

The Latest Developments of Chemical Legislation in China



*Enabling Chemical Compliance
for A Safer World*

2 Oct 2011, Training Course - SCHC Fall Meeting

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- Overview of Chemical Management Policies in China
- New Chemical Substance Management
- Existing Chemicals Management in China
- GHS Implementation: Current Status and Challenges
- Practical Advice for Chemical Companies Doing Businesses with/in China

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 (to be revised soon); - Sub 2: Measures for The Administration of Operating Licenses for Hazardous Chemicals (in consultation);	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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Provisions on Environmental Administration of New Chemical Substances (2010)

- New chemicals not listed on **IECSC** shall be **notified** to the Chemical Registration Center (CRC) of MEP **irrespective of volume**;



IECSC Online Search

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

3,166 substances marked as confidential,
further inquiry to CRC required

Search Readme Exit

Please select: CAS Registry Number Query content: 1038872-89-7

Token: ZR0Y ZR0Y

Results:

Your request: *1038872-89-7* is not found in IECSC.

Please check:

- ★ Your key words are right.
- ★ The chemical you searched is confidential.
- ★ Please ask CRC-MEP for more information. Email address: nrcncheck@crc-mep.org.cn



Exemptions

Chemicals subject to other laws	Pesticides, cosmetics, pharmaceuticals, food and feed additives, etc. (Intermediates or raw materials are not exempt).
Substances existing in nature	Natural polymers, etc;(Natural substances extracted or processed by chemical methods can not be exempted.)
Products of non commercial purpose or unintentionally produced	Impurities: single impurity less than 10% and total content of impurities shall not exceed 20% ; Waste and by-products.
Special categories	Glass, cement, alloys, non-isolated intermediate substances and articles, etc.

Notification Body

- Domestic manufacturer/importer;
- Foreign manufacturer/exporter: two options

Ask importer to notify;



Appoint qualified Chinese agent;



Types of Notification

- Scientific Research Record
- Simplified Notification Under Basic Conditions
- Simplified Notification Under Specific Conditions
- Typical Notification

Scientific Research Record

- For R & D substances less than 0.1t/y; or
- For the purpose of introducing sample to China for test.
- No test data is required;
- Only takes 5~10 working days;
- Results published by MEP regularly.

Simplified Notification under Basic Conditions

- For new chemical substances less than 1t/y;
- 1-3 eco-toxicological tests must be carried out in China;
- Takes 4-6 months.

No.	Test Name	Test Scheme
1	Ready biodegradability	The test must be conducted at first.
2	Acute toxicity study with <i>Brachydanio rerio</i>	The test must be conducted if the substance is not ready biodegradable.
3	Earthworm, acute toxicity test	The test must be conducted if the LC50 of fish cannot be obtained when the solubility of the substances in water is less than 100mg/L and the substance is shown to be toxic to aquatic life at its saturated concentration.

Simplified Notification under Specific Conditions

- For export only with volume under 1t/y;
- For scientific research with volume between 0.1-1t/y;
- For product and technological research with tonnage less than 10 ton per year (up to 2 years);
- For polymers with all monomers already listed in IECSC(if the polymer itself is not listed) or polymers containing less than 2% new chemicals weight by weight; and low concern polymers;

- No test data is required;

- Takes 2-3 months.

