October 23, 2023

Submitted via www.regulations.gov

Laura Buffo
Chair of the Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: Docket No. USTR-2023-0010, Request for Comments on Significant Foreign Trade Barriers for the 2024 National Tariff Estimate Report, Document No. 2023-19521

Dear Ms. Buffo:

The American Chemistry Council appreciates the opportunity to submit public comments to assist the Trade Policy Staff Committee (TPSC) in identifying foreign trade barriers for inclusion in the 2024 National Trade Estimate (NTE) Report.

The U.S. chemical industry is a $639-billion-dollar enterprise, contributing significantly to the U.S. gross domestic product (GDP), and providing 555,000 skilled, good-paying American jobs, with production in nearly every state. Many of these jobs are export dependent. In fact, the business of chemistry is one of the largest exporting sector in the United States and accounts for 10% of all U.S. goods exports. And because most manufactured goods are touched in one way or another by chemistry, the chemicals industry is the foundation for American manufacturing.

Trade is essential to the success of the U.S. chemical industry, and it benefits the broader economy as well. Access to global markets is critical for continued economic growth and job creation. The chemical industry is also a leader in capital investment, with more than $26 billion in new spending in 2022. These investments include projects to expand capacity to meet growing demand and make industry operations more sustainable. The chemical industry is expanding technological frontiers, with $13.4 billion in R&D investment in 2022. These investments in innovation are the key to developing new materials, applications, and processes to ensure a safe and plentiful food supply, clean air and water, safe living conditions, efficient and affordable energy sources, and life-saving medical treatments.

Given the above, the U.S. chemical industry and the many downstream users of our chemistries are poised to strengthen our competitive advantage by the removal of foreign trade barriers such as tariff and non-tariff barriers, which will improve efficiencies and reduce costs while protecting human health and the environment. We have identified multiple issues for inclusion in the 2024 National Trade Estimate Report in the submission below and look forward to working with U.S. government leaders and experts to address these issues.

Full implementation of World Trade Organization (WTO) commitments by U.S. trading partners, particularly those that relate to technical regulations and transparency (e.g., high standard notifications of proposed regulations to the WTO Technical Barriers to Trade (TBT) Committee), is important to our industry. ACC and our members rely on the opportunities to offer meaningful, detailed comments on proposed regulatory measures that the WTO TBT Agreement affords interested parties. Your efforts are critical to ensuring that all WTO Members adhere to the WTO TBT Agreement's transparency provisions and reinvigorate the WTO committee process in order to prevent and address barriers to trade.

We actively promote regulatory cooperation to create to promote free, fair, and open trade and investment, and supply chain resiliency for businesses and consumers, including through trade agreements such as the U.S.-Mexico-Canada Agreement (USMCA); ongoing trade negotiations with a range of trading partners, and in industry-led efforts in Asia, Latin America, Europe, the Middle East, and other regions. ACC and our members will also continue to advocate for well-researched and reasoned regulatory cooperation goals at the WTO, as regulatory cooperation is an important element for making the WTO agenda relevant to the business community.

Thank you for considering our comments below. We look forward to engaging with the TPSC further on these issues and welcome an opportunity to provide additional resources to USTR as it advances the U.S. trade policy agenda.

Sincerely,

Jason Bernstein

Jason Bernstein
Director for Global Affairs (International Trade and Supply Chain)
American Chemistry Council

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American Chemistry Council

Issues for Inclusion in the 2024 United States National Trade Estimate Report

1. Canada

1a. Use of Canadian Environmental Protection Act (CEPA) to Brand Plastics as "Toxic" and Ban Several Categories of Plastic Packaging

The Canadian government has banned certain products made of plastics. The basis for desired governmental action is concern about litter, marine debris, and solid waste management related to these products. However, rather than pursuing legislation or other approaches tailored to specific end-of-life concerns, Canada has enacted these restrictions through use of CEPA, and by adding substances (e.g., plastic manufactured items) to Schedule 1 of CEPA – the Toxic Substances List, despite a lack of any scientific- or risk-based rationale for its conclusion that "plastic manufactured items" are, in fact, toxic. Indeed, many targeted polymers are so safe that the U.S. Food and Drug Administration has approved them for use as food-contact materials. Adoption of this proposal would effectively result in a declaration by the Canadian government that various plastic products (and the plastics themselves) are toxic, which has the potential to distort billions in cross-border trade. Despite these concerns, Canada continues to move forward on its *Single-Use Plastics Prohibition Regulation* and has prohibited the manufacture and for imports of several plastic manufactured products.

This represents a significant barriers to trade, including bans on the import, production, use, and sale of certain plastic manufactured items in Canada, as well as bans on the movement of used plastics destined for recycling or other sustainable uses. Many of these materials are critical inputs to a wide range of highly integrated manufacturing value chains and will impact economies and highly skilled workers on both sides of the border.

Instead of this CEPA-based regulatory approach, the Canadian government should focus its efforts on directly addressing the issue of concern: used plastics entering the environment.

