March 3, 2022

Submitted via regulations.gov

Alie Muneer
Office of Pollution Prevention and Toxics (7404T)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re:  Docket ID No: EPA-HQ-OPPT-2019-0237
Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment [86 FR 74082, December 29, 2021]

Dear Ms. Muneer:

The Ad Hoc Downstream Users Coalition (Coalition) appreciates the opportunity to provide comments on the U.S. Environmental Protection Agency’s (EPA) draft risk determination “Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment”1 (hereafter, “the draft revision”). The Coalition is comprised of trade associations representing a broad cross-section of U.S. industry -- the Alliance for Automotive Innovation (Auto Innovators), the American Coatings Association (ACA), the American Forest & Paper Association (AF&PA), the Motor & Equipment Manufacturers Association (MEMA), the Plastics Industry Association (PLASTICS), the Toy Association, and the U.S. Tire Manufacturers Association (USTMA). These associations together speak for thousands of their respective individual member companies that are product and product component manufacturers and companies involved in downstream portions of the consumer and commercial product supply chain.2

The HBCD draft revision reflects the first time that EPA is implementing several significant changes in the approaches applied during the chemical risk determination process.3 The changes in assumptions used in the risk assessment will result in substantial and impactful changes in EPA’s risk findings for this and future chemical risk evaluations. EPA is requesting comments on its implementation of these new risk assessment approaches, including the application of the whole chemical approach and new policy of assuming no occupational use of PPE in making a determination for workers’ risk.

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2 Each association is a not-for-profit organization serving as a collective voice for their respective members. A detailed description of the Coalition members is provided in an attachment at the end of these comments.

3 In EPA’s draft revision to the HBCD risk determination, EPA has stated: “This draft revision supersedes the condition of use-specific no unreasonable risk determinations in the September 2020 HBCD risk evaluation (and withdraws the associated order) and makes a revised determination of unreasonable risk for HBCD as a whole chemical substance. In addition, this draft revised risk determination does not reflect an assumption that workers always appropriately wear personal protective equipment (PPE).” (86 FR at 74082.)
Therefore, these Coalition comments will focus on the risk determination policy changes that EPA has applied in this draft revision and the potential impacts those changes will have on future TSCA risk determinations and subsequent risk management actions.

**EPA’s New Policy Approaches for Risk Evaluations**

On June 30, 2021, EPA released a “Path Forward for TSCA Chemical Risk Evaluations.” This document includes new approaches and policies for risk evaluations that will have significant impacts on EPA’s unreasonable risk determinations, as implemented in the HBCD draft revision. These policy changes include: (1) the adoption of a whole chemical approach, where EPA plans to make the determination of unreasonable risk just once for the whole chemical when it is clear to EPA that the majority of the conditions of use warrant one determination; (2) assessments that assume no use of personal protective equipment (PPE) in workplace environments; and (3) expanding consideration of exposure pathways and fenceline community exposures.

1. **A Whole Chemical Approach May Have Unintended Consequences that Conflict with Some of TSCA’s Goals**

Prior to the issuance of the HBCD draft revision, EPA’s risk determination approach had been to make separate safety determinations for each relevant condition of use. The conditions of use reflected those identified in the associated scoping document and were those uses “as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” The resultant risk determinations were clear in terms of which conditions of use were determined to pose an unreasonable risk and which did not pose an unreasonable risk. For HBCD, the determinations that a particular condition of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1) and were therefore covered by TSCA’s preemption provisions.

EPA’s adoption and application of a whole chemical approach reduces the clarity and certainty provided by the previous approach of making separate risk determinations for every condition of use of a chemical. The consequences of this new approach will result in prolonged uncertainty for the regulated community, continued use of resources to research uses which pose no risk, and a negatively biased whole chemical “finding” that will undoubtedly be used to push back on uses that may not have an unreasonable risk. It may also potentially drive regrettable substitutions. In addition, the whole chemical approach will likely confuse the general public, because it does not inform the public as to which uses are safe and which pose risk.

