October 28, 2022

Submitted via www.regulations.gov

William Shpiece
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-2022-0013, Request for Comments on Significant Foreign Trade Barriers for the 2023 National Tariff Estimate Report, Document No. 2022-19896

Dear Mr. Shpiece:

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 2023 National Trade Estimate (NTE) Report.

The U.S. chemical industry is a $517-billion-dollar enterprise, contributing significantly to the U.S. gross domestic product (GDP), and providing 537,000 skilled, good-paying American jobs, with production in nearly every state. Thirty percent of these jobs are export dependent. The business of chemistry is 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 $30 billion in new spending in 2021. 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 $11.4 billion in R&D investment in 2021. 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 2023 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 and negotiations 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 2023 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 proposed to ban 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 is on a path to enact 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*.

Once regulations are proposed, there is potential for significant barriers to trade, including potential 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 high 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 under the United States-Mexico-Canada Agreement (USMCA) to cooperate with its North American trading partners, including with respect to chemical substances and marine litter and 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 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.

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

China has repeatedly stated its intention to abide by its WTO commitments. However, China's trade remedies regime falls short of a full commitment to the fundamental principles of transparency, procedural fairness and substantive obligations under applicable WTO agreements. This is particularly true with regard to China's anti-dumping and countervailing duty proceedings, which have increasingly targeted U.S. exports.

One concerning trend in many of these recent investigations is that China has preliminarily determined that a "non-market situation" ("NMS") exists in the U.S. oil, natural gas, renewable energy, coal, and electricity industries that distorts the cost of production and selling prices of the merchandise under investigation. As a result, China has arbitrarily and unjustifiably adjusted the cost of production reported by many U.S. companies to eliminate the alleged effects of the NMS in the U.S. market. This has caused the dumping margins calculated for these U.S. companies to increase significantly. China has taken these actions despite the fact that the WTO Anti-Dumping Agreement and China's anti-dumping laws and regulations do not provide any legal or procedural basis to conduct an NMS investigation or adopt an NMS methodology in its dumping margin calculations. Moreover, China's NMS investigations focus on U.S. chemical exports, which are the predominant target of China's recent trade remedy investigations.

Similarly, China's countervailing duty investigations are inconsistent with the basic legal obligations and procedural principles under the WTO Agreement on Subsidies and Countervailing Measures. Contrary to its WTO obligations, China continues to provide substantial subsidies to its domestic industries and has failed to provide the WTO a complete list of all subsidies maintained by its central and sub-central governments.

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

ACC has offered several constructive comments related to the Guidance on the Registration of New Chemical Substances issued by China's Ministry of Ecology and Environment's (MEE). ACC fully supports the efforts by the People's Republic of China to take a science- and risk-based approach to chemicals management and address any potential hazards of new chemicals. However, ACC strongly recommended several substantive changes to the Guidance as originally written. These comments recommend necessary changes to the Guidance that would streamline the registration process for both MEE and industry, while

still allowing an equivalent level of protection.

First, the Guidance does not incorporate a low volume exclusion for new chemical substances used for research with annual production or import volumes of less than 100 kilograms (kg). This exemption is nearly universally accepted and is paramount in encouraging innovation and ensuring that both MEE and industry are able to focus their time and resources on the chemicals that pose actual risk. Additionally, we suggested that MEE reduce the applicable minimum data requirement. As the draft is currently written, a full notification is required for a substance that is manufactured/imported at quantities less than 10 tonnes per annum, if it potentially meets the definition of "Persistent" or "Bioaccumulative". The notification must provide nearly the same eco-tox and health tox data currently required for substances manufactured in quantities of over 1,000 tonnes per annum. Considering the majority of chemicals have "potential" persistency, this addition significantly increases both the cost of lower volume registrations and the time it takes to launch a new chemical in China.

