

2011 Predictions for US Chemicals Management

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By Lynn L. Bergeson

The trends established by the Obama administration will continue despite the Congressional mid-term elections in November, says Lynn L. Bergeson. The elections' impact, notably the new Republican majority in the House and the razor thin Democratic majority in the Senate, will nonetheless have an important, but uncertain impact on the US Environmental Protection Agency. Early indications are jobs and the economy will enjoy a new prominence in the environmental policy debate and will have a major impact on the direction of environmental law and regulation.

TSCA legislation

Bipartisan support never materialised for Senate Bill 3209 (Safe Chemicals Act of 2010) and House of Representatives Bill 5820 (Toxic Chemicals Safety Act of 2010), the two Toxic Substances Control Act (TSCA) reform bills introduced last year and. Nor was it expected, given the nature of the reforms sought under each bill. Indeed they fuelled the hope by some that the super-charged regulatory initiatives issued under EPA's Enhanced Chemical Management Program would stave off the push for wholesale TSCA legislative reform.

With the change in Congressional politics, TSCA reform is unlikely any time soon. Most notably for EPA, House Energy and Commerce Committee chair Henry Waxman (D-CA) was replaced by Fred Upton (R-MI). In the Senate, Barbara Boxer (D-CA) was re-elected and will continue to chair the Senate Environment and Public Works (EPW) Committee. Senator Frank Lautenberg (D-NJ) was not up for re-election and is expected to continue to champion TSCA reform and attempt to keep it among committee priorities. While other legislative priorities will make that task challenging, senator Lautenberg reopened debate early by convening a Subcommittee on Superfund, Toxics and Environmental Health hearing on 3 February entitled "Assessing the effectiveness of US chemical safety laws". Witnesses included EPA assistant administrator Steve Owens, American Chemistry Council president Cal Dooley, former EPA assistant administrator Dr Lynn Goldman, BASF Corp vice president Steve Goldberg, SC Johnson vice president Kelly Semrau and Francis Beinecke, president of NGO the Natural Resources Defense Council. Some speculate that if greenhouse gas legislation stalls or becomes too hot to handle, TSCA reform may regain momentum, but in a more business friendly form. Wholesale legislative reform may give way to targeted fixes that are more than tweaks, but less than what the ambitious proposals that surfaced last year portended.

Administration reaction to Republican resurgence

Notwithstanding expected oversight hearings of legislative proposals, the Obama administration has considerable leeway to pursue its priorities. Presidents can, for example, unilaterally sign Executive Orders (EO), which is exactly what President Obama did on 18 January when he issued an Improving Regulation and Regulatory Review EO. Under the EO, each agency has 120

days to develop and submit to the information and regulatory affairs office in the Office of Management and Budget (OMB) (which is part of the White House) a preliminary plan, which must be consistent with law and its resources and regulatory priorities. Each agency must periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed to make its regulatory programme more effective or less burdensome in achieving the regulatory objectives.

Whether and how exactly the EO might impact EPA chemical management policy is unclear. Smart money is betting that at the least the EO telegraphs that the Obama administration is mindful of the need to view all initiatives, including chemical management policies and rules, through a business lens of impact on jobs and the economy.

EPA's Enhanced Chemical Management Program

In 2009 EPA Administrator Lisa Jackson targeted chemical management as a top priority, catapulting chemical management into unfamiliar high-profile status. The period since then has seen an unprecedented number of chemical management initiatives and many exhibited a high level of innovative thinking.

The first two years saw the introduction of the Chemical Action Plan. EPA released proposals for four chemicals or groups of chemicals in 2010; bisphenol A, benzidine dyes, hexabromocyclododecane (HBCD) and nonylphenol/nonylphenol ethoxylates. This equalled the number it released in 2009.

A key item under consideration is EPA's proposed "chemicals of concern" list under TSCA Section 5(b)(4). In May 2010 the proposed rule was submitted to OMB, which formally extended the review period. This rule is being subjected to close scrutiny because of the policy, legal, and commercial implications for chemical manufacturers and users.

