China New Chemical Substance Notification

EU Representative
Bo Bi
December 5th 2018
‘CHINA REACH’?
Timeline

**China**

- **Oct. 15, 2003**: Measures for the Environmental Management of New Chemical Substances (Order No.17) come into effect, administered by State Environmental Protection Agency (SEPA).
- **Mar. 27, 2008**: SEPA was upgraded to Ministry of Environmental Protection (MEP).
- **Oct. 15, 2010**: "Measures" (Order No.7) comes into effect, administered by the MEP and implemented by Chemical Registration Center (CRC-MEP).
- **2013**: NCSN Guidance revision was amended based on WTO member comments.
- **2017**: MEP issued an announcement and revealed the amendments on the data requirements in CNSN Guidance.

**EU**

- **Jun. 1, 2007**: EU REACH (EC 1907/2006) came into force, implemented by ECHA.
- **Nov. 30, 2010**: 1st Registration deadline: >=1000 T/Y; CMR >1 T/Y; R50/53 >100 T/Y.
- **May 31, 2013**: 2nd Registration deadline: 100~1000 T/Y.
- **May 31, 2017**: Pre-registration deadline.

**Hazard-based Emphasis on Registration**

**Risk-based Registration & Inspection**
Measure on the Environmental Management of New Chemical Substance’, MEP order 7.

- SCC-MEP (Solid Waste and Chemical Management Center) is responsible for the technical issue;
- Local Environmental Protection Bureaus are responsible for the supervision work.
CHINA NCSN

- Applicable Territory
- Who Can Apply?
- How to identify new substances?
- Notification process
- Post-notification Obligation
- Main Amendments
Applicable Territory

- Applicable region
  Within the Customs boundary of China
  Including Bonded Zones and Export Processing Zones

- Inapplicable region
  Temporarily stored in the Bonded Zones and entirely exported without any processing
  Within the Special Administrative Region- Hong Kong, Macao, Taiwan
Who can apply?

**Foreign entities**
- Cannot directly apply
- Need a Chinese entity to be the local representative

**Chinese entities**
- Domestic Manufacturers
- Domestic Importers
- **Chinese representative agents** can apply on behalf of non-Chinese companies

“Only Representative-like” Agent
- Fixed work place
- 3,000,000+ RMB registered capital
- Staff who have experience in new chemical substance notification.
- Must not have violated chemical regulations within the last 3 years, etc.
How to identify new substances?

Step 1: Rule out the possibility of Exemption (similar to EU REACH)

- Finished products covered by other laws and regulations (i.e. cosmetics, pesticides, foodstuffs, food additives, pharmaceuticals, tobacco etc.)
- Naturally occurring substances
- Impurities (<10% w/w)
- Alloys
- Non-isolated intermediates
- Some Materials (glass materials, ceramics, etc.)
How to identify new substance?

**Step 2:** Searching the Inventory of Existing Chemical Substance in China (IECSC)

IECSC 2013 (pdf)
45,612 substances

3,270 confidential substances
8,486 substances without CAS number

Not found in the public inventory?

—— The formal inquiry to SCC-MEP is needed!
Formal IECSC inquiry

Company information

Substance information

Inquiry result from SCC-MEP

Self declaration
**Step-Mode Notification**

**Tonnage Principle (Art. 11)**
- R & D < 0.1 t/a;
- Intermediates < 1 t/a
- Manufacture for export only < 1 t/a
- Scientific Research: 0.1 t/a – 1 t/a
- Polymers with low new chemical substance concentration of monomer which are (<2 % w/w) (“New Chemical Substance Monomer<2%”);
- Polymers of Low Concern
- For PPORD* purpose <10 t/a, valid no more than 2 years

**Level 4: >1000 t/a**
**Level 3: 100~1000 t/a**
**Level 2: 10~100 t/a**
**Level 1: 1~10 t/a**

**Basic: Domestic testing data required <1 t/a**

**Simplified Notification**

**Special: Notification w/o data**
- Intermediates < 1 t/a
- Manufacture for export only < 1 t/a
- Scientific Research: 0.1 t/a – 1 t/a
- Polymers with low new chemical substance concentration of monomer which are (<2 % w/w) (“New Chemical Substance Monomer<2%”);
- Polymers of Low Concern
- For PPORD* purpose <10 t/a, valid no more than 2 years

**PPORD*: Process and product orientated research and development**

**Regular Notification**

**Level 2: 10~100 t/a**
**Level 3: 100~1000 t/a**
**Level 4: >1000 t/a**

**Level 1: 1~10 t/a**
Notification Dossier Requirement
Documents for non-Chinese companies

- POA (Power of attorney)
- Signed authorization letter (optional)
- Business license copy of domestic agent