With regard to polymers, we strongly urge the MEE to develop a reasonable data requirement for polymers that would be subject to the "Simplified Registration" requirements, or "Full Registration" Requirements (if the new polymer contains a one of the identified functional groups or meet the polymer record filing's exclusion condition). The MEE should allow the applicant to self-evaluate the substance's safety via a predictive method and/or decide what constitutes reasonable testing based on exposure in the life cycle. Due to their unique properties, polymers are usually persistent but not toxic. Thus, it does not make sense to burden companies with requirements to complete expensive and lengthy toxicity testing for substances that globally are considered extremely low risk.

In ACC's view, MEE's proposal of this Guidance relates to China's obligations under the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement, and in particular Article 2.9, which concerns transparency and notification. As no international standard exists for this proposed regulation and as it may have a significant impact on international trade, Article 2.9 obligates China to notify this measure to the WTO TBT Committee. China notified the WTO TBT Committee of its proposed "Measures on the Environmental Management of New Chemical Substances" on September 2, 2019, in G/TBT/N/CHN/1351 and "Guidance for Environmental Management Registration of New Chemical Substances (Notification Draft) on September 8, 2020. In both notifications, China offered interested parties 60 days for public comment, consistent with the TBT Committee's recommendation.

ACC Recommendation: With China's notification of its draft regulatory measures and the guidance document to the TBT Committee, the U.S. government should continue to engage with China and promote meaningful stakeholder consultations. As there seem to be increase discrepancies between the way Chinese authorities implement regulations and the texts of regulations, China should re-notify amended legislation or revised guidance documents to the TBT Committee for additional input by interested parties. If China issues any new, relevant guidance documents, it should also notify these to the TBT Committee with at least a 60-day comment period.

2c. New Pollutants Control Action Plan

On May 4, 2022, the State Council of China (SCC) issued the final version of the New Pollutants Control Action Plan. The Plan introduces China's goal of regulating the production and use of toxic and hazardous chemicals that are the source of new pollutants. New pollutants are mainly defined as persistent organic pollutants, endocrine disruptors, and antibiotics. However, the Plan also refers to chemical substances included in the list of priority control chemicals, including microplastics, and other key new pollutants.

This Plan is expected to have far-reaching impacts on companies manufacturing, using, or discharging certain chemicals in China. It could also impact U.S. and other exports to China. The Plan sets forth wide-ranging initiatives including improving laws/regulations, assessing environmental risks, strictly controlling new pollutants, and prohibiting/restricting substances. Each initiative requires the identification of substances, the issuance of regulations or the taking of some sort of regulatory action. Since the Plan incorporates a series of new and extremely broad mandates, it will likely pose numerous challenges, especially because China typically does not provide meaningful notice of draft regulations or sufficient opportunity to comment.

One specific concern is the classification of ingredients or inputs used in consumer goods as new pollutants, resulting in the restriction or prohibition of such substances. This classification will require producers, importers, and retailers of these products to review the ingredients lists of the affected products and, in the case of producers, identify possible alternative ingredients. The classification is likely to negatively impact U.S. exports, especially if it is not risk- and science-based or follows international standards and conventions.

In addition to its breadth, the Plan calls for a multi-institutional approach, both horizontally and vertically. Horizontally, the Plan names at least 11 national government ministries that will participate, to some extent, in the issuance of the lists / regulations referred to in the Plan. Vertically, the Plan notes that, ultimately, the provincial governments will assume primary responsibilities, and city- and county-level governments will implement specific tasks. So far, there is no clear understanding of the duties of each layer of government or the offices/representatives that will have decision-making authority. This makes understanding and following the Plan difficult and subject to different interpretations, as ACC has seen with other regulations promulgated by the SCC or the MEE.

ACC Recommendation: China should provide ample notice and opportunity to comment on this Action Plan and carefully consider those comments as regulations are developed. China should consider aligning requirements with those of other major jurisdictions and incorporate globally accepted voluntary consensus standards. It is especially important, for example, that test data, risk assessments and certifications from globally accepted authoritative bodies (e.g., laboratories, governments, and research institutions) be accepted and that industry is not required to duplicate testing. Finally, China should issue clear guidance documents to allow industry to understand clearly what their obligations are at each relevant stage.

