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Chemical Regulations Updating In Asia Pacific

Report for 2017

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1 China

1.1 Mainland China (excluding Hong Kong, Macao and Taiwan)

1.1.1 NEW CHEMICAL SUBSTANCE NOTIFICATION

Measures on the Environmental Administration of New Chemical Substance in China is being revised

At the beginning of 2017, China Solid Waste and Chemicals Management Centre under the Ministry of Environmental Protection (MEPSCC) initiated the revision work to the Measures on the Environmental Administration of New Chemical Substance in China (hereinafter abbreviated as the Measures).

On 21 November 2017, MEPSCC launched a seminar regarding the revision to the Measures and discussed about the train of thoughts, purpose of legislation, types of registration, evaluation process, text structure as well as the expression of the draft Measures. The revised Measures will focus on investigating illegal enterprises and strengthening punishments. MEP will also consider conducting joint law enforcement in conjunction with the Customs as well as other departments in the future.

The revisions to the Measures lead to the further improvements of the measures for the environmental administration of new chemical substances, which is of great significance to the prevention of environmental and health risks of new chemical substances.

The data requirements under Guidance Documents for New Chemical Substance Notification in China is revised

On 31 August 2017, MEP released an Announcement on the amendments of the data requirements under the Guidance Documents for New Chemical Substance Notification in China (the 42nd Announcement in 2017). According to the requirements of the Guidance Documents, in order to make the data requirements more scientific and normative, MEP revised the minimum requirements of toxicological data and eco-toxicological data as well



as the exemption conditions of physic-chemical data, toxicology testing data and ecotoxicology testing data. The Announcement will be put into force on 15 October 2017. When the original Guidance Documents is inconsistent with the Announcement, the Announcement shall prevail.

The Guidance Documents for New Chemical Substance Notification in China (hereinafter referred to as Guidance Documents) is an important supporting document under the Provisions on the Environmental Administration of New Chemical Substance (MEP Order No. 7, hereinafter referred to as the Provisions). It played an important role for the criterion and the direction of applying notification of new substances for enterprises. In 2014, the Ministry of Environmental Protection (MEP) began to revise the Guidance Documents. In the following three years, MEP has released drafts for public comments for many times and formed the final opinion for revision. The revision this time simplified the data requirements for new chemical substance notification in China.

After detailed comparison and analysis, the new chemical substance notification experts from CIRS found that the revision of the Guidance Documents by MEP is based on the requirements of curbing the power of bureaucrats and reining in government spending as well as the principle of easing enterprises' burdens, simplifying the testing data requirements of new chemical environment management and notification. Compared with the current data requirements, the amended data requirements are more scientific and reasonable, conform to the requirements of new chemical substance management and reduce the cost of testing data greatly which apparently ease enterprises' notification burdens.

From the revised data requirements, it can be discovered that the requirements of toxicology and that of REACH are quite similar. For example, the mutagenicity tests were adjusted, the requirements for acute toxicity and repeated dose toxicity study of notification for level 1 and level 2 were lowered and the requirements for toxicokinetics and carcinogenicity were cleared. Meanwhile, MEP also takes the data requirements and testing method for international chemical management. Compared with the current data requirements, the amended data requirements are more scientific and reasonable. The



amended data requirements also conform to the requirements of new chemical substance management and reduce the cost of testing data greatly, which apparently ease enterprises' notification burdens.

The Quality Management System for Chemical Testing Data (Trail) Officially Takes Effect

The Quality Management System for Chemical Testing Data officially came into force on 1 Apr. 2017 and was under trial run. This system was developed in order to publicize the information of the testing institutions as required by the requirements for strengthening information disclosure.

Testing institutions shall release related information through this system. Testing institutions must bear all responsibilities for the authenticity and accuracy of the information and shall accept public supervision. With the above information, the public may choose an appropriate testing institution for their programs.

Up to 31 December 2017, a total of 15 testing institutions have publicized relevant information through the Management System.

