Chemicals Quarterly

Q3 Regulatory Update 2022

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Compliance & Risks

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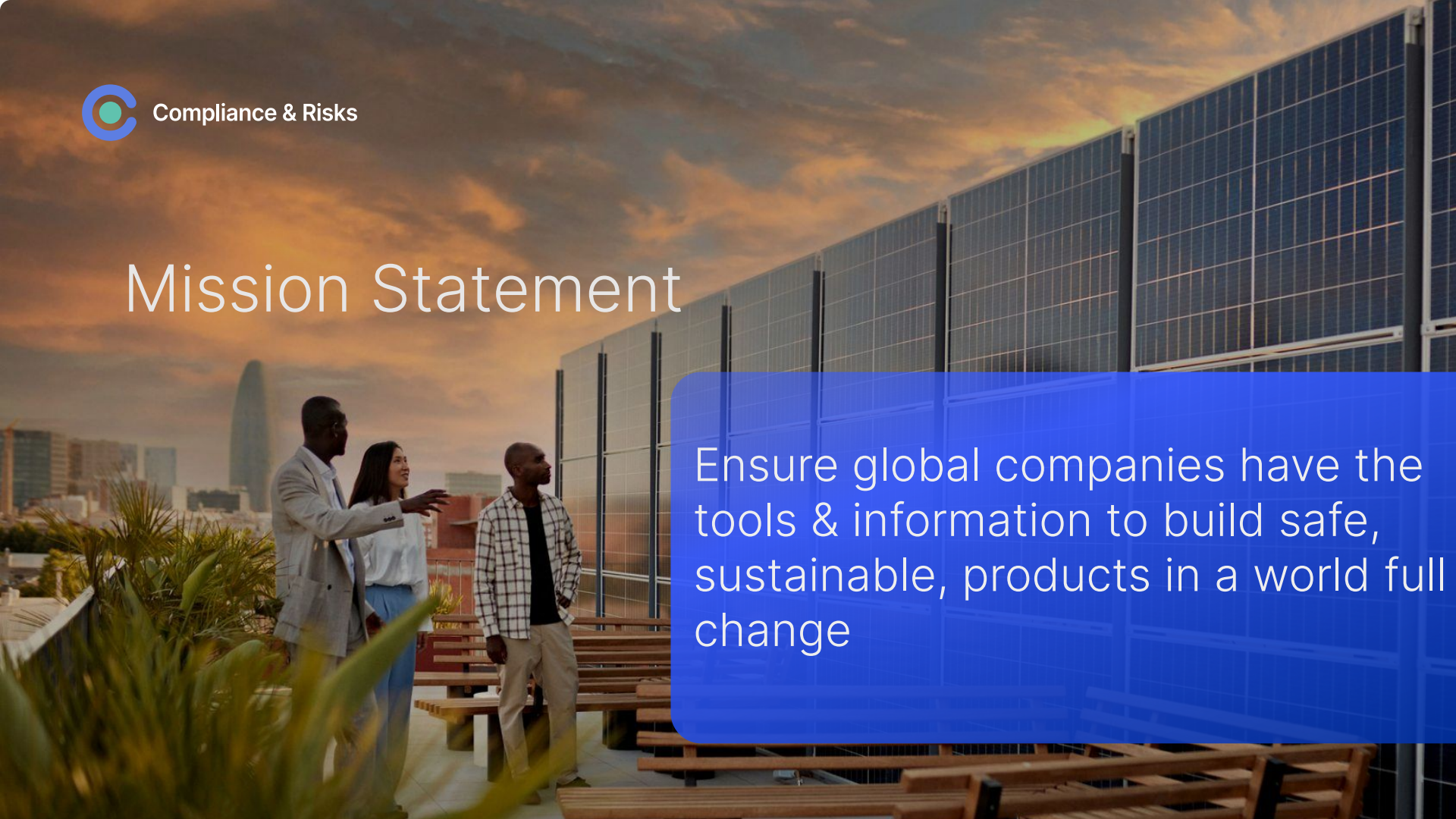
Mission Statement