2d. 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 2020, China's average most-favored nation (MFN) applied tariff rate for chemicals within Chapters 28-39 of the Harmonized System is 6.1 percent. Its average WTO bound rate for chemicals is 6.7 percent.

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. (2.8 percent), the EU (4.6 percent), and Japan (2.3 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 over $11 billion 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.

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. Colombia

3a. New Tax Provisions on U.S. Exports to Colombia

On August 8, 2022, Colombia proposed a new tax bill (No. 118/2022C) with new requirements for U.S. companies that export to Colombia. The proposed bill would negatively impact the export of U.S. goods and services and contravene the letter and spirit of the United States-Colombia Trade Promotion Agreement (USCTPA) in several ways. The bill passed in the Third Commission of both Chambers of Congress on October 6th, and a new draft will likely be presented for the last two debates in plenaries of both chambers in late October, with the objective of final passage in early November.

As currently drafted, the tax bill changes the status quo of tax residence from having a physical presence in Colombia to a significant economic presence test. This new test includes imposing taxes on non-residents if they have deliberate and systematic interaction with users or clients in Colombia. Factors include the non-resident's amount of gross in-country income, whether the entity uses a Colombian website and the number of such website's users. The bill will ultimately require virtually all U.S. companies to choose either: (1) to pay Colombian income tax and a 10% withholding tax at source; or (2) pay a 5% tax on all gross income from the sale of goods and/or the provision of digital services from abroad to users located in Colombia.

Colombia's new tax bill also eliminates de minimis treatment for VAT payments on imports valued at $200 or less. Article 96 of the proposed tax bill repeals Article 428(j) of the existing tax code, which granted VAT de minimis treatment for shipments up to $200. Article 5.7(g) of the USCTPA provides that "no customs duties or taxes will be assessed on, nor will formal entry documents be required for, express shipments valued at US$200 or less." (Emphasis added). Colombia previously delayed complying with its de minimis

obligation under the USCTPA. It only fully afforded de minimis treatment for both customs duties and VAT in 2020, more than five years longer than permitted by Article 5.11 of the USCTPA. The new tax law is now rolling back the country's commitment under the USCTPA, once again putting Colombia in breach of the agreement.

We also understand that Article 10 of the legislation would establish cascading thresholds for companies operating in free trade zones (FTZs) that do not have established export obligations (export performance requirement), regardless of whether they are a goods or services company. Under the new proposal, to qualify for the more favorable 20% tax rate, companies must develop and provide an "internationalization and annual sales plan" that demonstrates the "sum of their net income from operations of any nature in the national customs territory and the other income obtained by the industrial user different to the development of its activity for which it was authorized, etc." must be below increasingly smaller thresholds. Until now, U.S. companies obtained FTZ status and corresponding benefits based on specific investment and employment requirements, which did not include an obligation to draft an internationalization plan or meet a minimum export threshold.

ACC Recommendation: We would recommend that the Colombian government pause consideration of this draft bill and launch a broad consultation with impacted stakeholders across the region, including U.S. companies doing business in Colombia.

4. European Union

4a. The Chemical Strategy for Sustainability

On October 14th, 2020, the European 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 undertaken as part of the Strategy that will 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. Key actions that are considered significant parts of the Strategy are ongoing (i.e., work surrounding CLP Hazard

Classes, PFAS, and Microplastics).

Within the larger CSS, the Commission has stated that specific legal proposals, including a revision of 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 impacts 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 the topics addressed below.

4b. CLP Hazard Classes

On September 20, 2022, the European Commission released a Draft Delegated Act amending Regulation (EC) No 1272/2008 ('CLP Regulation') 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 Commission's choice of the Commission of using a delegated act rather than a full legislative procedure to amend the CLP is particularly problematic. Final approval of the Delegated Act is expected by the end of 2022.

