

Assessing the impact of the regulations on safe management of hazardous chemicals in China (Decree 591) on your business



*Enabling Chemical Compliance
for A Safer World*

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Chemical Management Policies in China

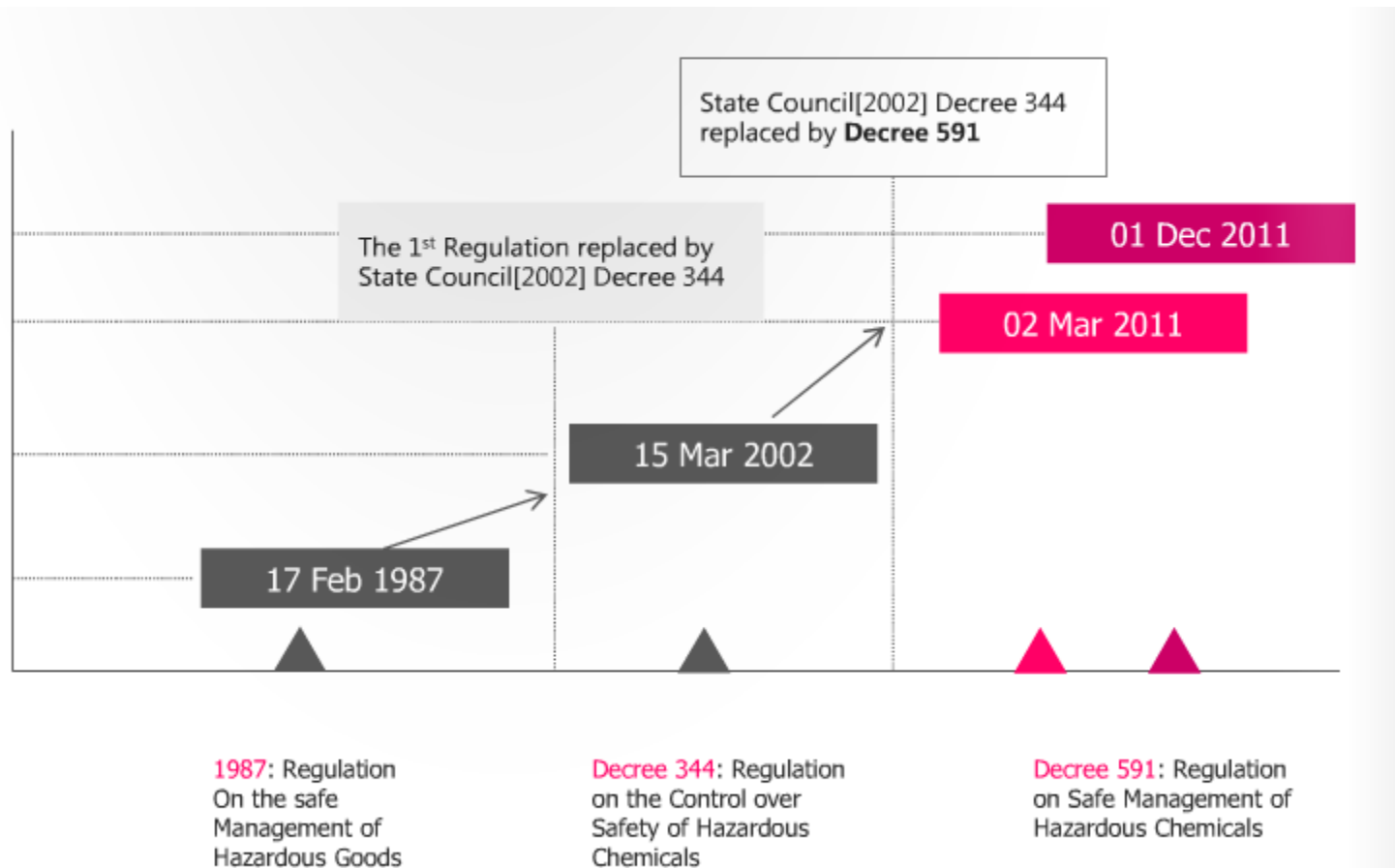
Category	Regulations	Key Words
New Chemicals Management	Order No. 7 - The Provisions on Environmental Administration of New Chemical Substances (15 Oct 2010)	IECSC, China REACH
Existing Chemicals Management - Import and Export of Toxic Chemicals	Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (1994)	List of toxic chemicals severely restricted to be imported into or exported from China
Existing Chemicals Management - Hazardous Chemicals	Decree 591 – The Regulations on Safe Management of Hazardous Chemicals in China(1 Dec 2011) - Sub 1: Measures for The Administration of Registration of Hazardous Chemicals (1 Dec 2011); - Sub 2: Measures for The Administration of Operating Licenses for Hazardous Chemicals (1 Dec 2011);	Catalog of Hazardous Chemicals (to be updated and released soon);
Classification, Labelling and SDS	GB 20576 ~ GB 20602-2006; GB 13690-2009; GB 15258-2009; GB 190-2009;GB/T 16483 -2008;	China GHS, national standards
Occupational Exposure Limits & Protection	Regulation on the Labor Protection in Workplaces Handling Toxic Materials	

