

The issuance of updated Guidance for China new chemical notification is still pending. The data requirements in the revised Guidance are supposed to be published individually. A further delay in release of the updated Guidance on China new chemical substance notification seems inevitable after several rounds of public consultation including the version notified to the WTO (CL news) and the later updated draft for internal discussion (CL news).

Speaking at ChemCon held in Beijing on 20 Jun 2017, Ms. Hong ZHOU from the Solid Waste and Chemicals Management Center (SCC) under MEP shared that the amendments on data requirements in the revised Guidance are supposed to be published separately this year. Data requirements including the data sources, minimum data requirements and exemptions form the core of the Guidance. An acceleration in the publication of revised data requirements will facilitate an effective planning and conduction of the test programs. However, for the whole Guidance, China MEP intends to firstly revise the MEP Order 7 and then consider the pending implementation of its revised Guidance.

MEP Order 7 and the supporting Guidance for China new chemical substance notification have been implemented for almost 7 years with over 25,000 notification applications approved.

At the beginning of 2017, Shanghai implemented a new chemical supervision regime (CL news). Although inspection results have not yet been published, severe violations have already been subject to punitive measures. More site inspections conducted by local EPA are expected to target new chemical substance certificate holders.

Another important update is that from 1 Apr 2017 the positive list system defining and limiting the accredited eco-toxicological testing institutions for China NCSN data generation has been replaced by an open system that will allow data to be generated in any lab that meets Chinese national standards and regulatory requirements (CL news). So far 13 test institutions have made self-declarations for GLP conformity and are now listed on the MEP-SCC website. On one hand notifiers now have greater flexibility to generate the data required for China NCSN but on the other hand their responsibility and liability for data quality and factual correctness is far greater than before.