Latest Developments in China

Webinar 26 September 2012
Today’s Webinar - Aims

- To provide an update on China's cosmetic ingredient notification regulations and rules on food contact additives;
- To explain the requirements of the new rules on hazardous chemicals registration and the update of the Hazardous Chemicals Catalogue;
- To look at a company's experiences under the notification regime for new substances.
If you have any unanswered questions please submit them to the Chemical Watch Forum, after the webinar.

http://forum.chemicalwatch.com
Speakers

**Jinhe Chen**, National Registration Center for Chemicals, the State Administration of Work Safety (NRCC-SAWS)

**Isabelle Jouve**, Product Steward, RHODIA Aroma Performance, member of the SOLVAY Group

**Yunbo Shi**, Managing Director, Chemical Inspection and Regulation Service, CIRS

**Moderator: Geraint Roberts**, Briefing and Global Content Editor, Chemical Watch
The administration measures on hazardous chemicals registration (2012) – an introduction

Jinhe Chen, 26 Sept 2012
National Registration Center for Chemicals, the State Administration of Work Safety(SAWS)
The administration measures on hazardous chemicals registration (SAWS’s Order 53)

1 Background and Legal Framework
2 Main Changes
3 The Scope
4 Time, Content and Procedure
5 Other Required Documents
6 Responsibilities of Registrants
7 Legal Liabilities
# Background & Legal Framework

<table>
<thead>
<tr>
<th>Background of Revision</th>
<th>Reference to Decree 591</th>
</tr>
</thead>
<tbody>
<tr>
<td>The State Administration of Work Safety is responsible for the safety supervision and administration of hazardous chemicals and the registration of hazardous chemicals</td>
<td>Article 6.1</td>
</tr>
<tr>
<td>The State operates a system of chemicals registration and provides technical and information support for the safety management of hazardous chemicals, chemical accident prevention and emergency rescue.</td>
<td>Article 66.</td>
</tr>
<tr>
<td>Manufacturers and importers of hazardous chemicals shall register hazardous chemicals with as Hazardous Chemicals Registration Office of State Administration of Work Safety.</td>
<td>Article 67</td>
</tr>
<tr>
<td>The Hazardous Chemicals Registration Office shall provide information and data related to hazardous chemicals registration to various ministries such as MIIT, MEP, AQSIQ, etc.</td>
<td>Article 68</td>
</tr>
</tbody>
</table>
### 2. Main Changes

<table>
<thead>
<tr>
<th>Items</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registrant</td>
<td>Registrants have changed to manufacturers and importers of hazardous chemicals. Storage companies and downstream users do not need to register.</td>
</tr>
<tr>
<td>Required Content</td>
<td>More detailed info will be now required for HazChem registration:</td>
</tr>
<tr>
<td></td>
<td>- Classification and labeling (GHS);</td>
</tr>
<tr>
<td></td>
<td>- Phyiso-chemical properties;</td>
</tr>
<tr>
<td></td>
<td>- Main uses;</td>
</tr>
<tr>
<td></td>
<td>- Hazard properties;</td>
</tr>
<tr>
<td></td>
<td>- Safety requirement for storage, use and transport;</td>
</tr>
<tr>
<td></td>
<td>- Emergency responses;</td>
</tr>
</tbody>
</table>
2. Main Changes

<table>
<thead>
<tr>
<th>Items</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Procedure</td>
<td>1) More clear procedure is given (online registration);</td>
</tr>
<tr>
<td></td>
<td>2) Required types of documents have been adjusted: New requirements for</td>
</tr>
<tr>
<td></td>
<td>importers have been added; Hazard identification report is no longer</td>
</tr>
<tr>
<td></td>
<td>required; 3) New requirement &amp; procedure for the update of registration;</td>
</tr>
<tr>
<td></td>
<td>4) New procedure for the renewal of registration certificate.</td>
</tr>
<tr>
<td>Emergency Telephone Number.</td>
<td>Article 22(1) sets detailed requirements on emergency telephone number.</td>
</tr>
<tr>
<td>New Supervision Measures</td>
<td>1) HazChem registration will become part of inspection;</td>
</tr>
<tr>
<td></td>
<td>2) New reporting obligations related to registration office and</td>
</tr>
<tr>
<td></td>
<td>registration centre.</td>
</tr>
</tbody>
</table>
3. The Scope of Registration

