Taiwan Chemical Substance Registration & Inventory Update

Webinar, 26 February 2014, 9:30am GMT
Today’s webinar - aims

- An overview of Taiwan’s key chemicals regulations with details of recent amendment progress.

- Registration of new and existing chemicals under the new TCSCA regulations. Update on existing chemical substance inventory.

- How Taiwan’s chemicals registration requirements compare with systems in China, South Korea and the EU and some key implications for registrants.
If you have any unanswered questions please submit them to the Chemical Watch Forum, after the webinar.

http://forum.chemicalwatch.com
Speakers

Dr. Jowitt Li, Director at Taiwan’s Safety and Health Technology Center (SAHTECH).

Yunbo Shi, Managing Director and Principal Consultant at the Chemical Inspection and Regulation Service (CIRS).

Chair: Sarah Thompson, Hubs Editorial Content Manager, Chemical Watch.
Chemical Watch Webinar
2014/2/26

Taiwan
Chemical Substance Registration and Inventory Update
1. Amendment progress of OSHA, TCSCA, and GHS
2. New and existing chemical substance registration
3. Existing chemical substance inventory and update
4. Summary and next step further
5. Reference

Sources: Amendments of OSHA and TCSCA, CLA and EPA public Seminars in 2013

Disclaimers: Contents provided in the presentation are not the final official regulations. Please use or quote the texts provided with proper notation.
Toward SAICM Objectives and Interagency Priorities

• In 2007/2008, Taiwan Ministry of Economic Affairs (MOEA) conducted surveys and gap analysis against UN SAICM 36 possible work areas, 273 Global Plan of Action (GPA), and timelines (2010, 2015, 2020), involving government agencies, industries, and trade associations to gather comments on national chemical management.

Interagency Priority Setting:

- Toward full GHS Implementation
- To continue interagency cooperation
- To establish the national chemical substance inventory
- To develop new chemical substance notification/registration scheme
Amendment of Acts

Management of new and existing chemical substances

• **Occupational Safety and Health Act (OSHA)**: Title and the complete text of 55 articles amended and promulgated by Presidential Order on July 3\(^{rd}\), 2013

• **Toxic Chemical Substance Control Act (TCSCA)**: Revisions of Articles promulgated by Presidential Order on December 11\(^{th}\), 2013

• **Full GHS implementation, classification and labelling of hazardous chemicals**: January 1\(^{st}\), 2016
Article 13 Manufacturers or importers shall not manufacture or import chemicals containing new chemical substances that are not on the inventory of chemical substances announced by the central competent authority prior to submitting a chemical substance safety assessment report to the central competent authority and receiving approval of registration of the new chemical substances.

This provision shall not apply to substances stipulated by other legislations or which the central competent authority announces shall not be subject to this requirement.

• **incompliance subject to warnings and penalty**
Purpose of TCSCA Amendments
Toxic Chemical Substance Control Act

- To establish upstream source control and enhance screening scheme of toxic/hazardous substances
- Shifting and sharing responsibility with manufacturer/importer
- To strengthen hazard communication in supply chain
- Designate Chemical Management Bureau in charge
- Risk-based management
- To facilitate trade and expand custom border control
- To promote international harmonization
- Information dissemination and community right to know
Article 7-1 Manufactures or importers of existing chemical substances with quantities reaching specific amount each year shall apply to central competent authority for chemical substances registration by the regulated deadline; those manufacturing or importing of new chemical substances shall apply to central competent authority for registration 90 days prior to commencement of manufacturing or import. Manufacturing or import of said existing and new chemical substances shall only be allowed when the registration is approved.

• incompliance subject to warnings and penalty
Registration Process Flow Chart for New (Draft)

Manufactures/ importers of chemical substances

If the chemicals are existing chemical substances?

If exemption rules are applicable?

Apply for registrations in terms of use and tonnage thresholds of chemical substances

Excluded from new chemical substances registration

Polymers of low concern (PLC) shall be confirmed in advance.

small quantity registration

simplified registration

standard registration

Sources: 2013 CLA and EPA Seminars
“New chemical substances” refers to those other chemical substances that are not included in the existing chemical substance inventory.