The Canadian government has also signaled its intention to propose a federal extended producer responsibility (EPR) program. This would supersede existing EPR programs at the Provincial level, creating market uncertainty and increasing business risk. EPR programs require careful design to avoid creating trade barriers; for example, manufacturers and importers may be held responsible for the recovery of plastic that is created in other jurisdictions and subsequently sold into Canada. EPR must be carefully designed, implemented, and managed to avoid the program or associated fees acting as a barrier to market entry.

By taking this action, the Canadian government is:

- Diminishing U.S. exports (over $8 billion worth of plastic manufactured items) and threatening in the future other U.S. manufactured products (i.e., cars with plastic components);

- Contravening the intent of commitments to ensure that technical regulations are no more trade-restrictive than necessary to fulfill a legitimate objective; and

- Establishing a precedent that plastic manufactured items are toxic, which will create consumer confusion and limit the ability of society to achieve a circular economy with the lowest carbon footprint.

ACC Recommendation: The U.S. government should urge the government of Canada to refrain from listing further plastic manufactured items under CEPA Schedule 1 and engage in discussions with Mexico and the United States on a North American approach to the challenge of used plastics leaking into the environment. The work done by the government of Canada can help to inform these discussions.

1b. Decabromodiphenyl Ethane (DBDPE)

On May 14, 2022, Canada published a proposed measure under *Canada Gazette Part I, Volume 156, Number 20:Prohibition of Certain Toxic Substances Regulations 2022*, that would add new substances, including DBDPE, to Schedule 1 of the Canadian Environmental Protection Act (CEPA). This measure would introduce new restrictions on the manufacture, sale, and import of Decabromodiphenyl ethane (DBDPE), a flame-retardant that is commonly used in a wide range of manufacturing sectors, including vehicles and light trucks, aircraft and aerospace, information and communications technology (ICT), and appliances. The effective date of application of this measure has been delayed several times and several countries have raised concerns about Canada's proposals to the WTO TBT Committee.

While Canada's assessment recognizes that DBPDE does not pose a risk to human health and that there is a lack of commercially available alternatives, the Canadian Departments of Environment and Health still propose a ban on its manufacture, sale, and import, providing only a limited permit period for manufacturers to develop an alternative.

DBDPE does not pose a risk either to human health or the environment. In addition, available science and studies do not support Canada's proposal, which would significantly restrict U.S.-Canadian trade and impair U.S.-Canadian supply chain resiliency for the defense, ICT, and transportation industries, as highlighted in the Executive Order of America's Supply Chains and by the U.S.-Canada/Canada-U.S. Supply Chain Working Group.

ACC Recommendation: Several countries have raised concerns about Canada's proposed measure, which needs both a more robust risk-based analysis and a longer review time to determine its potential effects on health, the environment, trade, and supply chain resiliency. In the meantime, implementation of this or similar measures should be postponed.

2. China

2a. Anti-Dumping and Countervailing Duties and Subsidy Transparency

U.S. chemical manufacturers continue to see growing politicization of Chinese trade remedy measures, raising concerns about China's commitment to WTO principles and core values such as procedural fairness. China has often targeted key imports of countries when disputes arise to pressure and damage foreign industry as well as to support China's domestic industrial development policies, often through unsubstantiated allegations of subsidies or non-market conditions. The process is non-transparent, unnecessarily burdensome and designed to ensure negative outcomes, establish maximum political and commercial leverage, and misuse the rationale and nature of the anti-dumping and countervailing duty processes. China maintains these discriminatory provisions despite the impact to their own domestic industry and would benefit from accelerating a sunset review and removal of these practices.

ACC Recommendation: ACC urges the U.S. government to request that China fully implement its WTO commitments under the Agreement on Anti-Dumping and the Agreement on Subsidies and Countervailing Measures by ensuring that determinations are based on law and facts and made pursuant to transparent and standardized procedures. ACC also urges the U.S. government to continue to press China to notify all its subsidies to relevant WTO committees in a timely manner.

2b. Chemicals Management

In 2023, we have seen new developments in China's chemical management process that act as significant foreign trade barrier to U.S. exports. In particular, the data requirements for new polymers registration are of concern. These are no different from those for new discrete chemical substances under the current China Ministry of Ecology and Environment (MEE) Order 12, including cationic polymers, degradable polymers, and other polymers containing hazardous chemical elements. This is different from the approach of other countries or economies, in which polymers require registration. Considering the relatively low risk of these polymers and the universality and complexity of polymers and their applications, the data requirement mandated under Order 12 is not necessary in order to generate scientific sound evidence for polymer hazard characterization and exposure assessment and represented a foreign trade barriers to U.S. exports.

We also see a lack of transparency in how China implements regulations with stark differences between the way Chinese authorities implement regulations and the texts of regulations. For example, Chinese authorities have started to adopt a "cumulative risk assessment" practice regarding new chemicals registration for foreign based producers, which puts new stricter controls on the volume of new substances granted approval that are not found in the regulation itself. Not only is this assessment practice inconsistent with international standards, but authorities have indicated that they will provide guidance for this practice after it has already been implemented and without adequate notice.