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Decree 591 – Regulations on Safe Management of Hazardous Chemicals in China

- Replace decree 344, enter into force on 1 Dec 2011



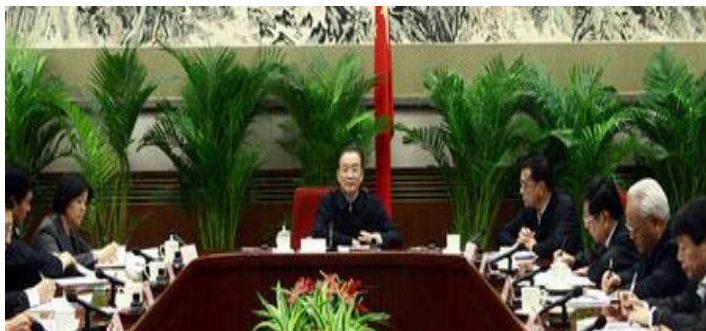
Decree 591 – Regulations on Safe Management of Hazardous Chemicals in China

- Decree of State Council, Multi-ministries Involved;
- Main legislation regulating existing/hazardous chemicals;
- Implementing a license system;
- Requiring registration of hazardous chemicals;
- Requiring mandatory GHS classification and labeling for hazardous chemicals.



Mains Reasons for Revision

- Reform of governmental authorities
- Incomplete management system: users of hazardous chemicals are not regulated;
- Integration with other existing laws(Order No. 7, GHS);
- Keeping up to date with international trend(TSCA reporting, reporting under CSCL, CLP);



A Break-down of Decree 591

	General	Production & Storage	Use	Operation	Transportation	Registration & Emergency Response	Legal liability	Appendix	Total
Decree 591	10	17	5	10	23	9	22	6	102
Decree 344	6	20		8	12	8	16	4	74

Supporting Measures and Laws for Decree 591

- **The Catalog of Hazardous Chemicals** (to be released in 2012);
- The Measures for the Administration of Production Licenses for Hazardous Chemicals;
- The Measures for the Administration of **Operating Licenses** for Hazardous Chemicals (2011);
- The Measures for the Administration of **Safe Use License** for Hazardous Chemicals(**new** in 2011);
- The Measures for the Administration of **Registration of Hazardous Chemicals**(revised in 2011)
By State Administration of Work Safety(SAWS), China
- The Measures for the Administration of Standardization of Management of Hazardous Chemicals(released in 2011);
- The Measures for the Administration of Safety Clearance on Construction Projects for Hazardous Chemicals;
- The Measures for the Administration of Safety Supervision of Major Sources of Hazard;
- The Measures for the Administration of Safety Management of Transmission Pipeline for Hazardous Chemicals.;
- The Measures for the Administration of Physical Hazard Identification and Classification for Hazardous Chemicals;
- The Measures for the **Registration of Environmental Administration of Hazardous Chemicals** for public consultations (issued by MEP);

