

Concepts of Selection of General Chemical Substances Not Requiring Notification of Manufacturing Quantities, etc.

Since the partial enforcement of the Act on the Partial Revision of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 39 of 2009), the notification of actual manufacturing and import quantities of General Chemical Substances*¹ has become mandatory. However, the Act stipulates that those chemical substances which are not Class I or Class II Specified Chemical Substances, and which are designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment as substances not requiring risk assessment are exempt from the notification of manufacturing quantities etc. (paragraph (1) of Article 8 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc. [hereinafter referred to as the “Japanese Chemical Substances Control Act”]*²).

However, the selection of those chemical substances to which this proviso applies is based on the following concepts (1) to (3).

*1 General Chemical Substances are chemical substances in the list of existing chemical substances, newly announced chemical substances, former Class II Specified Chemical Substances, former Type III Monitoring Chemical Substances and those chemical substances whose designation as Priority Assessment Chemical Substances have been rescinded (excluding Priority Assessment Chemical Substances, Monitoring Chemical Substances, Class I Specified Chemical Substances and Class II Specified Chemical Substances).

*2 Paragraph (1) of Article 8 of the Japanese Chemical Substances Control Act
A person who has manufactured or imported any General Chemical Substance shall, in each fiscal year, notify the Minister of Economy, Trade and Industry of the quantity of manufacture or import of each General Chemical Substance in the preceding fiscal year and other matters specified by Ordinances of the Ministry of Economy, Trade and Industry, pursuant to the provisions of Ordinances of the Ministry of Economy, Trade and Industry; provided, however, that this shall not apply to cases that fall under any of the following items:

(iii) Where a person manufactures or imports a chemical substance designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment as one that has been found not to fall under any item of paragraph (2) (Class I Specified Chemical Substance) or any item of paragraph (3) (Class II Specified Chemical Substance) of Article 2, or for which the evaluation prescribed in paragraph (5) of the same Article has been found not to be necessary (as it has not been found that the relevant substance does not pose, through causing environmental pollution, a risk of damaging human health or the population and/or growth of flora and fauna in the human living environment, the evaluation concerned here is to determine whether there is such a risk through collecting information on the properties of the substance and understanding use situations of the substance).

(1) Chemical substances not requiring risk assessment on the basis of judgment results from the Polymer Flow Scheme

The Polymer Flow Scheme is to determine whether polymers, among newly registered chemical substances, permeate through the biological membrane of human beings and flora and fauna and develop long-term toxicity, on the basis of data on the physico-chemical stability, solubility and low-molecular-weight component content of such polymers and the knowledge of their chemical structures and long-term toxicity, and on the basis of the council's consultation. Further, the Confirmation System for Polymers of Low Concern is to confirm that polymers do not possess such hazards as above in accordance with the criteria set by the Three Ministers for polymers

posing no risk of causing environmental and thereby damaging human health, etc. Accordingly, polymers which are judged as “White” in the Polymer Flow Scheme are those which have been found not to pose a risk of damaging human health or of interfering the population etc. of flora and fauna. Thus, the necessity for implementing risk assessment is not found for such polymers.

*** Handling of polymers which are Existing Chemical Substances, and which are judged as “White”^{*1} or are found to satisfy the criteria for the confirmation of polymers of low-concern^{*2}**

In light of the purpose of establishing the regulatory system to manage all chemical substances comprehensively upon the amendment to the Japanese Chemical Substances Control Act in May 2009, the implementation of risk assessment should be deemed not to be necessary with regard to those General Chemical Substances that originate from Existing Chemical Substances, if the aforementioned conditions are satisfied.

*1 The Polymer Flow Scheme is an evaluation scheme for polymers stipulated in paragraph 1 of the "Notification on the Handling of 'Available Information on Composition, Properties, etc.'" (March 30, 2010, PFB Notification 0329 No.3, MIB No. 1 of March 30, 2010, EHP Announcement No. 100329003). Furthermore, the judgment of “White” in the Polymer Flow Scheme means that upon implementation of an evaluation based on the Polymer Flow Scheme, an Existing Chemical Substance is found to be equivalent to the chemical under item (v) of paragraph (1) of the Article 4 of the Act.

*2 Satisfying the criteria for the confirmation of polymers of low-concern means the fulfillment of the “Criteria for Polymers Among Newly Registered Chemical Substances Which Pose No Risk of Causing Environmental Pollution Thereby Damaging Human Health or the Population or Growth of Flora and Fauna in the Human Living Environment” (Public Notice No. 2 of December 28, 2009, by the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment).

(2) Chemical substances primarily existing in abundance in the natural world

Where the exposure quantity of a manufactured chemical substance via the environment is clearly and remarkably less than a day-to-day exposure quantity of the same substance primarily existing in the natural world, the risk associated with the manufactured chemical substance can be disregarded. This applies to the chemical substances under [1] to [3] below.

