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Research Center for Chemical Information and Management
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Japan's challenge in chemical management
-from compliance approach to self-regulation-

1 Introduction

Fifty years have passed since the Industrial Safety and Health Act was separated from the Labor Standards Act and enacted and enforced in 1972.

During this period, the Industrial Safety and Health Act has been revised many times due to social demands or technological innovation. On the other hand, although the number of industrial accidents has been decreasing, serious diseases such as occupational cancer continue to occur. Over the past 10 years there have been approximately 800 cases of industrial accidents caused by chemicals resulting in absence from work of four days or more in each year. In recent years, 80% of occupational diseases were caused by chemicals that are not subject to existing special regulations (Ordinance on the Prevention of Organic Solvent Poisoning, Ordinance on Prevention of Hazards Due to Specified Chemical Substances, Ordinance on Prevention of Lead Poisoning, Ordinance on Prevention of Tetra-alkyl Lead Poisoning, Ordinance on Prevention of Hazards Due to Dust). Furthermore, it has been pointed out that chemical management in Japan is far behind the global trend of "self-regulation of chemicals".

Considering this situation, major revisions to regulations have been made to shift chemical management from the so-called 'compliance approach' based on conventional special regulations to 'self-regulation'. All the relevant revised regulations came into effect from the 1st of April 2024. The main points of this revision are (1) to ensure that workers be acknowledged the hazards of all chemicals they use, and (2) to require employers to carry out risk assessments according to the method of their choice and to take measures to prevent industrial accidents based on the risk assessment results. These two points are essential elements for preventing industrial accidents in the current situation where the number of chemicals is increasing and their uses are diversifying, but they have not been sufficiently regulated within the framework of conventional industrial safety and health regulations. It is envisaged that the special regulations will be repealed in five years. For five years from April 2024, self-regulation will be carried out while maintaining the existing system of special regulations.

Due to these legal amendments, employers, workers, and labor standards inspectors are being forced to drastically change their traditional concepts of chemical management. Furthermore, the content of the amendments is wide-ranging and not easy to understand. This article provides an overview of the 'self-regulation of chemicals' including the circumstances that led to this revision.

2 Characteristics of chemical management in Japan

Chemical management in workplaces is mainly based on Industrial Safety and Health Act, especially special regulations and these ordinances specify establishment of a management system, assessment of hazards and risks, labeling (a label and a safety data sheet (SDS) provision), facility requirements, use way, storage methods, installation of local exhaust ventilation, use of personal protective equipment, implementation of work environment measurements, health checkups, etc. Employers have been working to prevent industrial accidents caused by chemicals by complying with these regulations (this is called 'compliance approach'). However, special regulations cover only 123 chemicals *(https://cheminfo.johas.go.jp/useful/EN_List_RA_skin_R07R08.pdf)*.

The first step in chemical management is to inform workers about the hazards of chemicals, which requires comprehensive information on the hazards of all chemicals used. However, a system for providing easy-to-understand information (especially a label) was not developed in Japan.

In 2003, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) was published by the United Nations. In 2006, Industrial Safety and Health Act was revised for labels (Article 57) and SDSs (Article 57-2) which could be made in accordance with the GHS. This did not mean that the GHS was directly introduced into the Act, but rather that the Articles could refer to the GHS specified in the Japanese Industrial Standards (JIS-GHS). At that time, a label was required for approximately 100 chemicals, and SDS for 640 chemicals under the Industrial Safety and Health Act. An SDS was also required by the Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement and Poisonous and Deleterious Substances Control Act. The SDS was totally required for about 1,400 chemicals. The government (Ministry of Health, Labor and Welfare (MHLW), Ministry of Economy, Trade and Industry, and Ministry of the Environment) conducted GHS classification of the above 1,400 chemicals and published the results including rationale on the website of the National Institute of Technology and Evaluation (NITE). In addition, the MHLW created model labels and model SDS using the classification results to support businesses and posted these on the MHLW's 'Workplace Safety Site' (https://anzeninfo.mhlw.go.jp/anzen_pg/ghs_msd_fnd.aspx).