The Scope of Decree 591 – Hazardous Chemicals

- ❑ *Hazardous chemicals* are defined as highly toxic chemicals and other chemicals which are toxic, corrosive, explosive, flammable and do harm to human body, facilities and environment.
- ❑ Chemicals meeting GHS classification criteria shall be regarded as hazardous chemicals under Decree 591 (*CIRS's interpretation*);

- ❑ *Out of Scope*

- explosives for civil use ;
- fire cracker, fireworks;
- radio-active substances;
- dangerous chemical for national defense;



The Scope of Decree 591 – Catalog of Hazardous Chemicals

- ❑ *Hazardous chemicals* listed in the Catalog are subject to extra requirements(application for licenses, registration, etc);
- ❑ *Hazardous chemicals* not listed in the Catalog are subject to general requirements (GHS classification, labeling and SDS, etc);



Current Catalog of Hazardous Chemicals (2002)

<http://www.chinasafety.gov.cn/whpcx.htm>

- currently more than **3,700** chemicals;
- a new Catalog to be released in 2012.

The Scope of Decree 591 – Catalog of Hazardous Chemicals – Sub-lists

Sub-lists	Extra Requirements
List of Highly Toxic Chemicals	Purchase permit, record-keeping
List of Precursors for Explosives	Reporting, record-keeping
List of Hazardous Chemicals for Priority Management	Emergency response plan, safe use license, etc.
List of Priority Hazardous Chemicals for Environment Management	On-site inspection, environment risk assessment report

The Scope of Decree 591 - Activities

- The following activities involving hazardous chemicals are regulated in China



Production and Storage



Use

• Use hazardous chemicals to manufacture products



Operation

- Import
- Distribution
- Warehouse
- Sales



Transportation

Provisions for Safe Production and Storage of Hazardous Chemicals (Article 11-27)



Production & Storage

- **General Requirement for Production and Storage**
 - responsible person and qualified professionals;
 - regular inspection and maintenance to facilities;
 - safety evaluation report every three years;
 - recording substance flow for highly toxic chemicals and precursors for explosives;
 - suppliers of chemical packages or containers shall possess National Industrial Products Manufacture Certificate;
- **Extra Requirements for Producers**
 - Registration of hazardous chemicals;
 - Production license;
 - SDS and chemical labels according to national standards;
 - Application for National Industrial Products Manufacture Certificate if a chemical is within industrial products catalog;
 - Report environmental release information to MEP if a chemical is classified as priority hazardous substance for environmental management

Provisions for Safe Use of Hazardous Chemicals (Article 28- 32, 16, 21, 22, 23, 27)



Use

- **General Requirement**
 - responsible person and qualified professionals;
 - regular inspection and maintenance to facilities;
 - chemical management system to ensure safe use;
 - recording substance flow for highly toxic chemicals and precursors for explosives;
 - safe use license (*);
 - report environmental release information to MEP if a chemical is classified as priority hazardous substance for environmental management
- **Note(*)**
 - Not all users of hazardous chemicals need to apply;
 - Certain criteria must be met;

Provisions for Safe Operation of Hazardous Chemicals (Article 33-42)



Operation

- Import
- Distribution
- Warehouse
- Sales

- **General Requirement**
 - responsible person and qualified professionals;
 - application for purchase permit and recording substance flow for highly toxic chemicals and precursors for explosives;
 - **Operating license** (*);
 - cannot sell chemicals without right SDS and labels;
 - cannot buy hazardous chemicals from companies without proper licenses.
- **Note(*)**
 - Operating license from SAWS must be applied first before a business license is granted from Industrial and Commercial Bureau.

Provisions for Transportation of Hazardous Chemicals (Article 43-65)



Transport

- **General Requirement**
 - qualification tests required for operating employees ;
 - road transport permit;
 - signal labeling ;
 - extra requirement for transport of hazardous chemicals using inner waterways;

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Application of Licenses

- Any legal entities producing/using/operating hazardous chemicals in China shall obtain a license from local authorities of work safety.



Safe Production License



Safe Use License(*)



Operating License ()**



Transportation Permit

Note: Companies based outside of China cannot apply for a license.

Note:* This is a new requirement under decree 591.

