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A New Phase In EPA Chemical Risk Control

Law360, New York (February 25, 2013, 12:55 PM ET) -- On Jan. 9, 2013, the U.S. Environmental Protection Agency released for public comment draft risk assessments on the first five of the "work plan" chemicals identified for priority review by the agency last year. See 78 Fed. Reg.1856.

In March 2012, the EPA unveiled a list of 83 chemicals that the agency is targeting for risk assessments and possible risk management actions in the next few years. The EPA selected the chemicals through a two-step process.

First, the agency reviewed a wide range of internal and external data sources and identified 1,235 chemicals that met one or more of the following factors: chemicals identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects); chemicals identified as persistent, bioaccumulative or toxic (polybutylene terephthalate); chemicals identified as probable or known carcinogens; chemicals used in children's products; chemicals used in consumer products; and chemicals detected in biomonitoring programs.

The EPA then excluded chemicals that are regulated under federal laws other than the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq., (such as pesticides and drugs), as well as chemicals that generally do not present significant health hazards (such as polymers).

The agency also excluded chemicals that already were being addressed by the EPA's chemical action plans or already subject to extensive regulation (such as polychlorinated biphenyls). The EPA also grouped metals and their related compounds together rather than identifying them separately.

These steps resulted in an initial list of 345 chemicals that were assigned scores based on three characteristics: hazard; exposure; and potential for persistence and/or bioaccumulation. The EPA then narrowed the list of chemicals through an exposure review that considered a combination of chemical use in products, general population and environmental exposure and release information.

The EPA also looked at data from the Toxic Release Inventory (TRI) and the 2006 TSCA Inventory Update Reporting rule (IUR). The 83 chemicals identified by the EPA for risk assessment ranked high based on their scores on the ranking factors utilized by the EPA. The list includes chemicals that may not present human health concerns but has met all criteria for identification as persistent, bioaccumulative and environmentally toxic chemicals.

When the EPA released the list of 83 chemicals last year, the agency also announced that it would be conducting risk assessments on seven of the chemicals during 2012. The risk assessments released for comment in January by the EPA address five of those seven chemicals.

The EPA stated that the draft risk assessments for the other two chemicals (long-chain chlorinated paraffins and medium-chain chlorinated paraffins) will be released for public review and comment when they are completed later this year.

According to the EPA, the draft risk assessments focus on human health and/or ecological hazards for specific chemical uses that are regulated under TSCA. Importantly, the draft risk assessments for three of the chemicals — methylene chloride, or dichloromethane (DCM), n-methylpyrrolidone (NMP) and trichloroethylene (TCE) — indicate "a potential concern for human health under specific exposure scenarios for particular uses."

The five chemicals are:

- ATO (CASRN 1309-64-4): ATO is primarily used as a synergist for halogenated flame retardants and a catalyst for polyethylene terephthalate (PET) plastics. The EPA's draft risk assessment focused on potential ecological hazards that may be associated with ATO use in flame retardants. The EPA stated that it expects the risks from ATO to be negligible.

- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran (HHCB) (CASRN 1222-05-5): HHCB is a fragrance ingredient used in a wide range of commercial and consumer products, including perfumes, cosmetics, shampoos, lotions and washing and cleaning agents. The EPA's draft risk assessment focused on potential aquatic and terrestrial hazards associated with HHCB and stated that the ecological risks are expected to be negligible. The draft risk assessment also stated that human health risks of HHCB have been previously evaluated and determined to present minimal concerns.

- DCM (CASRN 75-09-2): Methylene chloride is a solvent used for a variety of purposes, including adhesives, paint stripping, pharmaceuticals, metal cleaning, chemical processing and aerosols. The EPA's draft risk assessment focused on human health hazards (noncancer and cancer) to workers and consumers, including bystanders, associated with acute and chronic inhalation exposures from paint stripping use. The EPA concluded that there are potential risks of concern for human health, but methylene chloride poses negligible ecological risks.

