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Major Issues and Policy Framework for Environmentally Sound and Strategic Management of Chemicals in China

gtz



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ABBREVIATIONS

Abbreviation	Detail
ACS	American Chemical Society
BAT/BEP	Best Available Techniques and Best Environmental Practice
BHC	Benzene Hexachloride
CAAC	Civil Aviation Administration of China
CCICED	China Council for International Cooperation on Environment and Development
CEC	Commission of the European Communities
ChemRTK	Chemical Right-to-Know
CMR	Carcinogenic, Mutagenic, or Toxic for Reproduction
COD	Chemical Oxygen Demand
CRAES	Chinese Research Academy of Environmental Sciences
DDT	Dichloro-diphenyl-trichloroethane
EC50	Median Effect Concentration
ECB	European Chemicals Bureau
EDCs	Endocrine Disrupting Chemicals
EIA	Environmental Impact Assessment
EPA	Environmental Protection Agency of the United States of America
EPA/OPPT	Office of Pollution Prevention and Toxics
EPCRA	Emergency Planning and Community Right-to-Know Act
GAC	General Administration of Customs
GAQSIQ	General Administration of Quality Supervision, Inspection and Quarantine
GDP	Gross Domestic Product
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
GLP	Good Laboratory Practice
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit (GmbH)
HCB	Hexachlorobenzene
HPV	High Production Volume
HPVCs	High Production Volume Chemicals
HPVCP	HPV Challenge Program
HSDB	Hazardous Substances Data Bank
ICCA	The International Council of Chemical Associations
IFCS	International Forum on Chemical Safety
ILO	International Labor Organization

IMOC	Inter-Organization Programme for the Sound Management of Chemicals
IPCS	The International Programme on Chemical Safety
ITC	International Test Commission
IUCLID	International Uniform Chemical Information Database
LC50	Median Lethal Concentration
LD50	Median Lethal Dose
MII	Ministry of Information Industry
MoA	Ministry of Agriculture
MoC	Ministry of Communication
MoFA	Ministry of Foreign Affairs
MoH	Ministry of Health
MoR	Ministry of Railways
MoST	Ministry of Science and Technology
MPS	Ministry of Public Security
MSDS	Material Safety Data Sheet
NCG	National Coordination Group for Implementation of the Stockholm Convention
NDRC	National Development and Reform Commission
NIOSH	The National Institute for Occupational Safety and Health
NIP	China's National Implementation Plan for the Stockholm Convention on Persistent Pollutants
NPC	National Patent Council
ODS	Ozone Depletion Substances
OECD	Organization for Economic Cooperation and Development
PBT	Persistent Bioaccumulative and Toxic Chemicals
PCBs	Polychlorinated Biphenyls
PCE	Perchloroethylene
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonate
PIC	Prior Informed Consent
POPs	Persistent Organic Pollutants
PRTR	Pollutant Release and Transfer Register
RC	Responsible Care
RCLG	Responsible Care Leadership Group
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RTECS	Registry of Toxic Effects of Chemical Substances
SAICM	Strategic Approach to International Chemicals Management
SASAC	State Asset Supervision and Administration Commission
SAWS	State Administration of Work Safety

SBIR	Small Business Innovation Research
SEPA	State Environmental Protection Administration
SETC	State Economic and Trade Committee
SFDA	State Food and Drug Administration
SMC	Environmentally Sound Management
TBT	Technical Barrier to Trade
TCE	Trichloroethylene
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
UNCED	United Nation Conference on Environment and Development
VA(s)	Voluntary Agreements
VCCEP	Voluntary Children's Chemical Evaluation Program
vPvB	very Persistent and very Bio-accumulative Chemicals
WHO	World Health Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization

EXECUTIVE SUMMARY

1. There are about 7 million chemical substances produced in the world with more than 70,000 in common use. Some 1,000 new substances are introduced each year. There are 45,000 substances listed in the 'Inventory of Existing Chemical Substances in China' and about 100 new substances are added into the inventory every year. Although to varying degrees, many chemicals may be harmful to human beings and the environment. According to the WHO, global cancer rates have increased rapidly since the last century that today, 4-5 million people die from cancer, about 12-25% of the total number of deaths; and chemical factors account for 80% of the total factors for cancer.

2. China has established laws and regulations governing Environmentally Sound Management of Chemicals (SMC). Relevant laws and regulations include: the 'Law on the Prevention and Control of Environmental Pollution by Solid Wastes'; 'Regulations on Safety Management of Hazardous Chemicals'; and 'Regulations on Pesticide Management'. Involved departments include environmental protection, commerce, safe production and customs. However, the environmentally sound management of chemicals in China is weak and cannot fundamentally safeguard the environment and human health. Major problems include: (a) lack of a clearly-defined national policy and/or strategy; (b) lack of well established legal system (laws and regulations); (c) inadequate capacity of administrative organs, law enforcement and supervision capacity; (d) public participation; (e) lack of well established technical support system for management, and insufficient integrated management measures.

3. 'Environmentally sound management of chemicals' is a term from chapter 19 subject 11 of Agenda 21, programmatic document for the international environmental management of chemicals, where six programme areas are proposed: (1) expanding and accelerating international assessment of chemical risks; (2) harmonization of classification and labeling of chemicals; (3) information exchange on toxic chemicals and chemical risks; (4) establishment of risk reduction programmes; (5) strengthening of national capabilities and capacities for management of chemicals; (6) prevention of illegal international traffic in toxic and dangerous products, moreover International Forum on Chemical Safety (IFCS) and Inter-Organization Programme for the Sound Management of Chemicals (IOMC) are proposed to be created here. The aim is to develop management of chemicals from an environmental viewpoint in order to protect the environment and human health.

4. The China Council for International Cooperation on Environment and Development (CCICED) established a multilateral consultation mechanism, which offers a platform for China to absorb international experiences in environmental

pollution prevention policy, precautionary mechanisms, pollution treatment and environmental management. In a deployment meeting of CCICED's work, Vice Premier Zeng Peiyan pointed out: "special attention should be paid to environmental pollution caused by chemicals, there are lots of pressing problems that need to be resolved in such areas as well as equipping environmental protection installations for chemical industrial enterprises, strengthening the safety management on storage and transportation of chemicals, prevention and timely control of the accidental leakage of hazardous chemicals; then, hope to arrange some specific studies and provide some effective intellectual support to the government".

4. To improve the regulatory system and chemical management capacity in China, it is desirable to analyze and evaluate the environmental management system on chemicals in China, learn from advanced international experiences, and bring forward major policy suggestions for the SMC in China.

5. This research is supported by the Environmental Policy Programme of the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH on behalf of the Sino-German Cooperation programme of the German Federal Ministry for Economic Cooperation and Development and the State Environmental Protection Administration. Four domestic experts, Jianxin Hu, Zhengyu Li, Jianguo Liu, Yan Mao and three international experts, Ulrike Kowalski, Silke Schmidt and David van Hoogstraten accomplished this report. In development of the report, stakeholders, at home and abroad, were consulted many times. Through symposium and consultation, opinions were listened to and taken into account from experts from related domestic agencies, local governments, and sectors, enterprises, non-governmental organizations, and revisions were made accordingly.

6. The study report recommendations for policies and regulatory framework building for SMC in China are the following:

(1) Establish a national strategy on SMC

All future measures on SMC should become a part of the national strategy. (a) The strategy of SMC in China should define the basic guidelines, principles, policies and overall strategic objectives of the nation's SMC, which should comprehensively consider the precautionary approach and the basic national situation of chemical industry and consumption of chemicals and set reasonable strategic objectives. (b) The strategy shall be consistent with 'scientific development'. To promote recycling and reuse, to protect the environment, to promote a resource-conserving and environment-friendly society, clean and safe development should be considered in the strategy. (c) The manufacture and management of chemicals shall follow the ideas of clean production and green chemistry. (d) Chemicals with high risks to health and environment should be replaced first provided economically feasible alternatives are

available. (e) The strategy of SMC in China should establish a national plan of capacity building on SMC including the legislative system, institutional functions, technical supporting systems, information exchange and public participation mechanisms etc. (f) Chemicals management strategy should include a long-term action plan for risk assessment and risk management of existing chemicals with set deadlines, following national specific priority principles to collect information on hazards of existing chemicals, carry on risk assessment and risk management actions, gradually reduce and eliminate the production and consumption of chemicals with unreasonable risk to the environment and human health, and last but not least achieve China's "environmentally friendly environment". The strategy chosen must be WTO compliant. (g) For development of the national strategy of SMC, one national coordination group should be established from environment and human health protection basis to insure the drafting strategy to reflect on interests of the stakeholders.

(2) Establish a law or administrative regulation on SMC

7. In light of current national legislation in regard to chemicals management establish a specialized law or an administrative regulation on SMC as the fundamental way to fill most of the existing gaps in SMC in China. The law or the administrative regulation of SMC should comply with the approach of risk management, establish hazard testing requirements, adopt the GHS for classification and labeling of chemicals to contribute to effective risk assessment and risk management of chemicals, include the GLP requirements for new tox and ecotox tests, establish basic SMC systems mainly including new chemical substances notification, risk assessment and risk management of existing chemical substances, environmental monitoring system for priority toxic chemical pollutants, information gathering and a right-to-know system for the release of toxic chemicals, a major environmental accident prevention and emergency response system, which should be coordinated with the current relevant legislation on occupational safety and public health management.

(3) Priorities for basic administrative framework (system building) on SMC

8. (a) Implementation of GHS as soon as possible in accordance with internationally agreed goals; (b) Promote and improve the new chemical substance notification system; (c) Establish the system of risk assessment and management of existing chemical substances; (d) Establish national criteria for the prioritisation of chemicals of high concern; (e) Establish a system of release recording and a publication system for toxic chemical pollutants; (f) Establishment of environmental monitoring system for emissions of priority toxic chemical pollutants; (g) Improve the system of registration and reporting of major hazard installations.

(4) Capacity Buildings

9. Build upon existing national administrative functions and organizations for environmental management of chemicals.

(a) Build upon the national system of administrative enforcement of environmental management of chemicals, supervision and management by setting up a coordination mechanism among all national level authorities responsible for chemicals management. (b) Elevate the role of SEPA within the Chinese chemical management system including by increasing the capacity of relevant divisions and departments. Set up specific administrative functions (departments or divisions) for chemicals management and increase the number of staff involved in environmental management of chemicals in central and provincial organizations for environmental protection, including additional relevant managerial departments and officers. (c) Reinforce corresponding staff training.

10. Establish a comprehensive national information system for chemicals.

(a) Carry out centralized collection, arrangement and publication of various relevant national information on environmental and health risks of chemicals based on systems such as notification of new chemical substances, risk assessment and risk management of existing chemical substances, environmental monitoring of priority toxic chemical pollutants and their emissions and registration and reporting of major hazard installations, consistent with the protection of confidential business information. (b) Link existing national chemical information sources and management system such as those concerning existing and new chemical substances, as well as occupational health and safety issues. (c) Further enhance global information exchange on chemicals.

11. Strengthen national capacity on testing, evaluation, research and monitoring of chemicals

(a) Increasing capacity for testing of environmental and health hazards of chemicals by establishing laboratories for testing and evaluation of chemicals in accordance with OECD / GLP guidelines and by introducing GLP monitoring and other programmes such as mutual acceptance of data (MAD). (b) Increasing capacity to conduct basic research on and to monitor the environmental and health components of risk assessment, particularly with respect to priority high-risk and toxic chemicals. (c) Development of international cooperation related to hazard testing and risk assessment of chemicals, learn and adopt international chemical risk assessment practices to continually improve capacity in China.

(5) Strengthen environmental governance on chemicals

12. Promote and support policies for voluntary risk management of chemicals

(a) Encourage the implementation of VA, RC and Product Stewardship in China, in communication with Chemical Industry Association. Research and establish a series

of relevant matching policies and measures of management to promote the gradual implementation of VA and RC of environmental management of chemicals in China on the basis of current regulations of "Cleaner Production Promotion Law".

(b) Improve performance under VAs including by clarifying their legal status, and control procedures, and engaging in performance audits.

13. Improve information publicity and public participation mechanisms for the environmental management of chemicals

(a) Enhance publicity of and communication information concerning the environmental and health risks of chemicals by making information on pollution emissions and environmental monitoring of toxic chemicals publicly available.

(b) Establish education programs on the environmental and health risks of toxic chemicals for the general public. (c) Establish public participation mechanisms that provide stakeholders with a platform to participate in government decision-making on chemicals management consistent with international trends.

1 Introduction

1.1 Chemicals: their Hazards and Risks

1. There are about 7 million chemical substances produced in the world with more than 70,000 in common use. Some 1,000 new substances are introduced each year. There are 45,000 substances listed in the 'Inventory of Existing Chemical Substances in China' and about one hundred new substances are added into the inventory every year. Chemicals are an indispensable means of production of consumer goods in the modern world, and are used in medicine, pesticides, fertilizer, plastic, textile fibre, electronic chemical, domestic decoration material, soap and laundry powder, cosmetic and food additive applications. However, many chemicals harm human beings and the environment in different degrees. Misuse, abuse, chemical accidents or improper disposal during production, storage, distribution, transportation, usage and waste disposal may bring negative influence to human health and environment.

2. It took a long time for the environmental and health hazards of chemicals to be well understood. Along with the development of human civilization, many chemicals have been produced and widely used, which has led to local and global environmental and health hazards and occupational safety issues, such as persistent, bioaccumulative and toxic chemicals (PBTs), endocrine disrupting chemicals (EDCs), accidental leakage of hazardous chemicals, transboundary movements of hazardous wastes and their disposal and ozone depletion substances (ODS), et al.. Hazards of unintentionally produced toxic and hazardous chemicals such as Dioxin also emerged. According to the WHO, global cancer rates have increased so fast since the last century that today, 4-5 million people die from cancer which accounts for about 12-25% of the total number of deaths; and chemical factors account for 80% of the total factors for cancer.

1.2 Demands for Environmental Management of Chemicals in China

3. In China, as traditional pollution problems are gradually addressed, the demand for environmentally-sound management of chemicals is gradually increasing.

1.2.1 Change of Governance Conceptions

4. The Chinese government has confirmed its determination to realize three transformations during 2006: (a) to change from emphasizing economic growth while ignoring environmental protection to stressing both environmental protection and economic growth; (b) to change from environmental protection lagging behind economic development to environmental protection progressing simultaneously with economic growth, to try to pay back the old debts without accumulating new debts and change the situation that treatment follows pollution and destruction accompanies treatment; (c) to change from depending mainly on administrative measures for environmental protection to comprehensively taking legal, economic, technical and

necessary administrative measures to solve environmental problems. The ‘Decision of the State Council on Implementing the Scientific Development Concept for Strengthening Environmental Protection’, part five, which concerns establishing and improving a long-term effective mechanism for environmental protection, points out that necessary environmental regulations and standard systems on chemical pollution should be improved.

1.2.2 Adjust the Industrial Structure to Meet the Demands of Economic Development and Sustainable Development

5. According to the ‘Outline of the Eleventh Five-Year Plan for National Economic and Social Development’, China will speed up the change of the economic growth model. Resource conservation should be considered as a basic national policy of China, to promote recycling and reuse, protect the environment, promote a resource-conserving and environment-friendly society, take a practical new road to industrialization, clean and safe development, and finally realize sustainable development. Chapters like ‘adjustment of industrial distribution’ et al. specify a development plan relevant to optimise the structure of the chemical industry, including basic chemical feedstock, and fine chemicals while eliminating pollution-intensive chemical enterprises.

1.2.3 Demand of International Environmental Protection

6. Since 1970, developed countries have established legal systems related to chemical management and they have also urged relevant UN bodies to establish and implement several global conventions and concepts successively, such as: Convention concerning Safety in the Use of Chemicals at Work, Prevention of Major Industrial Accidents Convention, Basel Convention on Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Rotterdam Convention on International Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, The Stockholm Convention on Persistent Organic Pollutants, The Globally Harmonized System of Classification and Labeling of chemicals and the Strategic Approach to International Chemicals Management, et al.. While developed countries and regions have established comparable improved chemical management systems, there is a big gap in chemical management between a majority of developing countries including China and the developed countries. Therefore Environmentally Sound Management of Chemicals (SMC hereafter) has become a requirement for economic development and social progress for developing countries, especially for China, which is a large producer and consumer of chemicals.

1.2.4 Demand of International Trade

7. China has become one of the world’s largest exporting countries. Foreign trade is an important driver for continuing increases in the national GDP. China faces a challenge meeting WTO requirements. However, in recent years, China has encountered stricter technical barriers to its export trade (hereafter TBT) from developed countries, and especially ‘green barriers’ to trade. According to an

investigation by the Ministry of Commerce, in 2002, the year China joined the WTO, exports in the six sectors including the agricultural product sector were frustrated severely by TBT constraints. About 71% of export enterprises and 39% of export products encountered the foreign TBT limit, which caused a loss of about 17 billion USD, equivalent to 5.2% of the total exports. Until now, nearly 90% of food and agricultural products were blocked resulting in a 9 billion USD loss. Laws and standards related to chemicals and their marketing in China still do not protect human health, and the environment sufficiently.

1.2.5 Existing Problems in Environmentally Sound Management of Chemicals

8. SMC is weak in China. Relevant laws and regulations include: the 'Law on the Prevention and Control of Environmental Pollution by Solid Wastes'; 'Regulations on Safe Management of Hazardous Chemicals'; and 'Regulations on Pesticide Management'. Involved departments include environmental protection, commerce, safe production and customs. However, the environmental management of chemicals in China cannot fundamentally safeguard the environment and human health. Major problems include: (a) lack of a clearly-defined national policy and/or strategy; (b) the legal system (laws and regulations) not being well established; (c) inadequate capacity of administrative organs, law enforcement and supervision capacity; (d) lack of public participation; (e) a technical support system for management not being well established, and insufficient integrated management measures.

1.3 Fields of Environmental Management of Chemicals

9. The management of chemicals includes (1) environmental management of chemicals; (2) management of protection of consumers of chemicals and (3) management of worker safety and health. 'Environmentally sound management of chemicals' is quoted from chapter 19 subject 11 of Agenda 21, programmatic document for the international environmental management of chemicals, where six programme areas are proposed: (1) expanding and accelerating international assessment of chemical risks; (2) harmonization of classification and labeling of chemicals; (3) information exchange on toxic chemicals and chemical risks; (4) establishment of risk reduction programmes; (5) strengthening of national capabilities and capacities for management of chemicals; (6) prevention of illegal international traffic in toxic and dangerous products, moreover the International Forum on Chemical Safety (IFCS) and the Inter-Organization Programme for the Sound Management of Chemicals (IOMC) are proposed to be created here. The aim is to develop management of chemicals from an environmental viewpoint in order to protect the environment and human health.

1.4 Task Source and Objectives of this Research

10. The China Council for International Cooperation on Environment and Development (CCICED) established a multilateral consultation mechanism, which offers a platform for China to widely absorb international experiences in

environmental pollution prevention policy, precautionary mechanisms, pollution treatment and environmental management. In a deployment meeting of CCICED's work, Vice Premier Zeng Peiyan pointed out: "special attention should be paid to environmental pollution caused by chemicals, there are lots of pressing problems that need to be resolved in such areas as well as equipping environmental protection installations for chemical industrial enterprises, strengthening the safety management on storage and transportation of chemicals, prevention and timely control of the accidental leakage of hazardous chemicals; then, hope to arrange some specific studies and provide some effective intellectual support to the government".

11. To improve the regulatory system and chemical management capacity in China, it is desirable to analyze and evaluate the environmental management system of chemicals in China, learn advanced international experiences about that, and bring forward major policy suggestions for the SMC in China.

1.5 Drafting of the Report

12. This research is supported by the Environmental Policy Programme of the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH on behalf of the Sino-German Cooperation of the German Federal Ministry for Economic Cooperation and Development and the State Environmental Protection Administration (SEPA). The report is accomplished by four domestic experts, Jianxin HU, Zhengyu LI, Jianguo LIU, Yan MAO and three international experts, Ulrike Kowalski, Silke Schmidt and David van Hoogstraten. In development of the report, stakeholders, at home and abroad, were consulted many times. Through symposium and consultation, opinions were listened to and taken into account from experts from related domestic agencies, local governments, and related sectors, enterprises, non-governmental organizations, and revisions were made accordingly.

2 Chemical Industry & the Main Environmental Issues

2.1 General Situation of Chemical Industry in China

13. Since the 1990s, the annual rate of production value of the Chinese chemical industry has increased more than 30% in China. According to the national standard classification of the national economy (GB/T4754-2002), the Chinese chemical industry includes 10 sectors: chemical ore mining, basic chemical raw materials, chemical fertilizers, chemical pesticides, paints, inks and dyes, synthetic materials, specialized chemical products, rubber products and chemical manufacturing equipment. The basic chemical raw materials and synthetic materials sectors account for 20% of the total production value of chemical industry, the fine chemicals, rubber products and chemical fertilizer sectors each account for 10-15% respectively. These five sectors account for about 85% of the total. In 2005, the total production value of the chemical industry in China was 2.1 trillion RMB (or 257.7 billion USD) which is

8.4% of the total GDP. The total value of import and export of chemicals in China was 133.5 billion USD in 2005. The value of exports is 48.1 billion USD, and the value of imports is 85.5 billion USD. There are about 4.1 million employees and more than 21,000 enterprises (with annual sales value of more than 5 million RMB) in the chemical industry, while 90% are small and medium sized enterprises.

14. At present, there are more than 20 kinds of chemicals with the world's leading production and consumption in China. Production capacity of sulfuric acid and ammonia and other basic chemical raw materials, chemical fertilizers and dyes, and synthetic fiber ranks the first in the world, production of chemical pesticides and painting output ranks second and third in the world respectively, production capacity of the main type of synthetic resin and synthetic rubber ranks the fourth in the world, consumption of pesticides, synthetic rubber and other chemicals ranks first in the world^{1,2}. According to the OECD, the annual increase in the rate of global production value of the chemical industry will be 2.6 to 3.5%, Considering China's economy and chemical industry development trends, future production and consumption of chemicals in China will keep rapidly increasing, and will have a significant impact on the global production and consumption of chemicals.

15. Chemical enterprises in China are mainly located in Eastern China (Shanghai, Jiangsu and Zhejiang, Anhui, Fujian, Jiangxi and Shandong Provinces) and the central region (Henan, Hubei, Hunan, Guangdong, Guangxi and Hainan Provinces), which accounts for 71% of the total chemical enterprises. Under the dual pressure of the need for environmental protection and industrial structure adjustment, chemical enterprises in China began to transform and restructure to collectivization and large-scale production in recent years, and have established many chemical industrial parks for centralized chemicals production. At present, more than 60 chemical industry parks have been approved by government above the provincial level.

16. The widest applications of chemicals include medicine, pesticide, fertilizer, plastic, textile fibre, electronics, domestic decoration material, soap and laundry powder, cosmetics, and food additives.

2.2 Environmental Issues of Chemicals in China

17. As a developing country, the technology of chemical industry and risk management of chemicals in China is still far behind the developed countries. Many

¹ Tuyuqin, China's pesticide Industry before entering the WTO, World Pesticide, 2001

² Feng Shiliang (China Association of Petroleum and Chemical Industry), the Economic Situation and Outlook on China's Petroleum and Chemical Sectors in 2005, Economic Analysis on China's Petroleum and Chemical Industry, 2005

harmful chemicals banned or severely-restricted by the international community or that have begun to be phased out in developed countries are still produced and consumed in China.

18. Scientific monitoring shows that the concentration of DDT and other chlorinated pesticides which have been banned internationally for nearly 30 years, is above the international standard of risk assessment in the Pearl River Delta region sediment. Concentration of POPs pollutants like DDT and BHC in tea and aquatic product like fish and shellfish in some regions are relatively high, concentrations of DDT and BHC in breast milk are still significantly higher than in developed countries. Due to the wide use of synthetic detergent nonylphenol is in the Beijing-Hangzhou Grand Canal and water in Jiangnan water, and is detected in tap water in Shanghai. Recent monitoring shows high concentrations of toxic organic pollutants in the lower reaches of the Yangtze. The detection rate of PCBs, HCB and lindane approaches 100%. In Chongqing waters of Three Gorges, there are 178 persistent organic pollutants detected and 18 of these substances are on the 'black list' of preferred controlled pollutant in water by EPA.

19. Many environmental incidents take place involving toxic chemicals. According to a SEPA report, the total number of environmental incidents was 1,406 in 2005, including: 693 water pollution incidents, 538 air pollution incidents, 19 ocean pollution incidents, 48 solid waste pollution incidents, and 108 other pollution incidents. Direct economic loss from pollution is about 105.15 million RMB (excluding the Songhua River incident). The polluted area reached 46.91 million m², including 43.1891 million m² of crop area, 3.455300 million m² of water ponds, and 266,800 thousand m² of nature reserve. In the November 13, 2005 explosion incident at Jilin Petrochemical Company of Petro China, six people died, 60 people were injured, and more than 10,000 people escaped in an emergency evacuation. The explosion caused about 100 MT benzene substances to be released into the Songhua River, seriously polluting its lower and middle reaches. Millions of coastal residents have been affected.

20. According to national statistics reports, from 2002 to 2004 there are 435 non-explosive hazardous chemical incidents occurred in Beijing, Chengdu, Chongqing, Guangzhou, Harbin, Nanjing, Qingdao, Shanghai, Shenyang, Wuhan, Xi'an and Zhengzhou, 189 people died, 390 people were injured and 962 people were poisoned in the incidents. Among the 435 hazardous chemical incidents, 70 happened in production enterprises near urban areas, resulting in heavy poisoning and evacuation. E.g. the chlorine tank explosion on April 16, 2004 in the Chongqing Tianyuan chemical plant led to an evacuation of 150,000 residents near the Jiangbei District.

21. Existing information indicates that these problems are getting worse. The whole society is facing increasing environmental and health risks from chemicals.

3 Safety and Environmental Management of Chemicals in China

3.1 Legislation on Safety and Environmental Management of Chemicals

22. China has promulgated a series of laws and regulations on safe management of hazardous chemicals, pesticides, pharmaceuticals, animal medicine, as listed in Annex 1, tables 1 and 2. Relevant ministries of the State Council also establish corresponding departmental rules and regulations for implementation. China has also promulgated a series of safety standards on classification of hazardous chemicals, storage, transportation, packaging and labeling, environmental standards for the control of chemical pollutant discharges and hazardous waste disposal, and occupational health standards.

