proposes them to the state.

In addition, NITE creates and publish a risk assessment tool for the Chemical Substances Control Law (PRAS-NITE*) according to the risk assessment method described in this technical guidance document proposal. Using this assessment tool enables calculation using the same formula as those of Assessments I and II of risk assessments (primary). This tool is useful for chemical management by business operators such as voluntary chemical management, risk communication with local residents, and transmission of information to outside.

The technical guidance document proposals and risk assessment tool for the Chemical Substances Control Law (PRAS-NITE) created by NITE are published on our Web site (Japanese-language only).

* PRAS-NITE: Tool created by NITE to support the risk assessments of Priority Assessment Chemical Substances implemented by the state according to the Chemical Substances Control Law
Overview of the Chemical Substances Control Law (From April 1, 2011)

General Chemical Substances
- Mandatory reporting of amounts manufactured and/or imported (≥1 ton/year), usage, etc.
- The risks on humans or flora and fauna in the human living environment are low enough
- Persistence and high bioaccumulation

Monitoring Chemical Substances
- Report of handling situation
- Hazard investigation order request

Class I Specified Chemical Substances
- Have long-term toxicity on human or predator animals at a higher trophic level

Class II Specified Chemical Substances
- Have risks on humans or flora and fauna in the human living environment

New Chemical Substances
- Total manufacturing and import/year
  - > 1 ton/year
    - Prior confirmation (manufacturing and import allowed)
  - ≤ 1 ton/year
    - Notification/Review (The company submits data)
  - ≤ 10 ton/year (low productivity)

Priority Assessment Chemical Substances
- Risk assessment (primary)
  - Request for report of hazard information and handling situation
  - Instructions on hazard investigation
  - Risk assessment (secondary)

Priority Assessment Chemical Substances
- Polymers of Low concern

Roles in Act Enforcement on Chemical Management

*5 General Chemical Substances: Chemical substances defined as follows in paragraph 7 of Article 2 of the Chemical Substances Control Law
Chemical substances other than the following ones are defined as "General Chemical Substance": Priority Assessment Chemical Substances, Monitoring Chemical Substances, Class I Specified Chemical Substances, Class II Specified Chemical Substances, and New Chemical Substances, for which notification rules, etc. are set up separately in this law.
**Efforts for utilization of structure-activity relationship and category approach**

Recently, structure-activity relationship\(^6\) ((Quantitative) Structure-Activity Relationship, (Q)SAR) method, category approach\(^7\), etc. has been considered globally as a method to assess the biodegradation, bioconcentration, hazards on human health, etc. of chemical substances without actual toxicity tests using mice, etc. from the viewpoint of animal protection, etc.

NITE makes efforts to utilize these methods effectively in order to perform chemical management in our country reasonably.

\(^6\) Structure-activity relationship: Characteristics of substances in terms of their chemical structures or correlation between physical and chemical properties and biological activities (biodegradation, bioconcentration, various toxicity endpoints, etc.)

\(^7\) Category approach: Method to assess the hazards of untested chemical substances, etc. grouping chemical substances whose hazards, etc. are known based on significant rules such as molecular structures and physical and chemical properties

**Creation of review reference materials of chemical substances subject to review of the Chemical Substances Control Law**

NITE summarizes the results of predictions of biodegradation/bioconcentration of new chemical substances and Existing Chemical Substances subject to the review of the Chemical Substances Control Law by various structure-activity relationship models and category approaches developed by NITE which target bioconcentration, and submit them as review reference materials to the committee of the Chemical Substances Control Law.

**Support for rationalization of New Chemical Substances review in the Chemical Substances Control Law**

NITE compiles and analyzes the test data of the biodegradation and bioconcentration of new chemical substances and Existing Chemical Substances deliberated in the past as well as supports for rationalization of review process of new chemical substances implemented by the Ministry of Economy, Trade and Industry as experts of structure-activity relationship methods and category approaches in order to consider the improvement in the management of the Chemical Substances Control Law (shortening of the review period, simplification of test/evaluation methods, etc.).