On 12 December 2017, China Ministry of Environmental Protection (MEP) released the Guidance Document for On-site Verification of Eco-toxicological Data for New Chemical Substance Notification. The document has been implemented since its release. China Solid Waste and Chemicals Management Centre under MEP (MEPSCC) will randomly select some of the eco-toxicological tests data for verification. MEPSCC will particularly verify the original record of the test data as well as whether the test labs are in compliance with the Good Laboratory Practices (GLP).

Enterprises applying for new chemical substance notification should pay particular attention to the verification results released on the MEPSCC official website and select a laboratory with relevant qualifications and good reputation for their eco-toxicological tests. Relevant



enterprises should also focus on testing method, data recording, quality control, result judgment, etc., to avoid notification failure due to the unqualified testing data.

Charges of the China IECSC Inquiry for the Classified/Confidential Part is Reduced

Charges of the China IECSC Inquiry for the Classified/Confidential Part will be reduced to 3000 RMB in accordance with a notice released by the China Solid Waste and Chemicals Management Centre under Ministry of Environmental Protection (MEPSCC).

Previously, the inquiry cost was 5000 RMB. The reduction of the inquiry fee this time is to ease enterprises' burdens.

IECSC Inquiry will help enterprises confirm whether their products are new chemical substances in China. There are two parts of IECSC, public part and classified/confidential part. Companies can check out the public part by themselves and shall only enquire Authorities for the classified/confidential part.

Shanghai carries out thematic evaluation for new chemical substance follow-up inspection

On 16 February 2017, Shanghai Environmental Protection Bureau organized a meeting on thematic evaluation for new chemical substance follow-up inspection. The purpose of this meeting is to prevent the environmental risks of new chemical substances and to protect the environment. Shanghai Environmental Protection Bureau aims to investigate the manufacturing, import, use and transfer status of new chemical substances in Shanghai by the thematic evaluation and to make sure the environmental risks of new chemical substances are under control.

During the evaluation, enterprises involving in new chemical substances should complete the Enterprise Self-inspection Table of Thematic Evaluation for New Chemical Substance Follow-up Inspection, Summary Table of Thematic Evaluation for New Chemical Substance Follow-up Inspection and other documents. The Enterprise Self-Inspection Table covers manufacturing/application status of the new chemical substance, information



communication situation, pollution control apparatus, supervision of hazardous new chemical substances, individual protection, emergency plan for environmental protection, relevant equipment, etc. Relevant enterprises must make sure that all the information is reported based on the actual situations. Enterprises should also fill in the Summary Table, which covers the current situation and existing problems of the enterprise, emission and transfer amount of hazardous substances, rectification situations, etc.

Shanghai environmental protection bureaus will carry out on-site assessment after receiving the feedbacks. The on-site assessment includes documents on the fulfilment of obligations, record of activities, analysis/supervision report and the implementation situation of the risk control measures.

Shanghai plans to carry out the inspection work once a year.

Enterprises should check whether their products contain new chemical substances requiring notification before they manufacture or import such products and carry out notification in accordance with Provisions on the Environmental Administration of New Chemical Substance if notification is required, or they will be punished; enterprises that have completed notification for their new chemical substances should fulfil relevant obligations and conduct manufacturing and import process in strict accordance with the risk control measures recorded in the registration certificate.

1.1.2 STORAGE AND TRANSPORT OF HAZARDOUS CHEMICALS

Regulation of Automobile Transportation of Dangerous Goods (JT617)

Regulation of Automobile Transportation of Dangerous Goods (JT617), also known as the ADR in China, is still being revised.

The implementation of JT617, especially the introduction limited quantity and excepted quantity, will reduce the cost of transportation of dangerous goods in small quantities.



Ministry of Transport notified to standardize the road transport of limited bottled gases

On 11 July 2017, the Ministry of Transport released a Notice concerning the standardization of the transport of limited bottled nitrogen and other gases. This notice ruled that qualifications of the transport enterprises can be exempted when 6 kinds of low-risk gases, including nitrogen, helium, neon, argon, krypton and xenon, are transported in the condition that the containers meet related requirements (the containers do not exceed specific volume and each transportation unit does not exceed specific quantity/volume). The special purpose vehicles and professional qualifications of employers are not required as well. That is to say, these 6 kinds of gases can be transported as general cargo. Relevant UN numbers are UN1066, UN1046, UN1065, UN1006, UN1056, UN1977, UN1963, UN1913 and UN1951. If packages, labels and quantities of the gases fail to fulfil relevant requirements, then they must be transported as dangerous goods.