23. China has established supervisory agencies for safe and environmental management of hazardous chemicals within the central government and at the local level. AT the State Council level, they include State Environmental Protection Administration (SEPA), State Administration of Work Safety (SAWS), Ministry of Health (MoH), State Food and Drug Administration (SFDA), Ministry of Agriculture (MoA), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), Ministry of Communication, Ministry of Railways and General Administration of Aviation, and the Ministry of Public Security (MPS). A description of their tasks is given in Annex 2.

24. Under the authority of relevant national laws, regulations and the State Council authorization, the National Development and Reform Committee (NDRC) is authorized to establish environmentally-friendly industrial policies, including cleaner production and recycling and reuse, and restriction or elimination of outdated production techniques, equipment, and products, as well as production licenses for some pesticides; the Ministry of Foreign Affairs (MoFA) has authority to engage in international negotiations on chemicals convention implementation; the General Administration of Customs (GAC) is authorized to inspect and audit the import/export of hazardous chemicals; the Ministry of Commerce, the Ministry of Science and Technology (MoST) and other ministries have authority over the import and export of chemicals and research and development of pollution prevention technologies.

25. SEPA has set up administration of solid waste and toxic chemicals specializing in registration of hazardous wastes, and review work on registration of import and export of toxic chemicals and reporting and registration of new chemical substances. The Bureau of environmental supervision is responsible for guidance and cooperation in the settlement of major environmental problems of local, departments, trans-regional and inter-basin; establishing emergency response plans in response to serious

environmental pollution accident and environmental damage. The Division of international cooperation is responsible for external negotiations of environmental conventions, coordinating with MoFA and managing implementation of environmental conventions related to chemicals.

26. Relevant ministries of the State Council have set up special agencies for management and technical support, such as the SEPA chemical registration center and solid waste management center. Under the direct guidance of respective administrations, they are responsible for specific functions such as registration of new chemical substances, environmental management and registration of import/export of toxic chemicals; safe registration of hazardous chemicals and pesticides, etc.

27. There are local supervision and management institutions of hazardous chemicals and environmental management in China. Environmental protection bureau, production safety bureau, the health bureau, agriculture bureau, quality and technical bureau in the provinces (autonomous regions and municipalities) and municipal districts and the county government are in charge of supervision and management of hazardous chemicals and pesticides for safety and environment protection in these areas.

28. The relationship between local government departments and relevant superior departments is generally one of operational guidance. E.g. local environmental protection bureaus in the people's governments above the county level are under the guidance of government of the same level, and also accept operational guidance from higher levels of environmental protection departments. There are local environment monitoring stations and environmental science research institutes in the local governments' environmental protection agency.

29. China has adopted 'Rules on Management of Hazardous Chemicals' and established a multi-sectoral system framework for national management of hazardous chemicals, which contains the full process of production, management, storage, transport, usage and waste disposal of hazardous chemicals. To coordinate supervision and safe management of hazardous chemicals by relevant ministries of the State Council, and approved by the State Council, an inter-ministerial meeting system for safe production supervision of hazardous chemical was set up in June 2007. It includes the following 16 ministries and committees of the State Council: SAWS, NDRC, MPS, MoST, Ministry of Finance (MoF), Ministry of Construction, Ministry of Railways, Ministry of Communication, State Administration for Industry and Commerce, AQSIQ, SEPA, CAAC, All China Federation of Trade Unions, Ministry of Labor and Social Security, MoH, SASAC, and the Information Centre Legislative Affairs Office of the State Council.

30. China also has established the National Coordination Group for Implementation of the Stockholm Convention (NCG), consisting of 13 ministries and agencies: SEPA,

MoFA, NDRC, MoST, MoF, the Ministry of Construction, Ministry of Commerce, MoA, MoH, the General Administration of Customs, and the AQSIQ, et al..

3.2 Major Environmental and Safety Management Regulations and their Implementation

31. The NPC Standing Committee and the State Council issue laws and regulations on management of drugs, cosmetics, food and food additives, feed and feed additives, pesticides and other specialty chemicals, a system of safety evaluation and production permit on special chemicals as set out in the Annex 1 Table 3. Supervision and management of other industrial chemicals used as industrial raw materials and raw materials of chemicals for daily use are primarily in accordance with the 'Regulation on Management of Hazardous Chemicals' issued by the State Council.

32. In May 1994, China began implementing environmental management of the import and export of toxic chemicals. SEPA placed the hazardous chemicals controlled by the 'Prior Informed Consent procedure for certain hazardous chemicals and pesticides under the Rotterdam convention' onto the list of toxic chemicals banned or severely restricted in China, implements registration of environmental management for import and export, and implements the PIC procedure. In June 2005, SEPA together with GAC, issued the 'List of Toxic Chemicals Banned or Severely Restricted in China (the second group)', and added seven highly toxic chemicals onto the management list and within the scope of import/export list of environmental management, which came into effect on July 10th, 2005. In December 2005, SEPA together with the GAC issued the 'List of Toxic Chemicals Severely Restricted on Import and Export in China', which came into effect on January 1st, 2006, and the number of restricted chemicals on the list increased from 34 to 188.

33. To prevent and control the hazard and risk to human health and the environment by industrial chemicals at the source, SEPA issued and implemented 'Measures for Environmental Management of New Chemical Substances (Order No.17)' on October 15th, 2003, and then began to implement the declaration and registration of new chemical substances before import or production. Based on the identification and assessment of health impacts and environmental hazard of new substances, it approves the registration and permits the production and import of new chemical substances which meet the risk evaluation standards, while taking measures to ban or restrict production and use of chemicals with high risk to human health and the environment.

34. Since the registration system of new chemical substances was put into practice in 2003, SEPA has established and updated the 'inventory of existing chemical

substances in China³. After the fifth supplement and update, identification information exists for 45,000 chemical substances.

35. To identify and evaluate hazards and environmental risks of new chemical substances, SEPA set up an accreditation committee of experts on new chemical substances consisting of technical and management experts on chemistry, toxicology and ecological toxicology, environmental science and safety science. The committee engages in physical, health, environmental hazard and environmental risk assessment for each new chemical substance based on ‘the guidelines for the hazard evaluation of new chemical substances (HJ/T154-2004)’, and makes recommendations on scientific management.

36. In the environmental management of construction projects for chemical production, China has made great progress in the strict environmental impact assessment (EIA) management of industrial construction projects and in strengthening capacity for management of responses to environmental emergencies. In the past years, the implementation rate of the EIA report (questionnaire) for large and medium-sized chemical construction projects remained at over 98%. Since 2005, SEPA has required that the project sites meet national industrial policy, plan and environmental requirements, and choose environmentally friendly production technology and product programs. New projects are required to reduce pollutants in the region. Expansion and reconstruction projects are required to implement ‘carrying the old with the new technologies’ and generally achieve ‘increased production without new pollution’ or ‘increasing production and reducing pollution’.

37. After the explosion in China’s Jilin chemical plant in November 2005 causing serious pollution in Songhua River, SEPA issued the ‘notice on strengthening the management of environmental impact assessment, environmental risk prevention [UNCED (2005) 152]’, requiring the strengthening of EIA and planning of chemical and petrifaction industries, preventing environmental risks from the source of decision-making, strict review of the projects, strengthening the environmental risk assessment management of construction projects and comprehensive investigation, supplementing and improving the preventive measures for environmental risks.

38. Based on the ‘national emergency plan for the environment’ issued by the State Council in 2005, the Environmental Monitoring Bureau of SEPA issued relevant emergency response procedures, and guided the provincial environmental protection departments to formulate and improve the local environmental contingency plans and emergency response systems.

³ Existing chemical substances means that the substance already include in the name list “inventory of existing chemical substances in China”. The existing chemical substances used to be produced or be imported in China.

39. In accordance with 'Regulation on Safe Management of Hazardous Chemicals' issued by the State Council, the SAWS, since 2002, carried out the system of licensing for the safe production, for operation production and safety registration for enterprises that r produce, store and use hazardous chemicals. It also established an emergency planning system for hazardous chemical facilities listed as major hazard sources, and established a national emergency rescue command center for safe production of hazardous chemicals and a local emergency rescue center.

3.3 Management List of Chemicals and Management Focus

40. Of the 45,000 chemical substances that China has produced or imported from 1992 to 2005 that are listed in the SEPA 'Inventory of the existing chemical substances in China', there are, according to the State Council 'Regulation on safe management of hazardous chemicals', 3,700 hazardous chemicals on the 'List of hazardous chemicals (2002 edition)' issued by SAWS.

41. By September 2006, there were more than 1,000 banned or severely restricted chemicals on the control list of safe and environmental management issued by relevant ministries of the State Council (see Annex 1 Table 4).

42. According to the 'Regulation on safe management of hazardous chemicals' by the State Council, the objects of management of hazardous chemicals in China are chemicals in the 'Name list of dangerous goods', acutely toxic chemicals, production and storage facilities of major hazardous sources of chemicals. Priority chemicals to be managed are chemicals with explosive, flammable, oxidizing, corrosive and acute toxic characteristics.

43. The environmental management of chemicals by SEPA is mainly focused on the supervision and management of toxic chemicals with acute toxicity. Management by SEPA is mainly focused on life cycle emissions of chemical pollutants, end of pipeline control and disposal of toxic chemicals released into the environment and the environmental management on import/export of toxic chemicals.

3.4 Technical Support for Management of Chemicals

44. Under the jurisdiction of the national and local environmental protection, public health, agriculture, quality inspection, industrial, technological and educational departments, there are thousands of national and local research institutes for research of environmental monitoring of chemical pollutants, monitoring of pesticide residues, research and development of pesticide alternatives, standards establishment, pollution prevention and control, prevention of diseases and poisoning, information management, et al. They provide the government departments with technical support.

45. Environmental monitoring in China is a four-grade monitoring and management system consisting of general station, provincial, the city and county stations. The general and provincial environmental monitoring centers (stations) are equipped with large-sized advanced analytical instruments, better specialized technical personnel and capabilities for detection and analysis of chemical pollutants.

46. China has established a number of laboratories testing physicochemical, toxicological and ecotoxicological properties of chemicals. Most of these laboratories belong in relevant research institutions of ministries or large enterprises.

47. There are 8 ecotoxicological testing laboratories under the SEPA system, including the key laboratory of ecological effect and risk assessment of chemicals, Chinese Research Academy of Environmental Sciences, et al., which may engage in assessment and test of environmental hazards.

48. There are 25 health toxicology testing laboratories under the MoH and the SFDA, including the occupational health and poison control stations of Chinese Disease Control and Prevention Center, etc., which may engage in testing research of acute toxicity, chronic toxicity, carcinogenicity, mutagenicity, reproductive toxicity, safety pharmacology and toxicokinetics of drugs, cosmetics and other chemicals.

49. There is a pesticide testing laboratory system consisting of hundreds of pesticide laboratories under the MoA, including the centers for agrochemical, biological and environmental technology, institute for the control of agrochemicals, MoA, which may engage in testing and evaluation projects of pesticide residues, pesticides toxicology, environmental toxicity, pesticide efficacy and in biological testing.

50. There is a group of testing and evaluation laboratories engaging in industrial chemicals, cosmetics, electronics chemicals and food under the AQSIQ system, including the institute of industrial product inspection, the Chinese Academy of Inspection and Quarantine, and there are 10 testing laboratories for hazardous characteristics of chemical combustion, explosion and other physico-chemical properties being built currently.

51. As for the certification and supervision of chemical testing laboratories (Good laboratory practice, GLP), these laboratories are supervised by different related ministries respectively. According to the 'OECD chemical testing criteria' and the GLP, SEPA promulgated 'the guidelines for the testing of chemicals - test method for chemicals (HJ/T153-2004)' and the 'guidelines for chemical testing good laboratory practices (HJ/T155- 2004)' in 2004, and began to develop management of ecotoxicology laboratory and inspection of qualified laboratory GLP.

52. SFDA issued 'information on promoting the implementation of quality management criterion for non-clinical drug research in November 2006, the notice

requirements since January 1, 2007, for Chemical Raw Pharmaceuticals and its preparation, biological products, traditional Chinese medicine injection that are not in the domestic market should have their non-clinical safety research and evaluation in GLP certified laboratories. Otherwise, their applications for drug registration will not be accepted. At the same time, a list of 22 GLP certified pharmaceutical laboratories is also issued.

53. MoA issued the ‘good laboratory practice for toxicological safety evaluation of pesticide’ in 2003, and implemented in the ‘measures on evaluation management of good pesticide laboratory’ in November, 2006, and began to carry out GLP inspection and evaluation of pesticide testing laboratories.

54. The MoH promulgated the ‘criterion of management of identification of toxicity of chemicals’ in 2001, raised regulatory requirements to the identification of toxicity of chemicals and identification agencies, but didn’t implement GLP criterion management to the safety evaluation laboratories of cosmetics and toxicological testing laboratories under its supervision.

55. The National Certification and Accreditation Regulatory Committee promulgated a ‘General requirements for the competence of calibration and testing laboratories’ and ‘criteria for laboratory accreditation evaluation’ in 2006. In accordance with international standards of ‘General requirements for the competence of calibration and testing laboratories (ISO/IEC17025: 2005)’ and national standard ‘General requirements for the competence of calibration and testing laboratories (GB/T15481: 2000)’, they begin to develop evaluation and certification of laboratories based on their capacity and qualifications

56. China is not a member of OECD. It does not fully adopt the internationally accepted ‘OECD guidelines for testing of chemicals’ and ‘principles of good laboratory practice’ on criteria for evaluation of new chemical substances, qualified laboratories assessment, certification and review, and supervision and management of Labs. Whether the testing methods, management program and management requirements in the majority of chemical testing laboratories accord with international management criteria must still be determined. Evaluation and certification management of chemical testing laboratories in China is in the beginning stages, laboratory testing ability and management cannot meet the domestic demand for safe and environmental sound management of chemicals. Therefore, chemical test results are not recognized and accepted by other countries.

4 Regulatory systems and good practices on SMC in developed countries and international policies

57. From 1970s to 1980s, as a result of the significant impact of and general concern over environmental issues caused by certain synthetic chemicals, ie., DDT and PCBs, Chemical legislation was widely established in developed countries. As a result of such chemical legislation, regulatory systems on environmentally sound management of chemicals were set up step by step, with risk assessment and risk management as the basic idea, whose core content is to carry out notification, evaluation and authorization of new chemicals newly produced, imported and entering into market, and to carry on hazard testing, risk assessment and risk management of existing chemicals in the market according to special priority principle and order. Meanwhile, the developed countries have established a number of basic systems on pollution control, accident prevention and emergency response during the life cycle of hazardous chemicals, to control the environmental and health risks of hazardous chemicals. Whereas the processes of information, collection, evaluation and risk assessment of hazards and risks of existing chemicals are slow, since the beginning of 21 century, to accelerate the information collection, evaluation and risk management processes of hazard and risk information of existing chemicals, some developed countries have further reformed the current system on risk assessment and risk management for existing chemicals, pursued chemicals testing, evaluation and priority chemicals risk management system by taking the “precautionary principle” and extending risk responsibility of chemicals’ manufacturers as main content, such as the EU REACH legislation. In addition, a number of effective new chemicals environmental management approaches were explored and implemented, to accelerate the process of existing chemicals hazard risk assessment, and to continually identify, screen, and eliminate the PBT chemicals and other hazardous chemicals with high environmental risks.

4.1 Basic Systems of Chemical Environmental Management

4.1.1 New Chemical Substance Notification System

58. New chemical substance notification system is a basic system for environmental management of chemicals. New chemicals manufacturers or importers notify the basic property and hazard information of new chemicals to the state administrative departments, and the competent departments carry on assessment and authorization of chemicals hazards and environmental and health risks and take management measures according to the actual condition before placing on the market or import of new chemicals, such as notification, prohibition or restriction etc. From 1970s to 1980s, most developed countries have established new chemicals notification systems by legislative acts specifically for chemicals, e.g. "Chemical Control Act" of Japan in 1973, Toxic Substances Control Act (TSCA) of the United States in 1976 and 79/831/EEC Directive for dangerous substances classification, packaging and labeling (the sixth amendment of EU 67/548/EEC) in 1979.

59. In the EU the volume for notifications of new chemicals marketed or imported was divided into three grades and the higher the marketed / imported volume of new

chemicals, the stricter and more detailed the data required. EU requires declarers to provide various health and environmental hazard data consistent with the OECD's Good Laboratory Practice (GLP) requirement and the testing guidelines. The OECD developed a unified minimum data requirement for new chemicals notification generally followed by EU and other OECD countries, the so-called "Minimum Data Set", and its contents are basically consistent with the "Base Set" shown in Annex 3.

60. TSCA can be divided into 4 parts: (1) general information, including types, molecular formulas, composition and purity of new chemicals, preparation process, production/import volume, use and the occupational safety notes of new chemicals, etc.; (2) human exposure and environmental release information, including operating rules, occupational exposure assessment and protection measures, environmental exposure assessment and control technology information; (3) appendix safety and testing information, including material safety data sheet (MSDS), existing health and environmental toxicity data, physical and chemical nature, etc. test data (optional); (4) information that is optional to provide, including related information of pollution prevention. The extensive health and environmental hazard information of chemicals evaluated and reviewed under the U.S. new chemicals notification system is shown in Annex 4. Unlike the EU, data in connection with new chemicals notification under TSCA, the U.S. statute, is based on existing data and usually additional testing is not mandated.

61. For new chemicals proven to have unreasonable health and environmental risks after the evaluation, new chemicals notification system prescribes to take risk management measures, such as the prohibition or restriction of their production, use, import and export.

4.1.2 Risk Assessment and Risk Management System on Existing Chemical Substances

62. "Existing chemical substances" are the chemical substances which were produced, sold and used in the market during certain time in the past (EU) or from certain time to now (USA). In 1993, EU promulgated "Regulation EEC (No) 793/93 on the evaluation and control of the environmental risks of existing substances", requiring the manufacturers and importers of chemicals for information notification who had produced or imported in quantities in excess of 10t/y by stages before 1998 and prescribing the manufacturers and importers of HPV chemicals which are produced or imported in quantities in excess of 1,000t/y to submit a few sets of chemicals risk assessment data including the approach to environment and fate, eco-toxicity, acute toxicity, sub-acute toxicity and so on. EU established an inventory of existing chemicals named "**EINECS**⁴: **E**uropean **I**nventory of **E**xisting **C**ommercial

⁴ "EINECS" means the European Inventory of Existing Commercial Substances. This inventory contains the definite list of all substances deemed to be on the Community market on 18 September 1981, see Article 2 para 1 lit. h) Council Directive 92/32/EEC (OJ L 154 p. 3, 5 June 1992).

Substances”, and started 1993 an existing chemicals priority risk assessment and risk management plan EU countries, in order to gradually assess and control the environmental and health risks of existing chemicals.

63. In TSCA, EPA may request the chemical producer or importer to provide hazard testing information of a chemical substance, and take regulatory measures in the form of prohibiting the manufacture of the substance, or of strictly regulating its use, or both, when the chemical substance presents an unreasonable risk of harm to health or the environment or the amount of the chemicals could cause significant human or environmental exposure but the data for basic risk evaluation was lacking and toxicity testing was necessary. TSCA also authorized the establishment of a testing advisory committee for EPA to provide priority chemical substance list for testing, evaluation and risk management of existing chemicals.

64. Given the large number of existing chemicals and the complexity of chemicals risk assessment, priority risk management has become the basic policy for the risk assessment and management of existing chemicals. This has led to institutional or systematic hazard testing for the high production volume chemicals (HPV, production volume > 1,000 tons / year) which generally means high exposure probability, and risk management measures being taken according to specific standards for certain high-risk or priority chemicals, e.g., prohibit or restrict the production or use of certain “priority toxic chemicals”, such as PBT, CMR or vPvB chemicals. Priority risk management is also reflected in the new EU-REACH system that requires manufacturers and importers of substances in quantities of 10 tonnes or more per year to assess the risks arising from the “identified” uses of their substances.

65. Risk assessment and risk management of existing hazardous chemicals, risk information notification, necessary testing and risk assessment, and risk management principles for priority chemicals, can enable governmental managers to obtain the basic information on hazards and risks of existing chemicals. Based on that, risk management actions including, prohibition or restriction of the production and use of certain priority chemicals with high environmental and health risk can be reasonably conducted by the governmental authorities, and the environmental and health risk of existing chemicals may be gradually reduced. Therefore, risk assessment and risk management system for existing chemicals has become another basic tool of chemicals environmental management, EU’s REACH legislation can be considered as its reinforcement. REACH aims at companies doing their risk assessments themselves. In addition, it provides mechanisms for the authorities to introduce European wide risk management measures for substances with unreasonable risks by adopting restrictions and through the authorization system.

4.1.3 EU-REACH System (2006/2007)

66. In December 2006 the EU adopted its “REACH-Regulation” which entered into force on 1st June 2007. The Regulation replaces a number of regulations on

environmental management of major chemicals that had been established since the 1970s. The purpose of the REACH-Regulation is “to ensure a high level of protection of human health and the environment, ..., as well as the free circulation of substances on the ...[EU] market while enhancing competitiveness and innovation.” Thus, it combines economic growth and the protection of human health and the environment. Also the precautionary principle has been taken into account when the REACH Regulation was developed and its requirements were fixed, and the principle now “underpins” the provisions of the Regulation.

67. REACH inter alia aims at resolving the problem of lack of information on existing chemical hazards and risks, and at accelerating the existing chemicals risk management process. REACH reverses the “burden of proof“ for existing substances from the authorities to the enterprises so that it is up to them to perform the risk assessment for the “identified” uses of the substances they manufacture or import above a certain quantity and to communicate the results both to the authorities and to downstream user-customers. The REACH system includes the main contents as in Annex 5⁵.

4.1.4 Pollution Control and Right-to-Know System—TRI or PRTR System

68. Pollutant Release and Transfer Register (PRTR) is the list or registration book for the release and transfer of toxic chemical pollutants from various sources to the environment, which includes the release data of toxic chemical pollutants from various of pollution sources to air, water and soil, and the transfer data of them to the pollution control facilities or disposal sites, and also includes integrated report of total situation of the toxic pollutants release to the environment.

69. Toxics Release Inventory (TRI) system is a major original version of PRTR system. The United States passed the "Emergency Planning and Community Right-to-Know Act" (EPCRA) in 1986, which established a TRI system, stipulating that all enterprises having the release of certain toxic chemicals regulated in the inventory up to a certain amount should annually report the amount released into the environment. At present, more than 600 toxic chemicals are reported in the TRI system. At the same time, EPCRA requires EPA to gather the above data, form a TRI report and publish it annually so that it is publicly available. The TRI system has been very effective with respect to pollution control and the prevention of major accidents of hazardous chemicals, e.g. gathering the release information of toxic chemicals which provided the basic support for identification of the risk, the evaluation of the effectiveness of the pollution control measures and then the environmental management decision-making.

70. Though the name and form of PRTR systems vary in different countries, it usually has the following basic elements: chemical pollutants are reported according to a toxic chemicals list); industrial enterprises report; total release and transfer report; the fate

⁵ For more information please check the Annex.

of various of environmental media (air, water, soil) report; periodic report (annually); unified data reporting formats and database systems; information open to the public (subject to protection of certain confidential commercial information); improve environmental quality and promote cleaner production technology. Currently, PRTR systems have been established in most OECD countries. At the third meeting of IFCS, establishing a PRTR system was listed as one of the major targets of the chemicals management action of the international community after 2000. In May, 2003, 36 European countries jointly signed a "PRTR Protocol" to build a unified PRTR system in the international community.

4.1.5 Environmental Standards and Monitoring System of Toxic Chemical Pollutants

71. In 1972, the "Clean Water Act" (CWA) issued by the United States put forward the "prohibit large emissions of toxic substances" policy requiring EPA to publish a list of toxic pollutants, and establishment an "adequate safety margin" standard. In 1977, the "Clean Water Act" amendment formally proposed a standard control inventory including 129 priority toxic pollutants, requiring EPA to establish corresponding emission standards of toxic pollutants for the temporal 21 types of industrial sources. Currently, water quality standards established by the United States, Europe and the WHO generally have more than 50 indexes, most of which are toxic pollutants. Current drinking water standards in the United States contain more than 50 kinds of toxic organic pollutants and more than 10 kinds of heavy metals and other inorganic toxic pollutants. Meanwhile, toxic pollutants are usually the important indexes in environmental standards of drinking water sources and hygienic standards of drinking water quality. In 1990, the United States put forward the toxic pollutant inventory including 189 species in the "Clean Air Act", requiring EPA to establish and enact the emission and control standards for 41 categories of pollution sources. Till 1996, EPA had established the water pollution emission standards for 52 industries and the toxic air pollutant emission standards for 47 types of pollution sources.

72. In the EU, under the Water Framework Directive, a list of EU priority substances will be established⁶, EU drinking water standards are also fixed in a Directive⁷, and there are also rules on air quality⁸.

73. Because of the many types of toxic chemical pollutants, they are often difficult to monitor on a day-to-day, routine basis, but in developed countries, toxic pollutants are always included in the annual environmental quality report. For example, the United States annual report on environmental quality has a specific chapter, "toxic chemicals", reporting the actual results of toxic pollutants environmental monitoring throughout the country. Monitoring and reporting of the environmental pollution of

⁶ http://ec.europa.eu/environment/water/water-framework/priority_substances.htm

⁷ http://ec.europa.eu/environment/water/water-drink/index_en.html

⁸ <http://ec.europa.eu/environment/air/index.htm>

certain priority hazardous chemicals is the basic work of chemicals environmental risk identification, assessment and risk management.

4.1.6 Major Hazard sources Management and Emergency Response Plan

74. Major hazard sources management and emergency plans system is a chemicals management system established especially for prevention and emergency disposal of major hazardous chemicals leakage accidents harming the environment and public health. In 1993, the International Labor Organization (ILO) organized countries all over the world to sign "Convention on the Prevention of Major Industrial Accidents" (Convention 174), to make the major hazard sources management system be universally established in the world. According to the definition of Convention 174, "major hazard sources" refer to the facilities used for permanent or temporary production, processing, transit, use, disposal or storage of one or more than one kinds of hazardous chemicals whose volume exceeds the threshold value. Convention 174 regulates that member states should establish, implement and periodically review the national policy on protection of workers, public and environment and prevention of major accidents risks in accordance with national legislation, conditions and norms.

