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CHEMLINKED FOCUS

China's Regulatory News & Database

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This is our small step and we hope it will be a big leap for China!

The year 2012 has been an eventful one. Environmental and chemical regulatory concerns have become a global issue and industry is prioritising the safe management of chemicals in all their markets. Ultimately, it is everyone's responsibility to protect others and the environment.

As a chemical consulting service company based in China, REACH24H has endeavoured to communicate the country's regulations and policies to ensure the safe use and management of chemicals.

In September 2012, we launched CHEMLINKED.com, a unique portal for essential information and assistance with China's environmental and regulatory issues. CHEMLINKED was created to meet the increasing needs of EHS professionals who need to keep updated on China's chemical & environmental news.

Happy New Year & A Prosperous 2013!

24 Dec 2012 Hangzhou

In this Issue:

Statistics of the Expert Review for ICAMA Registration in H2 of 2012

12 Dec 2012 / BY Fang Lin

Chinese National Expert Committee for Pesticide Registration consists of more than thirty specialists from agricultural, forestry, chemistry, hygiene, environmental etc. The experts are summoned up once or twice every year to issue expert opinions for authorizing full registration for new pesticides. Latest conference, the 11th plenary session of the 8th National Expert Committee was concluded in Urumqi, China. Of all the 29 applications, 12 of them have been granted the ICAMA's approval of full registration. The name, ai(s), formulation, range, uses, applicant, validation period of the applications and the results were summarized in the tables below.

Table 1 New pesticides approved by the 11th plenary session of the 8th National Expert Committee

ICAMA certificate number (validation period)	Ai(s) and Content(s)	Type of formulation	Target(s) and Crop(s)	Registrant[type]
PD20121663 (05/11/2012-05/11/2017)	JS399-19 95%	Technical		Jiangsu Pesticide Research Institute Company(JPRIC) [Fungicide]
PD20121670 (05/11/2012-05/11/2017)	JS399-19 25%	suspension concentrates	Foot rot on wheat and bakanae disease on rice	
PD20121674 (05/11/2012-05/11/2017)	orthosulfamuron 98%	Technical		Isagro[Herbicide]
PD20121667 (05/11/2012-05/11/2017)	orthosulfamuron 50%	Water dispersible granules	Cyperus, Barnyard grass and Broadleaved Weeds in transplanted paddy field	
WP20120209 (05/11/2012-05/11/2017)	Disodium octaborate tetrahydrate 98%	Water soluble powder(SP)	Rot and ant on wood	Borax[Biocide]
PD20121673 (05/11/2012-05/11/2017)	fluopyram 96%	Technical(TC)		Bayer CropScience [Fungicide]
PD20121664 (05/11/2012-05/11/2017)	fluopyram 41.7%	suspension concentrates (SC)	powdery mildew on cucumber	
PD20121675 (05/11/2012-05/11/2017)	maleic hydrazide 99%	Technical(TC)		Chemtura [Fungicide]
PD20121672 (05/11/2012-05/11/2017)	Fufenozide98%	Technical(TC)		JPRIC [Insecticide]
PD20121676 (05/11/2012-05/11/2017)	Fufenozide10%	suspension concentrates (SC)	beet armyworm on cabbage	
Note: JPRIC originally applied for the crop ranges of cruciferous vegetables and tea plant, the Committee finally agreed the pesticide to be only applied on cabbage as lack of residual data on the tea plant.				
PD20121671 (05/11/2012-05/11/2017)	picoxystrobin 97%	Technical(TC)		DuPont [Fungicide]
PD20121668 (05/11/2012-05/11/2017)	picoxystrobin 22.5%	suspension concentrates (SC)	Anthracnose and gummy stem blight on water-melon; black spot and leaf spot on banana	
DuPont's application of black spot and leaf spot on banana was rejected as the residue of the fungicide in banana has exceeded the EU's MRL requirement.				

Table 2 3 Applications pending upon supplementary submission

Name	Ai(s) and Content(s)	Type of formulation	Target(s) and Crop(s)	Applicant
Chlorempenthrin and permethrin combination	chlorempenthrin 0.2% +permethrin 0.2%	aerosol	Hygienic use against the fly	Jiangsu Youth Chem [Insecticide]
Screening study of the formulation type shall be supplemented. The MOA is anticipating reasonable design of the combination.				
novaluron	novaluron 98.5%	Technical(TC)		Jiangsu Jiannong Agchem[Herbicide]
	novaluron 10%	emulsifiable concentrate(EC)	Against wiggler in ditch and etange	FMC Suzhou [Herbicide]
Further submission of the risk assessment report conducted in the United State and 28 Day inhalation toxicity test of the ai.				

Table 3 14 applications temporarily rejected for full registration

Ai(s) and Content(s)	Type of formulation	Target(s) and Crop(s)	Applicant
Bacillus thuringiensis 10 billion cfu/g+ PuGV 3 billion cfu/g	Wettable Powder	Diamondback moth on cruciferous vegetables	Jiangsu Yangzhou Luyuan Bio-Chemical [Insecticide]
The Committee temporarily rejected the applications from Luyuan Bio-Chemical in that absence of the following data: toxicity test report on silkworm and fish of the two ais; Reproduction data on Bacillus thuringiensis and PuGV; Proof of PuGV's efficacy on diamondback moth			
Pythium Oligandrum 5 million cfu/g	Technical(TC)		Biopreparaty Co. Ltd. [Fungicide]
Pythium Oligandrum 1 million cfu/g	Wettable Powder	late blight on tomato	
Two applications from Biopreparaty for full registration were temporarily disapproved as absence of the following data: 1. Pathogenicity tests through oral, inhalation and injection are needed; 2. Non-pathogenic statement issued by the expert from Chinese domestic institute. 3. Environmental data			
Empedobacter brevis 30 billion cfu/g	Technical concentrates		Zhenjiang Runyv Biological Technology Co. , Ltd [Insecticide]
Empedobacter brevis 10 billion cfu/g	suspension concentrates (SC)	Against Diamondback moth and Spodoptera litura on cruciferous vegetables and leaf folder on rice	
The committee disapproved full registrations of Empedobacter brevis as reports of sepsis in babies and lung infections in adults caused by Empedobacter brevis. The applicant shall further provide the information of the classification and pathogenicity of the products and illustrate that the ingredient is non-pathogenic to human.			
Ethirimol 95%	Technical		
Ethirimol 25%	suspension concentrates (SC)	Powdery mildew on cucumber	

The committee temporarily disapproved full registrations of ethrimol in that: 1. The applicant shall data of two years' soil residue test conduct on one site; 2. The applicant shall refill the application form to complete the information such as chemical name, physico-chemical properties, etc; 3. The applicant need to submit the data of inhalation toxicity data and toxicokinetics			Jiangxi Heyi Chemical [Fungicide]
Berberine 0.5%	aqueous solution(AS)	gray mold and leaf mold on tomato; powdery mildew and downy mildew on cucumber; Phytophthora caprice on pepper	Zhejiang Jinghua Biological Technology Co. , Ltd [Fungicide]
The committee disapproved the application from Jinghua in that: 1. The application shall apply the registration of the technical concentration other than the aqueous solution; 2. The applicant shall submit the data of mutagenicity test. Explanation of why toxicity data sharing for technical concentration and the preparation are applicative and data exempting of reproductivity, teratogenicity, chronic toxicity and carcinogenicity			
Physcion 8.5%	Technical concentration		Qingyuanbao Bio-tech of Inner Mongolia [Fungicide]
Physcion 0.5%	aqueous solution(AS)	powdery mildew on cucumber	
The committee disapproved the applications from Qingyuanbao for the following reasons: The applicant need to refill the application form as the form was not properly completed. The applicant need to further explained the data gaps, such as the flash point of pure ingredient is 215.4°C ,while that of the technical concentrates is >150°C ; The boiling point of the pure ingredient is 560°C and that of the technical concentrates is 478°C ; The vapor pressure of pure ingredient is 4.8×10-11Pa while that of the technical concentrates is 1.5×10-13Pa. The pesticide is applied through spraying, but the applicant has not provide sufficient data of droplet and data exemption of acute inhalation toxicity test is not applicative; The Committee agreed to exempting on data of reproductivity, teratogenicity, productivity, teratogenicity, chronic toxicity and carcinogenicity, but the applicant need to further submit the data of vitro mutagenicity test on mammal.			
Isxaben	Technical	Export purpose	Zhejiang Shangyu nutriechem Fine Chemical [Herbicide]
Isxaben	Water dispersible granules		
The committee temporarily disapproved full registrations of Isxaben in that: The applicant need to submit the environmental report and the approve document; The applicant need to submit data of mutagenicity, sub-chronic toxicity, teratogenicity, chronic toxicity, carcinogenicity and metabolism; The applicant shall submit the toxic data on algea, flea, natural enemy and soil microbes and data of environmental behavior; The applicant needs to explain the inconsistency level of the ingredient between its registration in the United State and its application in China. Documentary evidence of the products have been registered in the United State is needed.			
Cyantraniliprole 93%	Technical		Dupont [insecticide]
Cyantraniliprole 10%	Dispersible oil-based suspension	Bemisia tabaci on cucumber; Diamondback moth on cabbage; Bollworm on cotton; beet armyworm on scallion; Etiella zinckenella on Cowpea; Bemisia tabaci on tomato; Bollworm on watermelon	
The committee temporarily disapproved full registrations of Cyantraniliprole as the ai is highly toxic to bee and the applicant need to supplement the risk assessment carried out in China and study the risk on bee if the ai was applied on honey crops.			

SAWS Publishes Draft Measures for the Management of Physical Hazard Identification and Classification for Chemicals

7 Dec 2012 / BY Liu Liu

China SAWS is seeking public comments on the draft "*Measures for the Management of Physical Hazard Identification and Classification for Chemicals*" by the deadline of 4 January 2013. Formulated in the context of the *SAWS Order 53* and the *State Council Decree 591*, the draft measures are designed to promote safety control over chemicals with unknown physical hazards. Presently, China's chemical manufacturers and importers will be facing a new mandatory program, that is, to conduct physical hazard identification and classification for chemicals with unidentified hazards. If identified as hazardous, the chemicals must be registered according to the SAWS Order 53.

Recent update: *English version of the draft measures is available now in our regulatory database!*

The whole draft comprises six chapters, with Chapter One governing general principles and subject scope; Chapter Two stipulating main obligations required of chemical companies; Chapter Three managing the qualifications of certified identification institutions; Chapter Four explicating the content of physical identification & classification; Chapter Five laying down legal liabilities and penalties and Chapter Six attaching supplementary instructions on exemptions, joint application and fee charging items. Chapter One, Two and Four are extremely important to potential chemical companies in need of chemical physical identification and classification.

WHAT IS CHEMICAL PHYSICAL HAZARD IDENTIFICATION/ CLASSIFICATION?

The physical hazard identification is to determine hazard characteristics of chemicals such as flammability, explosiveness, corrosion, fire-assistance, self-reaction and reaction when in contact with water, etc. The physical hazard classification of a chemical is conducted through assessment of its physical hazard identification result and relevant data documents.

WHAT CHEMICALS ARE REQUIRED TO TAKE PHYSICAL HAZARD IDENTIFICATION & CLASSIFICATION?

1) Chemicals listed in the *C&L Inventory (Catalogue of Hazardous Chemicals)*, yet found to have newly discovered physical hazards;
2) Mixtures containing more than one component substance listed in the Inventory with (known) physical hazards;
3) Chemicals that are not listed in the Inventory, but with unknown physical hazards; and
4) Newly developed chemicals for which physical hazard data are lacking.

