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The development and regulation of occupational exposure limits in Japan

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Abstract

The Ministry of Health, Labor and Welfare, on an administrative basis, establishes and supervises the Administrative Concentration Level, which can be viewed as an Occupational Exposure Limit (OEL) legally binding employers to maintain a good working environment. The Japan Society for Occupational Health, on a scientific basis, establishes the Recommended OELs, which can be viewed as a reference value for preventing adverse health effects on individual workers. In the case of carcinogens, Reference Values are recommended instead of OELs, corresponding to lifetime excessive risk of 10^{-3} and 10^{-4}. The former is based on monitoring of the ambient working environment (area monitoring) while the latter is based on the monitoring of the individual worker. The two OELs influence each other in the course of establishment.

1. Introduction

Japan is currently in the process of recovering from the major economic slowdown that started in the 1990s. It boasts the second most technologically powerful economy in the world after the United States. With a population of 127 million (M), the labor force (66.7 M) by occupation is composed of agriculture 5%, industry 25%, and services 70%. Industry is characterized as among the world's largest and technologically advanced producers of motor vehicles, electronic equipment, machine tools, steel and nonferrous metals, ships, chemicals, textiles, and processed foods (Central Intelligence Agency). The wide array of chemicals manufactured (for both industrial and consumer use) spans organic/inorganic chemicals, dyes, paints, pharmaceuticals, cosmetics, detergents, fertilizers, and plastics. Chemical production depends primarily on domestic demand but export (roughly 1.5 times the level of import) has been increasing since the mid 1990s (Ministry of Economy, Trade and Industry, 2002).

The Ministry of Health, Labor and Welfare (MHLW) is the government authority that regulates occupational exposures in the working environment. The MHLW, together with its umbrella of prefectural (regional) Labor Bureaus and Labor Standards Inspection Offices, has jurisdiction over the Administrative Control (AC) Level for various exposures, the supervision/oversight of workplaces in implementing exposure measurements and remedial actions when measurement data indicate excessive exposures.

The Japan Society for Occupational Health (JSOH) is a non-governmental academic society of occupational health professionals (academicians and practitioners) with a membership of ca. 7500 (Japan Society for Occupational Health; Takahashi, 2000). The Committee for Recommendation of Occupational Exposure Limits of JSOH is a permanent subcommittee within the Society delegated with the said purpose and assessment of carcinogenicity.

Hence, in principle, the two authorities are distinct by type (governmental/scientific) and purpose (regulation/

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recommendation), yet they are not completely independent of each other because membership may overlap in expert committees between the two parties and attention is paid to the position of the other party in the course of discussions. The aim of the present paper is thus to overview how occupational exposure limits of chemical substances are developed and implemented in Japan, with particular focus on the complementary role of the pertinent bodies.

2. Procedure of Occupational Exposure Limit development

The Industrial Safety and Health Law (ISH Law) of Japan (Department of Safety and Health, Ministry of Health, Labor and Welfare, 2002; Ministry of Health, Labor and Welfare, ISH Law) stipulates "Working Environment (WE) Management" as one of the core management activities designated for occupational health. Like many countries, the ultimate responsibility of WE and other management activities is borne by the employer. The premises of the WE Management rest on implementing WE Measurement by a qualified WE Measurement Expert (an employee of the company or via purchase of service from a third party) with reference to the AC Level specified for the respective substances.

In practice, the actual measurement data are compared with the AC Level, and according to their comparative status, employers are required to take the necessary measures to maintain or improve the WE as laid down by the ISH Law and subordinate regulations/rules. Hence, the AC Level is the Recommended Occupational Exposure Limit (OEL) with legal binding power. This should be viewed in contrast with the Recommended OEL issued by JSOH, which has no legal binding power but is considered to be a voluntary guidance value. There are differences in the rationale for establishing AC Level and Recommended OEL as well. However, as noted throughout the present paper, the two values often influence each other.