**Hazard Evaluation Support System Integrated Platform**

NITE has developed “Hazard Evaluation Support System Integrated Platform (HESS)” and HESS DB, which is the database system included in it, as the world first tool to support the assessments of the repeated-dose toxicities of untested chemical substances\(^8\) in the project sponsored by the New Energy and Industrial Technology Development Organization (NEDO)/the Ministry of Economy, Trade and Industry, and published it on the Web site of NITE from June 2012.


HESS can classify (categorize) chemical substances based on their molecular structures and the similarities of their toxicities mechanisms and support the assessments of the repeated-dose toxicities of untested chemical substances by category approaches. In addition, HESS is a system compatible with OECD QSAR Toolbox\(^9\) and equipped with repeated-dose toxicity test data, etc. provided from the development projects (EU COSMOS project and US EPA ToxCAST project) of the in silico\(^{10}\) model, etc. used in Europe and the U.S.

\(^8\) Joint development with Fujitsu Limited, National Institute of Health Sciences, Burgas “Prof. Assen Zlatarov” University, Tohoku University, and Kwansei Gakuin University

\(^9\) OECD QSAR Toolbox: Software to support category approaches, developed by OECD. It has databases for biodegradation, bioaccumulation, toxicities, etc., the functions required for grouping of chemical substances, etc. (free software)

\(^{10}\) in silico: Means “Using computers.” Method to predict results by calculation without actual tests nor measurements

Example of the screen of HESS. Toxicity test data can be compared extracting similar substance candidates for evaluation object substances.
2. Operations Related to 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 Organization 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, and also verifies the analysis results when any international inspectors perform an analysis. NITE also performs on-site inspections for permitted (or approved) manufacturers and permitted (or approved) users of specific substances based on the Chemical Weapons Act by order of the Minister of Economy, Trade and Industry.
Data aggregation and compiling of released amounts, etc.

NITE arranges and manages the notification management system for prefectural and city governments 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. NITE also provides the notification creation support system with an entry check function to enable business operators to make notifications easily. Data created in the notification creation support system can be notified as it is by the electronic notification system and processed efficiently by adding two-dimensional codes even in the case of a paper-based notification.

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.

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*1 system and SDS*12 system as its pillars.

The PRTR system obligates business operators to confirm and notify the amounts of chemical substances released into the environment or transferred to outside businesses as disposal associated with the business activities by themselves. 462 substances which may be hazardous to human health and ecosystem and is recognized to exist widely in the environment are specified as the object substances (as of 2014). Also 24 industries are specified as the industries subject to notification. Business operators which handle any designated chemical substances notify the released amounts into the environment, etc. through prefectural and city governments and the State aggregates them, adding estimation released amounts and publishes the result every year. 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 support such as responses to inquiries about the PRTR system and SDS system from business operators, etc. and dispatch of instructors to municipalities, etc. Moreover, it provides information related to the PRTR Law such as PRTR map which shows PRTR aggregation data on a map and comparison result of the past year data.

*11 PRTR: Pollutant Release and Transfer Register
*12 SDS: Safety Data Sheet

3. Operations Related to PRTR Law

NITE supports the enforcement of the PRTR Law multilaterally as shown in the following figure.

Operations related to the PRTR system based on the PRTR Law
Support for smooth enforcement of the 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*11 system and SDS*12 system as its pillars.

The PRTR system obligates business operators to confirm and notify the amounts of chemical substances released into the environment or transferred to outside businesses as disposal associated with the business activities by themselves. 462 substances which may be hazardous to human health and ecosystem and is recognized to exist widely in the environment are specified as the object substances (as of 2014). Also 24 industries are specified as the industries subject to notification. Business operators which handle any designated chemical substances notify the released amounts into the environment, etc. through prefectural and city governments and the State aggregates them, adding estimation released amounts and publishes the result every year.

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 support such as responses to inquiries about the PRTR system and SDS system from business operators, etc. and dispatch of instructors to municipalities, etc. Moreover, it provides information related to the PRTR Law such as PRTR map which shows PRTR aggregation data on a map and comparison result of the past year data.

*11 PRTR: Pollutant Release and Transfer Register
*12 SDS: Safety Data Sheet

Data aggregation and compiling of released amounts, etc.