Note: *The above may be viewed as the most updated official illustration on the definition of chemicals of unidentified physical hazards.*

WHAT INFORMATION WILL BE INCORPORATED INTO THE IDENTIFICATION REPORT (IR) AND CLASSIFICATION REPORT (CR) ?

Upon receipt of a company's application, a state certified institution should issue within 20 working days the identification report for physical hazards (three categories of chemicals — explosives, self-reactive substances and mixtures and organic peroxides are excluded). A complete identification report includes the following information:
1) Chemical name;
2) Applying chemical company;
3) Identification item(s) with their standards and methods;
4) Equipment employed;
5) Identification conclusion; and
6) Other information required in the identification guidelines for physical hazard identification.

A Classification Report should be produced by the applying company, based on the Identification Report issued or other physical hazard data held on hand, and then submitted to the NRCC. The Report includes the following,
1) Chemical name;
2) Important components;
3) Identification Report and other related data and sources; and
4) Classification results for chemical physical hazards.

The testing institutions need to keep samples for at least 180 days and documentation on record for at least 5 years, respectively. When the Classification Report reaches the NRCC, after the comprehensive analysis and assessment lasting up to 30 working days, a final conclusion on whether to approve the classification will be issued and delivered to the applying company. If there is any dissents to the conclusion drawn by the NRCC, companies have the right to request for arbitration from the technical committee within 15 working days upon receipt of the conclusion.

HOW SHOULD CHEMICAL COMPANIES CARRY OUT THE PHYSICAL HAZARD IDENTIFICATION?

Chemical companies are required to compile the Safety Data Sheet and the Precautionary Label if the involved chemicals are identified to be hazardous. The hazardous chemical must be registered with due registration documents within 6 months upon the receipt of the approved hazard classification from the NRCC, in accordance with the SAWS Order 53.

The chemicals with unidentified physical hazards, could be rejected by distributors and downstream users (including storage and transport companies) on the supply chain if the relevant classification documentation is lacking. In this case, distributors and downstream users could ask certified labs to do the identification.

Affected manufacturers or importers may refer to Figure 1 for the procedure of compliance.

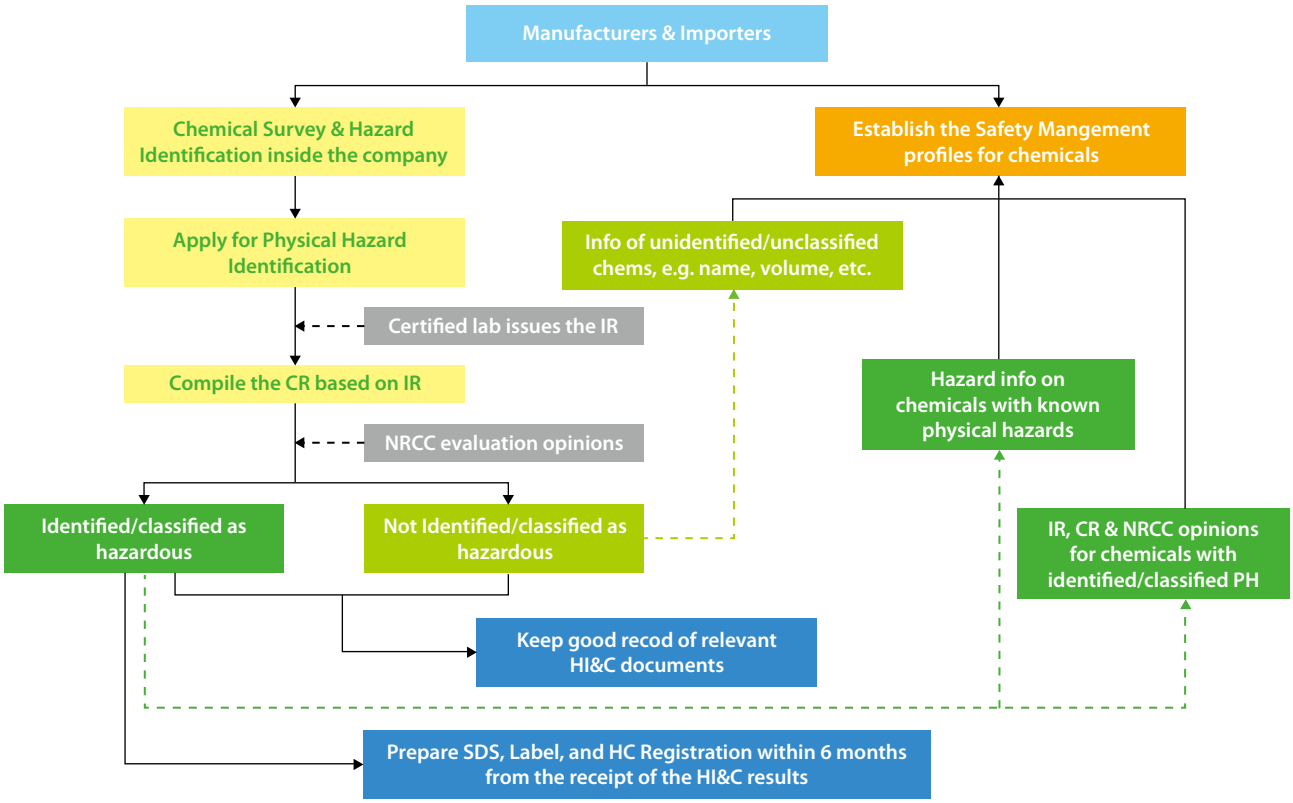

Figure: Physical Hazard Identification & Classification Procedure

Special Notice: *When a chemical is not classified to be hazardous, assessment documentation and other relevant information of the unidentified/unclassified chemical need to be kept on good record for future uses (such as supply chain communication or official checks and examinations). This information can be added to the company database of unidentified/unclassified chemicals, as it is very important to maintain a sound Chemical Safe Management Profile within the company.*

EXEMPTION, JOINT IDENTIFICATION AND OTHER INFORMATION

The draft measures contains a list of information on basic equipment required in the identification of the 16 chemical physical hazards (the same physical hazards incorporated in the China GHS system).

The Exemption rules under the draft measures claims that if the company could prove that its chemical does not contain any physical hazards with sufficient data, materials or human experience; the chemicals could be exempted from the physical hazard identification or classification. However, the exemption clause appears to have low feasiblity espicilally in the initial enactment of the measures.

For explosives, self-reactive substances/ mixtures and organic peroxides, companies can file an application for joint identification and share their identification/classification results so long as the concerned chemicals are of the same type.

Reference Links

- *SAWS news release and the draft*
- *State Council Decree 591: Regulations on the Control over Safety of Hazardous Chemicals (2011)*
- *Draft Measures on the Management of Physical Hazard Identification and Classification for Chemicals*
- *SAWS Order 53: Measures for the Administration of Hazardous Chemicals Registration (2012)*
- *C&L Inventory (Catalogue of Hazardous Chemicals)*

Taiwan's Toxic Chemical Substances Control Act is Under Revision

1 Nov 2012 / BY Nadine He

Taiwan's Toxic Chemical Substances Control Act (TCSCA) is under amendment, in which the management of toxic substances of Class 4 is tightened and a mandatory registration requirement for priority substances is ordered. Currently, the draft has been submitted to the Executive Yuan, if the proposed changes were approved, it will be further considered by the Legislative Yuan before notifying the WTO. "If all goes well, the new TCSCA shall be released at the end of this year or early next year", said by Mr. Lian from Taiwan EPA.

One big reason for the TCSCA amendment is the requirement of more rigorous management on the toxic chemical substance of Class 4. According to the Act in force, the EPA has posed restriction or ban on the handling of the toxic chemical substances of Class 1, Class 2 and Class 3. The manufacturer, importer or seller of Class 1, 2 or 3 toxic chemical substances shall apply to the competent authority for a permit, and shall operate in accordance with the content of the permit. However, for the Class 4, they are not subject to the restrictions of other regulations of this Act, apart from reporting the toxicological information of the toxic chemical substances. However, in the new TCSCA, the Class 4 substances shall be handled the same as the other three types.

Taiwan has concluded the *Supplementary Existing Chemical Substance Nomination(SECN)* on 31 August, 2012. Once Taiwan establishes the final version of the Existing Chemical Substance Inventory(ECSI), the Taiwan EPA will focus on the next phase of its chemicals management involving environmental and health risk-based screening. After that, there will be changes to the current situation that EPA has only regulated 298 toxic chemicals, of which 49 are forbidden to use, 156 are restricted to use conditionally, and 93 toxic chemicals of Class 4 are allowed to use. For the priority substances, which shall meet mandatory registration requirements under the new TCSCA, the detailed list has not been screened out.

Specified in the current version of the Taiwan TCSCA, the toxic chemical substances are classified into four classes:

- Class 1: chemical substances that are not prone to decompose in the environment or that pollute the environment or endanger human health due to bioaccumulation, bioconcentration or biotransformation
- Class 2: chemical substances that cause tumors, infertility, teratogenesis, genetic mutations or other chronic diseases
- Class 3: chemical substances that endanger human health or the lives of biological organisms immediately upon exposure
- Class 4: chemical substances for which there is concern of pollution of the environment or the endangerment of human health.

Reference Links

- *Toxic Chemical Substances Control Act (current version)*
- *List of toxic chemical substances on EPA website*

Chinese Official Clarifies Must-Know Issues on MEP Order No. 22

6 Nov 2012 / BY Nadine He

The Measures for the Environmental Management of Hazardous Chemical Registration (Trial), MEP Order 22, has been released on 10 Oct 2012 and shall come into effect since 1 Mar 2013. The Measures classifies hazardous chemicals into hazardous chemicals of priority environmental concern (HCPECs) and the general hazardous chemicals. On 31 Oct 2012, the Chinese official at the Open Seminaron Chemicals focusing on Management Policies among China, Japan and Korea has clarified some issues concerning MEP Order 22. The must-know information is collected from the seminar and organized into a Q&A format.

Q: Stipulated in the MEP Order 22, the enterprises have already handled hazardous chemicals prior to its promulgation can enjoy a three-year grace period. Does it mean the registration deadline is 1 Mar 2016?

A: Although mentioned in the Measures, not every HC company will be granted a three-year grace period. It is mentioned that for different types of comapnies the MEP will release notice specifying the length of the grace period, after which, only the companies holding the environmental management registration can engage in production, use, import and export of hazardous chemicals.

Q: MEP Order 22 requires the environmental risk assessment report, shall it be made according to the Technical Guidelines for Environmental Impact Assessment issued by the MEP previously?

A: As for the HCPECs, companies shall entrust qualified institutions to prepare the environmental risk assessment report when applying for a registration certificate This is different from the risk assessment report required by the Measures for the Administration of Hazardous Chemicals Regulation (SAWS Order 53). The MEP is about to release a particular technical guideline for the environmental impact assessment of hazardous chemicals. The environmental risk assessment under the MEP Order 22 shall be made according to it.

Q: When will the Catalogue of Hazardous Chemicals of Priority Environmental Concern be released?

A: The Catalogue of HCPECs will be screened out from the Catalogue of Hazardous Chemicals and released in batches. The batches are expected to be published before the implementation of the Measures.

Q: What's the difference between new hazardous substances with priority environmental concern under MEP order No.7 and hazardous chemicals of priority environmental concern under the MEP Order 22?