75. Major hazard sources identification standards and safety reporting system are basic elements of a major hazard sources management system. Annex 6, taken from the "Directive on Prevention of Major Accident Hazards of Dangerous Substances (96 / 82 / EC)" (Seveso Directive II) established in 1996 by EU, shows that this major hazard sources identification standard compartmentalizes the harmfulness of hazardous chemicals in accordance with the hazardous character and hazardous degree, which especially includes an "environmental harm" index. The EU major hazard sources identification standard is divided into two threshold levels, taking the management measures of different degree according to different magnitudes and differences in corresponding hazardous degree. EU classification identification standards of the major hazard sources have broad significance, and ILO has established the major hazard sources identification threshold for 180 species (categories) of chemicals according to Seveso Directive for reference by all countries in the world. The safety reporting system means that the enterprises with major hazard sources must first report various information and data related to major hazard sources to the governmental authorities, to carry on dynamic information management. Seveso Directive II respectively adopts the so-called "safety notification book" system and "safety report" system according to different magnitudes and corresponding different hazardous degree.

76. An emergency response plan is a plan or scheme established in advance of the possible major accidents or disasters, to ensure to that rapid, orderly, effective emergency and rescue actions are taken to reduce accidents and losses. It is an integrated and detailed arrangement based on the identification and assessment of potential major hazards, accident types, the possibility of occurrence, , consequences of the accidents and the severity of the impact, that elaborately designate the response

agencies and duties, personnel, technology, equipment, facilities, materials, rescue actions and their command and coordination, etc. In general, the emergency response plan creates a systemic emergency response mechanism in which enterprise, government, community and the public all play an active role. Most government agencies are involved, such as public security, fire protection, environmental protection, medical care, sanitation and the media, etc.

77. In the United States EPCRA places toxic chemical accident emergency response plans within the legal system. In the EU, emergency response plans are part of the Seveso II Directive.

78. In 1993, the International Labor Conference passed "Convention on the Prevention of Major Industrial Accidents" also list emergency plans as necessary measures for prevention of major accidents.

4.2 Non-regulatory Measures and Actions on SMC in Developed Countries

4.2.1 Voluntary Agreement (VAs)

79. Since the 1990s, voluntary agreements signed between the government and the chemical industry in order to implement risk assessment and risk management of chemicals is developed widely in developed countries, and it has become an important means of environmental management policies on chemicals in many countries. European Commission statistics showed that among the more than 300 Voluntary Agreements on environmental management signed by European governments and businesses, the proportion of the VAs between the government and the chemical industry is nearly 30%, while the remaining several industries probably about 10%. There has been greater use of VAs in chemical environmental management in the USA and they have become a major means of implementing chemical environmental management policies and strategies. "33/50 Plan" is a VAs plan developed by EPA to reduce the polluting emissions of 17 species of toxic chemicals. In 1998, the government of the United States issued a government motion called "Chemical Right-to-Know" in order to accelerate the test of environmental and health hazard caused by chemicals and the publication of the risk information, and initiated the "HPV chemicals challenges (HPVCP)" and "Voluntary Child Chemicals Evaluation Plan "(VCCEP), which have succeeded in establishing a working relationship among government, the chemical industry and public interest groups. Many community stakeholders voluntarily committed the hazardous test and risk assessment of most existing chemical substances and some preferential high risk toxic chemicals in more than 2800 HPV chemicals. In January 2006, EPA and 8 companies agreed on the "2010/15PFOA responsibility management plan", in order to reduce and eliminate PFOA; and its related precursors step by step before 2015.

4.2.2 Responsible Care

80. "Responsible Care" is chemical industry's voluntary action, hammering at improving the environmental, safety and health information and performance in

technology, throughout a chemical's life cycle, publicizing the information, communicating and cooperating with community stakeholders, prompting chemical businesses to take responsibility for chemical management in chemical industry and supply chain, and to protect the environment and human health.

81. The ideas of RC were first initiated by the Canadian Chemical Producers Association in 1985, they were then adopted by the U.S. Chemical Manufacturers Association and the Chemical Industry Association of the EU and Japan. Later, under the promotion of the International Council of Chemical Associations (ICCA), they have been adopted in 52 countries around the world; the production volume of those enterprises taking part in them is close to 90% of the global total. ICCA specially set up RC leading group responsible for the cooperation with the national chemical industry organizations, developing and improving the rules of RC, and continuing to promote the wider use of the RC norms. The RC operations are mainly implemented by chemical industry associations. ICCA/RCLG developed 8 terms of RC core criteria which should be followed by all of the countries. Also chemical companies must sign a formal commitment protocol, and take corresponding actions.

82. RC movements were recognized by UNEP at the Johannesburg Conference on sustainable development in August 2002.

4.2.3 Green Chemistry

83. The "Green chemistry" project aimed at establishing extensive partnerships among the governments, scientific and technological circles and industry's research institute to develop the innovation design of environmentally friendly products and the process, reduce environmental and health risks from chemicals. In 1991, EPA pollution prevention and toxic substances office (EPA/OPPT) launched the "pollution prevention substitutive synthetic route" plan. Its four main areas include: (1) Green chemistry research projects: in 1992 and 1994, EPA / OPPT signed a memorandum of understanding with the National Science Foundation (NSF), to build a partnership, establish a "sustainable environmental technology" Assistance Program, jointly funded green chemistry research. The Presidential Green Chemistry Challenge Program is an annual award scheme for outstanding performance of the chemical industry in promoting green chemistry Awards are given to honor those who promote green chemistry. Under the Green Chemistry Education Program, EPA and the American Chemical Society (ACS) establish partnerships and promote green chemistry education among chemical engineers, students and research staff in university or scientific research institutions. Under the Green Chemistry scientific communication plan, the "green chemistry" project provides funds to various industries, policy makers and the scientific community for green chemistry science, technology advocacy and popular activities.

4.3 Basic Principles and Policies in SMC in Developed Countries

84. Based on the systems and general practices of environmentally sound management of chemicals in developed countries, several basic principles and policies could be summarized as follows.

4.3.1 Prevention and Precaution

85. Many chemicals that had been produced largely and applied widely but lately were testified harmful to the environment and human health, such as DDT, PCBs in 1970s and PFOS recently. They have caused countries to introduce systems that require generation of information before new substances are produced or placed on the market (prevention). Furthermore “to protect the environment, every country should take appropriate precautionary measures. Where there are threats of serious or irreversible damage lack of full scientific certainty should not cause a country to delay cost- effective measures to prevent environmental degradation.” This basic approach was embodied not only in the basic policies and systems of environmental management of chemicals in developed countries and is reflected in the U.S. toxic chemicals regulatory regime, such as with respect to the notification systems of new chemicals, and the risk assessment and risk management systems of existing chemicals, but also underpins the new REACH Regulation. A balance was found in the new Regulation between the burden that enterprises will have to face and the amount of information to be generated on the hazards and risks of substances on which the risk management measures will be based.

4.3.2 Priority Management

86. At present, there are probably over 100,000 industrial and commercial chemicals circulating on the market. Many countries therefore adopt “priority management” as the basic policy and principle of environmental management of chemicals and first manage the chemicals which have higher health and environmental risk, such as HPVCs, PBT, vPvB and CMR. “Priority management” is not only carried out in every basic system of environmental management of chemicals, such as environmental monitoring of toxic chemicals, PRTR, control of major pollution, but is also embodied in international treaties such as POPs and PIC, etc.

4.3.3 Polluter Pays, “Burden of Proof” and Sharing Responsibility

87. During the strategy and system reformation of the environmental management of the chemicals in Europe in recent years, the responsibility of chemicals environmental management has been mainly devoted to manufacturers and importers. In REACH, downstream users are included as well, however the main burden with regard to the generation of information on hazards and risks lies with the manufacturers and importers. The REACH Regulation takes a different approach than United States where the government is mainly in charge of hazards test as well as risk assessment. REACH requires that the chemical manufacturers and importers are mainly responsible for hazard testing and risk assessment.

4.3.4 Public Participation

88. PRTR system as well as VAs and RC action widely pursued by chemical environmental management in developed countries to promote public participation.

4.4 International Policies and Actions on Environmentally Sound Management of Chemicals

89. In the 1992 Rio Conference on Environment and Development, the sound environmental management of chemicals was written into the sustainable development of human society programmatic document "Agenda 21". Since the 21st century, international chemicals management activities developed especially in three areas: the gradual promotion of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS); the extensive subscription of the chemical environmental management conventions; and the Strategic Approach to International Chemicals Management.

4.4.1 Globally Harmonized System of Classification and Labeling of Chemicals

90. Human society has developed a gradual awareness of hazards caused by chemicals. A classification system for hazardous chemicals was first applied by the United Nations Exports Committee on dangerous goods in the 1950s. It produced the concept of hazardous chemicals, and divided them into explosives, compressed gas / liquefied gas, flammable liquid, flammable solid, spontaneous articles / contacting-water-flammable materials, oxidizers / organic peroxides, drugs, radioactive materials and corrosion materials in total of 8 Classes. As human understanding of the hazardous caused by chemicals expanded, particularly for chronic, potential health and ecological hazard, the EU adopted the Directive 92/32/ EEC (the 7th Amendment of 67/548/EEC) to amend the existing classification system, expanding the classification of harmful chemicals from 8 to 15, and mainly adding health and environmental hazard categories of "sensitizing", "carcinogenic", "mutagenic", "toxic for reproduction" and "dangerous for the environment". In 1992, the establishment of GHS became an important element of international chemicals environmental management strategies in "Agenda 21". In 2003, GHS was completed and published. The basic classification system is shown in Annex 7. The international community has made the promotion of GHS in 2008 a basic strategic goal of international chemical management actions. GHS will become the future uniform classification system for hazardous chemicals generally followed by countries, and will greatly promote the process of international chemicals management.

4.4.2 Chemical Environmental Management International Conventions

91. In 1998, the international community came to an agreement on "Rotterdam Convention On the Prior Informed Consent Procedure for certain hazardous Chemicals and Pesticides in international trade". In 2001, it reached agreement on "Stockholm Convention on persistent organic pollution". UNEP and other international organizations are also active in their continued assessment of mercury and endocrine disrupting chemicals globally.

4.4.3 Strategic Approach to International Chemicals Management — SAICM.

92. This global voluntary initiative is built on the concept that “chemicals or chemical uses that pose an unreasonable and otherwise unmanageable risk to human health and the environment based on a science-based risk assessment and taking into account the costs and benefits as well as the availability of safer substitutes and their efficacy, are no longer produced or used for such uses.” The World Summit on Sustainable Development (WSSD) in 2002 developed an Implementation Plan for push forward the world to achieve sustainable development goals of a 21st Century Agenda. The Implementation Plan sets a strategic and time-specific goal to achieve environmentally sound management of chemicals: “to achieve the sound management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment.”

93. From Feb. 4-6 2006, through the common efforts of the international community, the “Strategic Approach to International Chemicals Management” was identically passed in the international chemicals management convention and 9th special conference of UNEP council global environment ministerial conference held in Dubai, United Arab Emirates.

94. SAICM and WSSD both help to achieve the objects of minimizing chemicals’ environmental and health risks, bringing forward collective policy strategies and a series of unified strategies and action schemes with time lines to synthesize and harmonize existing international chemicals safety management actions, including risk reduction, knowledge and information, public treatment, capacity building, and technology cooperation.

5 Gap Analysis of SMC between China and Developed Countries

5.1 Differences in Guidelines of Environmental Management of Chemicals

5.1.1 Guiding Principles for Environmental Management of Chemicals

95. Safe production of hazardous chemicals in China must ensure the safety of people’s life and property, and prevent accidents and environmental pollution. According to ‘Regulation on safe management of hazardous chemicals’, supervision and management scope includes the production, placing on the market, storage, transport, use and disposal of hazardous chemicals, but the regulation places particular emphasis on labor production safety and prevention of chemical accidents, while it does not emphasize health and environmental safety. The environmental supervision and management of chemicals by SEPA focuses particularly on hazardous chemicals with acute toxicity. Environmental management also particularly stresses the "end of pipe treatment" of discharged chemical pollutants.

96. The decision-making with respect to safe and environmentally-sound management of chemicals in China is basically according to certain inherent properties of a chemical and the degree of potential hazard, but less considering its exposure scenarios and risks. For example, China implements a very strict license management system for acutely toxic chemicals, including systems on purchase voucher, purchase license, record-keeping and registration and record of users et al. The 335 acutely toxic chemicals listed in "List of Management of Acutely Toxic Chemicals" in China are determined entirely by the acute toxicity of chemicals to mammals: Determining indicators do not involve the chronic toxicity health harm factors directly related with chemicals, such as the possible chronic toxicity, especially for carcinogenicity, mutagenicity, reproductive toxicity and other special toxicities caused by long and repeated exposure to chemicals, environmental fatality including biological toxicity, persistence and bioaccumulation et al., volume and methods of use and so on in the long-term and repeated exposure to chemicals. China still lacks a set of comprehensive and scientific policies and guiding principles for the environmentally-sound management of chemicals.

5.1.2 Key Objects of Chemicals Environmental Management

97. Environmentally-sound management of chemicals should establish clear objectives and management focus to spend the limited resources on priority areas for improvement.

98. Hazardous chemicals under key management in different countries generally have the following characteristics: (i) chemicals with carcinogenic, mutagenic properties and those toxic to reproduction, teratogenicity (CMR chemicals); (ii) PBT chemicals with persistence, bioaccumulation and toxicity; (iii) chemicals with dangerous characteristics, such as toxicity, flammability, explosiveness and hazardous to the environment and so on, which may lead to a major hazard installation when their production or storage volumes exceed a certain threshold value.

99. Safe management of hazardous chemicals in China doesn't distinguish between specific key objectives and general objectives. For any hazardous chemicals, no matter how serious the hazard, use volume and possible exposure are, relevant departments must implement registration management of it, and review and issue safe production licenses or operating licenses to relevant production and operating units. Currently there is no prioritization mechanism for the numerous existing chemical substances produced and marketed. Neither is there any requirement for production enterprises to carry out tests to determine its inherent hazards and assess the risks, nor any measures on identifying and managing PBT and CMR chemicals, which are chemicals of very high concern.

5.1.3 Social Responsibility for Enterprises

100. Inherent dangers and risks information of a chemical substance is important not only for proper risk control of chemical, but also for protection of environment and

human health, accident prevention and emergency rescue. In developed countries chemical manufacturers and importers have the clear responsibility to provide chemical safety information to the government, company staffs, their customers and to consumers. Enterprises which cause chemical contamination risks should be responsible for carrying out proper classification, packaging and labeling of the hazardous chemicals that they produce, providing the safety evaluation data of chemicals that they produce and sell, assessing the risks and identifying appropriate measures to control the risks, and for monitoring the risk management, the prevention and control of chemicals pollution taken by the competent departments of government.

101. Competent departments of chemicals in China lack understanding of the importance of requiring manufacturers and importers of chemicals to establish and report chemicals safety data by the laws and regulations implemented to identify and manage chemical risks. Although China follows the "polluter pays principle" and implements the pollution discharge system, the establishment and report of chemical safety information are not taken as the unshakable social responsibility for production and import enterprises in the chemicals management. Existing regulations like "Regulation on safety management of hazardous chemicals" do not require enterprises to develop tests of chemicals that they produce or import and to submit testing data and risk assessment reports. Furthermore, given the insufficient analytic ability of the testing laboratories for the supervision and management of chemicals, most of the industrial chemicals produced in China, even high volume chemicals, are not required to undergo hazard testing and assessment and cannot be classified and labeled properly, and their risks are not managed adequately.

5.2 Differences in Regulations and Management Systems

102. China lacks a comprehensive basic law or administrative regulation by the State Council on environmental pollution prevention and control and the management of industrial chemicals.

103. The main differences in regulations of environmental management of industrial chemicals and corresponding management system in China and developed countries are as follows:

5.2.1 Gaps in Control of New Substances

104. China began to implement the notification system of new chemical substance in October 2003. On the basis of identification and evaluation of health and environmental risks of new substances, the new substances according with the standards of hazard evaluation are required to register, before production and import, while chemical substances with high health and environmental risks are banned or restricted with respect to production and use.

105. Implementation of report and registration system of new chemical substances is still at beginning stage. Methods of assessment of new chemical substances are basically based on hazard evaluation, so there are many aspects of exposure evaluation and environmental risk assessment that need improving. 'Provisions on the Environmental Administration of the New Chemical Substances' issued by SEPA is a ministerial rule. Due to its low legal position, the executive implementation is quite unsatisfactory. There is also a big gap in implementation of Notification and Review System of New Chemical Substances in China compared to developed countries.

5.2.2 Gaps in Control of Existing Substances

106. Considering the numerous existing chemical substances produced and sold before chemical safety legislation was developed, and because there is no requirement for testing, evaluation and assessment of risks of most existing chemical substances, it is difficult to achieve accurate hazard classification and safety management. Starting from the idea of prevention and control of risks of chemicals of high concern and the implementation of key safety management, developed countries have universally established the priority chemical test, evaluation and assessment system. Priority chemicals are chemicals which may cause or are likely to cause serious adverse effects to human health or the environment, and are listed on the priority list by competent authorities for testing and evaluation to impose controls.

107. China has no regulation for prior testing and evaluation system of existing chemicals. There are no legislative provisions for screening of chemicals for potential health and environment risk, and relevant risk assessment in existing laws and regulations for safe management of chemicals. At present, China has established a system on prohibition or restriction of production and use of the chemicals under such international agreements as the POPs Convention and PIC Conventions. However, it is difficult for its national competent authorities to take timely countermeasures to forbid the production and use or limit the use of other chemicals of very high concern.

108. Chemicals of very high concern may be exported from developed countries to China, which might lead to a significant increase in risk relevant to hazardous chemicals and safe production in addition to the domestic safety problems.

5.2.3 Report and Emergency Plan of the Major Hazardous Installations – Gaps in Control of Major Installations

109. In China hazardous chemicals only include four categories of dangerous substances - those with explosive, combustibility, reactivity and acute toxicity characteristics. They do not include carcinogenic substances and environmentally hazardous substances and there are only 142 substances in the control list, but due to the lack of any Category criteria, it is impossible to identify other key sources of dangerous substances. Because many such substances, which have attracted international attention, are not included in the national standards on identification of major hazard installations, and the report and emergency plan system of major

environmental hazard installations is not established, it is impossible to ensure effective implementation of prevention and emergency management of accidents of environmentally hazardous chemicals.

5.2.4 Register System of Pollutant Release and Transfer: Gaps in Emission Control

110. Since the early 1990s, according to the authorization of environmental laws and regulations like "Law on Prevention and Control of Water Pollution ", "Law on Atmospheric Pollution Prevention and Control" et al., China has promulgated and implemented the "Provisions on administration of report and registration of pollutants discharge". There are 12 pollutants (COD, oil, cyanide, phenols, arsenic, mercury, cadmium, hexavalent chromium; smoke, dust, sulfur dioxide and industrial solid) the discharges of which are controlled, but other chemical pollutants are not included in the system. Implementation of the system enables environmental protection departments of the government to acquire discharge information of major pollutants from national enterprises, for environmental management purposes including checking the basis of pollution discharge, environmental statistics, analysis of pollution sources, and environmental planning, et al. The information acquired by report and registration for pollution discharge is regularly published in the "Annual Statistic Report on Environment in China" by SEPA for public inquiry usage.

111. There is no PRTR system for environmental management of chemicals in China, and the existing system of pollution discharge reporting and registration is very different from the international PRTR system Because it is hard to master and announce information on production, use, discharge and pollution prevention of environmentally hazardous chemical substances of high concern on health and environment, environmental management of chemicals is not fully reflected in pollution prevention regulations and management policies.

5.2.5 Classification and Labeling System of Chemical Hazards: Gaps in Classification Management

112. Classification and labeling of chemicals is an important means for hazard communication of chemicals. Developed countries have generally established and perfected communication systems for the classification, labeling and material safety data sheet (MSDS) of chemicals. China has already established a classification, labeling and MSDS system of hazardous chemicals. Hazardous chemicals in the existing 'Name list of chemicals' refer to the list of hazardous chemicals in the U.N. 'Recommendations on the transport of dangerous goods'. Chemicals in the current classification system of U.N. 'Globally Harmonized System Classification and labeling of Chemicals (GHS)' with other health and environmental hazard are not included within the scope of hazardous chemicals in China. There are no or very few chemicals of high concern with CMR and PBT characteristics within the scope of safety management in China.

113. Existing "List of Hazardous Chemicals" in China is also established in accordance with the list of hazardous goods in the UN "Recommendation on the Transport of Dangerous Goods", and only includes about 3,000 hazardous chemical substances. For substances or preparations for marketing but not included in the list of hazardous chemicals, manufacturers are not required to make risk assessments and carry out classification and labeling of other hazardous chemical substances or preparations. It is urgent to revise and perfect the category of classification and management of existing hazardous chemicals according to the United Nations GHS classification standards.

5.3 Differences in the Supervision and Management Methods

114. In order to prevent and control risks of chemicals, developed countries take many measures and countermeasures including (i) testing chemicals to identify their inherent properties; (ii) carrying out classification and labeling of dangerous chemicals and making dangerous warning marks; (iii) establish exposure scenarios and assess the risks, (iv) transferring and notifying hazard and risk information of chemicals by establishing MSDS and notifying information to the authorities; (v) taking measures to ban or restrict use of chemicals et al., when there is no appropriate way to control chemical risks.

115. In China, the competent departments favor command and control license management system and methods of registration management, but rarely consider other means to encourage and facilitate enterprises to voluntarily participate in the safe management of chemicals. Many leaders of domestic enterprises regard chemical safety and environmental protection as what the country requires and they have to deal with, rather than as a social and ethical responsibility of the enterprise. There are great gaps in the right-to-know and participation of the public on chemical safety and environmental protection decision-making between China and developed countries.

116. Considering the gaps mentioned above, priority area of Environmental Management of Chemicals in China should include following aspects:

5.4 Insufficient Regulations and Standards System of Environmental Management of chemicals

117. China has established management of special chemicals like pesticides, pharmaceuticals, veterinary drugs, and food additives, which keeps up with the international management program and standard of safety assessment of in-kind chemicals, but needs a set of laws or regulations on pollution control of environmental safety for industrial chemicals. There are many blank spots and imperfections in the aspect of industrial chemicals risk identification and assessment, authorization management system and pollution control standards, et al. Compared with the international chemical safety management system, there are great differences in

chemical health and environmental risk assessment and management and hazardous chemical classification and labeling system in China.

118. Current laws on environment prevention, such as ‘Law of prevention and control of atmospheric pollution’, ‘Law of prevention and control of water pollution’ and ‘Law of prevention and control of environmental pollution by solid waste’, place particular emphasis on end-of-pipeline controls on chemical pollution..

119. Therefore, it is necessary to establish a set of laws or administrative regulations of the State Council on pollution control of industrial chemical environment safety, and take measures of risk prevention and management to solve the pollution prevention problems of environmentally hazardous chemicals.

120. In order to identify and evaluate risks to human health and environment caused by chemicals, chemicals risk assessment guidelines, standards, chemicals environmental standards (such as quality standards of atmospheric environment and water environment, and pollutant discharge standards), and management technology standards, et al. are needed.

5.5 Lack of Clear Principles and Guidelines for Environmentally Sound Management of Chemicals

121. There is no comprehensive and scientific management policy and guiding principle for environmentally sound management of chemicals in China. For the following series of problems involved in national environmentally sound management of chemicals, the clear policy guidance should be suggested by research: (1) What are the position and importance of environmentally sound management of chemicals within the overall strategy on national environmental pollution prevention and control? (2) What are the objectives and guiding principles of environmentally sound management of chemicals? (3) What are the similarities and differences between environmentally sound management of chemicals and safe management of chemical? (4) Which categories of chemicals should be subject to environmentally sound management? (5) How to screen priority test substances from huge quantity of existing substances and assess to determine the list for priority management chemicals? (6) How to strengthen capacity building for environmentally sound management of chemicals?

122. China cries for more international cooperation, and needs to establish environmentally sound management of chemicals by referring to the successful management experience and effective practices of developed countries.

5.6 Strengthening of Enforcement and Supervision Abilities of Environmental Protection Administrative Departments

123. Although there are a series of environmental laws, regulations on management and prevention of environmental pollution of chemicals in China, for the numerous management links of production, management, usage, import/export and prevention of pollution from hazardous chemicals, and lack of personnel and necessary measures and experiences for evaluation and supervision, all of the above lead to insufficient safe and environmental supervision and management by some administrations. Especially in cities and towns with districts under the provincial administrations, many laws and regulations are not effectively implemented.

124. As a developing country, people's standard of living in many areas is low and China needs to develop the economy to resolve social problems such as food and clothing. For the consideration of economic benefit, some local administrations provide poor supervision, which leads to ineffective supervision and management of chemicals. It is urgent to enhance the understanding of people at all levels of environmental protection administrative departments on the importance of environmentally-sound management of chemicals, and strengthen the capacity building of executed supervision and management mechanisms.

125. Secondly, building a system for the environmentally-sound management of chemicals in China is still in the initial stages. With respect to environmental pollution prevention, there are neither clear guidelines for environmentally sound management of chemicals, nor the establishment of chemical risk assessment and risk management systems and technical guidelines that are in accord with international initiatives. China also lacks the experts needed to support a system of environmental risk assessment of chemicals and to develop the necessary evaluation and supervisory capacity

126. At present, the focus of national pollution prevention is still on prevention and control of problems caused by “three wastes” at the end of the pipeline of industrial production, and environmentally sound chemicals management has not yet been added as an important item on the environmental protection agenda. The State has not yet developed definite principles of environmentally sound management of chemicals policies to establish environmental risk assessment and risk management systems and technical guidelines that are in accordance with what the international community has done. The state also lacks the ability to support a chemical risk management system and to evaluate and monitor management.

