Safer Chemicals Healthy Families
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Principles of Risk Management under TSCA Section 6

After spending the last four years conducting risk evaluations for 10 chemicals under the Toxic Substances Control Act (TSCA), EPA is now finalizing those evaluations and transitioning into risk management rulemaking under section 6(a). TSCA's risk management framework provides the following key principles that must guide EPA as it develops these rules.

1. **To comply with TSCA section 6(a), EPA must eliminate unreasonable risks, without regard to costs and other non-risk factors.** Regulatory options that fail to fully eliminate unreasonable risks as determined in EPA's risk evaluation should receive no consideration under section 6(a). Since EPA's risk evaluations determine that risks exceeding its cancer and non-cancer benchmarks are unreasonable, section 6(a) rules must, at a minimum, reduce these risks to levels that are below the EPA benchmarks.

2. **"Subpopulations" that are at greater risk because of higher exposure, increased susceptibility or other factors must be fully protected under EPA's rule, consistent with TSCA's requirement to identify and eliminate unreasonable risks to "potentially exposed or susceptible subpopulations" (PESS).** Accordingly, exposure pathways relevant to these subpopulations (such as communities that live, work, or go to school near the locations where the substance is released into the environment) must be considered and addressed under the risk management rules.

3. **EPA should take immediate action to address imminent and serious risks presented by the 10 chemicals.** For example, methylene chloride is acutely lethal; at least four people died from exposure to methylene chloride paint strippers between the proposal and partial finalization of EPA's ban on use of these products. Similarly, EPA found that a single exposure to 1-BP during a critical window of fetal development may be sufficient to produce adverse developmental effects. EPA should protect against these risks by making proposed rules immediately effective under section 6(d) and/or using its imminent hazard authority under section 7. It should also encourage manufacturers to take voluntary actions to eliminate the risks presented by their products.

4. **Banning consumer products presenting unreasonable risks of adverse health effects may often be the only regulatory option that effectively and reliably protects consumers.** As EPA concluded in several of its initial risk evaluations and its ban on methylene chloride in consumer paint removers, label warnings and personal protective equipment (PPE) are inadequate to protect consumers from products that present unreasonable risks and therefore insufficient to eliminate such risks as required by section 6(a). Thus, a ban on the chemical's use in consumer products will often be the only effective and reliable requirement that complies with section 6(a).

5. **Industrial and commercial uses of chemicals presenting unreasonable risks should also be banned where workplace protections cannot reliably and effectively reduce exposure to levels sufficient to eliminate the unreasonable risk.** This would be the case, for example, for uses that occur in small businesses with high employee turnover and limited ability to establish and implement effective industrial hygiene controls. or where the chemical is used in open processes that cannot practicably be reengineered to reduce worker exposure below levels that present unreasonable risks.

6. **Where people are exposed to substances presenting an unreasonable risk by multiple routes or pathways, section 6(a) requirements must account for these aggregate exposures in determining the level of protection necessary to provide adequate protection against the risk.** Section 6(a) also requires EPA to eliminate the unreasonable risks presented by "any combination of" a chemical's conditions of use, and thus to requires EPA to consider the risks to workers, consumers, and communities that may be exposed to the chemical from multiple conditions of use.

7. **Where multiple regulatory options will effectively and reliably eliminate the unreasonable risk, EPA has broad discretion to select the most health protective option.** While section 6(c) requires EPA to "factor in" a range of considerations – including the health effects of the chemical, the benefits of regulation, and the cost-effectiveness of different regulatory options – TSCA does not dictate how EPA is to balance those considerations when presented with with multiple options that would eliminate unreasonable risk. EPA may thus choose a regulatory option that maximizes the rule's health and environmental benefits, even if it is more costly than other options.

8. **EPA's evaluations of risk management options must also consider all health and environmental benefits and co-benefits of these options, including those outside the scope of its risk evaluation.** For example, if a regulatory option confers health benefits on a population that was not considered in the risk evaluation, such as communities impacted by air emissions, EPA must evaluate those co-benefits at the risk management stage and may choose an option that not only eliminates the unreasonable risk but maximizes protection of exposed communities.

9. **EPA must account for and quantify all health benefits, including non-cancer health benefits**, The Agency can use existing approaches to calculate benefits but cannot assign a "zero" value if monetary estimates for certain benefits are not available; in cases where benefits are known but not quantifiable, assuming zero benefits would not be scientifically supportable. The Agency should use a default value for these benefits, possibly based on a percentage of the statistical value of life.

10. **EPA's section 6(a) rules should be designed to create incentives to transition to safer, more sustainable alternatives.** Where regulated chemicals will be replaced with other members of the same chemical class or with inadequately studied chemicals that may have similar toxic effects, EPA rules under section 6(a) will fail to eliminate unreasonable risks. EPA should use this opportunity to identify preferred green chemistry alternatives. Moreover, as it develops regulatory options, EPA should identify "regrettable substitution" scenarios that may result from restricting the regulated chemical and include safeguards in its rule and in future reporting/prioritization activities to prevent the use of unacceptable substitutes.

11. **Section 6 chemicals that have similar uses and/or chemical structures should be grouped together when developing regulatory options so that EPA adopts the best overall risk management strategy for these chemicals.** For example, the 10 chemicals include solvents (e.g. methylene chloride, TCE, PERC, NMP, carbon tetrachloride and 1-BP) that have interchangeable uses and, in some cases, similar chemistries and toxicity profiles. EPA should not address each solvent in isolation but frame its rules to maximize protection of solvent users broadly and encourage a shift to safer solvents across-the board. This would be consistent with EPA's authority to address "categories" of chemical substances or mixtures in TSCA section 26(c).

12. **The well-established OSHA/NIOSH hierarchy of controls should guide the selection of regulatory options to protect workers against unreasonable risks.** Under this approach, preferred tools for protecting workers are eliminating a chemical from the workplace, requiring engineering controls and imposing administrative controls. PPE is considered a tool of last resort, to be relied on only where other more effective measures are not feasible and available.