The Delegated Act will cause serious trade and supply chain disruptions because it adds additional hazard classifications that are not recognized in any other country or jurisdiction. This will cause a substantial inconsistency with respect to regulation between the EU and the rest of the world. Since the 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 will effectively signal the Commission's decision to abandon the GHS, thereby undermining 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 will embolden other governments to take their own approaches to GHS implementation, creating further divergences and market segmentation that will trade and 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).

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. In the case of the proposed additional classes, the related hazards (e.g., adverse effects) to human health or the environment that may occur as a result of exposure to a chemical with a potential endocrine mode of action or with persistence or bioaccumulative characteristics can and should be communicated via existing hazard classifications and communications. A disciplined approach that applies a risk evaluation to a specific chemical (or group of chemicals), followed by risk management where warranted, is a better and more scientifically sound method of regulating chemicals.

ACC has the following technical concerns related to the three new hazard classes:

1. Endocrine Disruptors

The Draft Delegated Act uses the World Health Organization (WHO) definition as the basis for the ED hazard class. The WHO definition is generally recognized by all stakeholders as the most comprehensive definition of "endocrine disruptors". However, the definition makes clear that to classify a substance as an "endocrine disruptor", there must be a level of certainty that a direct causal link exists between an endocrine mode of action and any corresponding adverse effect observed in an intact organism. To ensure consistency with the WHO definition, the distinction cannot involve altering the definition of endocrine disruptor or altering the criteria required to meet that definition.

In numerous instances, the Draft Delegated Act seems to use "endocrine activity" synonymously with "endocrine disruption". The two terms are not equal nor interchangeable: a substance may have "endocrine activity" without manifesting adverse effects at the organismal level. Of primary importance is that the WHO definition requires that these effects be adverse. As such, it needs to be understood that activity in an in vitro assay or an uniquely sensitive in vivo study (e.g., a uterotrophic screen with very low competing natural hormone) may indicate the potential ability of a substance to interact with and modify some component of the endocrine system, but that, in and of itself, is insufficient to conclude that a substance operates, or could operate, through an endocrine mode of action in an intact organism and that the corresponding effects would be adverse.

As currently drafted, the proposed definitions included in the Draft Delegated Act do not consistently reflect the causal link required by the WHO definition; nor do they consistently include a direct reference to an adverse effect.

The most critical determinants of whether an adverse effect of a chemical occurs as a consequence of an endocrine mode of action are:

a) the strength by which the chemical acts via the endocrine mode of action; and
b) knowledge that chemicals that act strongly via such mode of action cause the adverse effect in question.

As currently drafted, the criteria to distinguish between Categories 1 and 2 (known vs. suspected) are inconsistent and unclear, both for human health and environment. Different modes of action, including non-specific narcosis, can produce the same adverse effect, and since most chemicals may act via numerous modes of action. Additional consideration should be included in the text, for example in section 3.11.2.2, to clarify which types of evidence and consideration need to be assessed concerning the biological plausibility of the link between an adverse effect and an endocrine activity. Relevant aspects are:

- the chemical causes an adverse effect which has been demonstrated to be produced via an endocrine mode of action;
- the chemical can act via an endocrine mode of action with sufficient strength to cause the adverse effect; and

- Where the chemical also acts via non-endocrine modes of action that could produce the adverse effect, the substance shall be classified as ED where a weight of evidence assessment demonstrates that the ED mode of action is more likely to cause the adverse outcome than the other mode of action. If other modes of action are equally or more likely to lead to the adverse effect, classification in another hazard class is more appropriate.

2. *Persistent, Mobile, and Toxic*

There continues to be no reliable or robust methodology to judge mobility or which allow a determination of "Mobile" or "very Mobile" to be made. A more specific indicator of Mobility is needed to ensure relevant implementation of this proposed hazard class. Log Koc should be treated solely as an indicator of the potential for mobility in soil, as it highlights the propensity of a chemical to be absorbed (or not) into soil. Thus, it would be acceptable for screening, but not for the final assessment of Mobility in the context of environmental transport to drinking water resources. As companies implement this proposed hazard class, they will need to use or generate additional data to make the assessment. In practice, there will be a strong need for legal clarity on how and which results from higher tier studies (i.e., leaching or modelling) would be assessed against and to supersede Koc.

