

Typical Notification Service under China REACH

China REACH applies to new chemical substances that are not currently listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) irrespective of tonnage.



Notification Types under China REACH

There are three types of notifications under China REACH: typical notification, simplified notification (under basic or specific condition) and scientific research record.

Type of Notification	Applicable Scope
Typical notification	<p>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:</p> <ul style="list-style-type: none"> - First level (1 ~ 10 tons) - Second level (10 ~ 100 tons) - Third level (100 ~ 1,000 tons) - Forth level (>1,000 tons)
Simplified notification (under basic condition)	New chemical substance with tonnage under 1 ton per year;
Simplified notification (under specific condition)	<p>New chemical substance</p> <ul style="list-style-type: none"> - 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 listed in IECSC or polymers containing less than 2% new chemicals weight by weight; and - for low concern polymers <ol style="list-style-type: none"> i. The average molecular weight (MW) of the polymer is between 1,000~10,000 daltons. At the same time, the content of oligomer is less than 10 percent at MW < 500, and less than 25 percent at MW < 1,000. The polymer still shall not have an obvious content of active functional groups; ii. The MW of the polymer is more than 10,000, and the oligomer content is less than 2 percent at MW < 500, a



	<p>nd the oligomer content is less than 5 percent at MW < 1,000;</p> <p>iii. Polyester polymer.</p>
Scientific research record	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.

Data Requirements of Typical Notification

Typical notification applies to new chemical substances to be manufactured or imported at or above the annual volume of 1 ton. For typical notification, the applicant shall submit

- typical notification form
- Chinese Safety Data Sheets
- Recommended classification and labeling
- Risk assessment report
- Test report detailing the substance's physiochemical properties and its toxicity and eco-toxicity
- Certificates for the qualification of laboratories
- Other documents required for the typical notification

The core of typical notification is "data". The applicant shall submit enough data endpoints that could well describe the substance's physical chemical, toxicological and eco-toxicological properties. The data/information provided should be sufficient for the assessment committee to make a scientific evaluation of the dossier. The principle is that the higher the volume is, the more data is required.

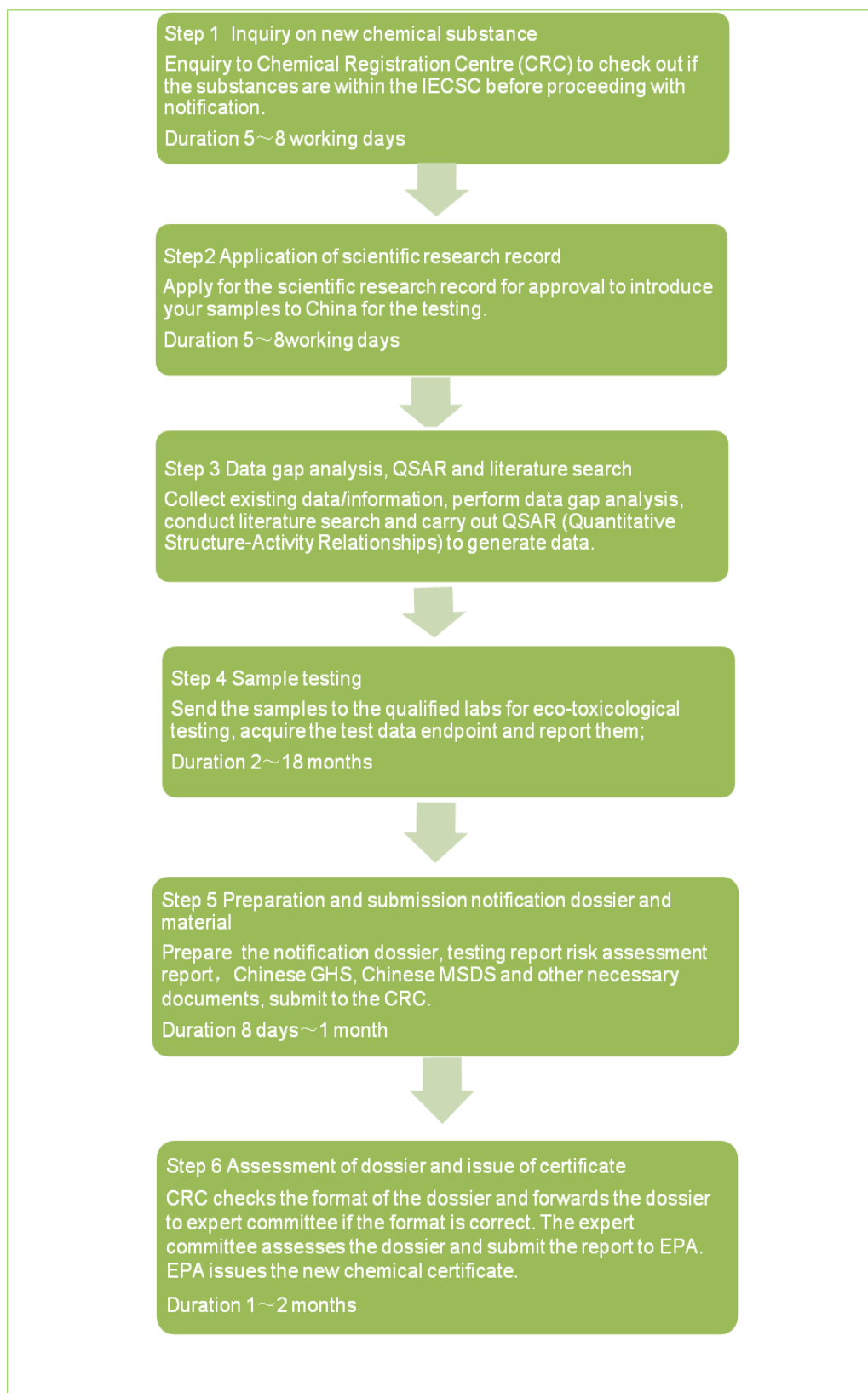
Please refer to next page for the checklist of data endpoints required for typical notification level (1-10t/y).

