# Obama and EPA Take on TSCA Reform

by Brett H. Oberst, Lynn N. Hang, and Lindsay K. Larris

Brett Oberst is Of Counsel and Lynn Hang and Lindsay Larris are associates at Gibson Dunn & Crutcher LLP.

Privionmental policy was a key issue during the presidential campaign in 2008. Then-Sen. Barack Obama pledged a major change in U.S. environmental policy: "We cannot afford more of the same timid politics when the future of our planet is at stake." In 2009, President Obama has started to deliver on his promise. From the treatment and storage of nuclear waste, to the programs implemented to slash carbon emissions, to the American Recovery and Reinvestment Act's inclusion of funds for environmental research and green-collar job creation, it is becoming apparent that this president is serious about environmental reform.

The Obama Administration's most recent focus has included the Toxic Substances Control Act (TSCA).<sup>2</sup> President Obama has said that he wants the U.S. Congress to reauthorize and significantly strengthen the effectiveness of TSCA.<sup>3</sup> That means that for the first time in 34 years, the law regulating toxic chemicals faces a potential major transformation.

Since the adoption of TSCA in 1976, the U.S. Environmental Protection Agency (EPA) has issued regulations to control only five chemicals.<sup>4</sup> On September 29, 2009, EPA Administrator Lisa Jackson said there are "troubling gaps" in the available data on many widely used chemicals.<sup>5</sup> "Many are turning to government for assurance that chemicals have been assessed using the best available science, and that unacceptable risks haven't been ignored," Jackson said. "Right now, we are failing to get this job done."

While environmental advocacy organizations and industry alike have applauded EPA's intention to reform TSCA, deciding how to reform this law will be far more compli-

 Obama for America, "Barack Obama and Joe Biden: Promoting a Healthy Environment," available at http://www.barackobama.com/pdf/issues/EnvironmentFactSheet.pdf.

2. 15 U.S.C. \$\$2601-2692, ELR STAT. TSCA \$\$2-412.

cated. Several key issues will likely be at the center of the debate, including what safety standard Congress should require EPA to apply, how EPA should prioritize chemicals to be regulated, and how Congress should address the potential economic impact of these reform efforts on both manufacturers and those downstream of the manufacturing process. Resolution of these issues will significantly shape the new legislation and determine its impact.

### I. EPA's Principles for Reform

Administrator Jackson outlined six key principles that address the Obama Administration's goals for legislative reform of TSCA. These concepts are expected to serve as the skeleton for Congress' discussion and debate over proposed legislation<sup>7</sup>:

1. Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-Based Criteria Protective of Human Health and the Environment.

EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Sound science should be the basis for the assessment of chemical risks, while recognizing the need to assess and manage risk in the face of uncertainty.

 Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical's risks to sensitive subpopulations.

Where manufacturers do not submit sufficient information, EPA should have the necessary authority and tools to

Lisa P. Jackson, U.S. Environmental Protection Agency (EPA) Administrator, Remarks to the Commonwealth Club of San Francisco, As Prepared, Sept. 9, 2009, available at http://yosemite.epa.gov/opa/admpress.nsf/a883dc3da-7094f97852572a00065d7d8/fc4e2a8c05343b3285257640007081c5!Open Document.

Id. The five chemicals include polychlorinated biphenyls, chlorofluorocarbons, dioxin, asbestos, and hexavalent chromium. See Lowell Center for Sustainable Production, "The Promise and Limits of the United States Toxic Substances Control Act," Oct. 10, 2003, available at http://www.chemicalspolicy.org/ downloads/Chemicals\_Policy\_TSCA.doc.

<sup>5.</sup> *Id* 

<sup>6.</sup> *Id*.

U.S. EPA, Essential Principles for Reform of Chemicals Management Legislation, available at http://www.epa.gov/oppt/existingchemicals/pubs/principles. html (last visited Dec. 17, 2009).

quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. EPA should also be provided the necessary authority to efficiently follow up on chemicals that have been previously assessed, e.g., requiring additional data or testing, or taking action to reduce risk, if there is a change that may affect safety, such as increased production volume, new uses, or new information on potential hazards or exposures. EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

3. Risk Management Decisions Should Take Into Account Sensitive Subpopulations, Cost, Availability of Substitutes, and Other Relevant Considerations.

EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

4. Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner.

EPA should have the authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable, and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive subpopulations.

5. Green Chemistry Should Be Encouraged, and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened.

The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research, education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy-efficient, and sustainable chemical products and processes.

TSCA reform should include stricter requirements for a manufacturer's claim of confidential business information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.

6. EPA Should Be Given a Sustained Source of Funding for Implementation.

Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals

should support the costs of Agency implementation, including the review of information provided by manufacturers.

