

## State Council of China Has Announced Revised Regulation on Control Over Safety of Dangerous Chemicals

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The State Council of the People's Republic of China announced the revised Regulation on the Control over Safety of Dangerous Chemicals (hereafter referred to as "the revised Regulation") on March 02, 2011. It will become effective on December 1, 2011 and replace the current version, which took effect in 2002 (hereafter referred to as "the current Regulation").

The revised Regulation covers the manufacture, use, operation, transportation and registration of dangerous chemicals. The revised Regulation will serve as the base regulation for various implementing rules to be published by various government agencies. These implementing rules will be announced by responsible agencies in the future.

### 1. General Rules

Article 3 of the revised Regulation provides a refined definition for dangerous chemicals. Dangerous chemicals are toxic chemicals and other chemicals that have properties of hazardous, corrosive, explosive, flammable, combustion supporting and are hazardous to human, facility and environment. A consolidated list of dangerous chemicals will be jointly announced by governing agencies under the State Council in accordance with the Chinese hazard classification standards of chemicals which were developed based on the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The standards include GB 13690, General rules for classification and hazard communications of chemicals, and 26 technical standards.

The scheme of regulating dangerous chemicals has been a complicated and fragmented one. Ten government agencies are authorized to regulate dangerous chemicals by imposing different responsibilities prescribed in Article 5. These agencies include State Administration of Work Safety (SAWS), Ministry of Industry and Information Technology (MIIT), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), Ministry of Public Security (MPS), Ministry of Environment Protection (MEP), Ministry of Health (MOH), Ministry of Transport, Ministry of Railways, Civil Aviation Administration of China (CAAC) and Ministry of Agriculture (MOA). The overall responsibility of policy coordination is transferred from the State Economic and Trade Commission (SETC) to the State Council to SAWS.

### 2. Manufacturer

According to Article 14, any company that produces dangerous chemicals must obtain the Safety Production License of Dangerous Chemicals from the local work safety agency (i.e., the local authority exercising the delegated authority of the SAWS) before manufacture. SAWS published a draft revision of the current rules on issuing production licenses for dangerous chemicals in November 2010, which would impose more rigorous requirements, however the final rules have not yet been announced.

Article 15 mandates that the manufacturers of dangerous chemicals provide the Material Safety Data Sheet (MSDS) and affix precautionary labels on the package. The MSDS and safety labels must comply with relevant national standards (GHS type GBs, such as GB 15258 General rules for preparation of precautionary label for chemicals and GB 16483 Safety data sheet for chemical products – Content and order of sections). When new dangerous characteristics are identified, the producer must notify the public and update the MSDS accordingly.

### 3. Use

Article 29 specifies that any chemical company that uses dangerous chemicals during production must obtain the Safety Use License of Dangerous Chemicals from the local work safety agency unless: 1) the amount of dangerous chemicals is below the threshold; or 2) its use is covered by a Safety Production License of Dangerous Chemicals issued to a manufacturer of dangerous chemicals. The threshold of exemption will be determined later and announced by SAWS along with MPS and MOA. Under the current Regulation, use or handling of dangerous chemicals is not subject to license so long as the facility design has appropriately addressed the concerns of waste emission and fire prevention. The new requirement may impose additional burdens on the chemical companies that do not produce, but only use dangerous chemicals. According to Article 101, these companies must obtain the Safety Use License of Dangerous Chemicals from the local work safety department within the period to be determined by SAWS in the future.

### 4. Operation

"Operation" is defined as sales and distribution. Any company that "operates" (sells, distributes or provides storage service) dangerous chemicals must apply for the Safety Operation License of Dangerous Chemicals from the local work safety department unless: 1) a manufacturer of dangerous chemical sells its product within its plant site; or 2) the operator of a harbor who holds the Harbor Operation License provides storage service of dangerous chemicals in the harbor (Article 33). A slight difference between the current and revised Regulation is the level within each government agency that is authorized to issue licenses. Generally, authorities that can issue such licenses are one step down the administrative hierarchy according to the revised Regulation. More specifically, the city level work safety department is responsible for issuing license to the companies that operate toxic or explosive chemicals or provide storage service of any dangerous chemicals, while the county level work safety department is responsible for other dangerous chemicals (Article 35).