- NMP (CASRN 872-50-4): NMP is a solvent used in a variety of applications, including petrochemical processing, engineering plastics, coatings (resins, paints, finishes, inks and enamels), paint stripping, agricultural chemicals, electronic cleaning and industrial cleaning products. The EPA's draft risk assessment focused on the human health hazards (noncancer) to workers and consumers, including bystanders, from acute and chronic dermal and inhalation exposures when NMP was used in paint stripping. The EPA stated that there are "significant uncertainties" in its understanding of dermal and chronic inhalation exposures of NMP. The draft risk assessment's findings are limited to women of child-bearing age, however, because the only observed toxicological endpoint is developmental toxicity. Specifically, the draft risk assessment concluded that workers may have potential risks of concern from dermal exposure when no gloves are worn; consumers may have potential risks of concern from dermal exposure assuming appropriate gloves are not worn; and consumers may have potential risks of concern from inhalation exposure if exposed for more than four hours in poorly ventilated areas. The EPA stated that NMP poses negligible ecological risks.

- TCE (CASRN 79-01-6): TCE is used as an intermediate chemical for manufacturing refrigerant chemicals, a solvent for metals degreasing, and other purposes. The EPA's draft risk assessment focused on human health hazards (noncancer and cancer) to workers and consumers, including bystanders, from inhalation exposures when TCE was used as a degreaser or a "clear protective coating spray" in the arts/crafts field. The EPA concluded that there are potential risks of concern for human health based on these exposures and that TCE poses negligible ecological risks.

Comments on the draft risk assessments must be submitted on or before March 15, 2013. The EPA also is asking for nominations of experts to serve on peer review panels for the draft risk assessments, which must be submitted on or before Feb. 13, 2013.

The release of the five draft risk assessments signal the next phase in the EPA's enhanced efforts, begun by outgoing EPA Administrator Lisa Jackson, to address and manage chemical risks. The EPA has stated that if its risk assessment on a chemical indicates significant risk, it will evaluate and pursue appropriate action to reduce the risk(s).

If an assessment indicates no significant risk, the EPA will conclude its current work on that chemical. How the agency determines what constitutes a significant risk, as well as determines what, if any, risk management actions may be needed, will be critical. Potential risk management actions by the EPA could range from the imposition of exposure limitations through TSCA § 5 Significant New Use Rules (SNURs) to more significant restrictions on the use or production of the chemicals under TSCA § 6.

It is anticipated that several other draft risk assessments also will be released later this year. In June 2012, the EPA announced that it would conduct risk assessments on 18 other work plan chemicals during 2013 and 2014, although it did not indicate when each specific chemical would be addressed. The 18 chemicals are:

- 1-Bromopropane
- Five chlorinated hydrocarbons:
    - 1,1-dichloroethane
    - 1,2-dichloropropane
    - 1,2-dichloroethane
    - Trans-1-2-dichloroethylene
    - 1,1,1-trichloroethane
- 4-tert-Octylphenol
- Three flame retardants:
    - Bis(2-ethylhexyl)-3,4,5,6-tetrabromophthalate (TBPH)
    - 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB)
    - Tris (2-chloroethyl)phosphate (TCEP)
- Four fragrance chemicals:
    - Ethanone, 1-(1,2,3,4,5,6,7,8-octoahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-4-sec-Butyl-2,6-di-tert-butylphenol
    - Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,5,5-tetramethyl-2-naphthalenyl)-
    - Ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8- tetramethyl-2-naphthalenyl)-
    - Ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8- tetramethyl-2-naphthalenyl)-
- 4-sec-Butyl-2,6-di-tert-butylphenol
- 2,4,6-Tri-tert-butylphenol
- P,p'-Oxybis(benzenesulfonyl hydrazide)
- Octamethylcycloetrasiloxane (D4)

The EPA's actions have significant implications for chemical manufacturers, producers of consumer and other goods that contain the targeted chemicals and other purchasers and users of these chemicals or products containing them. Any company that manufactures, imports, processes or uses any of the 83 priority chemicals should pay close attention to the EPA's actions regarding them.

Following on the heels of the action plan issued by the EPA during 2009 to 2011, the chemical prioritization approach announced by the EPA in 2012 and the recently released draft risk assessments underscore the agency's intent to continue to move aggressively on chemicals.

How the EPA finalizes — and then acts on — the risk assessments on the first five chemicals will provide important insights into the actions the agency intends to take toward both identifying potential risks associated with the chemicals and addressing those risks. The outcomes relating to these first risk assessments also will lay the groundwork for the agency's efforts with regard to the next 18 chemicals as well the rest of the 83 chemicals on the agency's priority list.

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