127. Third, enforcement managers of environmental protection lack the necessary training. The lack of experienced, well-trained hazardous chemicals environmental managers and professional and technical personnel is also a constraint on effective implementation of supervision and management.

128. The reform of the State Council and local governments and the reduction of personnel in all levels of environmental departments, would result in a great change of personnel and great changes in management posts. Currently, the protection agencies of environmental protection bureaus at the provincial and city levels only have 1 or 2 part-time management officials in charge of prevention of environmental pollution from toxic chemicals. Both of the discordant management capacities of managers and their unfamiliarity with relevant laws and regulations on environmental management of chemicals restrict supervision and management.

129. It is urgent to strengthen the technical training of environmental protection managers at all levels, improve their understanding of the importance of environmentally sound management of chemicals and improve their ability to manage, supervise and enforce.

5.7 Insufficient Technical Supporting System of SMC

130. The establishment of a technical support system for environmentally-sound management of chemicals is the important technical support for and guarantee of safe management of chemicals. The technical supporting system includes the criteria of a qualified laboratory system for testing and analysis of chemicals, guidelines for testing and evaluation, principle of qualified laboratory and risk assessment et al., and safety information management system of chemicals.

131. There is no unified qualified laboratory standard for testing and evaluation of chemicals in China. Most of the laboratories are not testing according to internationally agreed "Qualified Laboratories Norms Principle of OECD", and are not certified by national bodies, so they cannot ensure the reliability of testing results and meet the domestic demand of testing data for safe and environmental management of chemicals. The administrative departments of environmental protection, health, agriculture, safe production et al. and their technical supporting units have established their own chemicals registration and management database systems, and carried out related information queries through a chemicals safety database system established by foreign authorities, such as the RTECS database of NIOSH, USA, Hazardous Substances Data Bank (HSDB) of USA medical libraries, the INCHEM database of IPCS of UN, Search System for the International Chemical Safety Cards et al.. However, it is still difficult to obtain basic information on domestic production, use, location of production equipment and the storage, transport and disposal of chemicals, pollution hazards to human health and the environment by exposure of hazardous chemicals, hazard characteristics, toxicity, environmental fate and potential effects on health and environment of related chemicals and chemical products et al. It is difficult for the public to obtain information on classification indicators, fire protection, leakage disposal, and safety protection and pollution prevention of hazardous chemicals. Therefore, establishing and perfecting the management and notification system of safety information on chemicals is also an

important issue in strengthening capacity building when it comes to environmental management of chemicals in China.

6 Recommendations for Policies and Regulatory Framework Building for SMC in China

132. With increased globalization, developed countries have been facing various environmental problems step by step while today developing countries have to face these problems simultaneously. In China, environmental pollutions are characterized as “multiplex and compressed”. China is facing either the traditional or the first generation of environmental problems like city air pollution or lake eutrophication and so-called “new” or “second-generation” environmental problems like environmental issues of chemicals at the same time. Attention as well as understanding of environmental issues and environmental management of chemicals has always been insufficient. In addition, the current chemical management system is a traditional chemical hazard classification system which has great limitations both in management scope and goals. Chemical management in China so far, in fact, is primarily focused on the occupational safe management of specific hazardous chemicals with highly active physical and health hazards, i.e. flammable, explosive, acutely toxic chemicals etc., and there are many gaps in environmental management for a large number of chemicals with potential and long-term hazards to human health and environment. Because of the lack of a basic legislative and administrative foundation, the SMC in China requires improvement. The current environmental management related to chemicals is primarily limited to end of pipe treatment of a few toxic chemical pollutants rather than pollution prevention measures, which does not reflect the basic principles and methods of environmental management of chemicals, such as precaution and risk management.

133. While the environmental management of chemicals is underdeveloped, China is facing increasingly serious pollution from chemicals: many hazardous chemicals widely controlled internationally, are still produced and used without restriction in China. In addition, accidents involving hazardous chemicals happen frequently. Due to this, the ecological and health risks caused by chemicals in China are increasing. Besides, since the beginning of the 21st century, the developed countries have been constantly strengthening their environmental management of chemicals. Results are mainly reflected in legislation and a variety of measures to speed up testing, evaluation and management of health and environmental risks of chemicals. The international community vigorously pushes forward the global agenda on environmentally sound management of chemicals, which was always an important component of the global strategy of sustainable development, and has put forward a strategic goal and the corresponding strategic action plan - SAICM. The SMC is directly related to environment safety and human health in China. China is committed to reform the industrial infrastructure and build an environment-friendly society.

Environmental management of chemicals was sure to be put on the agenda of national environmental protection in the context of scientific development.

134. Based on an integrated analysis of the situation of environmental management of chemicals in China and the experience of developed countries and international policies, the following suggestions are put forward regarding policies and regulatory framework for the SMC.

6.1 Establish a National Strategy on SMC

135. Generally, all future measures on SMC should become a part of the national strategy.

Recommendations

- A. The strategy of SMC in China should define the basic guidelines, principles, policies and overall strategic objectives of the nation's SMC, which should comprehensively consider the precautionary approach and the basic national situation of chemical industry and consumption of chemicals and set reasonable strategic objectives.
- B. The strategy shall be consistent with 'scientific development'. To promote recycling and reuse, to protect the environment, to promote a resource-conserving and environment-friendly society, clean and safe development should be considered in the strategy.
- C. The manufacture and management of chemicals shall follow the ideas of clean production and green chemistry.
- D. Chemicals with high risks to health and environment should be replaced first provided economically feasible alternatives are available.
- E. The strategy of SMC in China should establish a national plan of capacity building on SMC including the legislative system, institutional functions, technical supporting systems, information exchange and public participation mechanisms etc.
- F. Chemicals management strategy should include a long-term action plan for risk assessment and risk management of existing chemicals with set deadlines, following national specific priority principles to collect information on hazards of existing chemicals, carry on risk assessment and risk management actions, gradually reduce and eliminate the production and consumption of chemicals with unreasonable risk to the environment and human health, and last but not least achieve China's "environmentally friendly environment". The strategy chosen must be WTO compliant.
- G. For development of the national strategy of SMC, one national coordination group should be established from environment and human health protection basis to insure the drafting strategy to reflect on interests of the stakeholders.

6.2 Establish a Law or Administrative Regulation on SMC

136. In light of current national legislation in regard to chemicals management establish a specialized law or an administrative regulation on SMC as the fundamental way to fill most of the existing gaps in SMC in China.

Recommendation:

- A. The law or the administrative regulation of SMC should comply with the approach of risk management, establish hazard testing requirements, adopt the GHS for classification and labeling of chemicals to contribute to effective risk assessment and risk management of chemicals, include the GLP requirements for new tox and ecotox tests, establish basic SMC systems mainly including new chemical substances notification, risk assessment and risk management of existing chemical substances, environmental monitoring system for priority toxic chemical pollutants, information gathering and a right-to-know system for the release of toxic chemicals, a major environmental accident prevention and emergency response system, which should be coordinated with the current relevant legislation on occupational safety and public health management.

6.3 Priorities for Basic Administrative Framework (System Building) on SMC

6.3.1 Implementation of GHS as Soon as Possible in Accordance with Internationally Agreed Goals

137. A scientific and comprehensive system of classification and labeling of chemicals is a fundamental condition of chemical hazard identification to contribute to effective risk assessment, information communication and risk management of chemicals. The currently used classification system from hazardous chemicals in China does not fully reflect various potential environmental and health hazards and risks of chemicals, which severely restricts the development of SMC in China.

Recommendation:

- A. Comprehensively implement the GHS for the classification and labeling of chemicals as the basis for new chemical substances notification, risk assessment and risk management of existing chemical substances, and major hazardous installation management system, MSDS system and other systems. This requires manufacturers and down-stream users of chemicals to classify, label and communicate information on the hazards of chemicals according to the GHS in order to effectively control environmental and health risks of certain chemicals.

6.3.2 Promote and Improve the New Chemical Substance Notification System

138. New chemical substance notification is a basic element of SMC. Developed countries have established such a system through specialized legislation in the 1970s, and built up a system with comprehensive guidelines, procedures and good technical and institutional supporting systems. By contrast, the new chemical substances notification system in China was established only three years and launched by a ministerial rule.

Recommendations:

- A. Raise the legal status to strengthen enforcement and establish a specialized legislation for SMC containing the system proposed above.
- B. Take full advantage of advanced experience from developed countries to further improve the enforcement procedure and the cooperation mechanism among relevant government departments.
- C. Create obligations to improve domestic cooperation and information exchange in both ways between relevant ministries and authorities horizontally and vertically
- D. Improve the corresponding technical guidelines and institutional supporting systems, such as GLP criteria and the international mutual recognition of test data, etc., so that the new chemical substance notification system is in accordance with international systems.
- E. Streamline procedures and introduce mechanisms to reduce bureaucracy for cases of less concern such as chemicals in very small quantities or samples. Pay special attention to those chemicals with high risk to health and the environment.

6.3.3 Establish the System of Risk Assessment and Management of Existing Chemical Substances

139. A system of risk assessment and management of existing chemical substances is the basis of collection of risk information of existing chemical substances and risk management. It is also the emphasis of current environmental management of chemicals all over the world. Because of the deficiency of the system, the Chinese government had little awareness of current domestic environmental and health risks of chemicals, did not conduct administrative measures for chemicals with high risks, and always lagged behind the international chemical management approaches.

Recommendations:

- A. Build upon a system of risk assessment and management of existing chemicals close to the requirement of testing and data corresponding to new chemical substances notification, which will mainly include: establishment of a system of priority setting and a system of collection of hazard and risk information of existing chemical substances,
- B. Regulate the obligation of the producers or importers on hazard testing and information notification, whose production or import of existing chemical substances is above a specific volume and collect the hazard and risk information on existing chemical substances in the market;
- C. Put forward basic principles, policies and regulations of priority risk management, e.g., prohibition or restriction of production, use, import and export on priority chemicals, such as PBT, CMRs and vPvB, etc.;
- D. Carry out classification and labeling of existing chemical substances according to GHS;
- E. Determine the implementation mechanisms of the system of risk assessment and management of existing chemical substances; establish specialized legislation for SMC containing the system proposed above is the appropriate

way forward.

6.3.4 Establish National Criteria for the Prioritisation of Chemicals of High Concern

140. National criteria for the prioritisation of chemicals of high concern shall be established according to domestic situation of the chemical industry while taking account of international criteria.

Recommendations:

- A. Set criteria and procedures for prioritisation of chemicals of very high concern while taking into account international criteria for prioritization of toxic chemicals, types (number of chemicals), and volumes of domestically produced and imported existing chemicals. Nationally prioritized chemical types may include PBT, vPvB, CMRs and EDCs, etc.
- B. The risk management of priority chemicals should be based on their different features and their potential risks and hazards towards environment and health. It should take into consideration the exposure during production, utilization and distribution of those prioritized toxic chemicals. Establish national principles for risk management of priority chemicals. Based on this approach, reformulate risk management policy and systems for prioritization of chemicals of very high concern such as PBTs.
- C. Draft a risk management strategy and action plan, in a step by step manner to reduce, restrict or ultimately ban the production and consumption of those chemicals of very high concern to promote the implementation of the Stockholm Convention and other international agreements and arrangements on chemicals management.

6.3.5 Establish a System of Release Recording and a Publication System for Toxic Chemical Pollutants

141. The PRTR is a model for gathering emission statistics on toxic chemical pollutants and informing the public. This type of system acts as a control of environmental pollution of toxic chemicals, prevention of accidents, information publicity and public participation in many countries.

Recommendation:

- A. Make suggestions to assimilate successful experiences from abroad, adopt specific principles of priority management, rationally determine the extension of inventory, industry and enterprises of toxic chemicals which are needed to notify, establish corresponding management information system of collection and publication of data, and gradually establish the system of collecting emission statistics of toxic chemical pollutants and informing the public in China.

6.3.6 Establishment of Environmental Monitoring System for Emissions of Priority Toxic Chemical Pollutants

Recommendation:

- A. Establish a system for the monitoring of priority toxic chemical pollutants, such as PBTs etc. commensurate with the capacity of the existing Chinese environmental and hygiene monitoring system carry out institutionalized and systemic environmental monitoring of the chemicals with high ecological and health risks, compile and release an annual report on the monitoring of national priority toxic chemical pollutants to enable the government and community to understand the situation of environmental pollution from chemicals and their ecological and health risks and provide the basis of decision-making for the efficient promotion of environmental management.

6.3.7 Improve the System of Registration and Reporting of Major Hazard Installations

Recommendation:

- A. Revise standards of identification of major hazard installations (especially need to add corresponding categories and standards of environmentally hazardous substances), improve the current mechanism of implementation and supervision of the registration and reporting system for major hazard installations, enhance data sharing and the responsibilities and rights of supervision and implementation in the system of registration and reporting of major hazard installations, strengthen the law enforcement ability of relevant organizations, sufficiently prevent serious leakage accidents of hazardous chemicals and their environmental effects. Improve the relevant legislative system for the management of existing major hazard installations by reference to relevant international rules and practices of management of major hazard installations, such as ILO, EU Seveso Directive and EPCRA etc.

6.4 Capacity Buildings

6.4.1 Build upon Existing National Administrative Functions and Organizations for Environmental Management of Chemicals

Recommendations:

- A. Build upon the national system of administrative enforcement of environmental management of chemicals, supervision and management by setting up a coordination mechanism among all national level authorities responsible for chemicals management.
- B. Elevate the role of SEPA within the Chinese chemical management system including by increasing the capacity of relevant divisions and departments. Set up specific administrative functions (departments or divisions) for chemicals management and increase the number of staff involved in environmental management of chemicals in central and provincial organizations for environmental protection, including additional relevant managerial departments and officers.
- C. Reinforce corresponding staff training.

6.4.2 Establish a Comprehensive National Information System for Chemicals

142. Availability of information on hazards of chemicals and risks is necessary for environmental management.

Recommendations:

- A. Carry out centralized collection, arrangement and publication of various relevant national information on environmental and health risks of chemicals based on systems such as notification of new chemical substances, risk assessment and risk management of existing chemical substances, environmental monitoring of priority toxic chemical pollutants and their emissions and registration and reporting of major hazard installations, consistent with the protection of confidential business information.
- B. Link existing national chemical information sources and management system such as those concerning existing and new chemical substances, as well as occupational health and safety issues.
- C. Further enhance global information exchange on chemicals.

6.4.3 Strengthen National Capacity on Testing, Evaluation, Research and Monitoring of Chemicals

143. Promote cooperation among departments including those managing national environmental protection, public health, science and technology, and others in the following areas.

Recommendations:

- A. Increasing capacity for testing of environmental and health hazards of chemicals by establishing laboratories for testing and evaluation of chemicals in accordance with OECD / GLP guidelines and by introducing GLP monitoring and other programmes such as mutual acceptance of data (MAD).
- B. Increasing capacity to conduct basic research on and to monitor the environmental and health components of risk assessment, particularly with respect to priority high-risk and toxic chemicals.
- C. Development of international cooperation related to hazard testing and risk assessment of chemicals, learn and adopt international chemical risk assessment practices to continually improve capacity in China.

6.5 Strengthen Environmental Governance on Chemicals

6.5.1 Promote and Support Policies for Voluntary Risk Management of Chemicals

144. While gradually improving the governmental management system, promote participation of all chemical stakeholders, especially the wide participation of the chemical industry as the basis for successful implementation of state environmental policies for the sound management of chemicals. Voluntary Agreements (VA) between government and enterprises and Responsible Care (RC) action taken by chemicals enterprises are good practices carried out for the environmental management of chemicals in developed countries. The Chinese "Cleaner Production

Promotion Law" has already established the legal status of VA, and put forward a number of incentive policies.

Recommendations:

- A. Encourage the implementation of VA, RC and Product Stewardship in China, in communication with Chemical Industry Association. Research and establish a series of relevant matching policies and measures of management to promote the gradual implementation of VA and RC of environmental management of chemicals in China on the basis of current regulations of "Cleaner Production Promotion Law".
- B. Improve performance under VAs including by clarifying their legal status, and control procedures, and engaging in performance audits.

6.5.2 Improve Information Publicity and Public Participation Mechanisms for the Environmental Management of Chemicals

Recommendations:

- A. Enhance publicity of and communication information concerning the environmental and health risks of chemicals by making information on pollution emissions and environmental monitoring of toxic chemicals publicly available.
- B. Establish education programs on the environmental and health risks of toxic chemicals for the general public.
- C. Establish public participation mechanisms that provide stakeholders with a platform to participate in government decision-making on chemicals management consistent with international trends.

Annex 1 Main Management Regulations on Environmental and Safety in China

Table 1 Main Environmental Laws, Regulations Related to Chemical Management in China

Name of law/regulations	Issued by	Enforce date	Scope of application
Environmental Protection Law	Standing Committee of the NPC	1989.12.26 amendment	Basic law of environmental Protection
Law on Prevention and Control of Water Pollution	Standing Committee of the NPC	1996 amendment	Prevention and control of pollution of rivers, lakes, canals, reservoir, surface and underground water
Law on the Prevention and Control of Atmospheric Pollution	Standing Committee of the NPC	2000.9.1 amendment	Prevention and control of air pollution, protection of living and ecological environment
Law on the Prevention and Control of Environmental Pollution by Solid Waste	Standing Committee of the NPC	2005.4.1 amendment	Prevention and control of pollution of solid wastes and hazardous wastes
Marine Environment Protection Law	Standing Committee of the NPC	1999 amendment	Protection of ocean environment and resources, prevention of pollution and damage
Law on the Environmental Impact Assessment	Standing Committee of the NPC	2003.9.1 amendment	Prevent environment from adverse impact of chemical and other construction projects, and promote coordinative development of economic, social and the environment
Law on Promotion of Cleaner Production	Standing Committee of the NPC	January, 2003	Promote cleaner production, eliminate and phase out backward production technologies, processes, equipment and products, which waste resources and severely polluted the environment
Decision on Implementing Scientific Development and Strengthening Environmental Protection	State council	December, 2005	Implement scientific development and strengthen environmental protection and pollution control of toxic/hazardous chemicals

Name of law/regulations	Issued by	Enforce date	Scope of application
National Emergency Response Plans for Environmental Emergency Incidents	State council	January, 2006	Establish emergency response mechanism for environmental emergency incidents, raise emergency response capability to protect public health and the environment
Provisions on Environmental Management of New Chemical Substances	SEPA	October, 2003	Notification and registration of new industrial chemicals before production and import
Provisions on Environmental Management of the First Import of Chemicals and the Import and Export of Toxic Chemicals	SEPA, etc.	May, 1994	Import/export management of China's banned and severely restricted chemicals
Interim Provisions on Environmental Protection Management of Import of Wastes	SEPA, etc.	1996	Environmental supervision of import of wastes
Measures for Pollution Prevention and Control of Wasted Hazardous Chemicals	SEPA	October, 2005	Measures for treatment, disposal and pollution control of wasted hazardous chemicals
Management Methods for Control of Pollution Caused by Electronic Information Products	MII, etc.	March, 2007	Environmental pollution Control of wasted IT products, reduction and elimination of use of certain toxic substances in electronic information products.

Table 2 The Laws and Regulations on Safe Management of Hazardous Chemicals in China

Name of law/regulation	Issued by	Enforce date	Scope of application
Law on the Safety Production	Standing Committee of the NPC	November, 2002	Supervision and management of work safety and accident emergency response
Food Hygiene Law	Standing Committee of the NPC	October, 1995	Sanitation management of production and sale of foods
Law on Prevention and Control of Occupational Diseases	Standing Committee of the NPC	May, 2002	Prevention and treatment of occupational diseases, supervision of occupational health

Name of law/regulation	Issued by	Enforce date	Scope of application
Law on Management of Medicinal Products	Standing Committee of the NPC	December, 2001	Supervision of research & development, production, sale, use and safety of medicinal products
Regulations on Safe Management of Hazardous Chemicals	State council	March, 2002	Supervision and management of production, sale, use, import/export of hazardous chemicals as well as major hazardous installations
Regulations of Management of Pesticides	State council	November, 2001 amendment	Supervision of registration, production licence, safe use and import of pesticides
Regulations on safe production licenses	State council	January, 2004	Implementing safety license systems for the production enterprises of hazardous chemicals, fireworks and civil explosive materials
Regulations on Labour Protection at the Workplace Using Toxic Substances	State council	April, 2002	Labour protection for occupational poisoning of toxic substances at work
Regulations concerning Hygiene Supervision of Cosmetics	State council	January, 1990	Supervision of production, purchase and sale of cosmetics
Regulations on Management of Production Licenses of Industrial Products	State council	September, 2005	Implementing production license systems for six categories of major industrial products (including hazardous chemicals) which affect production safety, public safety, personal properties and financial security
Regulations on Management of Narcotic and Psychotropic Drugs	State council	September, 2005	Supervision and management on research & development, production, sale, use, storage and transport of narcotic drugs and psychotropic drugs
Regulations on Management of Feeds and Feed Additives	State council	November, 2001	Quality and safety management of production, import, sale and use of feeds and feed additives
Regulations on Management of Explosives for Civil Use	State council	January, 1984	Safety management of various explosive materials, including explosives, detonators, black gunpowder, pyrotechnics, civil flares and fireworks and others

Name of law/regulation	Issued by	Enforce date	Scope of application
Regulations on Specially Monitoring and Controlling Chemicals	State council	December, 1995	Management of production, purchase and sale, use of specially monitoring and control chemicals which can be used as chemical weapons and their precursor
Regulations on Management of Chemicals Easy to Make Drug	State council	December, 2005	Implement license system for production, purchase and sale, transport, import and export of chemicals easy to make drugs
Provisions on Purchase and Sale Licenses of Hazardous Chemicals	SETC	November, 2002	Supervision of purchase and sale licenses of hazardous chemicals
Rules on Registration Management of Hazardous Chemicals	SETC	November, 2002	Registration management of hazardous chemicals
Rules on Safety Review for Production and Storage Projects of Hazardous Chemicals	SAWS	January, 2005	Safety review and assessment for the newly established, expanded production and storage projects of hazardous chemical enterprises
Rules on Implementation of Safe Production Licence of Hazardous Chemical Enterprises	SAWS	May, 2004	Issuance and management of safe production licenses of hazardous chemical enterprises
Rules on Transport Management of Dangerous Goods by Railways	MOR	January, 1996 amendment	Transport management of dangerous goods by railways
Rules on Transport Management of Dangerous Goods by Waterways	MOC	1996	Transport management of dangerous goods by water routes
Rules on Transport Management of Dangerous Goods by Roadways	MOC	1993	Transport management of dangerous goods by roadways

Table 3 Existing Safety and Environmental Management Systems of Hazardous Chemical in China

Items	Safe production management	Environmental management
Laws and Regulations	Regulations on Safe Management of Hazardous Chemicals; Provisions on Purchase and Sale Licenses of Hazardous Chemicals; Rules on Safety Review for Production and Storage Projects of Hazardous Chemicals, etc	Law on the Environmental Impact Assessment; Provisions on Environmental Management of New Chemical Substances; Provisions on Environmental Management of the First Import of Chemicals and the Import and Export of Toxic Chemicals, etc
Scopes of application	Production, storage, distribution, transport, use, emergency response, import, export of hazardous chemicals as well as wasted chemicals disposal	Notification of new substances pre-production or import; import and export of toxic chemicals; emergency response of environmental emergency incidents; treatment of wasted hazardous chemicals
Target chemical substances	Explosives; compressed or liquefied gases, flammable liquids, combustible solids, spontaneous solids and solids in contact with water to emit flammable gases, oxidizers and organic peroxides, toxic and corrosive substances	New industrial chemical substances; hazardous chemicals on the control lists of the PIC Convention, the POPs Convention and hazardous wastes controlled by the Basel Convention as well as toxic chemicals on the list of banned and severely restricted chemicals in China
Control lists	The List of Hazardous Chemical; The List of Acutely Toxic Chemicals; The Standard on Identification of Major Hazardous Installations;	China Inventory of Existing Chemical Substances; The List of Banned and Severely Restricted Toxic Chemicals in China; The List Severely Restricted Import and Export of Toxic Chemicals; The List of Restricted Import and Export of ODS; China List of Hazardous Wastes
Pre-manufacture and import	None	Notification and Registration system of new chemical substance before production and import

Items	Safe production management	Environmental management
Production and storage projects	Safety assessment system of construction project; Safety production licence system; Report for the record system of production and storage enterprise	Environmental impact assessment report and approval system
Distribution	Purchase and sale licence system; Permit purchase certificate system for acutely toxic chemicals	None
Use	Record-keeping system for acutely toxic chemicals; Keep use record systems; Classification, labeling and MSDS system	Supervision according to categories of banned or restricted toxic chemicals
Transport	transport permit system of dangerous goods ; Carriers certification review and approval system; Package, container, transport vehicle inspection system; Road transport permit system for acutely toxic chemicals; Prohibit to transport acutely toxic chemicals by inner rivers	Management according to the rules of transport of dangerous goods
Emergency response	Emergency response plan system; Report for record system for major hazardous installations; hazardous chemicals accident reporting system	Emergency response plans system for environmental emergency incidents; Environmental pollution and destruction accident reporting system
Wastes treatment	There is only responsibility authorization, but no specific provisions	Supervision of wasted hazardous chemicals according to the regulations of hazardous wastes; Hazardous wastes business permits; Hazardous waste manifest system ; Environmental risk assessment system for abandoned contaminated sites

Items	Safe production management	Environmental management
Import and export	There is only responsibility authorization, but no specific provisions	Environmental management registration system for import/export of toxic chemicals on the control lists of the PIC convention, the POPs convention and other banned or restricted lists

Table 4 Numbers of Controlled Chemicals under Current Safety and Environmental Management Lists in China

No.	Names of the control list	Issued organs	Number of controlled chemicals	Remarks
1	List of Acutely Toxic Chemicals (2002)	SAWS	335 substances	As the basis for identification of acutely toxic chemicals
2	National Standards for Identification of Major Hazardous Installations(GB18218-2000)	GAQSIQ	four categories including 142 kinds of explosive, flammable, toxic and reactive chemical substances	As the basis for identification of major hazardous installations and their threshold values
3	List of Highly Toxic Chemicals (2003)	MOH	54 substances	Occupational health and labour protection at work
4	List of Banned and Severely Restricted Toxic Chemicals in China	SEPA	27 substances (the first batch) 7 substances (the second batch)	Environmental management registration of import /export of toxic chemicals
5	List of Strictly Restricted Import/Export of Toxic Chemicals in China	SEPA	30 categories, including 183 substances	Environmental management registration of import /export of toxic chemicals
6	List of Import and Export Controlled of Ozone-Depleting Substances (2000-2006)	SEPA, China Customs	56 substances in four batches	Environmental management of import and export to implement Montreal Protocol for protection of the ozone layer

No.	Names of the control list	Issued organs	Number of controlled chemicals	Remarks
7	List of Banned and restricted pesticide (MOA Notice No. 199)	MOA	18 Banned, and 21 Restricted used pesticides	Safe management of pesticide
8	List on Categories of Chemicals Easy to Make Drugs (August,2005)	SAWS	23 substances easy to make drugs	Safe management of the chemicals easy to make drugs
9	List of the Specially Monitoring and Controlling Chemicals (1995)	National chemical weapon control office	53 chemicals (categories)	Safe control of Chemicals that can be used to make chemical weapons and their precursors
10	National Standards for hygiene of cosmetics □GB7916-87□	MOH/SEPA	359 banned used substances in cosmetics, including HCB, Dieldrin and DDT	Safety and health protection of cosmetics
11	National Standards for Occupational Health (GBZ2-2002)	MOH/SAWS	329 harmful substances	Maximum Allowable Concentrations in the workshop air
12	Catalogue for Elimination of Backward Production Capacity, Technologies and Products (January,1999)	SETC	29 chemicals in the first, the second and the third batch	Eliminate backward processes, technologies, and severe pollution products
13	Guidance Catalogue for Readjust of Industrial structures	NDRC	29 chemical products (categories) eliminated; 41 chemical products (categories) restricted	Eliminate backward processes and technologies; high resource consumption and severely polluting chemical products

Annex 2 Description of the Tasks of the Authorities

State Environmental Protection Administration (SEPA)

According to the ‘Law on Air Pollution Prevention’, ‘Law on Water Pollution Prevention’, ‘Law on the Prevention and Control of Environmental Pollution by Solid Waste’, ‘Law on Environmental Impact Assessment’ and ‘Regulation on Safety Management of Hazardous Chemicals’ and other laws and regulations, SEPA is authorized to uniformly supervise and manage discharges of chemical pollutants to the atmosphere, It also takes charge of supervision and management of chemical pollution prevention, registration of the new chemicals (substances), disposal of hazardous chemicals waste, investigations of serious pollution accidents caused by hazardous chemicals, and emergency monitoring, registration of import/export of hazardous chemicals, et al. SEPA acts as the internal compliance units and national focal point of the Rotterdam Convention, Stockholm Convention and Basel Conventions and on behalf of the State to participate in environmental protection in international activities, and organizes and coordinates the supervision and management of domestic environmental compliance activities.