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Compliance & Risks

California regulates PFAS in textiles

- California enacted AB 1817 in August
- The Act prohibits the manufacture, distribution, sale or offer for sale of any new textile articles that contain regulated PFAS and requires the use of the least toxic alternative when removing regulated PFAS from textile articles
  - "Regulated perfluoroalkyl and polyfluoroalkyl substances or PFAS" means either of the following:
    - PFAS that a manufacturer has intentionally added to a product and that has a functional or technical effect in the product or
    - PFAS in a product or product component at or above the following thresholds, as measured in total organic fluorine:
      - Commencing January 1, 2025, 100 ppm
      - Commencing January 1, 2027, 50 ppm
- The Act also requires manufacturers to provide persons that offer the product for sale or distribution with a certificate of compliance stating that the textile article is in compliance
- These requirements take effect January 1, 2025

New York State considers PFAS in apparel

- AAFA has urged New York State Governor Kathy Hochul to make changes to S.6291A/ A.7063A before signing it into law
- The bill would prohibit PFAS in apparel and footwear starting December 31, 2023
- AAFA urged the Governor to:
  - Extend the deadline to December 31, 2026;
  - Define the exception for extreme outerwear and
  - Create a *de minimis* of 100 ppm
- The Governor has until the end of the year to make changes or veto the bill

Maine considers extensions on PFAS reporting

- In July 2021, Maine enacted H.P. 113-L.D. 1503, An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution
- The Act requires companies to report whether they have PFAS in their products, starting January 1, 2023
  - "Product" means an item manufactured, assembled, packaged or otherwise prepared for sale to consumers, sold or distributed for personal, residential, commercial or industrial use, including components
- Several industry associations have notified members that Maine is unlikely to be able to implement these reporting requirements before January 1, 2023
- Associations are submitting requests for members, seeking 6-month extensions for reporting

Colorado requirements for PFAS in consumer products

- In June, Colorado enacted House Bill 22-1345
- The Act requires manufacturers of cookware containing "intentionally added PFAS chemicals" in the handle of the product or in any product surface that comes into contact with food or beverages to list the presence of such PFAS chemicals on the product label, starting January 1, 2024
- The label must also include both a hyperlink and QR-code (or equivalent) leading to a webpage providing information about why the PFAS chemicals were added

Colorado requirements for PFAS in consumer products, *cont.*

- The Act *also* phases out the sale and distribution of certain consumer products, if they contain intentionally-added PFAS chemicals, according to the following deadlines:

Phase 1 – prohibited after January 1, 2024	Phase 2 – prohibited after January 1, 2025	Phase 3 – prohibited after January 1, 2027
• Carpets and rugs • Fabric treatments • Food packaging • Juvenile products	• Cosmetics • Indoor textile furnishings • Indoor upholstered furniture	• Outdoor textile furnishings • Outdoor upholstered furniture

Massachusetts considers prohibition on PFAS in consumer products

- In June, the Massachusetts House introduced H4818
- The bill would prohibit distribution of certain products with intentionally-added PFAS substances, or with a PFAS level greater than 1 ppm
- Covered products include:
  - Child passenger restraints;
  - Cookware;
  - Fabric treatments;
  - Personal care products;
  - Rugs and carpets
  - Upholstered furniture; and
  - Children's products
- If enacted, these prohibitions would take effect January 1, 2023

New Jersey considers bans on PFAS in products

- On 3 October 2022, New Jersey introduced the Protecting Against Forever Chemicals Act (A4758/ S3177)
- The bills would require manufacturers of products that contain intentionally-added PFAS to submit written notification of the amount of each of the PFAS in the product
- The bills would also prohibit intentionally-added PFAS from cosmetics, carpet or fabric treatment, food packaging, and cookware, after two years
- Finally, the bills would also require cookware that contains intentionally-added PFAS in the handle of the product or in any product surface that comes into contact with food, foodstuffs or beverages to list the presence of PFAS on the product label