*Note**:* This has been revised under decree 591.

Safe Use License (Article 29)

- The Measures for the Administration of Safe Use License for Hazardous Chemicals (2011) – License Required When
 - **The industry sector** of a company is listed in the Catalog of Applicable Industry Sector for the Safe Use License of Hazardous Chemicals (for example, production of fertilizer); and
 - **The used quantity** has reached the threshold volume (*current 62 chemicals*) ;

Index	化学品名称/Name	别名/Other Name	Minimum Quantity (t/y)	CAS 号
1	氯/Chlorine	液氯、氯气	180	7782-50-5
2	氨/Ammonium	液氨、氨气	360	7664-41-7

Operating License

- **The Measures for The Administration of Operating Licenses for Hazardous Chemicals(2011) – Replace 2002 edition.**
 - Scope: Catalogue of Hazardous Chemicals;
 - Actives: Import, Distribution, Sales, Warehouse Operation, Other
 - No longer differentiate type A and type B license;
 - More documents are required: employment injury insurance, etc;



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Registration of Hazardous Chemicals in China(*)

Two Bodies

- National Registration Center for Chemicals(NRCC) of State Administration of Work Safety(SAWS) and;
- Local Environmental Protection Authorities (MEP).



****Only domestic companies can register.***

Registration of Hazardous Chemicals with NRCC (Article 67)

- The Measures for the Administration of Registration of Hazardous Chemicals(2011) – Replace 2002 edition.

	2002	2011
Scope	<ul style="list-style-type: none"> ▪ Hazardous Chemicals ▪ Highly Toxic Chemicals ▪ Not clearly defined 	<ul style="list-style-type: none"> • Catalog of Hazardous Chemicals • Hazardous Chemicals If Confirmed by Authorities
Registrant	<ul style="list-style-type: none"> • Producer • Storage Companies 	<ul style="list-style-type: none"> • Producer • Importer (New!)
24h emerg. number	<ul style="list-style-type: none"> • Not Specified 	<ul style="list-style-type: none"> • Mandatory
Annual Report, GHS SDS/Label	<ul style="list-style-type: none"> • No 	<ul style="list-style-type: none"> • Yes
Supervision	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Detailed procedure

Registration of Hazardous Chemicals with NRCC (Article 67)

■ Required Information

- Legal entity information;
- Classification and labeling(GHS);
- Physico-chemical properties;
- Main uses;
- Hazard properties;
- Safety requirement for storage, use and transport;
- Emergency responses;

■ Renewed every 3 years

■ Report volume annually;

The screenshot shows the NRCC web portal interface. At the top left is the NRCC logo, and at the top right is the text '网络版 V1.0'. The main header area has a blue background with the title '危险化学品登记信息管理系统' (Hazardous Chemicals Registration Information Management System) and the copyright notice 'COPYRIGHT (C) NATIONAL REGISTRATION CENTER FOR CHEMICALS'. Below the header is a login form with the following fields and options:

- 用户名(U): [input field]
- 密码(P): [input field]
- 验证码: [input field with text '请输入右边的数字']
- 找回密码 [button]
- 记住密码 [checkbox checked]
- 1549 [text next to verification code]
- 登录 [button]
- 我要申请 [button]
- 取消 [button]

Registration of Hazardous Chemicals with NRCC (Article 67) - Concept

- Reporting under Japan CSCL;
- TSCA IUR Rules;
- C&L notification.

Registration of Hazardous Chemicals with MEP (Article 6.4)

- The Measures for the Registration of Environmental Administration of Hazardous Chemicals (Draft 2011, **New!**)

	Registration with MEP	Registration with NRCC
Scope	<ul style="list-style-type: none"> ▪ Catalog of Hazardous Chemicals ▪ Priority hazardous chemicals for environmental management(PHCs) ▪ List of toxic chemicals severely restricted to be imported into or exported from China(LTCs) 	<ul style="list-style-type: none"> • Catalog of Hazardous Chemicals • Hazardous Chemicals If Confirmed by Authorities
Registrant	<ul style="list-style-type: none"> • Producer • Companies using hazardous chemicals to manufacture products • Importer/Exporter of LTCs 	<ul style="list-style-type: none"> • Producer • Importer (New!)



