

## China Chemical Regulatory Update Report 2012

*CIRS Regulatory Team, 15 Jan 2013*

There are lots of regulatory updates for chemicals, cosmetics, agrochemicals and biocides in China in 2012. We have summarized some main chemical regulatory updates that might be related to your businesses. The summary provides a glance at what is happening in China and what is to come in 2013. We hope it is helpful for your businesses and career.



*In this issue, the following topics will be covered:*

- New Chemical Substance Notification;
- Hazardous Chemicals Management;
- GHS implementation;
- Cosmetics;
- Agrochemicals/biocides;

### ***New Chemical Substance Notifications***

#### **55 Typical Notifications Approved by China MEP in 2012**

10 Jan 2013, Compared to 2 typical notifications of new chemical substances approved in 2011, 55 typical notifications are approved by China MEP in 2012. Around 10% of approved typical notifications in China are prepared and submitted by CIRS. Thousands of simplified notifications have also been approved. The full statistics can be found on CIRS's [China New Substance Registration Watch](#).



#### **China CRC to increase fee for searching the confidential section of IECSC from 2013**

12 Nov 2012, The Chemical Registration Centre (CRC) of China MEP has published a notice on its website announcing that their administrative fee for searching the confidential section of IECSC will increase from RMB 200 per enquiry to RMB 600 (~100 USD) per enquiry. The new fee will apply from 1st Jan 2013.

#### **China MEP to start national environmental investigation of new chemical substances**

30 Oct 2012, China MEP announced that it will start a national environmental investigation of chemicals manufactured in China, starting from January 2013, to increase the management of chemical substances in China. Inspection of new chemical substance is also part of the investigation in accordance with the Article 42 of Provisions on the Environmental Administration of New Chemical Substances in China (2010): MEP will organize a comprehensive inspection on new chemical substances every 5 years. Companies will need to declare whether their substances are new or not.

#### **185 companies failed to submit annual activity report for new substances.**

18 Oct 2012, CRC has published a notice to request 185 new substance notifiers to submit annual activity report before 1st Nov. According to the article 36 of MEP's order

No.7, certificate holder of simplified notification shall submit the actual volume of manufacture or import of the new chemical substance for the previous year before **1 Feb** of each calendar year.

#### **208 Substances Added Onto China IECSC (2010)**

14 May 2012, According to an internal notice from China MEP, 208 substances have been approved to be added onto the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). This list is available for free upon request.

### ***Hazardous Chemicals Management***

#### **SAWS's Order 53 - The measures for the administration of registration of hazardous chemicals enters into force on 1 August 2012**

11 July 2012, the order requires that manufacturers and importers in China register hazardous chemicals with the National Registration Center of Chemicals (NRCC) of SAWS prior to manufacturing or importation. It has triggered important new obligations for companies, especially importers in China because importers are not required to register under old measures. English version of the order is available for free upon request.

#### **Draft measures for the administration of physical hazard identification and classification of chemicals published by China SAWS**

4 Dec 2012, the draft measures provide clarifications about how to determine whether registration is required for a chemical product (substance or mixture) that is not listed in the Catalogue of Hazardous Chemicals. The draft measures require manufacturers and importers to carry out physical hazard identification and classification at SAWS-approved institutions for chemicals with unknown hazard properties and submit identification and classification report to the National Registration Centre for Chemicals (NRCC).

#### **China SAWS Publishes Documents for Hazardous Chemicals Registration**

25 Oct 2012, China SAWS has published a series of supporting documents for hazardous chemicals registration. The 8 supporting documents consist of hazardous chemicals registration form for manufacturers, registration form for importers, user application form, application form for renewal, and NRCC's draft notices to reject one application or request more data. English version of the form is available for free upon request.

#### **SAWS's Order 57 - the Measures for the Administration of Safe Use Permit for Hazardous Chemicals Published**

27 Nov 2012, the order requires companies who use hazardous chemicals to manufacture products in China (excluding manufacturers of hazardous chemicals and companies who use hazardous chemicals as fuel) to obtain a safe use permit from the administrative department of work safety when certain criteria are met.

#### **MEP's Order 22 - the Measures for Environmental Administration Registration of Hazardous Chemicals (2012)**

17 Oct 2012, the order requires that manufacturers and companies who use hazardous chemicals to manufacture products in China submit an environmental administration registration to local environmental protection authorities. The order will come into force on 1st March 2013.

#### **China State Council adds 2-Chlorophenyl cyclopentyl ketone to the list of category I precursor chemicals**

21 Sept 2012, China State Council has approved to list 2-Chlorophenyl cyclopentyl ketone, with CAS 6740-85-8 and HS code 2914399014, in the first category of precursor chemicals in Regulation on the Administration of Precursor Chemicals. This will impose strict management on commercial activities like manufacturing, transportation, operating and import/export from 15th Sep 2012.

### **GHS**

#### **GB 6944-2012 and GB 12268-2012 Enter into Force**

1 Dec 2012, China's revised national standards GB 6944-2012 Classification and code of dangerous goods and GB 12268-2012 List of dangerous goods enter into force. Both standards are based on UN Model Regulations on the Transport of Dangerous Goods Rev. 16.