US FDA considers PFAS in FCMs

- In July, FDA requested information on current food contact uses of fluorinated polyethylene
- Fluorination of polyethylene may result in the formation of per- and polyfluoroalkyl substances (PFAS)
- FDA seeks to ensure that permitted uses of these substances - per 21 CFR 177.1615 - continue to be safe
- Comments must be submitted by October 18, 2022

Hawaii prohibits PFAS in FCMs

- In June, Hawaii enacted HB 1644 (Act 152), regulating PFAS in certain food packaging
- The Act prohibits intentionally-added PFAS in food packaging comprised of paper, paperboard or other materials originally derived from plant fibers, such as:
  - Food boats;
  - Pizza boxes;
  - Plates and
  - Wraps and liners
- This prohibition takes effect December 31, 2024

Rhode Island prohibits PFAS in FCMs

- In June, Rhode Island enacted 2022 - H 7438 Substitute A to prohibit the sale and distribution of food packaging containing intentionally-added PFAS substances
- The Act prohibits the offer for sale or for promotional purposes of any food package to which PFAS have been intentionally introduced
- The prohibition takes effect January 1, 2024

ASTM tackles PFAS in consumer products

- ASTM International announced a new subcommittee to develop standards on per- and polyfluoroalkyl substances (PFAS) present in consumer products
- F15.81 will operate under ASTM's consumer products committee (F15) and provide guidance on how to prepare and analyze a wide variety of consumer product samples for PFAS
- My colleague, Cassie Pershyn, will participate in standards development :)

Belgium considers PFAS in FCMs

- In July, the Belgian federal parliament voted unanimously in support of a resolution to address PFAS in food contact materials
- If the EU does not ban PFAS in food packaging by 2023, the national government will take action
- The ban would impact paper and cardboard food packaging, such as pizza boxes, salad bowls, sandwich packaging, cereal boxes, etc.

China regulates bamboo FCMs

- In July, China's National Health Commission published GB 4806.12:2022
- The mandatory standard applies to bamboo-wood materials which may, under normal and foreseeable conditions of use, come into contact with food
- The standard lays down limits on thiabendazole, o-phenylphenol, imazalil and biphenyl
- It also specifies migration indicators, testing methods, microorganism limits and labelling requirements
- The standard enters into force December 30, 2022

India restricts antimony & DEHP in plastic FCMs

- In August, the Food Safety and Standards Authority of India (FSSAI) amended the Food Safety and Standards (Packaging) Regulations to establish overall migration limits for antimony and di-(2-ethylhexyl) phthalate (phthalic acid, DEHP) from plastic packaging

- The limits are as follows:
  - Antimony: 0.04 ppm of food; and
  - DEHP: 1.5 ppm of food

US FDA reopens comment period on phthalates in FCMs

- In July, FDA reopened the comment period for remaining phthalates authorized for use as plasticizers in food contact applications

- FDA previously:
  - Revoked authorizations for 23 phthalates and two other substances, removing these phthalates from the list of substances authorized by 21 CFR 175-178; and
  - Limited phthalates in food contact applications to nine phthalates – eight as plasticizers and one as a monomer

- The new deadline is December 27, 2022

Ukraine seeks to align its FCM regulations with the EU’s

- Ukraine notified the WTO of a draft Order "On approval of the Requirements for ceramic articles intended to come into contact with foodstuffs”
- Ukraine also notified the WTO of a Draft Order "On prohibition of the use of 2,4,4′-Trichloro-2′-hydroxydiphenyl ether in the production of plastic materials and articles intended to come into contact with foodstuffs”
- Both draft Orders are designed align Ukraine’s requirements with those of the EU

California prohibits PFAS in cosmetics

- In September, California signed AB 2771 into law
- The Act prohibits any cosmetic product that contains intentionally-added perfluoroalkyl and polyfluoroalkyl substances (PFAS)
- "Cosmetic product" means an article for retail sale or professional use intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance
- This prohibition takes effect January 1, 2025