Registration of Hazardous Chemicals with MEP (Article 6.4)

■ General Information

- Environment administration registration form including legal entity information, name, category, volume, uses, operational method, aquatic toxicity data and risk management measures;
- Production/safe use/operating licenses and business license;
- Environment emergency responses;

□ Extra requirement for PHCs

- Environmental risk assessment report;;
- On-site inspection;
- Report release and migration information annually.

Registration of Hazardous Chemicals with MEP (Article 6.4) – List of PHCs

- not easily degradable, bio-accumulative, causing serious harm to human health and living beings after long-term exposure;
- extremely un-degradable and extremely bio-accumulative;
- causing acute toxicity or chronic toxicity to aquatic environment;
- causing serious hazards to human health or the environment;
- chemicals subject to any international environment conventions;
- chemicals liable to accidents and causing severe hazards to the ecological environment;
- other chemicals for which risks need to be reduced;

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Labeling and SDS for Hazardous Chemicals

- Chapter 2, Article 15:

Producers of hazardous chemicals shall provide SDS and affix chemical safety labels on packages. The SDS and labels shall be prepared in accordance with national standards (in Chinese). – *NEW!*

- Chapter 4, Article 37:

Companies cannot sell hazardous chemicals that do not have proper SDS and chemical safety label;

Labeling and SDS for Hazardous Chemicals

Offences

Penalties

No proper license

RMB 100,000 to 200,000

No SDS or label; SDS and labels do not comply with national standards

RMB up to 50,000; Repeated infringement up to RMB 100,000

Manufacturers and importers fail to register hazardous chemicals

RMB up to 50,000; Repeated infringement up to RMB 100,000

Labeling and SDS for Hazardous Chemicals

■ New Catalog of Hazardous Chemicals

- To be released at the beginning of 2012;
- Two-step approach(~5000 chemicals for 1st step);
- Contain harmonized classification similar to annex VI of CLP;
- Classification based on CLP and Japan's official classification;
- Use of harmonized classification might be mandatory.

