

Serial Lecture: Regulations for Color Materials -8-

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Overview of China New Chemical Substance Notification (Regulation Framework, Key Point and Implementation Progress)

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Abstract

In China, new chemicals are regulated by Ministry of Environmental Protection Order No.7 and required to be notified before entering into Chinese market. The current regulation has been implemented for seven years and new amendments are in progress. Here the framework of the regulation, the key point and the implementations of China new chemical notification are reviewed before the revision release. Besides, the main possible amendments are also summarized according to the latest revision progress.

Key-words: China new chemical notification, MEP Order No.7, SCC, Framework, Guidance revision

1. Introduction

China is one of the countries in the world enforcing registration system for new chemical substance which has not been put into domestic market before. The regulation called ‘Measures on the Environmental Management of New Chemical Substances’ was published initially on 12th Sep 2003, as Order No.17 of State Environmental Protection Agency. At that time the companies which intend to produce new chemicals in China or import new chemicals into China were required to summarize the data of the chemical and submit it to China authority to get market approval. In the late 2000s, influenced by the ‘Risk Assessment’ concept in chemical management field, the ‘Measures’ in China was revised and subsequently issued by Chinese Ministry of Environmental Protection as Order No. 7 on 19th Jan 2010 (China State Environmental Protection Agency was upgraded to Ministry of Environmental Protection in 2008). The revised ‘Measures’ is usually called ‘the New Measures’ and it’s the current valid version to regulate new chemicals in China. According to ‘the New Measures’, companies which produce new chemicals in China or import new chemicals into China are still the main body obliged to notify chemicals to Chinese authority. What differs is, in addition to the hazard

data, the companies also take responsibilities of doing risk assessment for chemicals and submit the data set together with the risk assessment report to Chinese authority for approval.

2. Authorities and Functions

2.1 Major Administration Department

In the complicated legislative framework of chemical management in China, the level of ‘Measures on the Environmental Management of New Chemical Substances’ is right lower than the ‘Regulations on the Control over Safety of Hazardous Chemicals’, Decree No.591 of China State Council. Since it’s a ministerial regulation, Ministry of Environmental Protection (hereafter referred to MEP) is the primary administration department, which takes charge of publishing regulation, issuing registration certificates, making the public announcement and giving supervision notice to local environmental protection bureaus, etc.

2.2 Technical Supporting Department

Chemicals Registration Centre of MEP (hereafter referred to CRC-MEP) has been in charge of all the technical supporting work of new chemical notification since the 2003 version of ‘Measures’ was implemented. In 2013, CRC-MEP was combined with Solid Waste Management Centre of MEP and a new department named Solid Waste and Chemicals Management Center of Ministry of Environmental Protection (hereafter referred to SCC-MEP) was established. SCC is subordinated with MEP and mainly focus on the drafting and revising of relevant technical supporting documents of new chemical notification, the most important of which is China New Chemical Substance Notification Guidance, the main technical document that guides the notifiers to complete



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