

by **enhesa.**

Chemicals management recap Mid-year review 2024.

Explore chemicals management developments from
around the world

July 2024



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Stay ahead of changes in chemicals management

In Enhesa's annual Chemicals Management and Control Survey, the EU's REACH regulation is the leading driver of regulatory day-to-day activity for 82% of respondents – not surprising given the EU is one of the world's largest trading blocs, promising access to a large consumer base for compliant businesses. US regulation is a driver for 58% of respondents.

In this report, we share a sample of Chemical Watch News & Insight content written by our team of experienced journalists and analysts. We've included stories from the EU and the US and also put the spotlight on emerging chemicals management developments in other jurisdictions, including Brazil, Canada, China and Turkey.

As a provider of global intelligence on chemicals management, keeping our members informed of market changes around the world is part of our own day-to-day work. Wherever you'd like to know more about regulatory developments, you can be sure our team have it covered.

As always, our articles include commentary from regulatory authorities and industry stakeholders to add perspective and insight.

Thank you for downloading your complimentary report. We trust you'll find it valuable and look forward to sharing more with you in future.

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Chemical Watch News & Insight: coverage highlights.

Read a curated sample of Chemical Watch News & Insight curated content, featuring recent updates and developments affecting chemicals management.





Turkey adopts KKDIK registration deadline extensions of up to seven years

Final dossier submission for higher tonnages set at 2030

02 January 2024

Turkey's environment ministry has adopted amendments to the KKDIK law to extend registration deadlines by up to seven years to between 2026 and 2030 depending on the tonnage band and hazard properties.

The government published the modified law in the Official Gazette on 23 December, just days before the REACH-like regulation's registration deadline expired on 31 December.

The changes are in line with a draft proposal the Ministry of Environment, Urbanisation and Climate Change (MoEUCC) circulated in November in response to intense pressure from industry – both in Turkey and abroad – that struggled to meet the end-2023 single registration deadline.

That has now been delayed by three years, to 31 December 2026 for substances above 1,000 tonnes, with an additional two years – to the end of December 2028 – for those between 100 and 1,000 tonnes, and to the end of December 2030 for those between one and 100 tonnes.

The deadline of 2026 also applies to carcinogenic, mutagenic and reprotoxic (CMR) substances of one tonne per year or more, and to substances that are very toxic to aquatic life of 100 tonnes or more per year.

The extensions almost exactly mirror the deferment the UK government has conceded to for UK REACH, and go beyond what some in the industry had asked for. A consultation with stakeholders in Turkey ended on 20 November.

The date by which substance information exchange fora (SIEF) must cease to exist has been prolonged to December 2032 from December 2025, and the period for pre-registrations until the end of 2030.



Canada eyes 2027 'or sooner' for proposal defining highest risk substances

Consultation on CMR criteria among 'most important', attorney says

04 April 2024

A formal proposal on the criteria for substances considered to be of the highest risk under the Canadian Environmental Protection Act (CEPA) may not come until 2027, a Health Canada official has said.

Once finalised, the rules will set out standards for designating the highest risk substances under 'part 1' of the new two-part CEPA schedule 1 list of toxic substances. The government will prioritise part 1 substances for elimination, while focusing on pollution prevention for part 2 substances.

Health Canada and Environment Climate Change Canada (ECCC) recently set out a timeline of actions they are taking to develop new rules under CEPA, which saw a legislative overhaul last summer. The plan included consultations starting in winter 2025 on a discussion document about criteria to consider when classifying substances of the highest risk, as well as on a document outlining possible restrictions and authorisations of certain toxic substances.

Nicole Davidson, director of Health Canada's Existing Substances Risk Assessment Program, expanded on that timeline at last week's American Chemistry Council (ACC) GlobalChem conference, saying proposed regulations setting out potential criteria will follow by 2027 "or sooner".

The government aims to establish a stronger regime for controlling toxic substances that pose the highest risk, Davidson told attendees.

Persistence, bioaccumulation, CMR

Davidson said the government plans to prioritise prohibiting activities involving 'part 1' substances that are determined to be toxic and that pose the highest risk.

As set forth in the modernised CEPA, she said the criteria for highest-risk substances will include:

- persistence;
- bioaccumulation;
- carcinogenicity;
- mutagenicity; and
- reproductive toxicity.