**Simplified Notification (Special Case)**
- Notification Form
- Compliance statement for special case
- GPC+ monomer information for polymer case

**Simplified Notification (Basic Case)**
- Notification Form
- Eco-toxicological test reports

**Regular Notification**
- Notification Form
- Test reports/data (physico-chemical, toxicology and eco-toxicology)
- C&L for hazardous substances (based on GHS criteria)
- Risk Assessment Report
- Safety Data Sheet

**SRRN**
- Notification Form
- Research Info.

**Tonnage Principle (Art. 11)**
Minimum Regular Notification data

Physico-chemical
- Oxidising properties (Self-)Ignition temperature
- Flammability
- Explosivity
- Boiling point
- Density
- Vapor pressure
- Water solubility
- Partition coefficient
- pH value
- Surface tension
- Flashpoint
- Oxidising properties (Self-)Ignition temperature
- Flammability
- Explosivity
- Melting point
- Density
- Water solubility
- Partition coefficient
- Granulometry
- Oxidising properties (Self-)Ignition temperature
- Flammability
- Explosivity

Toxicological
- Acute toxicity (oral, dermal and inhalation), Skin/Eye irritation, Skin sensitisation
- Short-term toxicity study (28 days) (oral, dermal and inhalation)
- Bacterial Reverse Mutation Test
- In vitro Mammalian Chromosome Aberration Test
- Acute Daphnia toxicity
- Toxicity to algae
- Acute fish toxicity
- Activated sludge respiration inhibition testing
- Adsorption/desorption
- Readily biodegradation
- Short-term toxicity to earthworm
- Mammalian Micronucleus Test (or Chromosome Aberration Test)
- Sub-chronic toxicity study (90 days)
- Screening for reproductive /developmental toxicity
- Toxicokinetic test (only absorption)
- Teratogenicity
- Two-generation reproduction Test
- Toxicokinetic relevant information
- Chronic toxicity test
- Carcinogenicity
- Long-term toxicity to fish
- Seed germination and root growth test
- No additional tests

Eco-toxicological
- Inherent biodegradation
- Hydrolysis on effect of pH
- Fish prolonged toxicity: 14-day study
- Long-term toxicity testing on Daphnia
- Bioaccumulation
- Long-term toxicity to fish
- Seed germination and root growth test
- No additional tests

Level 1
- Level 2
- Level 3
- Level 4
Notifier

New Substances?

- Yes
  - SRRN
  - Simplified Notification
  - Regular Notification
  - SCC-MEP (Management Center of The Ministry of Environmental Protection)
    - Special
    - General
    - Expert committee
    - MEP
      - IECSC Updated

- No
  - No obligation

SRRN=Scientific Research Record Notification
IECSC =Inventory of Existing Chemical Substance in China
Certification
Public announcement
<table>
<thead>
<tr>
<th>Notification Certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certificate Number</td>
</tr>
<tr>
<td>Certificate holder</td>
</tr>
<tr>
<td>Notifier</td>
</tr>
<tr>
<td>English/Chinese name of the Chemical substance</td>
</tr>
<tr>
<td>CAS number</td>
</tr>
<tr>
<td>Notified Tonnage</td>
</tr>
<tr>
<td>Notified Use</td>
</tr>
<tr>
<td>Activity type</td>
</tr>
<tr>
<td>reason</td>
</tr>
<tr>
<td>category</td>
</tr>
</tbody>
</table>
**Notification**
- Obtain registration certificate
- Permission to manufacture/import

**Post-notification obligation**
- Safely use
- Report to the authority

**List in IECSC**
- existing chemicals

- Communication SDS and Risk Management information to the Downstream Users;
- Implement the Risk Management;
- Submission of updates if new hazard arises;
- Adhere to the “Safe management of hazardous chemicals;”

- First time activity report;
- Annual Report;
- Annual forecast;
- Every time transfer activity report once the DUs are changed;
- Five-year report before listing into IECSC
- Keep documents on file for 10 years;
Hazardous with priority environmental concern

First time activity report
Annual Reports
Annual Forecast (next year)
Every time transfer activity report
Five year actual activity reports before listing into IECSC

Hazardous

First time activity report
Annual reports (before Feb (April). 1st every year)
Five year actual activity reports before listing into IECSC

Regular Notification

Classified into three Categories

Simplified Notification

Annual reports (before Feb (April). 1st every year)