Amendments to storage standards for hazardous chemicals

Rule for the Storage of Hazardous Chemicals is still being revised. During this revision, 4 standards, including Specifications for Storage and Preservation of Combustible and Explosive Goods (GB17914-2013), Specifications for Storage and Preservation of Corrosive Goods (GB17915-2013), Specifications for Storage and Preservation of Toxic Goods (GB17916-2013) and Rule for Storage of Chemical Dangers (GB 15603-1995) will be simplified and merged into 1 standard. Name, main body and annexes of the standard will also be amended greatly.

This standard will apply to the management of storage of chemicals listed in the Catalogue of Hazardous Chemicals. Enterprises shall be aware that the management methods in the revised standard are quite different from that in the Rule for Storage of Chemical Dangers (GB15603-1995).

1.1.3 TOXIC CHEMICALS STRICTLY RESTRICTED TO IMPORT/EXPORT IN CHINA



On 20 December 2017, the Ministry of Environmental Protection (MEP) in China released the Inventory of Toxic Chemicals Strictly Restricted from Import/Export (2018 revision) to regulate the import and export of restricted toxic chemicals. Compared with the 2014 revision, the number of chemicals listed in the 2018 revision is greatly reduced, from 162 to 10. The 2018 revision only covers chemicals listed in Chemicals under the Control of Stockholm Convention on POPs and its amendments, Chemicals under the Control of Minamata Convention on Mercury and Chemicals under the Control of Rotterdam Convention.

If enterprises need to import chemicals listed in the Inventory of Toxic Chemicals Strictly Restricted from Import/Export, they must obtain the Release Permit for the Import Environmental Administration of Toxic Chemicals. Enterprises must make sure that the usage of the imported chemicals is also permitted by the Conventions before they handle the release permit. If the substance is also a new chemical substance, then enterprises must obtain the Certificate for Environmental Administration of New Chemical Substance in China as well. Besides, the import enterprise must establish a standing book, in which the imported chemicals, the flow of chemicals and the usage situations shall all be recorded. When MEP conducts on-site audit on the enterprise, it must apply the standing book to MEP.

If enterprises need to export chemicals listed in the Inventory, they must obtain the Release Permit for the Export Environmental Administration of Toxic Chemicals. Enterprises must make sure that their products fulfil the requirements of the imported country/region before they apply for the release permit.

Enterprises do not need to apply for the release permit for chemicals listed in the 2014 revision, but not listed in the 2018 revision. However, as most of these chemicals are also listed in the Catalogue of Hazardous Chemicals, enterprises still need to obtain related administrative permission, go through hazardous chemical registration and prepare SDS and labels for these products.



1.1.4 THE PRIORITIZED LIST OF SUBSTANCES TO BE SUBJECT TO CONTROL (1ST BATCH) IS RELEASED

On 28 December 2017, the Ministry of Environmental Protection (MEP) in China published the Prioritized List of Substances to be Subject to Control (1st Batch). This list contains a total of 36 chemicals, spanning a broad range of industries, including petrochemical industry, coking industry, agrochemical industry, dye industry and electroplating industry. To reduce the impact of these chemicals on human health and the environment, risk management measures should be carried out.

The List is prepared on the basis of Water Pollution Control Action Plan released in 2015. In accordance with the requirements of Water Pollution Control Action Plan, MEP should assess the environmental and health risks of existing chemicals, and release the prioritized list before the end of 2017. To minimize the adverse effect on the environment and human health, MEP should strictly control the manufacturing and use of these chemicals and gradually popularize substitute chemicals.

In June 2017, MEPSCC organized several seminars on the preparation of the prioritized list of chemicals and the manufacturing and usage status as well as the environmental release of chemicals that are suggested to be included into the list. In October 2017, MEP released the draft Prioritized List of Substances to be Subject to Control (1st Batch) for consultation.

