


On 19 Jan 2010, the Ministry of Environmental Protection (MEP) of China released the revised version (the Order No. 7) of the Measures on Environmental Administration of New Chemical Substances. The new regulation replaced the old regulation issued in 2003 and came into force on 15 Oct 2010. This regulation is similar to EU REACH and is also known as "China REACH".

Under this regulation, companies shall submit new chemical substance notification to the Chemical Registration Centre (CRC) of SEPA for the new chemicals *irrespective of annual tonnage*, ie chemicals other than the approximately 45,000 substances currently listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). The notification not only applies to new substance on its own, in preparation or articles intended to be released, but also applies to new substances used as ingredients or intermediates for pharmaceuticals, pesticides, veterinary drugs, cosmetics, food additives and feed additives, etc.

Note 1: New substances manufactured or imported to China before 15 Oct 2003 only require application for IECSC inclusion.

This guidance document will teach you how to comply with China REACH step by step.

Step One: Determination of Whether a Notification Is Required

- **Check Chinese Existing Chemical Inventory IECSC**

Chinese government released a new version of IECSC on 7 Dec 2010, which is known as IECSC 2010. There are 45602 substances in **IECSC 2010**, among which 3166 are confidential. There are 37427 substances with CAS number and 8175 substances that cannot be identified by CAS number.

Companies can go to CRC's IECSC portal to find out whether a substance is included in IECSC 2010 or not:

http://www.crc-mep.org.cn/iecscweb/IECSC.aspx?La=1

More than 3,100 notified substances are not included in the data base for confidentiality reasons. It is recommended that a formal enquiry be submitted to CRC to check whether a substance is new or not. The enquiry costs around 200 RMB, around 22 Euros or 30 USD.

Special notes: Polymer is not exempt from notification. Even if all monomers are listed in IECSC, notification is still required if the polymer itself is not listed in IECSC. More info can be found at simplified notifications under special conditions.

- **Check Exemption Conditions**

There are four major categories of chemical substances exempt from China REACH:

- Chemicals subject to other existing laws and regulations;
  Radioactive substances, military industry products, pyrotechnics, biotic substances, pesticides, veterinary drugs, pharmaceuticals, cosmetics, foods, food additives, feed, feed additives, tobacco and tobacco products.

- Substances existing in nature
  1. Substances that are unprocessed, or that are manufactured or processed only through the methods listed below: 1) Manual; 2) Mechanical; 3) Gravitational; 4) Soluble in water; 5) Floatation in water; 6) Heat dehydration.
  2. Extracted from the atmosphere through various means;
  3. Natural polymers, except for ones that are chemically modified;

- Substances of noncommercial purpose or unintentionally produced
  1. Impurities; 2. Products of random reactions; 3. Products of random reactions that occur when a chemical substance, mixture, or article is in storage; 4. Products of reactions that occur when a chemical substance, mixture, or article is in final use; 5. Waste water, waste gas, solid waste, and by-products.

- Special categories
  1 Glass; 2.Frit; 3. Pottery raw materials and ceramic ware; 4. Steel and steel products; 5. High-alumina cement; 6. Portland cement; 7. Articles 8. Homogeneous and heterogeneous alloys, except for metal compounds and precisely defined intermetallic compounds 9. Non-isolated intermediates.

■ **Check Whether You Will Be Allowed to Submit Notifications**

The follow companies are allowed to submit new chemical notifications under China REACH.

- Manufacturer of new substance in China;
- Importer of new substance in China;
- Foreign companies selling new substances to China.

Companies in China can submit new substance notification on their own or appoint a local agent to do so. Foreign companies have to appoint a local Chinese agent to submit new chemical notifications and the local agent shall be knowledgeable enough to carry out the notification. The role of the agent is very similar to the role of "only representative" under EU REACH regulation.

Note: The minimum registered capital of the local Chinese agent is 3 million yuan (around 330,000 Euros). China REACH has set out this requirement to avoid so called "shell" companies.