2.1. Administrative Control level

The AC Level, in combination with the various procedures for WE Measurement enforced in Japan, is unique (Sakurai, 2003). Unlike many other countries, the entire system is based on monitoring of the ambient working environment rather than monitoring of individual workers. Briefly, WE Measurement incorporates: (1) A-measurement implemented in a designated Unit Work Area (UWA) accounting for distribution of harmful substances and range of movement of workers within the area of the workshop concerned; and (2) B-measurement implemented at the time and point observed to entail the highest exposure. The actual procedure for A-measurement requires measurement during regular operation, at the height of 50–150 cm above the floor (workers' respiratory zone) of at least 5 intersection points of grid-lines drawn of 6 m or less drawn within a designated UWA. Air sampling should be continued for at least 10 min per sampling point, and for 2 days in principle (Sakurai, 2003; Ministry of Health Labor and Welfare, 2001a).

The distribution of measurement values will closely fit a log-normal curve, which provides the basis for adopting the following criteria. From the distribution of measurement values, Measurement Value 1 (E_A1) is calculated as the estimated upper 5-percentile value, and Measurement Value 2 (E_A2) as the estimated arithmetic mean value (Ministry of Health Labor and Welfare, 2001b; Labor Standards Bureau, Ministry of Health Labor and Welfare, 2004).

When only A-measurement is conducted, the A-measurement data are compared directly with the AC level to determine the following categories of outcome: Control Class (CC) 1 [Dai-ichi Kanri Kubun] is defined as $E_A1 <$ AC level. This is interpretable as 95% of the measurement values falling short of the AC level and indicates that the WE is good and should be maintained. CC 3 [Dai-san Kanri Kubun] is defined as $E_A2 >$ AC level. This is interpretable as more than half of the measurement values exceeds the AC level (because of the arithmetic mean > median on the distribution curve) and indicates that the WE is inappropriate, and employers are required to take immediate necessary measures for improvement. CC 2 is the intermediate range corresponding to $E_A2 <$ AC level $< E_A1$. This indicates that the WE is neither good nor inappropriate and employers should make effort for improvement.

When B-measurement is conducted, the B-measurement data (C_B) are compared with the AC level or 1.5 times the AC level. Hence, if $C_B <$ AC level, then the workplace is CC 1 (see indication above). If $C_B > 1.5 \times$ AC level then CC 3 (see indication above). If AC level $< C_B < 1.5 \times$ AC level, then the workplace is CC 2 (see indication above). B-measurements should always be combined with A-measurements, and in doing so, the poorer AG level for either A- or B-measurement is prioritized. Other detailed conditions are also regulated for WE Measurement, e.g., the type of worksite mandated to implement these procedures, the particular substance to be measured, periodicity of measurement, length of keeping records, and specific methods to analyze samples (Department of Safety and Health, Ministry of Health, Labor and Welfare, 2002; Ministry of Health, Labor and Welfare, ISH Law).

The current List of AC levels (Table 1 shows the format of the List but data are excerpted for benzene only) shows values for 81 chemical substances (Ministry of Health Labor and Welfare, 2001b). To reiterate, AC levels are established and updated by an expert meeting assembled ad hoc when deemed necessary by the MHLW in consideration of accumulation of scientific knowledge. This expert

Table 1
Excerpt from the List of Administrative Control (AC) Levels (MHLW)

Name of type and substance	AC Level (25 °C, 1 atmospheric pressure)
Benzene	10 ppm (until March 31, 2005) 1 ppm (from April 1, 2005)

meeting is not exclusive of but often involves the relevant members of JSOH. As a general rule, the expert meeting will discuss both the recommended OELs by JSOH and the Threshold Limit Values (TLV) by the American Conference of Governmental Industrial Hygienists (ACGIH) to finally adopt its own value. Amendments to the List of AC Level (examples are given for benzene in Table 1 and silica in the text) will become effective as of April 1, 2005.

Because employers are required to maintain documented records of the WE measurement and evaluation where the legal designation applies, the MHLW has been able to monitor the distribution of CC (CC 1, 2, and 3) for a variety of designated substances on a nation-wide scale. On average, the proportion of CC 1 achieved has increased substantially among the workplaces, i.e., during the period 1995 ($N = 102{,}679$ worksites)—2002 ($N = 188{,}897$ worksites), the respective changes in proportion were an increase from 87.0 to 89.7% for CC 1, a decrease from 8.4 to 6.3% for CC 2, and a decrease from 4.6 to 4.0% for CC 3 (Karasawa, 2005).