The discussion document and subsequent proposal will include

more detail on the criteria for carcinogenicity, mutagenicity and reproductive (CMR) toxicity, according to Davidson.

The current criteria for listing a substance on schedule 1, part 1 are persistence and bioaccumulation, as defined in the country's Persistence and Bioaccumulation Regulations, Health Canada told Chemical Watch News & Insight.

Health Canada and the ECCC have used these criteria in assessments drafted or finalised in recent months.

In January, they recommended a part 1 listing for two out of 15 assessed phenols that were found to be both persistent and bioaccumulative.

Subsequent draft and final assessments for NMP, fragrance oils and thallium, however, recommended part 2 listings for certain substances found to meet schedule 1 criteria, including some chemicals deemed to be persistent but not bioaccumulative.

'Most important consultation'

This is the most important consultation Canada will conduct as it works to implement CEPA's reforms, Ottawa-based attorney Scott Thurlow told conference attendees.

Many other jurisdictions will look at how Canada rolls out the rules and other strategies under the CEPA overhaul, he said.

If CMRs are not properly defined, it could have repercussions in Canada and elsewhere, he said.

Thurlow also noted that a future schedule 1, part 1 listing will not necessarily lead to full prohibition of a substance. Instead, a part 1 listing will lead to one of three outcomes:

- total prohibition;
- partial prohibition, depending on essentiality or low risk of exposure for certain uses; and
- conditional prohibition, such as where new activities involving the substance are prohibited unless Health Canada and the ECCC specifically authorise them, such as through a permit.



US EPA bans most uses of methylene chloride under TSCA

Final rule offers some industry concessions while holding firm on certain issues

30 April 2024

The US EPA has finalised a TSCA rule banning most uses of methylene chloride and imposing stringent workplace requirements for the handful of ongoing applications.

The rule is the second completed under the 2016 TSCA amendments' existing chemical review process and reinforces the agency's early trend of relying on bans and occupational safety measures to control 'unreasonable risk'.

Published in pre-publication form on 30 April, the final rule prohibits all but 13 of more than 50 conditions of use (COUs) for the solvent, including all consumer applications. According to EPA chemicals office head, Michal Freedhoff, the rule will halve the amount of methylene chloride used in TSCA-regulated applications.

Usage bans will take effect on a phased-in timeline, starting with distribution prohibitions (see box).

A "handful of highly industrialised uses" may continue under the rule, provided companies adhere to a workplace chemical protection programme (WCPP). Businesses will need to meet an existing chemical exposure limit (ECEL) of 2ppm for inhalation exposures over an eight-hour time-weighted average (TWA), conduct periodic monitoring, maintain records and develop exposure control plans.

The final rule includes several changes requested by industry following release of the April 2023 proposal. For example, it allows several COUs previously facing prohibitions to continue under a WCPP, extends certain compliance timeframes and adds a de minimis threshold of 0.1% in formulations.

The rule also includes a ten-year TSCA section 6(g) critical use exemption for specified essential applications by the National Aeronautics and Space Administration (NASA).

Pharmaceutical uses – which account for roughly 35% of methylene chloride's annual production volume – are not subject to TSCA and are not affected by the rule, the EPA said.

Uses allowed with WCPPs

Ten workplace uses identified in the proposal will be allowed to continue under the final rule, subject to WCPPs. These include domestic manufacturing, import, several processing applications, disposal, as well as industrial and commercial use as a laboratory chemical.

The rule also adds three industrial COUs and expands two categories on the list of uses that may continue under WCPPs, after commenters detailed how they could meet workplace safety requirements.

Additional allowable applications are:

- as a processing aid, including as a heat transfer fluid and in the production of separators for lithium-ion batteries;
- in plastic and rubber products manufacturing, including polycarbonate manufacturing;
- as a solvent that becomes part of a formulation or mixture and is later reclaimed;
- in paint and coating removal for safety-critical, corrosion-sensitive components of aircrafts and spacecrafts, removing a previous distinction that would have allowed only federal agencies to continue beyond ten years; and
- as a bonding agent for solvent welding, expanding the proposed allowance that had only extended to mission-critical military and space vehicle applications.

Changes to workplace requirements

Companies will have an extra six months to comply with the WCPP requirements relative to the proposal.