In Japan, the GHS was introduced into the Industrial Safety and Health Act in 2006, but the chemicals subject to classification and labeling were limited, though labeling was required for all hazardous chemicals in Western countries. It is customary in the Industrial Safety and Health Act to impose obligations by naming specific chemicals, and it has been difficult to impose obligations for all chemicals that are recognized to be hazardous. Therefore, the MHLW revised the Ordinance on Industrial Safety and Health in 2012, to make new Articles 24-14 (label) and 24-15 (SDS) for hazardous chemicals which are not regulated in the Industrial Safety and Health Act, Article 57 (label) and Article 57-2 (SDS). The ordinance does not impose obligations but obligations to make efforts (hereafter referred to as recommendation). As a result, in Japan, hazardous chemicals are required label and SDS, although there is a mixture of obligations and recommendation.

Risk assessment of hazardous chemicals has been recommended since 2006 under Article 28-2 of the Industrial Safety and Health Act, but in 2016 it became mandatory for specific chemicals under Article 57-3 of the Industrial Safety and Health Act. Furthermore, since June 2016, the chemicals that require labels, SDS provision, and risk assessments were consolidated (these are called risk assessment chemicals), bringing the number of subject chemicals to 640. As of April 2024, the number of chemicals is 896. For the other hazardous chemicals, labels, SDSs, and risk assessments are recommended.

Table 1 summarizes the progress of an increasing number of chemicals in labeling, SDS provision and risk assessment.

Table 1 Progress of increasing number of chemicals in labeling, SDS provision and risk assessment

Item	Obligation or recommendation (Related regulations)	2006	2016	2024	2026	2027～
Label	Obligation (ISH Act 57)	107	640	896	2,316	Approximately 100 chemicals added every year
	Recommendation (Ordinance 24-14)	—	All other hazardous chemicals	All other hazardous chemicals	All other hazardous chemicals	All other hazardous chemicals
SDS	Obligation (ISH Act 57-2)	640	640	896	2,316	Approximately 100 chemicals added every year
	Recommendation (Ordinance 24-15)	—	All other hazardous chemicals	All other hazardous chemicals	All other hazardous chemicals	All other hazardous chemicals
Risk assessment	Obligation (ISH Act 57-3)	—	640	896	2,316	Approximately 100 chemicals added every year
	Recommendation (ISH Act 28-2)	All hazardous chemicals	All other hazardous chemicals	All other hazardous chemicals	All other hazardous chemicals	All other hazardous chemicals

ISH Act: Industrial Safety and Health Act, Ordinance: Ordinance on Industrial Safety and Health

3 Overview of self-regulation

The revised legislation regarding ‘self-regulation’ came into full effect on April 1, 2024. The main points of this revision are (1) to ensure that workers be acknowledged the hazards of all chemicals they use, and (2) to require employers to carry out risk assessments according to the method of their choice and to take measures to prevent industrial accidents based on the risk assessment results. This revision was carried out to shift chemical management from the traditional ‘compliance approach’ to ‘self-regulation’. ‘Self-regulation’ can be described as a measure to share information about the hazards chemicals with workers and promote the management of chemicals in a manner selected by the employer (conducting a risk assessment and taking measures based on the results).

- **Framework of self-regulation from the perspective of chemicals**

Figure 1 shows framework from viewpoint of chemicals in terms of GHS classification, labeling (labels, SDS), risk assessment, and measures based on risk assessment. The classification of 1,400 chemicals subject to SDS provision as obligation, which began in 2006, has continued since then, reaching approximately 2,900 chemicals by the end of March 2021. Furthermore, model labels and model SDSs for these classified chemicals are published on the MHLW's ‘Workplace Safety Site’. In other words, it can be said that the judgment has been made by the government that even if a label, an SDS provision, and risk assessment are made mandatory for these chemicals, employers will be able to manage. However, the government's classification results are not mandatory and are meant to provide support to businesses.

Approximately 100 unclassified chemicals on the right side of Figure 1 will be classified every year and gradually transferred to obligation chemicals on the left side.