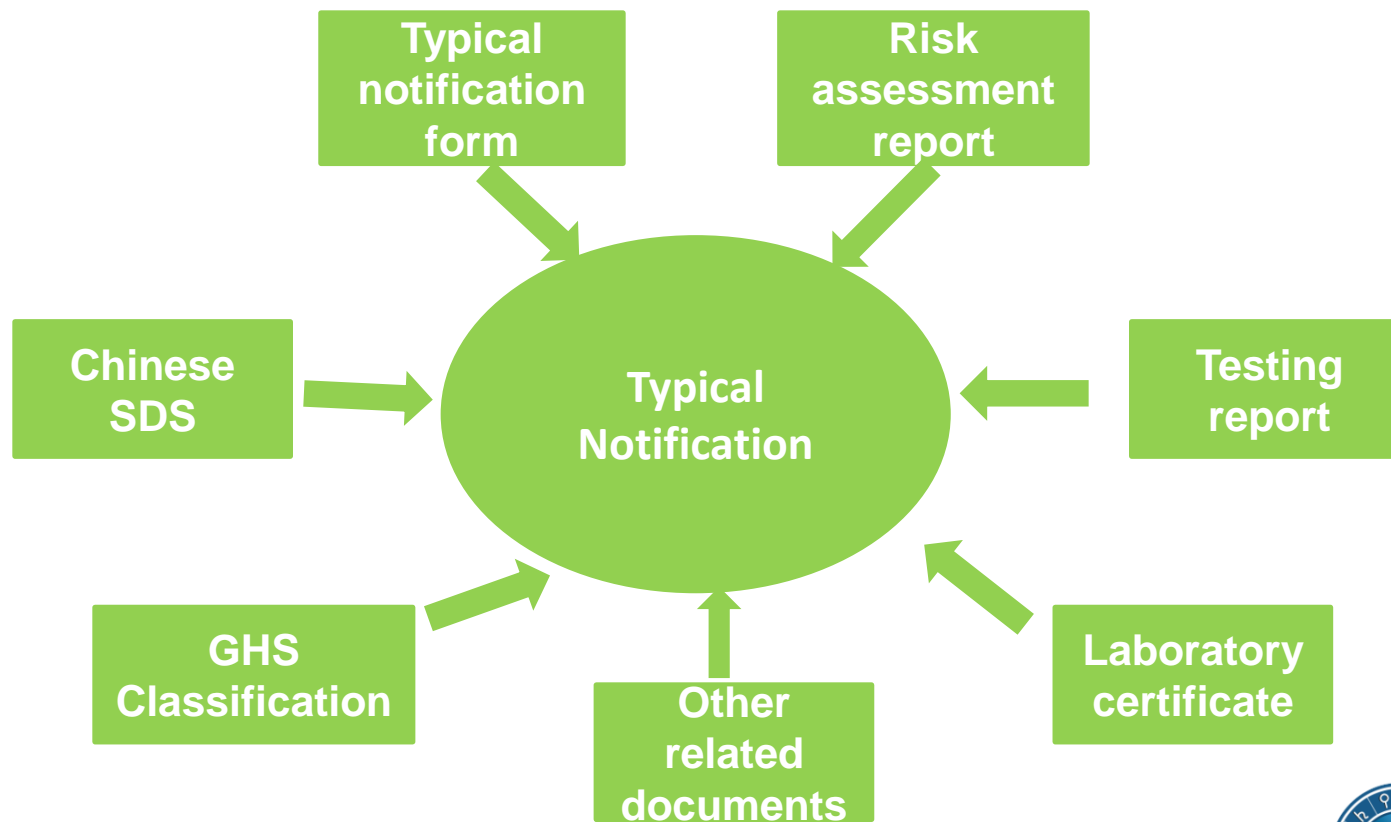
Typical Notification

- Four levels (1-10, 10-100, 100-1000, 1000+);
- The higher the tonnage band, more data required;

Notification Level		Level I	Level II	Level III	Level IV
Tonnage level (ton/a)		> = 1 t / a, < 10 t / a	> = 10 t / a, < 100 t / a	> = 100 t / a, < 1,000 t / a	> = 1,000 t / a
Minimum Data endpoint required	Qualitative & Quantitative	2~3	2~3	2~3	2~3
	Physico-chemical	9 (solid) 12 (liquid)	9 (solid) 12 (liquid)	9 (solid) 12 (liquid)	9 (solid) 12 (liquid)
	Toxicity	9	12	13	15
	Eco-toxicity	7	12	13	13
Estimated testing Period (months)		4 to 6	6 to 8	10 to 15	>15

