Polymer Regulations and Polymer Notifications
Update Report 2011

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Polymers have been widely used in a wide range of industries such as packaging and coatings, construction materials, consumer goods, electrical and electronic industry, medical equipment and agriculture. For downstream users and formulators in the chemical industry, polymers are often used as surfactants, fluid modifiers, thickeners, emulsifiers, stimuli-responsive agents, conditioners, foam stabilizers, and so on.

The extensive number and the daily use of polymers make it more important for the governments and organizations to regulate them while not hindering innovation.

Since 2007 when REACH came into force, many countries have updated or changed their own chemical legislation. In this report, we will focus on the latest updates regarding how existing polymers and new polymers are regulated in EU, USA, China, Japan and Korea.

This report consists of the following chapters:

- Definition of Polymer;
- Polymer of Low Concern (PLC) and non-PLC;
- Europe;
- USA;
- China;
- Japan;
- Korea
- Comparison;
Definition of Polymer

The OECD definition of a polymer has been widely adopted and incorporated in the regulations of many governments, including EU, USA, China, Japan, Korea and many other countries or regions.

The OECD definition of a polymer is listed as follows[1]:

A 'POLYMER' means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

By this definition, many low molecular weight substances, oligomeric reaction products, dimmers or trimers cannot be called polymer.

More simply put, a polymer must meet the following three criteria:

(1) Molecules must be distributed over a range of molecular weights;
(2) The weight percentage of molecules containing three monomer units or above should exceed 50%;
(3) The weight percentage of any molecule of the same molecular weight shall not exceed 50%.

The preferred method to determine whether a substance falls under the definition of a polymer is Gel Permeation Chromatography (GPC). Guidelines on the determination of the number average molecular weight (Mn) and molecular weight distribution using GPC are available in the OECD TG 118 (1996).

The best example available to explain the definition of a polymer can be taken from ECHA guidance document on polymers. This example is listed as below [2]:
In Example 1, the substance consists of 10% ethoxylated phenol with n=2, 85% with n=3 and 5% with n=4. Since this substance comprises 85 weight percent of the same polymer molecule (n=3), it does not meet the definition of a polymer. Therefore, it should be considered as a standard substance.

In Example 2, only 15+12+8+5=40 weight percent of the substance consists of polymer molecules, i.e. molecules for which n>=3. For this reason, example 2 does not comply with the criteria for polymer definition either. Therefore it should also be considered as a standard substance.

Example 3, meets the definition of a polymer since 20+30+20+10+5=85 weight percent of the substance consists of polymer molecules (i.e. molecules for which n>=3) and none of the different constituents are present at concentrations above 50 weight percent (each constituent having a different molecular weight).

References

[1] OECD Website
http://www.oecd.org/document/54/0,3746,en_2649_34379_35056054_1_1_1_1,00.html
[2] ECHA guidance monomers and polymers
Polymer of Low Concern (PLC) and non-PLCs

Polymers usually are divided into two groups: polymer of low concern (PLC) and non-PLCs. The rationale behind this is that polymers with high molecular weight are less likely to cross biological membranes and cause harm. OECD has defined polymers of low concern as those deemed to have insignificant environmental and human health impacts. Those PLCs should have reduced regulatory requirements.

Except in the EU system, all other jurisdictions (USA, China, Korea and Japan, etc) have integrated the concept of PLC into their regulation. In those countries, PLCs are either exempt from notification or can be notified with reduced data requirements. New polymers that do not meet the criteria for PLCs shall be notified as a regular new substance.

Even though the OECD definition of a polymer is widely adopted, the criteria used to identify PLC have not been harmonized. The criterion for a PLC in each country is different and will be discussed this issue later. However, those countries often use the following parameters to define a PLC:

- The number-average molecular weight (Mn); An Mn \( \geq 1000 \text{ Da} \) is a generally accepted Mn range for a PLC;
- The content of low molecular weight, oligomeric species (i.e., <1000 Da and/or <500 Da species);
- Whether specific reactive functional groups are present or absent in polymers;
- Solubility, stability and polymer class, etc.