State Administration of Work Safety (SAWS)

According to the ‘Law on Safe Production’, ‘Regulation on Safety Management of Hazardous Chemicals’ and other laws and regulations, SAWS is authorized to work in a unified manner on safe supervision and management of hazardous chemicals. It is also responsible for the approval of the safe production licenses, management licenses, and for organization and coordination work on emergency rescue necessitated by use of hazardous chemicals.

Ministry of Health (MoH)

According to the ‘Law on Prevention and Control of Occupational Disease’, ‘Regulation on Safety Management of Hazardous Chemicals’, ‘Regulations on Hygiene Supervision of Cosmetics’ and other laws and regulations, the MoH is authorized to engage in toxicity identification of hazardous chemicals, hazard evaluation on human health, safety evaluation of cosmetics, public health and occupational disease prevention.

State Food and Drug Administration (SFDA)

According to the ‘Law on Management of Drug’, ‘Law on Hygiene Management of Food’ and other relevant laws and regulations, the SFDA is authorized to govern and provide technical supervision on the research, production, distribution and usage of drugs, narcotic drugs, medical equipment; also authorized to provide integrated supervision on management of food, health care products and cosmetics, and to approve health care products.

Ministry of Agriculture (MoA)

According to 'Regulation on Management of Pesticide', 'Regulation on Management of Animal Drug' and other regulations authorized by the State Council, the MoA has authority over the registration and usage of pesticides, and to supervise and provide for safe management with respect to the import and export of pesticides controlled by the PIC Convention and veterinary drugs.

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

According to the 'Law on Product Quality', 'Regulations on Management of Industrial production license', 'Regulation on the management of hazardous chemicals' and other laws and regulations, AQSIQ has authority over the quality of industrial products and the import and export of goods health and quarantine, hazardous chemicals packaging and containers production licensing, supervision, inspection and licensing, certification and standardization work. There are two functional organs under the administration: certification and accreditation administration and standardization administration, charged with establishment of basic norms and rules for laboratory proficiency testing in accordance with relevant national standards and international regulations, unified supervision and coordination certification activities and drafting standardized national laws, regulations and policies and their implementation; charged with formulation, revision, review and dissemination of national standards, respectively.

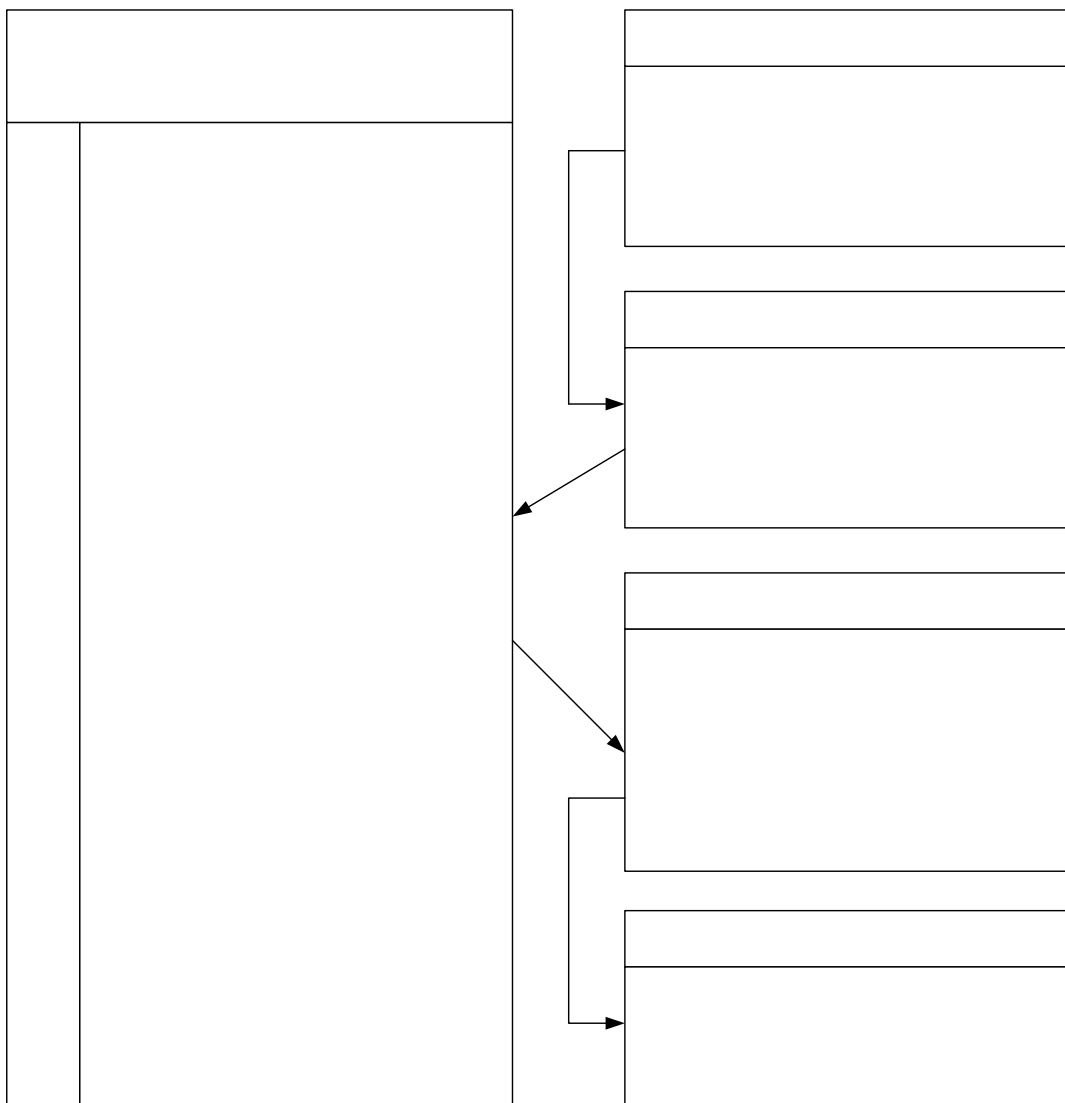
Ministry of Communication, Ministry of Railways and General Administration of Aviation

According to 'Regulation on Safety Management of Hazardous Chemicals' and other administrative regulations, Ministry of Communication and Ministry of Railways and General Administration of Aviation has authority over the safe supervision and management of transportation units by road, sea, railway and air and relevant conveyances for hazardous chemicals.

Ministry of Public Security (MPS)

According to 'Regulation on Safety Management of Hazardous Chemicals' and other administrative regulations, MPS has authority over public safety management of hazardous chemicals, distribution of purchase warrant and purchase permit of toxic chemicals, review and issuance of transport licenses of highly toxic chemicals and safety supervision and management of road transport of hazardous chemicals.

Annex 3 The Data Requirement of New Chemicals Notification Scheme in EU



Annex 4 US EPA Requirements for Test Data in New Substance Notification

EXAMPLES OF TEST DATA

Following is a list of the types of test data which you must attach to the notice form if it is in your possession or control. This list is illustrative, not exhaustive.

	Health Effects Data	Environmental Effects Data
Physical and Chemical Properties and Environmental Fate Data		
◆ Chromatograms	◆ Mutagenicity	◆ Microbial bioassay
◆ Spectra (ultraviolet, visible, infrared)	◆ Carcinogenicity	◆ Algal bioassay
◆ Density / relative density	◆ Teratogenicity	◆ Aquatic macrophyte bioassay
◆ Solubility in water	◆ Neurotoxicity / behavioral effects	◆ Seed germination and root elongation
◆ Melting temperature	◆ Pharmacological effects	◆ Seedling growth
◆ Boiling / sublimation temperature	◆ Mammalian absorption	◆ Plant uptake
◆ Softening point	◆ Distribution	◆ Acute toxicity to invertebrates
◆ Vapor pressure	◆ Metabolism and excretion	◆ Life cycle test on invertebrates
◆ Dissociation constant	◆ Cumulative, additive and synergistic effects	◆ Acute toxicity to fish
◆ Particle size distribution	◆ Acute, subchronic and chronic effects	◆ Early life stage (fish)
◆ Octanol / water partition coefficient	◆ Structure / activity relationships	◆ Avian dietary / reproduction
◆ Henry's law constant	◆ Epidemiology	◆ Bioaccumulation / bioconcentration
◆ Volatilization from soil	◆ Reproductive effects	◆ Model ecosystem studies
◆ pH	◆ Clinical studies	◆ Physical environment impairment effects
◆ Flammability	◆ Dermatoxicity	◆ Flesh staining of aquatic organisms
◆ Explodability	◆ Phototoxicity	
◆ Adsorption / desorption characteristics	◆ Irritation	
◆ Photochemical degradation	◆ Sensitization	
◆ Viscosity	◆ Allergy	
◆ Odor	◆ Skin staining	
◆ Hydrolysis		
◆ Thermal analysis		
◆ Chemical analysis		
◆ Chemical oxidation		
◆ Chemical reduction		
◆ Biodegradation		
◆ Transformation to persistent or toxic products		

From: US EPA Instruction Manual for Reporting Under the TSCA §5 New Chemicals Program; 2004

Annex 5 The Main Contents Included in REACH System

- **Registration:** Registration under REACH requires manufacturers and importers to collect and/or generate information on the hazards and risks of substances in quantities of 1 tonne or more per year before they manufacture or import such substances (this includes the import of substances in preparations). The complete registration dossier will have to be sent to the European Chemicals Agency in Helsinki.

For existing chemical substances (~ 30,000) there will a transitional period, i.e. extended deadlines to enable companies to adapt to the new system. Thus they will have about 11 years to complete hazard testing and risk assessment etc. and register within deadline in batches. This includes the completion of registration of the priority chemicals with a production > 1,000 tonnes/year and of likely CMR and PBT chemicals by the 1.12.2010; with a production > 100 tonnes/year by 1.6.2013; and with a production > 1 tonnes/year by 1.6.2018.

Manufacturers and importers of substances also apply the identified risk management measures and communicate them along the supply chain, in most cases in the safety data sheets.

- **Evaluation:** The newly established Chemicals Agency in Helsinki EU will evaluate and assess the testing proposals for substances in quantities of 100t/a and more. It will furthermore evaluate the quality of a selection of the submitted registration dossiers and, in justified cases, request more information on prioritised substances with a high suspicion of risks.
- **Downstream user obligations:** REACH includes downstream users of substances into the system to ensure the adequate control of the risks of substances along the supply chain.
- **Authorization and restrictions:** Under REACH, the main idea is that enterprises take the responsibility to ensure adequate control of risks of the substances that they manufacture, import or use. Therefore, the restrictions system will be the safety net for cases in which substances pose unacceptable risks that need to be addressed on the European level. The manufacture, use and placing on the market of such substances can be banned or otherwise restricted on the Community level. For substances “of very high concern” a specific authorization procedure may be applied. Substances of very high concern are CMRs, PBT, vPvB chemicals, or substances with an equivalent level of concern as the other substances mentioned like EDCs. In a first step these substances will have to be identified, prioritized and included in an Annex to the REACH Regulation. In the second step, companies who want to place on the market or use such substances included in that Annex need to apply for an authorization for the use of the substance. The authorization will be granted by the European Commission if either the risks arising from the use of the substance are adequately controlled or if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance.

Annex 6 EU Identification Standards of Major Hazard Sources

PART 1

Named substances

Where a substance or group of substances listed in Part 1 also falls within a category of Part 2, the qualifying quantities set out in Part 1 must be used.

Dangerous substances	Qualifying quantity (tonnes) for the application of	
	Notification/ Major- accident prevention policy	Safety report
Ammonium nitrate	5,000	10,000
Bromine	20	100
Chlorine	10	25
Nickel compounds in inhalable powder form (nickel monoxide, nickel dioxide, nickel sulphide, trinickel disulphide, dinickel trioxide)		1
Ethyleneimine	10	20
Fluorine	10	20
Formaldehyde (concentration $\geq 90\%$)	5	50
Hydrogen	5	50
Hydrogen chloride (liquefied gas)	25	250
Lead alkyls	5	50
Liquefied extremely flammable gases (including LPG) and natural gas	50	200
Acetylene	5	50
Ethylene oxide	5	50
Propylene oxide	5	50
Methanol	500	5,000
4,4-Methylenebis (2-chloraniline) and/or salts, in powder form		0.01
Methylisocyanate		0.15
Oxygen	200	2,000
Toluene diisocyanate	10	100
Carbonyl dichloride (phosgene)	0.3	0.75
Arsenic trihydride (arsine)	0.2	1
Phosphorus trihydride (phosphine)	0.2	1
Sulphur dichloride	1	1
Sulphur trioxide	15	75
Polychlorodibenzofurans and polychlorodibenzodioxins (including TCDD), calculated in TCDD equivalent		0.001

Dangerous substances	Qualifying quantity (tonnes) for the application of	
	Notification/ Major- accident prevention policy	Safety report
The following CARCINOGENS at concentrations above 5 % by weight: 4-Aminobiphenyl and/or its salts, Benzotrichloride, Benzidine and/or salts, Bis (chloromethyl) ether, Chloromethyl methyl ether, 1,2- Dibromoethane, Diethyl sulphate, Dimethyl sulphate, Dimethylcarbamoyl chloride, 1,2- Dibromo-3- chloropropane, 1,2- Dimethylhydrazine, Dimethylnitrosamine, Hexamethylphosphoric triamide, Hydrazine, 2- Naphthylamine and/or salts, 4-Nitrodiphenyl, and 1,3 Propanesultone	0.5	2
Petroleum products: (a) gasolines and naphthas, (b) kerosenes (including jet fuels), (c) gas oils (including diesel fuels, home heating oils and gas oil blending streams)	2500	25000

PART 2

Categories of substances and preparations not specifically named in Part 1

Categories of dangerous substances	Qualifying quantity (tonnes) as delivered in Article 3 (4), for the application of	
	Notification/ Major- accident prevention policy	Safety report
1. VERY TOXIC	5	20
2. TOXIC	50	200
3. OXIDIZING	50	200
4. EXPLOSIVE where the substance, preparation or article falls under UN/ADR Division 1.4	50	200

Categories of dangerous substances	Qualifying quantity (tonnes) as delivered in Article 3 (4), for the application of	
	Notification/ Major-accident prevention policy	Safety report
5. EXPLOSIVE where the substance, preparation or article falls under any of: UN/ADR Divisions 1.1, 1.2, 1.3, 1.5 or 1.6 or risk phrase R2 or R3	10	50
6. FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (a))	5,000	50,000
7a. HIGHLY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (b) (1))	50	200
7b. HIGHLY FLAMMABLE liquids (where the substance or preparation falls within the definition given in Note 3 (b) (2))	5,000	50,000
8. EXTREMELY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3 (c))	10	50
9. DANGEROUS FOR THE ENVIRONMENT risk phrases: i) R50: 'Very toxic to aquatic organisms' (including R50/53) ii) R51/53: 'Toxic to aquatic organisms; may cause long term adverse effects in the aquatic environment'	100 200	200 500
10. ANY CLASSIFICATION not covered by those given above in combination with risk phrases: (i) R14: 'Reacts violently with water' (including R14/15) (ii) R29: 'in contact with water, liberates toxic gas'	100 50	500 200

From: Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances

Amended by: Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003

Annex 7 Classification of Chemical Hazards in the GHS System

Hazard category	Category
Physical hazards	Explosive; flammable; oxidizing; Gases under pressure; Self-reactive; Pyrophoric; Self-heating; contact with water emit flammable gases; Organic peroxides; corrosive to metals
Health and Environmental hazards	Acute toxicity; Skin corrosion/irritation; Serious eye damage/irritation; Respiratory or skin sensitization; Germ cell mutagenicity; Carcinogenicity; Reproductive toxicity; Specific target organ systemic toxicity; Hazardous to the aquatic environment

Annex 8 Chemicals Management in Europe, Germany and in the United States of America

By: Ulrike Kowalski⁹, Silke Schmidt¹⁰, David J. van Hoogstraten¹¹

A8-1 Introduction

The China Council for International Cooperation on Environment and Development (CCICED) is a high-level international advisory body, established in 1992 with the approval of the Chinese Government. CCICED has conducted in-depth research on a number of key environmental and development issues and has submitted its policy recommendations to the Chinese government. CCICED is now entering its fourth phase of activity from 2007 to 2011. During this phase, several Special Policy Studies Projects will be carried out. The first is on “Environmentally-Sound Management of Chemicals in China” and consists of a study on major issues and policy framework for Chemicals Management. In this project, a multilateral team of experts will analyze and evaluate the environmental management system on chemicals in China and will learn from advanced international experiences.

This report is a contribution of the International Team that provides an overview on German and European as well as American experiences and trends on Chemical Management.

A8-2 European and National Chemicals Legislation in Germany

A8-2.1 Introduction

“Sustainable development” is the overarching long-term goal of the European Union (EU) set out in the Treaty. The European Sustainable Development Strategy aims, in tandem with the “Lisbon Strategy for Growth and Jobs“, for a more prosperous, cleaner and fairer Europe. As an overarching concept, the EU Treaty requires the integration of sustainable development into all European policies, so that they contribute in an integrated way to meeting environmental, economic and social objectives. Art. 6 of the EC-Treaty provides that “Environmental protection requirements must be integrated into the definition and implementation of the

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Community policies and activities [...], in particular with a view to promoting sustainable development.”

Recognising these linkages, the EU is exploiting the mutually reinforcing elements of environmental, social and economic policy. The Commission now undertakes impact assessments for all major policy proposals to assess whether these are consistent with better regulation and sustainability principles.

As chemicals legislation sets rules for products on the EU market, it is based on Art. 95 of the EC-Treaty, which allows the Community to set rules for establishment and functioning of the internal market. However, chemicals legislation strongly affects areas such as health, consumer and environmental protection in the European Union and therefore the EU institutions need to consider them and find a good balance when developing of any new piece of chemicals legislation.

The first EEC-Directive on chemicals was adopted in 1967. Thereafter, EU Chemicals legislation consisted of a mixture of EC Directives - which must be transposed into national law by national regulations - and EC Regulations, which apply directly. The main pieces of the future general EU Chemicals legislation will be two Regulations: The REACH Regulation¹² and the GHS Regulation¹³. *General* EU chemicals legislation thus means legislation focussing on substances and preparations rather than addressing specific products at a later stage in the life cycle like e.g. rules on toys or batteries or addressing specific environmental compartments like air, water or soil. The waste stage is also excluded from chemicals legislation as there is specific legislation for it.

The Federal Republic of Germany is a member of the European Union and is therefore subject to “primary” EU legislation like the "Treaty for the Foundation of the European Community (EC)" as well as to “secondary” EC-legislation in form of Regulations and Directives. Regulations are directly applicable in Germany, whereas Directives need to be transposed into German law.

Germany is a Federal State. The Powers between the Federal level and the 16 Länder are distributed in the German Constitution. The legislative competencies are divided between the federal level and the Länder level. In contrast, the Länder are generally solely responsible for the enforcement of laws. In the area of chemicals legislation, federal authorities also perform some tasks. Some of these tasks will be shifted to the European Chemicals Agency (ECHA) in future.

¹² Regulation on the Registration, Evaluation and Authorisation and Restrictions of chemicals

¹³ Regulation on the classification, labeling and packaging of substances and mixtures (based on the Globally Harmonized System)

The concept of environmental protection is also set out in Article 20a of the German Constitution which provides a basis for the development and interpretation of environmental legislation in Germany. In most areas, laws are adopted on the federal level, however the Länder contribute to the legislative process in the “Bundesrat”, which is the “Federal Council of Germany”, the “Chamber of the Länder”.

A8-2.2 The "Old" European System of Industrial Chemicals Legislation

A8-2.2.1 Introduction

The German Chemicals Act is the central part of German chemicals legislation. It entered into force on 1st January 1982 to implement the 6th amendment of Directive 67/548/EEC. It was amended 1994 to implement Directive 92/32/EC, which was the 7th amendment of Directive 67/548/EEC. With the latest change in 2002 the Biocides Directive 98/8/EC had been included.

There are different European directives implemented in the German Chemicals Act and its ordinances (Hazardous Substance Ordinance and the Chemicals Prohibition Ordinance): Directive 67/548/EEC on notification, information exchange, risk assessment, classification, packaging and labeling of chemicals, Directive 1999/45/EC on Classification, packaging and labeling of preparations and Directive 76/769/EEC on Limitations of Marketing and Use.

The European Regulation (EEC) No 793/93 on the Evaluation and Control of Risks of Existing Substances, those chemicals which have been produced and marketed before 1981, is directly applicable in Germany. This Regulation however will be repealed on 1st June 2008. Most parts of the German chemicals Act will become obsolete at the same time, as then REACH will become operational and most parts of the REACH Regulation apply.

The purpose of the German Chemicals Legislation is the protection of human health (both workers and consumers) and the environment from harmful effects of hazardous chemical substances. This purpose is achieved by the identification of the hazard through testing of chemicals, by the warning of hazards through classification and labeling of the chemicals, the communication of basic information about hazards and risks in safety data sheets and by bans or other restrictions, if no other means of protection is possible.

To perform the tasks of gathering, exchange of information and assessment on chemicals for the performing the risk assessment and for proposing risk management measures and restriction the **BAuA, Division 5**, as the appointed Competent Authority (*thereafter: CA*) co-operates with the following German authorities, the **UBA**, the Federal Environmental Agency, the **BfR**, the Federal Institute for Risk Assessment, the **BAuA, Division 4**. In certain cases the **Federal Biological Research Centre for Agriculture and Forestry (BBA)** and the **Federal Institute for Materials Research**

and Testing (BAM) are included in the process.

The Chemicals Act regulates the duties to test, notify, classify, label and package new substances properly. New substances are all substances not listed in EINECS, the European Inventory of Existing Commercial Chemical Substances. Substances, preparations or products which are regulated by special laws are exempted or only subject to the scope of the law to a limited extent.

The Chemicals Act follows the following main principles: The Producer or importer is responsible for the chemical, not the user or the consumer. The producer or importer of a new chemical has to submit a notification before marketing of the substance by testing the chemical and providing the Competent Authority with a defined set of information. Dangerous (= classified) chemicals must be properly packed and labelled. The Government (under the conditions of art. 95 (4) und (5) EC-Treaty) and the Länder authorities in individual cases are empowered to restrict or ban a chemical if no other means is present to ensure the protection of health and the environment. The Länder authorities are also responsible to pursue regulatory offences and where violations of chemicals legislation result in criminal offences, they will be prosecuted.

A8-2.2.2 Procedure for Notification of New Chemical Substances

Pre-Marketing Notification of a New Chemical Substance in Germany thus means that the producer or importer submits notification documents to **BAuA, Division 5, Chemicals, Notification and Authorization**. This procedure will be replaced by the registration procedure under REACH from 1st June 2008.

A8-2.2.2.1 Tonnage-Related Procedure

The Chemicals Act provides for the tonnage-related notification of each new substance placed on the market in quantities of ≥ 10 kg per year. Once the next tonnage threshold, 10, 100 or 1000 tonnes per year has been reached, further documents must be submitted. The decisive factor with regard to import notifications is the total quantity of the substance which is imported into the EU and the EEA states per producer/importer.