Typical Notification

■ Required Notification Materials



New Substance Management: China vs US

	US TSCA	China REACH
R & D Exemption	No approval is required	Scientific research record(<0.1t/y) or simplified notification.
Test Marketing Exemption	Application for test market exemption	Simplified notification is required. Up to 10t/y and 2 years.
Low Volume Exemption(1-10t/y)	Submission of standard PMN form and prior approval is required.	Does not exist. Full data set for typical notification (1-10t/y) is required.
Low Release / Low Exposure	Prior approval is required	Equivalent exemption does not exist.
New Polymer	No approval is required if polymer meets certain conditions.	Simplified notification or typical notification with reduced data requirement.
General new chemical substances.	Physio-chemical/toxicological/eco-toxicological data is not mandatory	Minimum data requirement must be met.

Post-notification Obligations

Type	Category	Management Type	Obligations of certificate holder
Typical notification	General new substances	Basic management (6 requirements)	<ol style="list-style-type: none"> 1. Communicate SDSs; 2. Implement risk management measures; 3. Submit first-activity report; 4. Keep documents on file for over 10 years; 5. Do not sell chemicals to downstream users who are not capable of implementing risk management measures; 6. Submit updates if a new hazard arises;
	Hazardous new substances	General management (8 requirements)	<ol style="list-style-type: none"> 7. Submit annual report (for previous year); 8. Comply with <<The Measures for The Administration of Registration of Hazardous Chemicals>>;
	High environmental concern substance	Key management (11 requirements)	<ol style="list-style-type: none"> 9. Submit report on disposal information; 10. Submit substance circulation info; 11. Submit annual plan (for next year);
Simplified notification		Annual management (2 requirements)	<ol style="list-style-type: none"> 1. Submit annual plan (for next year); 2. Keep documents on file for over 10 years;
Scientific research record		Specified management (2 requirements)	<ol style="list-style-type: none"> 1. Shall be used in special facilities and under the direction of professional personnel; 2. Can only be used for R&D



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Existing Chemicals Management

- Toxic chemicals restricted to be imported/exported
- Hazardous chemicals
- Other existing chemicals are less regulated or subject to other laws.

Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (issued in 1994);

- Foreign exporters shall apply for a registration certificate with CRC of MEP with its partner and pay \$10,000 if exporting toxic chemicals;
- Domestic importers or exporters shall apply for import or export clearance notification to customs;

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

(total 156 substances, updated in 2011, full list available from CIRS website)

Serial No	Chemical Name	CAS No	Customs Goods ID	Serial No	Chemical Name	CAS No	Customs Goods ID
1	Mercury sulfide	1344-48-5	2617901000	81	ZINC ARSENIDE	12044-55-2	2853009022
2	Arsenic	7440-38-2	28048000000	82	gallium arsenide	1303-00-0	2853009022
3	Mercury	7439-97-6	28054000000	83	Dichloromethane	75-09-2	2903120001
4	arsenic acid	7778-39-4	2811199020	84	Dichloromethane	75-09-2	2903120090
5	meta-arsenic acid	10102-53-1	2811199020	85	Chloroform	67-66-3	2903130000
6	pyroarsenic acid	13453-15-1	2811199020	86	1,2-dichloroethane	107-06-2	2903150000



Regulations on Safe Management of Hazardous Chemicals in China (2011)

- 《危险化学品安全管理条例》 or Decree 591;
- Issued on 2 March 2011 and will come into force on 1 Dec 2011;
- Main legislation regulating existing chemicals;
- Requiring mandatory GHS classification and labeling for hazardous chemicals.



Regulations on Safe Management of Hazardous Chemicals in China (2011)

- Definitions of Hazardous Chemicals
- The Scope of the Regulation
- Main Obligations
- Operating License
- Registration of Hazardous Chemicals
- Labeling and SDSs for Hazardous Chemicals

Definitions of 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.



国家安全生产监督管理总局

危险化学品 查询

类 别

关键字

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 soon.