China has also recently taken steps to further implement a mandatory QR code for hazardous chemical management in China under the "one enterprise, one chemical product, and one QR code" system managed by the Ministry of Energy Management (MEM). However, the process for generating a QR code has fallen to local provincial authorities and is not aligned with new chemicals approvals in China, which is now mandatory for applying for the QR code. Since the QR code will now be required on all GHS labels in China, this is causing delays in new approvals of chemical substances since these processes are misaligned between federal and local authorities.

Relatedly, we are also seeing an increasing tendency from the MEE to not announce new chemical requirements publicly but instead pass on new requirements to local provincial authorities for implementation. Examples of this are the recent MEE's chemical substance environmental information statistical investigation. This often leads to differences in deadlines for when implementations take effect and how such regulations are implemented. Therefore, we recommend a process where there is a single database or process of announcing and receiving comments by PRC ministries on proposed regulations at the PRC level.

ACC Recommendation: We would appeal to Chinese authorities to establish proportional data requirements for polymers that require registration as soon as possible in order to allow the innovation on these new polymers. Possible ways to achieve this goal include reasonably reference to data and information requirements of other countries/economies, technical communication, and dialogue on specific polymers between industries and authorities. In response to the enactment of the "one enterprise, one chemical product, and one QR code" system, we would appeal for more implementation guidance on this requirement and a delay in making it mandatory until such guidance is provided. Finally, in response to MEE new requirements, we would recommend a process where there is a single database or process of announcing and receiving comments by PRC ministries on proposed regulations at the PRC level.

2c. Protection and Enforcement of Intellectual Property, including Trade Secrets

Protection and enforcement of trade secrets and other intellectual property rights is essential for the success and competitiveness of U.S. chemical manufacturers globally. This is particularly true in the China market. While China has made some progress on intellectual property rights, it still lags on enforcement of those rights.

Significant trade secret cases often languish in Chinese courts for years, even when there are clear cut cases of Chinese violations of the intellectual property rights of foreign companies. Similarly, the courts have stalled recognition and enforcement proceedings for international arbitral awards obtained by foreign companies against Chinese companies. The delay or denial of prompt and credible enforcement of intellectual property rights violations erodes U.S., international and, ultimately, Chinese interests in protecting intellectual property and preventing further trade secret misappropriation.

ACC Recommendation: We encourage the U.S. government to continue to press China to ensure broad protection of intellectual property rights, as required under China's WTO commitments and the Economic Agreement between the government of the United States and the government of the People's Republic of China.

2e. Tariffs

According to the WTO Tariff Profiles 2023, China's average most-favored nation (MFN) applied tariff rate for chemicals within Chapters 28-39 of the Harmonized System is 6.2 percent. Its average WTO bound rate for chemicals is 6.7 percent[1].

Relative to other large emerging markets, China's average MFN applied and bound rates are low. For example, India's average MFN applied rate is 10.3 percent, and its WTO bound rate is 39.6 percent. However, China's average MFN applied and WTO bound tariff rates for chemicals are still higher than the average MFN applied rates for chemicals for the U.S. (2.7 percent), the EU (4.5 percent), and Japan (2.1 percent). China's relatively low rates are the result of China joining the WTO Chemical Tariff Harmonization Agreement as a part of its WTO Accession Protocol. The stability of China's tariff rates for chemicals and plastics had in the past provided U.S. chemical manufacturers certainty when exporting product to China.

China's retaliatory tariffs in response to U.S. Lists 1, 2, 3, and 4 under Section 301 of the Trade Act of 1974 impact billions of dollars in U.S. exports of chemicals and plastics. The additional tariffs on U.S. exports of chemicals and plastics have obviated the certainty of China's MFN tariff rates, thereby jeopardizing investments in chemical manufacturing in the United States. U.S. chemical manufacturers now face additional tariffs of up to 25 percent depending on the product, on top of existing MFN tariff rates.

ACC Recommendation: ACC and our member companies support an outcome where the United States and China resolve their trade dispute and eliminate these additional tariffs. reverting to the previous status quo of MFN trade. Barring that, China should extend and expand its tariff exclusions on U.S. chemical exports.

2f. WTO TBT Agreement Implementation

ACC and our members have a significant interest in China's full implementation of the WTO Agreement on Technical Barriers to Trade (TBT Agreement). Chemical manufacturers operate in highly regulated markets all over the world. They benefit from the TBT Agreement obligation in Article 2.9 to allow interested parties the opportunity to provide public comments on proposed regulations that are not based on international standards.

China's membership in the WTO has made a measurable impact on its ability to make its proposed regulations more transparent, notify its measures for review by stakeholders, and take the view of stakeholders into account.