Step Two: Determination of Type of Notification

Type of Notification	Applicable Scope
• Typical notification • 4~18 months;	New chemical substances to be manufactured or imported at or above the annual volume of 1 ton. Based on tonnage band, there

	are four notification levels: - First level (1～10 tons) - Second level (10～100 tons) - Third level (100～1,000 tons) - Forth level (>1,000 tons))
• Simplified notification basic condition • 3~4 months	New chemical substance with tonnage under 1 ton per year;
• Simplified notification specific condition • 2~3 months	New chemical substance - for export only with tonnage under 1 ton per year; - for scientific research with tonnage between 0.1 to 1 ton per year; - for technological research with tonnage less than 10 ton per year - for polymers with all monomers already listed in IECSC or polymers containing less than 2% new chemicals weight by weight; and - for low concern polymers.
• Scientific research record • 3~5 working days	New chemical substances used for scientific research with an annual quantity lower than 0.1 ton or if the sample is to be tested in laboratories in China.

Step Three: Data Evaluation and Data Gap Analysis

The following paragraphs have summarized the data requirements for different types of notification under China REACH. You shall evaluate existing data based on the principles listed as below and carry out data gap analysis.

■ **Data Source**

Data generated through the following sources is accepted for the notification of new chemical substances in China: test reports, published authoritative literature, authoritative database, and

other non-testing methods such as QSAR, read-across and expert opinion. However, test reports are more important than other data sources. Data generated by non-testing methods is usually not accepted at initial stage of review unless the testing could not be conducted scientifically.

For different data sources, the required supporting documents are different. For the data generated by testing, the certificate of the test agency must be provided. For the data generated from published literature, the original text of the literature must be provided. A summary or a quotation is not enough. For the data generated from authoritative database, the name of the database, the issuing agency, and the version number shall be given. For the data generated by QSAR, the QSAR model, parameters, the recommending agency or research agency of the model, the version, the valid illustration of results and other useful information shall be provided. For expert opinions, the general information about the expert, such as the title/duty, company/organization, field of research, and main research achievements shall be mentioned.

- **Data Sharing**

Data sharing is not mandatory but encouraged under the regulation. If several companies would like to notify the same substance, they will have two options to share data for typical notification: joint notification or repeated notification.

> ***A joint notification*** refers to the case in which a notification dossier is jointly submitted by two or more applicants. When a joint notification is approved, an independent Registration Certificate will be issued for each applicant.

> ***Repeated notification*** allows a late applicant to refer to the dossier and data prepared by the previous applicant. Furthermore, the written authorization from the previous applicant is required. This is similar to the joint submission process under REACH.
>
> It shall be pointed out that in both cases, the notification tonnage band shall be the sum of the annual tonnage of each applicant.

If one company or several companies would like to register several substances with similar structures and toxicological properties, he or they can submit one serial notification or one joint serial notification dossier for the group of chemicals. This is similar to the registration of chemicals by categories under REACH.

- **Test Agencies and Test Methods**

According to the regulation, the test report must be written in Chinese or in English for the minimum data required. Test reports shall indicate clear methods used and be accompanied by the accreditation materials provided by competent authorities.

Some of the eco-toxicology tests must be carried out in SEPA-approved eco-toxicity laboratories in China. Other tests can be carried out in domestic laboratories with certain qualifications and/or overseas testing agencies (GLP laboratories are preferred). The laboratories based outside of China

must be certified by the local country and the copy of certificate of the laboratory must be provided. They may complete the test as per Chemical Test Guidelines (HJ/T153—2004) of China or follow better standards such as internationally renowned OECD methods and ISO standards.

■ **Data Requirement for Different Types of Notification**

There are three types of notification: Scientific Research Record, Simplified Notification and Typical Notification. The difference between Scientific Research Record and other two types of notifications is that for the former the related activities could be started once the notification form is submitted and for the latter related activities (manufacturing or importation) can only be started after the applicant receives the registration certificate issued by CRC.

- **Scientific Research Record**
  Scientific research record applies to new chemical substances used for scientific research purpose with an annual quantity lower than 0.1 ton and samples to be introduced to China for testing purpose. Testing data is not required. Only a Scientific Research Record form needs to be submitted.

- **Simple Notification Under Basic Conditions**
  Simplified notification under basic conditions applies to the new chemical substances with tonnage band less than 1 ton per year manufactured in/imported to China;

  For simplified notification (under basic condition), applicants shall submit

  - simplified notification form;
  - test report of mandatory eco-toxicological testing in China;

✓ **Minimum Data Requirement for Organic Substances**
1~3 tests must be conducted in China depending on the property of the substance.