A: Compared with the new hazardous substances with priority environmental concern under the Measures for the Environmental Management of New Chemical Substances (MEP Order 7), the management of the HCPECs under MEP Order 22 mentioned above is different. There's a possibility that the new hazardous substance with priority concern registered under Regular Notification will be merged into the Catalogue of Hazardous Chemicals of Priority Environmental Concern after it is listed into the IECSC. While whether the new hazardous substance with priority concern can beincluded in the IECSC should be evaluated by the expert committee of the MEP. The committee makes the decisions based on the actual activity report submitted no less than 6 months before the end of the 5-year period dated from the first day of the substance's manufacture or import. Figure1 presents the relationship of the two types of hazardous chemicals.

Wenchao Zang
Department of Pollution Prevention and Control, MEP

Q: The expansion construction of production projects for the hazardous chemicals shall apply for the certificate prior to the project completion. What if the enterprise has been in the stage of pilot production and missed the time for registration?

A: The certificate for environmental management of hazardous chemicals has a validation period of 3 years. Reconstruction, new and expanded construction of production projects for the hazardous chemicals shall apply for the certificate prior to the project completion. There would be some implementation guidelines to clarify these existing issues soon.

Q: As for the registration certificate, is it one certificate for one hazardous substance?

A: No. The registration certificate is issued for the whole company with all the hazardous substances listed on it. This is the so-called "one certificate for the whole company" principle.

Q: If a company handled both the HCPECs and other general hazardous chemicals, how can it apply for the environmental management registration?

A: The local environmental protection administrations (EPAs) above county level are responsible for the environmental management of the hazardous chemicals registration. The manufacturers and enterprises using the hazardous chemicals listed in the Catalogue of Hazardous Chemicals should apply to the local EPA at county level for Production/Use Registration. For the HCPECs, if the submitted materials are sufficient, an on-site inspection will be conducted by the EPA at municipal level, after which the EPAs at provincial level will organize a technical evaluation. Upon receive approval from the evaluation, the registration certificate for the HCPECs will be issued by the EPA at provincial level. However, for the general hazardous chemicals, there will be no on-site inspection and the registration certificate can be obtained after the re-examination by the EPA at municipal level. Since one registration certificate is issued for the whole company with all the hazardous substances listed on it, , even if the company has only one substance characterized as the HCPEC, it will need to get the certificate from the EPA at provincial level after the on-site inspection and technical review by experts. The registration procedure is displayed in Figure 2.

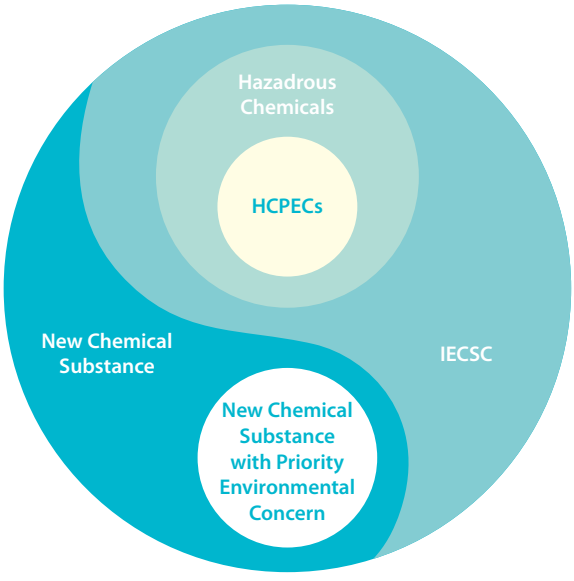

Figure 1. Illustration of the Relationship between the New Chemical Substance with Priority Envrionmental Concern under MEP Order 7 and the HCPECs under MEP Order 22.

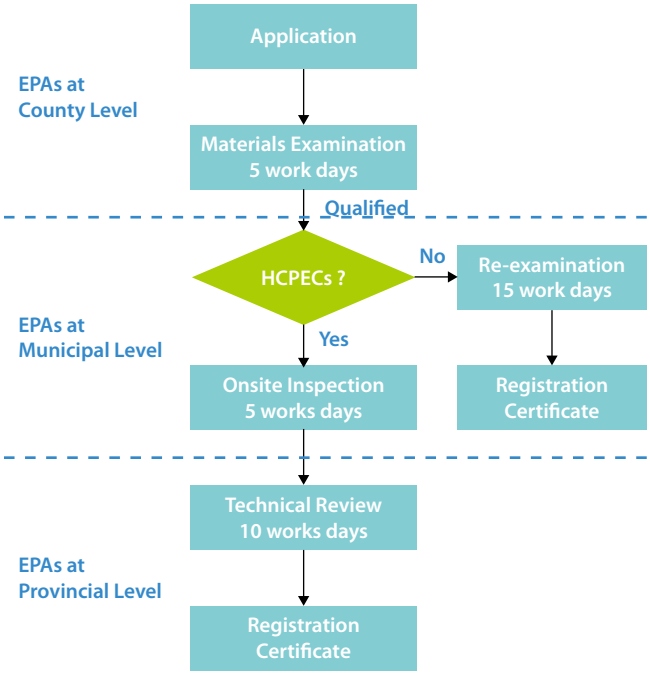

Figure 2. Registration Procedure for general hazardous chemicals and HCPECs

Pilje Kim
National Institute of Environment Research (NIER)

Korea REACH to be Issued

2 Nov 2012 / BY Nadine He

Speaking at the Open Seminar on Chemicals Management Policies among China, Japan and Korea, in Hangzhou of China in 31 Oct 2012, Mr. Pilje Kim confirmed that the South Korea's proposed Act on Registration and Evaluation of Chemicals (K-REACH) has been submitted to National Assembly and will be released in the first half of 2013. The K-REACH is expected to come into force since 2015.

120 officials from the Environmental Protection Departments of China, Korea and Japan and more than 160 representatives from the industry and non-government organizations have attended the seminar. In the seminar, responsible officials of the three countries proclaimed the chemical management prospect and regulatory concerns in their own countries. The seminar, held annually with location rotating among cities in China, Korea and Japan, is committed to set up a platform for the experts and representatives from chemical industry to communicate with the competent authorities.

Stipulated in the K-REACH, the manufacturers or importers of new chemicals and priority evaluation chemicals (PECs) shall submit registration to the Ministry of Environmental (MOE) prior to manufacture and import. The PECs are screened out among the existing chemicals concerning the exposure, hazard and trading volume, etc., including about 2000 to 2500 chemicals. The PECs list is planned to be released in 2014. The registration grace periond for the PECs varies across the priority 1, 2 and 3 chemicals, which is 2, 5 and 8 year respectively.

In the previous draft version, manufacturers or importers of existing chemicals manufactured or imported in quantities above 0.5 ton per year must submit a registration. However, the final draft has changed the criterion from 0.5 ton/yr to 1 ton/yr, which is consistent with the requirements of the EU REACH and Japan CSCL. The pre-registration process has been deleted earlier this year, and the reporting frequency has been changed from once a year to once every two years.

Similar to the EU REACH, the K-REACH also allows foreign companies to apply for notification to authorities through the appointment of a only representative in Korea. Any foreign-invested entities which officially registered in Korea are qualified as ORs without overall size limit.

In cases of modification on volume (manufacture or import), usage or hazardous properties, dossiers with updated information should be submitted. Companies can make joint submissions on the same substance. In the K-REACH, there's a prohibition on repetitive generation of vertebrate animal test data. In cases of refusal of vertebrate test data sharing without justification, the submission of such data for registration can be prohibited.

Since South Korea is a member state of OECD, the test data generated from the GLP laboratories overseas will be acceptable under K-REACH. However, the complete test report should be submitted for registration under the K-REACH.

As for the chemicals management in Japan, Ms Keiko Segawa introduced the Chemical Substance Control Law (CSCL), the Pollutant Release and Transfer Register (PRTR) and the other pollution control laws. In 2011, the number of notifications of new chemical substances counts for 684, and 28,519 notifications of the low volume of new chemical substances have been approved which is increased over 10% compared to the previous year.

Japan's PRTR system is a registration and announcement system for hazardous chemicals' release and transfer into the environment. In Japan, the PRTR system is voluntarily managed by business operators and the information is disclosed to the public. According to statistics from 2003 to 2010, the emission and transfer amount has been significantly reduced.

CRC-MEP Updated FAQs on China NCSN

14 Nov 2012 / BY Nadine He

The CRC-MEP has updated on 8 Nov 2012 the FAQs concerning the China New Chemical Substance Notification(NCSN), which includes 103 the most-frequently-asked questions submitted by notifiers to the Chemical Registration Center of the Ministry of Environmental Protection in China (CRC-MEP) with additional 14 questions appended to the previous version.

Although stipulated in the Guidance Document (2010), as for the serial notification, the minimum data requirements can be met by grouping the testing data of one or more of the serial substances, there has been some believes that at least a complete set of data of toxicological and eco-toxicological testing of one substance in the series should be submitted. In the updated FAQs, Q.92 has clarified that the physic-chemical data are needed for all the serial substances, while for the toxicological and eco-toxicological data. The CRC accepts data combined by testing data of more than one substances in this series. This clarification might relieve the notifiers since the CRC-MEP allows more flexibility on data requirements of serial notification.

Although notifiers were familar with the concept of tonnage accumulation for joint and serial notification, most notifiers do not know that this principle also applies to repeat notification when the same testing reports from the previous notifiers are used. It should be emphasized that even if only one same testing report is found to be used, the tonnage accumulation will occur.

In another case, if the same testing report used is gained from the successful notification under the MEP Order 17 (the old version for the China NCSN, now replaced by the MEP Order 7), the post-notifier do not need to notify the same chemical substance under repeat notification and therefore no tonnage accumulation will occur.

Reference Links

- *FAQs updated by CRC-MEP in Chinese*
- *China REACH FAQs from Q1-Q82 in Expert Articles in English*

The full PDF version in English of FAQs including Q1 to Q82 is available. If you want to have the newest version please contact us. Any feedback concerning the China NCSN is welcome and we'll collect and submit them to the CRC-MEP.

Dangerous Goods: GB 6944-2012 and GB 12268-2012 Take Effect since 1 Dec

3 Dec 2012 / BY Cao Yunyan

Since 1 Dec 2012, Classification and Code of Dangerous Goods (GB 6944-2012) and List of Dangerous Goods (GB 12268-2012) enter into force to replace their 2005 versions. Together with Packing Symbols of Dangerous Goods (GB 190-2009), they are three basic and significant national standards mainly applicable to the transport of dangerous goods by waterway, road, railway and air in China.

国 家 标 准

Chinese standard-setters always take reference from international legislations/ rules and have the standard revised accordingly. In terms of GB 6944 and GB 12268, their 2005 and 2012 versions are formulated according to the corresponding parts of the different versions of UN Recommendations on the Transport of Dangerous Goods-Model Regulations (UN RTDG-MR), which is revised every two years.

GB 6944

GB 6944-2005	UN RTDG-MR Part2: Classification (13th editior)
GB 6944-2012	UN RTDG-MR Part2: Classification (16th editior)

By comparison, major changes in the 2012 edition are listed as follows,

- More concrete and specific criteria for identification of the Classes and Divisions of dangerous goods are described;
- The assignment and composition of compatibility groups of explosives are added;
- The precedence of hazard characteristics of the 9 classes of dangerous goods is prescribed;
- The packing group of dangerous goods is added.