A8-2.2.2.2 Prior Inquiry Duty / Utilization of Existing Test Reports

Each notifier has the duty to make a prior inquiry before performing animal tests for the purpose of preparing a notification or a reduced notification. Within the framework of this procedure the potential notifier must inquire about the need to perform animal tests. If the Competent Authority already possesses sufficient knowledge about the relevant substance from a third party's test reports, a procedure for the utilization of the third party's test reports is initiated whereby the third party and the subsequent notifier have the opportunity to reach an agreement about joint utilization of the test reports. If no agreement is reached, so-called compulsory referencing is undertaken. According to this procedure, the third party whose test reports are utilized has the right to seek compensation from the subsequent notifier at

a level of 50% of the saved expenditure. For his part, the subsequent notifier has a right to be provided with a copy of the utilized test report.

A8-2.2.2.3 Good Laboratory Practice (GLP)

Non-clinical experimental tests whose results are to be submitted within the framework of the notification procedure must be performed in accordance with the principles of Good Laboratory Practice (GLP). Proof that the test results satisfy these demands must be furnished in the form of a certificate from the competent authority (GLP certificate) that the test institute and the tests it performs comply with the principles of good laboratory practice and a written declaration from the test institute that the particular test has been performed according to the principles of good laboratory practice.

Test results are regarded as not having been submitted if one of the above-mentioned reports has not been provided.

A8-2.2.2.4 Submission of Notification Documents

The notification procedure requires the completion of a form in the German language. The use of the SNIF format (Structured Notification Interchange Format) on disk is the preferred option here. This format is a development for the information exchange within the EU. The documents consist of a notification form with test results, spectral and analytical data confirming/proving the chemicals identity and the test reports (physical-chemical properties, toxicology, and eco-toxicology). The submitted documents are checked for completeness and forwarded to the assessment authorities.

The assessment units and the CA examine, within their area of competence, the plausibility and validity of the notification documents. In total a period of **30 days** for reduced notifications and **60 days** for a complete notification at base-set level is available for this procedure.

If the documents are in compliance with the legislative provisions the CA confirms this fact by issuing a notice of acceptance. If the submitted notification documents and test reports do not permit adequate assessment of whether the notified substance has adverse effects on man or the environment and if this inability to perform an assessment is due to incomplete or incorrect notification documents, the CA requests the notifier to supplement or correct his documents within the 30/60-day period.

A consequence of this request is that the notifier is not allowed to place the substance on the market until 30 or 60 days respectively after receipt of all the required corrections or supplementary data to the CA. If adequate assessment is not possible even after the subsequent submission of further documents, the procedure is repeated. On conclusion of the procedure the notifier is sent a notice of the relevant costs.

The CA can issue further requests due to incomplete or incorrect test reports even

after expiry of the notification period if, for example, new aspects have come to light after expiry of the specified period. However, where an assessment of the notified substance would not otherwise be possible, supplementary information can also be demanded in the case of complete and correct documents, too. Furthermore, the CA can request the submission of test reports at an earlier stage if there are grounds for suspecting a particular substance of being dangerous. Such grounds may, for example, result from structure-activity-relationships and exposure to the substance or exist in cases where the test reports are required for performance of the risk assessment. In addition, the CA can order that substances may only be placed on the market if certain conditions are fulfilled or after a future event has occurred. If documents are not submitted within the specified period or if obligations or conditions are not met, the CA can prohibit the marketing of the substance concerned.

A Summary with the relevant information on the substance, the test results, the proposals on classification and labeling and the assessment of the risks is sent to the European Chemicals Bureau (ECB) of the EU Commission, which is located in Ispra in Italy. The ECB circulates the summary to all other member states of the Community. This procedure ensures that the Member States CAs are informed about the notified substances in the Community with the effect, that a producer or importer has to notify only once before marketing. After a notification has been undertaken, producers or importers may freely market the substance throughout the entire EU area as well as in states within the European Economic Area which have transposed the 7th Amendment into national law.

However, the producer or importer has to submit his notification to that CA where his headquarter or the importer's office is located. A choice of the CA is therefore not possible.

In addition the CA forwards information about notified substances to the German Länder. They need it for reasons of monitoring and controlling and to inform e.g. fire workers.

A8-2.2.3 EC Regulation No 793/93 on Existing Substances

Substances produced and marketed before 1981 are the so called „Existing Substances“, they are listed in the EINECS (European Inventory of Existing Commercial Chemical Substances).

Council Regulation No. 793/93 of 23 March 1993 on the Evaluation and Control of the Risks of Existing Substances came into force on the 04.06.1993. It takes direct effect in the Member States. It will be repealed on 1st June 2008 and replaced by the REACH Regulation.

About 100,000 substances, which in principle can be freely traded and used, are listed in the EINECS. As there was a lower level of information, it was therefore necessary

for existing substances to be regulated on their own - in accordance of Annex VII of Directive 67/548/EEC, the procedure for new substances - in order to be able to perform, at EU level, systematic assessments of the risks posed by chemicals from which, if necessary, specific protection measures for workers, consumers and the environment can be derived. Work on existing substances took place in four steps:

A8-2.2.3.1 Information Gathering

Producers or importers of high volume or dangerous chemicals submitted data to the EC-Commission. It was a collection of available information, at first for substances produced or imported in quantities of more than 1,000 tonnes per year, and at a later date for substances in quantities between 10 and 1,000 tonnes per year. The **European Chemicals Bureau** in Ispra/Italy therefore possesses an extensive pool of data on substances produced in large volumes. In particular, data on producers, quantities and intended uses are available.

A8-2.2.3.2 Priority Setting

Based on this information the EC-Commission drew up a priority list and divided the substances among the Member States. If there was an information gap in the data or due to problems related to handling, substances were included in a priority list after joint discussion between the European Commission and the Member States. Four priority lists, containing a total of 140 substances, currently exist. A Member State was assigned to each substance as rapporteur. Germany was designated as the rapporteur for 37 of the 140 substances.

A8-2.2.3.3 Completion of Data

Each Member State responsible for a substance checked whether the information submitted by the manufacturer or importer was at least equivalent to the data necessary for marketing a new substance. It included test protocols, data relating to use, exposure data and other available knowledge concerning the priority substances. The minimum amount of data required in connection with the properties of the substance depends on the extent of testing at base-set level within the framework of the procedure for new substances. If certain data were missing, tests had to be conducted within 1 year to close the data gap.

A8-2.2.3.4 Risk Assessment (and Risk Management)

The Member States produce comprehensive risk assessments for the substances for which they are rapporteur, using the documents conveyed to them as well as available knowledge.

A Risk Assessment includes an assessment of the risks to workers, consumers and the environment which are posed by the substance, a report includes a proposal for protective measures and, if necessary, the indication of substitute substances and their risks and availability.

In Germany, the responsibility for performing this work is regulated by the

Administrative Provision for Existing Commercial Chemical Substances (ChemVwV-Altstoffe) of the 11.09.1997. Accordingly, the national rapporteur is the **BAuA Division 5, Notification Unit within the Chemicals Act** and the assessment units are the **Federal Environmental Agency (UBA)**, the **Federal Institute for Risk Assessment (BfR)** and the **Federal Institute for Occupational Safety and Health, Division 4 (BAuA)**, each having responsibility for the specific areas targeted by them for protection. The **Advisory Committee on Existing Chemicals of Environmental Relevance (BUA)**, which comprises experts from the scientific field, industry and the authorities, can be called upon if the above-mentioned state bodies consider external support with selected risk assessments to be appropriate.

The draft risk assessments produced by the individual Member States were distributed to the **European Commission** and all the other Member States. In several different phases of work, the risk assessments were discussed and, if necessary, altered before being accepted by all of those participating in the procedure. The results obtained were subsequently published in the Official Journal of the European Communities, while protecting confidential business information.

Necessary measures such as, inter alia, classification, labeling, establishment of limit values for the workplace, restrictions, and prohibitions must then be derived from the generally accepted risk assessments and pushed through politically.

A8-2.2.4 Directive 76/769/EEC and its Implementation in Germany

The German Chemicals Act empowers the ministries to issue ordinances e.g. for the restrictions of chemicals as adopted in Directive 76/769/EEC. These restrictions will be replaced by Annex XVII of the REACH Regulation on 1st June 2009.

A8-2.2.4.1 Chemicals Prohibition Ordinance

The Chemicals Prohibition Ordinance implements Directive 76/769/EEC, which also is a source for the PIC procedure. It restricts and bans the marketing of certain dangerous chemicals. The central part is the annex with the 3-column table, the first column includes the substance, the second one the kind of restriction and the third one the exemptions of the regulation. REACH will combine the restriction and the exemptions in one column.

A8-2.2.4.2 Hazardous Substance Ordinance

The Hazardous Substance Ordinance is another ordinance based on the Chemicals Act and implements Directive 76/769/EEC by restricting the use of certain dangerous chemicals.

A8-2.2.5 Classification and Labeling Rules and Work-Place Related Rules: Hazardous Substance Ordinance

The Hazardous Substance Ordinance implements Directive 1999/45/EEC on preparations as well as other EC-Directives on classification, packaging, labeling, and

handling of chemicals. It also regulates and restricts chemicals at workplaces. However, it does not apply to private households. The classification, labeling and packaging provisions will be replaced by the GHS Regulation in future.

A8-2.3 The "New" European System of Industrial Chemicals Legislation: The REACH Regulation and the Future GHS Regulation

A8-2.3.1 Introduction

Chemicals Policy in the EU has been revised in the past decade and will soon mainly consist of two Regulations (i.e. directly applicable European laws), the REACH Regulation EC no 1907/2006¹⁴ and the proposal for the GHS Regulation¹⁵. REACH stands for the “Registration, Evaluation, Authorisation and Restrictions of chemicals”; GHS Regulation stands for the Regulation on the classification, labeling and packaging of substances and mixtures (based on the Globally Harmonised System). The REACH-Regulation was adopted on 13.12. 2006 and entered into force on 1st June 2007. As the new European Chemicals Agency has to be established, most provisions will only have to be applied after the Agency will have been set up and the IT-System will be ready which shall be the 1st June 2008.

The REACH Regulation and the GHS Regulation follow the same main principle as the new substance regime: The manufacturer or importer is responsible for the chemical, not the user or the consumer. The REACH regulations contains rules on the following subjects:

1. Information to be generated, including by testing, on substances in quantities of 1 tonne or more per year by enterprises manufacturing or importing such substances
2. Chemical Safety Assessment for substances in quantities of 10 tonnes or more per year
3. Submission of the defined dataset in a registration dossier to the European Chemicals Agency (ECHA) before manufacturing or importing the substance
4. Communication via safety data sheets or other means and application of identified measures by enterprises in the supply chain, i.e. manufacturers, importers and downstream users
5. Review of the quality of the information submitted to the ECHA and clarifying suspicion of risks
6. Procedures and requirements for European wide chemicals management

¹⁴ OJ L 396 30.12.2006, p. 1

¹⁵ Document COM(2007) 355 final, Proposal for a Regulation of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006, 27.06.2007

The GHS Regulation contains rules on determining the hazards of substances and preparations i.e. classify and properly package and label classified substances and preparations.

In Germany the Länder authorities will remain responsible to take administrative decisions needed to ensure the application of the two Regulations and to pursue regulatory offences and prosecute companies in case of criminal offences. The information necessary will be submitted by the BAuA, Division 5, who will be appointed as the Federal Agency for Chemicals in Germany. The BAuA is establishing an IT-system that is linked with the European ECHA-IT-system.

These regulations will also be the – legal or factual - basis for numerous other European provisions dealing with the protection of the environment and human health as well as emergency management. Sound knowledge about hazards and risks of chemical substances is not only essential for the adequate control of chemicals, but also for the protection of the environment and human health as well as for accident and emergency prevention. Therefore, the table below shows the different areas of law and how they can benefit from the REACH and the GHS Regulation:

Subject of protection/rules	Intended production process		Unintended production process	
			Disturbed working processes	Disturbed plant processes
Product	GHS and REACH:			Quality assurance: Measures against disturbance of intended processes
Workers (within plant)	information about hazard of substances and exposure (risks) of the use of substances covering life cycle and	protection of health measures against long term exposure due to - surroundings and - work/process	worker protection measures against risks due to surroundings and work-related, spontaneous risks, accidents	plant safety measures against - fire - explosions - release of substances
Environment and neighbourhood (outside plant)	workers and environment and people via the environment	environmental protection: measures - against emissions into air - against emissions into water - waste disposal saving of resources		Measures to reduces the consequences of accidents emergency management

A8-2.3.2 Procedure for Registration of Chemical Substances under REACH

Registration under REACH requires manufacturers and importers to collect and/or generate information on the hazards and risks of substances in quantities of 1 tonne or more per year before they manufacture or import such substances (this includes the import of substances in preparations). The complete registration dossier will have to be sent to the European Chemicals Agency in Helsinki. Enterprises also apply the identified risk management measures and communicate them along the supply chain. Thus, the aim of registration is to screen, collect and gather information about substances in order to ensure the application, communication and documentation of

responsible risk management measures on the basis of sound information.

A8-2.3.2.1 Scope

For reasons of workability, focussing of resources and considerations of risks, some substances are exempted either from the REACH Regulation as a whole or from the registration part: These are

- radioactive substances
- waste
- non isolated intermediates
- polymers (but monomers have to be registered under certain conditions)
- substances in medicinal products for human or veterinary use
- food or feeding stuff
- substances listed in Annex IV or described in Annex V, e.g. substances occurring in nature unless chemically modified or classified as dangerous
- re-imported substances provided the substance is the same and the information flow is ensured

For scientific research and development, REACH does not need any specific exemption as this form of research takes place in quantities of less than 1 ton per year. For product and process orientated research and development, REACH requires a simple notification for an exemption from the obligation to register for 5 years. The Agency may extend this exemption for another 5 or 10 years. There is no tonnage limit for this exemption, however, customers must be known.

A8-2.3.2.2 Information Requirements

The Registration dossier consists of two parts, the **technical dossier** for all substances in quantities of 1 tonne or more per year and for substances in quantities of 10 tonnes or more per year also of the **chemical safety report**. The amount of test data or other information on the properties and hazards of substances mainly depends on the volume manufactured or imported (there are different requirements for substances ≥ 1000 t/year, ≥ 100 t/year, ≥ 10 t/year and ≥ 1 t/year). There are some general rules for the use of available data and the adaptation of testing requirements, including lack of exposure.

The **Chemical Safety Assessment** includes for classified substances an exposure assessment and risk characterisation. To that end, the registrant has to develop exposure scenarios or exposure categories. Exposure scenarios/categories are recommendations by the manufacturer/importer of a substance to those carrying out identified uses with the substances on how to control exposure. They describe the conditions (operational conditions and other identified risk management measures) for the use of substances. The objective of the exposure assessment is to derive a quantitative or qualitative estimate of the dose/concentration of the substance to which humans or the environment may be exposed. Quantification of exposure is needed

where a DNEL¹⁶ and/or PNEC¹⁷ can be determined (6.4. of Annex I).

A8-2.3.2.3 GLP Requirement

New ecotoxicological and toxicological tests and analyses have to be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the

Agency and with the provisions of Directive 86/609/EEC, if applicable. Whether available non GLP tests are accepted, depends on whether the conditions set out in Annex XI are fulfilled.

A8-2.3.2.4 Data Sharing and Consortia Formation

To avoid the duplication of test data, in particular those involving vertebrate animals, mechanisms have been set up to organise the sharing of data and the preparation of joint dossiers by several enterprises manufacturing or importing the same substance. Two situations have to be distinguished:

For newly created substances, it is presumed that companies will not register those substances at the same time, thus registrants of the same substance will be subsequent registrants in most cases. Therefore a mechanism has been set up that is similar to that of the new substances regime, where the Agency helps to put a later registrant into contact with an earlier one for them to reach an agreement on the sharing of studies.

For substances that have already been on the market, in a first step, the “pre-registration”, information is needed on which substances might be registered later in which tonnage band by more than one company. Thus, to bring together companies preparing registrations for the same substance is a prerequisite for their joint work. Possible registrants of the same substance will then form part of a substance information exchange forum (SIEF) where they have to share data involving vertebrate animals, and should also agree on the classification of the substance. They should also prepare most parts of the registration dossier jointly in a consortium.

A8-2.3.2.5 Submission of Information to the European Chemicals Agency (ECHA)

REACH requires that a registration, where required, is submitted prior to the manufacture or import of substances (thus according to the principle: no data – no market). While the information requirements are now identical for existing and new substances, a mechanism had to be found to “phase in” the existing substances into the new system. Therefore there are longer periods for enterprises to prepare the registration dossier for those substances that have already been on the market.

¹⁶ Derived no effect level

¹⁷ Predicted no effect concentration

Substances in quantities of 1000 and more t/a and those with CMR properties in quantities of ≥ 1 t/a and those which are dangerous to the environment (R 50/53) in quantities of ≥ 100 t/a have to be registered until the 1st December 2010, substances in quantities of 100 t/a and more until the 1st June 2013 and substances in quantities of 1t/a and more until the 1st June 2018.

The Agency will perform a completeness check within 3 weeks (or another defined period for phase in substances), and if there is no indication to the contrary within this time period, the manufacture or import may be started. A more in-depth quality check of the information will only be done at the evaluation stage.

A8-2.3.3 Evaluation

Under Evaluation the quality of information that is submitted to the European Chemicals Agency will be checked. For all missing tests for substances in quantities of 100 tonnes or more per year, only testing proposals have to be submitted in the registration dossier, and the Agency will check the quality to save animals' lives and costs. Also the quality of the other information can be checked by the Agency and in case of insufficient information submitted; enterprises will have to (re-)submit the missing information.

Finally, in case that despite the information already submitted on a substance, there is still a suspicion of risk that needs to be clarified; the Agency will be able to request this information from companies in justified cases.

A8-2.3.4 Communication in the Supply Chain

The tool for the communication in the supply chain is taken from the globally harmonised system (GHS), i.e. the safety data sheet, which is an internationally widely used instrument and which has already been well known also in the EU since 1991. REACH adds an Annex to the safety data sheet for classified substances in quantities of 10 tonnes or more per year, the exposure scenarios/categories. They sum up the chemical safety assessment and thus contain the conditions for the use of the substance. They explain how to control exposure and how to ensure adequate control of the risks arising from the use of the substance. If customers, i.e. downstream users do not agree for with the conditions for use provided to them, they have to inform their suppliers about this fact.

A8-2.3.5 Obligations on Downstream Users to Manage their Uses

REACH includes downstream users of substances into the system, however limits their obligations as far as possible. There is no obligation on downstream users to submit a registration dossier for their substances. REACH aims at the generation of information on the top end of the supply chain. The idea is that customers, downstream users, get "ready-made" information on the conditions for their uses of the substances supplied to them. But downstream users have a choice: if they do not want to reveal their uses or any other information with regard to them to their

suppliers, they may choose to assess the chemical safety of these uses themselves and report this to the Agency. If they start communicating with their suppliers well in advance, they may not have to do any assessments themselves. Therefore communication between customers and suppliers will be very important. Downstream users and importers in the EU will therefore also need to communicate with suppliers in non EU Countries.

A8-2.3.6 Procedures and Requirements for European-wide Chemicals Management: Authorisation and Restrictions System in the REACH Regulation

Under REACH, the main idea is that enterprises take the responsibility to ensure adequate control of risks of the substances that they manufacture, import or use.

Therefore, the restrictions system will be the safety net for cases in which there are risks that – still - need to be addressed on the European level. The procedure in which decisions are taken will start in the Agency on the basis of a dossier prepared either by a Member State or the Agency. The dossier will be discussed in the risk assessment and the socio economic assessment committee in the Agency and the Commission will then take the final decision (comitology) based on the Agency's committees' opinions. Decisions can either prohibit the use of a substance altogether or restrict certain uses, this includes defining conditions for use. The restrictions will be included in Annex XVI. Starting point for this Annex will be the restrictions that are currently included in Directive 76/769/EEC. The Directive will be repealed on 1st June 2009.

For substances of very high concern, which are defined as carcinogenic, mutagenic and toxic to reproduction (CMR) and for substances which are persistent, bioaccumulative or toxic (PBT) or very persistent or very bioaccumulative (vPvB) and substances of equivalent concern like e.g. endocrine disruptors, a specific system is designed, the authorisation procedure to ensure that the risks from these substances are properly controlled and that they are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

The authorisation system is a two step procedure:

In a first step substances with the described properties will have to be selected for inclusion into the system in a several stage process (hazard identification, publication on a list of the Agency, inclusion in the Agency's work programme, prioritisation and finally inclusion in Annex XIV of the REACH Regulation by a Commission comitology decision).

Only after the inclusion of the substances in the Annex, thus at the second step, enterprises that want to use or place on the market such substances have to apply for an authorisation for each use of such substances (some uses may be exempt though either in the Articles of the REACH Regulation or in the Annex).

A8-2.3.7 Classification and Labeling of Substances and Mixtures: The Future GHS Regulation

The REACH regulation does not contain the rules for classification and labeling of substances and preparations. These rules are currently regulated in different European acts which will be replaced by the future GHS regulation. The Commission proposal has been discussed by the Council and Parliament for some months now.

A8-2.4 Rules on Specific Substances or Specific Procedures

A8-2.4.1 Regulation (EC) No 2037/2000 on Substances that Deplete the Ozone Layer

Regulation (EC) No. 2037/2000 of the European Parliament and Council dated 29 June 2000 on substances that deplete the ozone layer regulates the production, import, export, placing on the market, use, recovery, recycling, preparation and destruction of substances that harm the ozone layer. As a regulation it is directly applicable.

The production and placing on the market of the following substances is prohibited within the EU:

- CFCs
- Other fully halogenated CFCs
- Halons
- Carbone tetrachloride
- 1,1,1-trichlorethane
- Partially halogenated halons
- Methyl bromide

Exempted are the use and placing on the market for destruction within the Community, as well as the use as starting and processing auxiliary. Methyl bromide may still be used for quarantine and pre-shipment applications. Halons are used in aviation and military areas (see annex VII of the regulation for further information).

Other uses of regulated substances require the explicit consent of the European Commission. The Commission annually allows companies to produce limited amounts of these substances for critical uses where no acceptable substitute is available. Companies have to apply in advance for these licences. Temporary exemptions can be authorized for pharmaceutical implants, military purposes or in case of sudden pest infestations.

The use of partially halogenated CFCs is not prohibited, but severely restricted. Their use as refrigerant is being reduced step by step until 2015, when it will be generally prohibited. Apart from that they may only be used in a limited amount of areas. These are: the production of foams, carrier of sterilisation substances, solvent in aviation and astronautics, laboratory use, research, halon replacement in fire systems and as starting and processing auxiliary. For further details, see article 5 of the regulation.

The import and placing on the market of products and equipment containing partially halogenated CFCs is prohibited, unless they were produced before the prohibition on use came into force. All imports or exports of regulated substances to or from the EU require a licence by the European Commission.

Going beyond the European Regulation, the national Chemikalien-Ozonschichtverordnung (Substances - Ozone layer Regulation) further regulates the production, the placing on the market and the use of ozone depleting substances in pressurized gas packages and fire extinguishers. It also extends the obligations of producers and owners of products or facilities that contain ozone depleting substances regarding containment and recycling.

A8-2.4.2 Regulation (EC) No. 304/2003 and ROTTERDAM (PIC) Convention

Council Regulation (EC) No 304/2004 dated 28 January 2003 concerning the export and import of dangerous chemicals (Export-Import Regulation) came into force on 7 March 2003. It implements the Rotterdam Convention and is directly applicable as an EC Regulation.

The exports of dangerous chemicals that are banned or severely restricted within the Community are subject to a common export notification procedure. Accordingly, dangerous chemicals, whether in the form of a substance by itself or in a preparation, which have been banned or severely restricted by the Community as plant protection products, as other forms of pesticides, or as industrial chemicals for use by professional users or by the public, are subject to similar export notification rules to those applicable to such chemicals when they are banned or severely restricted within either or both of the use categories laid down in the Convention, namely as pesticides or chemicals for industrial use. In addition, chemicals subject to the international PIC procedure are subject to the same rules. This export notification procedure applies to Community exports **to all third countries**, whether or not they are Parties to the Convention or participate in its procedures.

Thus the Regulation goes beyond the provisions of the Convention, this is allowed according to Article 15 paragraph 4, and Parties have the right to take an action that is more stringently protective of human health and environment, provided it is consistent with the provisions of the Convention and international law.

The main chemicals legislation, which triggers the listing of chemicals in Regulation (EC) 304/2003 is related to the Directive 91/414/EC, Agricultural Pesticides, and to the Biocide Product Directive 98/8/EC and the Directive 76/769/EEC, industrial pesticides and chemicals.

Under this regulation every exporter must notify certain substances or preparations to the national DNA (Designated National Authorities) responsible, at least 30 days prior

to exporting them for the first time in the calendar year in order to make the recipient country aware of the export and, where necessary, obtain permit. If the **European Chemicals Bureau (ECB)** acting as common European authority does not receive an acknowledgement of receipt of the first export notification within 30 days of the dispatch of the notification, a second notification has to be submitted. In Germany, the **Federal Institute for Occupational Safety and Health (BAuA), Division 5** has been appointed as the Designated National Authority (DNA).

The national DNAs work closely together with the Joint Research Centre of the ECB. Each notification has to be inserted in the database, called EDEXIM. The public as well as the DNAs of the Member States, the Customs Service, and the applicants, have access to the database to get information about the export and import of certain dangerous chemicals. DNAs are also in the position to follow the latest development of a notification. An explicit consent status list is also available on EDEXIM. The Export notification procedure applies to exports to any country, irrespective of the intended use. If the statutory EU regulations for placing on the market or for using or labeling the substance concerned have significantly altered or if the composition of the relevant preparation has changed to such an extent that its labeling has also changed it is necessary for the exporter to renew his announcement

The European Union participates in the PIC procedure within the environmental programme of the United Nations (UNEP) and the Food and Agricultural Organization (FAO). The Rotterdam Convention entered into force on the 24.02.2004. The German Federal Government has designated the **Federal Office of Consumer Protection and Food Safety (BVL)** as the competent national authority vis-à-vis the FAO in connection with plant protection products and the **Federal Institute for Occupational Safety and Health (BAuA)**, as the competent national authority vis-à-vis UNEP with regard to all other chemicals.