- Hazardous chemicals listed in the Catalog of Hazardous Chemicals;

- For chemicals with unknown hazard properties, the registrants shall entrust the eligible institute to do hazard identification. If the chemical is identified to be hazardous, the applicants shall register it in accordance with this Measures.
Definition of Producer and Importer

According to SAWS’s order 41 - The Measures for the Administration of Production Licenses for Hazardous Chemicals:

Manufacturers are enterprises that have obtained business license to manufacture finished products or intermediate products that are listed in the Catalog of Hazardous Chemicals.

Enterprises who make concentrated hazardous chemicals belong to manufacturers. Companies who purchase hazardous chemicals and repack them or dilute the hazardous chemicals with non-hazardous solvents do not belong to manufacturers.

Intermediate products refer to raw materials that are produced in order to participate chemical reactions in the next step (article 54).
Importers of hazardous chemicals are enterprises that have obtained business licenses and the following documents to engage in the activities of importing hazardous chemicals:

（I）Foreign trader registration certificate; or
（II）Import and export enterprise qualification certificate; or
（III）Foreign investment approval certificate; or
（IV）Hong Kong and Macao and overseas Chinese investment enterprise approval certificate.
4. Time, Content & Procedure

4.1 Time

1) **Newly built chemical plant** - Prior to the issue of acceptance statement of a construction project.
2) **Importer** - Prior to importation;

Note:

1. Enterprises producing and importing the same type of hazardous chemicals shall register as production entities by providing the information of the imported hazardous chemicals.
2. Enterprises importing the same type of hazardous chemicals from different manufacturers shall register the chemical for the first time and from the first importers, and providing the information of such chemicals from other manufacturers.
3. Manufacturers and importers importing the same type of hazardous chemicals from the same manufacturers for many times only need to register the chemical once.
4.2 Content/Required Information

1). Classification and labeling information, including hazard category, pictogram, warning signals, hazard statements, precautionary statements, etc.

2). Physical properties (appearance, features, solubility, melting point, boiling point, etc.) and chemical properties (flashing point, explosion limit, spontaneous ignition temperature, decomposition temperature, etc.);

3). Main uses, including recommend uses, prohibited or restricted uses, etc.

4). Hazard properties, including physical hazards, health hazards and environmental hazards of dangerous chemicals;
5) **safety requirements on storage, usage and transportation**, 

I. **safe storage requirements** on buildings such as warehouses, security conditions, environment, sanitation, temperature and humidity;

II. **safe use requirements** on operation conditions, protective measures for operators, and hazard control measures for use areas; safe transportation;

III. **safe transportation requirements** on transport or delivery methods, approaches for disclosure of hazard information to related transportation staff, and protective measures for loading, unloading and transportation.
6) **emergency response measures**

emergency response measures, including measures against and consultation line for fire, explosion, leakage, poisoning suffocation, burns and other chemicals-related accidents.
4.3 Registration Procedure

1. Application
2. Prepare Documents

Registrant

Registration Office at Provincial Level

Qualified: Stamp and submit it to NRCC of SAWS

Unqualified: Send notice to registrant

Deliver Certificate

Qualified: Stamp and Issue Certificate

Unqualified: Send notice to registration office and enterprise

Electronic copies and hard copies are submitted separately
5. Other Required Documents

1. Hazardous chemicals registration forms (2 copies)

2. For production entities: One copy of business license from the industrial and commercial administration; for importing entities: One copy of foreign trade dealer registration form, or qualification certificate of import and export enterprises in the People’s Republic of China, or certificate of approval for establishment of enterprises with foreign investment, or certificate of approval for establishment of enterprises with investment from Taiwan, Hongkong, Macao and overseas Chinese.