This list will be updated dynamically. In view of the environmental and health risks these chemicals cause, relevant risk measures should be carried out. They include: 1. Enterprises should obtain the sewage discharge permission before they discharge these chemicals; 2. The State will restrict the use of these substances in some products and encourage enterprises to use substitutes; 3. Clean production audit will be implemented.

Many of the priority chemicals are also listed in Annex XIV of REACH Regulation, which means that, these products are similar to substances listed in the REACH authorisation list and should be eliminated gradually.

Note: Below is the 1st batch of priority chemicals



No.	Chemical name	CAS No.
PC001	1,2,4-trichlorobenzene	120-82-1
PC002	1,3-butadiene	106-99-0
PC003	5-tert-Butyl-2,4,6-trinitro-m-xylene (xylene musk)	81-15-2
PC004	N,N'-Bis(methylphenyl)-1,4-benzenediamine	27417-40-9
PC005	Short-Chain Chlorinated Paraffins (SCCPs)	85535-84-8 68920-70-7 71011-12-6 85536-22-7 85681-73-8 108171-26-2
PC006	Dichloromethane	75-09-2
PC007	Cadmium and cadmium compounds	7440-43-9
PC008	Mercury and mercury compounds	7439-97-6
PC009	Formaldehyde	50-00-0
PC010	Hexavalent chromium compounds	
PC011	Hexachloro-1,3-cyclopentadiene	77-47-4
PC012	Hexabromocyclododecane	25637-99-4 3194-55-6 134237-50-6 134237-51-7 134237-52-8
PC013	Naphthalene	91-20-3
PC014	Lead compounds	
PC015	Perfluorooctanesulfonic acid (PFOS) and its salts and PFOSF	1763-23-1 307-35-7 2795-39-3 29457-72-5 29081-56-9 70225-14-8 56773-42-3 251099-16-8
PC016	Nonylphenol and nonylphenol polyoxyethylene ether	25154-52-3 84852-15-3 9016-45-9
PC017	Trichloromethane	67-66-3
PC018	Trichlorethylene	79-01-6
PC019	Arsenic and arsenic compounds	7440-38-2
PC020	Decabromodiphenyl ether (DecaBDE)	1163-19-5
PC021	Perchlorethylene	127-18-4
PC022	Acetaldehyde	75-07-0



1.2 Taiwan

1.2.1 TAIWAN DRAFT OF PRIORITY EXISTING CHEMICALS (1ST BATCH) IS ISSUED

In June 2017, Taiwan's Environmental Protection Administration published the draft of priority existing chemicals (1st batch) for public comments in accordance with the requirements of TCSCA and Regulation of New and Existing Chemical Substances Registration as well as the results of Phase I registration. This list contains 122 existing substances that require standard registration.

The second and third batch will be released later, together with the tonnage as well as the registration period. The draft list for the first batch released in 2017 will be finalized in 2018.

Registrants should submit relevant documents, including basic information of the substance and registrant, manufacturing information, usage and exposure information of the substance, hazard classifications and labels, physicochemical property, toxicological information, eco-toxicological information, hazard assessment information as well as exposure assessment information.

1.2.2 TAIWAN'S EXECUTIVE YUAN PASSED AMENDMENTS TO THE TOXIC AND CHEMICAL SUBSTANCES OF CONCERN CONTROL ACT

On 9 November 2017, Taiwan's Executive Yuan passed the revision to the Toxic and Chemical Substances of Concern Control Act and submit it to the Legislative Yuan for review.

The changes were formulated with reference to the UN's Strategic Approach to International Chemicals Management (Saicm) and other international frameworks. The scope of the Act will be expanded to other chemical substances of concern and point of origin control will be strengthened. The revision is considered as part of the Taiwan government's 'five ring' food safety regulation strategy.