References

[1] OECD Publication on PLCs
Europe

The main chemical legislations regulating polymers in the EU are the REACH regulation and the CLP regulation.

EU does not differentiate between new polymers and existing polymers. All polymers are exempt from registration and evaluation under REACH. However, any manufacturer or importer of a polymer shall submit a registration to the European Chemicals Agency (ECHA) for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met[1]:

(a) The polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);  
(b) The total quantity of such monomer substance(s) or other substance(s) makes up to 1 tonne or more per year.

Non-EU manufacturers of polymer may submit a registration to ECHA via a REACH only representative.

Any monomer is by definition an intermediate. Nonetheless, the specific provisions for the registration of intermediates under REACH does not apply to monomers. Only additives used to preserve the stability of the polymer and impurities are regarded as one part of the polymer and do not need to be registered separately under REACH. If other additives have been added to improve the performance of the polymer (for example, flame retardant), those additives shall be registered separately if the concentration of such additives are above 2% w/w and the annual quantity of such additives are above 1 ton per year.

Polymers may also be subject to authorization and restriction under REACH.

No-longer Polymers

Please note that the definition of a polymer in EU is different from the OECD definition before the 7th amendment of Directive 67/548/EEC was adopted in 1992. As a consequence of the implementation of this amendment, some substances which were considered to be polymers under the reporting rules for EINECS are no longer considered to be polymers under the 7th amendment [2]. Therefore, these substances are called “No-Longer Polymers” (NLP). Those no-longer polymers shall be registered as a normal phase-in substance.
The NLP list mainly consists of the following groups:
1. alkoxylated substances
2. oligomeric reaction products
3. oligomers from one monomer only
4. dimers and trimers
5. polymer-like substances containing 50% or more by weight of species with the same molecular weight

More information on NLP substances can be obtained through the website of the European Commission Joint Research Centre:

Polymers are not exempt from CLP regulation[3]. A polymer is a substance and must be notified if it fulfils the criteria for classification as hazardous and it has been placed on the market. Importing a polymer does not correspond to the placing on the market of the monomers and any other substance from which the polymer substance originates. The C&L notification provisions for the import of a polymer can therefore only apply to the polymer substance itself.

References
[1] ECHA guidance on monomers and polymers
[2] ECB website
[3] ECHA Website CLP FAQ
USA

The main regulation for polymers in US is the Toxic Substances Control Act (TSCA).

All polymers are excluded from the TSCA Inventory Update Reporting which requires manufacturers and importers of certain chemical substances included on the TSCA Chemical Substance Inventory to report site and manufacturing information for chemicals manufactured (including imported) in amounts of 25,000 pounds or greater at a single site.

New polymers are subject to the requirements of pre-manneufacture notification (PMN). Under the terms of the TSCA polymer exemption rules amended in 1995, manufacture and distribution of new polymers meeting the following exemption criteria can take place without submission of a pre-manufacture notification (PMN) or an exemption notice prior to commencement of manufacture for a commercial purpose [1]:

- Polymer must meet the OECD polymer definition;
- The average molecular weight (MW) of the polymer is between 1,000~10,000 Da. At the same time, the weight percentage of oligomer with MW<500 is less than 10 percent, and the weight percentage of oligomer with MW<1000 is less than 25 percent;
- The average molecular weight (MW) of the polymer is greater than 10,000 daltons. At the same time, the weight percentage of oligomer with MW<500 is less than 2 percent, and the weight percentage of oligomer with MW<1000 is less than 5 percent;
- Polyester polymer that are manufactured from a list of acceptable reactants;

However, there are five exclusions under paragraph (d) in the 1995 polymer exemption [2].