3. One copy of Safety Data Sheet and precautionary label of the hazardous chemicals compliant with national standards;

4. Emergency consultation phone number meeting the requirements specified in Article 22 of the Measures, or emergency service agency agreement (one copy);

5. Product standard of the hazardous chemicals to be registered
6 Responsibilities of Registrants

6.1 Build a file for hazardous chemicals;
6.2 Register hazardous chemicals & accept inspection;
6.3 Designate staff to be responsible for registration.
6.4 Entrust qualified institutions to conduct hazard identification;
6.5 Set up 24h emergency telephone consultation.
7 Legal Liabilities

Article 29 If the Applicants fail to go through procedures for registration of hazardous chemicals, or fail to renew registered items of hazardous chemicals when finding new hazard properties on hazardous chemicals they make or import, the departments of work safety supervision and management of counties or above shall order them to correct, and impose a fine of less than 50000 Yuan; if they refuse to do so, they shall be fined between 50000 Yuan and 100000 Yuan; if circumstances are serious, they shall be ordered to suspend business for rectification.
Article 30 If the Applicants commit any of the following acts, the departments of work safety supervision and management of counties or above shall order them to correct, and impose a fine of **30,000 Yuan**

1. failed to provide emergency consultation service to users or in line with specified requirements;
2. failed to renew registered items of hazardous chemicals when any of the enterprise name, registered address, registered variety or emergency consultation phone number, changes in the validity of hazardous chemicals registration certificate;
3. continue production or import without renewing hazardous chemicals registration certificate upon expiry thereof;
4. transfer, fraudulent use or use fraud certificates for hazardous chemicals, or failed to provide accurate registration information and relevant dossiers
5. refuse to accept or interrupt field check given by the Registration Authorities on registered items of hazardous chemicals.
Update of the Catalog and Other Information
<table>
<thead>
<tr>
<th>序号</th>
<th>品名</th>
<th>别名</th>
<th>英文名</th>
<th>CAS号</th>
<th>用途</th>
<th>危险性分类</th>
<th>备注</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>苯</td>
<td></td>
<td>benzene; benzol</td>
<td>71-43-2</td>
<td>1114</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 易燃液体, 类别 2
- 皮肤腐蚀/刺激, 类别 2
- 严重眼损伤/眼刺激, 类别 2
- 生殖细胞致突变性, 类别 1B
- 致癌性, 类别 1A
- 特异性靶器官毒性-反复接触, 类别 1
- 吸入危害, 类别 1
- 危害水生环境-急性危害, 类别 2
- 危害水生环境-长期危害, 类别 3

危险化学品登记管理

Catalog of Hazardous Chemicals（Being Revised）
Plans for HazChem Registrations

I. Preparation Work

（1）Publish relevant documents for registration

（2）Upgrade online registration system.
（II）Training

Provide training to officers at Registration Office

Training include the interpretation of new measures for registration, how to fill in application forms and evaluate data, GHS classification, national standards for SDSs & label, and introduction to the online registration system.

（III）Prepare Registration Guidance for Chemicals with Unknown Hazard Properties.

Include the definition of chemicals with unknown hazard properties, requirements on hazard identification, list of approved institutions, data requirements, procedure for classification and registration.

（IV）Conduct registration at selected locations

Mainly target at importers beginning from November.
Plans for Nationwide HazChem Registrations

(1) Complete registrations for importers;

(2) Complete review and renewal of registration certificates for producers and build a new hazardous chemical database (in 3 years);

(3) Start hazard identification on chemicals with unknown hazards;
Contact

Website:  www.nrcc.com.cn
National Chemical Accident Emergency Consultation Number:  0532-83889090
Email:  cjh53271@163.com
New Substance Notification in China

Rhodia’s feedback on notification process

Isabelle Jouve

Chemical Watch Webinar
September 26, 2012
Agenda

• Presentation of Rhodia, member of the Solvay Group

• Brief overview of New Chemical Notification Regulation in China

• Rhodia’s feedback on notification process in China
SOLVAY : AN INTERNATIONAL CHEMICAL GROUP