Moreover, ACC has concerns about the limited scope of the mobility criteria. As noted, the PMT criteria was developed to address general concerns regarding the presence of contaminants in drinking water and is based on assumptions about bank filtration and the transport of substances from soil to groundwater. However, from a scientific perspective, it is difficult to determine the likelihood of contamination using a single uniform cut-off value: soil properties and climate, in addition to the physical properties of the substance in question, are both equally (or more) pertinent factors to determine whether a substance reaches a groundwater source. Of equal importance are the specific routes of exposure, i.e., use patterns and routes of environmental releases and local contaminations.

In areas with high rainfall, surface water is generally the source of drinking water, and the use of bank filtration is very limited. As currently drafted, the PMT standard is not a standard that would be appropriate to be implemented universally. The Commission has stated that its goal is to include PMT in the UN GHS Purple book. If the current PMT definition were to be adopted, industry would be required to comply with a standard that is not fit-for-purpose in regions with high rainfall.

ACC does not consider PMTs to be analogous to other hazards because PMT evaluations are reliant on both the volume of the chemical (e.g., if it is only used in a small amount vs. larger volumes) and conditions of use (e.g., a dispersive use vs. used in a closed system), both of which are typical metrics to inform exposure. These qualifications are key to determining whether there is a perceived risk of release into the environment, which might require the substances in question to be regulated accordingly. If a chemical is not toxic, but is persistent and mobile, it is counterproductive to classify and label it as "hazardous to the environment" without undertaking the corresponding risk evaluation.

3. Persistent, Bioaccumulative, and Toxic

A screening process should be a first step in any classification process, followed by tiered testing. To classify a substance as PBT, there should be tangible evidence, based on testing, that the chemical in question meets the threshold requirements and that exposure levels can cause significant adverse outcomes in humans and environmental species. Then, and only then, should it be categorized as PBT. Any deviation from this approach will lead to the overclassification of substances labelled as having potential PBT concern.

To classify a substance as PBT requires the use of the best available science, and threshold criteria must be updated and maintained to reflect advancements in the science. The science associated with assessing the potential persistence and bioaccumulation characteristics of chemicals has evolved remarkably over the past 10-15 years; however, the criteria used as the basis for the CLP PBT hazard classes have not kept pace. For example, the bioconcentration factor (BCF) is not necessarily the most appropriate criterion for identifying a substance that may or may not be bioaccumulative. For substances that are not water soluble, the biomagnification factor (BMF) or Trophic Magnification Factor (TMF) are likely more suitable.

ACC Recommendation: ACC recommends that the European Commission delay the introduction of the new hazard classes because they are not based on sound science. In addition, the addition of such classes should be subject to the full legislative procedure. If the Delegated Act is adopted, the European Commission should prioritize the development of scientifically-sound guidance documents well before the Act enters into force, especially as there are a number of new proposals that will require significant engagement from all global stakeholders.

4c. Per- and polyfluoroalkyl substances (PFAS)

On May 11, 2020, the European Chemicals Agency 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.

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.[1] Restricting

[1] 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.

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, 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.

Further, a focus on "persistence" alone undermines the critical innovation needed to produce materials that support the EU's and other broadly held societal sustainability goals.

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 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 the declaration of essential (or non-essential) uses as the basis for restriction under REACH.

4d. Use of REACH to Regulate Intentionally Added Microplastics

The European Chemicals Agency (ECHA) has recently completed its public consultation with respect to a proposal under REACH to regulate intentionally added microplastics (now called 'polymer microparticles') in a wide suite of products and in various applications. The sweeping proposal would restrict the use of intentionally added microplastics in products which are placed 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 European Union'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: If the European Union insists on using REACH to address microplastics, the U.S. government should request that the European Commission perform a foundational determination of risk to move ahead with regulation that is proportionate and workable in practice – based on a high-quality scientific review.