NITE arranges and manages the notification management system for prefectural and city governments 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. NITE also provides the notification creation support system with an entry check function to enable business operators to make notifications easily. Data created in the notification creation support system can be notified as it is by the electronic notification system and processed efficiently by adding two-dimensional codes even in the case of a paper-based notification.

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.
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**Analysis of PRTR data and provision of information**

NITE creates and publishes PRTR maps and comparison reports of prior year data as provision of information for people to deepen the understanding of the safety of chemical substances and for the government to manage chemical substances appropriately in order for business operators to improve voluntary management.

The PRTR maps (Japanese-language only) can show "release amount map" to show notified release amount data for each region and "concentration map" to show the estimated atmospheric concentration for each 5-square-km mesh based on the notified release amounts and estimated ones.

The prior year comparison reports summarize the transition of notification data by each substance, industry, and prefecture.

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*11 PRTR: Pollutant Release and Transfer Register
*12 SDS: Safety Data Sheet
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.

1. Provision of Information on Chemical Management

Chemical Risk Information Platform (CHRIP®)

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

CHRIP http://www.safe.nite.go.jp/english/db.html

NITE provides general information such as the names, CAS Registry Numbers, etc. of chemical substances, domestic and foreign laws and regulations information, hazard information, and exposure-related information. NITE confirms and updates the listed data regularly, and secures the reliability of the database.

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

![Display part related to the Chemical Substances Control Law](image.png)

List of substances subject to laws and regulations
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 and Arrangement of Technology Infrastructures on Chemical Management**

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

In order to widely transmit the safety information of chemical substances pertaining to the Chemical Substances Control Law, the Ministry of Economy, Trade and Industry, the Ministry of Health, Labour and Welfare, and the Ministry of the Environment have constructed Japan Chemicals Collaborative Knowledge Database (J-CHECK) and NITE is managing it. J-CHECK provides information obtained in the Japan Challenge Program, Existing Chemical Substances survey program by the State, etc. J-CHECK also participates in OECD eChemPortal*13.

NITE provides general information such as the names, CAS Registry Numbers, etc. of chemical substances, domestic and foreign laws and regulations information, hazard information, and exposure-related information. NITE confirms and updates the listed data regularly, and secures the reliability of the database.

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

**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.

NITE publishes the classification results conducted by the GHS-related ministries and agencies and the related information on the Web site in order to knowledge diffusion and promotion of the implementation of GHS. In addition, the classification in English is published on the English Web site in order to share the Japanese classification results internationally. The classification is searchable and available from CHRIP.

**Characteristics of J-CHECK**

- Lists the controlled substances of the Chemical Substances Control Law.
- Transmits Japanese safety data globally.
- Provides the safety data of chemical substances for risk assessments.

**Japan Chemicals Collaborative Knowledge Database (J-CHECK)**

In order to widely transmit the safety information of chemical substances pertaining to the Chemical Substances Control Law, the Ministry of Economy, Trade and Industry, the Ministry of Health, Labour and Welfare, and the Ministry of the Environment have constructed Japan Chemicals Collaborative Knowledge Database (J-CHECK) and NITE is managing it. J-CHECK provides information obtained in the Japan Challenge Program, Existing Chemical Substances survey program by the State, etc. J-CHECK also participates in OECD eChemPortal*13.

**J-CHECK**

http://www.safe.nite.go.jp/jcheck/top.action?request_locale=en

**OECD eChemPortal**

http://www.echemportal.org/echemportal/

*13 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.

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**GHS-related information**

http://www.safe.nite.go.jp/english/ghs_index.html

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**Table: Example of a GHS classification**