No.	Test Name	Test Scheme	Remarks
1	Ready biodegradability	The test must be conducted at first.	Mandatory eco-toxicological testing in China.
2	Acute toxicity study with Brachydanio rerio	The test must be conducted if the substance is not ready biodegradable.	
3	Earthworm, acute toxicity test	The test must be conducted if the LC50 of fish cannot be obtained due to the fact that the solubility of the substances in water is less than 100mg/L and the substance is not shown to be toxic to aquatic life at its saturated concentration.	
4	Melting Point (°C)		

5	Partition coefficient n-octanol/water		
6	Water solubility		

✓ **Minimum Data Requirement for Inorganic Substances**
1~2 tests must be conducted in China depending on the property of the substance.

No.	Test Name	Testing Scheme	Remarks
1	Acute toxicity study with Brachydanio rerio	The test must be carried out if the substance is not ready biodegradable.	Mandatory eco-toxicological testing in China.
2	Earthworm, acute toxicity test	The test must be conducted if the LC50 of fish cannot be obtained due to the fact that the solubility of the substances in water is less than 100mg/L and the substance is not shown to be toxic to aquatic life at its saturated concentration.	
3	Melting Point (°C)		
4	Partition coefficient n-octanol/water		
5	Water solubility		

■ **Simple Notification Under Specific Conditions**

If a new chemical substance meets any of the following conditions, simplified notification under specific conditions shall be submitted:

- for export only with tonnage under 1 ton per year;
- for scientific research with tonnage between 0.1 to 1 ton per year;
- for technological research with tonnage less than 10 ton per year (up to 2 years);
- for polymer consisting of monomers already listed in IECSC(if the polymer itself is not listed in IECSC);
- for polymers containing less than 2% new chemical substance weight by weight; and

- for low concern polymers(if the polymer itself is not listed in IECSC);.

Polymer that meets one of the three conditions below can be regarded as low concern polymer.

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

ii. The average molecular weight (MW) of the polymer is greater than10,000 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 WW<1000 is less than 5 percent.

iii. Polyester polymer.

For simplified notification under specific conditions, the applicant shall submit:

- Simplified notification form;
- Corresponding document of evidence.
- For polymers, composition data about monomer, GPC data, and polymerization mechanism shall be given.

The difference between simplified notification under specific conditions and basic conditions is that there is no mandatory testing requirement for simplified notification under specific conditions. However, the applicant shall list any existing physicochemical, toxicological or other information in the notification form that could describe the properties of the substance.

Additionally, the applicant shall provide the documents of evidence that could prove the substances are within the scope of simplified notification under specific conditions.

■ **Typical Notification**

For typical notification, there are four levels depending on the tonnage band: 1-10t/y, 10-100t/y, 100-1000t/y and 1000t+/y.

For different tonnage bands, the data required is different. The minimum data requirements for each tonnage band are listed in the tables below. Please note that many high-level tests can be waived based on the results of low-level tests.

✓ **Minimum Data Required for 1~10t/y**

Qualitative and quantitative identification of the notified substance(not all tests are required)	
IR	GC
UV	GPC
NMR	ICP-AES
MS	XRD
HPLC	AAS

Physico-chemical Properties Testing	
1	Melting Point (solid)
2	Boiling Point (liquid)
3	Density (solid, liquid)
4	Vapor Pressure (liquid)
5	Partition coefficient n-octanol/water (solid, liquid)
6	Water solubility (solid, liquid)
7	Surface tension (liquid)
8	PH value (liquid)
9	Flash point (liquid)
10	Granulometry / Particle size (solid)
11	Oxidizing properties (solid, liquid, gas)
12	Self-ignition temperature (solid, liquid, gas)
13	Flammability (solid, liquid, gas)
14	Explosive properties (solid, liquid)
15	Explosive limit (gas)
16	Critical point (gas)
Toxicology Properties Testing	
10	Acute toxicity by oral