#### **China to Adopt the 4th Revised Edition of UN GHS**

24 Oct 2012, officials at the 2<sup>nd</sup> Shanghai Chem Summit have disclosed that China is currently revising its GHS national standards based on the 4<sup>th</sup> revised edition of UN GHS. It is no clear when the revised GHS standard will be published yet.

#### **China publishes draft national standards on chemical reagent packaging and labeling**

27 April 2012, The Standardization Administration of China (SAC) has published a draft national standard (GB 15346-201x) on chemical reagent packaging and labeling. The standard is expected to replace GB 15346-1994. In general, China GHS national standards also apply to SDSs and labels for chemical reagents. However there are extra labeling and packaging requirements for chemical reagents.

#### **China CIQ has initiated strict inspections on the import of hazardous chemicals since 01 Feb 2012**

2 Feb 2012, China's entry-exit inspection and quarantine administrations (CIQ) have started compulsory inspections on hazardous chemical substances exported to China and their packages from 1st Feb 2012. If the goods fail to pass CIQ's inspections (for example, incompliant SDSs and labels), the goods might be detained by customs. This is a clear signal of GHS enforcement in China.

### **Cosmetics**

### **Three New Cosmetic Ingredients Approved by SFDA**

China SFDA has approved three new cosmetic ingredients in 2012: PM-Lysine, Nivitol and Phenylethyl Resorcinol. In the past 4 years, only 3 ingredients have ever been approved by SFDA.

### ***China SFDA publishes draft Inventory of Existing Cosmetic Ingredient in China (IECIC) in three batches.***

In 2012, the draft IECIC now includes 3667 cosmetic ingredients which are allowed to be used in cosmetics in China. The English version of the draft IECIC is available for free upon request. According to the hygiene supervision over cosmetics (1990), the use of new ingredient for cosmetics production must be approved first.

### **China SFDA to Revise Hygienic Standards for Cosmetics and Lower Pb/As Level in Cosmetics**

4 Dec 2012, China SFDA has published a notice to invite public comments on revised Hygienic Standards for Cosmetics, now renamed as Technical Safety Standard for Cosmetics. The deadline for comments is 15 Dec 2012.

The Hygienic Standards for Cosmetics issued by the Ministry of Health in 2007 is the most important cosmetic standard in China that sets detailed safety requirements on finished cosmetic products manufactured or sold in China. The Hygienic Standard for Cosmetics have banned over 1200 substances in cosmetics and restricted the use of 73 substances, 56 preservatives, 156 colorants, 28 sun block agents and 93 dyes in cosmetics.

Compared to the old regulation, the new standard contains the following proposed changes:

- Hygienic Standards for Cosmetics will be renamed as Technical Safety Standard for Cosmetics;
- Safety requirements on cosmetic ingredients will also be added;
- More detailed requirements for special use cosmetics & cosmetics for special human groups will be added;
- The max allowable amount of Pb and As in cosmetics will be reduced from 40mg/kg and 10mg/kg to 10mg/kg and 4mg/kg respectively;
- Quantitative limits for 1,4-dioxane(30mg/kg) and asbestos(not detected) in cosmetics will be added;

The new draft standard has also emphasized the importance of safety evaluation of cosmetics and cosmetic ingredients. According the standard, companies shall carry out safety evaluation of cosmetics and cosmetic ingredients (including risk substances) to ensure safe use.

### **China SFDA issues guidelines for children's cosmetics registration**

12 October, the Guidelines have outlined the main factors (i.e., formulation, safety

assessment) to consider during the evaluation and approval of new cosmetics for children under 12 years old (including babies).

#### **China SFDA Publishes A Notice to Simplify the Procedure of Changing Name and Address of Cosmetic Manufacturer and Chinese Responsible Agent**

15 Nov 2012, the State Food & Drug Administration (SFDA) has issued a notice No.307-2012 to simplify the procedure of changing the name or address of cosmetic manufacturer or Chinese responsible agent provided that production site remains unchanged.

#### **China SFDA re-consults on categorized management measures for non-special use cosmetics.**

29 May 2012, the Chinese State Food and Drug Administration (SFDA) has issued a notice No. 263-2012 inviting public comments on the amended categorized management measures for non-special use cosmetics. According to the latest draft administrative measures, non-special use cosmetics will be regulated based on the safety risks of the cosmetics. Non-special use cosmetics intended for whitening and keratin removal will be treated as special use cosmetics due to their high risks.

#### **Shanghai CIQ publishes detailed implementation rules for the inspection of cosmetic samples imported into China**

22 May 2012, Shanghai Exit-Entry Inspection and Quarantine Bureau (Shanghai CIQ) has published detailed rules for the implementation of the inspection and supervision of cosmetic samples imported into China. The rules are of particular importance to companies who are involved in bringing cosmetic samples to China for testing, exhibition or research & development purpose.