4e. 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. In addition, the EU is developing another restriction on siloxanes D4, D5, and D6 in leave-on personal care applications, including both consumer and professional applications.

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, health care 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.

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.

5. India

5a. 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[2], 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 offer at least 60 days 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.

5b. BIS Mandatory Standards and Conformity Assessment Regime

In 2019, the Government of India proposed to make mandatory a suite of voluntary domestic standards for chemicals management. Throughout the past few years, the government notified 43 proposed mandatory standards for specific chemicals to the WTO Committee on Technical Barriers to Trade (TBT Committee). In these notifications, the Government of India offered 60 days for WTO Members and interested parties to provide comments. However, they only notified the "Quality Control Orders" on making the voluntary standards mandatory. They have not included the standards themselves in the TBT notifications. Most of these standards are antiquated, unique to the Indian market, and are not based on international standards.

Under this scheme, chemicals manufactured in India are subjected to a preferentially light set of standards, but imports are subjected to much more burdensome conformity assessment procedures, including but not limited to an extensive factory auditing process. Such exclusionary conformity assessment procedures potentially contravene Article 5 of the TBT Agreement.

- Are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other members under conditions no less favourable than those accorded to suppliers of national origin or originating in any other country, in a comparable situation; access entails suppliers' right to an assessment of conformity under the rules of the procedure, including, when foreseen by this procedure, the possibility to have conformity assessment activities undertaken at the site of facilities and to receive the mark of the system; and

- Are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade, which means that, *inter alia*, that

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

> conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing member adequate confidence that products conform with the applicable technical regulations or standards, taking into account the risks non-conformity would create

India may also develop new standards for chemical substances to include in this mandatory regime. Ensuring compliance under this approach would require significant Indian government resources and would also create further blockages and supply chain disruptions. These mandatory standards and conformity assessment procedures could again prejudice global exports of chemicals and plastics to India.

Certain compliance requirements, such as unnecessary and trade restrictive labelling requirements, should be reconsidered as they cause significant business disruptions and increase costs for domestic manufacturing. On process, India should establish clear timelines and deadlines to avoid uncertainty in supply chains and allow for "temporary" certification for imports during the application period. Broader and regular stakeholder consultation that includes foreign industry and manufacturers would support these common goals while also ensuring fair trade and supporting India's domestic manufacturing industries. Foreign industry and manufacturers should also be allowed greater access to standards development activities within India

ACC Recommendation: The U.S. government should ask India to re-notify all the measures concerning making certain BIS standards for chemicals mandatory and include the standards themselves in the notifications. The Government of India should align its domestic standards for chemicals with international standards (for example, under ASTM or ISO) and keep non-aligned Bureau of India Standards (BIS) standards voluntary.

5c. Tariffs

On numerous occasions, and most recently in 2019-2020, the Government of India has explored raising import tariffs on wide range of chemicals.[3] Also in 2020, the Ministry of Chemicals proposed to the Ministry of Commerce an across-the-board 15 percent tax on all imports of chemicals and plastics, with the objective of protecting India's domestic chemical industry and funding its COVID-19 response efforts.[4]

Such proposals would create challenges for the broader manufacturing value chain and adversely impact the business and consumer environments in India in the long run. Chemicals are essential inputs to agricultural production and almost all manufactured goods, which means that higher tariffs will lead to higher costs and less supply. Higher costs will exacerbate inflationary pressures and impact to consumer costs and jobs in the Indian

[3] For Chemicals, India has both relatively high applied MFN rates (10.3%), high bound rates (39.6% average) and many unbound tariff lines (11.1%). Therefore, the Government of India has the discretion to raise import tariffs to rates higher than other large trading nations.
[4] A better policy to enable India's chemical manufacturers to respond to the pandemic would be to provide temporary tariff relief. This action could be further bolstered by the provision of broad fiscal measures to support all industries, including the chemical industry, like actions taken in many other countries during the pandemic. While it is understandable that the COVID-19 pandemic might impact domestic industry, additional tariffs would not provide sustainable benefits and may result in unintended consequences. In this context, the imposition of a 15 percent tax on imports of chemicals could potentially be viewed as an infringement of India's WTO obligations.

manufacturing chain.