Key facts

SOLVAY ACQUIRED RHODIA, SEPTEMBER 2011

→ Offering a broad range of products that contribute to improving quality of life and the performance of its customers

→ Among the world leaders with 90% of its sales in markets where it is among the top 3 global

→ A strong commitment to sustainable development

→ A clear focus on innovation & operational excellence

23% of combined net sales realized with new products

EUR 12.7 billion net sales

EUR 2.1 billion REBITDA

110 major industrial sites

30,000 employees

26% sales in Asia-Pacific

All 2011 figures pro forma
Rhodia, Member of the Solvay group

Solvay

Rhodia

Plastics

Chemicals

Eleven GBU's - growth engines focused on their markets …

Aroma Performance

Polyamide & Intermediates

Energy Services

Silica

Novecare

Coatis

Fibras

Engineering Plastics

Rare Earths

Acetow

Eco Services
A reference framework integrated into our management processes

Continuous improvements:
- Individual and collective commitment of the Group’s employees
- Commitment toward our six stakeholders
- Social and environmental approach. Reference framework implemented to assess and improve practices
- Strictly controlled process audited by independent organizations

<table>
<thead>
<tr>
<th>REACH</th>
<th>(to be) Registered Substances</th>
<th>Rhodia Lead Registrant</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>85</td>
<td>26</td>
</tr>
<tr>
<td>2013</td>
<td>111 (on-going)</td>
<td>24</td>
</tr>
<tr>
<td>2018</td>
<td>~700</td>
<td></td>
</tr>
</tbody>
</table>

Product Stewardship / REACh:
- Comply with local regulation applicable to all its products
- Anticipate regulation evolution in order to reach timely compliance

China
On-going notifications 6
Agenda

• Presentation of Rhodia, member of the Solvay Group

• **Brief overview of New Chemical Notification Regulation in China**

• Rhodia’s feedback on notification process in China
Notification Process

- Concerns substances that are not on the Chinese Existing Chemical Inventory IECSC (substances manufactured or imported in China until 15 October 2003)

- Authority
  - CRC (Chemical Registration Center) under supervision of MEP (Ministry of Environmental Protection)

- Notification type
  - Normal notification: chemicals > 1t/a
  - Simplified notification: R&D or export or Intermediate 0.1-1t/a, Polymer
  - Scientific Research Record: <0.1t/a

- Data sharing: recommended but not mandatory
  - Risk to perform the same study many times: ethical issues
  - What if 2 registrants of the same substance do not have the same classification?

- Data and notification ownership
  - Only 5 years exclusivity
Notification Process

• Data requirements depend on tonnage bands for normal notification:
  - 1-10 T/y
  - 10-100 T/y
  - 100-1000 T/y
  - > 1000 T/y

… and does not differentiate between intermediates and substances

• Dossier content:
  - Notification form
  - Chinese Safety Data Sheets
  - Recommended classification and labelling
  - Test reports detailing the substance's physiochemical, toxicity and ecotoxicity properties
  - Certificates for the qualification of laboratories
  - Risk assessment report: starting from 1t/a tonnage band (10t/a for REACh)

• Notifier can only be a China based legal entity:
  - Local agent
  - Affiliate in China
Post-notification Obligations

• General new chemical substances
  - Communicate MSDS to downstream users
  - Implement risk management measures
  - Do not sell chemicals to downstream users who are not capable of implementing risk management measures
  - Submit first-activity report
  - Keep documents on file for over 10 years
  - Submit updates if new hazard arises

• Hazardous new chemical substances
  - Submit annual report (for previous year)
  - Comply with "The Measures for The Administration of Registration of Hazardous Chemicals"

• Priority hazardous new chemical substances for environmental management
  - Submit report on disposal information
  - Submit substance flow chart
  - Submit annual plan (for next year)
Agenda

• Presentation of Rhodia, member of the Solvay Group

• Brief overview of New Chemical Notification Regulation in China

• Rhodia’s feedback on notification process in China
Rhodia’s notifications of new chemicals in China