## II. Determining the Appropriate Safety Standard

Defining TSCA's safety standard could be an area of significant debate. Under EPA's recently announced principles, greater responsibility would shift to industry. For example, under the current law, EPA must show why it believes a chemical poses a health threat and must use the least burdensome alternative to restrict a chemical's use. That standard, according to Administrator Jackson, "has been a bugaboo for quite some time." This is because the burden is placed on EPA to first establish that a chemical poses a health threat before it can act. Now, EPA wants Congress to shift that burden to industry to prove that a chemical is safe. Under EPA's proposal, manufacturers will be required to develop and submit data to show that existing chemicals are safe.

Although EPA did not say that it will require industry to submit data for all chemicals, there are concerns that this approach will be similar to the European Union's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulations. The basic principle of REACH is that industry is responsible for ensuring that substances contained in products do not adversely affect human health or the environment, under normal and reasonably foreseeable conditions of use. REACH is based on the precautionary principle, which advocates taking precautionary action when chemicals pose possible threats to human health and the environment, rather than waiting for scientific proof of cause and effect. The precautionary principle has not traditionally been a basis for policymaking in the United States.

#### III. Prioritizing Chemical Regulation

Another area of likely debate is the task of determining which chemicals should receive priority in regulation. Considering there are approximately 80,000 chemicals approved for use in commerce, it is essential that there be a statutory and/or regulatory basis for identifying the chemicals that will be evaluated first.

This issue was addressed on November 17, 2009, during a U.S. House of Representatives Hearing on Prioritizing Chemicals for Safety Determination before the House of Representatives Subcommittee on Commerce, Trade, and Consumer Protection.<sup>13</sup> At that hearing, representatives of

<sup>8. 15</sup> U.S.C. §2605(a).

<sup>9.</sup> Daily Environment Report, Toxic Substances: Analysts Say Key Question Is How Principles for TSCA Reform Are Written Into New Law, Oct. 1, 2009.

<sup>10.</sup> Id.

European Parliament, Committee on the Environment, Public Health and Food Safety, available at www.europarl.europa.eu/meetdocs/2004\_2009/.../ am/.../566816en.pdf.

<sup>12.</sup> *Id.* 

<sup>13.</sup> U.S. House of Representatives, Committee on Energy and Commerce, Prioritizing Chemicals for Safety Determination, Nov. 17, 2009, *available at* http://energycommerce.house.gov/index.php?option=com\_content&view=article&

industry and environmental and public health advocacy groups agreed that human health should be the top factor to consider in determining whether or not a chemical is safe; however, the groups diverged on whether this was the only priority to consider, and how this factor could be measured.

Industry representatives proposed a priority-setting process that takes into consideration a chemical's hazards, as well as its use and opportunities for people to be exposed to the chemical. Under such an approach, a chemical that was particularly hazardous but had low incidents of exposure could have a lower priority than a less hazardous chemical with more frequent exposure. This approach avoids the difficult decision of prioritizing among many chemicals that are potentially harmful. By taking into account more than the inherent properties of a chemical, Congress and EPA can better focus on those chemicals that pose a greater risk to the public, and particularly any more susceptible populations such as children, based on who is exposed and how much exposure occurs.

In contrast, advocacy groups favor a "health-based standard" to prioritize chemicals that should be subject to regulation. <sup>16</sup> Under this approach, the focus would be on the "worst of the worst" chemicals—those chemicals with persistence, bioaccumulation, and toxicity, and that therefore present a long-lasting risk to human health and the environment. <sup>17</sup> Because the inherent qualities of a chemical would be determinative, more attention would be placed on chemicals for which exposure data is lacking, and manufacturers would be required to provide minimum data requirements for all such chemicals. What would be left out is consideration of how the chemical is used, e.g., is it used in industrial applications or consumer products, or whether people are exposed to enough of the chemical to cause any risk of harm.

## IV. The Economic Impact of Expanding EPA's Authority Under TSCA

A significant feature of EPA's six principles of reform is placing the burden on industry to evaluate the safety of chemicals. In addition to focusing on chemical and product manufacturers, EPA would also like to expand its authority to require submission of use and exposure information to "downstream processors and users of chemicals." This would mean that product manufacturers, wholesalers, and retailers would each be responsible for providing safety information to EPA and the public.