- A substance or a polymer occurred in nature without physical and chemical process
- A polymer that is applicable to 2 % Rule
- Chemical substances accompanied in the machines and equipment of test-run purpose
- Inseparable intermediates from the chemical reaction in the reaction vessel or production process
- Mixture (not applicable to substances in mixtures containing new chemical substances)
- Article (not applicable if the substances contained in articles release in use)
- Chemical substances under custom supervision or for national defense purpose
- Incidental reaction products or impurities without commercial intended purpose
- Wastes
- Substances regulated by other laws and proclaimed by central agency

Sources: 2013 CLA and EPA Seminars
Types of Registration for New (1)

<table>
<thead>
<tr>
<th>Types of Registration</th>
<th>100kg/yr</th>
<th>1t/yr</th>
<th>10ts/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacture/import New chemical Substances</td>
<td>small quantity registration</td>
<td>simplified registration</td>
<td>standard registration</td>
</tr>
<tr>
<td>Manufacture/import chemicals used for pilot R&amp;D</td>
<td>small quantity registration</td>
<td>simplified registration</td>
<td>standard registration</td>
</tr>
<tr>
<td>Manufacture/import chemicals used for scientific research</td>
<td>simplified registration</td>
<td>standard registration</td>
<td>standard registration</td>
</tr>
<tr>
<td>Manufacture/import Polymer Of low concern</td>
<td>small quantity registration</td>
<td>standard registration</td>
<td>standard registration (+reports of hazard and exposure assessments)</td>
</tr>
<tr>
<td>Manufacture/import CMR substances</td>
<td>standard registration</td>
<td>standard registration</td>
<td>standard registration (+report of hazard and exposure assessment)</td>
</tr>
</tbody>
</table>

Sources: 2013 CLA and EPA Seminars
Information Requirement of New Registration

**Standard Registration**

1) Basic information of the registrant
2) Basic information of substances identification
3) Substances manufacture & use information
4) GHS hazards classification
5) Safe use information
6) Physical/Chemical Characteristics
7) Toxicological Information
8) Ecotoxicological Information
9) Hazard assessment report*
10) Exposure assessment report*

**Simplified Registration**

1) Basic information of the registrant
2) Basic information of substances identification
3) Substances manufacture & use information
4) GHS hazards classification
5) Safe use information
6) Designated Physical/Chemical Characteristics

**Small Quantity Registration**

1) Basic information of the registrant
2) Basic information of substances identification
3) Substances manufacture & use information

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- New chemical substances over 1t/yr
- Chemicals used for pilot R&D/ scientific research over 10ts/yr
- New chemical substances at 100-1,000kg/yr
- Chemicals used for pilot R&D/ scientific research at 1-10t/yr
- New chemical substances less than 100kg/yr, or; low concern polymer at 1 t/yr
- Chemicals used for pilot R&D less than 1,000kg/yr

Sources: 2013 CLA and EPA Seminars

*: Additional information required for standard registration for chemicals over 10t
Phase in Registration of Existing Chemical Substances

I. Phase I Registration
   - Issue 3 groups of phase II designated registration list

   Phase in information requirement for standard registration
   - 1. Basic information of registrant*
   - 2. Basic information of substances identification*
   - 3. Substances manufacture & use information*
   - 4. GHS hazards classification
   - 5. Safe use information
   - 6. Physical/Chemical Characteristics
   - 7. Toxicological Information
   - 8. Ecotoxicological Information
   - 9. Hazard assessment report**
   - 10. Exposure assessment report **

* Information submitted for Phase I registration
** Additional information requested for standard registration for chemicals over 10t

Periodical Reporting

II. Phase II Registration
   - Registration of 1st batch
   - Registration of 2nd batch
   - Registration of 3rd batch
   - Registration of 4th batch

Individual or joint registration of each substance
- 1st group of designated inventory: 10t and more
- 2nd group of designated inventory: 10 ts and more
- 3rd group of designated inventory: 10t and more
- Other designated substances by the central competent authority shall be registered according to other binding regulations

Sources: 2013 CLA and EPA Seminars
Scheme for Prioritization of Existing Registration

Based on Existing Chemical Substances Inventory and survey of Phase I Registration to conduct prioritize & establish designated substances for registration

All Domestic Chemical Substances

National Existing Chemical Substances Inventory

Phase I Registration

prioritization

Large Production Volume

High Hazard Concerns

Substances that lack of data

Proposed Criteria for Prioritization

3 groups of phase II designated substances

Sources: 2013 CLA and EPA Seminars
Chemical Substance Nomination Program (1)

- Consensus reached by interagency coordination decision to develop the national inventory.
- In Nov. 2nd 2009, the CLA published the *Directions for Existing Chemical Substance Nomination (ECN)* in accordance with the interagency Action Plan authorized by the Executive Yuan to constitute the **National Existing Chemical Substance Inventory**.
- **Supplementary ECN (S-ECN)** was carried out during June, July and August 2012.

- ECN and S-ECN received over 370,000+ dossiers
- Total nominated substances: 79,000
- Eligible for data protection claim subject to conditions

Sources: 2013 CLA and EPA Seminars
Chemical Substance Nomination Program(2)

In 2014 (preparatory stage)
• Supplementary Nomination and Correction before law implementation is in planning for completing the National Inventory

• Direction and Tools will be similar to ECN and S-ECN

Eligibility for nomination: Chemical substances imported to Taiwan, or manufactured, handled, used, or sold domestically, during the period of January 1\textsuperscript{st}, 1993 to December 31\textsuperscript{st}, 2011
Online searchable Inventory

Taiwan Chemical Substance Inventory website launched in April 2012
✓ Updated in December 2012

http://csnn.cla.gov.tw/content/Substance_home.aspx In Chinese/English Interface

Search functions:
• By CAS NO.
• By Chinese Name search
• By English Name search
• By Serial No.