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5 TSCA Section 3(4): Definitions.
a. Treatment of Replacement Parts

We believe it is necessary to clarify that EPA’s new whole chemical approach does not and should not impact the treatment of replacement parts in the HBCD draft revision. TSCA section 6(c)(2)(D) clearly states that the Administrator “shall” exempt replacement parts unless the Administrator makes the findings contained in section 6(c)(2)(D):

(D) Replacement parts
   (i) In general
      The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation. [emphasis added]

For the Coalition, particularly those of us with companies producing and assembling complex products with long product lifetimes, the use of replacement parts is critical to maintaining, servicing and ensuring a high level of quality to meet our customers’ needs. Recognizing that replacement parts do not contribute significantly to any risk posed, in this instance by HBCD, EPA’s whole chemical approach should not change the unreasonable risk determination for replacement parts and move them to the “unreasonable risk” category. The Coalition believes that EPA’s no unreasonable risk finding as stated in the September 2020 final risk determination for HBCD is still justified, appropriate, and based on the statutory requirements, must be upheld. EPA must continue its responsibility to consider and apply the provisions of TSCA section 6(c)(2)(D) and consequently exempt replacement parts when they are being considered as a condition of use.

Therefore, we recommend that EPA affirm the exemption for replacement parts based on the direction in TSCA section 6(c)(2)(D) and also exempt them from the scope of any risk mitigation measures being considered. To provide certainty to the regulated community, EPA should make this determination at the final risk determination phase, as it did in the previous September 2020 risk determination.

b. Preemption for the First Ten TSCA Work Plan Chemicals

Our comments on preemption for the first 10 Work Plan chemicals are based on our understanding that: (1) the 10 Work Plan chemicals are exempt from pause preemption, and (2) permanent preemption is triggered when EPA issues a final agency action. A final agency action would include a TSCA section 6(i)(1) order or any EPA final rule issued for the chemicals.

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EPA’s implementation of its whole chemical approach and EPA’s reluctance to make a no unreasonable risk determinations at the final risk evaluation stage under this new whole chemical approach, appears to undermine or potentially ignore the intent of TSCA section 6(i)(1):

(i) FINAL AGENCY ACTION.—Under this section and subject to section 18—
(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order[.]

EPA has announced that it intends to withdraw the previously issued TSCA 6(i)(1) orders for those conditions of use for which no unreasonable risk was found for the first 10 risk evaluations. Since TSCA does not provide for pause preemption when EPA is preparing risk evaluations for the initial batch of 10 Work Plan chemicals (i.e., those that must be identified under section 6(b)(2)(A) of TSCA\(^2\)), if risk findings are not made separately for each condition of use based on the final risk evaluation, orders of “no unreasonable risk” will not be issued. Given the length of time between EPA’s initial risk determinations for the 10 Work Plan chemicals and issuing a final risk management rule, states may implement patchwork regulations on any and all uses until EPA issues a final risk management rule. Following an EPA final risk mitigation rule, permanent preemption would apply both to uses found to present an unreasonable risk and those found not to present an unreasonable risk, unless EPA granted a permanent preemption waiver to a state that could show good cause for a separate and different approach. As a result, states that choose to fill the void with their own risk management programs may use that as justification for requesting and receiving a waiver from preemption. In that case, conditions of use that EPA ultimately finds present no unreasonable risk may be captured in these potential state programs.

In the September 2020 HBCD final risk evaluation, the determinations that certain conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1). This action was considered a final agency action and precluded states from promulgating risk management rules for those conditions of use covered by TSCA section 6(i)(1) orders. In the event EPA were to withdraw those orders and issue a risk evaluation that HBCD as a whole chemical poses an unreasonable risk, states would be free to promulgate risk mitigation measures until such time as EPA promulgates a final risk management rule.

One of the compelling TSCA amendments was the preemption provision that provided assurance that in most cases TSCA regulatory actions would preempt a patchwork of inconsistent state regulations of the same chemical. By issuing orders of “no unreasonable risk” at the final risk evaluation phase for certain conditions of use, those specific uses would automatically be granted permanent preemption, effective at the time the TSCA section 6(i)(1) orders were issued. These final agency actions would preclude any inconsistent state regulations and provide industries with additional regulatory certainty.

