

How are the first 100 days of the Biden administration shaping chemicals regulation?

Chemicals regulation is front and centre for the Biden-Harris administration thanks to its relevance to the president's top priorities of transparency, science and environmental justice, say Alexandra Dapolito Dunn, Allison Watkins Mallick, Jeff Oliver and Jeff Wood of Baker Botts LLP

01 April 2021



When day 100 of the Biden-Harris administration arrives on 30 April, chemical manufacturers and users will want to be updated on several important regulatory and policy actions affecting the sector, to enable business planning, engagement and operation in a dynamic and changing industry.

TSCA

High on the priority list is continued implementation of TSCA as the industry looks for smoke signals regarding potential changes in policy and approaches. Work continues on the [first ten chemical risk management rulemakings](#) with extensive engagement and outreach taking place. For all ten, the US EPA has established small business advocacy review (SBAR) panels, which is required for rules that may have a significant economic impact on a substantial number of small entities. The panels provide input on how the agency might develop proposed rules so that any unreasonable risks identified in the final risk evaluation for each chemical are addressed. Additionally, the EPA is conducting formal consultations with state and local governments, tribes and environmental justice communities. There will also be an open public comment period on any draft risk management regulation.

The EPA has stated that while it continues with the risk management outreach and engagement process, it is

“reviewing [each] final risk evaluation to ensure it uses the best available science and protects human health and the environment”. The agency could embark on making some changes to the final ten risk evaluations, but the more likely way forward is that it will address any identified limitations in them through the risk management rulemaking process.

The administration moved forward promptly with the TSCA persistent, bioaccumulative and toxic (PBT) rules which were finalised by the [22 December 2020 deadline](#) and went into effect on 5 February. The PBT rules address five chemicals – decaBDE, PIP (3:1), 2,4,6-TTBP, HCB and PCTP – and contain various phase-outs, substitution requirements, packaging changes, and other risk management approaches to reduce exposure to these chemicals for the general population, consumers and commercial users, and susceptible subpopulations. One important lesson from their implementation came to light when several electronics and other article importers realised for the first time that the final PIP (3:1) rule would prohibit processing and distribution of the substance for use in articles from 8 March this year.

On learning of the implementation concerns, the EPA issued a temporary 180-day no action assurance, stating it will not pursue enforcement around PIP (3:1) in articles, or articles it has been added to, to allow companies to assess their supply chain. It also said it may extend

the compliance date if needed after gathering more information. And the agency also announced a 60-day public comment period to collect additional input on the final PBT rules, suggesting that it may revise them. This provides an opportunity for chemical users that may not have previously participated in the PBT rulemakings to ensure they do not use these chemicals and can meet the various phase-out and substitution requirements.

As for the next 20 chemicals, the scoping documents remain available, although the administration may assess the scopes and determine if changes are needed. Companies responsible for the risk evaluation fees have been invoiced and are making payments. Recent EPA presentations indicate that the agency hopes to spread out the work on the 20 chemicals, allowing stakeholders to engage more thoughtfully and with less time pressure. As the agency embarks on the three-year risk evaluation process, it has announced that it will “refine its approach to selecting and reviewing the scientific studies that are used to inform TSCA chemical risk evaluations” and that it is not using, and will not again use, the 2018 systematic review approach that was [reviewed by the National Academies of Sciences](#) in a report issued in mid-February. The agency has not fleshed out how the systematic review process will change, although some concern has rippled through the chemical community with its statement that it will “incorporate approaches from the Integrated Risk Information System (IRIS) programme”. IRIS is known for conservative risk evaluation, and for long timeframes to complete the work. Chemical companies and users will have an opportunity to engage in the reframing of systematic review, because the EPA has said it will publish and take comment on a revised protocol later this year.

PFAS

The administration will prioritise activities to reduce exposures to emerging contaminants of concern such as per- and polyfluoroalkyl substances (PFASs). An important upcoming federal requirement for companies not eligible for the de minimis exemption is the 1 July reporting deadline for 172 PFAS compounds under the Toxics Release Inventory, with a reporting threshold of 100lbs for the 2020 reporting year. The EPA moved ahead in February with the final regulatory determination that will set in motion the process of proposing national drinking water standards, ‘maximum contaminant levels’, for perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA). The agency removed the toxicity assessment for perfluorobutane sulfonic acid (PFBS) from its website – completed in mid-January by the Trump administration – after expressing concern with the conclusions.

Transparency

The new administration quickly and successfully went to federal court to have the controversial EPA science transparency rule [taken off the books](#) and sent back to the agency. The heart of the rule was the principle that less weight should be assigned to scientific studies where underlying data – particularly medical and confidential human study information – could not be made available for stakeholder review. Environmental groups asserted this would prevent the EPA from using many key toxicology studies that contain personal data yet offer important information for agency regulatory decision making. Given the opposition from environmental groups and even some industry groups to the final science transparency rule, it is highly unlikely that the EPA will take this up in any form soon.

The administration also quickly halted further implementation of the Clean Air Act (CAA) cost benefit rule, which became effective on 23 December 2020 and is on its list of rules for further review. The rule required the EPA to prepare a benefit-cost analysis for significant rulemakings under the CAA, including separating out benefits directly linked to the rulemaking from secondary benefits.