Results:
• listed in the Inventory? Yes or No
Summary and Next Steps

- Detailed Registration Regulations are in the stage of drafting, followed by public consultation and pre-announcement by the end of 2014.

- Supplementary nomination and correction of inventory will be carried out as soon as June 2014 before law implementation.

- Guidelines, IT tools/platforms, case examples to facilitate registration.

- Continue interagency cooperation to launch registration scheme.

Sources: 2013 CLA and EPA Seminars
References and Links

- TCSCA full Articles in English (Ministry of Justice)

- OSHA full Article in Chinese (Ministry of Justice)
  http://law.moj.gov.tw/Law/LawSearchResult.aspx?p=A&t=A1A2E1F1&k1=%E8%81%B7%E6%A5%AD%E5%AE%89%E5%85%A8%E8%A1%9B%E7%94%9F%E6%B3%95

- CSNN website (news and online searchable inventory)
  http://csnn.cla.gov.tw

- GHS implementation website
  http://ghs.cla.gov.tw
Thanks for your attention

Sources: Amendments of OSHA and TCSCA, CLA and EPA public Seminars in 2013

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Comparing Chemical Registrations in Taiwan with Korea, China & EU

Mr Yunbo Shi, Principle Consultant
26 Feb 2014, CW Webinar
Email: yunbo.shi@cirss-reach.com
Main offices: China, Ireland;
No. of Employees: ~120;
Services: Product Registration & Regulatory Compliance Services for EU & Asia;
Business Units: Industrial Chemicals, Cosmetics, Pesticides & Biocides, Food Contact & Food, Medical Devices
Taiwan: Overview of TCSCA

New substance
- Exempt
- PLC
- R&D, Nano, etc

Existing substance
- Designated Existing Substances>=1t/y

90d prior to M/I
Grace Period

Registration

Effective:
11 Dec 2014

TCSCA: Toxic Chemical Substance Control Act

www.cirs-group.com
Korea: Overview of K-REACH

- **Existing substance ≥ 1t/y**
- **Designated existing substance >= 1t/y**
  - Grace Period
  - Prior to M/I

- **Registration**
  - Hazard evaluation
  - Risk Assessment

- **New substance**
  - Prior to M/I
  - Effective: 1 Jan 2015

- **Toxic substance**
- **Authorization substance**
- **Restricted / prohibited substance**

K-REACH: The Act on the Registration and Evaluation of Chemicals
P.R. China: Overview

New substance
MEP Order No. 7
Effective: 15 Oct 2010

Hazardous Chemicals
SAWS Order No. 53
Effective: 1 Aug 2012
MEP Order No. 22
Effective: 1 Mar 2013

More like reporting
EU REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
# Chemical Substance Registrations (1/4)

<table>
<thead>
<tr>
<th>Items</th>
<th>Taiwan (*)</th>
<th>Korea (*)</th>
<th>P.R. China</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>New substance; Designated substance $\geq$ 1t/y;</td>
<td>New substance; Designated substance $\geq$ 1t/y;</td>
<td>New substance;</td>
<td>New &amp; existing substance $\geq$ 1t/y;</td>
</tr>
<tr>
<td>Who</td>
<td>M/I/OR</td>
<td>M/I/OR</td>
<td>M/I/OR</td>
<td>M/I/OR</td>
</tr>
<tr>
<td>When</td>
<td>90d prior to M/I for new substance; Grace period for existing substance.</td>
<td>Prior to M/I for new substance; Grace period for existing substance.</td>
<td>Prior to M/I for new substance.</td>
<td>Prior to M/I for new substance; Grace period for pre-registered existing substance.</td>
</tr>
<tr>
<td>Types</td>
<td>Small volume, simplified, standard</td>
<td>Confirmation letter on exemption, simplified, full</td>
<td>R&amp;D, simplified, full</td>
<td>PPORD, intermediate, full</td>
</tr>
</tbody>
</table>

*May change when final guidance is published.*
# Chemical Substance Registrations (2/4)