GB 12268

GB 12268-2005	UN RTDG-MR Part3: Dangerous goods list, special provision and exceptions (13th editior)
GB 12268-2012	UN RTDG-MR Part3: Dangerous goods list, special provision and exceptions (16th editior)

In line with the UN RTDG-MR, the 2012 edition makes the following amendments:
1) The structure of the List of Dangerous Good is adjusted: the column "special provisions" is added to replace the column "remarks";

The list of dangerous foods

UN No.	Name and description	English name	Class or division	Subsidiary risk	Packing Group	Special Provisions
0015	发烟弹药，带有或不带起爆装置、发射剂或推进剂	AMMUNITION,SMOKE with or without burster, expelling charge or propelling charge	1.2G			204

2) Two new appendixes are added:
• Appendix A: List of generic and N.O.S. proper shipping names;
• Appendix B: Special provisions applicable to certain articles or substances.
Meanwhile, three parts in the GB 12268-2005, including the Appendix A assignment and compatibility groups of explosives, the Appendix B precedence of hazards and the packing groups of dangerous goods, are removed but incorporated into the GB 6944-2012.

3) An "index", which is a list of dangerous goods ordered according to the Chinese Pinyin, is added.

危险货物品名表索引 (Index)

名称和说明 (Name and description)	英文名称 (English name)	类别和项别 (Class and division)	联合国编号 (UN No.)
1H- 四唑	1H-TETRAZOLE	1.1D	0504
1- 己烯	1-HEXENE	3	2370

Units and individuals involved in the transport of dangerous goods shall comply with the two newly effective standards to do the classification, determine predominant or subsidiary risks, assign the compatibility groups of explosives and packing groups of some classes and divisions and so on. Besides, it is highly recommended to check the special provisions in the list of dangerous goods and make sure the goods have carried correct packing symbols.

Reference Links

• *News from Standardization Administration of China: GB 6944-2012; GB 12268-2012*
GB 6944-2012 (The English version is available in our regulatory database)
GB 12268-2012 (The English version is available in our regulatory database)

NRCC Official Explains Registration of Chemicals with Uncertain Hazard Properties

11 Dec 2012 / BY Lizzy Liu

At the International Chemical Regulation REACH Workshop, Hangzhou 2012, Mr Guo Zongzhou, the NRCC speaker in charge of the HC registration, claimed that the NRCC has already drafted *a supporting document for the identification and classification of chemicals' physical hazards*, which is formulated to assist the registration of chemicals with unidentified hazard properties.

The management of chemicals with uncertain hazard properties has became one noticeable adjustment to the new "*Measures for the Administration of Hazardous Chemicals Registration (SAWS Order 53)*". Mr Guo clarified the term "chemicals with unidentified (uncertain) hazard properties" as follows. They are subject to potential HC registration under the SAWS Order 53.

• Chemicals included in the C&L Inventory (Catalogue of Hazardous Chemicals) but with unidentified hazard properties;
• Chemicals not included in the C&L Inventory, but which are found to have newly discovered hazards.
• Other chemicals to be will be defined in the future official guidances.

According to Article 22 of the SAWS Order 53, potential registrant should appoint a state-certified agency to conduct the hazard identification for chemicals with uncertain hazard properties. The draft on the identification and classification of chemicals' physical hazards has just been released on 3 Dec 2012 and the final version is expected early next year. Two other concrete guidelines on the identification testing methods and the qualification assessment for certified identification institutions are right on the way. Hopefully, these supporting measures plus the long-awaited C&L Inventory will display a clearer roadmap for the affected companies undertaking the HC registration.

Q&A Session

Concerns centering on the to-be-registered chemicals were widely raised in the wake of the 30-minute presentation. Several questions touched upon the hazard identification of articles, preparations or chemical mixtures that may have potential hazard properties (such as toxicological or environmental hazard characteristics) but are not included in the C&L inventory. Mr. Guo suggests potential registrants keep close watch on the release of the NRCC guidance document.

Q: Most of our products are mixtures (or preparations) which share similar components with only differences in the content proportion. Shall we arrange HC registration for them? And how shall I fill out their physic-chemical data if necessary?

A: Mixtures containing one or more component substances that are listed in the Inventory with known physical hazards are required to carry out physical hazard identification and classification. When identified to be hazardous by the NRCC evaluation, they are subject to the HC registration. As to how to provide the corresponding data, for whatever mixtures, preparations, or articles, we will publish a technical guidance on the practical issues (See *Chemlinked news on Sep 29*), such as how to conduct the registration and what tests to be performed.

Q: You mentioned the hazard identification for hazardous chemicals. I see that the SAWS is currently working on the standard with regard to physical hazard identification of chemicals (See Chemlinked news on Dec 7). How about

Guo Zongzhou
National Registration Center for Chemicals(NRCC) – SAWS

the hazards other than physical hazards?

A: SAWS is only responsible for compiling the identification and classification standard of chemicals' physical hazard. However, identifications of environmental hazards and toxicological properties of chemicals are governed by the China Ministry of Environmental Protection (MEP) and the Ministry of Health (MOH), respectively.

Other highlighted topics in Guo's speech include the clarification of registering manufacturers, registration timeline, registration content, procedure duration, required documents, post-registration obligation and legal liabilities.

Q: If our business involves the refinement of a hazardous chemical product, Shall I register the product as the HC manufacturer?

A: If your product turns to be a high-purity hazardous chemical after the purification, you will be considered as a "HC manufacturer". Otherwise, if you repackage the hazardous chemicals or dilute them with non-hazardous solvents for the purpose of sale or use, you are not defined as "a HC manufacturer".

Q: Shall I acquire a HC registration certificate for my hazardous chemical products imported prior to the enforcement of the SAWS Order 53 (1 Aug 2012)?

A: No, you are only required to register products imported after August 1, 2012. However, if you are still importing or plans to continue the imports, the HC products need to be registered.

Reference Links

- *A "Guidance-like" Document to Clarify the Hazardous Chemicals Registration*
- *SAWS Publishes Draft Measures for the Management of Physical Hazard Identification and Classification for Chemicals*
- *Draft Measures on the Management of Physical Hazard Identification and Classification for Chemicals*
- *SAWS Order 53: Measures for the Administration of Hazardous Chemicals Registration (2012)*

SFDA to Approve another 4 Testing Institutions for Cosmetics

10 Oct 2012 / BY Cao yunyan

The SFDA-approved testing institutions are accountable to undertake tests for cosmetic products/new ingredients and issue testing reports for companies applying for cosmetic administrative licensing. With the growing demand of cosmetic testing, another 4 units (marked red in Table 1) have been approved to undertake tests since 1 Nov, 2012.

Pursuant to Article 3 of Measures for Qualification of Cosmetic Administrative Licensing Testing Institutions, there are two types of institutions:

- hygiene safety testing institutions to perform all microbiological, hygienic chemical and toxicological tests;
- human safety testing institutions to conduct human safety tests (including human skin patch test and using test) and cosmetic sunscreens efficacy test.

According to the announcement No. 18 and No. 86 of 2011, 17 hygiene safety testing institutions and 6 human safety testing institutions have been approved in 2011. The newly-approved four ones belong to the first type.

Every testing institution bears a unique serial number. The SFDA will supervise the testing quality by requiring monthly and annual reports from institutions, in addition to non-scheduled on-site inspections.

- Table 1: List of the SFDA-approved testing institutions for cosmetics
- Table 2: Compulsory testing items of hygiene safety testing institutions
- Table 3: Optional testing items of hygiene safety testing institutions
- Table 4: Testing items of human safety testing institutions

Table 1: List of the SFDA-approved testing institutions for cosmetics

Type	Testing Institution	Serial Number
Hygiene safety testing institution (microbiological test, hygienic chemical test, toxicological test)	Institute of Environmental Health and Related Product Safety, China CDC	001
	Beijing CDC	002
	Liaoning CDC	003
	Shanghai CDC	004
	Jiangsu CDC	005
	Zhejiang CDC	006
	Guangdong CDC	007
	Sichuan CDC	008
	Beijing institute for Drug Control	014
	Shanghai institute for Food and Drug Control	015
	Guangdong institute for Drug Control	016
	Zhejiang Institute for Food and Drug Control	018
	Shandong Institute for Food and Drug Control	019
	Fujian Provincial Institute for Drug Control	020
	Guangzhou Institute for Drug Control	021
	Shenzhen Institute for Drug Control	022
	Hubei Provincial Center for Disease Control and Prevention	023
	National Institute for Food and Drug Control	024
	Liaoning Institute for Food and Drug Control	025
	Guangxi Institute for Food and Drug Control	026
	Xiamen Institute for Drug Control	027
Human safety testing institutions (human safety test and in vivo test of UV protection efficacy of cosmetic sunscreens)	General Hospital of Chinese People's Liberation Army Air Force	009
	Shanghai Skin Disease Hospital	010
	The third Affiliated Hospital of San Yat-sen University	011
	West China Hospital of Sichuan University	012
	The first hospital of China Medical University	013
	kin Disease Hospital of Chinese Academy of Medical Sciences	017

Table 2: Compulsory testing items of hygiene safety testing institutions

Testing Category	Compulsory Testing Item
Microbiological	Aerobic bacterial count
	Fecal coliforms
	Staphylococcus aureus
	Pseudomonas aeruginosa
	Molds and yeast count
Hygienic chemical	Mercury
	Arsenic
	Lead
	Methanol
	PH
	Formaldehyde
	Thioglycollic Acid
	Hydroquinone and Phenol

Hygienic chemical	Chlormethine and Cantharidin
	Sexual Hormones
	UV filters
	Oxidative Hair Dyes
	α-Hydroxy Acid
	Antidandruff agent
	Antibiotics
Toxicological	Acute oral toxicity test
	Acute dermal toxicity test
	Skin irritation/corrosion test
	Eye irritation/corrosion test
	Skin sensitization test
	Skin phototoxicity test
	Salmonella typhimurium/reverse mutation assay
	In Vitro Mammalian Cells Chromosome Aberration Test
	In Vitro Mammalian Cell Gene Mutation Test

Table 3: Optional testing items of hygiene safety testing institutions

Testing Category	Optional Testing Item
Hygienic chemical	Anti UVA parameter-critical wavelength
	Free Hydroxide
	Cadmium
	Total Selenium
	Boric Acid and Borate
	Selenium Disulfide
	Preservatives
	Vitamin D2, Vitamin D3
	Dissolvable zinc salt
Toxicological	In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test
	Mammalian Erythrocyte Micronucleus Test
	Testicle Cells Chromosome Aberration Test
	Subchronic Oral Toxicity Test
	Subchronic Dermal Toxicity Test
	Teratogenicity Test
	Combined Chronic Toxicity/Carcinogenicity Test
	Metabolic toxicity test

Table 4: Testing items of human safety testing institutions

Testing Category	Testing Item
Human safety test	Human Skin Patch Test
	Safety Evaluation of Using Tests of Cosmetics on Human Body
Tests in vivo of UV Protection Efficacy of Cosmetic Sunscreens	SPF test
	PFA test
	Waterproof performance test

Reference Links

- *SFDA news alert*
- *Measures for Qualification of Cosmetic Administrative Licensing Testing Institutions*

Test Methods for Prohibited or Restricted Substances in Cosmetics

6 Dec 2012 / BY Cao Yunyan

On 20 Nov 2012, the SFDA is seeking public comments on test methods for certain prohibited or restricted cosmetic ingredients,including 10 colorants and 7 hair dyes, listed in the *Hygienic Standard for Cosmetics (2007)*, which has been revised and under public consultation.