There are eight EPA Office of Pollution Prevention and Toxics (OPPT) actions that were submitted to OMB since the November elections. These include chemical action plans for toluene diisocyanate (TDI) and methylene diphenyl diisocyanate (MDI), the combined TSCA Section 4 test rule and significant new use rule (SNUR) on certain polybrominateddiphenyl ethers (PBDEs), a notice on testing of bisphenol A, SNURs for the glymes and certain uses of elemental mercury, and a reporting rule for certain nanoscale materials. The PBDEs action is interesting because it will attempt to combine SNUR requirements with a test rule, forcing industry to choose to abide by the SNUR or confront potentially significant testing costs if a chemical such as decabrominateddiphenyl ether (deca-BDE) is to remain on the market.

The SNUR is also likely to break new ground with the inclusion within its scope of imported articles containing penta-BDE, octa-BDE and/or deca-BDE. This is the first time that EPA will attempt to manage importation of articles containing a chemical as a significant new use. This is a potentially difficult undertaking considering that it remains to be established that such importation is not ongoing and that EPA has stated it intends to allow continued reprocessing of PBDE-containing foam and plastics that would then be involved in domestic manufacture of new PBDE articles. Importantly, the rule promulgating the proposed changes to the inventory update

rule (IUR) was also submitted to OMB for review in January. Whether industry obtains some of the fixes it requested will be telling.

Other initiatives include the High Production Volume (HPV) orphan TSCA Section 4 test rule that was published in January 2011. EPA reportedly intends to issue several other HPV orphan test rules this fiscal year.

EPA is expected to continue increasing its pressure on diminishing the number of confidential business information (CBI) claims. It is expected to follow up on policy approaches announced in 2010 generally to deny CBI claims for chemical identity in health and safety studies submitted under TSCA Section 8(e), and to send letters to trade associations and companies asking them voluntarily to declassify previously submitted CBI and to reduce their future CBI claims.

Endocrine disrupters

The year 2011 may also see the issuing of Safe Drinking Water Act (SDWA)/Federal Food, Drug, and Cosmetic Act (FFDCA) testing orders requiring endocrine screening of “other SDWA chemicals” identified by EPA in its proposed rule in November. Among the challenges that EPA will face is determining who should receive the orders given the diversity of the chemicals included among this grouping and the fact that only a subset were the subject of reporting under the last IUR in 2006. EPA may also be challenged as to the adequacy of the information relied on for listing chemicals on the third chemical contaminant list (CCL3) as the basis for establishing that the chemicals satisfy SDWA Section 1457 requirements for the issuing of testing orders.

EPA also announced its draft policies and procedures for requiring tier 1 screening under the Endocrine Disruptor Screening Program (EDSP) and a new guidance document outlining weight-of-evidence policies. Meanwhile, regarding submissions of other scientifically relevant information (OSRI), EPA has routinely rejected arguments that OSRI submissions eliminate the need for new, lower-tier tests as required under the EDSP.

Nanoscale materials

Early this year EPA is expected to propose a TSCA SNUR for nanoscale substances. The SNUR is expected to require manufacturers of nanoscale substances to obtain EPA approval of “new” uses of existing nanoscale substances deemed significant new uses, and to identify existing nanoscale substances that share the same molecular identity as their conventionally-sized counterparts listed on the TSCA Inventory as a “category” of chemical substances.

EPA is working on a TSCA test rule that would require manufacturers to develop data to determine the health effects of certain multi-walled carbon nanotubes (MWCNTs) and nanosized clays and alumina. It is also developing a proposed TSCA section 8(a) rule to establish reporting requirements for “certain nanoscale materials.” The rule, which is also at OMB for review, is likely to include “existing chemical nanoscale materials.”

As for nanopesticide activity, EPA is considering adopting a policy that would require any pesticide registrant that is aware that a constituent of a registered pesticide product is at the nanoscale to submit the information to EPA pursuant to section 6(a)(2) (adverse effects reporting) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) . The policy was submitted to OMB for review on 31 July 2010, and lingers there, perhaps telegraphing concern with the policy implications of “repurposing” Section 6(a)(2) in this regard.

California green chemistry legislation

In response to concerns expressed by stakeholders over the final draft of the Safer Consumer Product Alternatives (SCPA) regulation, the California Environmental Protection Agency (CalEPA) has its delayed implementation. Scheduled to go into effect on 1 January 1 2011, the start date of the game changing regulation is now indeterminate.

And on 2 December European Commission officials reportedly expressed concerns with the draft regulation, agreeing with industry that the rules are unduly complex and may raise “technical barriers to trade” in violation of World Trade Organization agreements. Because the revised draft was not officially notified under the agreement, the EU has not submitted official comments.

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