[1] WTO, ITC and UNCTAD, 2023, "World Tariff Profiles 2023", pg., 72, https://www.wto.org/english/res_e/booksp_e/world_tariff_profiles23_e.pdf

ACC Recommendation: We support efforts by the U.S. government to continue working with regulatory agencies and the government of China to ensure that it implements the TBT Agreement in full and adopts good regulatory practices, as embodied by the APEC-OECD Integrated Checklist on Regulatory Reform[2].

3. European Union

3a. The Chemical Strategy for Sustainability

On October 14th, 2020, the European Commission (the Commission) published the "Chemical Strategy for Sustainability" (CSS, or the Strategy), a multi-faceted long-term strategic document that will completely revamp how chemicals are addressed within the European regulatory framework. The Strategy stems from the European Green Deal and aims to push Europe towards a "toxic-free environment." The Strategy recognizes the EU chemical regulatory system as one of the most comprehensive and "protective" in the world but outlines the development of an even more aggressive and precautionary regulatory framework.

There are five components of the Strategy:

a. Innovating for safe and sustainable EU chemicals;
b. A stronger EU legal framework to address pressing environmental and health concerns;
c. Simplifying and consolidating the current legal framework;
d. Developing a comprehensive knowledge base on chemicals; and
e. Global outreach on the EU method of chemicals management.

Each of the above components involves a number of actions and measures to be undertaken by the Commission to achieve its goals. These can all be found in the Action Plan, which contains 56 measures to be rolled out between 2021 and 2024. Industry has been, and continues to be, engaged with a number of the measures that were involved in the creation of the Action Plan.

Within the larger CSS, the Commission has stated that specific legal proposals, including a revision of Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) will be accomplished "in the most targeted way possible and limited to achieving the objectives of this Strategy"; made on the basis of public consultations; and subject to comprehensive impact assessments, with a special focus on impacts for SMEs and innovation.

Although not fully implemented, the CSS is already having a significant impact on the U.S. chemicals industry. Understanding the context of the regulatory environment and political and social pressures within Europe is of utmost importance when addressing the following challenges. We have included our recommendations for each of the topics addressed below.

3b. CLP Hazard Classes

In late December 2022, the Commission released Delegated Regulation (EU) 2023/707 amending regulation (EC) No 1272/2008 on hazard classes and criteria for the classification, labeling, and packaging of substances and mixtures, for the purpose of adding new hazard classes, including classes for Endocrine Disruptors (ED), Persistent, Mobile and Toxic substances (PMT), and Persistent, Bioaccumulative, and Toxic substances (PBT). The amended CLP regulation entered into force on April 20, 2023, whereas the procedure for adopting the legislation into European law is still ongoing. Companies have until May 1, 2025, to prepare for the first round of changes when the requirements to label substances in line with the new rules begin to apply.

The Commission's choice to act through a Delegated Act rather than a full legislative procedure to amend the CLP sets a problematic precedent when, in order to expedite the process, a less inclusive policymaking approach is applied. ACC is concerned that a similar approach may be taken with revisions to other critical EU chemicals management legislation, such as REACH.

The amended CLP regulation adds additional hazard classifications that are not recognized in any other country or jurisdiction. As a result, it may cause serious trade and supply chain disruptions by creating substantial inconsistency with respect to classification and labeling regulations between the EU and the rest of the world.

Although CLP is the implementation vehicle for the U.N. Global Harmonized System (GHS) of Classification and Labeling of Chemicals (GHS) in the EU, the amended CLP does not signal an intention of the Commission to abandon the GHS. Instead, the EU is pressuring the international community to consider the addition of these new CLP classifications to GHS. OECD expert work groups are being convened for accelerated review to inform this process. The EU has therefore deployed CLP to undermine the longstanding efforts of the U.S. and other countries to harmonize the classification and labeling requirements for chemical substances through the GHS.

The Commission's actions may encourage other governments to take their own approaches to GHS implementation and to pressure GHS to conform to their approaches, creating further divergences and market segmentation of the supply chain not just for chemicals, but for many downstream products. If products placed into the EU territory have to be classified for certain CLP hazard classes that don't have an equivalent in any other national GHS implementation, these new hazard classes will automatically trigger restrictions and bans foreseen by the Commission's proposed generic approach to risk management (GRA). It is highly concerning that the Commission essentially imposes the EU's internal agenda on considerations taking place at the UN GHS subcommittee level.

The CLP has traditionally focused on the consistent and accurate labeling of hazardous chemicals to ensure that hazards presented by chemicals are clearly communicated to workers and consumers. However, the proposed new classes are not hazards. Endocrine disruption is not a hazard but is instead a mode of action. Similarly, persistence and bioaccumulation are not hazards but are instead environmental fates. Any adverse effects on human health or the environment that result are appropriately and sufficiently communicated via existing hazard classifications and communications.