The Hygienic Standard for Cosmetics, formulated by the Ministry of Health in 2007, plays a significant role in managing the safety of cosmetic ingredients and finished products. The Standard contains lists of substances that are banned or restricted in cosmetics in China as well as the toxicological, hygienic chemical, microbiological test methods, etc. Its revision will bring about update of supporting documents relating to cosmetic ingredients and their testing methods in order to reinforce the cosmetic evaluation.

Recently, Shanghai food and drug administration revealed that the antibiotics and metronidazole which are banned cosmetic ingredients are found to be illegally added in some cosmetic products. The release of those test methods will contribute to improve the regulation of the testing of banned or restricted cosmetic ingredients and curb their illegal addition.

10 annexes with illustration of testing methods and their drafting background are displayed on the SFDA's website. The following table shows different test methods for the corresponding banned or restricted cosmetic ingredients and the cosmetic products which may contain those tested substances.

The deadline for this consultation is 15 Dec 2012.

For any comment, you need to fill out the feedback form of test methods or contact Mr. Lin Qingbin from the SFDA:

- Tel: 010-88330884
- Fax: 010-88373268
- E-mail: linqb@sfda.gov.cn

Note: *You can also post your comments on our website and we would help you to deliver them to the SFDA.*

Reference Link

- *SFDA news release*
- *Hygienic Standard for Cosmetics (2007)*

Annex	Test method	Substance	Applied cosmetics	Property
1	LC-MS-MS method	10 quinolones	may be in cosmetics for acne treatment	banned
2	LC-MS-MS method	9 antifungal substances	may be easily added in anti-dandruff cosmetics	banned
3	Gas chromatographic method	α-Chlorotoluene (CAS 100-44-7)	hair care products, creams, emulsions	banned
4	Headspace gas chromatographic method-flame ionization detector	thylene oxide(CAS 75-21-8) Methyloxirane(CAS 75-56-9)	cleansing cosmetics and other liquid products	banned
5	High performance liquid chromatographic method (HPLC)	Diethyl maleate(CAS 141-05-9)	sun-screen lotions (creams), nail polish, perfumes	banned
6	HPLC	10 colorants	blush, lipstick, foundation, nail polish, eye shadow, mascara	restricted
7	HPLC	7 hair dyes	hair perm and hair dye products	restricted
8	HPLC	aminocaproic acid	liquid, cream and powdered products	banned
9	HPLC	Chlorphenesin (preservative)	liquid, cream and powdered products	restricted
10	Ion chromatographic method	5 organic amines	liquid, cream and powdered products	ban or restricted

China SFDA Updates the Hygienic Standard for Cosmetics

7 Dec 2012 / BY Cao Yunyan

Revised from Hygienic Standard for Cosmetics 2007, the Technical Standard for Safety of Cosmetics is under public consultation until 15 Dec 2012.

At present, the SFDA only releases the body text while the Annexes are still under amendment and will be put on the website for public comments later. China sees rapid development of cosmetic production and consumption. However, the Hygienic Standard 2007 is not comprehensive and scientific enough to oversee the whole process of the research and development, production and use of cosmetics. First, the 2007 Standard puts more emphasis on the safety of cosmetic finished products other than ingredients; Second, some outdated tests and evaluation methods are not specific and instructive enough for effective safety assessment of cosmetics.

Compared with the Hygienic Standard 2007, the Technical Standard gives consideration to the safety of both cosmetic finished products and ingredients. A new part "general requirement for safe use of cosmetic ingredients" has been added, with the key points listed as follows,

• Some risk substances (such as banned or restricted substances) which may be introduced inevitably from cosmetic ingredients, are required to be kept under the limits prescribed. For those which do not have restrictions specified, risk assessment needs to be carried out.
• The manufacturers must provide the information on quantitative and qualitative test methods of ingredients, the test method of impurities as well as control measurements for possible safety risk substances.

• In case that the ingredient is a hazardous chemical, its label must conform to the relevant regulations for hazardous chemicals.

Furthermore, the Technical Standard also revises the prohibited and restricted lists and improves the toxicological, hygienic chemical, microbiological, and human safety test methods, all of which will be compiled in the Annexes.

Besides, the revised standard makes some changes in the limits of hazardous or banned substances in cosmetics.

• It greatly reduces limits for the lead and the arsenic in cosmetic products, from 40 mg/kg and 10 mg/kg to 10 mg/kg and 4 mg/kg, respectively.
• It stipulates the limit for dioxane to be 30 mg/kg. Although dioxane is a prohibited ingredient, the safety evaluation shows that the dioxane would cause no harm to human if controlled within the limit, according to the SFDA.
• The asbestos is prohibited in cosmetic products according to the revised Standard.

Overall, the Technical Standard will act as an indispensable criteria for all commercially available cosmetics in China and serve as a key reference for supervisory departments, manufacturers and testing institutions to conduct safety evaluation on cosmetic products and ingredients in a more scientific manner.

Note: *for any comment on this opinion-soliciting draft, you need to fill out the feedback form and send it to the SFDA before 15 Dec.*

Reference Links

- *SFDA news alert*
- *Technical Standard for Safety of Cosmetics (download in Chinese)*
- *Hygienic Standard for Cosmetics*
- *Technical Standard for safety of cosmetis*

DuPont's Cyantraniliprole Full Registration Denied for Bee Risks

20 Nov 2012 / BY Fang Lin

The 11th plenary session of the 8th National Expert Committee for Pesticide Registration was concluded in Urumqi on 18th August. The experts have reviewed the submissions for full ICAMA registration. DuPont's novel insecticide cyantraniliprole failed to convince the experts because of its effect on bees.

Among the 29 applications collected from 16 applicants, only 12 have been granted the ICAMA's approval of full registration. In total, the Committee has approved full registrations to 6 companies, namely Isagro's orthosulfamuron, JPRIC (Jiangsu pesticide research institute Company)'s JS399-19(Development Codes) and Fufenozide, Borax's Disodium octaboratetetrahydrate, Bayer's fluopyram, Chemtura's maleic hydrazide, DuPont's picoxystrobin. Three companies have filed the petition asking for an approval of the application for muscicide incense products. However, the committee insisted on suspending the products but suggested the ICAMA to further conduct a risk assessment.

However, DuPont's two applications of the novel insecticide cyantraniliprole were all denied for its high toxics to bees. The Committee required the company to study the risks for bees on honey crops, which should be carried out in China. The current provisional cyantraniliprole registration held by DuPont will be invalid from 14 Sep 2013.

Reference Link

- *Statistics of the Expert Review for ICAMA Registration in H2 of 2012(in English)*

ICAMA Promotes China's New Pesticide Regulation in Hangzhou

16 Nov 2012 / BY Fang Lin

A seminar regarding China's pesticide regulation was held by the ICAMA (the Institute for the Control of Agrochemicals, Ministry of Agriculture) in Hangzhou on Nov 12nd and 13rd. Mr Gu, Baogen, the deputy director of the ICAMA, together with other government officials in the pesticide management field , have presented detailed information on the new "Regulation on Management of Agricultural Chemicals"and explained their preliminary thoughts on data requirements in the dossiers.

Up to 500 local officials of pesticide control and the representatives from crop protection industry have attended the symposium. As the new pesticide regulations are taking effect, this event had quite a good turnout of pesticide-related companies seeking for information that may affect their future.

Liu Shaoren, chief of the supervision office, stated that final version of the regulation has been approved by the Standing Committee of the State Council and the

copies were distributed to other Ministries. However, the issuance was postponed as a result of the delay of the18th National Congress of Communist Party of China. In short, the regulation aims at supporting the R&D and HES oriented companies and eliminating the incompetent players and products. The other goal of the regulation is to encourage China's pesticide industry to enter the global crop protection market.

• According to the new regulation, the applicants of a new pesticide will not be restricted to manufacturers. Moreover, commission process between the registrants and the manufacturers will be conditionally accepted. A registrant who wishes to quit the market may transfer the dossier data to another applicant to recover some costs;
• More than 20 articles related to penalty have been incorporated to the new regulation in which the misbehaviors and minimum level of penalties were explicated. In serious circumstances, the company may be revoked of the ICAMA registration and manufacturing permit and in that case, it will be suspended for further application for registration in next five years. Furthermore, the responsible persons of the companies will be expelled from the whole pesticide industry for up to 10 years;
• According to the new regulation, the field trial and residual test are required to be carried out in China, while other data such as toxicity or physic-chemical obtained by the overseas GLP-compliant laboratories will be acceptable for registration as long as they have mutual agreement on multilateral acceptance with China;
• Over 349,000 distributors are selling pesticide to the peasants in China and most of them are incapable of instructing the consumers how to properly use the products. The new regulation will introduce licensing system and sales recording system to the distributors. The general pesticide products will be labeled with bar-code and the restricted products will be marked with anti-fake labels for traceability;

Due to the toxic or hazardous nature, some of the pesticide categories will be listed in the Chinese "C&L" inventory (Catalogue of hazardous chemicals), which was under the scope of both the "Measures for the Administration of Hazardous Chemical Registration (SAWS Order 53)" and the "Measures for the Environmental Management of Hazardous Chemical Registration (Trial)" (MEP order 22). The Ministry of Agriculture (MoA) is now participating in the compilation of the inventory with the other Ministries/Departments. The MoA will try to avoid duplication in management by controlling the number of entries of the inventory. An organophosphates insecticide malathion is already listed in the "Inventory of Chinese Highly Toxic Chemicals".The MoA is also trying to remove the insecticide from the inventory and asking the industry to submit the evidence for its safeness.

Although two staple herbicides, the paraquat and the glyphosate were consecutively restricted in China early this year, the official affirmed that China will not adopt reassessment system on the registered ais as the EU or the US did. However, the authorities will give more consideration to safety, risk controls when assessing a dossier and will carefully monitor the pesticide incidents after the approval.

New Pesticide MRLs Standard to be Implemented on 2013

7 Dec 2012 / BY Fang Lin

6 Dec 2012, China's Ministry of Agriculture and Ministry of Health co-published the "Maximum Residue Limits for Pesticides in Food(GB2763-2012)", which will be uniquely and compulsorily implemented from 1 Mar 2013.

Meanwhile, other 6 national standards and 10 industrial standards regarding pesticide MRLs will be repealed from then on.

The new MRLs standard contains 2293 limits for 322 ais on 10 categories of commodities and foods. The establishment was more tailored to the Chinese dietary and all of the 2293 limits were developed based on the risk assessment results and the data collected from the field trials and residual monitors in China.
The newly released standard is characterized by the following,

• Most of the MRLs in the new standard are prescribed for fresh commodities such as the fruits and vegetables.
• MRLs for crop classes and primary agriculture products were firstly introduced.
• Limits for re-residue of the persistent pesticides such as aldrin were covered.
• Test methods for the residuals on the commodities were prepared for better supervision of agricultural commodities, which might deter the illegal and excessive uses of pesticides in China's crop protection market.

Reference Links

- *MoA's News Release (in Chinese)*
- *MoH and MoA's Announcement 22 of 2012(in Chinese)*
- *GB2763-2012(Download in Chinese)*
- *[Sample]GB2763-2012(Download in English)*

SFDA Plans on Quality Consistency Evaluation for Generic Drugs

11 Dec 2012 / BY Nadine He

China SFDA has released the Work Plan for Quality Consistency Evaluation for Generic Drugs (draft) in accordance with the Twelfth Five-Year plan for drug safety (Drug Safety Plan) issued by the State Council earlier this year. Through the quality consistency evaluation, the generic drugs which haven't measure up to the quality requirements will be potentially eliminated from the market.

