

On July 22, 2016, the US Environmental Protection Agency (US EPA) issued its first safety determinations on premanufacture notices (PMNs) for new chemicals under the Toxic Controls Substances Act (TSCA) as amended by the recently enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act. US EPA announced the decisions exactly one month after President Obama signed the Lautenberg Act into law on June 22, 2016.

In decisions [posted to its website](#), US EPA determined that four new chemical substances were “not likely to present an unreasonable risk” to health or the environment, the new TSCA standard established by the Lautenberg Act. The PMNs for all four substances had been submitted to US EPA prior to enactment of the Lautenberg Act, but because US EPA concluded that the Lautenberg Act had “effectively reset” the 90-day review period for all PMNs, the agency had reviewed the four chemicals further under the new standard.

The specific chemical identity of each chemical is confidential. The generic names of the four chemicals (and their PMN numbers) are:

- Generic: Fatty alcohols-dimers, trimers, polymers (P-16-0281)
- Generic: Depolymerized waste plastics (P-16-0292)
- Generic: Propyl silsequioxanes, hydrogen-terminated (P-16-301)
- Generic: Organic modified propyl silsequioxane (P-16-302)

While US EPA appears to have selected non-controversial chemicals for its first safety determinations under the new TSCA review standard, US EPA’s decisions give at least some insight into the agency’s thinking, including the methodology it will use to review PMNs, the scope of its consideration of the potential effects of a new chemical and the documentation explaining its decision on a PMN.

US EPA’s Determination Documents

The determination document issued for each chemical is fairly short, only three pages long in each case. In general, each document articulates the agency’s determination about the chemical, the chemical’s name, the chemical’s “assessed conditions of use,” and a summary of US EPA’s evaluation and conclusion. Each document also provides information about the fate, persistence, bioaccumulation, human health hazard and environmental hazard of the chemical, as well as the potential exposures and potentially exposed or susceptible subpopulations relating to the chemical’s conditions of use.

Assessed Conditions of Use: US EPA stated that a chemical’s “intended uses” for purposes of the safety determination are the uses identified in the PMN itself. US EPA identified the “known” and “reasonably foreseen” uses “based on evidence of current use of the chemical substance outside the United States and evidence of the current uses of chemical substances that are structurally analogous to the new chemical substance.” US EPA further explained that it identifies such uses “based on searches of internal CBI EPA PMN databases (containing use information on analog chemicals), other US government public sources, the National Library of Medicine’s Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.”

Fate: US EPA estimated “a number of physical-chemical and fate properties” of each new chemical substance using the Estimation Programs Interface (EPI) Suite, “a suite of physical/chemical property and environmental fate estimation programs” developed by the agency.

Persistence: US EPA estimated “the half-lives for each chemical substance in environmental media (i.e., air, water and soil)” using the agency’s EPI Suite. The agency explained that a chemical substance is considered to have “limited persistence” if it has a half-life in water, soil or sediment of less than two months, to be “persistent” if it has a half-life greater than two months but less than or equal to six months, and to be “very persistent” if it has a half-life greater than six months.

Bioaccumulation: US EPA stated that a chemical substance is considered to have a low potential for bioaccumulation if there are bio-concentration factors (BCF) or bioaccumulation factors (BAF) of less than 1,000, to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than or equal to 5,000, and to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater.

Human Health Hazard: US EPA estimated the human health hazard of each chemical based on its estimated physical/chemical properties (which indicate whether it can be absorbed if inhaled or ingested or by dermal contact) and by comparing it to “structurally analogous chemical substances for which there is information on human health hazard.” The agency explained that a chemical substance is considered to have “low human health hazard” if effects are observed in animal studies with a No Observed Adverse Effect Level (NOAEL) equal to or greater than 1,000 mg/kg/day and to have “moderate human health hazard” with a NOAEL less than 1,000 mg/kg/day. A substance is considered to have “high human health hazard” if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies with a NOAEL of less than or equal to 10 mg/kg/day.

Environmental Hazard: US EPA estimated the environmental hazard of each chemical by comparing it to “structurally analogous chemical substances” using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model, a “predictive system” that estimates a chemical’s acute and chronic toxicity to aquatic organisms, such as fish, aquatic invertebrates and aquatic plants, by using computerized Structure Activity Relationships (SARs).