California considers several ‘Priority Chemicals’ in cosmetics

- California's DTSC has proposed, or is considering, the following product-chemical combinations for listing as Priority Products under Safer Consumer Products Program:

Nail Products	Hair Straighteners	Beauty/ Personal Care Products	Quaternary Ammonium Compounds
Nail products containing: (1) Toluene, (2) Methyl methacrylate (MMA) or (3) Triphenyl phosphate (TPhP) Additional research on: (1) Acrylic Acid; (2) N, N-Dimethyl-p-toluidine (DMPT); and (3) N-Methyl-2-pyrrolidone (NMP)	Hair straighteners containing: (1) n-Butylparaben, or (2) Sodium hydroxide for listing as Priority Products Draft “Product-Chemical Profile” documents to be released in November 2022 and July 2023	Draft “Product-Chemical Profile” to be released in October 2022 for an as-yet unnamed personal care product containing 1,4-Dioxane DTSC initially was considering naming either a beauty product or a cleaning product, but now appears interested in regulating 1,4-Dioxane in both categories	DTSC is also starting to examine quaternary ammonium compounds in beauty products

EU warnings for formaldehyde in cosmetics

- The EU enacted Commission Regulation (EU) 2022/1181
- The Regulation amended the Cosmetics Regulation to require the warning, “releases formaldehyde,” where the total concentration of formaldehyde released in the finished product exceeds 10 ppm
- Finished products which comply with the Cosmetics Regulation as applicable on July 30, 2022, may be:
    - Placed on the market until July 31, 2024, and
    - Made available on the market until July 31, 2026

UK considers endocrine disruptors in cosmetics

- The UK's Office for Product Safety and Standards called for data on the safety of cosmetic ingredients with suspected endocrine disrupting properties

- Interested parties are invited to submit any scientific information relevant to the safety assessment of:
  - Propylparaben,
  - Resorcinol,
  - Benzophenone,
  - Benzyl salicylate,
  - Genistein and
  - Daidzein

- Comments must be submitted by November 30, 2022

UK restricts CMRs & fragrance allergens in toys & cosmetics

- The UK enacted The Toys and Cosmetic Products (Restriction of Chemical Substances) Regulations 2022

- The Regulations amend the Cosmetics Regulation to prohibit deoxyarbutin and to permit the use of salicylic acid for uses other than as a preservative at 0.5% in body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant applications

- It also amends the Toys Regulations to:
  - Reduce limits for aniline and formaldehyde for toys intended for use by children under 36 months old or other toys intended to be placed in the mouth;
  - Reduce permitted migration limits for aluminium;
  - Prohibit fragrance the allergens atranol, chloratranol and methyl heptane carbonate; and
  - Add additional CMR substances to Annex 2 (prohibited substances)

Washington State considers phthalates in cosmetics

- In August, Washington State's Department of Ecology released a Preliminary Draft Rule on phthalates in cosmetics
- The Draft Rule would change the 100 ppm limit on intentionally-added phthalates to a complete ban on all intentionally-added phthalates
- The prohibition would apply to:
  - Fragrances (perfumes and colognes); and
  - Fragrances used in beauty products and personal care products
- The prohibition would *not* apply to:
  - Ortho-phthalates used in beauty products or personal care products; or
  - Active ingredients in products regulated by the US FDA as drugs
- The prohibition would take effect on January 1, 2025

China considers POPs restrictions

- In July, the Chinese Ministry of Ecology and Environment (MEE) opened a consultation on three persistent organic pollutants (POPs):
  - Dechlorane Plus,
  - UV-328 and
  - Methoxychlor

- These substances are used in a wide range of products, including consumer and commercial chemicals, DIY products and electrical and electronic equipment