• 4 new chemicals to be notified by Aroma Performance in China
  - Intermediates for Agrochemicals & Electronics
  - Normal notification
  - 10-100 t/a tonnage band
  - Individual notification: no other notifier to share data

• Decision to work with European GLP-certified labs
  - No GLP-certified labs for Toxicology studies in China
  - Easier studies monitoring by Rhodia Tox & Ecotox Experts team in Europe
  - Possibility to use the studies for REACH (or any other regulation)

  .... Except for those ecotox tests that are mandated to be done in China
Project Management of Notification Dossiers within Rhodia

Rhodia R&D
- Analytical Dossier

Rhodia Responsible Care
- Physchem, Tox & Ecotox Studies
- GHS Classification & Labelling
- Chinese Safety Data Sheet

Rhodia Industrial & Business
- Chemical Safety Report On Uses & Manufacture

CIRS Expertise
- Dossier Completion

Rhodia Product Stewardship China
- Dossier Submission

Product Stewardship
Europe & China
### Notification timeline

<table>
<thead>
<tr>
<th>Required data listing</th>
<th>Labs contact (Europe and China)</th>
<th>Analytical dossier</th>
<th>Studies</th>
<th>Chemical Safety Report</th>
<th>Dossier completion</th>
<th>Dossier submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
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<td></td>
<td>13</td>
<td></td>
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</tbody>
</table>

### Advantages

- Responsible Care global network (Product Stewards & Experts)
- Local chinese PS team : good relations with Local Authorities
- CIRS consultant involvement at the early stage of the project
Data requirements as compared to REACh Regulation

Physico-chemical data

<table>
<thead>
<tr>
<th>Physico-chemical data</th>
<th>China 10-100T</th>
<th>REACh 10-100T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting Point (solid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Boiling Point (liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Density (solid, liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vapor Pressure (liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (solid, liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Water solubility (solid, liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Surface tension (liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PH value (liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Flash point (liquid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Granulometry / Particle size (solid)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Oxidizing properties (solid, liquid, gas)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Self-ignition temperature (solid, liquid, gas)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Flammability (solid, liquid, gas)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Explosive properties (solid, liquid)</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

no difference
### Toxicology data

<table>
<thead>
<tr>
<th>Toxicology</th>
<th>China 10-100T</th>
<th>REACH 10-100T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity by oral</td>
<td>X</td>
<td>X (only one route required)</td>
</tr>
<tr>
<td>Acute toxicity by dermal</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Acute toxicity by inhalation</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Skin irritation or skin corrosion</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Repeated dose 28-day toxicity study</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Repeated dose 90-day toxicity study</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacterial reverse mutation test (Ames)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>In vitro mammalian chromosome aberration test</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Rodent Bone marrow chromosome aberration test</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Screening for reproductive/developmental toxicity</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Toxicokinetics</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

#### Extra costs

- Not compatible (90-days study has to get ECHA's authorization to be launched)

#### Chinese Regulation more demanding than REACh
Data requirements as compared to REACh Regulation

### Eco-toxicology data

<table>
<thead>
<tr>
<th>Eco-toxicology</th>
<th>China 10-100T</th>
<th>REACh 10-100T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae growth inhibition study</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Acute toxicity study with Daphnia magna</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Acute toxicity study with Brachydanio rerio (can be waived by 14days study)</td>
<td>Test in China</td>
<td>X</td>
</tr>
<tr>
<td>Activated sludge respiration inhibition testing</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Adsorption/desorption properties</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Degradation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ready biodegradability</td>
<td>Test in China</td>
<td>X</td>
</tr>
<tr>
<td><strong>Inherent Biodegradability</strong></td>
<td>Test in China</td>
<td></td>
</tr>
<tr>
<td>Hydrolysis test with PH function</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Earthworm, acute toxicity test</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 days extended toxicity study in fish</td>
<td>Test in China</td>
<td></td>
</tr>
<tr>
<td>Daphnia magna Reproduction study</td>
<td>Test in China</td>
<td></td>
</tr>
<tr>
<td>Bioaccumulation in aquatic species, preferably fish</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Some specific tests have to be done in China