Major changes are as follows:

1. Scope of this Act is expanded to other chemical substances of concern and the name of the Act is changed to Toxic and Chemical Substances of Concern Act;
2. Chemical Substance of Concern is newly added in to the Act. Scope of chemical substances subject to evaluation is expanded; and chemicals will be administered by different levels (Article 3, Article 30 to Article 38, Article 44, Article 45 and Article 59 are amended);
3. Accident treatment capability should be strengthened (Article 17 and Article 35 are amended);
4. The chemical substance operating fee, purpose, targets and usage of the fund are added (Article 47 and Article 48 are amended); and
5. To encourage the public to report illegal activities, individual reporting articles, witness protection system and illegal income recovery system are newly added;

The amended Toxic and Chemical Substance of Concern Control Act is far stricter than the current TCSCA, which expands the scope of substances subject to administration and refines the management. Enterprises should pay more attention to the chemical regulatory compliance in the future to avoid unnecessary losses due to illegal activities.

1.2.3 AMENDED DRAFT OF REGULATION OF NEW AND EXISTING CHEMICAL SUBSTANCE REGISTRATION IS RELEASED

In September 2017, Toxic and Chemical Substance Bureau released the Amended Draft of Regulation of New and Existing Chemical Substance Registration. Detailed information is as follows:

1. The amended draft unifies the inconsistency in regulations for chemical substance registration under EPA and DOL;
2. Cost of administrative fee will be reduced so that the burden of registrants can be eased. Registration documents are replaced by registration codes;



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3. The deadline for late pre-registration is clearly recorded in the amended draft. The amended draft stipulated that enterprises manufacturing or importing chemicals in tonnages over 100kg should get pre-registered within 6 months after manufacturing and import; enterprises manufacturing or importing chemicals in tonnages less than 100kg can apply for late-preregistration on their own initiative; and
4. Annual reporting system will be implemented from 1 January 2019. Registrants must submit the manufacturing or importing information of the previous year to the competent authority between 1 March and 30 June after they get registered.



2 South Korea

2.1 Updates of K-REACH

K-REACH officially took effect from 1 January 2015. This regulation required that existing chemical substances exceeding 1tonne per year and new chemical substances should carry out K-REACH registration. On 30 June 2015, South Korea' s Ministry of Environment released the first batch of existing chemicals (510 substances in total).

Up to 30 November 2017, 38 registration dossiers have been submitted. Among them, 27 registration dossiers are still under evaluation.

In accordance with the statistics of a consulting agency in South Korea, among all the 510 PECs, 370 substances established the Chemical Substance Information Communicative Organization (CICO). Hereinto, 10% of the substances in CICO apply for registration in volumes over 1000t/y; 22% of the substances in CICO apply for registration of 100-1000t/y; 27% of the substances in CICO apply for registration of 10-100t/y; while 41% of the substances in CICO apply for registration of 1-10t/y.

Among all the 370 substances in CICO, 47 substances still do not have lead registrants.

2.2 Amendments to K-REACH

On 28 December 2016, South Korea' s Ministry of Environment released the amended K-REACH for public consultation. Major amendments are as follows:

1. All ≥ 1 t/y existing substances (about 7,000) will need to be registered within tonnage-based grace periods;
2. A new pre-registration scheme will be introduced to all ≥ 1 t/y existing substances;
3. Annual report system will be abolished;



4. Substance authorisation becomes stricter;
5. Sellers of a hazardous chemical substance should provide hazard information to the person who purchases such hazardous substance regardless of its registration or content in product;
6. Penalty provisions are newly made for wrong test results;
7. Penalty provisions are newly made for substances requiring registration that caused damages to human health during applications.

On 16 January 2017, the Ministry of Environment disclosed more information on K-REACH amendments, including the transitional period for pre-registration:

- Substances exceeding 1000 ton/y should be registered before 2021;
- Substances exceeding 100 ton/y should be registered before 2024;
- Substances exceeding 10 ton/y should be registered before 2027.

Besides, the Ministry of Environment stated that if the amended K-REACH could be passed and released to the public in 2017, then it could be implemented in 2018. MOE notified WTO of the amended K-REACH as well. However, MOE also confirmed that even if the amended K-REACH is passed, PECs should still be registered before 30 June 2018.

On 8 August 2017, South Korea's Cabinet approved the K-BPR and the amended K-REACH.