- Comments were accepted through August 20, 2022

EU considers restrictions on CA:C14-17

- In September, the European Chemicals Agency (ECHA) launched a consultation to restrict medium-chain chlorinated paraffins (MCCPs) and other substances that contain chloroalkanes with carbon chain lengths from C14 to C17 (CA:C14-17) under REACH Annex XVII
    - Option A: A ban on articles containing more than 0.1% of CA:C14-17 with PBT and/ or vPvB properties, after a two-year transition period
    - Option B: The same ban, with an exemption for metalworking fluids, where either a longer transition period (7 years) or a derogation could be considered
- The public consultation will end March 22, 2023

Vietnam considers POPs restrictions

- In September, Vietnam's Ministry of Natural Resources and Environment (MONRE) notified the WTO of a Draft on Persistent Organic Pollutants (POPs) in articles, products, commodities and equipment

- The draft would regulate several POPs, including:
  - Hexabromodiphenyl ether and Heptabromodiphenyl ether (HBDE);
  - Perfluorooctane sulfonic acids (PFOS), their salts and perfluorooctane sulfonyl fluoride (PFOSF);
  - Hexabromocyclododecane (HBCDD);
  - Chlorine-containing short-chain paraffins (SCCP); and
  - Perfluorooctanoic acid (PFOA), their salts and compounds related to PFOA

- It would also designate standards for the analysis of POPs, including providing for acceptance of international standards

- These requirements will become effective six months after publication

New York State draft on flame retardants in displays

- The NYS Department of Environmental Conservation (DEC) is developing a program to implement portions of the Environmental Conservation Law
- Beginning December 31, 2022, manufacturers of electronic displays who sell their products in the state must annually report the presence of organohalogen flame retardants in the enclosures or stands of those displays
- DEC published a Draft Program Policy which establishes the process for manufacturers to follow when submitting the necessary report
- DEC accepted public comments through October 7, 2022

Turkey considers RoHS II

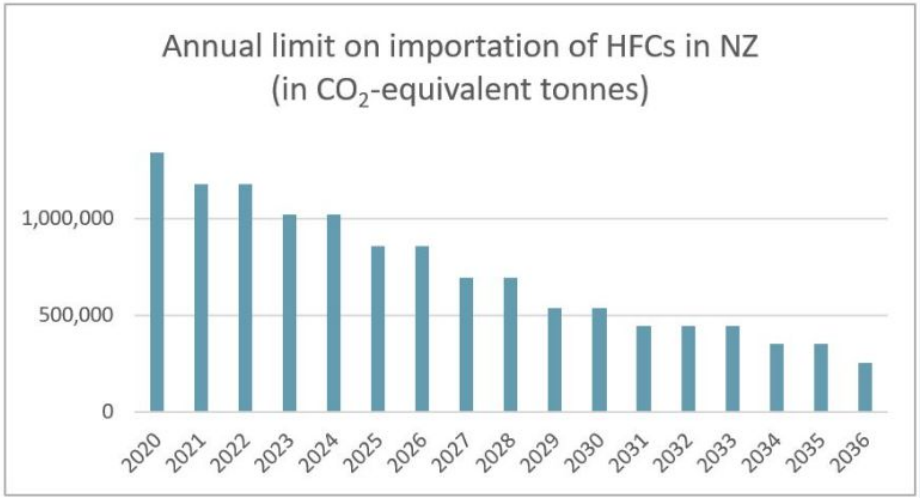
- In July, the Turkish Ministry of Environment, Urbanization and Climate Change published a draft on the restriction of the use of certain hazardous substances in electrical and electronic equipment
- The draft is modeled on the EU's RoHS II
- The draft is proposed to enter into force on the date of publication, however the provisions for EU Declarations of Conformity and CE marking will apply from January 1, 2025
- The comment period ended July 29, 2022

Vietnam considers RoHS

- In August, Vietnam's Ministry of Industry and Trade released a draft Circular on hazardous chemicals in electrical and electronic equipment
- The draft would restrict the same 10 substances at the same concentrations as the EU's RoHS II; such as lead (0.1%), mercury (0.1%) and PBDE (0.1%)
- Compliant E&E would be required to bear the technical-regulation conformity mark and bear certificates of conformity
- The comment period ends October 17, 2022