Chemical substances primarily existing in the natural world do not include those manufactured ones which have been released into and accumulated in the environment.

[1] Chemical substances existing in abundance in the natural world, such as in the earth’s crust, water areas or the atmosphere

Human beings and flora and fauna are considered to be exposed, through inhalation etc. on a daily basis, to chemical substances existing in abundance in the natural world, such as in the earth’s crust, water areas or the atmosphere.

Since chemical substances such as SiO₂ and Al₂O₃ contained in the entire crust exist in abundance on a wide scale in the environment, the same manufactured ones are considered not to pose a risk of interfering with the population etc. of flora and fauna. Thus, basically, the implementation of risk assessment on such substances is not found to be necessary.

Although a large amount of chemical substances also exist in water areas and the atmosphere, those in water areas are included as ions in the notification on available information, and those in the atmosphere are elements. For this reason, examinations of substances in the earth's crust are considered to be sufficient.

[2] Chemical substances which only degrade into those ions in the environment indicated by the notification of available information

The available information confirms that among chemical substances generated by degradation tests etc. using micro-organisms (including elements), those substances degrading into "Na⁺, K⁺, NH₄⁺, Mg²⁺, Ca²⁺, BO₃³⁻, SiO₄⁴⁻, PO₄³⁻, SO₄²⁻, F⁻, Cl⁻, Br⁻ and I⁻" are not handled as Class I Specified Chemical Substances, Type II Monitoring Chemical Substances or Type III Monitoring Chemical Substances. "H⁺, OH⁻, O²⁻, CO₃²⁻, and NO₃²⁻" which are generated in the same manner are conventionally presupposed not to be hazard assessment subjects.

Accordingly, chemical substances which degrade only into the aforementioned ions have been found not to pose a risk of damaging human health or of interfering the population etc. of flora and fauna. Hence, the implementation of risk assessment is not found to be necessary for those substances.

[3] Chemical substances essential or important to biological activity of living organisms

Among chemical substances essential or important to biological activity of living organisms, those (such as sugar, amino acid, higher fatty acid, cellulose and vitamins) which are found in human beings and flora and fauna as regularly ingested as food, etc., have been found not to pose a risk of damaging human health or of interfering with the population etc. of flora and fauna. Hence, the implementation of risk assessment is not found to be necessary for such substances.

However, those substances whose tolerable upper limit quantities are prescribed in "The Dietary Reference Intakes for the Japanese (the 2010 version)" (by Health, Labour and Welfare Ministry) are not to be selected in order to eliminate chemical substances that affect health if taken in large quantities.

*** Chemical substances subject to the control of other Acts for the purpose of preventing damage to human health or environmental pollution**

The Acts regulating chemical substances include, other than the Japanese Chemical Substances Control Act, the Law for PRTR and Promotion of Chemical Management*¹, the Poisonous and Deleterious Substances Control Law, the Industrial Safety and Health Act, Pharmaceutical Affairs Law, the Agricultural Chemicals Regulation Law, the Food Sanitation Act, the Air Pollution Control Law and the Water Pollution Control Law. Each of the Acts/Laws regulate substances in accordance with their own purposes. Moreover, a new provision was incorporated into the amended Japanese Chemical Substances Control Act, "Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, or the Minister of the Environment obtains knowledge, etc. of the properties, etc. of a chemical substance based on this Act, in order to contribute to measures based on another Act concerning said chemical substance, he/she shall notify the Ministers governing the offices responsible for the enforcement of said other Act of the details of said knowledge, etc where needed."

In light of the purpose of the Japanese Chemical Substances Control Act, "To prevent environmental pollution by chemical substances that poses a risk of impairing human health or of interfering with the population and/or growth of flora and fauna," it is appropriate to organize even the chemical substances falling under [1] to [3] as subjects of risk assessment where such substances are the control subjects of other Acts/Laws with similar purposes to that of the Japanese Chemical Substances Control Act.

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

(3) Chemical substances potentially subject to marketing regulations under other

Acts/Laws

There exist Acts/Laws other than the Japanese Chemical Substances Control Act that not just control emissions of chemical substances but prohibit the marketing of them in light of preventing environmental pollution. In that case, such Acts/Laws enable prevention of environmental pollution by prohibiting the marketing of high risk chemical substances, just as the Japanese Chemical Substances Control Act does.

On that basis, it is not contrary to the purpose of the Japanese Chemical Substances Control Act that the notification obligation regarding the quantity of manufacture/import under the Japanese Chemical Substances Control Act is not imposed, where other Acts/Laws with similar purposes to that of the Japanese Chemical Substances Control Act apply.

It is necessary to examine individual applicable Acts/Laws to determine under which Act/Law a marketing regulation can achieve the same objective as the one of the Japanese Chemical Substances Control Act.