These regrettable developments in the EU and the pressure on the international community exemplify the ongoing conflict between precautionary principle- and risk-based approaches to chemical regulation. These developments also show that jurisdictions that utilize a precautionary principle-based approach to chemical regulation create their own trade weakness by restricting their own markets, leaving little choice but to undermine GHS in order to maintain their own global trade competitiveness. This underscores the power and superiority of a science-and risk-based approach to chemical regulation for competitiveness, as well as the importance of supporting this superior approach worldwide.

ACC Recommendation: ACC recommends that the Commission prioritize the development of scientifically sound guidance documents as the Act enters into force, especially as there are a number of new proposals that will require significant engagement from U.S. and other stakeholders. We ask the U.S. government to urge the European Commission to take a more coordinated global approach to issues that impact the global classification, labeling, and packaging of chemicals through GHS.

3c. Per- and polyfluoroalkyl substances (PFAS)

On May 11, 2020, the European Chemicals Agency (ECHA) announced that the national authorities of Germany, the Netherlands, Norway, Sweden, and Denmark agreed to prepare a joint REACH restriction proposal for per- and polyfluoroalkyl substances (PFAS) and launched a call for evidence to inform their development of the proposal. Between March and September 2023, ECHA conducted its first public consultations on the proposal, receiving over 5600 comments.

This proposal as, currently considered by the EU, will have a significant impact on many U.S. and global supply chains and acts as a significant trade and investment barrier. The time-limited derogations included in the proposal are inadequate and will likely result in the lack of alternatives or regrettable substitutions, whereas production only for derogated uses may not be economically viable. The proposed restriction also undermines innovation, R&D planning, and major investment decisions. While we strongly support the responsible production, use and management of fluorinated substances and support a comprehensive approach to managing PFAS that is protective of human health and the environment, there are several reasons why this proposal is much more trade restrictive than necessary.

PFAS are a large, diverse group of substances with different properties and should not be treated as a single regulatory class. The premise of the consultation—to inform consideration of restriction proposals for *all* PFAS substances—is both inappropriate and unnecessary. PFAS are a large, diverse group of chemical compounds. They should not be regulated as a single group because it is possible to scientifically define distinct classes of PFAS based on shared properties. For example, fluoropolymers are a group of PFAS with specific physical and chemical properties. Their environmental and toxicological profiles are distinctly different from other classes of PFAS, and they have been shown to meet established criteria to be identified as polymers of low concern.[2] Restricting fluoropolymers would unnecessarily disrupt multiple industries and public infrastructure without benefiting human health or the environment (and potentially the opposite).

*Persistence alone is an insufficient basis for regulation***.** The European effort is premised on the concept that persistence alone may be the basis for restriction under REACH. In fact, persistence is not an intrinsic hazard. It does not in itself imply an adverse effect, and persistence alone is not enough to assess present or future risks to human health and the environment. Indeed, there is no language in REACH supporting the notion that persistence alone justifies risk management measures. On the contrary, REACH combines persistence with bioaccumulation and toxicity (or "very persistent" with "very bioaccumulative") to justify the designation of a Substance of Very High Concern and consideration of potential risk management measures for uses associated with unacceptable risk. Therefore, any regulation should not be based only on persistence, as it would be overly simplistic and excludes other relevant and explicit criteria.

Society depends on durable materials in a wide variety of applications, e.g., medical devices, aerospace, renewable energy, information technology, and infrastructure. The durability of materials and products contributes directly to increased product safety and to the circular economy by extending the lifecycle of products and thereby moving towards waste prevention, which is consistent with the European Green Deal. A sole focus on durability – "persistence" – is inherently limited and insufficient to support a risk-based conclusion. A focus on "persistence" alone undermines the critical innovation needed to produce materials that support the EU's and other broadly held societal sustainability goal*s.*

Essential use should not be used as a criterion for market access. The concept of essential use should not be used to justify restrictions under REACH. There is no definition of "essential use" under EU law, and the concept is, at this time, insufficiently robust to justify regulatory decisions. Applying an essentiality criterion without regard to other factors will lead to unnecessary and unjustified restrictions on large groups of chemicals that may be deemed non-essential even though they do not pose an unacceptable risk to human health or the environment. Restriction should be triggered only if a risk associated with a specific use has been identified, and the risk is significant enough to justify regulation. It is neither legally consistent with REACH nor scientifically acceptable to use a "non-essential" determination to justify a restriction.

Although REACH is silent on the concept of essentiality, it does require the Commission to address the socio-economic impacts of any restriction proposal. Socio-economic analyses should include an assessment of a substance's ability to enable and support priority economic sectors and critical public infrastructure.

ACC Recommendation: The U.S. government should strongly question the departure from the REACH chemical management framework and the intent to use persistence alone and

[2] B.J. Henry, et al. 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management 14:316-334. Open access. Available at https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035.

the declaration of essential (or non-essential) uses as the basis for restriction under REACH. The U.S. government should also consider the impact of the proposed restrictions in the EU on many critical sectors of the U.S. economy and on U.S. and global supply chains.