New Zealand lowers import HFC limits in HVACR

- On 7 October 2022, New Zealand's EPA lowered import limits for hydrofluorocarbons (HFCs) used in heat pumps, air conditioning and refrigeration
- The limit for importing HFC gases has been reduced more than 13% for 2023, compared with 2021 and 2022
- This will be decreased further every two years, in line with the Ozone Layer Protection Regulations



US EPA notifies companies of 2023 allowances for HFCs

- In October, EPA issued calendar year 2023 allowances for the production and consumption of hydrofluorocarbons (HFCs)

- Applications include products such as:
  - Semiconductors,
  - Metered dose inhalers and
  - Structural composite foam

- These allowances were established under the American Innovation and Manufacturing Act

- The Act directs the EPA by October 1 of each calendar year to determine the quantity of production and consumption allowances for the following calendar year

US EPA proposes acceptable refrigerants in HVACR

- In July, EPA proposed a list of acceptable substances - subject to use conditions - for:
  - Chillers (i.e., comfort cooling);
  - Dehumidifiers;
  - Residential and light commercial air conditioning;
  - Heat pumps and
  - Very low temperature refrigeration

- These proposals were undertaken per the EPA's Significant New Alternatives Policy program

- Comments were due September 12, 2022

Australia publishes Chemical Evaluations

- On June 30, 2022, the Australian Inventory of Industrial Chemicals (AICIS) published 28 completed chemical evaluations about the human health and environmental risks associated with the use of certain chemicals

- Chemicals included:
  - 1,4-Dioxane;
  - Lead and lead manufacturing byproducts;
  - Compounds of dimethyltin;
  - Compounds of dioctyltin and
  - Compounds of dibutyltin

- In most cases, AICS made a recommendation to regulatory body regarding workers and recommended including information relating to the safe introduction and use of the chemicals

Australia assesses decafluorobibenzyl

- In June, the Australian Industrial Chemicals Introduction Scheme published a new chemical assessment statement on decafluorobibenzyl

- The chemical is used:
  - As a component of articles for electrical and electronics applications, including home appliances;
  - For building and construction, as a component of wires, cables and plastic parts; and
  - In coatings

- Per the statement:
  - No risks are identified for public health through direct exposure that require specific risk management measures
    - Indirect exposure levels could increase over time due to persistent and bioaccumulative properties of the chemical
  - The risk to the health of workers from use of the chemical is not considered to be significant

Canada guidance on consumer products containing lead

- In July, Health Canada issued guidance on the Consumer Products Containing Lead Regulations
- The Regulations restrict lead content in five covered categories of consumer products to a limit of 90 ppm in each accessible part
- The guidance provides examples for each of the categories, such as:
  - A product that is brought into contact with the user's mouth during normal use, except for a kitchen utensil, or a product that is subject to the Glazed Ceramics and Glassware Regulations:
    - Pacifiers and teethers;
    - Sports mouthpieces and mouth guards; and
    - Drinking aids, including straws and parts of bottles, sippy cups, and other drinking vessels in contact with the user's mouth during normal use
- The guidance also addresses exceptions and test methods

CEH tests socks for BPA

- The Center for Environmental Health (CEH) issued a report, "BPA in Socks: Are There Harmful Chemicals in Your Socks?"
- In CEH's research, "socks from over 100 different brands [exposed] people to BPA at levels as high as 31 times over the limit deemed safe by California's Office of Environmental Health Hazards Assessment (OEHHA)"
- CEH raised a petition "to tell fashion CEOs to take The BPA out of their products"
- As of October 11, only 1,240 signatures have been collected