The timeframe, which is consistent with a longer WCPP implementation outlined as the 'primary alternative regulatory action' in last year's proposal, allows a year to complete initial monitoring and 18 months to fully implement the safety scheme.

Federal agencies and their contractors will get an additional year beyond these dates, due to concerns like budgets and procurement, the EPA said.

Another change from the proposal expands the types of labs that may help with air monitoring documentation.

The EPA said it will accept laboratories accredited for Good Laboratory Practice (GLP) standards, as proposed. It will also allow those accredited by the American Industrial Hygiene Association (AIHA) or another "analogous industry-recognised programme", according to the final rule.

The rule specifically states that air sampling must measure ambient concentrations without accounting for respiratory protections. This will "[empower] owners or operators to

appropriately consider the hierarchy of controls”, the EPA said.

However, if exposure above an ECEL is still “reasonably likely”, the rule contains minimum respiratory personal protective equipment (PPE) requirements.

Changes signal shifts ahead?

The changes incorporated into the final version of the methylene chloride regulation may be a template for how future rulemakings might shift between their draft and final versions, the agency said.

“This one looks a lot more like the [rules] that will follow than asbestos does,” Dr Freedhoff told reporters at a 29 April press conference.

The rule, however, contains a mixed bag of amendments, making the path ahead difficult to discern.

One noteworthy inclusion is a de minimis threshold of 0.1% in products, as requested by many industry stakeholders. According to Dr Freedhoff, the limit serves as a compliance tool, because “you can’t really be sure that someone is complying with your rule unless you have a number that you can measure to”.

The 0.1% cutoff is consistent with what the National Institute for Occupational Safety and Health (NIOSH) recommends for

carcinogens, Dr Freedhoff said, adding that the body’s suggested threshold for non-carcinogens is 1%.

The final rule also backed off certain controversial prohibitions, including by now allowing the continued use of methylene chloride as a heat transfer fluid and for coating removal in critical aerospace applications.

However, the agency only wavered slightly on its planned furniture refinishing prohibition, despite small business pushback.

Also unchanged was the ECEL. The agency finalised a rule last week laying out how occupational exposure limits may shift between risk evaluation and risk management in the future, but the one outlined for methylene chloride stayed consistent throughout the process.

The final rule also did not include any changes addressing NGO concerns about ensuring adequate protections for fenceline communities.

As the TSCA risk management programme continues to evolve, stakeholders will be watching closely to see what tweaks appear in upcoming final rules for trichloroethylene (TCE), carbon tetrachloride, perchloroethylene (Perc) and other priority chemicals.

Prohibition timeline

The agency provided additional time to phase in most bans, citing concerns about the need to identify and qualify alternative substances or processes.

However, it did not extend the deadline to end retail distribution, to “expeditiously remove exposures to consumers”.

Beginning from the rule’s formal publication, the prohibition timeframes are:

- 270 days – distribution to retailers;
- 360 days – distribution by retailers;
- 360 days – manufacturing;
- 450 days – processing;
- 630 days – non-retailer distribution; and
- 720 days – most industrial and commercial use.

Five-year bans

In a change from the proposal, two COUs will see their bans take effect in five years. These are:

- commercial use in refinishing wood pieces of artistic, cultural or historic value; and
- commercial use in adhesives and sealants used in speciality aircraft, space and turbine applications.

Many furniture refinishing businesses raised concern about the proposal to extend a 2019 TSCA prohibition on consumer uses of methylene chloride paint removers to almost all commercial uses, saying it could threaten small businesses or force transitions to flammable alternatives.

Nevertheless, the EPA stuck to its proposed determination that a TSCA section 6(g) critical use exemption was not justified for this COU and that long-term compliance with a WCPP could present “significant and widespread difficulties in the sector”.

Recognising a lack of available alternatives for removing coatings from wooden items with historic or artistic significance, the agency included a five-year transition period for those applications, contingent on a “minimum standard of exposure control”.

The agency said it is willing to review data about how furniture refinishers could meet the ECEL and “could revise this final rule accordingly”.

With respect to the adhesives and sealants category, the agency said it provided five years for the sector to find a methylene-chloride free alternative that meets industry and federal standards.

Unlike with the furniture refinishing extension, no interim controls apply, because the agency “does not have the same concerns for magnitude of risk that could result in occupational fatalities from acute exposures” as exist with furniture.