The Scope of the Regulation

- The following activities involving hazardous chemicals are regulated in China



**Production and
Storage**



Use



Sales and Marketing



Transportation

Main Obligations

For companies in China	For foreign companies
<ul style="list-style-type: none">• Production permit for producers;• Transport permit for transporter;• Operating license for other actives;• Registration of hazardous chemicals;• Labeling and SDS;• Safety management system;• Qualified professional;• Other requirements.	<ul style="list-style-type: none">• Labeling and SDS compliant with Chinese GHS national standards.

Operating License

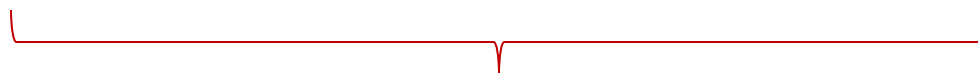
- Any legal entities operating and marketing hazardous chemicals in China shall obtain operating license from the State Administration of Work Safety (SAWS).



Production and Storage

Use

Sales and Marketing Transportation



Need to Apply

Road transport permit,
No operating license

More info can be found in the Measures for The Administration of Operating Licenses for Hazardous Chemicals, which is in public consultations.



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Registration of Hazardous Chemicals

Domestic manufacturers and importers of hazardous chemicals in China shall register hazardous chemicals with National Registration Center for Chemicals (NRCC) of SAWS- *Chapter 6, Article 67*



<http://en.nrcc.com.cn>



Note*: Foreign companies **do not** need to register.

Registration of Hazardous Chemicals (Online)

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



The screenshot shows the login page of the '危险化学品登记信息管理系统' (Hazardous Chemicals Registration Information Management System). The page features the NRCC logo in the top left and '网络版 V1.0' in the top right. The main title is '危险化学品登记信息管理系统'. Below the title, there is a copyright notice: 'COPYRIGHT (C) NATIONAL REGISTRATION CENTER FOR CHEMICALS'. The login form includes fields for '用户名(U):', '密码(P):', and '验证码:'. There are also buttons for '找回密码', '记住密码', '登录', '我要申请', and '取消'. The verification code '1549' is displayed next to the verification code input field.

More info can be found in the Measures for The Administration of Registration of Hazardous Chemicals , which is to be revised soon.

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 SDS and chemical safety label;

Labeling and SDS for Hazardous Chemicals

Offences

Penalties

No proper operating 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

Our Interpretation

China GHS applies to all chemicals. However, only failure to classify and label hazardous chemicals in accordance with China GHS will incur penalties



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Labeling and SDS for Hazardous Chemicals

■ New Catalog of Hazardous Chemicals

- To be released before the beginning of 2012;
- Might double in capacity (~7000 chemicals);
- Might 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.

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GHS Implementation: Current Status

2006

Publication of 26 compulsory national standards (prefixed with "GB")
-GB 20576 ~ GB 20602-2006 *"Safety rules for classification, precautionary labeling and precautionary statements of chemicals"*;

2008

Publication of two recommended standards (prefixed with "GB/T")
- GB/T 16483-2008 (SDS);
- GB/T 22234-2008 (Labeling of chemicals according to the GHS);

2009

Publication of three compulsory standards
-GB 190-2009 (packaging): implements the 15th revised edition of the UN recommendations on the Transport of Dangerous Goods
-GB 13690-2009 (classification and hazard communication) – implements GHS
-GB 15258-2009 (precautionary labeling) - implements GHS

2010

The three compulsory standards published in 2009 entered into force on 1 May 2010. 1 year transitional period started from 1 May 2010 and will end on **1 May 2011**.

2011

Publication of revised Regulations on Safe Management of Hazardous Chemicals in China in March (expected enter into force on **1 Dec 2011**)

GHS Implementation: Deadline

- 1 May 2011 - Official Deadline

All chemical substances must be classified and labeled in accordance with those standards.