2.2. Recommended OELs

The JSOH, through the aforementioned permanent subcommittee, recommends OELs "as reference values for preventing adverse health effects on workers caused by occupational exposures." The subcommittee meets periodically to choose substances requiring recommendation and, more importantly, discuss the scientific information on health and exposure regarding the substance. It will ultimately produce a proposal document (new or update) on the recommended OEL and classification of carcinogenicity for the substance in question. The JSOH carefully expresses 10 points of reservations regarding how the OELs should and should not be used. A noteworthy reservation regarding OELs can be found in clause 6, which states: "Because OELs do not represent a definitive borderline between safe and hazardous conditions, it is not correct to conclude that working environments above OEL are the direct and sole cause of health impairment in workers, or vice versa" (The Japan Society for Occupational Health, 2004).

Similar to ACGIH, the recommended OELs include chemical substances and physical agents, as well as biological exposure indices. Specifically, for chemical substances, exposure concentration is defined as "the concentration of a chemical substance in air which will be inhaled by a worker during a job without the use of protective respiratory equipment." Hence, in contrast to the AC Level, personal sampling is the presupposed method of measurement for making reference to the Recommended OELs. In addition, because OELs are set at conditions under which no skin absorption will take place, substances that may be absorbed through the skin at significant levels are designated by "S" marks in the tables listing specific OEL values.

OEL-Mean (OEL-M) is defined as "the reference value to the mean exposure concentration at or below which adverse health effects caused by the substance do not appear in most workers working for 8 h a day, 40 h a week under a moderate workload (The Japan Society for Occupational Health, 2004)." Exposure above OEL-M should be avoided even where duration is short or work intensity is high. The List of OEL-M values of 2004 (Table 2 shows the format of the List but data are excerpted for benzene only) includes 206 chemical substances.

For some substances, an OEL-Ceiling (OEL-C) [defined as "the reference value to the maximal exposure concentration of the substance during a working day at or below which adverse health effects do not appear in most workers"] is recommended mainly because the toxicity in question can induce immediate adverse effects such as irritation or suppressive effects on the central nervous system (The Japan Society for Occupational Health, 2004).

3. Examples

3.1. Benzene

For carcinogens, JSOH affirms that concentration levels corresponding to lifetime excessive risk should not be recommended as OELs but rather as Reference Values (RV)s. In the case of benzene, RVs were recommended after it was designated as Group 1 for carcinogenicity or human carcinogen (The Committee for Recommendation of Occupational Exposure Limits, 1997). Consequently, in the Table of OELs (Table 2), benzene is annotated for being included in the List of RV (Table 3) and is denoted with the "S" mark for possible absorption through the skin, and indicated as a carcinogen.

The rationale for establishing the RV for benzene adopted the basic logic used conventionally by JSOH and data derived from the literature, which can be summarized as follows: (1) risk was estimated from the findings of the cohort study by Pliofilm (The Committee for Recommendation of Occupational Exposure Limits, 1997; Rinsky et al., 1987); (2) exposure was estimated by Paustenback's method (The Committee for Recommendation of Occupational Exposure Limits, 1997; Paustenback et al., 1992); (3) extrapolation was made from the average relative risk

Table 2
Excerpt from OEL for chemical substances (JSOH)

Substance [CAS No.]	Chemical formula	OEL	Skin absorption	Class of carcinogenicity	Class of sensitizing potential		Year of proposal
		ppm			Airway	Skin	
Benzene [71-43-2]	C_6H_6	Separate table[a]	S	1			1997

[a] See Table 3.

