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Polytopics

Quarter 4 - 2011

EPA's Designation of Trichloroethylene ("TCE") as a Human Carcinogen

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On September 28, 2011, the U.S. EPA issued the Integrated Risk Information System ("IRIS") assessment for TCE. The conclusion of the IRIS assessment is "based on the weight-of-evidence analysis for kidney cancer and in accordance with U.S. EPA guidelines, TCE is characterized as "carcinogenic to humans. This hazard descriptor is used when there is convincing epidemiologic evidence of a causal association between human exposure and cancer."

The assessment goes on to conclude "in addition to the body of evidence described above pertaining to kidney cancer, non-Hodgkin lymphoma and liver cancer, the available epidemiologic studies also provide suggestive evidence of an association between TCE exposure and other types of cancer, including bladder, esophageal, prostate, cervical, breast and childhood leukemia."

The EPA's designation of TCE as a human carcinogen may create significant changes on how TCE is viewed and used in the future.

BACKGROUND

TCE is a colorless liquid used mainly as a solvent degreaser for metal parts. It is also used as a compo-

nent in adhesives, lubricants, paints, varnishes and other chemicals, including cleaning solvents. As a result of its common usage, TCE has a pervasive presence in the environment. TCE is a common volatile organic compound contaminant detected in groundwater, and it has been found in a variety of foods. Indoor levels of TCE are generally higher than outdoor levels because of releases from building materials. Higher exposures have occurred in various occupational groups such as aircraft personnel that work with TCE.

Exposure to TCE can occur through inhalation, oral and dermal routes; however, the most notable environmental releases are to the air with inhalation as the main route of potential environmental exposure. TCE is rapidly absorbed from the stomach, intestines and lungs and readily crosses biological membranes. Thus, TCE can transfer from mothers to fetuses and to newborns through breast milk. Important target organs of TCE toxicity are the brain, kidneys and liver. TCE leaves the body mainly by lungs (by breath) and the kidneys and liver (through excretion).

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2012 Annual Meeting & PTS

April 21-22 - PTS • April 22-24 - Annual Meeting

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See page 4 for more details



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.

State Council of China Has Announced Revised Regulation on Control Over Safety of Dangerous Chemicals **continued from page 5**

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.