3d. Use of REACH to Regulate Intentionally Added Microplastics

On September 25, 2023, the Commission adopted measures under Annex XVII of REACH that restrict microplastics internationally added to a wide suite of products and in various applications in consumer and professional markets and impose labeling and reporting obligations for derogated uses across a wide range of sectors including cosmetics, inks and printing, packaging, paints and coatings, pharmaceuticals, and food and feed. The restriction entered into force on October 17, 2023.

The EU's approach to microplastics may lead to stifling innovation and unintended consequences. For example, particles used for the reinforcement of adhesives and concrete are captured by this regulation. Limiting the types of construction materials available may prevent new, lighter and stronger materials technologies from being developed. The use of microparticles in agriculture is also key to the safe use of biocides by limiting a user's exposure to potentially hazardous biocides. While there is a transitional phase of 8 years to reformulate, a new product will need to obtain authorization for use. The authorization process itself may represent a barrier. As discussed above, the mere fact that a material is durable (persistent) does not mean that it presents a health or environmental hazard.

ACC Recommendation: Given the requirement of microplastics to be considered by the Intergovernmental Negotiating Committee (INC) to develop an international legally binding instrument on plastic pollution, the U.S. government should request that any related provisions be based on best-available science and require a foundational determination of risk to move ahead with adoption.

3e. Siloxanes Restrictions

In 2018, the EU imposed restrictions on the use of two siloxanes (D4 and D5) in wash-off personal care products. The 2018 restriction entered into force in early 2020. On June 22, 2023, a draft amendment to the REACH regulation Annex XVII was published to introduce restrictions on the use of D4, D5, and D6 silicones in cosmetics and other consumer and professional products. Under the proposed amendments, the use of D4, D5, and D6 in a concentration equal to or greater than 0.1% by weight of the respective substance would be strictly restricted, with a two-year transitional period. These substances would not be allowed to be placed on the market as a substance on its own, as a constituent of other substances, or in mixtures. Leave-on cosmetics would have a three-year transitional period.

D4, D5, and D6 are chemical intermediates that are used primarily to make silicone polymers. These polymers provide unique product performance characteristics that spur innovation in thousands of products that benefit key segments of the global economy, including building and construction materials, electronics, healthcare applications, and transportation. They are key enablers towards global and regional sustainable development goals. The EU siloxane restrictions limit consumer choice, reduce product quality, and jeopardize innovation without any measurable environmental benefit. They would also have significant trade and supply chain effects, if they result in an export or import ban of such substances or affect the supply chain resiliency of critical goods which use such substances (e.g., semiconductors).

The new leave-on restriction was proposed without any assessment to determine whether the initial wash-off restriction was sufficient to achieve the European Union's risk management goals for siloxanes. Actual monitoring data collected to evaluate the impact of the wash-off restriction indicate that the levels of D4, D5, and D6 measured in wastewater treatment plant (WWTP) influent are already at, or approaching, the concentration goals established by the European Union as goals for risk management. These data were collected prior to the entry of the initial wash-off restriction into force, and questions the need for either restriction in the first place.

ECHA's recommendation to include D4, D5 and D6 in Annex XIV is inconsistent with previous EU regulatory conclusions finding that Authorisation was not an appropriate risk management measure for the three siloxanes. In addition, Authorisation would have virtually no additional risk management benefit for these substances, whilst causing unwarranted reputational damage for these substances, blacklisting, and automatic global deselection in the value chain.

Finally, unlike numerous regulatory evaluations for siloxanes, the REACH evaluations for D4, D5, and D6 did not consider the wealth of international exposure data, which demonstrates that none of the materials have been measured in the environment at sufficient concentrations to merit regulatory restrictions. Environmental monitoring studies conducted by the silicone industry, the government of Canada, and numerous academic experts at locations in North America, Europe, and Asia consistently demonstrate that environmental loadings of D4, D5, and D6 pose low risk to organisms in the environment. Both Canada and Australia have conducted robust risk-based evaluations for D4, D5, and D6 which considered the available exposure data, and neither country has imposed any restrictions on their use in commerce.

ACC Recommendation: We urge the U.S. government to request the European Union not to pursue Authorisation for D4, D5 and D6, on grounds that this will have no additional risk management benefit and would be inconsistent with several previous regulatory decisions by the EU, undermining regulatory predictability for these critical substances, while imposing unwarranted damage to the reputation of the substances and to their application and benefits globally.

3f. EU Export Ban

Between May and July of 2023, the Commission conducted a public consultation on a proposal to ban the export of chemicals that are currently banned or restricted in the EU. The initiative is also part of the commitments made under the EU's Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. Under the socio-economic impact assessment currently underway, the Commission is considering various policy options, including a revision of PIC export regulations, an increase in the amount of information made available to non-EU countries, the introduction of a prohibition to produce and export of chemicals not approved or prohibited in the EU, or a combination of the above. Part of the initiative also includes working with non-EU countries to ban and restrict the same chemicals, which would affect global supply chains.