Higher tariffs will undermine India's goal of attracting more foreign direct investment. Many chemicals are essential raw materials used by Micro, Small and Medium Enterprises (MSMEs) in India. Such tariffs will negatively impact these MSMEs and other downstream industries and will impair their production of key consumer goods and their workforce growth

ACC Recommendation: Given the ongoing bilateral dialogue between the United States and India, we urge both governments to focus on reducing tariffs particularly for necessary inputs that are not manufactured in India but are critical to the downstream value chain, such as silicones. In that regard, ACC would welcome an opportunity to work with the U.S. government to define a key list of targeted tariff reductions for consideration by government of India.

6. Republic of Korea

6a. Chemical Management

There are widespread concerns about the Republic of Korea's implementation of its Act on Registration and Evaluation, Authorization, and Restriction of Chemical Substances (AREC), which is more trade restrictive than necessary. ACC and its members continue to engage with Korea's Ministry of Environment to offer more trade- and investment-friendly approaches to AREC implementation.

Korea's ongoing efforts to amend AREC create uncertainty for those exporting and importing chemical products and substances into Korea. There has been a concerning lack of clarity and guidance from the Ministry of Environment and the Ministry of Employment and Labor regarding the amendments. We support the view that the Republic of Korea will find it more cost-effective to complete full implementation of AREC and develop a full set of guidance documents before introducing modifications to the Act.

Completion of AREC's implementation will provide the government with sufficient data on types of registration and levels of compliance that will provide a basis for determining the need for amending AREC.

Further, ACC would support the removal of the amendment's requirement for updating pre-registration information. Although the number of pre-registrations could be substantial (i.e., as an indication of a company's intention to use a substance), the statement of intention does not mean that all pre-registered chemicals eventually will be registered.

Additionally, ACC encourages the Republic of Korea to accept Quantitative Structure-Activity Relationship (QSAR) models under its AREC amendments. Consistent with global practice, it is critical to provide a QSAR as part of a Weight of Evidence (WoE) approach for registration, regardless of the tonnage band, for regulatory efficiency and for fulfilling AREC's principle of minimizing animal testing (as specified in Article 14 of the Act).

ACC Recommendation: It's important that the U.S. delegation continue to ask the Republic

of Korea for information on its implementation of AREC and urge the Republic of Korea to respond to comments from interested parties.

6b. Protection of Trade Secrets

Under Article 29 of AREC, there are significant requirements to register existing chemicals above 1000 ton/year will be registered by the end of 2021. When a chemical substance is registered, chemical name, CASRN, registration no., use, classification and safety information must be provided to the downstream users using MSDS + Form No. 26 or Form No. 25. AREC makes a provision in case of trade secrets that the chemical name can be provided using the generic name specified in the public notice of the MOE. However, this generic name under the public notice of the MOE does not sufficiently protect the confidential business information (CBI) when it's linked to a commercial product as given the linkage to the commercial name. According to MOE, a different generic name rule is not allowed.

ACC Recommendation: The U.S. government should strongly encourage MOE to ease regulation on the generic name or amend the requirement of the provision of information on chemical substances to make it more practical.

7. Vietnam

7a. Draft Chemicals Management Law and Inventory Building

The government of Vietnam is 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 Thailand to abide by Principle 6 of the APEC CD Best Practice Chemical Regulation Principles, i.e. that chemical regulations should be developed in consultation with stakeholders, subject to public review and comment and periodic review.