Brazil Senate moves closer to passing chemicals management legislation

REACH-inspired law would establish national inventory on chemical substances

01 May 2024

Brazil's Senate Committee on Science, Technology, Innovation and Informatics (CCT) has approved a REACH-inspired chemicals management bill, bringing the country one step closer to a national framework law.

The bill (PL 6120/2019), which was advanced by the Senate committee on 24 April, would establish a national inventory for industrial chemicals in Brazil, prioritise risk assessment, require authorisation for certain substances and establish a committee to review substances and recommend management measures.

The Senate received the bill late last year, after the Chamber of Deputies approved a consolidated draft bill in the autumn of 2023. The CCT advanced a substantially similar version of the bill, adding only one amendment to exempt medical and diagnostic devices.

Brazil's chemical industry is the sixth largest in the world and is among the three most innovative sectors in the country, according to Senator Beto Faro, the bill's rapporteur in the committee and a member of the ruling Workers' Party. Having a policy for chemical management "is in line with the best practices developed and recommended" internationally, he added in his approval report.

Products subject to controls under other legislation would be exempt under the bill, including cosmetic and personal care products, pharmaceuticals, pesticides and sanitisers, food and food additives, wood preservatives and more. Exempt substances would include those under development, those intended only for research and intermediates.

The bill is now in the hands of the Senate environment committee, and must also be reviewed by the committee on social affairs. If these committees approve it, the bill would then go to the president for final sanction.

Stakeholders would have a period of three years to register substances after the law takes effect and a national registry is available.

If approved and signed into law, Brazil would join countries like Chile, Colombia and Costa Rica as the only Latin American countries with national chemicals management legislation. Last year Peru issued a national chemicals framework by decree and is working on implementing regulations.



China adds 41 substances to existing chemicals inventory

Listing removes registration and notification requirement

31 May 2024

China's Ministry of Ecology and Environment (MEE) has added 41 chemicals to the Inventory of Existing Chemical Substances in China (IECSC), rendering them no longer subject to registration or notification under the country's overarching regulation for new chemical substances MEE Order 12.

Of the entries, 34 were included on the IECSC because they had already been registered under MEE Order 12 or its predecessor, MEP Order 7.

MEE Order 12 replaced MEP Order 7 on 1 January 2021. Substances registered under either of the two regulations are added to the IECSC five years after being approved.

The MEE has also added seven other substances to the IECSC following a public consultation early this year and after receiving proof from companies that they had manufactured, imported or used the chemicals in China before 15 October 2003.

The ministry regularly updates the IECSC. In December, it added 25 chemicals to the inventory.



Ministers call on European Commission to uphold ambition of chemicals strategy

Listing removes registration and notification requirement

19 June 2024

EU ministers have urged the European Commission to maintain its ambition in implementing the chemicals strategy for sustainability, in lieu of the long-awaited REACH revision.

At a 17 June meeting in Luxembourg, environment ministers urged the Commission to their position in a document, adding that the EU executive has "not fully delivered on the chemicals strategy".

The call is part of the ministers' response to the mid-term review of the 8th Environment Action Programme, which guides the EU's environmental agenda up to 2030. The review found that although the EU is on the right trajectory to reach a non-toxic environment, most initiatives to reach that goal still have to be fully implemented.

In the document, ministers also underlined the need to phase out PFAS in a "well-managed process, as soon as possible while respecting the scientific findings of the risk assessment process and, where appropriate, the transition time needed to develop safe and sustainable alternatives".

The Commission said earlier this month that is now "pretty sure" it will not be able to publish its universal PFAS restriction in 2025 as originally foreseen due to complexity of the file. ECHA's risk assessment committee (RAC) is currently assessing a record number of comments received in a public consultation, using a sector-by-sector approach.

Testing methods

The ministers also invited the EU executive to develop a European strategy that would ensure coordination and prioritisation, as well as funding, to develop and validate test methods. The initiative, which was proposed by Germany and the Netherlands in a paper shared ahead of the meeting, would focus on developing new or updating existing test methods for human and environmental toxicological endpoints.

Ahead of the meeting, the NGO HEAL called on ministers to renew their commitment for the implementation of the chemicals strategy, and to double down on upgrading the EU chemicals regulatory framework and phasing out the most harmful chemicals.

Helsinki Chemicals Forum

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Report



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