- Positively charged polymers
  Cationic or potentially cationic polymer cannot be exempt unless its charge density is sufficiently low or it is a non-dispersible, non-soluble solid;

- Atomic element limitations
  All eligible polymers must contain as an integral part of their composition two or more of the atomic elements, carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur;

- Instability
Polymers that substantially degrade, decompose, or depolymerize are not eligible for exemption;

- Un-reviewed reactants (2% rule)
  Polymers that contain 2% w/w or more reactants or monomers which are not listed on TSCA inventory are not eligible for exemption;

- High molecular weight, water-absorbing polymers
  Polymer that is capable of absorbing its own weight of water and has a number-average molecular weight $\geq 10,000$ are excluded from exemption;

- Reactive functional group

Many of the US polymer exemption rules have been adopted by China, Japan and Korea.

For polymers that meet the exemption criteria, manufacturers and importers shall submit a report to the USEPA once a year regarding the number of polymers manufactured or imported for the first time. There is no need to give the identity or any other information concerning the polymers in the report. The only other information required is the name and address of the manufacturer or importer and the name and phone number of a technical contact. It is recommended that companies keep good records in case of on-site inspection. Such record shall include chemical identity, supporting evidence that the substance meets the exemption criteria and production or import records.

Reference:

[1] EPA website
China

In China, new chemical substances, toxic chemicals and hazardous chemicals are regulated by different legislation. Polymers are generally regarded as representing a low concern due to their high molecular weight and they are less likely to be classed as toxic chemicals or hazardous chemical substances. Therefore, most of existing polymers are not regulated in China. However, the monomers might be regulated by relevant laws (for example, vinyl chloride).

The main regulation affecting polymers is the Measures on Environmental Administration of New Chemical Substances (China REACH), which came into force in October 2010.

Under China REACH, any polymer that is not listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) will be regarded as a new chemical substance. Domestic companies shall notify the new chemical substance to the Chemical Registration Centre (CRC) prior to the manufacturing or importation. Foreign companies can notify the new substance by appointing a local Chinese agent. Please note that even if all monomers are listed on IECSC, notification is still required if the polymer itself is not listed on IECSC [1].

Note: IECSC is available at http://www.crc-mep.org.cn/iecsweb/IECSC.aspx?La=1

Nomenclature Rules for Polymers in China and How to Search Polymers on IECSC

Before searching IECSC, it is very important for a company to know the nomenclature rules in China. The Chinese name of a polymer should be named in accordance with <Chinese Nomenclature in Polymer Chemistry (2005 edition)> . English name shall follow IUPAC or CAS nomenclature rules. Chinese name must match English name precisely.

Polymers with defined molecular and structural formula should be named after their molecular structure, for example, polyethylene, polystyrene, otherwise, be named on the basis of starting monomer(s) and reactants. Only the starting monomer(s) and reactants with 2 % weight by weight (w/w) or more need to be included in the name of the notified polymers, which is the so-called “2% rule of polymer”.

Searching for polymers by name on online IECSC is very difficult as the names are long and chemical names are sometimes in different formats (sequence matters). Therefore searching for polymers on IECSC using the CAS number is the best option. However, if no CAS number is available,
submitting enquiry to CRC is the best way. Do not waste your time by searching the names of monomers or trying different names.

There are three types of notifications for new polymers in China: simplified notification under special conditions, simplified notification under basic conditions and typical notification [2].

**Simplified Notification under Special Conditions**

Polymers listed below qualify for simplified notifications under special conditions.

- polymer consisting of monomers or building blocks that are already listed in IECSC (if the polymer itself is not listed on IECSC);
- polymers containing less than 2% new chemical substance weight by weight (if the polymer itself is not listed on IECSC); and
- polymer of low concern (if the polymer itself is not listed on IECSC).