Table 3
Reference Values (RV)s corresponding to an individual excess lifetime risk of cancer, excerpt (JSOH)

Substance	Individual excess lifetime risk of cancer	Reference value (ppm)	Method of estimation	Year of estimation
Benzene	10^{-3}	1	Average relative risk model	1997
	10^{-4}	0.1		

Separate table indicated in Table 2.

model by WHO (The Committee for Recommendation of Occupational Exposure Limits, 1997). Exposure to benzene at 1 ppm for 40 yrs was calculated to cause excessive mortality risk (EMR) of 0.762×10^{-3} (95%CI $0.621-0.987 \times 10^{-3}$) for leukemia. This is translatable to 1.31 (1.01–1.61) ppm for 10^{-3} EMR and 0.13 (0.10–0.16) ppm for 10^{-4} EMR. Considering 40 yrs of exposure, the RV was thus determined to be 1 ppm to suppress lifetime risk below 10^{-3} and 0.1 ppm to suppress lifetime risk below 10^{-4} (The Committee for Recommendation of Occupational Exposure Limits, 1997).

As exemplified by benzene, RVs have been calculated corresponding to EMR of cancer of 10^{-3} and 10^{-4}, although the precise logic and factors used to establish RV differ by substance, e.g., for asbestos the average exposure period was assumed for the those 16–65 yrs old of age (or 50 yrs of exposure) (The Committee for Recommendation of Occupational Exposure Limits, 2000).

3.2. Respirable Crystalline Silica

Respirable Crystalline Silica (RCS) is currently regulated by an AC Level expressed in the following formula: E (in mg/m^3) $= 2.9/(0.22Q + 1)$, where Q is the proportion of free silicate in percent. In the case of $Q = 100$, equivalent to 100% pure silica dust, the formula will produce a value of $E = 0.13$ mg/m^3. The revised AC Level of silica will be expressed in the following formula (effective as of April 1, 2005): E (in mg/m^3) $= 3.0/(0.59Q + 1)$, where Q is the proportion of free silicate in percent. In the case of $Q = 100$, equivalent to 100% pure silica dust, the formula will produce a value of $E = 0.05$ mg/m^3.

The former formula was originally adapted from the formula designated for respirable dust (dusts containing more than 10% free silica) as the Recommended OEL by JSOH. Hence up to March 31, 2005, the two OELs were expressed by exactly the same formula. Recently, JSOH upgraded RCS to Group 1 for carcinogenicity (or carcinogen) (The Committee for Recommendation of Occupational Exposure Limits, 2001; Takahashi, 2003). JSOH is currently discussing a revision of the Recommended OEL value.

4. Harmonization within Japan and with other countries

The AC Level is established by a National Expert Meeting (NEM) authorized by the MHLW and has legal binding power once it is issued. In one of its official documents, the MHLW explicitly states that the NEM, in the course of establishing the AC Level, shall take into due account the OELs recommended by JSOH as well as the OEL designated by ACGIH. On the other hand, JSOH, and the Committee for Recommendation of Occupational Exposure Limits in particular, aspires to conduct its own evaluation. During preparation for recommended OELs, committee members will seriously consider the OELs by ACGIH as one of the most reliable source of information [the recommended OEL-M is analogous to the TLV-TWA (and OEL-C to TLV-STEL) by ACGIH]. However, JSOH makes every effort to add its own perspective, particularly by taking into account recent and domestic publications.

Table 4 shows the OEL values (AC Level and Recommended OEL) adopted for selected organic solvents in Japan along with the TLV-TWA by ACGIH. The close values are indicative of the aforementioned efforts for achieving harmonization within the country as well as the international norm, in particular, that of ACGIH.

On the other hand, it has been acknowledged that there is lack of coherence between the system of AC Level, which is based on area sampling, and that of the Recommended OEL, which is based on personal sampling. The justification widely accepted is that the former method is effective to reduce the average level of exposure as a group of workers (conceptualized as "WE management") (Sakurai, 2003). Furthermore, as mentioned earlier, if CC 1 [Dai-ichi Kanri Kubun] is achieved, 95% of the measurement values will fall

Table 4
Comparison of OELs for selected organic solvents[a]