While EPA has announced intent to withdraw the TSCA section 6(i)(1) orders for the 10 Work Plan chemicals, the Coalition believes there is no compelling reason to withdraw these orders at this time. These orders should remain in place until EPA has completed its second round of final risk evaluations for the 10 Work Plan chemicals and has determined which conditions of use would be subject to risk management action. By keeping these orders in place, EPA would have time to review additional input that will be submitted on the revised draft risk evaluations for the 10 Work Plan chemicals and adjust the unreasonable risk findings as appropriate. Given that EPA’s new assumptions about PPE use are driving many of the shifts to “unreasonable risk” determinations, it is highly likely that risk determinations will be revised to their original “no unreasonable risk” findings as industry input is reviewed and evaluated. The Coalition recommends that EPA maintain the TSCA section 6(i)(1) orders for the 10 Work Plan chemicals until the risk management rule is completed. As part of the rulemaking process, EPA can propose to remove these orders, given new risk determinations and its proposed chemical management requirements. Then in the final risk management rule, EPA can withdraw the orders, or maintain them if deemed appropriate.

c. Preemption for High Priority Substances

While the 10 Work Plan chemicals are exempt from pause preemption, EPA’s revised approach also raises questions about the application of pause preemption, for instance for EPA’s high priority substances. These concerns are based on our understanding that (1) chemicals designated as high priority chemical under TSCA are subject to pause preemption, (2) pause preemption is activated when EPA issues the scoping document for a high priority chemical, (3) pause preemption ceases when EPA issues a final risk evaluation or reaches the statutory deadline for publication of the final risk evaluation; and (4) permanent preemption is activated when EPA issues a final agency action related to the chemicals. A final agency action would include a TSCA section 6(i)(1) order or any final rule issued by EPA for the substances. Our comments also assume that EPA will adopt a whole chemical approach for the high priority chemicals, given the volume of uses for each chemical, as well as the assumption that no PPE is used by workers, occupational non-users, and consumers.

Based on the changes applied in the HBCD draft revision and the impact of those changes on preemption, a whole chemical approach will likely interfere with permanent preemption for the high priority substances. If EPA takes the same whole chemical approach as that used with the 10 Work Plan chemicals for the high priority substances, EPA will not issue 6(i)(1) orders at the final risk determination stage. At this point, pause preemption would cease, and states may implement regulations on any of the uses until EPA issues a final risk mitigation rule. It is unclear what benefits are to be gained by extending the period of time before EPA signals that a condition of use does not present an unreasonable risk and by creating a lengthy period of uncertainty when some conditions of use could be removed from regulatory consideration.

2. Assumptions that Personal Protective Equipment Is Not Routinely Used

In the initially issued final risk evaluations for the 10 Work Plan chemicals, estimates of worker exposure were calculated both with and without the use of PPE, assuming PPE use as stipulated
by the Occupational Safety and Health Act (OSHA) standards. Since then, EPA has determined that it is now more appropriate to assume that PPE is not used by workers when working with these chemicals during the risk assessment phase. EPA released the following text regarding this new approach for PPE:

In the final risk evaluations for the first 10 chemicals, the previous administration generally assumed that workers were always provided, and used, personal protective equipment (PPE) appropriately. However, data on violations of PPE use suggest that assumptions that PPE is always provided to workers, and worn properly, are not justified. Continued use of this assumption could result in risk evaluations that underestimate the risk, and in turn, risk management rules may not provide the needed protections.

EPA is therefore revisiting the assumption that PPE is always used in occupational settings when making risk determinations for a chemical. Instead, the agency plans to consider information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process.

The first 10 risk evaluations already include exposure analysis with and without PPE. Therefore, removing this assumption does not create need for new analysis. However, this shift could change some of the conclusions about risk on some conditions of use for six of the first 10 chemicals for which “no unreasonable risk” findings were made based on the use of PPE. Specifically, this shift could impact conclusions about risk for some conditions of use for methylene chloride, 1-bromopropane, HBCD, NMP, perchloroethylene, and 1,4-dioxane.8 [emphasis added]

EPA further clarifies this approach in the HBCD draft revision, stating:

Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.9

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9 86 FR at 74082.
Nonetheless, EPA’s plan to incorporate information on PPE use, or other industry practices used to protect workers, only during the risk management process will likely impact risk determinations for some conditions of use for the first six of 10 Work Plan chemicals, but also for a majority of the high priority chemicals currently undergoing risk determination.

Further, if EPA believes that assuming the PPE use in workplace facilities will underestimate potential exposure to certain subpopulations of workers, such as occupational non-users or self-employed individuals, assuming no PPE use in any workplace will overestimate exposure to workers. As a result, the draft and final risk determinations may be inaccurate and misleading and result in extra workload and resources for EPA and the regulated community alike going into the risk management phase. This approach doesn’t appear to fix a perceived problem but rather replace it with a potentially greater problem – creating a false and misleading perception of worker risk. For the extended period between EPA’s release of its risk assessments and its issuance of final risk management rules, the public will likely be left with the perception that risks are greater than they are and that manufacturing facilities are out of compliance with federal and state safety standards.