China has adopted the concept of PLC proposed by OECD even though China is not a member of OECD. China’s PLC criteria are very similar to USEPA PLC criteria. In China, polymer that meets any one of the following three criteria will be regarded as PLC:

- The average molecular weight (MW) of the polymer is between 1,000~10,000 Da. At the same time, the weight percentage of oligomer with MW<500 is less than 10 percent, and the weight percentage of oligomer with MW<1000 is less than 25 percent. Besides, the polymer shall not contain functional groups of high concern (for example, heavy metals) and highly reactive functional groups;
- The average molecular weight (MW) of the polymer is greater than 10,000 daltons. At the same time, the weight percentage of oligomer with MW<500 is less than 2 percent, and the weight percentage of oligomer with MW<1000 is less than 5 percent;
- Polyester polymer;

The following information shall be submitted for the simplified notification of polymers:

- List of monomer (s)/reactants, including the name, CAS number, the content of monomer (s)/reactants as well as whether if monomer (s)/reactants are listed in IECSC;
- Molecular weight and its distribution, including GPC or other testing results to indicate molecular weight and its distribution;
- Description of the mechanism of polymerization process, manufacturing process or flow chart;

Please note that no mandatory toxicology or eco-toxicology data are required for simplified notification under special conditions in China. Many new polymers placed on Chinese market meet the criteria of simplified notification under special conditions.

**Simplified Notification under Basic Conditions**

For polymers that are not listed on IECSC and not eligible for simplified notification under special conditions, simplified notification under basic conditions shall be submitted if the volume of the polymers is less than or equal to 1 ton per year. If the volume is above 1 ton per year, typical notification shall be submitted.

The following information shall be submitted for the simplified notification under basic conditions for polymer:

- Composition information about the polymer and GPC data;
- Existing physio-chemical data (Melting point, partition coefficient n-octanol/water and water solubility are mandatory);
- 1~3 of the following tests must be carried out in Chinese labs approved by MEP: ready biodegradability, acute toxicity study with Brachydanio rerio, acute toxicity test with earthworms depending on substance properties;

**Typical Notification**

For polymers that are not listed in IECSC and do not meet the conditions of simplified notification under special conditions, simplified notification under basic conditions shall be submitted if the volume of the polymers exceeds 1 ton per year. More data will be required for typical notification depending on the tonnage band. However, the overall data requirement is still less than the requirement for a regular substance because chemical risk assessment report is not required for polymers. Besides, a series of identification procedures could be used to determine if the data requirements could be reduced further (solubility and stability are the key factors).

The following diagram shows to how to determine the right type of notification for polymers and corresponding data requirements in China.
Polymer

Is the concentration of new substance contained in the polymer below 2% (w/w)?

No

Simplified Notification

Is the tonnage over 1tpa?

No

Typical Notification

Yes

Is it a low concern polymer?

Yes (optional)

Contains heavy metal or its cation?

No

Is it soluble in water?

No

Is it soluble in organic solvent?

No

Is it stable in different PH solutions?

No

Yes

Typical notification with reduced requirement (only physio-chemical data is required)

Yes

General condition

Specific condition

References

http://www.crc-mep.org.cn/A108/_FILE_DOWNLOAD/_DOC/%E6%96%B0%E5%AD%A6%E7%89%A9%E6%8A%A5%E6%8C%87%E5%8D%97.pdf

[2] Practical guidance on new chemical notification in China (English)
Japan

Polymers are mainly regulated by the Chemical Substances Control Law (CSCL) in Japan. The amended CSCL entered into force completely from 1 April 2011. Polymer is also regulated by the Industrial Safety and Health Law (ISHL) and mainly the new polymer is affected by ISHL.

Under amended CSCL, manufacturers and importers of both new and existing polymers (except polymer of low concern) will be required to report their quantities and usage (use category) to the government annually starting from 2011 if the volume of the polymers exceed 1 ton per year.

For new polymers, there are extra obligations. Polymers, which are produced even from only existing monomers, shall be notified if that polymer itself is not listed on the Japanese Existing and New Chemical Substances Inventory (ENCS).