- 1 Dec 2011

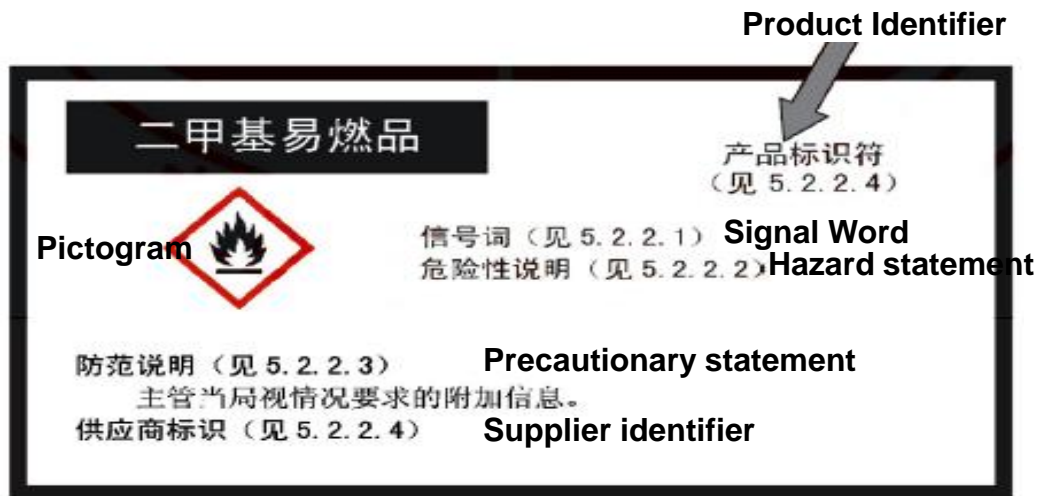
Failure to prepare SDSs and labels for hazardous chemicals according to those national standards after this date will incur penalties.

GB 20576 ~ GB 20602-2006 – 26 Classification Standards

- Based on the 1st edition of UN GHS(2003), 8 yrs behind;
- The following building blocks from the 4th revised edition of UN GHS(2011) are not adopted in China
 - Chemically unstable gases category A and B;
 - Non-flammable aerosols category 3;
 - Respiratory sensitization subcategory 1A & 1B (China does have category 1);
 - Skin sensitization subcategory 1A & 1B (China does have category 1);
 - STOT- single exposure category 3;
 - Aspiration category 1 and 2;
 - Hazardous to the ozone layer category 1.

GB 13690-2009 , GB 15258-2009 – Classification and Labeling Standard

- Consistent with UN GHS Rev 2;
- Referring to 26 classification standards;
- Example of a chemical label (refer to GB 15258-2009);
- Example of SDS (refer to GB/T 16483-2008);



One example label from
GB 13690-2009;

GB/T 16483-2008 – Content, Order and Sections of SDS

- Recommended standard, not mandatory;
- 16 headings, order and content the same as UN GHS;
- 24h emergency number must be a domestic number.

化学品安全技术说明书

根据 GB/T 16483-2008 标准制作

中文名

CSDS Record 号: CSDS-TCO-010-110001CN

1.0 版本

修订时间: 2010 年 10 月 29 日

打印日期: 2010 年 10 月 29 日

皮肤过敏反应。

2.1.2.4 主要的环境影响危险性信息: ..

未知。

2.2 标签要素。

象形符号: ..



警示词: ..

危险性说明: ..

警告。

H302 吞咽有害。 ..

H317 可能引起皮肤过敏反应。 ..

H410 对水生生物毒性极大并具有长期持续影响。 ..

防范说明: ..

P264 作业后彻底清洗手。 ..

P270 使用本产品时不得进食、饮水或吸烟。 ..

P261 避免吸入粉尘/烟/气体/烟雾/蒸汽/喷雾。 ..

P272 受污染的工作服不得带出工作场地。 ..

P280 戴防护手套/穿防护服/戴防护眼罩/戴防护面具。 ..

P273 避免释放到环境中。 ..

P301 + P312 如误吞咽: 如感觉不适, 呼叫解毒中心或医生。 ..