General

First time activity report

SRRN

No Obligations

Post-notification Obligation
Notification Statistics 2011-2017

<table>
<thead>
<tr>
<th>Year</th>
<th>SRRN</th>
<th>Simplified notification-Special Case</th>
<th>Simplified notification-General Case</th>
<th>Regular Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>964</td>
<td>1800</td>
<td>2450</td>
<td>0</td>
</tr>
<tr>
<td>2012</td>
<td>896</td>
<td>1800</td>
<td>2450</td>
<td>0</td>
</tr>
<tr>
<td>2013</td>
<td>890</td>
<td>2109</td>
<td>2092</td>
<td>43</td>
</tr>
<tr>
<td>2014</td>
<td>899</td>
<td>2455</td>
<td>4792</td>
<td>72</td>
</tr>
<tr>
<td>2015</td>
<td>2455</td>
<td>4792</td>
<td>4502</td>
<td>108</td>
</tr>
<tr>
<td>2016</td>
<td>2455</td>
<td>4792</td>
<td>5292</td>
<td>158</td>
</tr>
<tr>
<td>2017</td>
<td>2455</td>
<td>4792</td>
<td>4922</td>
<td>143</td>
</tr>
</tbody>
</table>

Simplified notification - Special Case
Simplified notification - General Case
Regular Notification
## Main Amendments - Data Requirements

<table>
<thead>
<tr>
<th></th>
<th>Guidance Revision (draft) published in Mar 2016</th>
<th>Guidance 2\textsuperscript{nd} Revision published in Oct 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regular Notification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level I</td>
<td>• Acute dermal &amp; inhalation toxicity test can be waived conditionally.</td>
<td>• Only one route of acute toxicity test is required; • The sub-acute toxicity (28-day) study is no longer required.</td>
</tr>
<tr>
<td>(1-10 t/a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Regular Notification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level II</td>
<td>• Change the criteria under which the sub-chronic toxicity (90-day) study is required.</td>
<td>• The sub-chronic toxicity (90-day) study is no longer required.</td>
</tr>
<tr>
<td>(10-100 t/a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxico-kinetics</strong></td>
<td>• Loosen the data requirement.</td>
<td>• TK assessment is acceptable</td>
</tr>
</tbody>
</table>

**Toxico-kinetics**

- Loosen the data requirement.
Comparison: EU REACH vs China NCSN
EU REACH vs China NCSN

Management Pattern

EU REACH

Registration number = Market access permission

China NCSN

Registration certificate = Market access permission (except the SRRN type)
EU REACH vs China NCSN

Scope

**EU REACH**

- New Chemicals & Existing Chemicals
- Full registration >1t/a

**China NCSN**

- Only New Chemicals
- Regular Notification: >1t/a
- Simplified Notification
- SRRN (Scientific Research Record Notification)
EU REACH vs China NCSN

Polymer

- **EU REACH**: Register Monomers instead of the polymers based on their tonnage level
- **China NCSN**: Notify the new polymer itself
EU REACH vs China NCSN

Notifier in the Importation Supply Chain

**EU REACH**

One Registration Number can cover the whole supply chain

**China NCSN**

Direct importer or direct exporter
EU REACH vs China NCSN

Who should be the notifier?

China Customs

Manufacturer /Supplier A → Supplier B → Importer C → Distributor D → DU E

Chemical X
EU REACH vs China NCSN

Who should be the notifier?
EU REACH vs China NCSN

OR-Only Representative/Domestic Agent

EU REACH

“A natural or legal person”

China NCSN

Legal Entity with fixed work place; 3,000,000+ RMB registered capital; Staff who have experience in new chemical substance notification; No violation record within the last 3 years...
EU REACH vs China NCSN

Notification Procedure

**EU REACH**
- Online submission via software only
- Completeness check (100%), technical review (>5%)

**China NCSN**
- Online submission via software + printed copy (signed and sealed)
  - Regular Notification: Disk + printed copy (signed and sealed)
- Completeness check (100%), technical review (100% for Regular Notification)
## EU REACH vs China NCSN

### Data requirements & Sharing

<table>
<thead>
<tr>
<th>EU REACH</th>
<th>China NCSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data sharing is obliged, SIEF/Consortium</td>
<td>No data sharing obligation nor official platform</td>
</tr>
<tr>
<td>Special rule for SCC intermediate</td>
<td>No special rule for SCC intermediate</td>
</tr>
</tbody>
</table>
Data sharing is encouraged, but not a mandatory requirement in China

Animal testing is still the dominant tool for safety assessment in China

Certain eco-tox tests are required to be done in China
Thanks for your attention!

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