It is estimated that the amended K-REACH will officially take effect from 1 July 2018 and the K-BPR will be implemented from 1 January 2019. Before the implementation of K-BPR, namely before 1 January 2019, enterprises can make an application for the submission of toxicological data if their products are already sold on the market and may enjoy a transitional period.

2.3 KOSHA

Enterprises manufacturing or importing new chemical substances exceeding 0.1t/y in South Korea should not only get registered under K-REACH, but should



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comply with KOSHA. The competent authority for KOSHA is the Ministry of Labor. In accordance with the requirements of KOSHA, substances of different tonnages have different data requirements.

3 Vietnam

3.1 Updates of Existing Chemical Substance Inventory

In March 2017, Vietnam's Ministry of Industry and Trade updated the inventory of existing substances. The late 1627 substances are newly added.

In November 2017, Nguyen Thi Ha from International Convention and International Cooperation Division said that Vietnam focused on improving the existing substance inventory in the International Conference on Chemicals Management. It is estimated that the inventory will be finalized at the beginning of 2019.

3.2 Implementation of 113/2017/ND-CP

On 25 November 2017, 113/2017/ND-CP, the Vietnam Chemicals Decree took effect. Detailed information of the Decree is as follows:

- Updates of restricted substance inventory and list of substances requiring registration;
- Improvement to the existing chemical substance inventory; and
- Introduction of annual report.

The Vietnam Chemicals Decree No. 113/2017/ND-CP replaced the regulation released before. The lists of regulated chemicals are included in Decree No. 113/2017/ND-CP as annexes:

- The list of chemicals subject to conditional production or import;
- The list of chemicals restricted from production or trade;
- The list of banned chemicals; and
- The list of chemicals subject to compulsory registration;

Compared with the 2007 version, the number of substances in the above lists was reduced which is because repetitive substances have been deleted.



In accordance with the requirements of Article 35 of the Vietnam Chemicals Decree, enterprises must submit the annual report to the local industry and trade ministries if they need to manufacture regulated substances.

Substances listed in the list of chemicals subject to compulsory registration should get registered as required. Details are as follows:

1. Bottled and packaged chemical substances must apply for registration;
2. Substances contained in the list are clearly standardized in accordance with GHS;
3. List of toxic chemicals is deleted and the toxic chemicals are regulated under Law on Chemicals;
4. Obligations of chemical substance record for usage is not required; and
5. Annual report is required for all activities relevant to chemicals;



4 Turkey

On 23 December 2017, KKDIK was published in the Turkey's Official Gazette. This Regulation is modelled on REACH and officially took effect on 23 December 2017.

This regulation brings 3 Turkish chemicals legislation under one law by replacing three existing regulations: Regulation on the Inventory and Control of Chemicals; Regulation on the Preparation and Distribution of Safety Datasheets for Hazardous Materials and Products; and Regulation on the Restrictions Relating to the Production, Supply to the Market and Use of Certain Hazardous Materials, Products and Goods.

Pre-registration is also introduced in KKDIK.

Besides, this law sets a pre-registration deadline of 31 December 2020 and a registration deadline of 31 December 2023.



5 India

In December 2017, India stated that a new regulation will be put into effect for the management of paints and biocides in other industrial applications.

Early in 2015, India's Central Pesticide Insecticide Board and Registration Committee already formed a team of experts to study the use and registration of biocides in paints.



6 Philippines

6.1 The Philippine Draft Policy for Polymers is Released for Public Comments

In December 2017, the Philippine Department of Environment and Natural Resources (DENR) released the Polymers and Polymer of Low Concern (PLC) Exemption from the Pre-Manufacture and Pre-Importation Notification (PMPIN) for public comments. Detailed requirements and standards for polymer exemption are given in this draft for public comments.

Pursuant to Section 11 (item c) of Republic Act 6969 (Toxic Substances and Hazardous and Nuclear Waste Control Act) and Section 22, Chapter VI of DENR Administrative Order (DAO) No. 29, Series of 1992 (Implementing Rules and Regulations of RA 6969) that state for the polymer exemption from the Pre-Manufacture Pre-Importation Notification (PMPIN) process, this memorandum circular shall provide specific criteria and requirements of polymers.