<table>
<thead>
<tr>
<th>Items</th>
<th>Taiwan(*)</th>
<th>Korea(*)</th>
<th>P.R. China</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymer of Low Concern (New substance)</td>
<td>Exempt (&lt;1t/y); Small volume (&gt;=1t/y);</td>
<td>Confirmation letter on exemption</td>
<td>Simplified notification</td>
<td>Full registration of monomer &amp; reactant (&gt;=2%)</td>
</tr>
<tr>
<td>Scientific Research</td>
<td>Exempt (&lt;1t/y); Simplified (1~10t/y);</td>
<td>Confirmation letter on exemption</td>
<td>R&amp;D (&lt;0.1t) or simplified (0.1~1t/y)</td>
<td>Exempt if volume is &lt;1t/y; PPORD (volume &gt;=1t/y);</td>
</tr>
<tr>
<td>Product/Process Development (Pilot R&amp;D)</td>
<td>Small volume (&lt;1t/y); Simplified (1~10t/y);</td>
<td>Confirmation letter on exemption</td>
<td>Simplified (&lt;10t/y)</td>
<td>PPORD (volume &gt;=1t/y); Exempt if volume is &lt;1t/y.</td>
</tr>
<tr>
<td>Small volume (&lt;1t/y, non R&amp;D)</td>
<td>Simplified</td>
<td>Simplified</td>
<td>Simplified</td>
<td>Exempt</td>
</tr>
</tbody>
</table>

*May change when final guidance is published.*
<table>
<thead>
<tr>
<th>Items</th>
<th>Taiwan(*)</th>
<th>Korea(*)</th>
<th>P.R. China</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced Data Requirements for Intermediates</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>For &lt;1t/y only</td>
<td>For &lt;1t/y or non-hazardous intermediate</td>
<td>For &lt;1t/y only</td>
<td></td>
</tr>
<tr>
<td>Joint submission – New substance</td>
<td>- Possible</td>
<td>-Mandatory</td>
<td>- Possible</td>
<td>-Mandatory</td>
</tr>
<tr>
<td></td>
<td>- Accumulated tonnage rules</td>
<td></td>
<td>- Accumulated tonnage rules</td>
<td></td>
</tr>
<tr>
<td>Joint submission – designated existing substance</td>
<td>Mandatory with government interference.</td>
<td>Mandatory with government interference.</td>
<td>-</td>
<td>Mandatory, no government interference in cost-sharing</td>
</tr>
<tr>
<td>Post-notification reports</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

*May change when final guidance is published.*
## Chemical Substance Registrations (4/4)

<table>
<thead>
<tr>
<th>Data Required for Full Registration</th>
<th>Taiwan(*)</th>
<th>Korea(*)</th>
<th>P.R. China</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Registrant info;</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>2) Substance identifier;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Info on manufacture &amp; Use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) GHS classification</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>5) Guidance on safe use;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Physio-chemical property;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7) Toxicology data;</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>8) Eco-toxicology data;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9) Risk assessment report.</td>
<td>&gt;=10t/y</td>
<td>&gt;=10t/y</td>
<td>1-10t: qualitative; &gt;=10t: quantitative</td>
<td>&gt;=10t/y</td>
</tr>
<tr>
<td>10) Other issues</td>
<td>-</td>
<td>Only testing proposals issued by Korean labs may be accepted(*).</td>
<td>Some eco-toxicology data must be generated in MEP approved labs.</td>
<td></td>
</tr>
</tbody>
</table>

*May change when final guidance is published.*
Results & Implications

1) Data requirements
   - One data-set possible for all registrations but not sufficient;
   - Data waiving criteria and data acceptance criteria are different;
   - Language issues and local requirements to be respected;

2) Adoption of OR concept
   - Good for protecting CBIs;
   - Different qualifications for OR;

3) Adoption of risk-based assessment approach
   - Harmonized assessment of chemical risks;
   - More scientific;
   - A good waste of resources?
4) Similar to EU REACH but different.
   - Small volume of new substance – not exempt;
   - New polymer – not exempt;

5) Intermediates
   - Over-regulated in China, Korea & Taiwan?

6) Registration of existing substances
   - A trend for Asia;
   - New tests; or
   - Obtaining REACH data from lead registrant or REACH consortium?
China - Inventory of Existing Chemical Substances Produced or Imported in China (IECSC 2013)
http://cciss.cirs-group.com/

Taiwan – Existing Substance Inventory
http://csnn.cla.gov.tw/content/englishHome.aspx

Korea - Existing Chemicals Inventory (KECI)
http://ncis.nier.go.kr/ncis.jsp

EU - EINECS, ELINCS and NLP
http://esis.jrc.ec.europa.eu/

Asian Chemical Regulatory Update
http://chemicalwatch.com/
Thank You!

谢谢！

Please consider the environment before printing this document.
If you have any unanswered questions please submit them to the Chemical Watch Forum, after the webinar.

http://forum.chemicalwatch.com
Thank you for attending

A downloadable recording of this presentation (with slides) will be available shortly.

If you have any questions, please contact Lorna (lorna@chemicalwatch.com)

Korea Chemical Regulations Update – 6 March, 9:30am GMT
www.chemicalwatch.com/asiahub/korea-webinar