The recently passed Consumer Product Safety Improvement Act (CPSIA) implemented a similar approach. The CPSIA bans the manufacture for sale, distribution in com-

merce, or import of children's products that contain lead or phthalates in greater concentrations than those outlined under the timeline detailed in the CPSIA. Section 102 of the CPSIA requires only the manufacturers of children's products to obtain certificates of compliance from third parties who test each product.<sup>19</sup> However, even though the testing requirement only falls on manufacturers, retailers or resellers must abide by regulations in the CPSIA as well and could be subject to hefty fines if a product fails to meet the guidelines.<sup>20</sup> Thus, retailers, including those who own small shops and second-hand stores, are responsible for knowing the content of their inventory.<sup>21</sup> These retailers can be held liable under the Act for selling noncompliant products.<sup>22</sup>

These requirements have resulted in significant impacts on industry, and especially small and medium sized businesses. Smaller businesses have pointed out that they do not have the same resources available as large manufacturers and retailers to conduct product testing and must turn to expensive outside labs to perform this task.<sup>23</sup> Many of these small businesses had never before been subject to such testing requirements, and the CPSIA adds a great and unanticipated expense to the cost of doing business.<sup>24</sup> Further, the CPSIA offers no exemption from this testing requirement for products that already are in commerce, so thrift stores and other second-hand shops must evaluate their entire inventory, much of it of unknown origin, to determine which products require testing.<sup>25</sup> The burden and costs involved with these requirements have threatened to drive many small manufacturers and retailers out of business.<sup>26</sup> As a result of protests by several small business groups, the Consumer Product Safety Commission imposed a one-year stay of testing and certification requirements on January 30, 2009.<sup>27</sup> The same type of impacts may be seen from EPA's proposal to similarly reform TSCA.

- CNN.com, New Lead Rules May Be Toxic to Thrift Stores, http://www.cnn.com/2009/US/02/08/thrift.stores.lead/index.html (last visited Dec. 28, 2009).
- Walter Olsen, Scrap the Consumer Product Safety Improvement Act, Forbes.com (Jan. 16, 2009), http://www.forbes.com/2009/01/16/cpsia-safety-toys-oped-cx\_wo\_0116olson.html.
- Consumer Product Safety Commission, Notice of Stay of Enforcement of Testing and Certification Requirements, 74 Fed. Reg. 6396 (Feb. 9, 2009), available at http://cpsc.gov/businfo/frnotices/fr09/stayenforce.pdf.
- 24. Id.
- 25. Olsen, supra note 22.
- See Handmade Toy Alliance, http://www.handmadetoyalliance.org (last visited Dec. 20, 2009) (describing the cost imposed by the CPSIA for many small toy manufacturers).
- Consumer Product Safety Commission, Notice of Stay of Enforcement of Testing and Certification Requirements, 74 Fed. Reg. 6396 (Feb. 9, 2009), available at http://cpsc.gov/businfo/frnotices/fr09/stayenforce.pdf; Consumer Product Safety Commission, CPSC Grants One Year Stay of Testing and Certifi-

id=1820: prioritizing-chemicals-for-safety-determination & catid=129: subcommittee-on-commerce-trade-and-consumer-protection & Itemid=70.

<sup>14.</sup> *Id.* 15. *Id.* 

<sup>15.</sup> *Id*.

<sup>16.</sup> *Id.* 

<sup>17.</sup> *Id*.

U.S. EPA, Essential Principles for Reform of Chemicals Management Legislation, http://www.epa.gov/oppt/existingchemicals/pubs/principles.html (last visited Dec. 19, 2009).

<sup>19. 15</sup> U.S.C. §2063(a).

<sup>20.</sup> For example, \$217 of the Act provides that failure to conform with the product safety standards outlined in the Act is punishable by a civil fine of up to \$100,000 for each violation. 15 U.S.C. \$2069(a). Although the civil penalties section limits penalties only to those who "knowingly" fail to conform to the standards, knowingly is defined as not only actual knowledge, but "the presumed having of knowledge deemed to be possessed by the reasonable man who acts in the circumstances including knowledge obtainable upon the exercise of due care to ascertain the truth of the representations" (emphasis added). Id. at \$2069(d). A retailer cannot absolve itself of responsibility by simply stating that it was not provided with a testing certificate. That retailer would be responsible, under the Act, to conduct the testing on its own if it could not ascertain a certificate for its products or face civil liability.

The impact on manufacturers alone may be significant, especially given our weakened economy. If Congress required all manufacturers to produce data for each of the 80,000 chemicals in commerce, regardless of exposure or frequency of use, this could have disastrous consequences for many small manufacturers who do not have the resources available to test every chemical. Moreover, businesses—both small and large—may not be willing to invest in the research necessary to develop new chemicals because of the costly testing associated with doing so, even if the new chemical has an extremely low rate of exposure. The potential impact on jobs, innovation, and economic growth cannot be ignored as inconsequential.

Regardless of the particular approach that Congress adopts in reforming TSCA, it is important that its decisions are guided by the principles of reform that are settled upon as those that best balance the competing needs and priorities. In particular, Congress must be careful not to allow these core principles to be swayed by the politics of the day in its decisionmaking process. Otherwise, we will likely look back in another 34 years, debating how to once again fix a broken piece of legislature.

cation Requirements for Certain Products (Jan. 30, 2009), http://www.cpsc.gov/cpscpub/prerel/prhtml09/09115.html.