Finally, the industry should be prepared for a potential second boomerang effect from the EPA’s Risk Management Program (RMP) requirements, which apply to sources that use, manufacture or store certain hazardous chemicals. These sources are required to develop a risk management plan and implement measures to prevent accidental releases. Soon after President Trump’s inauguration, his administration began working on modifications to President Obama’s 2017 RMP amendments. Published on 19 December 2019 these rescinded the major accident prevention programme provisions added by the 2017 RMP amendments and most other minor changes to the prevention programme. They also eliminated the public information availability provisions required by the 2017 RMP amendments. President Biden has identified the rule as among those that will be reviewed.

Emissions regulations

Chemical facility operators should watch several potential changes to emissions requirements under the CAA, as several of the prior administration’s notable rulemakings in this area are likely to be reversed or significantly modified. For example, the EPA is reviewing its decisions in December 2020 to maintain the current levels of the National Ambient Air Quality Standards (NAAQS), retaining the current NAAQS for both PM2.5 and ozone instead of

making them more stringent. The review of these rules is particularly newsworthy in light of recent studies linking air quality to Covid-19 risk and the administration's focus on environmental justice issues.

The administration is also reviewing the EPA's 9 October 2020 guidance memorandum that reflected the Trump administration's efforts to reverse course on its predecessor's treatment of excess emissions during periods of startup, shutdown and malfunction (SSM). As a result, the prospect that facilities may be able to rely on exemptions or affirmative defences for exceeding emissions limitations during SSM periods has dimmed.

Finally, the EPA's "once in, always in" rule, which was final on 19 November last year, may be ripe for review. This amended the general provisions of the National Emission Standards for Hazardous Air Pollutants (NESHAP) to allow major sources to 'reclassify' themselves as area sources (by limiting their potential to emit hazardous air pollutants to below the major source thresholds) so they can immediately become subject to generally less stringent requirements. The rule may be a target for the Biden administration, because NGOs have raised particular concerns about the potential for it to increase emissions in overburdened communities (including from chemical plants).

Environmental justice

Environmental justice and climate are other areas where the administration has moved rapidly. While currently being addressed together, the subjects have many independent parts. For example, the President's Executive Order 13990 (Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis at Home and Abroad) puts a focus on "environmental and economic justice", establishes a White House environmental justice council, and would form a specialist office at the Department of Justice to develop a comprehensive environmental justice enforcement strategy. The Order also directs that 40% of government sustainability investments be spent in disadvantaged communities. Under it, the White House Council on Environmental Quality (CEQ) will create a geospatial climate and economic justice screening tool and annually publish interactive maps highlighting disadvantaged communities. The EPA is directed to strengthen enforcement of environmental violations that have a disproportionate impact on under-served populations, and to create a community notification programme to monitor and provide real-time data to the public on current environmental pollution, including emissions,

criteria pollutants and toxins, in frontline and fence-line communities. Certainly, chemical manufacturers and users should be aware of their releases and interactions with their communities. Proactive outreach and engagement approaches should be accompanied by robust internal policies, ensuring that environmental justice is embedded in an organisation's activities and mission from top to bottom. Auditing and measuring progress on internal environmental justice integration and protocols to assure accountability is also important.

Environmental enforcement

As for environmental enforcement, chemical manufacturers and users should be watching for new developments and actions at the governmental and non-governmental levels. New leaders at the EPA and DOJ are charting a new direction on this, promising an increase in resources for facility inspections and enforcement activities. While the prior administration moved away from industry-specific enforcement initiatives, most observers expect the new administration to place renewed attention on the energy and industrial sectors, including the chemicals sector. Early indications of new directions would include more frequent government information requests for facility compliance data and records. Federal enforcement cases may also become more costly to resolve, as the new administration has already rescinded several Trump-era enforcement policies and signalled a return of third-party payments and supplemental environmental projects as part of major settlements. Alongside civil enforcement, the industry should also be mindful of the new administration's stated intention of enhancing criminal enforcement of environmental laws as well.

At the non-governmental level, the chemical sector should anticipate an increase in citizen suits under the Clean Air Act, Clean Water Act, and other statutes. After contesting the Trump administration's regulatory rollbacks for the last few years, citizen groups are now expected to refocus their resources on enforcement activities. Industry should be alert to an increase in Freedom of Information Act (Foia) requests submitted to federal and state agencies seeking compliance records, as well as increased use of 'citizen science' to support their enforcement initiatives.

The views expressed in this article are those of the expert authors and are not necessarily shared by Chemical Watch.

Disclaimer: Content on Chemical Watch (including any of its websites) shall not be regarded as professional advice and is not intended as such. CW Research Ltd does not accept liability for inaccuracies in published material. Customers are advised to take appropriate professional advice to inform business decisions.

Copyright: Documents and web pages downloaded from Chemical Watch (including any of its websites) are for the use of registered users only. Such documents and web pages must not be distributed or republished without consent from CW Research Ltd (email enquiries@chemicalwatch.com). Copyright in original legal texts and guidance remains with the respective government authorities.