If EPA believes that workers not covered by OSHA standards are at a greater exposure risk, using TSCA to address OSHA through this workaround approach is inappropriate. The more straightforward approach would be to identify real and actual risks and then to coordinate with OSHA to update and enforce its requirements and compliance program. For workers not covered by OSHA standards, we recommend that EPA work with OSHA to find an appropriate means for providing any necessary requirements, preferably under OSHA, if unreasonable risk is determined.

Further, if EPA believes that certain workplace risks are not being adequately controlled, then EPA has an obligation under TSCA section 9(a) to consult with OSHA before superseding OSHA’s authority. Any such result from coordination and consultation with OSHA should also be made publicly available to further transparency, process, and due diligence. In the case of the HBCD draft revision, any such information has not yet been made available to the public, i.e., via the docket, as would be expected under the requirements of 15 U.S.C. § 2608.10

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10 15 U.S.C. § 2608(a)(1) states that: “...the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)

(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register.”
The first 10 risk evaluations already include exposure analysis with and without PPE. If EPA feels compelled to assess chemicals with and without PPE, the Coalition recommends that EPA continue the approach of presenting both scenarios in its risk determinations for all future risk determinations – with and without PPE. This dual scenario would provide the appropriate bounding scenarios for risk exposures in the workplace. Moreover, when businesses provide information during the risk determination stage that demonstrates compliance with PPE and/or other information that demonstrates workplace exposures are limited or minimal, e.g., a closed-loop manufacturing process, then EPA should apply that information as part of the risk determination.

Waiting until the risk management phase to include the use of OSHA-required PPE and related workplace standards creates a false impression of risk that lacks transparency. It may result in the draft and final risk determinations being inaccurate and misleading for the public, as well as for businesses, because it overestimates the risk of exposure in workplaces that require workers to follow PPE practice and suggests that manufacturing facilities are out of compliance with federal and state safety standards. In addition, this approach will likely result in extra workload and resources for EPA, because it creates an extra layer of work for EPA and industries to work through the risk management phase, when adequate protections may already be in place. This approach doesn’t appear to fix a perceived problem but rather replace it by creating a false and misleading perception of worker risk.

Ensuring appropriate and necessary workplace protection for workers should be given high priority. The industries that we represent employ millions of workers at our facilities and have spent decades designing safe and compliant workplaces for our workers and building state-of-the-art manufacturing facilities. It is our intent to work with EPA to find ways to accurately account for the protections in place in our facilities and identify real risks of exposures and appropriate use scenarios. In addition to assessing risk with and without PPE use, it would be appropriate for EPA to review and revise its modeling assumptions for various manufacturing industries to ensure they reflect the state-of-the-art facilities and current industry practices used today.

*In closing,* the Coalition believes it is important to weigh in on EPA’s first implementation of its new approaches. These policy changes will impact future chemical risk assessments, and it is necessary that we fully evaluate and understand the impact of these changes.

Based on our understanding of the TSCA statute and EPA’s new approaches, the Coalition recommends that EPA exercise its authority under TSCA section 6(c)(2)(D) and categorically exempt replacement parts at the final risk determination phase, because they do not contribute significantly to risk.

The Coalition also recommends that the EPA:

- Reconsider and/or revise two of its new risk determination policy approaches that it has applied in this draft revision of HBCD, the whole chemical approach and assumptions
related to PPE. As discussed above, there appears to be limited benefit to adopting a whole chemical approach in risk determinations, leaving much uncertainty for pause preemption and long-term preemption for the first 10 and future chemical risk assessments.

- Maintain the existing TSCA section 6(i)(1) orders for the first 10 Work Plan chemicals until the risk management rule is complete. There are also limitations related to the approach of assessing exposure for workers in OSHA-covered facilities without the use of PPE.
- Continue to assess individual conditions of use for each chemical and make any “no unreasonable risk” findings at the final risk determination phase. The issuance of appropriate 6(i)(1) orders for those uses would allow EPA, the regulated community and the public to focus time and resources on any uses that pose an unreasonable risk.
- Continue to assess worker exposures by applying OSHA workplace requirements, which are standard industry practice for our sectors. If EPA is concerned about workplaces that are not subject to OSHA requirements, then adding an exposure estimate specific to that concern may be appropriate if clearly identified as such. EPA should instead work with OSHA in the event that unreasonable risks are identified.