Delaware prohibits flame retardants in children’s products

- In August, Delaware enacted House Bill No. 77
- The Law bans flame retardants in children’s products, upholstered furniture and mattresses, with the following limits:
  - ≤0.1% of a listed flame retardant or ≤0.1% of a mixture that includes one or more listed flame retardants in children's products and upholstered furniture and
  - ≤0.1% of an organohalogen or ≤ 0.1% of a mixture that includes one or more organohalogens in mattresses
- These restrictions will take effect on July 1, 2023

EU considers microplastics restrictions

- The EU is considering a proposal to restrict intentionally added microplastics in cosmetics, cleaning products, pesticides and sports fields, amongst other products
- The restriction would apply to synthetic polymer microparticles below 5 mm and to fiber-like particles below 15 mm
- Companies may be given 12 years to adapt to the law
- In September, the draft proposal was debated at the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Committee

EU extends deadline on cobalt in toys

- In August, the European Commission extended the deadline for comments on a proposal on cobalt in toys through September 8, 2022
- SCHEER recommends the following revised migration limits:

	Category 1: Dry, brittle, powder-like or pliable materials	Category 2: Liquid or sticky materials	Category 3: Scraped-off materials
Current	10.5 ppm	2.6 ppm	130 ppm
Recommended	0.12 ppm	0.03 ppm	1.5 ppm

Saudi Arabia restricts heavy metals in jewelry

- In September, the Saudi Arabian Standards, Metrology and Quality Organisation (SASO) issued a Technical Regulation on jewelry and accessories made of metal, plastic, glass or textiles

- The Regulation restricts heavy metals, as per Annex 2:
  - Lead (Pb): 0.5 ppm
  - Cadmium (Cd): 0.1 ppm
  - Nickel (Ni):
    - Earrings (migration percentage for a week of normal use): (0.2) mg/cm^2
    - Other products that are attached to the body (the percentage of migration for a week of normal use): (0.5) mg/cm^2

- The Regulation will enter into force March 22, 2023; however, impacted parties have until September 23, 2023, to comply

US House considers chemicals in menstrual products

- The US House is considering H.R. 8724, Robin Danielson Menstrual Product and Intimate Care Product Safety Act of 2022
- The Bill would research the risks posed by dioxins, phthalates, pesticides, chemical fragrances and other components of menstrual products and intimate care products

UK REACH developments

- Chris Robertson from RINA added Expert Commentary to C2P about the latest UK REACH developments
- A Regulatory Management Options Analysis (RMOA) for PFAS was due to be completed this summer
- A similar program is also planned for formaldehyde and formaldehyde releasers in articles
- The UK plans to borrow from the US EPA's assessments of PIP 3:1, 2,4,6-Tri-tert-butylphenol and pentachlorothiophenol (PCTP), and determine whether these persistent, bioaccumulative and toxic (PBT) chemicals should be restricted in the UK
- "Hazardous flame retardants" are also prioritized for assessment; these are not confined to brominated substances

Canada Guidance on formaldehyde in composite wood

- Health Canada issued Guidance on the Formaldehyde Emissions from Composite Wood Products Regulations

- The Guidance provides general information on the Regulations, addressing:
  - The scope of the Regulations;
  - Testing, including frequency of testing;
  - Certification;
  - Labeling of composite wood panels and of laminated products and finished goods; and
  - Recordkeeping and reporting

- The Regulations align with the US EPA's Formaldehyde Emission Standards for Composite Wood Products

Mexico considers restrictions on formaldehyde in wood

- In July, Mexico notified the WTO of Draft PROY-NOM-203-SE-2020
- The draft would establish limits for formaldehyde emissions from wood particleboard and fiberboard and from furniture and all other products manufactured from this type of board
- The draft would require manufacturers to obtain a certificate of conformity from an accredited third-party laboratory
- Manufacturers would also be required to establish a traceability system to ensure continued compliance
- The draft references CARB's Airborne Toxic Control Measure (ATCM), ASTM D6007 and ASTM E1333; and UNE-EN 120 and UN-EN 717-1

Q&A

Thank you!

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