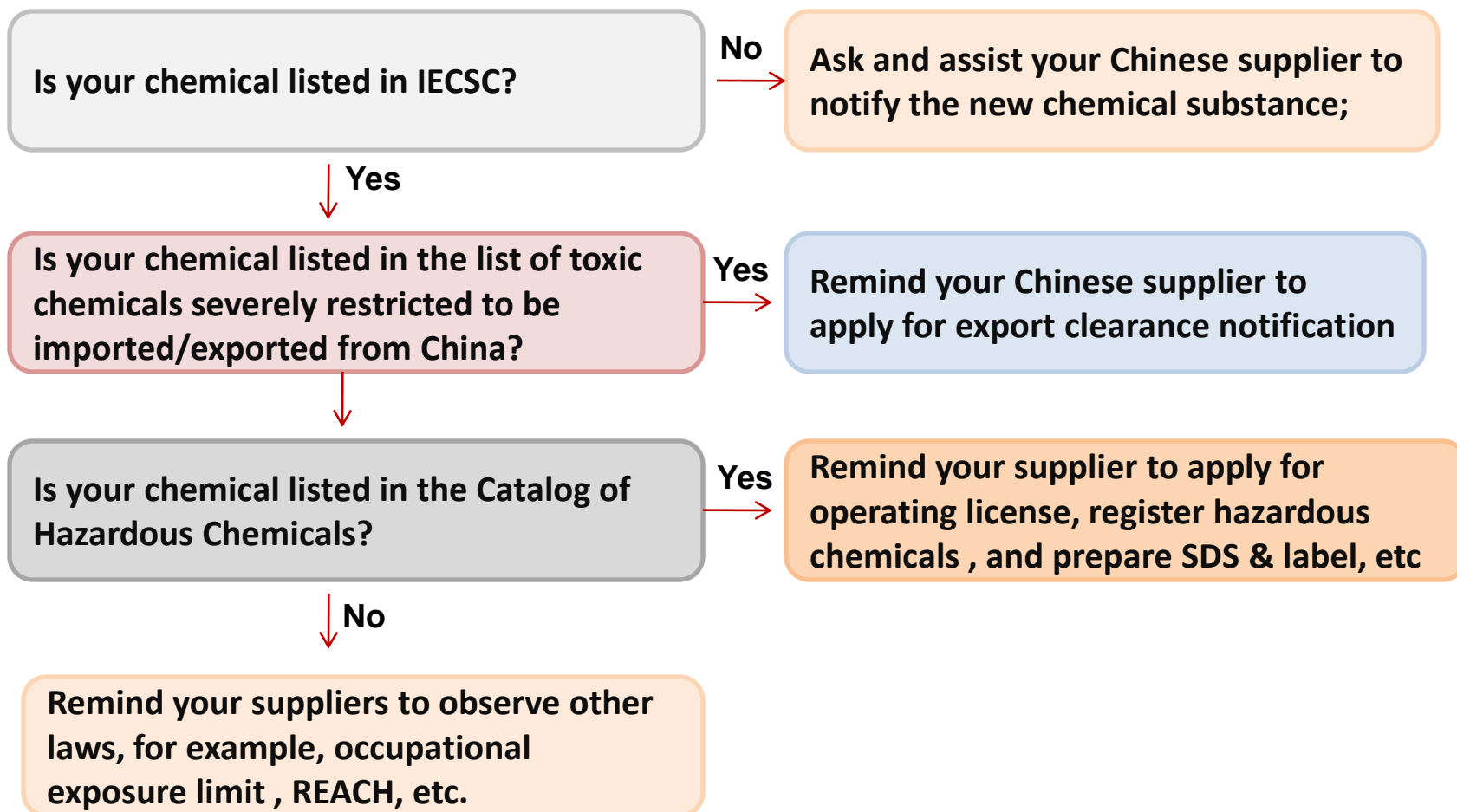
GHS Implementation: Challenges

- New Catalog of Hazardous Chemicals not available;
- Lack of data or expertise;
- No differentiation between substances and mixtures;
- Too many government bodies involved;
- Enforcement is weak.