Fatty Alcohols-dimers, Trimers, Polymers (P-16-0281)

In the [determination document](#) for this chemical US EPA identified the “intended use” as “reactive polyol (generic)” and the “known and reasonably foreseen uses” as “lubricant and lubricant additive.” US EPA considers the chemical to have “low potential” to volatilize into the air or migrate into groundwater and could be effectively removed if released into wastewater. Although US EPA considers the chemical to be “persistent,” the agency concluded that this “did not indicate a likelihood” that the chemical would present an unreasonable risk, since the agency also estimates that it has low potential for bioaccumulation, low human health hazard and low environmental hazard because of its similarity to other fatty alcohol polymers. Interestingly, US EPA stated that “it was unnecessary to estimate the potential for exposure” to the chemical because the agency concluded that the chemical “presents both low human health hazard and low environmental hazard.” The agency stated that the chemical “would be unlikely to present an unreasonable risk even if potential exposures were high.” Finally, US EPA determined that because of the chemical’s intended use only “workers in a certain industrial sector” will be exposed to it, and the agency further stated that even though it is “foreseeable” that chemical might be incorporated into “lubricants with the potential for exposures of workers in other industrial sectors or exposures to consumers,” the chemical is still “estimated to present only a low hazard.”

Depolymerized Waste Plastics (P-16-0292)

In the [determination document](#) for this chemical, US EPA identified the “intended use” as “intermediate for use in the manufacture of polymers” and the “known and reasonably foreseen uses” as “lubricant and lubricant additive.” US EPA considers the chemical to have “low potential” to volatilize into the air or migrate into groundwater and could be effectively removed if released into wastewater. Although US EPA considers the chemical to be “very persistent,” the agency concluded that this did not indicate a likelihood that the chemical would present an unreasonable risk, since the agency also estimates that it has low potential for bioaccumulation, low human health hazard and low environmental hazard based on estimates from “analogous chemical substances/structure-activity relationships.” As with P-16-0281, US EPA stated that “it was unnecessary to estimate the potential for exposure” because the chemical “presents both low human health hazard and low environmental hazard” and “would be unlikely to present an unreasonable risk even if potential exposures were high.” “Workers” are the only potentially exposed or susceptible subpopulation identified by the agency.

Propyl Silsesquioxanes, Hydrogen-terminated (P-16-0301)

In the [determination document](#) for this chemical, US EPA identified the “intended use (generic)” as “intermediate” and the “known and reasonably foreseen uses” as “lubricant and lubricant additive.” US EPA considers the chemical to have “low potential” to volatilize into the air or migrate into groundwater and could be effectively removed if released into wastewater. US EPA concluded that the chemical is not likely to present an unreasonable risk since the chemical has “limited persistence,” “low bioaccumulation potential,” “low concern for human health hazard” and low environmental hazard, based on the physical/chemical properties of the chemical and analogous chemical substances/structure-activity relationships. As with P-16-0281 and P-16-0292, US EPA did not estimate the potential for exposure to the chemical because the chemical “presents both low human health hazard and low environmental hazard” and “would be unlikely to present an unreasonable risk even if potential exposures were high.” Again, “workers” are the only potentially exposed or susceptible subpopulation identified by the agency.

Organic Modified Propyl Silsesquioxane (P-16-0302)

In the [determination document](#) for this chemical, US EPA identified the “intended use (generic)” as “plastic additive” and the “known and reasonably foreseen use” as “finishing agent.” US EPA considers the chemical to have “low potential” to volatilize into the air or migrate into groundwater and could be effectively removed if released into wastewater. Although US EPA considers the chemical to be “very persistent,” the agency concluded that this “did not indicate a likelihood” that the chemical would present an unreasonable risk, since the agency also estimates that it has low potential for bioaccumulation, low human health hazard and low environmental hazard, based on the physical/chemical properties of the chemical and analogous chemical substances/structure-activity relationships. Like the other three chemicals, US EPA here too did not estimate the potential for exposure because the chemical “presents both low human health hazard and low environmental hazard” and “would be unlikely to present an unreasonable risk even if potential exposures were high.” And, again, “workers” are the only potentially exposed or susceptible subpopulation identified by the agency.

Looking Ahead

The four safety determinations issued by US EPA are collectively the first substantive action taken by the agency under the recently amended TSCA, and they are instructive in many ways. The long-term utility of the determinations as guidance remains to be seen, however, given, as noted, that all of the chemicals reviewed are non-controversial, with low potential to volatilize into the air or migrate into groundwater, low potential for bioaccumulation, low human health hazard and low environmental hazard. Moreover, US EPA identified workers as the only potentially exposed or susceptible subpopulation and did not estimate the potential for exposure for any of the chemicals. Of much greater significance will be the determinations that US EPA makes hereafter for chemicals that have greater potential for adverse fate and hazards, more impactful exposures and broader potentially exposed or susceptible subpopulations. Our lawyers will monitor US EPA's actions closely.

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