

CLIENT ALERT

EPA Releases Broad Chemical Reform Principles and Seeks Industry Data for Immediate Risk Management Plans

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On Tuesday, September 29, 2009, EPA Administrator Lisa Jackson announced the release of the Obama Administration's guiding principles to inform Congress' ongoing efforts to substantially strengthen the Toxic Substances Control Act (TSCA).

These changes have been anticipated since Administrator Jackson listed her top five priorities – which included chemical regulatory reform – and reflect increasing pressure from similar reform in other areas outside the United States, such as Europe's implementation of the new REACH legislation. The principles, entitled the *Essential Principles for Reform of Chemical Management Legislation*, propose sweeping changes within TSCA, but also have broad ranging impacts across product liability and the toxic tort landscape. Given the delay of Climate Change legislation to next year and the political landscape surrounding greenhouse gas regulation, the resulting TSCA reform stands a good chance of receiving serious attention in Congress over the next 12 months.

In the release announcement, Administrator Jackson stated that the principles are grounded in the Administration's intent "to guide Congress in writing a new chemical risk management law that will fix the weaknesses in TSCA." She further stated that TSCA must be modernized and strengthened "to increase confidence that the chemicals used in commerce...are safe and don't endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment."

This approach echoes the Administration's aggressive stance on chemical regulation in other areas involving consumer safety and chemicals, such as the direction of the Consumer Product Safety Commission (CPSC) to ban or limit lead and phthalates in children's products.

Significant Impacts

If implemented, the principles would require manufacturers to prove that a chemical is safe prior to its introduction into interstate commerce. This contrasts with the current approach, where only basic information is required prior to marketing. Also under the current approach, once entered into the market, EPA must prove that a chemical is hazardous before regulatory restrictions may be imposed. If enacted as part of new legislation, these new principles would allow EPA to require manufacturer testing and submission of that testing to determine the safety of chemicals prior to introduction into commerce. Authority regarding future reassessments of currently utilized chemicals would be strengthened, as would EPA's authority to require downstream processors and users to submit use and exposure information. These changes to the regulatory landscape would likely impose obligations across all aspects of manufacturing in the United States.

A revised approach to chemical exposure risks for sensitive subpopulations, another goal of the principles, would also have broad impacts on the toxic tort landscape. As risk assessment standards are frequently cited as causation evidence in litigation involving chemical exposure, revised standards for children and the elderly will change the approach to both bringing and defending against chemical exposure suits.

From a product liability standpoint, changing regulations will pose challenges for manufacturers which incorporate chemicals into their products; not only will anticipated changes complicate future ordering and production planning, but also require greater vigilance to ensure compliance with changing regulations regarding component chemicals. Products containing chemicals subject to changing limits and bans will undoubtedly reach the market despite best corporate efforts, and resulting lawsuits from both consumers and downstream users are nearly guaranteed.

Proposed Chemical Risk Management Plans

In parallel with the announcement of the principles, EPA also announced a comprehensive enhancement of the current chemicals management program within the limits of its existing authority. EPA is developing chemical risk management plans on several chemicals of concern, including lead, mercury, formaldehyde, PCBs, glymes and certain carbon nanotubes. Additionally, EPA is developing chemical action plans to target certain chemicals for action plans that may ultimately restrict or ban the use of these chemicals, including bisphenol A (BPA), perfluorinated chemicals (PFOAs), and phthalates. The first wave of these action plans is slated for a December 2009 release.

As part of these processes, EPA is aggressively pursuing additional information on hazard, use, and exposure data critical to prioritizing chemicals for risk review, requiring action from industry, including:

- Requiring companies to submit information to fill the remaining gaps in basic health and safety data on HPV chemicals.
- Requiring additional reporting on nanoscale chemical substances.

As a result of EPA's actions, manufacturers and distributors of targeted substances may be called upon to provide new information and data sought by the Agency. In addition, such entities will face potentially stringent regulation now as well as under possible new legislation. As a result, such entities will want to track EPA's actions and provide input to proposed requirements to ensure any controls or restrictions are appropriate and necessary.

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The Principles

The Administration's goals for legislation that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals in commerce are summarized below.

- Chemicals should be reviewed against risk-based safety standards based on sound science and protective of human health and the environment.
- 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.
- EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account sensitive subpopulations, costs, social benefits, equity and other relevant considerations.
- Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner.
- Green Chemistry should be encouraged and provisions assuring Transparency and Public Access to Information should be strengthened.
- EPA should be given a sustained source of funding for implementation.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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