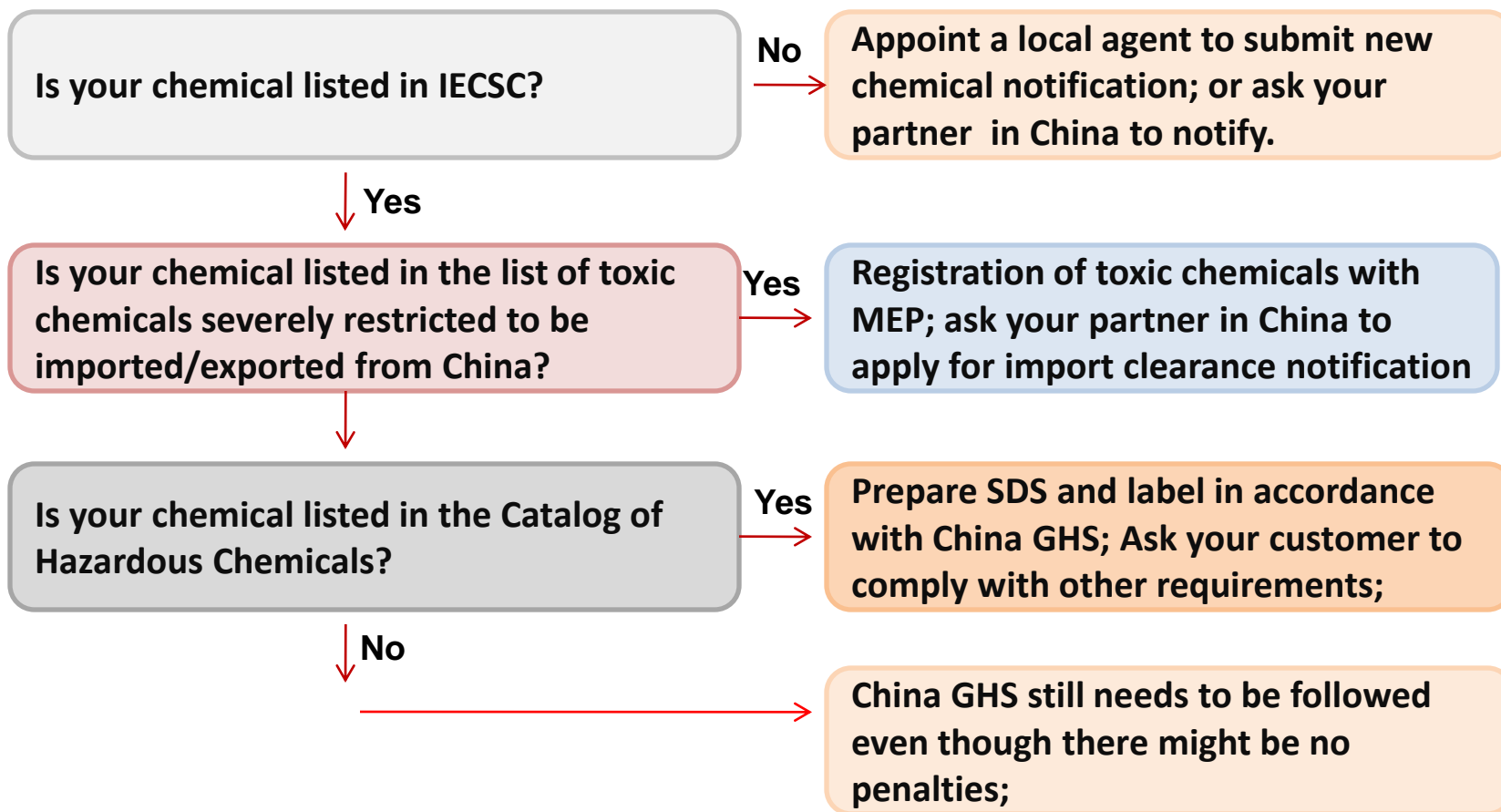
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Practical Advice – Buying Chemicals from China



Practical Advice – Exporting Chemicals to China



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

- English version of the Provisions on the Environmental Administration of New Chemical Substances in China (2010)

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

- 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！