11	Acute toxicity by dermal	
12	Acute toxicity by inhalation	
13	Skin irritation or skin corrosion	
14	Eye irritation	
15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Mutagenicity	Bacterial reverse mutation test (Ames)
18		In vitro mammalian chromosome aberration test
Eco-toxicology Properties Testing		
19	Algae growth inhibition study	
20	Acute toxicity study with Daphnia magna	
21	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
22	Activated sludge respiration inhibition testing	
23	Adsorption/desorption properties	
24	Ready biodegradability (The study should be conducted in China)	
25	Earthworm, acute toxicity test	

- ✓ **Minimum Data Required for 10~100t/y**

Qualitative and quantitative identification of the notified substance	
IR	GC
UV	GPC
NMR	ICP-AES
MS	XRD
HPLC	AAS

Physico-chemical Properties Testing		
1	Melting Point (solid)	
2	Boiling Point (liquid)	
3	Density (solid, liquid)	
4	Vapor Pressure (liquid)	
5	Partition coefficient n-octanol/water (solid, liquid)	
6	Water solubility (solid, liquid)	
7	Surface tension (liquid)	
8	PH value (liquid)	
9	Flash point (liquid)	
10	Granulometry / Particle size (solid)	
11	Oxidizing properties (solid, liquid, gas)	
12	Self-ignition temperature (solid, liquid, gas)	
13	Flammability (solid, liquid, gas)	
14	Explosive properties (solid, liquid)	
15	Explosive limit (gas)	
16	Critical point (gas)	
Toxicology Properties Testing		
10	Acute toxicity by oral	
11	Acute toxicity by dermal	
12	Acute toxicity by inhalation	
13	Skin irritation or skin corrosion	
14	Eye irritation	
15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Repeated dose 90-day toxicity study (At least one study of the	by oral

	three exposure routes must be provided according to the use of the substance)	by dermal
		by inhalation
18	Mutagenicity	Bacterial reverse mutation test (Ames)
19		In vitro mammalian chromosome aberration test
20		Rodent Bone marrow chromosome aberration test or micronucleus test
21	Screening for reproductive/developmental toxicity	
22	Toxicokinetics (Absorption)	
Eco-toxicology Properties Testing		
23	Algae growth inhibition study	
24	Acute toxicity study with Daphnia magna	
25	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
26	Activated sludge respiration inhibition testing	
27	Adsorption/desorption properties	
28	Degradation	Ready biodegradability (The study should be conducted in China)
29		Inherent Biodegradability (The study should be conducted in China)
30		Hydrolysis test with PH function
31	Earthworm, acute toxicity test	
32	14 days extended toxicity study in fish, (The study should be conducted in China)	
33	Daphnia magna Reproduction study	
34	Bioaccumulation in aquatic species, preferably fish	

✓ **Minimum Data Required for 100~1000t/y**

Qualitative and quantitative identification of the notified substance	
IR	GC
UV	GPC
NMR	ICP-AES
MS	XRD
HPLC	AAS
Physico-chemical Properties Testing	

1	Melting Point (solid)	
2	Boiling Point (liquid)	
3	Density (solid, liquid)	
4	Vapor Pressure (liquid)	
5	Partition coefficient n-octanol/water (solid, liquid)	
6	Water solubility (solid, liquid)	
7	Surface tension (liquid)	
8	PH value (liquid)	
9	Flash point (liquid)	
10	Granulometry / Particle size (solid)	
11	Oxidizing properties (solid, liquid, gas)	
12	Self-ignition temperature (solid, liquid, gas)	
13	Flammability (solid, liquid, gas)	
14	Explosive properties (solid, liquid)	
15	Explosive limit (gas)	
16	Critical point (gas)	
Toxicology Properties Testing		
10	Acute toxicity by oral	
11	Acute toxicity by dermal	
12	Acute toxicity by inhalation	
13	Skin irritation or skin corrosion	
14	Eye irritation	
15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Repeated dose 90-day toxicity	by oral