The evaluation is focused on the consistency of the composition and clinical efficacy between the generic drug and the branded original drug. Any generic drugs registered before 1 Oct 2007 when the Provisions for Drug Registration (SFDA Order 28) came into effect shall fall into the scope of the quality consistency evaluation. The SFDA will pilot the quality consistency evaluation on the oral solid preparations, which will be accomplished by 2015, followed by the injections and other forms of the generic drugs by 2020.

Apart from the compilation of a reference inventory for the correlation of generic drug and its corresponding branded original drug, the SFDA will formulate evaluation methods, standards and technical guidelines before launch of the evaluation work. Manufacturers of generic drugs need to carry out a self-assessment of the quality consistency based on these documents and submit the relevant materials to the provincial FDA. Accordingly, the provincial FDA will organize an on-site inspection and take sampling of three batches of to be evaluated drugs. Subsequently, the samples shall be passed to the drug testing institutes for further review and the feedback need to be submitted back to the provincial FDA. All these materials and the evaluation report will be submitted to the special office under the SFDA for expert review. If approved by the SFDA, the basic information of the generic drug will be publicized, e.g. the name of manufacturer, the drug name, the approval number, etc., if not, the drug would be eliminated from the generic drug market. Detailed procedure is displayed in the diagram below.

Reference Link

- *SFDA news* release in Chinese

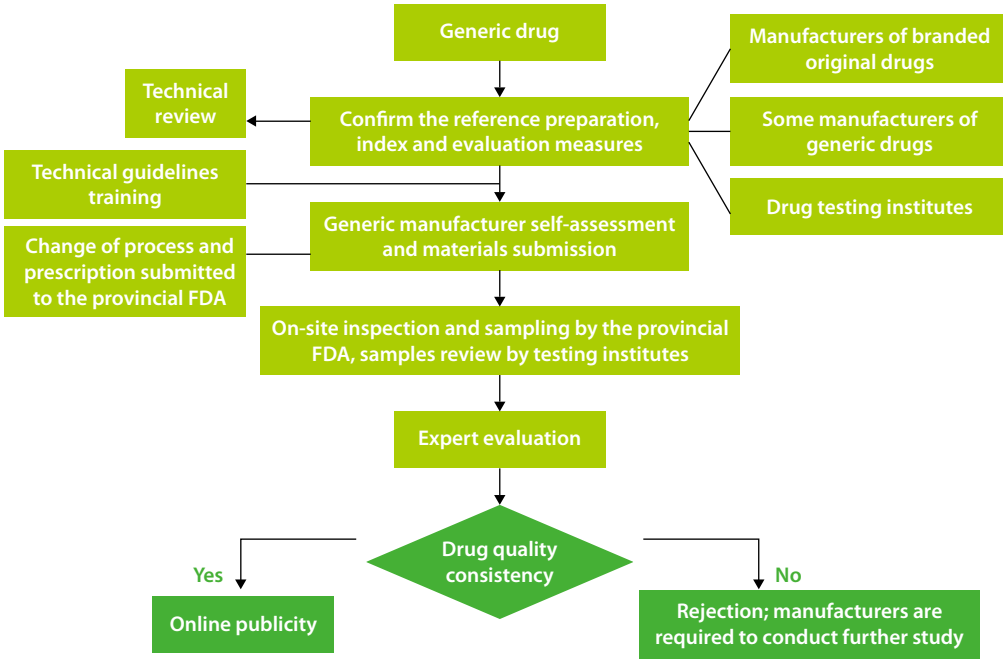

Figure. Flow Chart of Proposed Quality Consistency Evaluation

MEP Order No 22: A Big Step but Long Way Ahead

5 Nov 2012 / BY Fang Lin

Risks of the chemicals can be acute or chronic, as a necessary part of our economy and lives, they shall be properly managed on work safety and environmental aspects. In China, the hazardous chemicals are mainly governed by two authorities, the State Administration of Work Safety (SAWS) and the Ministry of Environmental (MEP). The former is in charge of preventing chemical accidents in the work place, which generally involving the "acute risks", while the MEP concerns more on health, emission, accumulativeness and other environmental issues with relevance to chemicals.

As one of the most costly market-entry barriers, the "Measures for the Environmental Management of New chemical Substances (MEP Order7)" has become effective since 15 Oct 2010. Since then, a large number of hazardous chemicals are indulgently applied and released by the profit-driven companies. On 10 Oct 2012, MEP has promulgated the Order No 22, "Measures for the Environmental Management of Hazardous chemical Registration (Trial)". The Measures required the HC companies to obtain registration certification of environmental management on hazardous chemicals. This is considered as an important supplement of environmental risks management. However, management on the new chemicals and HCs will differently impact the industry and economy as the two measures differs in aims, scopes, means and formations. Table 1 listes an explicit comparison between the two Measures.

The Measures required that the HC companies shall obtain registration certification for environmental management on hazardous chemicals.

Table 1. MEP Order 7 vs. Order 22

Category	Order 7	Order 22
aim	To identify the risks of New Chemicals by collecting information from the notifying companies	To collect information from the HC producers and users on the volumes, hazardous profile, emissions of the HCs
Major Responsible authorities	Chemical Registration Centre of the China Ministry of Environmental Protection (CRC-MEP)	Local environmental protection organization
	Information of the risks on new chemicals are collected at the national level as risks of a new chemical are unknown, while information of the HCs are collected from local environmental protection organizations in a bottom-up manner for the risks of the hazardous chemicals are already recognized.	
Scope	New chemicals outside the Inventory of Existing Chemical Substances in China (IECSC)	chemicals included in the "Catalogue of Hazardous Chemicals", also known as the Chinese "C&L Inventory"
	The number of the new chemicals to be notified and the affected companies are more difficult to predict than the companies registering the HCs as the new chemicals are continously developed.	
Affected companies	R&D, manufacturing, importation, processing/using activities of the producers and importers of the new chemicals.	Manufacturing and using companies of the hazardous chemicals.
	The new chemical notifying companies are usually research and technology oriented companies while the HC manufacturing/using companies are characterized by poor technology and a lot of environmental concerns.	
Chemical classification	According to the test data from the submitted dossier, new chemicals are classified into general chemicals, hazardous chemical, hazardous chemical of priority environmental concern, i.e.,, the chemicals are classified during/after the notifying.	Chemicals included in the "C&L" inventory have already classified into three categories, the general HCs, "hazardous Chemicals Severely Restricted for Import and Export in China"(known as the "Toxic Chemicals Severely Restricted for Import and Export in China"), "Hazardous Chemicals of Priority Environmental Concern"(HCPEC).
Information submitted	Test data and risk assessment report on the new chemicals.	Categories, volumes, classifications, SDSs, usages of the HCs, Approval document of the Environmental Impact Assessment Report (EIA), Monitoring data of the HCs, and/or environmental risk assessment (ERA) report on the hazardous chemicals of priority environmental concern chemicals (HCPECs).
	Time and costs for the new chemicals notification are relatively higher as more animal test are involved while the HC registration requires more skills and knowledge for monitoring and estimation on the release and transfer of the HCs.	
certificate	"One substance, one certification" One companies can hold more than one certification for several chemicals	"One company, one certification" One company will be issued one with certification, and all the relevant HCs will be listed on the certification
Post-registration	Registrant shall receive supervision from local environmental protection bureaus. Registrants of hazardous chemicals or hazardous chemicals of priority environmental concern shall report to the CRC-MEP the actual activity of the HC and/or the forecast of the chemicals in the following year.	HC companies shall annually report the category, hazardous properties, pollutant emissions, pollutant discharges, incidents, pollutant control measures of their HC relevant operations. The HCPEC companies shall submit environmental release and transfer registration report, and environmental risk management plan.
Work Load ratio	70% on notification and 30% on the post-notification supervision	presumably 40% on registration and 60% on post-registration supervision

ERA and R&T Reporting Obligations upon the HCPEC Companies

According to the Order 22, the environmental risk assessment and release & transfer report are required for the hazardous chemicals of priority environmental concern. The third party could be appointed to compose the environmental risk assessment report for the companies. This report system will acquaint both the authorities and the company's better awareness of their environmental risk management capability. The HCPEC list has not been released yet. During a tripartite environmental ministerial meeting among China, Korea and Japan, a Chinese official revealed that the first batch of the HCPEC list would be formulated before 1 Mar 2013.

Another big progress in the release of the Order 22 is the public's right to know. Although the release & transfer report system has its root in the EU's Pollutant Release and Transfer Register (PRTR) and the Toxic Release Inventory (TRI) from United States, differences were found between them. The differences are listed in Table 2.

	Order 22	PRTR or TRI
publisher	Registered HC companies	Top-level national authorities
Way of report	The release & transfer data was first submitted to the county environmental protection agencies and delivered to the national ministry in a level by level way, which might acquainted the organization at different level a better awareness of the environmental impact of the HCs in their jurisdictions.	Under the TRI, the gathered data was electronically submitted to the EPA headquarter, and the state-level agency will extract the information from EPA headquarter.
content	In addition to the data collection for the past year, the companies shall submit the management plan of the HCPECs. The authorities will check whether the company has fulfilled its plan by the end of the year.	Collections for the release & transfer data of the past year.

The scope and classification of the HCs under Order 22 is presented in the figure below. As shown, HCs could be classified as general hazardous chemicals, hazardous chemicals severely restricted for import and export and hazardous chemicals of priority environmental concern. Overlap will exist between the latter two categories of HCs.

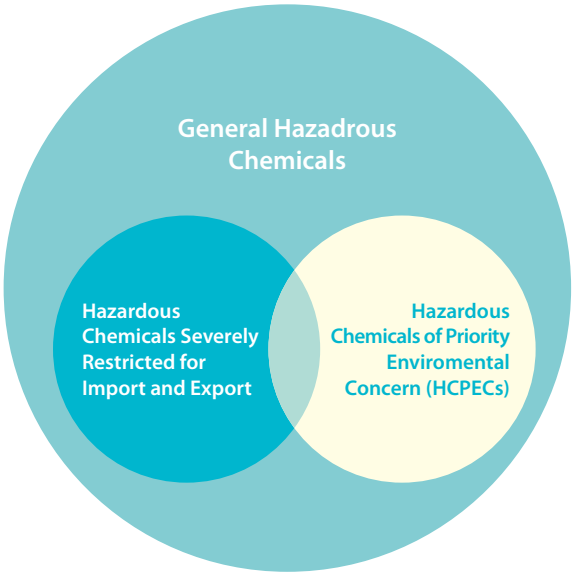

Figure. Classification of HCs under Order 22

Reference Links

- *MEP Order No 22(in Chinese)*
- *Measure for the Environmental Management of Hazardous Chemical Registration (Trial)*
- *List of Toxic Chemicals Severely Restricted for Import and Export in China (2012)*

If you want to track whether the substance of your concern is covered by the List of Toxic Chemicals Severely Restricted for Import and Export in China (2012), please enter Chemlinked Inventory Toolbox

Is Short-term Toxicity to Earthworm Test Conducted in China a Must?

14 Nov 2012 / BY Olivia Sun

The question whether the short-term toxicity to earthworm test has to be conducted in China received ambiguous answers. Recently, officials from Chemical Registration Center of Ministry of Environmental Protection (CRC-MEP) clarified this question.

If the short-term toxicity to earthworm test data is required to meet the minimum data requirements, the question could be answered as follows,

1. In case of the testing data unavailable from overseas accredited labs at the time of submission, the notifier will be requested to conduct the test in Chinese territory.
2. In case of available testing data obtained from overseas accredited labs, the notifier is allowed to submit the data in the notification dossier, instead of conducting additional test in China.