This Circular aims to provide guidelines for importers and manufacturers of polymers that are considered or determined by this Office as polymers of low concern or low risk to human health and to the environment and are exempted from the Pre-Manufacture and Pre-Importation Notification (PMPIN) process.

Specific definitions of Cationic Polymer, Functional Group Equivalent Weight, Gel Permeation Chromatography (GPC), Infrared (IR) Spectroscopy, Molecular Weight (MW), Monomer, New Monomer, Reactant, Oligomer and Polymer are given in this Circular.

Among them, Polymer of Low Concern (PLC):

- (a) must meet the definition of polymers;
- (b) cationic polymer can be exempted if the FGEW is >5000 Daltons; and
- (c) must not be unstable, degradable, decomposed, or depolymerised.



This Circular also indicates that to be exempted from PMPIN process, a polymer shall meet any of the following criteria:

1. All of its monomers must be listed in the PICCS;
2. Polymers containing the monomers and other reactants (including cross linking, chain transfer agents, and post polymerization reactants) not in the PICCS added at total quantities less than 2 percent (by weight); and
3. The low concern polymer shall fall into one of the following categories:
 - a. Polymers that have:
 - Number Average Molecular Weight (NAMW) equal to or greater than 10,000 Da;
 - Less than 5% of oligomers with MW lower than 1000 Da and less than 2% of oligomers with MW lower than 500 Da; and
 - An FGEW for cationic polymers of greater than 5000 Da.
 - b. Polymers that have:
 - NAMW equal to or greater than 1000 Da and less than 10,000 Da,
 - Less than 25% of oligomers with MW lower than 1000 Da and less than 10% of oligomers with MW lower than 500 Da, and
 - No reactive functional groups in excess of the levels of 2% by weight.

When applying for polymer exemption, applicants shall submit:

1. A duly notarized and accomplished polymer exemption form (signed by the top management i.e., CEO, President, General Manager (Annex 1));
2. Polymer information like specific chemical name, chemical structure, CAS number (if available), use/s of the polymer;
3. Safety Data Sheet (SDS) for the polymer alone or as isolated as possible;
4. 100% composition including CAS numbers of monomers of the polymer;
5. Test data/report to prove that the polymer falls in the criteria of low concern polymer (GPC, IR Spectroscopy and others); and



6. Processing fee of PhP 500.00 per polymer per product.

Besides, applicant can indicate in the polymer exemption form and the covering letter for Confidential Business Information (CBI) applications. The details for CBI shall be sent by the supplier.

All polymers previously granted Exemption are no longer subject to this policy. All new polymers that meet the criteria are given one year to comply. Polymers that do not meet the PLC criteria should comply with the PMPIN procedures.

The DENR-EMB shall review the Polymer Exemption application within forty (40) working days from receipt of the application. In the case of incomplete submission of the requirement, a letter for additional information shall be issued to the applicant. Failure to submit the additional information within 60 days upon receipt of letter shall consider their application “null and void”.

The polymers that are exempted shall not be listed in the PICCS.



7 UN GHS

7.1 Amendments to the UN GHS 7th Revised Edition

In July 2017, UN GHS 7th Revised Edition was officially released. Compared with the 6th Revised Edition, major amendments are as follows:

7.1.1 Definitions and acronyms

Dermal corrosion, dermal irritation, eye irritation, serious eye damage, skin corrosion, skin irritation and acute toxicity are redefined; In the definition of respiratory sensitizer, “a substance” is replaced by “a substance or mixture” .