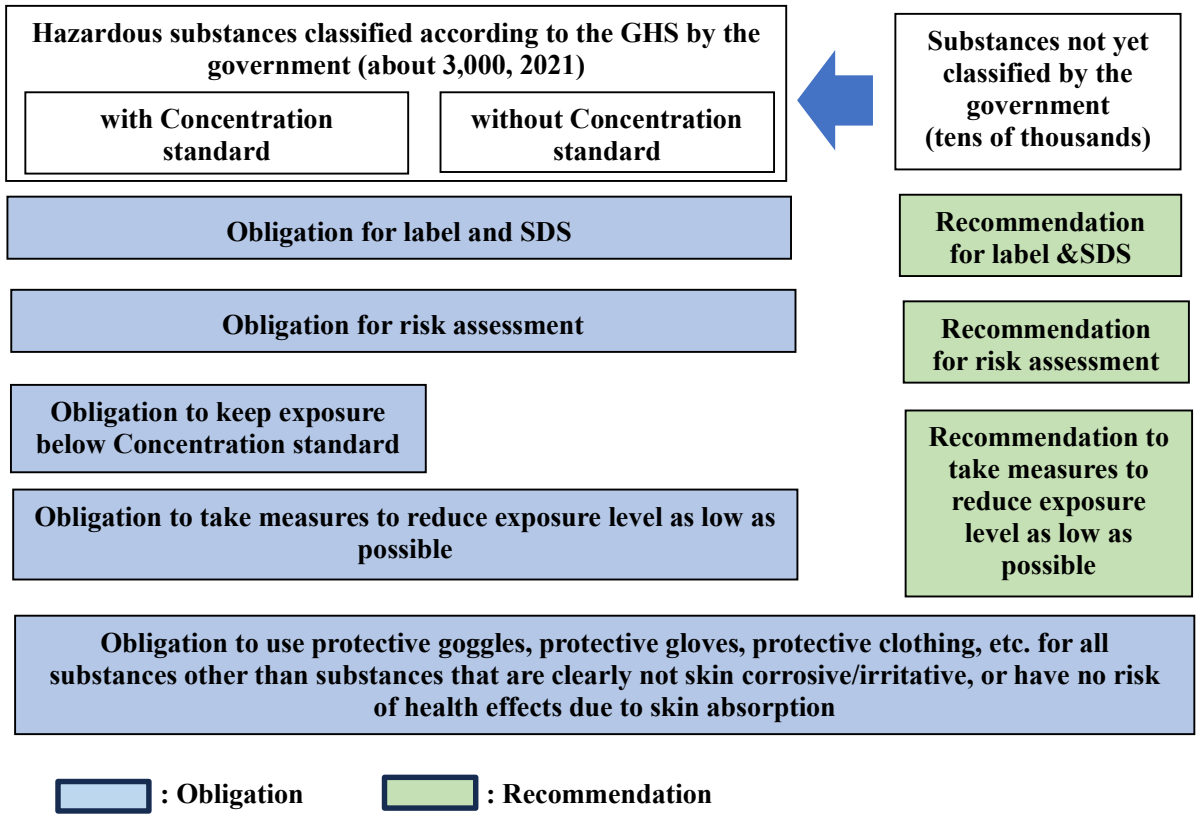

Figure 1 Regulatory framework for self-regulation from the perspective of chemicals

The amendments cover a wide range of topics. An overview is provided below, divided into 'Strengthening hazard communication', 'Risk assessment', 'Establishing an implementation system', 'Measures for carcinogenic chemicals' and 'Health checkup'.

- **Strengthening hazard communication**

In Japan, there are only a limited number of chemicals for which a label and an SDS are mandatory, so the government decided to gradually increase the number of chemicals. As seen in Table 1, the number of chemicals subject to obligations in 2024 is 896, but this will increase to 2,316 from 2026. This number differs from the number of chemicals for which GHS classification has been completed (3,000). The reason for this discrepancy is that while the number of GHS classified chemicals is based on CASRN, the legal number of chemicals counts compounds and isomers as one chemical. The lists of chemicals (2,316) are scattered among related laws and regulations; chemicals permitted for manufacture (7 chemicals in the Order for Industrial Safety and Health Act, Appended Table 3), compounds (Order for Industrial Safety and Health Act, Appended Table 9; 33 compounds), chemicals (Ordinance on Industrial Safety and Health, Appended Table 2; 2,276 chemicals). A list of all these chemicals is available at the following URL *(https://cheminfo.johas.go.jp/useful/EN_List_RA_skin_R07R08.pdf)*. In addition, approximately 100 chemicals will be added every year from 2027 onwards, and a label and an SDS will be newly required for these chemicals as described before.