	study (At least one study of the three exposure routes must be provided according to the use of the substance)	by dermal
		by inhalation
18	Mutagenicity	Bacterial reverse mutation test (Ames)
19		In vitro mammalian chromosome aberration test
20		Rodent Bone marrow chromosome aberration test or micronucleus test
21	Reproduction/developmental toxicity study	Aberration Test
22		Two-generation reproductive toxicity study
23	Toxicokinetics (Whole)	
Eco-toxicology Properties Testing		
24	Algae growth inhibition study	
25	Acute toxicity study with Daphnia magna	
26	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
27	Activated sludge respiration inhibition testing	
28	Adsorption/desorption properties	
29	Degradation	Ready biodegradability (The study should be conducted in China)
30		Inherent Biodegradability (The study should be conducted in China)
31		Hydrolysis test with PH function
32	Earthworm, acute toxicity test	
33	Daphnia magna Reproduction study	
34	Bioaccumulation in aquatic species, preferably fish	
35	Chronic toxicity test in fish (in China), at least one of the three)	Fish Early life-stages Toxicity Test
		Fish short-term toxicity test on embryo and sac-fry stages
		Fish larvae growth tests
36	Seed Germination/Root Elongation Toxicity Test	

✓ **Minimum Data Required for 1000t/y+**

Qualitative and quantitative identification of the notified substance	
IR	GC
UV	GPC
NMR	ICP-AES
MS	XRD
HPLC	AAS

Physico-chemical Properties Testing	
1	Melting Point (solid)
2	Boiling Point (liquid)
3	Density (solid, liquid)
4	Vapor Pressure (liquid)
5	Partition coefficient n-octanol/water (solid, liquid)
6	Water solubility (solid, liquid)
7	Surface tension (liquid)
8	PH value (liquid)
9	Flash point (liquid)
10	Granulometry / Particle size (solid)
11	Oxidizing properties (solid, liquid, gas)
12	Self-ignition temperature (solid, liquid, gas)
13	Flammability (solid, liquid, gas)
14	Explosive properties (solid, liquid)
15	Explosive limit (gas)
16	Critical point (gas)

Toxicology Properties Testing	
10	Acute toxicity by oral
11	Acute toxicity by dermal
12	Acute toxicity by inhalation
13	Skin irritation or skin corrosion
14	Eye irritation

15	Skin sensitization	
16	Repeated dose 28-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
17	Repeated dose 90-day toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
18	Mutagenicity	Bacterial reverse mutation test (Ames)
19		In vitro mammalian chromosome aberration test
20		Rodent Bone marrow chromosome aberration test or micronucleus test
21	Reproduction/developmental toxicity study	Aberration Test
22		Two-generation reproductive toxicity study
23	Toxicokinetics (Whole)	
24	Chronic toxicity study (At least one study of the three exposure routes must be provided according to the use of the substance)	by oral
		by dermal
		by inhalation
25	Carcinogenicity study	
Eco-toxicology Properties Testing		
26	Algae growth inhibition study	
27	Acute toxicity study with Daphnia magna	
28	Acute toxicity study with Brachydanio rerio (The study should be conducted in China)	
29	Activated sludge respiration inhibition testing	
30	Adsorption/desorption properties	
31		Ready biodegradability

	Degradation	(The study should be conducted in China)
32		Inherent Biodegradability (The study should be conducted in China)
33		Hydrolysis test with PH function
34	Earthworm, acute toxicity test	
35	Daphnia magna Reproduction study	
36	Bioaccumulation in aquatic species, preferably fish	
37	Chronic toxicity test in fish (The study should be conducted in China, at least one of the three)	Fish Early life-stages Toxicity Test
		Fish short-term toxicity test on embryo and sac-fry stages
		Fish larvae growth tests
38	Seed Germination/Root Elongation Toxicity Test	

Step Four: Filling Data Gaps by Testing

After collecting all the available substance information and analyzing the data gaps based on your tonnage band, you shall carry out testing in qualified testing institutions to fill the data gaps. This might involve:

- Apply for scientific research record before introducing sample to China for testing;
- Deliver sample to qualified labs and arrange testing schedule;
- Adjust the high level testing items according to the basic level testing results;
- Analyze the testing results, collate testing report and translate testing report.

Step Five: Preparation and Submission of Notification Dossier

You shall gather all needed information and documents to complete the new substance notification application form, which might include:

- Notification form;
- Chinese Safety Data Sheets;
- Recommended classification and labelling;
- Risk assessment report;
- Test report detailing the substance's physiochemical properties and its toxicity and eco-toxicity properties;
- Certificates for the qualification of laboratories;

- Other supporting documents required ;

Test reports and other documents shall be provided as attachments. All forms and reports must be written in Chinese.