A8-2.4.3 Regulation (EC) No. 850/2004, Stockholm (POP) Convention

Regulation (EC) No. 850/2004 dated 29 April 2004 on persistent organic pollutants and to amend Directive 79/117/EEC is aimed at banning or suspending at the earliest opportunity or restricting the production, placing on the market and preventing the use of intentionally produced persistent organic pollutants. Furthermore, it is intended to reduce the release of such substances to a minimum until the earliest possible cessation of such releases.

The focal activities will be to collect information available in Germany in a decreased form and to pass it on to the European Commission within the framework of the reporting duties provided for in the Regulation.

A8-2.4.4 Directive 98/8/EC Concerning the Placing of Biocides Product on the Market

The German Biocide Act came into force on the 28 June 2002. It essentially integrated

into the Chemicals Act (ChemG, in particular section II a) the rules required for transposition of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. The authorization procedure for biocidal products which came into force as a result states that biocidal products may only be marketed and used after prior authorization.

The authorization authority is the **Federal Institute for Occupational Safety and Health (BAuA), Division 5, Chemicals, Notification and Authorization.**

The national expert authorities included in the procedure as authorities whose consent is sought are **Division 4** of the Federal Institute for Occupational Safety and Health (responsible for the protection of workers), the Federal Environmental Agency, **UBA** (responsible for protection of the environment) and the Federal Institute for Risk Assessment, **BfR** (responsible for the protection of consumers).

The Federal Institute for Materials Research and Testing (**BAM**), the Federal Office of Consumer Protection and Food Safety (**BVL**) and the Robert-Koch Institute (**RKI**) participate in the authorization procedure for certain types of products as consultation authorities.

A8-2.4.4.1 Procedure for Active Biocidal Substances

The active substances procedure is an essential process of the statutory rules for biocides. Within the framework of this European procedure it is decided whether an active biocidal substance is included in one of the Annexes I, IA or IB of Directive 98/8/EC. The inclusion of the active biocidal substance in one of the aforementioned Annexes is a precondition for the authorization of biocidal products.

Within one year after acknowledgement of the documents the participating authorities undertake an assessment and make a recommendation about the inclusion or non-inclusion of the active biocidal substance in the particular annex. If further information is required from the applicant, the one-year deadline is suspended until the documents have been submitted. The recommendation (the report by the competent authority) is passed on to the Commission, the other Member States and the applicant. Subsequently this report will be peer reviewed by other Member States.

At the latest 12 months after receipt of the documents the Commission decides, with the assistance of a Standing Committee containing of all Member States, whether or not the active biocidal substance is included in one of the Annexes I, IA or IB of the Directive.

A8-2.4.4.1a 10 Year Work Programme for Existing Active Substances

Existing active substances are active biocidal substances that were already used in biocidal products in an EU Member State prior to the 14th of May 2000. Consequently, in consideration of the already existing statutory rules, they can continue to be marketed for biocidal purposes during the programme for existing active substances as long as they have either been notified or identified.

The notified active biocidal substances which are subjected to examination within the framework of the existing active substances programme are listed in Annex II of Regulation (EC) No 2032/2003. If after examination one of these active substances it is not included in one of the Annexes I, IA or IB of Directive 98/8/EC, all of the biocidal products that include this active substance must be withdrawn from the market. The same applies to the active substance itself. If the active biocidal substance is included in one of the above-mentioned annexes, the corresponding biocidal products require authorization.

Within the framework of the above-mentioned Regulation, which is going to be amended the fifth time, dossiers have to be submitted, related to the product types, according to the deadlines laid down in the Review Regulation.

A8-2.4.4.1b New Active Substances

New active substances are active biocidal substances which have not been placed on the market in an EU Member State before the 14 May 2000. In contrast to the existing active substances programme, the new active substances may only be marketed in biocidal products after inclusion in one of the annexes of Directive 98/8/EC.

A8-2.4.4.1c Basic Substances

A basic substance is a substance which is listed in Annex I B, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use. Certain substances could potentially enter Annex IB, in accordance with the procedure laid in this Regulation

A8-2.4.4.2 Authorization of a Biocidal Product

The product authorization itself is subject to the rules cited in Article 5 of Directive 98/8/EC. As a rule, the authorization unit decides on fulfilment or otherwise of the preconditions for authorization within one year of receipt of the application. The procedure for the authorization of biocidal products is similar in structure to the active substances procedure.

A precondition for a successful authorization of a biocidal product is that the active biocidal substances contained within it are included in Annex I or IA of Directive

98/8/EC. The authorization procedure therefore builds upon the active substances procedure.

Special facilities during the authorisation procedure are foreseen for the registration of biocidal products with low risk potential, frame formulations and reference products as well as provisional authorization of a biocidal product that may be granted for a limited time period.

A8-2.4.4.2a Mutual Recognition of an Authorization or Registration

Initially, authorisations and registrations of biocidal products are only valid in the particular Member State in which it has been authorised. In the mutual recognition procedure a biocidal product that has already been authorized or registered in another Member State this authorisation/registration may be recognized in Germany. The decision is taken within 120 or 60 days respectively after receipt of the application by the authorization unit.

A8-3 Enforcement of Chemical Control in Germany, Responsible Authorities and Co-operation amongst the Authorities

A8-3.1 Enforcement Authorities in Germany: The Länder level

The European community is not in charge of enforcement, this is due to the principle of subsidiarity a matter of the Member States. However, regarding the chemicals the Federal Authorities are not empowered to enforce the compliance in the factories and at the production sites. This Task is in the sovereignty of the Federal States (Länder, like Bavaria, Saxony, or North Rhine Westphalia).

The enforcement agencies of the Federal States check that chemicals are properly packed and labelled, new chemicals are notified before marketed or prohibitions or restrictions on chemicals are observed. They are empowered by the chemicals Act to take all the necessary administrative decisions to ensure the application of the chemicals legislation and to prevent possible breaches. If a company is in breach of the regulation, both administrative decisions as well as decisions on regulatory offences may be taken. In case of crimes, there is no discretion – they have to be prosecuted.

An action might be initiated by (yearly) enforcement programmes, by certain European or National projects or if the authorities have become aware of a violation of some provisions.

A8-3.2 BAuA, Federal Institute for Occupational Safety and Health, www.baua.de

The **Federal Institute for Occupational Safety and Health (BAuA)** is a public law institute without legal capacity. The BAuA is an authority within the portfolio of the Federal Ministry of Labour and Social Affairs.

The **BAuA** has been empowered by the Chemicals Act to become the **Competent Authority (CA)**, also known as **Notification Unit**, for the chemicals notification procedure as well as Authorisation Unit for biocidal products.

The tasks of the **BAuA** are on one side to support the Minister of Labour and Social Affairs, and to generate the knowledge on occupational safety by research done by the **BAuA** itself and by contractors. As a pool of competence and a knowledge service provider in matters of safety and health at work, the **BAuA** offers advice and practical assistance to companies, government, the social partners, the general public and, gives technical assistance to third Countries. The knowledge on occupational safety is transferred by an exhibition, a library, an information centre and a Health Data Archive of German Uranium Mines.

An additional task is the implementation of the notification procedure of chemicals and the authorisation of biocidal products. The **Division 5, Chemicals Notification and Authorisation**, which is, inter-alia, responsible for these tasks, supports the Minister of Environment. It has been appointed as REACH-Helpdesk, Competent Authority and DNA for the Rotterdam Convention for Germany, and provides members for relevant committees and fora.

Division 5, Chemicals Notification and Authorisation is divided into 4 units: The Units are responsible for the Notification of Existing Substances, Chemical Survey, for the time being, for Notification of New Substances, and Information on Chemicals, for the Authorisation of Biocides and for Chemical Law, Legal and Administrative Matters. In Addition to that BAuA has been appointed as DNA for the Rotterdam convention, CA for the Stockholm Convention and CA for the Ozone Depleting Substance Regulation.

The CA informs the German Federal States/Länder about the properties of the substance data and the assessment results. Non-confidential information on the substances is published in the Federal Gazette.

A8-3.3 Co-operation within Germany

The Federal Ministry of Environment and their subordinated authorities like the BAuA co-operate with the Länder/Federal State authorities in working and sub-working groups on "Chemical Safety". They exchange information and discuss procedures with regard to enforcement and special enforcement projects as well as

questions of how to interpret the Chemicals Act. There are different working groups and sub working groups for different items like technical questions, or legal questions or preparing enforcement facilities for REACH.

In addition to that enforcement authorities and customs service are invited on a regular basis to the BAuA Division 5, to discuss the latest developments within the Chemicals Management process. Combined or bilateral meetings with industry and industry associations are at the same time part of the co-operation.

A8-3.4 The European Chemicals Agency (ECHA)

With REACH, the role of the CA in the EU Member States will change. The ECHA will be responsible to accept the registration dossiers, to draft decisions in the evaluation procedure, which will be prepared by the CAs. To prepare results in the evaluation process and to come to decisions in the authorisation and restrictions procedure, i.e. scientific reasoning with, a close cooperation with the member states and the committees will be necessary.

The Agency will consist of the following parts: the Director and its Secretariat, the Management Board, the Risk Assessment Committee, the Socio Economic Analysis Committee, the Member State Committee, the Forum, and the Board of Appeal.

Member States have to appoint members to the Member State Committee and the Forum and they are invited to appoint candidates for the risk assessment committee and the socio economic analysis committee. The authorities in the Member States will then help the appointed members of the committees in performing their tasks. Decision making rules are defined in the REACH Regulation in detail.

A8-3.5 Co-operation on EC-Level

In addition to the staff in the Agency, the Member States Competent Authorities meet several times per year. The Joint meetings regarding new and existing chemicals and the CA-Meeting for Biocides are organised several times per year by the European Commission together with the respective Member State who has the council presidency. The CA-meetings are focused more on general, legal or political issues while Technical Meetings are addressed to scientific and chemical items. Since 2008 the meetings for industrial chemicals will be organised by the ECHA in Helsinki/Finland.

The DNA-meetings for PIC and meetings on POPs or GLP, organised by the European Commission once or twice per year, take place in Brussels.

CLEEN (Chemicals Legislation European Enforcement Network) is a network that co-ordinates and improves the enforcement of EU chemicals legislation. It is basically a network for information exchange and it discusses, in collaboration with the Member States, priorities for enforcement projects in the EU.

Germany is a member of the CLEEN Network, the BAuA Division 5 is the focal point. Under the auspices of CLEEN, chemical inspectorates of the EU Member States discuss priorities and joined enforcement projects, exchange information. In 2006 **Austria** together with **Poland** took over the CLEEN secretariat.

A8-4 Instruments of International Chemical management - SAICM

The Strategic Approach to International Chemicals Management (SAICM) is a policy framework for international action on chemical hazards under the umbrella of the United Nations, which had been adopted on 6 February 2006 in Dubai, United Arab Emirates. It supports the achievement of the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that, by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.

In Germany the **Federal Environment Agency** (UBA) has been designated as a Strategic Approach national focal point to act as an effective conduit for communication on Strategic Approach matters.

The strategic approach is an overarching policy strategy according to the precautionary principle. It should enable that initial capacity building activities for the implementation of Strategic Approach objectives will be supported by the establishment of the Quick Start Programme (QSP). The QSP contains a voluntary, time-limited trust fund, administered by the United Nations Environment Programme, and may include multilateral, bilateral and other forms of cooperation.

The strategic priorities highlight that the QSP should mobilize resources for national priority initial enabling activities in keeping with the work areas which are in particular the development or updating of national chemical profiles and the identification of capacity needs for sound chemicals management, the development and strengthening of national chemicals management institutions, plans, programmes and activities to implement the Strategic Approach, building upon work conducted to implement international chemicals-related agreements and initiatives, and to undertaking analysis, interagency coordination, and public participation activities directed at enabling the implementation of the Strategic Approach.

An aim of SAICM is to concentrate diverse existing and partly competing activities regarding chemical safety on a global level. Therefore it seems appropriate to use synergy effects and closing gaps by using to a large extent an integral approach that takes into account the Multilateral Environmental Agreements dealing with a certain amount of chemicals with certain properties. The SAICM process is able to establish

Chemical Management for all, countries in transition, industrial and less-industrialised countries.

A8-5 Overview of the United States' Regulatory Regime for Toxic Chemicals and Pesticides Management; Its Relevance to the Contemporary Regulatory Needs of the People's Republic of China

A8-5.1 Introduction

From the outset, it is important to stress that the United States (US) environmental regulatory regime, though imbued with a precautionary approach, firmly rejects unscientific or chemo phobic regulation and management of toxic chemicals and pesticides. This would include any approach not firmly rooted in science. The U.S. approach to toxic chemicals management both permits a thorough understanding and appreciation of genuine chemical risks and actions to deal with those, as well as concurrent enjoyment of the enormous benefits that chemistry has provided. Modern life and high standards of living that Americans now take for granted, are dependent in part on chemicals. However, Americans also know that full enjoyment of those living standards also depends upon the sound and safe management of those chemicals and pesticides. TSCA makes clear that it is the intent of Congress that the Administrator of EPA shall carry out the statute in a reasonable and prudent manner and shall consider the environmental but also the social and economic impact of any taken or proposed to be taken.

Since the early 1970's, and particularly after the formation of the US Environmental Protection Agency (EPA) in December of 1970, the US has committed substantial resources to the development, elaboration and enforcement of a toxic chemicals management and control regime. The People's Republic of China (PRC), as a major chemical producer, importer and consumer of chemicals, and possessed of a fast-growing domestic chemicals industry, now seeks to strengthen existing structures and create an environmentally sound management system as a key component of future plans for environmental and social progress.

Today, as SEPA plans to prepare a new law/regulation on toxic and hazardous chemicals involving the management of such chemicals for submission to the State Council for approval, the PRC is seeking to glean helpful information from the successful experiences and practices of key developed countries including the US. Much of what the US has done, especially in terms gathering information about toxic chemicals within its borders and the subsequent controls it has imposed with respect to certain substances, is relevant to the situation in the PRC and could be modified to fit the Chinese experience and unique local conditions.

The PRC might focus on those U.S. experiences that could help it to develop a readily available means of auditing or screening what chemicals exist within the PRC and how they are being used. This requires a notification scheme capable of facilitating

the review of new chemicals and producing a comprehensive data base of existing substances so that information on which toxic substances are being produced and imported is available - and risks of those substances may be assessed, testing consistent with international standards and protocols and reporting of information relevant to chemicals assessment and management can be required, and further regulatory action pursued where appropriate - including the restriction and even the banning of certain substances where warranted. The desire to invest in such a regime reflects the growing recognition within the PRC that if significant resources are not devoted to the enterprise, given the size of the country and its population and the magnitude of the environmental challenge, an even higher price in terms of environmentally harmful consequences, with potentially severe economic implications, may have to be paid. It is much the same recognition that impelled the US to enact the Toxic Substances Control Act of 1976 (TSCA) and the 1947 Federal Insecticide, Fungicide, and Rodenticide Act as amended.

A8-5.2 Toxic Substances Control Act (TSCA); 15 U.S.C. Section 2601 et seq.; Implementing Regulations Set Forth at 40 C.F.R., Section 700 et seq.,

A8-5.2.1 Introduction:

In the United States, the Environmental Protection Agency is responsible for implementing most of TSCA. Under TSCA, EPA is charged with ensuring that chemicals manufactured, imported processed or distributed in commerce, or used or disposed of in the US, do not pose an unreasonable risk to human health or the environment. It is important to recall that before TSCA was passed just over thirty years ago, it was not known how many chemicals were in commerce in the United States, where chemicals that were in the United States were being produced, or from where they were being imported and in what quantities they were being produced and/or imported.

TSCA established a national program for oversight of toxic chemicals through initiation of a systematic review process for evaluating new chemicals *before* they enter commerce and by creating a set of tools for responding to potential risks from existing chemicals already in commerce. For the very first time, TSCA established as a national policy of the US that the development of adequate data with respect to chemical substances and mixtures, including information on their toxicity and the extent to which people and the environment are exposed to them, is the responsibility of those who manufacture and process such chemical substances and mixtures. With this information potentially available through rulemaking and otherwise, the government can, through its chemical assessment procedures, regulation, and other programs ensure that adequate measures are taken to protect against unreasonable risks to humans and the environment.

TSCA contains provisions which allows the government to regulate any chemical that presents an “unreasonable risk” of harm to human health or the environment. Because

of the broad scope of its potential coverage, coupled perhaps with underutilization, it could be referred to as a “sleeping giant.” However, though it may be underutilized, the statute is capable of regulating virtually all chemical substances and is the only US environmental statute that can completely ban production of a chemical.

A8-5.2.2 Key TSCA Provisions of Particular Applicability to the Situation in the PRC

A8-5.2.2.1 The TSCA Chemical Substance Inventory

TSCA Section 8 mandates that EPA create and maintain a list of all *existing* chemical substances manufactured or processed in the United States. This “TSCA Chemical Substance Inventory” is used to allow the regulating agency to determine whether any given substance is existing or new. The inventory currently contains over 80,000 existing substances. If the substance is not on the inventory list, it is considered to be “new.” The list continues to grow as new chemicals that have been reviewed under EPA’s new chemical review program are added. Chemical companies are generally required to notify EPA at least 90 days before beginning manufacture or import of a “new” chemical by submitting a pre-manufacture notice. (See Section 5 discussion below.)

The existing inventory, and how EPA chooses to manage the information reported via periodic updates, is very much about setting priorities in the face of limited resources. This has led to a focus on a subset of chemicals of greatest concern. For Priority setting purposes EPA/OPPT has concentrated its data development and data collection efforts on a subset of approximately 15,000 non-polymeric chemicals reported in the two most recent inventory update cycles and produced in quantities greater than 10,000 pounds per year. The greatest focus is currently on a smaller subset of approximately 3,000 high production volume chemicals produced and/or imported in annual volumes of 1 million pounds or more across all U.S. companies. In parallel with these undertakings, data development efforts are also focusing on other chemicals of concern, including perfluorooctanoic acid (PFOA) and perfluorooctyl sulfonate (PFOS). All of this information is generally made accessible to the public; however steps are taken to safeguard confidential business information (CBI). However, certain health and safety information is not protected from disclosure under TSCA

A8-5.2.2.2 Reporting and Record-Keeping Requirements

Section 8 also establishes extremely broad reporting and record-keeping requirements that provide EPA mechanisms to ensure access to information regarding health or environmental effects associated with chemical substances. This section gives the EPA authority to request a wide variety of information about chemicals or processes that it may not otherwise have authority to investigate under other statutory programs. The Agency can issue rules under TSCA section 8(a) on specific substance or categories of substances requiring the reporting to EPA of hazard and/or exposure-related

information, and mandate record-keeping.

The Preliminary Assessment Information Rule is one type of section 8(a) information gathering rule that is intended to allow EPA to gather exposure data on chemical substances. TSCA section 8 also provides authority so that EPA can require manufacturers and processors to keep records of significant adverse reactions, including, consumer allegations of personal injury or harm to health, reports of occupational diseases or injuries, and complaints of injury to the environment. The allegations, which must be retained for 5 years (or 30 years if the allegation arises from an employment-related exposure) can provide a means of identifying previously unknown hazards, need only be submitted by manufacturers and processors to EPA upon request.

TSCA section 8(d) requires manufacturers and processors to submit unpublished health and safety studies (“any study of any effect of a chemical substance or mixture on health or the environment”) that are in their possession, or known to them but not in their possession, to EPA with respect to the chemicals they propose to manufacture or process. This, among other things, can help EPA to determine which chemicals may present risks that require industry testing under Section 4 (See below). TSCA Section 8 (e) requires chemical manufacturers, processors and distributors to notify EPA immediately of any new (unreported) unpublished information on chemicals that reasonably supports a conclusion of substantial risk of injury to health or the environment. This provision is viewed by EPA as a critical information gathering tool that can serve as an early-warning system for newly found risks. EPA screens the submissions and identifies particular chemicals for further assessment, referral or follow-up. This reporting has also heightened industry awareness of potential chemical risks.

A8-5.2.2.3 Regulation of Existing Chemicals

Sections 6 and 7 of TSCA permit EPA to regulate or take other action to protect against unreasonable risk or imminent hazards associated with the manufacture, processing, distribution, use and disposal of chemical substances and mixtures. Events that may trigger such assessment include new monitoring or test data from within EPA, other public or private sector sources, or from other countries. This relatively high standard takes into account the interruption of an ongoing industrial process which would have higher social costs (job loss, investment in plant and material, etc.) than forbidding or imposing restrictive conditions on new manufacture. Regulation can take the form of prohibiting the manufacture of these substances, or of strictly regulating their use, or both. Prior to taking any such actions, however, EPA must publish a statement in the Federal Register - essentially a cost-benefit analysis – that considers and addresses the effects on health and the magnitude of human exposure, the effects on the environment and the magnitude of environmental exposure, the benefits of using the substance or mixture, the availability of substitutes, and any reasonably ascertainable economic consequences of the action. After considering

public comments on the rule-making, EPA has a number of regulatory options. These include prohibition or placement of limitations on the manufacture, processing, distribution, use of disposal of the chemical, or of its use in a concentration in excess of a specified level. There may be imposed specific labeling requirements, or warnings or instructions to be provided prior to use. Whichever action is taken, EPA must use the least burdensome methods to regulate or prohibit the use of chemicals found to present an unreasonable risk. The Agency's actions to ban completely the importation, manufacture and processing of nearly all asbestos-containing products in 1989 were largely overturned by U.S. Courts because, in summary and among other things, the Court found that EPA failed to evaluate the possible health effects of substitute products, and was therefore found to have failed to consider less burdensome regulatory alternatives as TSCA requires.

In fact, there are only a very few existing substances the manufacture, processing, use, distribution in commerce or disposal of which have been regulated under Section 6 to date. These include PCBs, fully halogenated chlorofluorocarbons for aerosol propellant uses, and certain mixtures (metal working fluids) capable of producing nitrosamines (carcinogens). EPA has also used its section 6 authority to regulate the use of hexavalent chromium chemicals in certain heating, ventilation, air conditioning and refrigeration systems and has promulgated regulations to address human exposure to airborne asbestos in school buildings. This regime clearly requires analysis of risks and benefits to support regulatory controls. Some have complained about TSCA section 6's cumbersome nature and its ineffectiveness.

A8-5.2.2.4 Regulation of New Chemicals_

Section 5 of TSCA creates an effective "gatekeeper" function that can facilitate the identification of concerns and provide authority for the imposition of conditions on the commercialization of new chemicals before they enter commerce. The statute requires any company intending to manufacture or import a *new* chemical substance not on the TSCA Chemical Inventory, to give EPA 90 days notice prior to manufacture or importation by sending a Pre-Manufacture Notification (PMN). PMNs must include any data in the PMN submitter's possession or control on the chemical's health and ecological effects, potential exposures and on their physical and chemical properties. As a result of the Significant New Use Rules (SNURs), PMN requirements now also apply to new or increased use of *existing* chemicals manufactured or processed in, or imported into, the US. Certain genetically modified microorganisms are also considered as new chemicals. The scope of the notification requirements does *not* extend, for example, to mixtures, pesticides, food additives, drugs and cosmetics, very low volume quantities manufactured or imported for research purposes, chemical substances imported solely for export, and chemicals imported as part of an article. In accordance with U.S. administrative procedure, EPA publishes a short notice in the Federal Register after receiving a PMN, which information is publicly available. If EPA takes no regulatory action on the PMN within a review period, the submitter may commence commercial manufacture or importation without any approval. However,

within 30 days of commencing manufacture or import, the submitter must file a notice of commencement of manufacture or import. Once that notification is received, the new substance is added to the TSCA inventory and the chemical is viewed under the statute as an *existing* chemical substance.

This so-called PMN review period (during which the public is also notified) is an aspect of the U.S. regulatory regime that may hold particular interest for regulators in the PRC. It is a process that recognizes the limited resources that even a developed country has available for chemicals assessment and management and that has evolved to focus most effort on the relatively few new chemicals of greatest potential concern, such as those which are structurally related to known chemicals of concern and those about which little is known. The review period is intended to afford EPA the opportunity to assess, on the basis of data submitted by the importer or manufacturer, other information from government data bases, and the existing scientific literature, whether follow-up regulatory controls and/or additional data are needed for assessment to prevent potential unreasonable risks. EPA's review of new chemicals under TSCA Section 5 relies on the knowledge and experience of engineers, scientists, information management specialists and regulators (65 full time staff in 2006) to identify and evaluate concerns.

If, as a result of its assessment, an "unreasonable risk" is detected or suspected, EPA has the authority to take a number of control actions to prevent or mitigate those risks. In only about 5% of all cases does EPA determine that some type of controls is necessary for the substance. There are an additional 5% of new chemicals that are voluntarily withdrawn by the notifier, often in the face of EPA action. If the available information is insufficient to permit a reasoned evaluation, EPA may issue a proposed order to prohibit or limit manufacture or import of the substance. EPA may propose a rule limiting or conditioning manufacture or import of the substance or issue "pending the development of information" needed to adequately assess the chemical, or a proposed order, for example, completely banning the manufacture or importation if there is a "reasonable basis to conclude that the manufacture...presents or will present an unreasonable risk of injury to health or the environment." EPA must choose the least burdensome requirement that will adequately protect against the risk which presents a high evidentiary burden. In the United States, in keeping with its elaborate system of checks-and-balances, control actions that EPA might take are subject to review by the courts.

A8-5.2.2.5 Mandatory Chemical Testing

TSCA Section 4 was enacted in response to the concern that the effects of many chemical substances and mixtures on human health and the environment were insufficiently characterized or understood. That is a concern that the PRC has today. Section 4 gives EPA authority to require that manufacturers, importers and processors of existing chemicals to conduct testing of any substance or mixture where the Agency finds that there is insufficient data upon which the effects of a chemical on

health or the environment can be determined or predicted and testing is necessary to develop such data. The agency must further find *either* that the chemical substance's or mixture's manufacture, distribution in commerce, processing, use or disposal may present an unreasonable risk of injury to health or the environment *or* it is or will be produced and/or imported in substantial quantities (generally considered to be 1 million pounds per year or more) and there are human exposure and/or environmental release-related concerns. Those subject to the testing requirement must bear its costs. This section is in keeping with the general objective of TSCA to gather and maintain sufficient information about chemicals to allow government to act if that is warranted, based on a reasonable concern for human health and the environment.