Note: Testing is not the only method to acquire the data endpoints. The applicant could acquire data endpoints by other scientific sources, such as literature and database search, QSAR simulation; in addition, some data endpoints could be waived by scientific judgment based on the intrinsic properties of the substance. The data endpoints originating from qualified foreign laboratories are accepted if the applicant can provide the certificate of the laboratories and corresponding testing reports. However, ecotoxicological tests must be carried out on Chinese specific creatures in certified Chinese laboratories, such as acute toxicity tests with *Brachydanio rerio*, ready biodegradability tests using closed bottle test and acute toxicity test with earthworms, etc.

Data end points required for typical notification (Level 1, 1~10 tons)

	Items	Duration(days)
Physiochemical Properties Testing	Melting point (°C) (for solid)	3
	Boiling point (°C) (for liquid)	5
	PH degree (for liquid)	3
	Density (kg/m ³)	5
	Vapor pressure (for liquid)	3
	Surface tension (for liquid)	3
	Auto-ignition temperature (°C)	10
	Flash point (for liquid)	3
	N-octanol/water distribution	60
	Water solubility (g/L)	60
	Particle size distribution (for solid)	5
	Oxidability	14
	Flammability	10
	Explosibility	10
Toxicological Properties Testing	Acute oral toxicity test	30-60
	Acute dermal toxicity test	30-60
	Acute inhalation toxicity test	30-60
	Acute dermal irritation/corrosion test	30
	Acute eye irritation/corrosion test	30-60
	Skin Sensitization test	60-90
	Repeated dose 28-day oral toxicity study in rats	120
	Repeated dose 28-day dermal toxicity study	
	Repeated dose 28-day inhalation toxicity study	
	Bacterial reverse mutation test	30-60
	In vitro mammalian chromosome aberration test	60
Eco-toxicological Property Testing	Alga growth inhibition test	45
	Acute toxicity test with Daphnia magna	45
	Acute toxicity test with Brachydanio rerio (China)	45
	Activated sludge, respiration inhibition test	30
	Adsorption/Desorption	45
	Ready biodegradability using closed bottle test (China)	60
	Earthworm, acute toxicity test (China)	100

Application Procedure for Typical Notification



Cost Estimation and Duration

The total cost consists of two major parts: Testing fee and consulting fee (if an agent is appointed).

Charge items	Description	Fee (RMB)
Testing fee	is charged by certified laboratories and varies on a case by case basis.	Case by case
Consulting fee	is charged by CIRS and varies on a case by case basis	Case by case

The duration of the whole process (from application until the acquisition of new chemical certificate) is approximately 4~18 months depending on the level of typical notification.

How to Save Costs on China REACH

As the consulting fee only accounts for a small portion of the total costs and different service providers might give similar quote, one company shall focus more on one service provider's ability to minimize testing fee. Those capabilities include:

- Literature search and using existing data;
- Getting a discount on testing fee from certified labs;
- Waving high-level testing items based the result of low-level testing;
- QSAR and READ Across;

Our Services

Initially set up by China Inspection and Quarantine Bureau, CIRS has strong presence in China and close links with Chinese Government Agencies including the Chemical Registration Center and state testing laboratories such as Shanghai Environmental Academy of Sciences and Shenyang Research Institute of Chemical Industry Testing Center. As the largest REACH only representative in the world, our expertise with REACH has given us extra advantages of using non-testing method to generate data and minimize costs.

We provide all services in one package to help you complete notification at the most competitive price in the market. Our services include:

IECSC Search

- Evaluation of whether a substance is within the scope of China REACH and determination of right notification type;

New Chemical Substance Notification

- Data evaluation, data gap analysis, and resorting to non-testing methods such as literature search, QSAR and Read Across to minimize data costs;
- Writing testing proposal, sending sample to certified labs and waving high-level testing items based on the results of low-level testing;
- Dossier preparation and submission;

Post-notification Maintenance

- Updating the notification dossier if tonnage band has changed
- Reporting the trade/manufacture activities of the new substance to local enforcement authorities
- Fulfillment of other post-notification obligations after the Registration Certificate has been issued.

IECSC Inclusion

- Application for IECSC inclusion for substances manufactured or imported before 15 Oct 2003.

Contact

If you have any inquiries, you are welcome to contact:

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