Step Six: Post-notification Obligations

After notification is completed, a registration certificate containing specific management category will be issued. Certificate holder needs to fulfill different post-notification obligations depending on the management category of the substance.

Chemical substances will be categorized as **general new chemical substances** or **hazardous new chemical substances**. Hazardous new chemical substances possessing persistent, bioaccumulative properties or are harmful to ecological environment and human health will be further classified as **priority hazardous new chemical substances for environmental management**.

Category	Post-notification Obligations
General new chemical substances (6 Requirements)	1. Communicate MSDS to downstream users; 2. Implement risk management measures; 3. Submit first-activity report; 4. Keep documents on file for over 10 years; 5. Do not sell chemicals to downstream users who are not capable of implementing risk management measures; 6. Submit updates if new hazard arises;
Hazardous new chemical substances (8 Requirements)	7. Submit annual report (for previous year); 8. Comply with <<The Measures for The Administration of Registration of Hazardous Chemicals>>;
Priority hazardous new chemical substances for environmental management (11 Requirements)	9. Submit report on disposal information; 10. Submit substance flow chart; 11. Submit annual plan (for next year);

Simplified Notification(2 Requirements)	1. Submit annual plan (for next year); 2. Keep documents on file for over 10 years;
Scientific Research Record (2 Requirements)	1.Requirements of professionals and facilities; 2. Can only be used for scientific research purpose;

Frequently Asked Questions About China REACH

1. One Chinese company A produced two new chemical substances P1 and P2 and sold them to two Chinese companies B and C. Company B made P1 and P2 react to produce a new chemical substance P3. Company C mixed P1 with other substances to produce a preparation P4. Company B and C exported P3 and P4 respectively to customers outside China.

Question: Which of the above companies should notify? Which substances from P1 to P4 need to be notified?

Answer: Company A and B have notification obligations. P1, P2, P3 shall be notified.

2. Question: If one substance is listed in IECSC but its hydrate not, does its hydrates require notification?

Answer: No.

3. Polymer P consists of 4 monomers A, B, C and D. Monomers A, B and C are listed in IECSC. Monomer D is not listed IECSC and its concentration in P is lower than 2% w/w in P. One company produced monomer D and then used it directly to produce polymer P.

Question: How should the company submit notification for polymer P and monomer D?

Answer: The Company should submit simplified notification under specific conditions for polymer P. Notification of substance D depends on the actual situation: if D is not isolated and used directly for the synthesis of P, there is no need to notify D; if D has been isolated before being used to produce P, the company should submit notifications for D.

4. Suppose we are doing research and our goal is to synthesize D by taking the synthesis route of A-B-C-D. However, we might produce other new chemicals such B’ and C’ during the synthesis process. Question: Should I notify all of B, C, B’ and C’?

Answer: The basic principle is that except for non-isolated intermediates, all new chemical substances used in the research process should apply for scientific research record or simplified notification. If B, C, B’ and C’ are non-isolated intermediates, there is no need to submit notifications.

5. After a registration certificate is issued, if our volume exceeds the allowable limit on the certificate, do we have to submit new notifications or just provide more data?

Answer: There is no need to submit new notifications. The certificate holder only needs to provide more data based on the new tonnage band and update the registration certificate.

6. Can we keep molecular formula and molecular structure confidential when we submit notifications?

Answer: No. Molecular formula and molecular structure are necessary for CRC to determine whether a substance is the same with one substance in IECSC. CRC has taken strict measures to ensure all documents submitted by a notifier are kept confidential. All staff of CRC are well trained. There is no need to worry about the disclosure of sensitive information.

7. When a test is to be carried out in a lab outside of China, does the lab have to follow the chemical test guidelines in China or the local standards?

Answer: Overseas test organizations which provide new chemical substance declaration for test data shall meet the qualifications mentioned in the guidance document of CRC. They may complete the test as per Chemical Test Guidelines (HJ/T153－2004) of China or follow better standards such as internationally renowned OECD methods and ISO standards. Test reports shall indicate clear methods used and be accompanied by the accreditation materials provided by competent authorities.

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 offer one-stop solutions to your chemical compliance in China and our services include new substance notification, registration of the import and export of toxic chemicals, and classification and labeling in according to China GHS and the Chinese SDS. We also deliver the most up-to-date regulatory information about chemical control laws in China.

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