Labeling and SDS for Hazardous Chemicals

■ New Catalog of Hazardous Chemicals

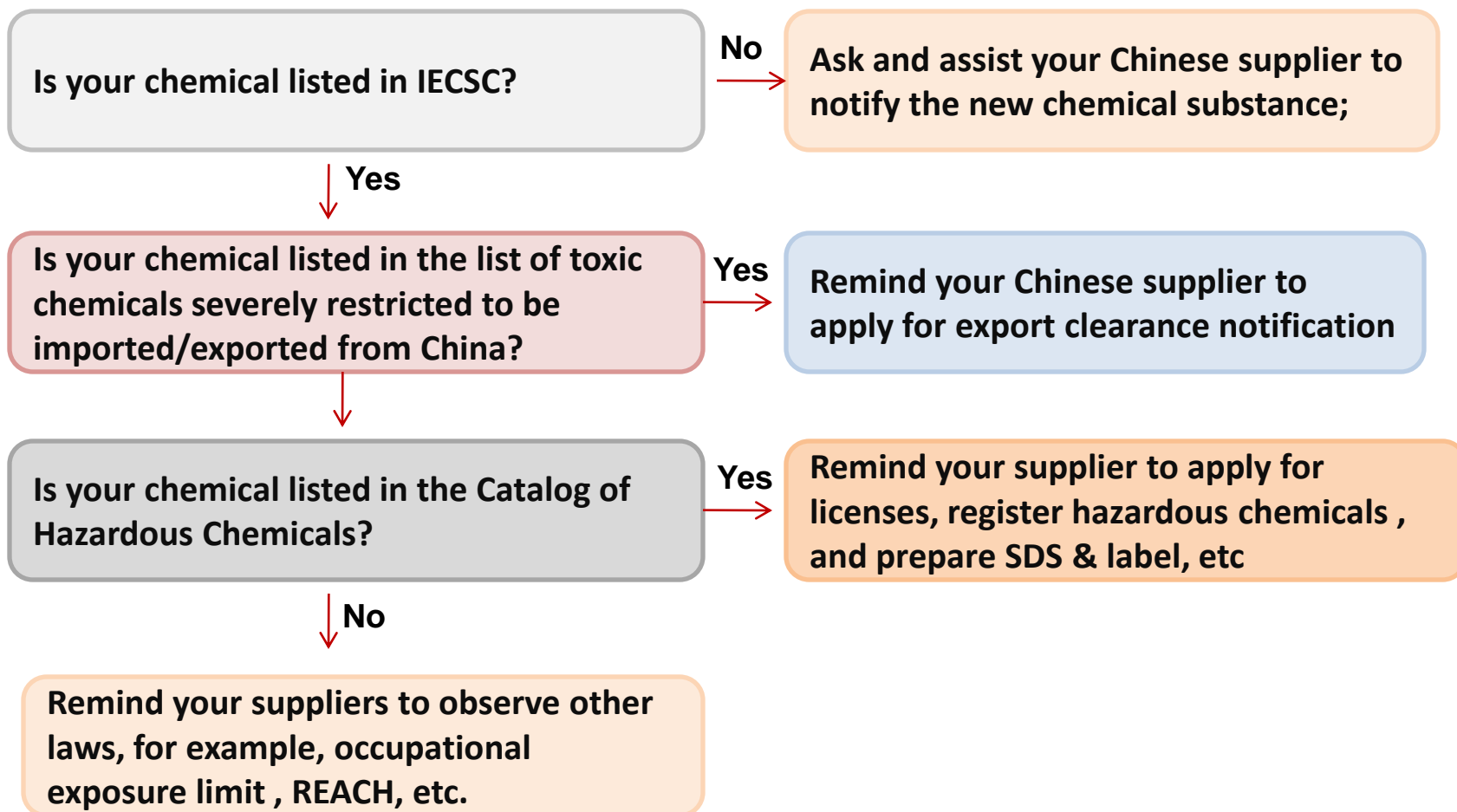
《危险化学品目录》（第二版）

序号	品名	别名	英文名	英文别名	CAS号	UN号	危险性类别	标志	警示词	危险性说明	备注
1	苯		Benzene		71-43-2	1114	易燃液体（类别2）； 急性毒性（类别4）； 皮肤腐蚀/刺激（类别2）； 严重眼损伤/眼刺激（类别2A）； 致突变物（类别2）； 致癌物（类别1A）； 生殖毒性（类别2）； 特异性靶器官系统毒性 一次接触（类别1）； 特异性靶器官系统毒性 反复接触（类别1）； 吸入危险（类别1）； 对环境的危害（急性类别2）。	  	危险	高度易燃液体和蒸气； ；吸入有害；引起皮肤刺激；引起严重眼刺激；怀疑可致遗传性缺陷；可疑致癌；怀疑损害生育力或胎儿；一次接触致器官损害；长期或反复接触可致器官损害；吸入和进入呼吸道可能致死；对水生生物有毒并且有长期持续影响。	

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Practical Advice – Buying Chemicals from China



Practical Advice – Exporting Chemicals to China



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Summary – New Challenges

- Double registration with NRCC and MEP;
- Enlarged catalog;
- Importers need to register hazardous chemicals with NRCC from 1 Dec 2011;
- New requirements for users of hazardous chemicals in China: safe use license;
- SDS and labels must be China GHS compliant;

Resources

- IECSC(2010)

<http://www.crc-mep.org.cn/iecscweb/IECSC.aspx?La=1>

- Catalog of Hazardous Chemicals(2002)

<http://www.chinasafety.gov.cn/whpcx.htm>

- List of Toxic Chemicals Severely Restricted to Be Imported into or Exported from China

http://www.cirs-reach.com/toxic_chemicals_list

- [Overview of Chemical Management Polices in China](#)

- Download English version of Chinese SDS and labeling standards.

http://www.cirs-reach.com/China_GHS_Implementation



Thank you for your time!

谢谢您的时间！

시간 내주셔서 감사합니다!

お時間をいただき！

*Happy
Holidays*