Supplementary studies vs REACh: extra costs, compatibility with REACh
Chemical Safety Report

- Support of Chemical Inspection and Regulation Services (CIRS) early in the notification process

- Guidance on Risk Assessment Report published lately (January 2012)

- Risk Assessment:
  - Environmental:
    - same approach and methodology as for REACh (PEC/PNEC ratio)
  - Occupational:
    - different from REACh
    - Based on a qualitative assessment
    - Human Exposure Factor: ratio $S_{HE} / S_{HE_{max}}$
Dossier submission

• Simple process

• Word format dossier

• Technical completeness check:
  - made by an examiner
  - Can be subject to different interpretations depending on the examiner

• Acceptance number normally delivered within 5 days

  • Evaluation committee review of MEP

  • Issuance of certificate from MEP

  Very long process …
## Chinese Regulation vs REACh

<table>
<thead>
<tr>
<th></th>
<th>China</th>
<th>REACh</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>Intermediates considered as substances</td>
<td>Lower level of data requirement for intermediates</td>
</tr>
<tr>
<td></td>
<td><strong>Extra costs</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Data requirements</strong></td>
<td>Higher level than REACh for the same tonnage band</td>
<td>Consideration of ethical concerns</td>
</tr>
<tr>
<td></td>
<td>Some ecotox tests to be done in China: only a few labs approved by MEP</td>
<td>Consideration of waivings</td>
</tr>
<tr>
<td></td>
<td><strong>Extra costs</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Incompatibility with REACh</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Longer delays</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Waivings ?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Data sharing</strong></td>
<td>Not mandatory</td>
<td>Mandatory</td>
</tr>
<tr>
<td></td>
<td><strong>Extra costs</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Risk of different classifications for the same substance</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Chemical Safety Report</strong></td>
<td>Qualitative method for the Human Exposure Assessment</td>
<td></td>
</tr>
<tr>
<td><strong>Communication with Competent Authority</strong></td>
<td>Very easy</td>
<td>Very difficult</td>
</tr>
<tr>
<td></td>
<td><strong>Need for a solid expertise</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Dossier submission</strong></td>
<td>Word format</td>
<td>IUCLID format</td>
</tr>
<tr>
<td></td>
<td><strong>Complicated</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Dossier technical completeness evaluation</strong></td>
<td>Manual</td>
<td>Automated (« Business rules »)</td>
</tr>
<tr>
<td></td>
<td><strong>Subject to interpretation</strong></td>
<td>Rigid</td>
</tr>
</tbody>
</table>
A few notes of advice to European notifiers of new chemicals in China

• Build a local Product Stewardship competency:
  - Local regulation survey
  - Relations with Competent Authorities

• Anticipate as much as possible

• Build a dedicated project team

• Involve an efficient consultant, specialized in new chemicals notifications
Aroma Performance

Thanks for your attention
Enabling Chemical Compliance for A Safer World

Regulatory Updates for New Cosmetic Ingredient and Food Contact Additive Regulations in China

26 Sept 2012, CW Webinar,
Yunbo Shi, Managing Director, CIRS
Email: yunbo.shi@cirs-reach.com
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- Overview of Chemicals Management in China
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- Updates About Food Contact Additive Laws
  - Legal Framework
  - Regulatory Updates 2009-2012
  - List of Permitted Food Contact Additives in China
- Summary
# Overview of Chemicals Management in China

<table>
<thead>
<tr>
<th>Category</th>
<th>Main Laws</th>
<th>Main Authorities</th>
</tr>
</thead>
</table>
| General Industrial Chemicals | Provisions on Environmental Administration of New Chemical Substances (MEP Order no. 7); Regulations on Safe Management of Hazardous Chemicals in China (Decree 591) | The Ministry of Environmental Protection (MEP)  
  The State Administration of Work Safety |
| Cosmetics                 | Regulations Concerning the Hygiene Supervision over Cosmetics                                        | State Food & Drug Administration                      |
| Disinfectants             | Measures on Disinfectant Administration                                                              | The Ministry of Health                                  |
| Food Additive/Food Packaging | Food Safety Law                                                                                      | The Ministry of Health                                  |
| Pesticides                | Regulation on Pesticide Administration                                                                | The Ministry of Agriculture                             |
| Cosmetic Ingredient       | Both chemical regulations & cosmetic regulations                                                    | State Food & Drug Administration (SFDA) and MEP, SAWS  |
| Food Contact Additive     | Both chemical regulations & food safety regulations                                                  | The Ministry of Health (MOH) and MEP, SAWS             |
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Legal Framework and Guidelines