- **Strengthening chemical risk management based on self-regulation**

In the future, the number of risk assessment chemicals will increase. The risk assessment is conducted by recognizing the hazard of the chemicals used and evaluating the exposure concentration concerning health hazards (by personal exposure measurement, work environment measurement, qualitative estimation, etc.). The risk assessment method can be selected by employers for themselves. Measures based on risk assessment will also be implemented at the discretion of the employer. This also makes it possible to use limited resources based on the priorities of the employer. For chemicals that are not risk assessment chemicals and have been identified as hazardous by GHS classification, risk assessment is recommended.

The government sets ‘Concentration standards’ that serve as indicators of inhalation exposure in risk assessments, and employers are required to take measures to keep workers' exposure below these levels. Actual measurements (personal exposure measurements, etc.) are recommended to assess the level of exposure concentration of workers, but methods that do not necessarily rely on actual measurements (software estimation, descriptive evaluation, etc.) may also be used. Table 2 shows the risk assessment methods recommended by the government.

Concentration standards are basically determined by a review committee of the MHLW, with reference to exposure limit values (TLV) (approximately 750 chemicals) recommended by the American Conference of Governmental Industrial Health (ACGIH) and others. Concentration standards were determined and enforced for 67 chemicals in 2024, and will be for 119 chemicals in 2025, and for more than 700 chemicals over the next few years. Concentration standards are not determined for chemicals that are clearly carcinogenic.

Employers are obligated to take measures to reduce the exposure of workers to risk assessment chemicals as low as possible or to keep the exposure concentration below the concentration standard (Figure 1). It is recommended that the following priorities as measures be implemented: (1) changing to a chemical with lower toxicity, (2) installing sealing and ventilation equipment, (3) improving work procedures, etc., and (4) using effective respiratory protection equipment.

Employers must educate workers about the hazardous chemicals they use and involve workers in risk assessments (hearing their opinions, etc.). For workplaces with 50 or more employees, employers must share the implementation status of risk assessments with the health committee to monitor the status of chemical management within the workplace. For workplaces with less than 50 employees, information concerning risk assessment must be shared with workers, and opinions heard from them. It is expected that this will further advance workers' awareness of hazards, and that risk assessments will more accurately capture workplace conditions.

Risk assessment methods, results, and implementation status of measures based on risk assessments must be recorded and saved.

Some kind of inspection is necessary even in ‘self-regulation’. The implementation status of self-regulation must be recorded. These will be verified by labor standards inspectors as necessary. Traditionally, industrial accidents must be reported to the Labor Standards Inspection Office, furthermore under this revision in particular, workplaces where industrial accidents have occurred or are likely to occur, and when the Chief of the Labor Standards Inspection Office deems it necessary, he instruct employers to receive confirmation and guidance from external experts (chemical management experts) regarding the status of self-regulation.

The bottom box of Figure 1 states the obligation to use protective equipment against skin irritation and corrosive properties. The reason for this is because recent data on occupational diseases (four or more days off work) shows

that skin disorders account for 60% of the total, and that 90% of skin disorders are caused by chemicals that are not subject to special regulations. From April 2024, it has become mandatory by the MHLW to use appropriate protective equipment (goggles, gloves, clothes, etc.) against chemicals classified as Category 1 in the GHS classification for skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitization or skin sensitization and chemicals that may cause health disorders due to skin absorption. The number of these amounts to approximately 1,000 chemicals *(https://cheminfo.johas.go.jp/useful/EN_List_RA_skin_R07R08.pdf ; https://cheminfo.johas.go.jp/useful/EN_List_NOT-RA_skin_R07R08.pdf)*. A manual for handling these chemicals has been published by the MHLW.

Administrative levels, which have been used in special regulations, are evaluation indicators based on the working environment measurements, and were determined for 97 chemicals *(https://cheminfo.johas.go.jp/useful/EN_List_RA_skin_R07R08.pdf)*. Administrative levels are also determined for some carcinogenic chemicals. On the other hand, concentration standards have not been determined for carcinogenic chemicals. Risk assessment of chemicals stipulated by special regulations should be generally carried out in compliance with previously established regulations or may be shifted to self-regulations by employers' decision.