The international trade of hazardous chemicals is governed by the Rotterdam Convention on PIC procedure, which is implemented in the EU through Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (EU PIC regulation). If the Commission plans to revise the current export requirements under the EU PIC regulation, it should continue to adhere as closely as possible to the common export notification procedure requirements accepted internationally. This will promote greater harmonization and prevent increasing and unnecessary administrative burdens on industry, as well as on national regulators.

A prohibition on producing chemicals for export that are otherwise restricted or banned in the EU will cause a significant disruption in U.S. and global supply chains. These global supply chains extend all the way to consumer products. The effects of such descriptions on supply chains would increase significantly if non-EU countries also adopted these prohibitions, which is an aim of the EU proposals. An EU ban on the production and export of certain chemicals will not affect demand. Neither will it affect the development or availability of alternative chemistries in importing countries. However, the proposed export ban could lead to massive disruption in manufacturing operations globally. It could force U.S. companies to shut down their entire EU production and move their operations out of the EU. Either would result in longer delivery times and higher costs for importing countries and for the global supply chain partners that rely on these chemicals. Moreover, the ban could increase the export of chemicals from countries lacking strong regulatory controls, potentially leading to illegal trade and the use of dangerous counterfeit chemicals. This unintended effect could further compromise the health and environment in the importing countries, instead of protecting them.

ACC Recommendation: We would ask the U.S. government to urge the EU not to take unilateral actions that have global consequences and to continue to have a dialogue and seek common solutions on issues impacting supply chains. ACC would also welcome opportunities for stakeholder input on these issues through bilateral cooperation mechanisms, such as the TTC.

4. India

4a. Chemicals Management

In December 2019, India's Ministry of Chemicals and Petrochemicals released a proposed large-scale draft chemicals management rule entitled "Draft Chemicals (Management and Safety) Rules, 20xx". Since then, the government of India released a series of draft rules for stakeholder comment. ACC has actively participated in all of India's regulatory processes.

In the most recent draft, the proposed regime would impose higher upfront compliance costs on both domestic manufacturers and global chemical manufacturers seeking to export to India. It is also largely inconsistent and incompatible with regimes of India's trading partners, which may fragment India from the global market, further limiting the availability of critical inputs for India's manufacturers. The Government of India should adopt tenets of regulatory cooperation and work with key trading partner countries, such as ASEAN member economies, to coordinate an inclusive, efficient development of new chemical management rules.

In addition, of critical importance is ensuring the mutual recognition of data generated under different regulatory schemes in other jurisdictions. This would be in alignment with the OECD MAD (Mutual Acceptance of Data) Agreement, to which India is a signatory, which states that there should be no requirements for test laboratories to be certified by a government agency nor for laboratories to perform tests in the country of registration. According to the OECD[3], India is a full adherent to the OECD MAD program, including for industrial chemicals significant undertaking, especially in a jurisdiction where there is very little current regulation surrounding chemicals management.

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ACC Recommendation: The U.S. government should ask India to re-notify this measure to the TBT Committee in order to allow interested parties to familiarize themselves with the revisions; to provide a satisfactory time for interested parties to provide comments; and to avoid adopting the proposed regulation until it has considered and responded to comments from interested parties into account.

4b. Quality Control Orders

In 2023, the Bureau of Indian Standards (BIS) issued a new Draft Quality Control Order on Polypropylene (PP) Materials for Moulding and Extrusion (PP QCO). The PP QCO mandates that products meet the criteria articulated in either in the QCO itself and/or the related product manuals published by BIS. These criteria include compliance with Indian Standards for the products and the requirement that the BIS Standard Mark appear on product packaging.

To use the Standard Mark, all producers must apply for a license from BIS. The application process involves, among other things, a physical inspection by BIS officials of the producer's manufacturing facilities and products to assure that they meet the criteria included in QCO or the product manuals. Concerns about the implementation of this QCO are similar to other quality control orders that are pending implementation by BIS, i.e., Polyethylene (PE) Material for Moulding and Extrusion (Quality Control) Order, 2021 and Ethylene Vinyl Acetate (EVA) Copolymers (Quality Control) Orders, 2020.

The facilities and product inspection requirements to obtain a BIS License disproportionately affects U.S. and foreign manufacturers and acts as a barrier to U.S. exports and investment. Moreover, the Indian Standard adopted by BIS for certain chemical substances are not up to date or reflect current testing methods, and the related

[3] https://www.oecd.org/chemicalsafety/testing/contact-points-working-group-on-good-laboratory-practice.htm

QCO does not allow use of corresponding international acceptable standards for these substances. BIS does not accept third-party or internationally recognized facility inspection companies and testing laboratories to conduct the inspection of the applicant's facilities or products. The PP QCO may ultimately require that the Standard Mark and that the License number of both the manufacturer and the applicant's repacking entity appear on even the smallest product package. This requirement, also applicable to the PE QCO, is unique to India and requires industry to incorporate additional processes into existing systems, including the consolidation of artwork for labeling, conducting supplier trials to demonstrate the re-design of the product bags, procurement of new bag materials etc. Implementation of these QCOs before all foreign stakeholders applications for the BIS License are duly reviewed and adjudicated and providing the time to comply with the QCO's requirements will not only affect U.S. exporters will result in a disproportionate impact on Indian downstream users, especially MSMEs.