- **Hygiene supervision over cosmetics (1990)**
  - The use of new ingredient for cosmetics production must be approved first;

- **Rules for the application of administrative licenses for cosmetics (2009)**
  - The use of new ingredient in cosmetics in China must be licensed;
  - Applicant can be the manufacturer of the new ingredient or the manufacturer of cosmetics;
  - Detailed requirements for registration of new cosmetic ingredient;
Definition of A New Cosmetic Ingredient (NCI)

“A new cosmetic ingredient is any natural or artificial ingredient that is used in cosmetics in China for the first time!"

3 Criteria for A Used Cosmetic Ingredient

☑ Listed on the Inventory of Existing Cosmetic Ingredients in China (IECIC) and is not a banned substance; or
☑ Has been used in a licensed special use cosmetic product (proof required); or
☑ Part of a plant that has been approved as cosmetic ingredient.
### IECIC 2003 vs IECIC (2012 draft)

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ 3265 cosmetic ingredients; ➢ Includes banned ingredients; ➢ Only ingredient names are given.</td>
<td>➢ 1674 cosmetic ingredients (<a href="#">First Batch</a>) + 673 ingredients (<a href="#">Second Batch</a>) + 1356 ingredients (<a href="#">Third Batch</a>); ➢ Has removed banned ingredients; ➢ Has indicated both the name and the maximum allowable dose level;</td>
</tr>
</tbody>
</table>

9 New Cosmetic Ingredients Approved Since 2004

Ministry of Health (MOH)

2004

- ALKYL(C12-22)TRIMONIUM CHLORIDE
- Potassium Methoxysalicylate
- Methylisothiazolinone
- Carnitine(and)Tartaric Acid
- LATHYRUS ODORATUS FLOWER EXTRACT
- FRUCTOOLIGOSACCHARIDES

State Food and Drug Administration (SFDA)

2008

- Dimethoxytolyl Propylresorcinol
- POLYMETHACRYLOYL LYSINE
- Phenylethyl Resorcinol (Public consultation)

Source: MOH & SFDA Website
Statistics on Applications of New Cosmetic Ingredient Approval 2010-2012

Registration of Domestic NCI

Registration of Imported NCI

Source: Dietary Supplement Review Centre of SFDA
Regulatory Updates Related to NCI Approval

- **Aug 2010**: Guidelines on The Risk Assessment of Potential Safety Risk Substances Published
- **Dec 2010**: Standard Chinese Name of INCI Published
- **Jul 2011**: Guidelines on the Registration and Assessment of New Cosmetic Ingredient Published (Key Change)
Key Guidelines

Guidelines for the registration and evaluation of new cosmetic ingredient (2011)

Set detailed toxicology data requirements and exemptions;
Give detailed guidelines for preparing other documents.

关于印发化妆品新原料申报与审评指南的通知

国食药监许[2011]207号

2011年05月12日 发布

各省、自治区、直辖市食品药品监督管理局（药品监督管理局），有关单位：

为加强化妆品新原料行政许可工作，确保化妆品产品质量安全，依据《化妆品卫生监督条例》及其实施细则等有关规定，国家食品药品监督管理局制定了《化妆品新原料申报与审评指南》。现予印发，请遵照执行。