Table 2 Risk assessment methods

Risk assessment method		Remarks
Without concentration measurement	Mathematical models (CREATE-SIMPLE, etc.)	Comparing the exposure concentration estimated from handling conditions (amount used, content rate, ventilation conditions, working time/frequency, presence or absence of protective equipment, etc.) and exposure limit values (or GHS classification information)
	Control Banding	Estimation from the toxicity information of chemicals, the volatility/dispersibility of the substances used, and the amount used
	Screening a support tool for explosions, fires, etc.	Focuses on easily 'knowing' typical hazards and potential risks of chemicals and work. In addition to the potential risks, typical risk reduction measures provided
	Matrix method, numerical method, etc.	Considering the severity of injury or illness and the likelihood to be occurred
	Accordance with specific measures stipulated in special regulations	Carrying out measures stipulated in special regulations
	According to industry manuals etc.	Implementing work procedures and countermeasures in accordance with industry manuals etc.
With concentration measurement	Simple measurement (detection tube)	Measuring airborne concentrations of chemicals by detection tubes
	Simple measurement (real - time monitor)	Measuring airborne concentrations of chemicals by real-time monitor
	Personal exposure measurement	Comparing the concentration standard or exposure limit value with the individual exposure concentration
	Working environment measurement	Applying the working environment measurement system

https://anzeninfo.mhlw.go.jp/user/anzen/kag/ankgc07.htm#h2_2

- **Establishment of an implementation system in the workplace**

A new system was established to promote self-regulation based on risk assessment, as a premise of sharing information with workers on the hazards of chemicals. However, no training of in-house personnel to take the lead in this regard has been conducted. The recent revision of the regulations stipulates the obligation for employers to appoint 'a chemical manager' to take this role. Regardless of the type of industry or the number of workers, a chemical manager must be appointed in the workplace that manufactures or uses risk assessment chemicals. The duties of the chemical manager include checking labels and SDSs, performing risk assessment-related tasks and taking record and saving them, educating workers, and taking measures for accidents. The specialized training for chemical managers (minimum 12 hours) includes more lecture time on hazard communication (contents of GHS etc.), risk assessment methods, and measures based on risk assessment, which had not been sufficiently taught to work supervisors and health managers in the special regulations. The training course also includes practical training (3 hours). This educational program can be implemented in the workplace itself as well as specialized institutions.

Furthermore, employers of workplaces where the use of protective equipment (respiratory protection equipment, protective clothing, protective gloves, etc.) is necessary to prevent exposure must appoint a protective equipment wearing manager. A training curriculum for this manager (minimum 6 hours) is determined.

Education for workers on hazardous work at the time of employment and when work content changes will be expanded to all industries.

Through the above, the expansion of worker participation, education and protection for workers will more reliably guarantee workers' right to work in good health.

- **Measures for carcinogenic chemicals**

In recent years in Japan, some specific chemicals caused multiple cancer patients in one workplace. Since there was no system for early detection of cancer cases caused by industrial chemicals, it was stipulated that when multiple cancer patients occur in the same workplace, the employer must seek the opinion of an industrial physician, etc., and report to the Labor Bureau if the cause of the cancer is suspected as occupational. In addition, employers must keep work records and health checkup results for 30 years for workers who use carcinogenic chemicals (GHS classification: carcinogenicity category 1 (1A, 1B), and special control chemicals under the Ordinance on Prevention of Hazards Due to Specified Chemical Substances).
(https://cheminfo.johas.go.jp/useful/EN_List_RA_skin_R07R08.pdf)

- **Health checkup**

For the next five years starting in April 2024, consideration will be given to abolishing the special regulations. In other words, it is necessary to conduct health checkups based on risk assessment (risk assessment chemical health checkup), as well as periodic special health checkup according to special regulations that are currently mandatory. The necessity of a health checkup is determined by the employer based on the results of the risk assessment. In other words, if a risk assessment indicates that a worker has been exposed to chemicals that poses health concerns, or if there is a possibility that the worker may have been exposed to the chemical at the concentration that exceeds the concentration standard, medical checkups must be conducted.