Besides, one should also understand that the CRC-MEP sticks to the principle that once submitted to the authority, the notifier acknowledges that what is included in the dossier is all that is available. Therefore, if the notifier fails to include the short-term toxicity to earthworm testing data when submitting the notification dossier, they will be asked to conduct the test in China even if they do own the testing data generated from the MEP-accepted overseas labs. As an extrapolation from this case, the notifiers should submit as much available information as possible in their notification dossier, which is compliant with the original intention of CRC-MEP to promote complete submission of materials at the first time.

The above only applies when the short-term toxicity to earthworm test data is compulsory to be included in the dossier, according to the MEP Order 7.

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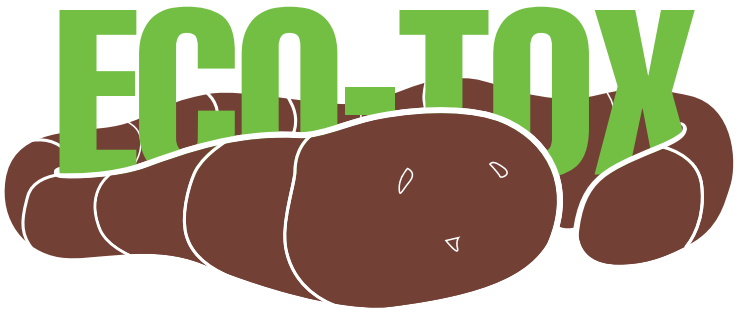

Overview of Legislative System for TDG in China

15 Nov 2012 / BY Sunny Wang

China still has a long way to go before an integrated legislative system for transport of dangerous goods to be established.

In recent years, accidents caused by the transport of dangerous goods in China have increased together with the rapid development of chemical industry. In order to minimize the chances of accidentsand reduce the damage to property, personal health and the environment, it is significant for China to set up special transport conditions for dangerous goods.

In China, the legislative system for transport of dangerous goods can be divided into four levels: International Conventions/Rules, National Laws/Administrative Regulations, Departmental rules and Technical Standards.

Contents

- International Conventions/Rules
- National Laws and Administrative Regulations
- Departmental Rules
- Technical Standards

INTERNATIONAL CONVENTIONS/RULES

In order to ensure consistency between different regulatory systems, "the UN Recommendations on the Transport of Dangerous Goods - Model Regulations" (hereafter referred to as "the UN Model Regulations") have been developed by the United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods. The Model Regulations consist of seven parts, covering principles of classification and definition of classes, listing of the principal dangerous goods, general packing requirements, testing procedures, marking, labelling or placarding, and transport documents.

Recommendations on Tests and Criteria, which are incorporated by reference into certain provisions of these regulations, are published as a separate manual ("Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria"). The UN Model Regulations prescribe detailed requirements applicable to the transport of dangerous goods. For the purposes of adaptation to technical and scientific progress, the Model Recommendations are updated every two years and the current version is the 17th revised edition (2011 version).

The Model Regulations aim to present a basic scheme of provisions that allows uniform development of national and international regulations governing the various modes of transport, yet they remain flexible enough to accommodate any special requirements that might have to be met. Various organizations publish Dangerous Goods Codes based on the UN Model Recommendations for different modes of transport. These rules are now closely aligned with the UN Model Recommendations with the text for classification, identification, marking and labeling reproduced from the UN Model Regulation. Such International rules are as follows:

International Rules	Developing Organization
International Maritime Dangerous Goods Code (IMDG Code)	International Maritime Organization (IMO)
• International Air Transport Association- Dangerous Goods Regulation (IATA-DGR) • International Civil Aviation Organization Technical Instructions on the Safe Transport of Dangerous Goods by Air	ICAO-TI
International Carriage of Dangerous Goods by Road (ADR) International Carriage of Dangerous Goods by Inland Waterways (ADN)	Economic Commission for Europe Committee
Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)	Convention concerning International Carriage by Rail (COTIF)

In China, the International Conventions/ Rules are the basis for developing its own National Standards and Industry Standards for transport of dangerous goods. The rules and standards related to the railway and road transport of dangerous goods are mainly based on the UN Model Regulation. Since most of the dangerous goods are imported/ exported by waterway or by air, the relevant waterway and air dangerous goods transport rules and standards in China are basically consistent with the International Maritime Dangerous Goods Code (IMDG Code) and the International Civil Aviation Organization Technical Instructions on the Safe Transport of Dangerous Goods by Air (ICAO-TI).

NATIONAL LAWS/ ADMINISTRATIVE REGULATIONS

The national laws and regulations are the important basis for the development of the departmental rules of dangerous goods transport. The revised "Regulations on the Control over Safety of Hazardous Chemicals" (hereafter referred to as "the State Council Decree 591") came into force since 1 Dec 2011. Considered as the principal legislation for the management of dangerous goods and hazardous chemicals in China, Decree 591 regulates them through the entire supply chain, ranging from manufacture, importation, distribution, storage, to transportation and use. The enterprise's responsibilities and obligations, as well as the punishment measures of non-compliance for dangerous goods transport are stipulated in the Regulation.

DEPARTMENTAL RULES

Departmental rules were established for different modes of transport, which are developed for full implementation of the national laws/administration regulations. These main rules are as follows:

• "Rules on the Administration of the Railway Transport of Dangerous Goods" (铁路危险货物运输管理规则), issued by the Ministry of Railways, implemented from 1 Dec 2008.
• "Provisions on the Administration of the Road Transport of Dangerous Goods" [Order of the Ministry of Communications (No. 9 [2005]) (道路危险货物运输管理规定), issued by Ministry of Communications, came into force on August 1, 2005.
• "Rules on the Administration of the Waterway Transport of Dangerous Goods"[Order of the Ministry of Communications (No. 10 [1996]) (水路危险货物运输规则), issued by Ministry of Communications, came into force on December 1, 1996. This rule applies to domestic waterway transport, but for international maritime transport, the IMDG Code should be applied.
• "Provisions of the Administration of Civil Air Transport of Dangerous Goods in China" (CCAR-276) (中国民用航空危险品运输管理规定), Promulgated by Order No.121 of the Civil Aviation Administration of China on July 12, 2004, came into force on September 1, 2004.

TECHNICAL STANDARDS

Three types of technical standards are established in China: general basic safety standards, safety technical standards and safety management standards. The most important general basic safety standards for transport of dangerous goods are as follows:

• "Classification and Code of Dangerous Goods" (GB 6944-2012)

The latest standard was issued on 11 May 2012, and will come into effect since 1 Dec 2012. It is based on the 16th revised edition of the UN Model Regulation, and closely aligned with the "PART 2 CLASSIFICATION" of the Regulation.

This standard includes mandatory classification (including "category", "division" and "packing category"), hazard priority and codes of dangerous

goods. Chemicals (including mixtures and solutions) and articles subject to this standard are assigned to one of the nine classes according to the hazard or the most predominant hazards they present. Some of these classes are subdivided into divisions. These classes and divisions are:

Class 1: Explosives	Division 1.1: Substances and articles which have a mass explosion hazard Division 1.2: Substances and articles which have a projection hazard but not a mass explosion hazard Division 1.3: Substances and articles which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard Division 1.4: Substances and articles which present no significant hazard Division 1.5: Very insensitive substances which have a mass explosion hazard Division 1.6: Extremely insensitive articles which do not have a mass explosion hazard
Class 2: Gases	Division 2.1: Flammable gases Division 2.2: Non-flammable, non-toxic gases Division 2.3: Toxic gases
Class 3: Flammable liquids	
Class 4: Flammable solids; substances liable to spontaneous combustion; substances which, on contact with water, emit flammable gases	Division 4.1: Flammable solids, self-reactive substances and solid desensitized explosives Division 4.2: Substances liable to spontaneous combustion Division 4.3: Substances which in contact with water emit flammable gases
Class 5: Oxidizing substances and organic peroxides	Division 5.1: Oxidizing substances Division 5.2: Organic peroxides
Class 6: Toxic and infectious substances	Division 6.1: Toxic substances Division 6.2: Infectious substances
Class 7: Radioactive material	
Class 8: Corrosive substances	
Class 9: Miscellaneous dangerous substances and articles, including environmentally hazardous substances	

• **"List of Dangerous Goods" (GB 12268-2012)**

The latest standard was issued on 11 May 2012, and will come into effect since 1 Dec 2012. It is also based on the 16th revised edition of the UN Model Regulation, and closely aligned with the "PART 3 DANGEROUS GOODS LIST, SPECIAL PROVISIONS AND EXCEPTIONS" of the Regulation.

This standard provides the structure of the dangerous goods list, and lists the dangerous goods most commonly carried but is not exhaustive. Each entry in the Dangerous Goods List is characterized by a UN number. This list also contains relevant information for each entry, such as proper shipping name and description, hazard class or division, subsidiary risk(s) (if any), UN packing group (where assigned), special provisions, packing and tank transport requirements, etc.

Where a substance or article is specifically listed in the Dangerous Goods List, it should be transported in accordance with the provisions concerning the substance or article of interest.

• **"General Specifications for Transport Packages of Dangerous Goods" (GB 12463-2009)**

The latest standard was issued on 21 Jun 2009, and implemented from 1 May 2010. This standard specifies the packaging groups, basic requirements, technical requirements, performance test, inspection method, code and marking of transport packages of dangerous goods. For packing purposes, substances other than those of Classes 1, 2 and 7, divisions 5.2 and 6.2 and self-reactive substances of Division 4.1,. are assigned to three packing groups in accordance with the degree of danger they present:

- Packing group I: Substances presenting high danger;
- Packing group II: Substances presenting medium danger;

- Packing group III: Substances presenting low danger.

• "Packing Symbol of Dangerous Goods" (GB 190-2009)

The latest standard was issued on 21 Jun 2009, and implemented from 1 May 2010. It is based on the 15th revised edition of the UN Model Regulation. This standard specifies the pictogram, size, color, methods of application for the package labeling symbols of dangerous goods.

In conclusion, the legislative system for transport of dangerous goods consists of a large number of regulations and standards in China at present. Independent regulation systems have being established to adapt to different modes of transport. However, the high level and comprehensive rule/regulation which can be applicable to all modes of transport is still lacking. In this sense, China still has a long way to go before an integrated legislative system for transport of dangerous goods to be established.

Reference Links

- *State Council Decree 591: Regulations on the Control over Safety of Hazardous Chemicals (2011)*
- *GB 6944-2005 (Note: the 2012 version will be soon available on our regulatory database.)*
- *GB 12268-2005 (Note: the 2012 version will be soon available on our regulatory database.)*
- *GB 190-2009*

Guidance for the Plant Extract Manufacturers/ Importers to Comply with China REACH

23 Nov 2012 / BY Martin Hu

Notification of plant extract under China REACH is no longer a vague area since the CRC-MEP has released clarification through the official FAQ.


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While the cosmetic finished products are not under the supervision of the MEP (the SFDA is in charge of cosmetics management), the manufacture and importation of cosmetic ingredients in China are under the control of the "Measures on the Environmental Management of New Chemical Substances" (dubbed as China REACH, MEP Order 7) in China, the same as industry chemicals.

Many popular cosmetic ingredients are plant extract which are advertised to bring the "natural, green and healthy effect" into the cosmetics, e.g. essential oil. Generally, plant extract could be obtained through water-steam distillation, extrusion, decoction, enfleurage (like making tea) or solvent extraction. The regulatory obligation of this kind of ingredients under China REACH is usually complicated due to their diverse processing methods. Some compliance guidance is shared as follows.