### ***Agrochemicals/Biocides/Food Contact/Other***

#### **New China National Standard “85 PESTICIDE MRLS IN FOOD INCLUDING ABAMENCTIN” Published**

15 April 2012, the Ministry of Agriculture (MOA) and Ministry of Health (MOH) have released a new national food safety standard GB 28260-2011 85 PESTICIDE MRLS IN FOOD INCLUDING ABAMENCTIN to limit the maximum residue limits (MRLs) of 85 pesticides in food. The standard will enter in to force on 1 April 2012. GB 28260-2011 specifies 181 MRLs of 85 pesticides in food and was formally issued on 16 Feb 2012 after being reviewed by the Food Safety National Standard Review Committee in the light of China Food Safety Act. 13 MRLs in GB 28260-2011 are consistent with the CAC standard pesticide MRLs in food while the other 168 MRLs are not equivalent.

#### **China to restrict the production and use of Paraquat**

1 May 2012, the Ministry of Agriculture (MoA), the Ministry of Industry and Information Technology (MIIT) and AQSIQ have published a joint notice 1745 to place restrictive administration measures on the production and use of Paraquat in China. From the date

of the issue of this notice, new applications for the approval of manufacturing plant to manufacture and formulate Paraquat TK will no longer be accepted. From July 1, 2014, registration and production license of Paraquat SL shall be cancelled, and the production of Paraquat SL shall be stopped.

### **More Food Contact Additives Approved by MOH**

27 Nov 2012, The Ministry of Health of China publishes the third batch of 261 food contact additives for public consultations. The list includes the names of food contact additives, CAS numbers, the scope of use, maximum level and maximum permitted quantity (QM) or specific migration limit (SML). In China, new additives used in food packaging materials must be approved by health authorities first. More than 1,200 food contact additives have been approved by the Ministry of Health up to date. GB 9685-2008 Hygienic Standard for Use of Additives in Food Containers and Packaging Materials (2008) has included 959 approved food contact additives (including monomers). MOH Notice [2012] No. 5 approved 301 food contact additives in April 2012 after seeking public comments on the first & second batch of food contact additives.

### **What Is To Come in 2013?**

<b>Category</b>	<b>What is to expect?</b>
<b>New Substance Notifications</b>	<ul style="list-style-type: none"> <li>➤ Increased fee for searching IECSC;</li> <li>➤ Online submission system;</li> <li>➤ National investigation of chemicals;</li> <li>➤ More approved labs;</li> <li>➤ More approved typical notifications;</li> </ul>
<b>Hazardous Chemicals Management &amp; GHS</b>	<ul style="list-style-type: none"> <li>➤ HazChem registrations for importers: when?</li> <li>➤ Environmental registration of HazChems;</li> <li>➤ Revised Catalog of HazChems?</li> <li>➤ Final hazard identification rules?</li> <li>➤ New Chinese GHS standards?</li> </ul>
<b>Cosmetics</b>	<ul style="list-style-type: none"> <li>➤ More new ingredients getting approved?</li> <li>➤ Alternative methods getting accepted?</li> <li>➤ IECIC finalized?</li> </ul>
<b>Agrochemicals/Biocides/Food Contact/Other</b>	<ul style="list-style-type: none"> <li>➤ Revised regulations on pesticide registration?</li> <li>➤ Final guidelines for registration of disinfectants?</li> <li>➤ More ban on existing pesticides?</li> <li>➤ List of approved food contact additives and food packaging materials finalized?</li> </ul>

### **Free Resources & Publications Available Upon Request**

<b>Title and Topic</b>	<b>Author</b>
Chinese Chemical Regulatory Updates 2011-2012	<i>Yunbo Shi</i>

GHS Labelling for Small Containers & Awkward Packaging	<b>Morgan Prendeville</b>
China New Substance Notification Training(Chinese)	<b>Eric Xiong</b>
Risk Assessment: China New Substance Notification vs New Cosmetic Ingredient Approval in China	<b>Yunbo Shi</b>
SFDA Registration of New Cosmetic Ingredient	<b>Yunbo Shi</b>
Latest Updates of SFDA Regulations on Cosmetics	<b>April Guo</b>
Workshop on Safety Assessment of Personal Care Products & New Ingredients in China	<b>April Guo</b>
Consolidated List of IECIC(2012)	<b>April Guo</b>
English version of SAWS's Order 53 - The measures for the administration of registration of hazardous chemicals	<b>Yao Feng</b>
How non-agricultural pesticide is regulated in China	<b>Emma Huang</b>
How biocides are regulated in China	<b>David Wan</b>
Registration of Disinfection Products in China - Past, Present and Future	<b>David Wan &amp; Emma Huang</b>

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### **Contact Us**

#### **Chemical Inspection and Regulation Service Limited – China Office**

■ 11/F., Building 1, Dongguan Hi-Tech Park, 1288 Chunbo Road, Binjiang District, Hangzhou 310052, China

■ Tel: +86 571 8720 6555 ■ +86 5718720 6533

■ Email: [service@cirs-reach.com](mailto:service@cirs-reach.com) ■ <http://www.cirs-reach.com>

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