Note: ENCS is available at [http://www.safe.nite.go.jp/english/db.html](http://www.safe.nite.go.jp/english/db.html)

Japanese manufacturers, importers and foreign companies shall submit new chemical notification to three authorities: the Ministry of Economy, Trade and Industry (METI), the Ministry of Health, Labor and Welfare (MHLW), and the Ministry of the Environment (MOE), to obtain approval notice from the governments before manufacturing or importing new polymers.

However, the following polymers are not deemed as new substances and thus will be exempt from notification:

- Inorganic polymer consisting of monomers which are existing chemical substances (for example, polyphosphoric acid);
- Block-polymer consisting of unit-polymer all of which are listed in the ENCS;
- Graft-polymer consisting of stem polymers and branch polymers all of which are listed in the ENCS;
- Polymers that meet 99% rule or 98% rule;

99% rule: For a copolymer obtained from A, B, and C, when the sum of the weight percentage of A and B in the copolymer exceeds 99%, and the copolymer of A and B is an existing chemical substance, the copolymer of A, B, and C is not treated as a new chemical substance (even if C is a new substance).

98% rule: For a copolymer obtained from A, B, and C, when the sum of the weight percentage of A and B in the copolymer exceeds 98%, and the copolymer of A and B is an existing chemical substance, the copolymer of A, B, and C is not treated as a new chemical substance only if C is also an existing chemical substance.
Please note: In Japan, monomer with concentration below 1% w/w is not regarded as one component of the polymer. In EU, China and Korea, the concentration limit is 2% w/w (“2% rule”).

**Polymer Flow Scheme Test and Polymers of Low Concern**

Japan has required a series of standard screening tests for new polymers (called “polymer flow scheme test”) to help evaluate the potential environmental and human health impacts of the new polymers. Those tests include GPC, solubility, stability and other physio-chemical tests (for example, IR). The test results are used to determine if the polymer meets the criteria of PLC. Only those new polymers that have been confirmed by the government as polymer of low concern will be exempt from new substance notification and the mandatory reporting of the manufacture and import under CSCL. Please note that an official notice of confirmation is required.

Polymer of low concern shall meet all of the following criteria; otherwise, the new polymer is not PLC and shall be subject to standard requirements of the notification of a new substance:

- Number average molecular weight(MW) \( \geq 1,000 \text{ Da} \);
- Physically and chemically stable; if chemical composition changes in neutral, acid, and alkaline water, the polymer not PLC. However, if transformed product is PLC, the original polymer is also PLC;
- Meet following a or b:
  - insoluble in water, organic solvents and in acid or base, or insoluble in water, organic solvents and having specific molecular structure;
  - soluble in water and organic solvents, but the weight percentage of Oligomer (MW<1,000) is \( \leq 1\% \text{ w/w} \) and no information to indicate high accumulation;
- No heavy metals or cationic properties;
- Not polymers that the government concludes that they might have adverse effect on human health or environment.

**Polymer and ISHL**

In Japan, new chemical substance (including new polymer) shall also be notified under the Industrial Safety and Health Law (ISHL).

If all monomers of a polymer are existing substances and the number average molecular weight of the polymer is greater than or equal to 2,000, the polymer will be exempt from notification. Besides, other new polymers that do not meet all the criteria below could also be exempt from
notification. However, companies are required to report its details prior to the manufacturing or importation.

- Positively charged polymers;
- Carbon content is less than 32%;
- Having covalent bond with any atom(s) other than S, Si, O, H, C and N;
- Having ionic bond with any other atom(s) other than Al, K, Ca, Na and Mg;
- Extracted from organism and its derivatives, and having similar chemical structures;
- Synthesized with halogen or cyano-group containing compound(s);
- Containing reactive groups and (Mn of polymer) / (number of reactive groups in polymer) <=10,000 (Example of reactive groups: isocyano, epoxy, phenol, etc.)
- Having risk to decompose or de-polymerize at room-temperature and standard pressure.