*** Act on the Quality Control of Gasoline and Other Fuels (Fuels Quality Control Act)**

The Fuels Quality Control Act obliges producers of volatile oil and light oil for automobiles, kerosene as indoor burning fuel, and heavy oil for vessels and offshore drilling facilities, to confirm the quality of such oils, and obliges sellers to refrain from selling such oils where the oils do not conform to technical regulations.

Further, technical regulations have been established on the basis of the one regarding exhaust gas emitted from automobiles under the Air Pollution Control Law. With the technical regulation, the Fuels Quality Control Act regulates fuel properties of such oils as above to ensure, "quality that does not lead to environmental pollution." Therefore, the technical regulations of the Fuels Quality Control Act has already covered those substances included in volatile oils etc. and potentially generating environmental pollution. Hence, when further measures are necessary, the Fuels Quality Control Act ensures that required actions are taken.

The Japanese Chemical Substances Control Act allows marketing regulations such as the prohibition of the manufacture and import of Class I Specified Chemical Substances, and an order to change the quantity of manufacture or import of Class II Specified Chemical Substances. Moreover, the Fuels Quality Control Act has also prescribed the obligations of quality confirmation and sales prohibition, forming a system to prevent the market distribution of volatile oils etc. that do not meet the technical regulations.

Accordingly, the Fuels Quality Control Act, which are based on the characteristics of those volatile oils etc. subject to the Act, has established regulations including the prohibition of marketing from the aspect of environmental pollution prevention. Hence, it is considered not to be necessary to separately control such oils through risk assessment under the Japanese Chemical Substances Control Act.

(Reference 1) Main component compositions of the earth's crust, sea water (accounting for 97.2% of natural water on earth) and the atmosphere

Main component composition of the entire crust

Component	Ratio (%)	Component	Ratio (%)
SiO ₂	55.2	Fe ₂ O ₃	2.79
Al ₂ O ₃	15.3	K ₂ O	1.91
CaO	8.80	TiO ₂	1.63
FeO	5.84	P ₂ O ₅	0.26
MgO	5.22	MnO	0.18
Na ₂ O	2.88	Total	100.0

(Source: "Chronological Scientific Tables" of the National Astronomical Observatory of Japan)

Concentrations of the main chemical components in seawater

Ion	Concentration (g/kg)	Ion	Concentration (g/kg)
Cl ⁻	18.98	K ⁺	0.38
Na ⁺	10.65	HCO ³⁻	0.14
SO ₄ ²⁻	2.65	Br ⁻	0.065
Mg ²⁺	1.27	H ₃ BO ₃	0.026
Ca ²⁺	0.40	Sr ²⁺	0.008

(Source: "The Dictionary of Chemistry" from Tokyo Kagaku Dojin)

Main component composition of the atmosphere

Component	Ratio (%)	Component	Ratio (%)
N ₂	78.1	Ar	0.93
O ₂	20.9	Other	0.07

(Source: "Chronological Scientific Tables" of the National Astronomical Observatory of Japan)

(Reference 2) The Dietary Reference Intakes for Japanese (2010 Edition)

Nutrients for which dietary reference intakes are set, and formulated indicators (1 year old or older)

		Estimated average necessary intake	Recommended intake	Adequate intake	Upper limit of tolerable intake	Target intake	
Protein		○	○	-	-	-	
Fat	Fat	-	-	-	-	○	
	Saturated fatty acid	-	-	-	-	○	
	n-6 fatty acids	-	-	○	-	○	
	n-3 fatty acids	-	-	○	-	○	
	Cholesterol	-	-	-	-	○	
Carbohydrate	Carbohydrate	-	-	-	-	○	
	Dietary fiber	-	-	-	-	○	
Vitamin	Fat-soluble	Vitamin A	○	○	-	○	-
		Vitamin D	-	-	○	○	-
		Vitamin E	-	-	○	○	-
		Vitamin K	-	-	○	-	-
	Water-soluble	Vitamin B ₁	○	○	-	-	-
		Vitamin B ₂	○	○	-	-	-
		Niacin	○	○	-	○	-
		Vitamin B ₆	○	○	-	○	-
		Vitamin B ₁₂	○	○	-	-	-
		Folate	○	○	-	○ ²	-
Mineral	Large amount	Pantothenic acid	-	-	○	-	-
		Biotin	-	-	○	-	-
		Vitamin C	○	○	-	-	-
		Sodium	○	-	-	-	○
		Potassium	-	-	○	-	○
	Trace amount	Calcium	○	○	-	○	-
		Magnesium	○	○	-	○ ²	-
		Phosphorus	-	-	○	○	-
Iron		○	○	-	○	-	
Zinc		○	○	-	○	-	
Copper		○	○	-	○	-	
Manganese		-	-	○	○	-	
Iodine	○	○	-	○	-		
Selenium	○	○	-	○	-		
Chromium	○	○	-	-	-		
Molybdenum	○	○	-	○	-		