ACC Recommendation: We ask the U.S. Government to urge India to extend the implementation dates of all pending QCOs and allow for more proactive and prior engagement with industry before these and future QCOs are drafted or implemented. Many legislative or regulatory rules have been issued with little prior notification, which does not allow industry the time required to adopt new compliance measures and presents challenges for businesses vis-à-vis long-term sourcing strategies. In addition, we ask the U.S. Government to urge India to extend the implementation dates of all pending QCOs until all applications filed by foreign manufacturers and related repacking entities, as applicable, have been duly reviewed and adjudicated.

4c. Central Board of Indirect Taxes and Customs Circular on Additional Qualifiers

On 6 June 2023, India's Central Board of Indirect Taxes and Customs issued a Circular requiring additional information for many chemical imports into, and exports from, India, including chemicals listed under the chapters 28, 29, 32, 38 and 39 of the Indian Customs Tariff Act. The Circular requires that importers submit the CAS number and the IUPAC names of main / active ingredients on the import Bill of Entry. Manufacturers routinely consider this information confidential and of primary concern has been an apparent lack of adequate protection of Confidential Business Information (CBI) especially for U.S. and foreign manufacturers exporting to India. Moreover, existing import requirements already include the submission of a chemical's safety data sheet (SDS) which provides all the information required by either Customs or the Department of Chemicals and Petro-Chemicals (DCPC) to determine a chemical's hazard classification. The Circular was slated to enter into force on 1 July 2023 but a three-month extension of the Circular's requirements was given until 1 October 2023; a new Circular with revised requirements was issued (30 September 2023) and entered into force 15 October 2023. Since entry into force, India has added additional data elements to these original requirements,"Percentage"; and "Yield%". During public consultations, the Central Board and the DCPC orally stated that these elements would not be required. India has not provided any specific instructions on why they need this information. These could cause delays in holding shipments with India Customs.

ACC Recommendation: We ask the U.S. Government to urge India that the implementation of this circular be postponed. We would also suggest organizing a workshop on how other countries in the region approach defining and protecting CBI to provide the Central Board with options to address industry's comments.

5. Vietnam

5a. Draft Chemicals Management Law and Inventory Building

The government of Vietnam is in the process of establishing a new chemicals management regime after more than 12 years of implementation of Law on Chemical Management. As Vietnam is an important, growing market for the consumption and production of chemicals, the government of Vietnam will need to take appropriate steps to consult stakeholders in its regulatory process. We understand that the Ministry of Industry is in the process of developing the Vietnamese Chemical Inventory. We encourage Vietnam to continue to meaningfully consult and engage with industry and welcome the opportunity to further progress a sound science- and risk-based draft regulation.

ACC Recommendation: The U.S. government will want to encourage Vietnam to adopt the ASEAN Regulatory Project Guidance Document on Developing a Chemical Inventory.

Additionally, for any future regulatory changes, the U.S. government should urge Vietnam to abide by Principle 6 of the APEC CD Best Practices Chemical Regulation Principles, i.e., that chemical regulations should be developed in consultation with stakeholders, subject to public review and comment and periodic review.

5b. Customs Clearance Processes

Starting in March 2023, several companies encountered frequent requests from Vietnam Customs for complete disclosure of a chemical product's constituents, including the names, CAS number and percentages of all components in the respective products. This seems to be an implementation of Chemicals Regulation (Decree 113/2017/ND-CP), which is based on Decree 82/2022/ND-CP (effective date: 22 Dec 2022), mandating that the substances listed in Annex 5 of the Regulation must be identified by a CAS number as well as content percentage. However, Customs appears to be requiring the disclosure of substances beyond those listed in Annex.

The disclosure of Confidential Business Information (CBI) information presents significant challenges for industry as companies do not have sufficient safeguards to protect their know-how. There is a lack of adequate CBI protection, especially for foreign manufacturers exporting to Vietnam. This has resulted in significant impacts on U.S. chemicals trade, business, and operations in Vietnam. Moreover, disclosure of such information is unnecessary as existing Vietnamese import requirements already include the submission of a Safety Data Sheet (SDS) which provides all the information needed by Vietnam Customs or the Vietnam Chemicals Agency (VCA) to determine a chemical's hazard classification.

ACC Recommendation: We would urge the U.S. Government to urge Vietnam that all information classified as trade secrets / CBI is sufficiently protected by a well-defined policy and process across all Vietnamese government institutions that may have access to such information. The definition of CBI in any regulatory system should be aligned with the definitions and commitments stated in the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement and UN GHS whereby competent authorities allow for CBI of compositional data within their implementation based on relevant cut-off thresholds and hazards.