References

[1] JETOC presentation about CSCL and ISHL in 2006
http://www.jetoc.or.jp/0605JKTregulation.pdf


[3] Provisional CSCL full text – English
Korea

In Korea, polymers are mainly regulated by the Toxic Chemicals Control Act (TCCA). The following picture shows how polymers are regulated in Korea and how to comply [1]. Existing polymers are not regulated by TCCA if they are not toxic Chemicals, observational chemicals or restricted chemicals.

Polymers are exempt from the new chemical notification under Toxic Chemical Control Act if they meet one of the following criteria below [2]:

- Polymers that contain 2% w/w less reactants or monomers which are not listed on Korean Existing Chemicals Inventory (KECI);
- Graft polymer, if the stem and all branches are listed on KECI;
- Block polymer of which all blocks and stems are listed on KECI;
- Low concern polymer:
  - Non-ionic polymer with Mn\(\geq\)10,000 Da;
  - Non-ionic polymer with Mn\(\geq\)1,000, which meets the following conditions: Polymers are not synthesized from toxic chemicals, observational chemicals or new chemicals, and epoxy-compound; and the water solubility should be less than or equal to 5mg/g at PH 2,7 and 9;
For polymers that meet the criteria of exemption, manufactures and importers in Korea shall apply for confirmation of exemption from the Korean Chemical Management Association (KCMA). For new polymers that are not exempt, manufacturers and importers may submit notification to the National Institute of Environmental Research (NIER) with reduced data requirements.

It shall be mentioned that foreign companies can notify new polymers or apply for exemption in China and Japan. In Korea, only domestic companies can do that under current TCCA.

**Polymer and Korea REACH**

Attention shall also be paid to “the Act on the Registration and Evaluation of Chemicals” in Korea that will overhaul the current TCCA and regulate both new and existing substances [3]. The REACH-like act is also known as" Korea REACH" and is expected to come into force in 2013.

Korea REACH requires manufacturers and importers of chemicals to notify substances (i.e. submit data such as quantities of production or import in the previous year) to the MOE, which will then designate certain existing chemicals as "chemicals subject to assessment" for registration. Polymers are not excluded from this notification requirement.

Under Korea REACH, existing substances (including polymers) that have been designated as “chemicals subject to assessment” will be given a transitional period up to 8 years to register if they are pre-registered. New chemical substances shall be registered prior to the manufacture or importation. However, it is less likely that polymers be designated as “chemicals subject to assessment” due to their low concern. Only two tonnage bands are available (>100t/y and <100t/y).

To pre-register, manufacturers or importers of existing chemicals subject to assessment manufactured or imported in quantities above 0.5 ton per year must submit a pre-registration to the ministry within 6 months since the publication of the chemical substances subject to assessment. Similarly to REACH, foreign exporters can submit pre-registration or registration to authorities through the appointment of only representative.

The picture below shows how to determine whether chemical require pre-registration or registration or not under Korea REACH.
References

[1] Nam & Nam International
   http://www.jetoc.or.jp/0605JKTregulation.pdf
[3] South Korea REACH by Keller and Heckman
## Comparison

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<td>Registration of monomer or reactant &gt; 2% w/w is required if the volume of monomer or reactant exceeds 1t/y; Also regulated by CLP;</td>
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## About CIRS

Chemical Inspection and Regulation Service (CIRS) is an independent firm providing comprehensive hazardous substance testing and chemical regulatory consulting services with a strong focus on worldwide chemical compliance. We are dedicated to providing valued chemical compliance services and solutions, and delivering valued information through original expert analysis.

CIRS’s two large operations are based in China and Ireland. Since 2007, we have helped over 2,400 companies achieve chemical compliance in EU and China.

CIRS’s R&D centre consists of around 15 chemists and toxicologists. They gather the latest regulatory updates regarding chemical industry and downstream users of chemicals carry out in-depth analysis of regulatory requirements and provide the technical know-how to help our clients achieve compliance.

- End-