Article 37 also states that companies must not purchase dangerous chemicals from unlicensed manufacturers or operate dangerous chemicals without MSDS or precautionary labels.

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## **EPA's Designation of Trichloroethylene ("TCE") as a Human Carcinogen** **continued from cover**

### **BRIEF ASSESSMENT HISTORY FOR TCE**

EPA's proposed designation of TCE as a human carcinogen has evolved over time. IRIS's last assessment regarding TCE was in 1989. Also, in 1989, the EPA Science Advisory Board ("SAB") disagreed that TCE was a probable human carcinogen. However, by 1995 TCE was noted as "probably carcinogenic to humans." In 2001 TCE was noted by other studies as "reasonably anticipated to be a human carcinogen" and "highly likely" to be carcinogenic to humans. In 2005, EPA characterized TCE as "carcinogenic to humans" by all routes of exposure. Subsequently, in October 2009, the EPA prepared the draft report (EPA/635/R 09/011A) entitled Toxological Review of Trichloroethylene in Support of Summary Information on the Integrated Risk Information System (IRIS), in which the EPA proposed to classify TCE as "carcinogenic in humans by all routes of exposure." EPA's 2009 conclusion was based on "convincing evidence of a causal association between TCE exposure in humans and kidney cancer." Finally, as noted in the first paragraph, EPA designated TCE as a human carcinogen in September, 2011.

Thus, EPA's recent designation of TCE as carcinogenic to humans is the capstone of work conducted over the past two decades.

### **FUTURE**

The September 2011 EPA assessment that TCE is a human carcinogen will enable the EPA and states to move forward and set more health protective TCE standards for drinking water, air emissions, soil contamination and vapor intrusion. There may also be an uptick in litigation involving communities and citizens impacted by exposure to TCE in various media including through vapor intrusion, to the sources of the TCE. Finally, EPA's designation may spur development of non-hazardous or less hazardous substitutes for TCE.

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### **5. Transportation**

Chapter 5 (Article 43 to 65) specifies detailed requirements for the transportation of dangerous chemicals. Only licensed service providers may be used to transport dangerous chemicals via any route: road, railway, air or water. The major changes in the transportation of dangerous chemicals are the issuance of a Road Transportation Permit and the expansion of inland water transportation.

Under the current Regulation, the consigner must obtain a Road Transportation Permit from the police department of the destination before shipping the toxic chemicals via road transport. The revised Regulation allows the consigner to apply for the permit from the police department of either origination or destination place. It remains a preclearance procedure of road transport for toxic chemicals, but the modification will make the process far more efficient.

Inland water transportation will be allowed for certain dangerous chemicals. The current Regulation prohibits the transport of toxic chemicals and other prohibited chemicals via inland rivers and other closed waters. The revised Regulation narrows the prohibition to inland closed waters. Other inland waters may be used to transport dangerous chemicals other than those toxic chemicals and other chemicals explicitly prohibited.

### **6. Registration**

Article 66 and Article 67 specify the registration system of dangerous chemicals. According to these two articles, all manufacturers and importers must go through a company/substance specific registration by submitting information about hazard characteristics and safe handling. China has already implemented a registration system, under which MEP is in charge of registering imported dangerous/toxic chemicals, and the SAWS is handling the manufacture registration of dangerous chemicals. It is still unclear how the current system is going to be modified and administered by SAWS.

### **7. Penalties**

Penalties are specified in Chapter 7 (Article 75 to 96), including the new provision regarding the contravention against the MSDS related and labeling requirements.

### **8. Conclusion**

These new base regulations become effective December 1, 2011; various implementing rules must be promulgated by the governmental agencies.