<table>
<thead>
<tr>
<th>Health Hazards</th>
<th>Classification</th>
<th>Exclamation mark</th>
<th>Warning</th>
<th>Hazard statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>Category 1</td>
<td>Exclamation mark</td>
<td>Warning</td>
<td>Causes death or serious health damage</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>Category 1</td>
<td>Exclamation mark</td>
<td>Warning</td>
<td>Causes death or serious health damage</td>
</tr>
<tr>
<td>Acute toxicity (inhalation: gas)</td>
<td>Category 1</td>
<td>Exclamation mark</td>
<td>Warning</td>
<td>Causes death or serious health damage</td>
</tr>
<tr>
<td>Acute toxicity (inhalation: vapour)</td>
<td>Category 1</td>
<td>Exclamation mark</td>
<td>Warning</td>
<td>Causes death or serious health damage</td>
</tr>
<tr>
<td>Acute toxicity (inhalation: dust, mist)</td>
<td>Category 1</td>
<td>Exclamation mark</td>
<td>Warning</td>
<td>Causes death or serious health damage</td>
</tr>
<tr>
<td>Skin corrosion / irritation</td>
<td>Category 1</td>
<td>Exclamation mark</td>
<td>Warning</td>
<td>Causes death or serious health damage</td>
</tr>
<tr>
<td>Serious eye damage / eye irritation</td>
<td>Category 1</td>
<td>Exclamation mark</td>
<td>Warning</td>
<td>Causes death or serious health damage</td>
</tr>
</tbody>
</table>

Example of a GHS classification
Information for mutual understanding of the interested parties related to chemical risks

NITE provides the hazard/exposure information of chemical substances, information/assessment methods for risks, etc. through various media such as Web sites and brochures for the purposes of risk assessments/management and propagation of risk communication according to the needs of each level from ordinary citizens to business operators and persons in charge in municipalities, etc.

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

http://www.safe.nite.go.jp/english/shiryo/yoriyoku.html

Introduction of cases of risk communication
NITE collects information on cases of risk communication conducted by business operators and introduces the contents of the efforts on the Web site (Japanese-language only) as well as provides reference information for business operators and municipalities to start such efforts from now on.
NITE also provides a collection of links to the pages of activities related to chemical management published by municipalities such as prefectural and city governments.

About Chemical Substances Contained in Household Products
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 Web site (Japanese-language only).
These brochures are used for responses to consultations, workshops, etc. for chemical substances in products in consumer centers of municipalities, etc.

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 chemical management.
This brochure and Web site are used for provision of information for ordinary citizens, etc. in municipalities, etc.

http://www.safe.nite.go.jp/english/shiryo/shiryo_index.html
International activities

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

- **Under the Environment, Health and Safety (EHS) Program of OECD (Organisation for Economic Co-operation and Development), NITE participates in activities such as the Task Force on Exposure Assessment, Clearing House on New Chemicals, Working Group on GLP, (Q) SAR program, and Task Force on PRTRs, makes efforts in information exchange with other countries, consideration of international issues, and 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 QSAR Toolbox.

- **NITE supports for the construction of “ASEAN Chemical Safety Database,” (provisional name) which will be the information infrastructure common to the East Asian/ASEAN countries from technical viewpoints.

- **NITE promotes bilateral cooperation with Asian countries which the Ministry of Economy, Trade and Industry performs or NITE will perform as well as support for human resource development for chemical management of the related institution in Asian countries, etc.

- **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 as well as promote exchange of information and opinions and technical cooperation between Japan and Europe.

- **NITE exchanges people with EPA (US Environmental Protection Agency) and information through conference calls regularly.

2. Arrangement of Technology Infrastructures on Chemical Management

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

**Risk assessments of chemical substances contained in products**

NITE promotes risk assessments of chemical substances contained in consumer products around us such as components of flame retardants and air fresheners contained in textile products. The risk assessment results are used for administration, etc.

**Guidance on a consumer product risk assessment for GHS labelling**

It is allowed to determine the necessity for labelling based on the result of the risk assessment conducted by the method recognized by the governing agency when adding GHS labelling to any consumer products for chronic hazards on human health.

NITE reviewed the method to assess chronic health risks of consumer products and summarized it as a guidance receiving a request from 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 Web site.

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**About 10 minutes’ walk from “Hatagaya” station of Keio New Line**  
**About 15 minutes’ walk from “Yoyogi-Uehara” station of Odakyu Line and Tokyo Metro Chiyoda Line**

**About 3 minutes’ walk from Exit 5 of “Tanimachi 4-chome” station of Tanimachi Subway Line and Chuo Line**