In Section 4(e) of TSCA, Congress created an Interagency Testing Committee ("ITC") to make recommendations to EPA concerning which chemical substances that should be given priority consideration for testing under TSCA. It consists of representatives from many agencies and organizations from across the government and has generally given priority to chemicals about which it has suspicions of toxicity or exposure such as potential carcinogens and for which there is little, if any, testing data on ecological effects, environmental fate, or health effects. Generally, in making its recommendations, the ITC will consider such factors as looking at production volume, quantities released into the environment, the extent of human exposure, existing health effects data and the extent to which testing may result in useful data. Over the past 20 years, the ITC has recommended testing of more than 130 chemicals. EPA is required to act on the recommendation within 12 months of receipt and has issued over 60 so called "Section 4 test rules". The Agency has also made use of consent agreements for testing to avoid lengthy rule-making proceedings. Within 30 days after the effective date of a test rule, each party subject to the rule must either notify EPA that it will conduct testing, submit an application for an exemption, or be covered by regulatory provisions that relieve them of obligations. Should no manufacturer or processor notify EPA that it will conduct testing as required, EPA will notify all subject manufacturers and processors of that fact and 30 days after that, all subject persons manufacture and processing of the chemical will be in violation of the rule. All persons that are subject to testing under section 4 test rules are required to provide equitable testing cost reimbursement to persons who actually conduct the testing, as determined by EPA regulations if no cost sharing arrangement is otherwise agreed to. If after completion of all testing, EPA receives test data or other information indicating that "there may be reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations or birth defects" the EPA must within 180 days initiate the appropriate rulemaking under TSCA Sections 5, 6 or 7 (See above) or publish in the Federal Register reasons for not taking such action. EPA and other Federal Agencies can also can use information developed under TSCA 4 to otherwise support action under TSCA or other regulatory authorities (e.g., Clean Air Act).

A8-5.2.2.6 Export and Import into the United States of TSCA-Covered Chemicals

TSCA Sections 12(b) and 13 provide EPA with authority to deal with notifications for exports of certain chemicals and United States Treasury Department (United States Customs Service, which is now part of Customs and Border protection under the Department of Homeland Security) to promulgate rules regarding the importation of certain substances. Section 12(b) requires exporters to notify EPA if they export or intend to export certain chemical substances and mixtures. The purpose of this section is to inform foreign governments, in a general manner of what EPA knows of the hazards associated with these chemicals and provide information about the nature of TSCA regulatory actions affecting the chemical. Under TSCA Section 13, the US Customs Service must refuse entry into the United States of any chemical substance that fails to comply with TSCA. The burden is on importers to certify to US authorities that the chemical substances, mixtures and articles being imported (this could include chemicals, items containing chemicals, materials for recycling, hazardous waste and genetically-engineered micro-organisms) either comply with TSCA, which is a so-called “positive certification” or are not subject to TSCA, which is a so-called “negative certification.” Blanket import certificates may be used to certify TSCA compliance for multiple shipments of the same chemical substances over a one year period. If, for example, the chemical is on the TSCA existing chemical inventory list, and all testing and reporting requirements have been complied with, all that need be submitted is a signed positive certification. The Customs Service will detain any shipment containing chemical substances that is not accompanied by an import certificate or, even in cases where a certificate is provided, if it has reasonable grounds to conclude that the shipment is not in compliance.

A8-5.2.2.7 TSCA Enforcement

TSCA Sections 11, and 15-17 create enforcement authority for EPA and list prohibited acts, civil and criminal penalties and requirements for enforcement or seizure. Section 11 grants to EPA broad authority to conduct inspections to enforce the Act. Inspection authority extends from all things within the facility where the chemicals are manufactured or stored to any conveyance used to transport the chemical substances. If EPA is denied entry it may seek a search warrant to conduct inspections, or when it considers an surprise inspection crucial to the enforcement goal. In most cases, however, the inspection takes place only after the facility has received a written notice of inspection. EPA is further authorized to issue administrative subpoenas to require the attendance and testimony of witnesses, the production of documents and other information that the EPA deems “necessary.”

It is unlawful under TSCA Section 15 to: fail or refuse to comply with a test rule or order; to use for commercial purposes any chemical substance or mixture which the person knows or had reason to know was manufactured, processed, or distributed in violation of the Act; to fail or refuse to establish or maintain records or submit reports or notices or other information; and to fail or refuse to permit entry or inspection as

required by Section 11 (See above). EPA can impose civil penalties of up to \$27,500 per day for each such violation but most civil penalty proceedings result in negotiated settlements. These are carried out pursuant to a written consent agreement and a consent order. EPA is also authorized to seek criminal penalties against any person who “knowingly or willfully” violates any provision and can seek criminal fines and /or imprisonment of up to one year. US District Courts may also seize and condemn any chemical substance, mixture or product manufactured, processed or distributed in violation of TSCA.

TSCA Section 21 deals with citizen petitions. Any citizen may petition EPA to take action under Section 4 (rules requiring chemical testing); Section 6 (rules imposing substantive controls on chemicals, or Section 8(information gathering rules). The statute also authorizes a citizen-petitioner to request the issuance, amendment or repeal of orders under Section 5(e) (orders affecting new chemical substances) and Section 6(b)(2) (orders affecting quality control procedures. The Administrator of EPA must either grant the citizen petition or make publicly available the reasons for denial by publishing them in the Federal Register. Within 60 days of denial or no action, petitioners may commence a civil action in a US district court to compel initiation of the requested rulemaking. After hearing the petition, the court can order EPA to initiate the requested action.

Not all chemicals are subject to TSCA. Pesticides are regulated under the Federal Insecticide, Fungicide and Rodenticide Act which is discussed briefly below. Food additives, drugs, cosmetics and medical devices are regulated by the Federal Food Drug and Cosmetics Act, administered by the US Food and Drug Administration has not been included within the scope of this discussion.

A8-5.3 The Pollution Prevention Act and Voluntary Pollution Prevention Programs

When EPA/OPPT was established in 1977 to implement TSCA, the Agency was generally concerned with control of current sources of pollution and used “end-of-pipeline command and control” approaches. Over the years, this approach has evolved into placing a stronger emphasis on the prevention of pollution at the source. In 1990, the Pollution Prevention Act was passed which sought to reduce or eliminate the creation of pollutants at the source through: increased efficiency in the use of raw materials, energy, water or other resources or protection of natural resources by conservation. “Source reduction” includes any practice that: reduces the amount of hazardous substances that enter any waste stream or are otherwise released into the environment prior to recycling, treatment or disposal. Two Executive Orders, issued by the President have served to incorporate pollution prevention approaches within federal government practice. In 1998, Executive Order 143101: Greening the Government Through Waste Prevention, Recycling and Federal Acquisition, mandated that the federal government, an huge purchaser of goods within the US, adopt environmentally preferable purchasing including with respect to the purchase of

chemicals and pesticides. There are also wholly voluntary programs such as “Green Chemistry” which focuses on pollution prevention through the environmentally conscious design of chemical products and processes.

Under the US system, EPA has broad authority for toxic chemical management. Such a broad regulatory authority is important for China to study. When considering TSCA, it is important to bear in mind, especially when considering limitations on resources, that chemical risk reduction activities can have not only statutory, but important voluntary dimensions. EPA, therefore, is both a gatekeeper and guardian against chemical hazards but also a facilitator and promoter of environmental stewardship. In the United States, it has been shown that cost-and time-effective risk management can sometimes be accomplished through voluntary partnerships with broad-based stakeholder groups EPA has frequently acted as a convener, bringing together groups that might not otherwise communicate and cooperate

A8-5.3.1 Key EPA Public/Private Partnerships that Address Certain Highly Toxic Chemicals

Perfluorinated acids are man-made chemicals with uniquely valuable properties and functionality. Concerns began with perfluorooctyl sulfonate (PFOS) in the late 1990’s when reporting under TSCA Section 8(e) indicated that it was persistent, widespread in the environment and caused reproductive/developmental toxicity in animal studies, and was present in humans at low levels. The investigation expanded to include perfluorooctanoic acid (PFOA) and fluorinated telomers. The main producer in the U.S. of PFOS voluntarily phased out production worldwide between 2000 and 2002. Small quantities continue to be produced overseas by other companies. Significant new use rules under TSCA Section 5(a) were published to restrict the return of these chemicals to the US market. With respect to PFOA, the EPA invited the eight major companies in the industry to commit to achieve, no later than 2010, a 95% reduction in both facility emissions to all media and product content of PFOA. They further committed to work toward the elimination of PFOA by 2015. Polybrominated diphenyl ethers (PBDEs) is a group of brominated flame retardant chemicals that have been of increasing interest to EPA and the US public. Current information suggests that, as a class, they are persistent and may bioaccumulate. EPA is leading a furniture flame retardancy partnership to evaluate alternatives to PBDEs in furniture applications. Also, with respect to lead, the EPA has promulgated regulations that establish hazard standards for lead in residential paint, dust and soil.

A8-5.4 The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); & U.S.C. Sections 136-136y

The benefits of pesticides are well known and have done much to spare the US from the ravages of disease, crop infestations, noxious animals and weeds. They enable the US to feed itself and to feed others. Since the early 1960’s, however, there has also arisen a growing awareness of the hazards as well as the benefits of chemicals. What the US statutory scheme attempts to do and what may be of particular interest to the

PRC, is to balance these often conflicting environmental risks and benefits in light of scientific uncertainty. Though many other environmental issues have clearly arisen in the interim, it was probably pesticides and their implications for the food supply and their effects on people in agricultural areas that was the most important reason for the creation of the EPA. Congress first enacted the Federal Insecticide, Fungicide and Rodenticide Act in 1947. In 1970, the functions and many of the personnel assigned to a number of federal agencies with some responsibility for implementing the pesticide laws were all assigned to EPA. Within EPA, FIFRA is administered by the Office of Pesticide Programs (OPP). In 1972, FIFRA was amended and transformed into a comprehensive scheme for the regulation, distribution and sale of pesticide products through passage of the Federal Environmental Pesticide Control Act

At the heart of FIFRA, is the pesticide registration program. Before a pesticide may be manufactured, distributed, or imported, it must be approved by EPA. Registrations are expensive and involve a complex process more akin to a drug registration under the federal food and drug laws (not discussed here) than to the notification required for non-pesticidal chemicals under TSCA, discussed above. All new pesticide products used in the US, with minor exceptions, must first be registered with the EPA. A complete formula, a proposed label, and full description of the tests made and the results obtained upon which the claims are based, must all be submitted. The registration obtained is very specific and is not valid for all formulations or even uses of a particular chemical. A separate registration is required for each crop or insect on which the pesticide product may be applied as well as for different dosages of the application. Pursuant to FIFRA, several types of pesticide registration have been established

Registrations must be granted unconditionally if the EPA determines that: the composition is such as to warrant the proposed claims for it; the labeling and other material required to be submitted comply with FIFRA; it will perform its intended function without unreasonable adverse effects on the environment and, when used in accordance with widespread and commonly recognized practice, it will not generally cause “unreasonable adverse effects on the environment” (this phrase is defined elsewhere in the statute to mean “any unreasonable risk to man or the environment taking into account the economic, social and environmental costs and benefits of the use of the pesticides). The registration is valid for 15 years and automatically expires unless there is a petition for renewal. Though the States may not permit any sale or use of pesticides prohibited under FIFRA, states may provide for additional uses of federally registered pesticides to meet “special local needs”. These state uses are, however, subject to possible disapproval by EPA.

Until the 1972 amendments, the US federal government had no control over the actual use of a pesticide once it left a manufacturer or distributor properly labeled. In reality, however, a chemical that could be safe for use on a dry field might be environmentally hazardous if applied in a marshy area. Other pesticides might be too

dangerous for general use but could be used safely by trained professionals using special equipment. The amendments limit certain uses to qualified individuals. A pesticide may be placed into a restricted category that is only available to certified applicators.

To facilitate its registration and product labeling decisions, EPA has promulgated elaborate requirements for the numerous scientific studies that it directs pesticide manufacturers to conduct to obtain and maintain registrations for pesticide products. In accordance with EPA regulations, pesticide registration studies must be conducted in compliance with good laboratory practice (GLP) requirements. This is intended to ensure the quality and integrity of all data submitted to EPA in support of pesticide registrations.

Re-registration is a review of existing pesticide registrations for a pesticide active ingredient to determine whether those registrations meet the statutory standard, or whether any registered products should be canceled or their use modified or limited. It also identifies data gaps in the database that supported registration, and acts as a screening process to select pesticides for more intense review. EPA also has broad authority under the statute to require existing registrants to submit additional test data that is identified by EPA as necessary to support the continued registration of a pesticide. EPA may suspend the registration of any registrant who fails to take appropriate steps to respond to a notice for such data.

While the registration process is key, the tool available to EPA that draws the most public attention is cancellation of a pesticide registration. The cancellation process is used to initiate a review of a substance suspected of posing a substantial question of safety to humans or the environment. While cancellation proceedings are pending, the product may continue to be manufactured and shipped in commerce. The cancellation order itself, though final if not challenged within 30 days, usually leads to a public hearing or scientific review committee or both and the process culminating in cancellation can be quite lengthy. A suspension order is an immediate ban on the production and distribution of a pesticide and is mandated when a product constitutes an imminent hazard to humans or the environment and may be invoked at any time. An “emergency suspension” is the strongest environmental action EPA can take under FIFRA. It immediately halts all uses, sales and distribution of the pesticide. The EPA may only use this procedure when it determines that an emergency exists and time does not permit a hearing prior to suspension of use. EPA may also order that sales be halted when claims are made about a pesticide that are unsupported by the registration. Cancellation and suspension decisions are meant to apply only in the US because the risk-benefit calculations applied to the challenged pesticides are based upon conditions in that country and would not necessarily be valid abroad where there are different risks and benefits. An important question faced by EPA following a cancellation or suspension action is whether to recall those products already in commerce. Generally, EPA has allowed banned pesticides to be used until remaining

supplied are exhausted and does not subject them to recall.

If at any time after the registration of a pesticide, the registrant has additional factual information regarding unreasonable adverse effects on the pesticide on the environment, the registrant is required to submit that information to EPA. Types of information that must be reported include toxicological studies in ecological studies, human epidemiological and exposure studies, and toxic or adverse effect incident reports. There are also significant record-keeping requirements. These include that the producer keep certain records regarding the shipment of all pesticides and active ingredients used in producing pesticides. A pesticide registrant/producer must keep documents including the inventory records for the types and amounts of registered pesticides produced, records regarding the disposal of pesticides or active ingredients, records of tests conducted on human beings, and records containing research data.

A pesticide may only be imported into the US if it is registered under FIFRA and a Notice of Arrival is completed prior to the shipment's arrival in the United States. A pesticide, or active ingredient used in a pesticide, may be exported from the US when prepared or packaged according to the specifications of the foreign purchaser subject to the producer meeting certain FIFRA requirements including the labeling requirements (labeling must include the information that the pesticide or active ingredient is not registered for use in the US and appear in English and in the language of the country of import) and books and records requirements. The US is not yet a party to the Stockholm (POPs) or Rotterdam (PIC) Conventions though it has signed both treaties and played leading roles in their negotiation in the 1990s. US instruments of ratification have not yet been deposited because implementing legislation amending FIFRA and TSCA, which would allow the United States to fully meet its obligations under those instruments, has not yet been passed by both houses of the US Congress. This is largely due to continuing controversy over legislative provisions regarding the manner in which that legislation would deal with the addition of other "POPs" chemicals beyond the so-called "dirty dozen," none of which are still in commerce within the United States. That said, the United States as a signatory to both the PIC and POPs Conventions, upholds their object and purpose by cooperating fully with Parties implementing the convention. Moreover, the statute provides that any person exporting a pesticide not registered under FIFRA shall obtain a "foreign purchaser acknowledgment statement" from the purchaser stating that the purchaser understands that such pesticide is not registered in the United States and cannot be sold in the United States consistent with US law. This requirement can be satisfied annually or on a per-shipment basis and foreign purchaser statements have to be filed with EPA according to deadlines specified by regulation. An unregistered pesticide may be transferred within the US solely for export if it meets the labeling and packaging requirements of US regulation and the foreign purchaser has signed the acknowledgment statement.

The precursor to any enforcement action is likely to be either an inspection or a

subpoena from EPA. EPA's employees may inspect facilities where pesticides are held for distribution or sale or where cancelled or suspended pesticide products are being held. EPA may also obtain and execute warrants to enter, inspect and copy records that are required to be maintained.

Under FIFRA, It is unlawful for any person to sell or distribute a pesticide that: is unregistered; though registered, is accompanied by claims different from those approved by EPA; has not been colored or discolored if coloration is required; or that is adulterated or misbranded. A pesticide is misbranded if, for example, it bears any false or misleading statement or does not contain directions for use adequate to protect human health and the environment. Adulteration occurs when the strength or purity of the pesticide differs from that stated on the label or if any substance has been substituted in whole or in part for the pesticide, or if any valuable component of the pesticide is not present. EPA is authorized to bring a seizure action in federal district court against a pesticide that violates any of these requirements. EPA also has the authority to issue "stop-sale" or "removal" orders to prevent the sale, distribution, or use of a pesticide, or require the removal of a pesticide, that is in violation of FIFRA. Fines may be imposed for these violations. However, EPA may also bring criminal charges against a registrant, applicant or producer who knowingly violates any provision of the law with penalties ranging up to \$50,000 and/or 1 year in prison. It is important to note that in many cases, EPA and the defendant are able to reach a settlement in conference and sign a written "consent agreement" that is filed at the conclusion of the case along with a consent order . The consent agreement, which settles the matter, usually includes, among other provisions: a stipulation that EPA has jurisdiction over the subject matter alleged in the complaint; a statement that the respondent admits, or neither admits nor denies, the factual allegations in the complaint; a recitation of the amount and terms for payment of a penalty, and the justification for such a penalty and of any other terms and conditions that are part of the settlement; and a statement that the respondent will not contest EPA's reliance on the consent agreement and consent order as demonstrating a prior violation in a future enforcement action.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA (and other pesticide law) to establish a more consistent regulatory agenda grounded in science by (i) mandating a single, health-based standard for all pesticides in all foods; (ii) providing special protections for infants and children; (iii) expediting the approval of safer pesticides; and (iv) requiring periodic reevaluation of pesticide registrations and tolerances (maximum permitted residues on food) to ensure that the scientific data supporting pesticide registrations will remain up-to-date in the future. By 2006, after ten years, over 99% of the tolerance reassessments were completed by EPA.

A8-5.5 The Federal Emergency Planning and Community Right-to-Know Act (EPCRA)

EPCRA was signed into law on October 17, 1986 and codifies the concept that

residents in a community have a right to know about the presence in their community of particularly hazardous substances that could be released into the environment. The primary purpose of the law is to provide the U.S. public with access to information concerning hazardous chemicals present in the community and to use such information to adopt local emergency response plans in the event of a chemical release. EPCRA both compels the establishment of state and local emergency planning bodies as well as the development and implementation of local emergency plans. It further requires certain facilities to provide detailed reports on the presence and health effects of specified chemicals and releases.

A facility must engage in emergency planning based on the presence of an “extremely hazardous substance” (EHS) only if that substance exists at the facility in an amount greater than its threshold planning quantity (TPQ). This amount will be different for each EHS. If the facility has that amount, it must meet all of the emergency planning requirements. However, if the EHS exists in forms where it constitutes less than one percent by weight if a compound or a mixture, it is regarded a de minimis and its volume is not considered in determining where the TPQ level has been met.

If such amounts of an EHS are present at a facility, its owner/operator shall, within sixty days, notify the State Emergency Response Commission (SERC) that the facility is covered by the emergency planning requirements of the law. The facility then appoints an emergency response coordinator and notifies the Local Emergency Planning Committee (LEPC). The LEPC must be notified of any changes occurring at the facility that may affect community planning. Each LEPC is required to prepare (and annually update) an emergency plan. Information to be included in the program includes identification of emergency equipment and facilities available in the community and at each covered facility as well as evacuation plans and methods and schedules for carrying out such plans.

A facility owner/operator may be required to notify federal, state or local authorities upon the release of specified substances from the facility unless it is fully contained and only persons within the facility are exposed. The owner/operator must immediately notify the community emergency coordinator of the LEPC and the SERC of any reportable release. The EPA has made available summaries of the Toxic Release Inventory (TRI) data covering a number of industrial sectors on the internet. The TRI contains the EPCRA pollutant release data.

EPCRA contains so-called “citizen suit provisions” which permit “any person” to commence a civil action against a facility owner or operator for various violations of the statute.

A8-5.6 US Involvement in International Efforts to Promote the Environmentally-Sound Management of Chemicals; Cooperative Efforts between the US and the PRC

Multilateral environmental agreements and arrangements are negotiated by the United States under the leadership of the State Department and its Bureau of Oceans and International Environmental and Scientific Affairs. These negotiations are always undertaken in close cooperation with the EPA and/or other relevant technical and scientific agencies and components of the US government. As most of these international environmental regimes affect goods-in-commerce, there is also often involvement from the Office of the US Trade Representative and the Commerce Department. In the US experience, full coordination among all agencies that have jurisdiction over any aspect of policy that might be affected by an environmental regime, including particularly economic, trade, foreign and national security policies, is required to ensure a workable and successful outcome.

The United States has played a leadership role in the international negotiation of a number of chemicals management regimes where it was clear that *only* international action engaged in by most, if not all, of the world's major emitters, was required to address the concern. Prime examples of this would be the Montreal Protocol for the Protection of the Ozone Layer, that successfully promoted the international phase out of ozone-depleting chemicals and pesticides. The United States has been a Party to that treaty for over 15 years and though some ozone-depleting substances have proven difficult to phase-out on the schedule agreed to initially (a prime example of a widely used pesticide that is effective and has few effective and environmentally sound substitutes in certain regions of the world, is the nematocide, methyl bromide which has proven difficult for the United States to phase out as quickly as desired), international action has made significant progress in alleviating the international problem. Another example of where global action is *necessary* is the Stockholm Convention on Persistent Organic Pollutants (POPs) which seeks to prohibit or restrict the production, use, release and/or transboundary movement of, certain identified POPs which can travel long distances in the environment, are persistent, bio-accumulative, and can have severely adverse human health or environmental effects. Here again, given the long range transport of POPs, only a global solution can have the desired environmental and health effect. The Rotterdam Convention on Prior Informed Consent (PIC) for certain toxic chemicals and pesticides, constructs an international regime that gives the recipient of those chemical substances that the international community has agreed should be added to a so-called "PIC list" the opportunity, prior to import, to refuse them. Strictly speaking, an international regime, might not be necessary in this case, were each country to adopt this type of an arrangement into its domestic laws, as the United States had already done under FIFRA. See above. However for reasons of efficiency, uniformity-of-approach, and to ensure that such regimes are wisely adopted and can function together, an agreement such as the PIC is extremely useful in promoting sound chemicals management world-wide. The United States has signed both the Stockholm and Rotterdam

agreements and intends to ratify both; it attends the conferences of the parties and various working groups as an observer.

The United States, along with the PRC and Germany have participated fully in the development of a Strategic Approach to International Chemicals Management (SAICM) which was developed under the auspices of the United Nations Environmental Program (UNEP) and in coordination with the Intergovernmental Forum on Chemical Safety (IFCS). Among other things, the non-binding output is intended to provide information to countries with incomplete chemical management regimes and/or those who wish to strengthen such regimes, with options for doing so. The Organization for Economic Cooperation and Development, consisting of 30 industrialized developed countries, has a number of chemicals programs in which the United States actively participates. These include the Screening Information Data Set (SIDS) to facilitate the investigation of high production volume chemicals, the globally harmonized system of classification and labeling (GHS) to promote better exchange of information on the hazards of chemicals to human health and the environment, and a proposed Mutual Acceptance of Notifications process in response to concern over the need to better align new chemicals systems in the global market. Also, there is the OECD Test Guidelines Program, a foundation of which is the Mutual Acceptance of Data (MAD) agreement among OECD countries to accept the test guideline-run studies for review regardless of where the study is performed.

The PRC and the US have an important, growing, almost 30 year-old, bi-lateral environmental relationship that has led to significant cooperation in the chemicals management arena. The two most important pillars of this relationship is the US-PRC Agreement on Cooperation in Science and Technology dated January 31, 1979, and the Memorandum of Understanding between EPA and SEPA on scientific and technical cooperation in the field of the environment dated December 8, 2003. Under the MOU, a joint EPA-SEPA Committee on Environmental Cooperation is charged with developing cooperative activities on pollution for POPs and other toxic substances. The concept is further elaborated in Annex 3 to the MOU. EPA and SEPA are also currently engaged in a "Toxics Strategy" that is intended to implement Annex 3.

Within the Toxics Strategy, in addition to joint work to address pollution from unintentional POPs (dioxins and furans) and pesticides (lindane), mercury, PCBs and PBTs, there is a chemicals management component. This component includes risk assessment training for industrial chemicals that will include selecting modes and identifying assumptions. It also includes providing SEPA with a better understanding of EPA's New Chemicals Program which is designed, as described herein, to prevent environmental risks before they occur. There will also be collaboration on the management of risks associated with particular existing chemicals of concern, such as PFOA and PDBE's. The US will share program strategies for working with industry through voluntary means to provide health and safety data on high production volume

chemicals and efforts to make basic screening-level data available to the public.

There is also collaboration in the area of pesticide management, including harmonization of risk assessment, and enhancement of regulatory capacity. This includes guidance for the private sector in the PRC to develop basic data for the risk assessment process and development of procedures for the evaluation and determination of appropriate internationally harmonized pesticide residue levels on foods. There will also be work to improve regulatory decision making capacity and collaboration on the establishment of good laboratory practices (GLPs) for the development of data used in the risk assessment process, as well as development of a GLP compliance monitoring program which will support sound pesticide risk management.

A8-5.7 Conclusion

Consistent with the joint work in the area of chemicals management that the US and the PRC are already undertaking, this exercise and the further review and study of US regulatory experiences and paradigms should provide a relevant template for chemical and pesticides management in the PRC, as it works to strengthen its regime and further develop its regulatory capacity. A number of US chemicals management practices are well suited to a nation faced with the challenge of setting priorities and making progress in key areas but constrained by limited resources.