附件：化妆品新原料申报与审评指南
Required Documents for Registration of NCI

✓ Application form;
✓ A research & development report consisting of the following information:
  o Background of research, R&D process and relevant technical files;
  o The source of ingredient, physio-chemical properties, molecular structure, molecular structure and molecular weight, etc;
  o Intended use in cosmetics, supporting proof, scope and extent of use in cosmetics;
✓ Brief description and diagram of production process;
✓ Standards for quality and safety specifications for the ingredient and impurities (quantitative and qualitative analytical methods required);
✓ Toxicology safety assessment data including safety assessment of risk substances;
✓ Power of Attorney in case of using a Chinese agent;
✓ 1 sample and other information which are helpful for review;
Main Issues

- Alternative methods are rarely accepted;
- Identification and analysis of impurities;
- The extent of details of manufacturing process;
- Approval process can be very long;
- No protection period for approved new ingredient;
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Legal Framework

- **Food Safety Law (came into force on 1 June 2009)**
  - Prohibits the use, purchasing and import of food contact materials, that are not in compliance with applicable Chinese standards on food safety.

- **Administrative Rules for Licensing of New Varieties of Food-Related Products (came into force on 1 June 2011)**
  - New food package materials and food contact additives must be approved by health authorities first;
Legal Framework

  - Contains 959 food contact additives (including monomers);
  - Sets the scope of use, maximum level and maximum permitted quantity (QM) or specific migration limit (SML);
  - Does not include food contact additives approved through MOH’s public notice after 2009.

<table>
<thead>
<tr>
<th>Scope</th>
<th>Maximum Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubber</td>
<td>1.2(SML)</td>
</tr>
<tr>
<td>Adhesive</td>
<td>1.2(SML)</td>
</tr>
<tr>
<td>Paper</td>
<td>1.2(SML)</td>
</tr>
</tbody>
</table>

**Example**

- **添加剂名称**: 1,2-苯并异噻唑啉-3(2H)-酮  
  **Name**: 1,2-benzeisothiazoline-3-one  
  **CAS 号**: 2634-33-5  
  **QM or SML**:
Regulatory Updates for Food Contact Additives


- The Letter to Solicit Comments on Approved Additives and Resins in Two Batches was issued in May 2011.

- Administrative Rules for Licensing of New Varieties of Food-Related Products were published in May 2011.

- MOH Notice [2011] 23 to Approve 107 Resins as Food Package Materials was issued in November 2011.

- MOH Notice [2012] 5 to Approve 301 Food Contact Additives was issued in April 2012.
Permitted Food Contact Additives in China

  - Contains 959 food contact additives (including monomers);
  - Sets the scope of use, maximum level and maximum permitted quantity (QM) or specific migration limit (SML);

- **MOH Notice [2012] No. 5 to Approve 301 Food Contact Additives**
  - Contains 301 food contact additives;

### Example
硼酸等301种食品包装材料用添加剂名单

<table>
<thead>
<tr>
<th>序号</th>
<th>CAS号</th>
<th>中文名称</th>
<th>批准的使用范围</th>
<th>最大使用量</th>
<th>特定迁移量/最大残留量</th>
<th>备注</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>10043-35-3</td>
<td>硼酸</td>
<td>塑料</td>
<td>PE: 不宜混合使用; EVOH: 0.16%</td>
<td>6.0 mg/kg (SML，以硼计)</td>
<td></td>
</tr>
</tbody>
</table>
New Food Contact Additive Notification

Summary

- New cosmetic ingredients and new food contact additives require approval in China;
- Inventory of Existing Cosmetic Ingredients in China published in two batches in 2012;
- SFDA has expedited approval of new cosmetic ingredients in 2012;
- List of permitted food contact additives consolidated in 2012;
Thank You!

Please don’t print this presentation unless you really need to! Go green.
If you have any unanswered questions please submit them to the Chemical Watch Forum, after the webinar.

http://forum.chemicalwatch.com
a recording of the presentations with slides will be available shortly. Please contact Lorna Madeley if you have any questions: lorna@chemicalwatch.com

Practical supply chain solutions under REACH and CLP – 1 day workshop
Brussels, 22 January 2013
See: www.chemicalwatch.com/events_webinars
WE WILL RESUME SHORTLY

Thank you for your patience