7.1.2 Transfer of hazard communication: SDS

For the hazard class “aspiration hazard” in table 1.5.1, the cut-off value/concentration limit of categories 1 and 2 was updated and the condition of kinematic viscosity was deleted. Details are shown as follows:

	6 th Revised Edition	7 th Revised Edition
Aspiration hazard (category 1)	$\geq 10\%$ of category ingredients, kinematic viscosity ≤ 20.5 mm ² /s at 40° C.	$\geq 1.0\%$
Aspiration hazard (category 2)	$\geq 10\%$ of category ingredients, kinematic viscosity ≤ 14 mm ² /s at 40° C.	$\geq 1.0\%$

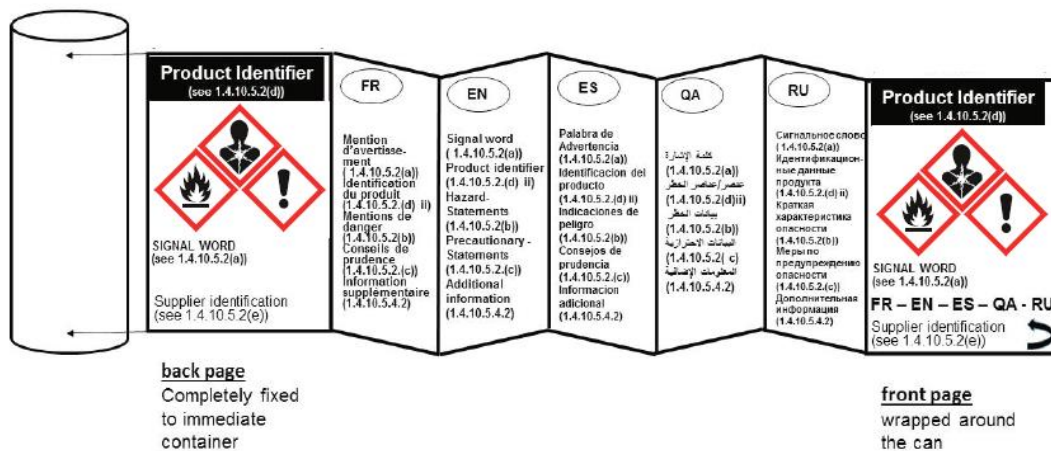
7.1.3 Addition of new classification criteria under flammable gases and updates of criteria for categorization

The 7th Revised Edition integrated the Table 2.2.1, 2.2.2 and 2.2.3 in the 6th Revised Edition; Flammable gases are classified in 1A, 1B or 2 and flammable gases that are pyrophoric and/or chemically unstable are always classified in Category 1A.



7.1.4 Labels: A new example for fold-out labels of small containers was added

Fold-out labels include front page, text page and back page. The front page should contain at least: product identifier, hazard pictogram(s), signal word and supplier identification. A symbol to inform the user that the label can be opened to illustrate that additional information is available on inside pages is also required. The text page should contain: product identifier (including hazardous components contributing to the classification), signal word, hazard statements, precautionary statements and other information (such as directions for use and information required by other regulations). If more than one language is used on the fold-out label, the country codes or language codes are required. The back page should contain: product identifier, hazard pictogram(s), signal word and supplier identification.



Additionally, there are different fold-out labels styles, e.g. book style, order book style and window style.

The 7th Revised Edition amended the classification criteria for flammable gases, which makes it stricter and also easier for understanding; updated the definitions of some health hazards, such as acute toxicity, skin corrosion/irritation and serious eye damage/eye irritation, mainly called off the specific requirements for exposure time or symptom observation time. The use and preparation of precautionary statements were amended. Besides, the latest GHS also added a new example of fold-out labels for small containers. In this way, even if the



container is small, the large number of hazard statements assigned to the chemical can be placed on the label.

8. Overall Assessment

In 2017, especially at the end of 2017, a large number of regulations and inventories were updated in China and many of them will take effect in 2018. The implementation of the Prioritized List of Substances to be Subject to Control (1st Batch) will gradually eliminate products contained in the list; the release of Toxic Chemicals Strictly Restricted from Import/Export (2018 revision) in China simplifies the import/activity activities for substances withdrawn from the 2018 revision. It is certain that more regulations and standards will be released in 2018. Enterprises should pay close attention to the upcoming regulations for their activities, such as new chemical substance notification and transport/storage of hazardous products, may be influenced.

Globally, 2018 will be the last registration deadline for EU REACH and the first batch of PECs under K-REACH. Furthermore, enterprises will face major challenges this year as multiple regulations, including KKDIK and the amended K-REACH, will be implemented in 2018.