The Coalition welcomes the opportunity to discuss these comments further with the agency and appreciates EPA’s consideration of our comments.

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For the Coalition:
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Attachment
Attachment: About the Ad Hoc Downstream Users Coalition

The Ad Hoc Downstream Users Coalition is comprised of trade associations representing a broad range of U.S. industry -- the Alliance for Automotive Innovation (Auto Innovators), the American Coatings Association (ACA), the American Forest & Paper Association (AF&PA), the Motor and Equipment Manufacturers Association (MEMA), the Plastics Industry Association (PLASTICS), the Toy Association, and the U.S. Tire Manufacturers Association (USTMA). These associations together speak for thousands of their respective individual member companies that are product and product component manufacturers and companies involved in downstream portions of the consumer and commercial product supply chain.

**Alliance for Automotive Innovation (Auto Innovators)**

Formed in 2020, the Alliance for Automotive Innovation is the singular, authoritative and respected voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, the Alliance for Automotive Innovation represents the manufacturers producing nearly 98 percent of cars and light trucks sold in the U.S., original equipment suppliers, as well as technology and other automotive-related companies. This organization, a combination of the Association of Global Automakers and the Alliance of Automobile Manufacturers, is directly involved in regulatory and policy matters impacting the light-duty vehicle market across the country. The auto industry plays an important and critical role to our nation’s economy, accounting for 10 million jobs and 5.5% of the annual Gross Domestic Product. The Alliance for Automotive Innovation is headquartered in Washington, DC, with offices in Detroit, MI and Sacramento, CA. For more information, visit our website [http://www.autosinnovate.org](http://www.autosinnovate.org).

**The American Coatings Association**

The American Coatings Association (ACA) is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA’s membership represents over 90 percent of the total domestic production of paints and coatings in the country.

**American Forest & Paper Association (AF&PA)**

The American Forest & Paper Association (AF&PA) serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry’s sustainability initiative — Better Practices, Better Planet 2020. The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures nearly $300 billion in products annually and employs approximately 950,000 men and women. The industry meets a payroll of approximately $55 billion annually and is among the top 10 manufacturing sector employers in 45 states.
Motor & Equipment Manufacturers Association (MEMA)

The Motor & Equipment Manufacturers Association (MEMA) represents more than 900 members that manufacture vehicle systems and component parts for the original equipment and aftermarket segments of the light vehicle and heavy-duty industries. Motor vehicle suppliers provide over 77 percent of the value of a new vehicle and more than 900,000 jobs are directly supported by the vehicle supplier industry in all 50 states. MEMA represents its members through four divisions: Automotive Aftermarket Suppliers Association (AASA); Heavy Duty Manufacturers Association (HDMA); MERA – The Association for Sustainable Manufacturing; and, Original Equipment Suppliers Association (OESA).

Plastics Industry Association (PLASTICS)

The Plastics Industry Association (PLASTICS) is the only organization that supports the entire plastics supply chain, representing over one million workers in the $432 billion U.S. industry. Since 1937, PLASTICS has been working to make its members and the industry more globally competitive while advancing recycling and sustainability.

The Toy Association

The Toy Association is the North America-based trade association for the toy sector; our membership includes more than 950 businesses – from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry of more than US$90 billion annually, and our members account for more than half this amount, and approximately 90% of North American toy sales by dollar volume. Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard, and it serves as a model for other countries looking to safeguard the health and safety of their citizens with protective standards for children. The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.

U.S. Tire Manufacturers Association (USTMA)

USTMA is the national trade association for tire manufacturers that produce tires in the U.S. Our 12 member companies operate 58 tire-related manufacturing facilities in 17 states and generate over $27 billion in annual sales. We directly support more than a quarter million tire manufacturing U.S. jobs – totaling almost $20 billion in wages. USTMA advances a sustainable tire manufacturing industry through a commitment to science-based public policy advocacy. Our member company tires make mobility possible. USTMA members are committed to continuous improvement of the performance of our products, worker and consumer safety and environmental stewardship.

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