Data Requirements for New Chemical Notification in China

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On 19 Jan 2010, the Ministry of Environmental Protection (MEP) 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. Under this regulation, companies shall submit new chemical substance notification to the Chemical Registration Centre (CRC) of MEP for the new chemicals irrespective of annual tonnage, i.e. chemicals other than the approximately 45,000 substances currently listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC).

There are three types of notification: typical notification, simplified notification and scientific research record. Each type of notification requires different sets of data. In this article we will discuss data source, data sharing, test agencies and test methods for the notification of new chemical substance in China first. After that we will summarize the data requirements for each type of notification.

- **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	
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 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	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 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)	
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	by oral
		by dermal
		by inhalation

	substance)	
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	Degradation	Ready biodegradability (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	

More info

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