Substance	AC Level[b] [MHLW]	Recommended OEL (or RV when indicated) [JSOH]	TLV-TWA[c] [ACGIH]
Benzene	10 ppm (until March 31, 2005) 1 ppm (from April 1, 2005)	RV = 1 ppm (10^{-3} Lifetime Risk) RV = 0.1 ppm (10^{-4} Lifetime Risk)	0.5 ppm
Xylene	100 ppm (until March 31, 2005) 50 ppm (from April 1, 2005)	50 ppm	100 ppm
Toluene	50 ppm	50 ppm	50 ppm

[a] See text for acronyms.
[b] Date is shown for only the substances scheduled for amendment effective as of April 1, 2005. For other OELs, current values effective at the time of manuscript submission are shown.
[c] By American Conference of Governmental Industrial Hygienists, 2003.

short of the AC level, which would restrict exposure to the safer side. In contrast, the latter method is effective to reduce the level of exposure of the individual worker (Sakurai, 2003). Moreover, the two values influence each other in the course of discussion on their establishment and produce close values.

For occupational carcinogens, JSOH has long considered that "the classification of occupational carcinogens proposed by the International Agency for Research on Cancer (IARC) is appropriate" but "in principle." Therefore the current classification scheme for carcinogens adopted by JSOH closely resembles that of IARC. However, here again, the system is headed towards introducing more original reasoning and justification by JSOH. Aside from the OEL-M and OEL-C, JSOH will estimate a reference value corresponding to an individual excess lifetime risk of cancer due to exposure to a Group I carcinogen, but "only when scientifically reasonable information is available" (The Japan Society for Occupational Health, 2004).

5. Enforcement and communication (recognition) of OEL

In the ISH Law, an array of penalties is designated for violation of specific provisions therein. For example, if an employer fails to implement WE measurement when the worksite is actually required to implement such procedures (Article 65-1 of the ISH Law, same here after), the employer is subject to a fine or imprisonment (Article 119-1). However, the penalty is seldom executed in practice. Due to good awareness of the ISH Law in general, most employers abide by this provision. Of further importance is the provision on the result of the WE measurement, in particular, if CC 1 is not achieved. In this case, the ISH Law stipulates that employers must take necessary procedures including improvement of facilities and equipment and health examinations, etc (Article 65-2.1). However, there is no penalty for breach of this provision. Concerned parties acquire essential information via documents, e.g., law books (Department of Safety and Health, Ministry of Health, Labor and Welfare, 2002), guidebooks (Labor Standards Bureau, Ministry of Health Labor and Welfare, 2004), and official notices from the government. Increasingly, such information is accessed via websites of the MHLW and prefectural Labor Bureaus. Full provisional records of the related national committees are also web-accessible in most instances, which greatly enhances the transparency of the decision process.

Once every year JSOH publishes in its official journal *Sangyo Eiseigaku Zasshi* (in Japanese) newly recommended OELs and evaluation of carcinogenicity as proposals. Their summaries are published in its official English journal, Journal of Occupational Health. The full text of both journals is available on the Internet (http://joh.med.uoeh-u.ac.jp/). It should be noted that, after a proposal is made on any of these issues by JSOH, one year is allowed for concerned parties to raise opinions/objections before the proposal is finalized. JSOH will review the opinion, respond accordingly, and officialize the proposal in due course. In some instances industry will raise objections as to the feasibility of the proposed OEL, but such cases are rare.

6. Conclusion

To reiterate, the AC Level value controlled by the MHLW and the OEL value recommended by JSOH stem from contrastive premises, the former on area monitoring and the latter on individual monitoring. Although it has been acknowledged that the "dual premises" lack coherence, such criticism has not gained momentum. However, the reasoning is not straightforward and is prone to cause confusion among practitioners. As both values tend to converge over time, the obvious question is then, whether the dual premises can be justifiably maintained in the long run. It is only natural that the ultimate value of the system will depend on the extent to which the health of workers can be adequately protected from exposure to hazardous substances and conditions. For further improvement, the complementarity of the system should be scrutinized carefully and periodically, harmonization with international norms should be given weight, and more scientific (epidemiologic and experimental) evidence should be acquired from domestic studies.

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