For workers who are not subject to health checkup for chemicals subject to risk assessment (e.g., those whose exposure to chemicals subject to risk assessment is not at a level of concern, or who use chemicals other than those subject to risk assessment), it is recommended by the notification for doctors to take into account the using conditions of chemicals and pay attention to the health effects during the general regular health checkup conducted for all employees (mandatory).

3 Information on 'Self-regulation of chemicals'

Since 'self-regulation of chemicals' is a completely different concept from conventional chemical management in Japan, and because it is a wide-ranging revision, each workplace is expected to face various problems.

Related Act, Regulations, Notices, etc. regarding new chemical management are posted on the following website (Japanese). It is suggested for overseas businesses to consult with their business partners in Japan.

・Regarding new regulations to prevent industrial accidents caused by chemicals - Promulgation of ministerial ordinance to partially revise Ordinance on Industrial Safety and Health, etc.
https://www.mhlw.go.jp/stf/newpage_25984.html

・Amendment of laws and regulations regarding concentration standard
https://www.mhlw.go.jp/stf/newpage_32871.html

・Health checkup for risk assessment chemicals
https://www.mhlw.go.jp/content/11302000/001156454.pdf

The MHLW has received many questions so far and has created the following Q&A site.

・Q&A regarding new regulations to prevent industrial accidents caused by chemicals
https://www.mhlw.go.jp/content/11300000/FAQ_20240228.pdf
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000099121_00005.html

・Q&A regarding countermeasures against hazard chemicals (label/SDS)
https://www.mhlw.go.jp/stf/newpage_11237.html

・Q&A regarding countermeasures against hazard chemicals (risk assessment)
https://www.mhlw.go.jp/stf/newpage_11389.html

・Q&A regarding health checkup for risk assessment chemicals
https://www.mhlw.go.jp/content/11300000/001181772.pdf

A variety of information regarding chemical management is already distributed on various sites. 'Chemical support' (Japanese), developed by the National Institute of Occupational Safety and Health, Japan (JNIOSH), is a useful reference because it links to a lot of related information and is designed to help you understand the basics of the new chemical management.

https://cheminfo.johas.go.jp/

In addition, based on the risk assessment chemicals, information on cut-off values for labeling and SDS provision, concentration standard, administrative levels, chemicals to be recorded and saved for 30 years (carcinogenic chemicals, special control chemicals), and necessity of impermeable protective clothing are provided in the list (in English) *(https://cheminfo.johas.go.jp/useful/list.html#sec2)*.

4 Remarks and hope

As mentioned above, the new chemical management system is very different from the previous one based on special regulations. The government and related organizations will need to support businesses or employers regarding concerns and solutions to the following issues.

(1) For the next five years, chemical management based on existing special regulations and new self-regulation will coexist.

(2) Chemicals subject to obligations or recommendations are mixed in hazard communication and risk assessment.

(3) Risk assessment methods are diverse and must be selected for each worker or workplace.

(4) Classification according to the GHS and risk assessment should be carried out at the discretion of businesses or employers, but chemicals subject to mandatory risk assessment, carcinogenic chemicals, and chemicals harmful to the skin etc. are basically based on the GHS classification conducted by the government.

(5) There may be a discrepancy between the government classification results and the business classification results for the same chemical, leading to discrepancies in the contents of labels and SDSs.

(6) Although the label or SDS items stipulated in the act or regulation are different from those in JIS-GHS, labels and SDSs created in accordance with JIS are said to satisfy the regulations.

(7) Experts regarding the use of concentration standards are not sufficiently trained.

(8) The timing, items, etc. of medical checkup must be determined by the employer in consultation with an industrial physician, etc. based on risk assessment.

It is strongly hoped that ‘self-regulation’ will take root in Japan. This concept is necessary to prevent industrial accidents in all fields, not just for chemicals, and the Government is trying to steer in this direction (see the 14th Occupational Safety & Health Program (https://www.mhlw.go.jp/content/11200000/001253683.pdf). The ‘self-regulation of chemicals’ is at the forefront of this Program, and its success or failure might determine the future of occupational accident prevention in Japan.