STEP I. EXEMPTION

Stipulated in the guidance of China REACH, the naturrally occuring substances are free from the obligations. The exemption clause goes

(i) Unprocessed substances or substances processed only by manual, mechanical or gravitational methods, or by water dissolution, water displacement or thermal dehydration etc.;

Although all plant extracts meet the category of "Naturally occurring substances" because they are the components from natural plants, it is the processing methods that determine whether they are eligible for exemption. Only a few processing techniques could be exempted from China REACH, i.e. manual, mechanical or gravitational methods, or by water dissolution, water displacement or thermal dehydration etc. Therefore, if a plant extract is produced through extrusion, enfleurage, it would be exempted for sure. However, regarding the other two common methods not mentioned in the Guidance, the Chemical Registration Center of Ministry of Environmental Protection (CRC-MEP) published an official updated FAQ on its website in which the two situations are specified:

- Water-steam distillation---not exempted;
- Solvent extraction---not exempted if any solvent other than water is applied.

STEP II. IECSC INCLUSION

If you determine that your ingredient could not be exempted, check if they are included in the existing chemical inventory--*IECSC 2010*.

Some plant ingredients are included in the IECSC and considered as existing substances under China REACH, e.g. Orange, sweet, extract, and Chrysanthemum, extract.

Since the INCI (International Nomenclature of Cosmetic Ingredients) name is not listed in the IECSC, the chemical name should be used in search instead. CAS No is recommended to improve the searching accuracy if applicable.

Besides the self-check with the online IECSC, it is strongly recommended to submit a formal inquiry to confirm the status of the ingredient since the confidential substancs are not known to the public. Only the plant extract not included in the IECSC is obliged to notify under China REACH. Moreover, the solvent in the product should not be neglected, for which a substance status inquiry is also needed.

STEP III. NOTIFICATION

In most cases, the annual tonnage of plant extract is lower than 1 ton per year since it is difficult to collect and the yield of required plant is limited (Remember to calculate the "real" annual tonnage, excluding the amount of solvent). Hence, the simplified notification (general case) is most probably applicable for the company.

Besides the paper work, the notification requires 1~3 eco-toxicity test(s): (biodegradability, acute fish toxicity, acute earthworm toxicity) conducted by the MEP-approved-labs, depending on the substance properties. The test requirement does cause some confusion as to whether it is necessary to purify the plant extract in solution to perform the tests. It could be difficult to since the purification process could lead to deformation of the substance into other unwanted ones, which makes it impossible to explain the study results. We inquired the authority about the question and got the response that the notifiers could use the whole mixture/ preparation containing the new substance to perform the eco-toxicity test, the authority will accept the study report and the notified substance name is requested to be "extract of xxx plant by xxx solvent" *(See the FAQ recently updated on the CRC-MEP website, ChemLinked News Release)*.

On the other hand, we have discussed with the eco-toxicity lab experts on the possibility that this testing approach might be abused by some dishonest companies. The lab confirmed that if some companies intentionally dilute the plant ingredient with specific solvent, the testing expense could be saved due to the falsified eco-toxicity study result. For example, the acute fish & earthworm tests could be avoided if the substance is tested to be biodegradable due to dilution. This dishonest trick could expose the notifying company to the risk of being caught by the expert committee of the MEP. Therefore, it is strongly recommended to use the actual commercial product to run the test.

In case that the cosmetic ingredient company might manufacture or import a few samples for eco-toxicological testing before the commercial activity, the SRRN (Scientific Research Record Notification) could be applied if the annual

tonnage is lower than 0.1 t. More complicated regular notification has to be filed for annual tonnage of over 1t.

To Sum up, notification of plant extract under China REACH is no longer a vague area since the CRC-MEP has released clarification through the official FAQ. Meanwhile, profound experience has been accumulated through our successful notification for many cosmetic ingredients of plant extract following the guidance of the authority and advices from the labs.

Inspection and Supervision over Entry-Exit Hazardous Chemicals and their Packages in China

7 Dec 2012 / BY Julian Zhu

However, according to the AQSIQ Order No.30 published on 29 Feb 2012, the inspection scope is expanded to cover all the hazardous chemicals listed in the Catalogue of Hazardous Chemicals.

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BACKGROUND

The revised "*Regulations on the Control over the Safety of Hazardous Chemicals*", also known as Decree 591, came into force since 1 Dec 2011. As a key piece of legislation on management of hazardous chemicals in China, it prescribed that the Chinese entry-exit inspection and quarantine authorities (CIQ) at different administrative levels are responsible for the inspection-related duties for the entry-exit hazardous chemicals and their packages.

On 29 Dec 2011, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and General Administration of Customs (GAC) jointly issued the "*Adjustment of 2012 Catalogue of Entry-Exit Commodities Inspected and Quarantined by the Competent Entry-Exit Inspection and Quarantine Authorities*" (hereinafter referred to as "the Legal Inspection Catalog"), also known as AQSIQ Notice 1466-2011. One of the biggest changes is that 160 hazardous chemicals listed in the Catalog of Hazardous Chemicals (2002 version) have been added to the Legal Inspection Catalog. Any import/export of the 160 hazardous chemicals would receive compulsory inspections by the CIQ as of 1 February 2012. However, according to *AQSIQ Order No. 30* published on 29 Feb 2012, the inspection scope is expanded to cover all the hazardous chemicals listed in the Catalogue of Hazardous Chemicals. AQSIQ Order 30-2012 over Inspection and Supervision Issues of Entry-Exit Hazardous Chemicals and their Packages: The AQSIQ Order 30-2012 took effect immediately after its release. Therefore, the imported and exported hazardous chemicals that have been listed in the *Catalogue of Hazardous Chemicals (2002)* are subject to the inspection and quarantine by the CIQ authorities of China since 29 Feb 2012. It is noteworthy that the revised Catalogue of Hazardous Chemicals, which will contain more than 7000 hazardous chemicals, is expected to be released next year.

I. DOCUMENTS REQUIRED FOR INSPECTION AND QUARANTINE

Importers	Exporters
1. Declaration of Conformity for Hazardous Chemicals Importers (officially standard format);	1. Declaration of Conformity for Hazardous Chemicals Exporters (officially standard format);
2. Information on the name, quantity (and other conditions) of the inhibitors and stabilizers contained in the imported products, if available;	2. Information on the name, quantity (and other conditions) of the inhibitors and stabilizers contained in the imported products, if available;
3. Chinese SDS and label (required to be in line with relevant Chinese national standards);	3. SDS and label (The Chinese translations should be provided if the SDSs and labels are non-Chinese);
4. Inspection materials such as contracts, invoices, bills of loading /packing list, etc.	4. Inspection materials such as contracts, invoices, bills of loading /packing list, etc.
-	5. Final Packing Performance Inspection List for Exit Goods Transportation" (bulk products are exempted);
-	6. The Hazard Identification and Classification Report for Chemicals.

II. THE INSPECTION ITEMS OF IMPORTED AND EXPORTED HAZARDOUS CHEMICALS

The inspection items of imported and exported hazardous chemicals include compliance requirements regarding safety, hygiene, health, environmental protection and prevention of fraud as well as items on the related product quality, quantity and weight, etc.

Specifically, inspection items on safety include the following requirements:

1. Whether information on the main compositions/constituents of the product, its physical- chemical properties and hazard category is compliant with the relevant standards;

2. Whether a precautionary label has been affixed on the packaging (For imported products, a China GHS-based label should be provided) and whether a Safety Data Sheet has been provided along with the goods; whether the contents of the label and SDS are compliant with the relevant national standards.

III. INSPECTION ON THE PACKAGES OF THE IMPORTED AND EXPORTED HAZARDOUS CHEMICALS

1. For packages of imported hazardous chemicals: Identify whether the models, category, specification, unit quantity and mark of packaging meet the requirements of relevant standards.

2. For packages of exported hazardous chemicals: Conduct the performance and use test on the packages in accordance with the measures on the management of packaging inspection of dangerous goods exported by air, sea, road and railway, respectively. The "Performance test result of transport packages for exit goods" and "Use test result of transport package for exit dangerous goods" should be displayed by manufactuers of packaging and hazardous chemicals exporters, respectively.

SUPERVISION INFORMATION FROM CIQS AND OUR ADVICES

The inspection of imported hazardous chemicals mainly focuses on whether the contents and formats of the labels and SDSs for hazardous chemicals conform to the relevant national standards. Recently several batches of chemicals have been held or detained by the entry port due to the unqualified SDSs or labels. Statistics from the CIQs shows that reasons for the unqualified labels or SDSs are mainly concentrated on the language problem (such as hazardous chemicals were labelled only in English other than Chinese); unqualified emergency telephone number; and non-compliance in formats and contents with Chinese national standards, etc.

It is strongly recommended that companies shall prepare Chinese SDSs and labels in compliance with Chinese GHS national standards beforehand for all hazardous chemicals to avoid any delay in customs clearance and possible fines.

Database Update

Unified Documents for HC Registration Released

Following three months' public consultation upon the draft application documents pertaining to China's hazardous chemicals registration (SAWS Order 53), 8 registration documents have been finalized and published by the SAWS on 17 Oct 2012. The documentation shall be put into formal use as of 15 Oct 2012.
The English version of the 8 registration documents are available in the ChemLinked Regulatory Database Now! *View Details*

GB 6944-2012 Classification and code of dangerous goods

GB 6944-2012 comes into effect as of 1 Dec 2012 to replace its previous version GB 6944-2005, which stipulates the classification, precedence of hazard characteristics and UN number of dangerous goods.
The English version of GB 6944-2012 has been produced by referring to the UN Recommendation on the Transport of dangerous Goods-Model Regulation Part 2: Classification (the sixteen revised edition). *View Details*

GB 12268 - 2012 List of Dangerous Goods

GB 12268-2012 comes into effect as of 1 Dec 2012 to replace it previous version GB 12268-2012. This updated standard is formulated in correspondence with UN Recommendations on the Transport of Dangerous Goods-Model Regulations (the sixteen revised edition). It stipulates general requirements and structure of the dangerous good lists with the complete list attached. *View Details*

Ebook Update

Operating License for Hazardous Chemicals in Shanghai

This document is a translated copy of "Operating License for Hazardous Chemicals in Shanghai".
In order to regulate the application, acceptance, review and approval for Operating License for hazardous Chemicals in accordance with the Regulations on the Control over Safety of hazardous Chemicals (State Council Decree 591) and the Measures for the Administration of Operating Licenses for Hazardous Chemicals (SAWS Order 55), Shanghai Administration of Work Safety issued this bylaw. It specified the scope, approval authority, submission requirement, procedure of the authorization and other relevant matters for applying the license in Shanghai. *View Details*

Events

Date	Title	Location
6-8 Mar, 13	**Pharmaceutical Regulatory Summit Asia 2013**	The Westin Beijing Chaoyang, China
Spring, 13	**China New Chemical Regulations Workshop Japan 2012**	Ivy Hall - 4-4-25 Shibuya, Shibuya-ku, Tokyo, Japan
26-28 Feb, 13	**14th China International Agrochemical & Crop Protection Exhibition**	Shanghai New International Expo Center, Shanghai, China
26-28 Feb, 13	**FSHOW 2013—4th China International Fertilizer Show**	Shanghai New International Expo Center, Shanghai, China
10 Jan, 13	**REACH24H -U.S Commercial Service Webinar: Registering & Selling Chemicals in China**	Hangzhou, China

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