

January 27, 2023

Minnesota State Senate Conferees
Committee on Environment and Natural Resources Finance and Policy
Minnesota State Capitol
St. Paul, MN 55155

RE: HF 372 (Hollins): Product Notice Requirements - OPPOSE

Dear Chair Hansen, Vice Chair Jordan, & Honorable Committee Members:

The Household and Commercial Products Association (HCPA) appreciates the opportunity to provide comments to the Committee on Environment and Natural Resources regarding House File 372. HCPA supports sensible regulation of priority chemicals, however we respectfully oppose HF 372 due to the proposal's overly broad language and redundancy, which will capture products that do not represent the features commonly attributed to PFAS. The bill further duplicates efforts already underway through the U.S. Environmental Protection Agency (EPA) and other states.

As North America's premier household and commercial products trade association, HCPA represents the interests of entities engaged in the manufacture, formulation, and distribution of trusted and familiar supplies that help our communities create a cleaner and healthier environment. Products that HCPA represents include, but are not limited to, disinfectants that are designed for use against germs and human pathogens in homes and institutional settings; pest management products in homes as well as for lawns and gardens; cleaning products to keep homes and businesses clean and safe from viruses; polishes; aerosol products; and a host of other everyday consumer products.

Legislation is Redundant of New Federal Requirements

Recently, Congress and the Biden Administration enacted laws and developed new rules for regulating PFAS.¹ Additionally, the EPA has implemented a PFAS Action Plan that has served as a roadmap for the agency's activities addressing the chemical and issues related to contamination. Moreover, HCPA supports the reporting and record-keeping requirements for PFAS under the Toxic Substances Control Act (TSCA) as amended by the National Defense Authorization Act for Fiscal Year 2020, and seeks to assist the EPA in gathering that information in an effort to better characterize the sources and quantities of manufactured PFAS in the United States. The federal program includes a requirement for anyone that manufactures or imports, or has manufactured PFAS in any year since 2011, to report uses, production volumes, disposal, exposures, and hazards.

HCPA urges the Legislature to avoid additional state-level reporting requirements that will multiply redundant state mandates, divert state resources, and duplicate the EPA's efforts to identify PFAS substances. Last year, the Governor of California vetoed similar legislation in part because the EPA "is currently undergoing rulemaking to require reporting of PFAS."²

¹ S.1790 - National Defense Authorization Act for Fiscal Year 2020

² AB-2247 (Bloom -2022)

PFAS Nomenclature

Perfluoroalkyl and polyfluoroalkyl (PFAS) substances are a large, diverse group of more than 1,000 chemical compounds. PFAS properties vary widely across uses and applications. For this reason, it is important to distinguish between PFAS categories, use, function, exposure, and chemical properties as opposed to treating the substance as a single group. Chemical and structural differences among different types of PFAS may create properties that underline legitimate concerns over potential health and environmental risks associated with some substances—this most certainly does not apply to all PFAS chemicals and applications. For this reason, PFAS should not be considered as a single group or class, especially given it is possible to scientifically define distinct categories of PFAS based on shared properties.

Unintended Consequences

A single-class approach to regulation is not scientifically accurate and can lead to unjustified or unintended product restrictions. For example, HCPA represents the aerosol industry, as this is a common delivery form for many household and commercial products. Aerosol propellants are highly regulated by state and federal governments, and producers have gone to great lengths in recent years to manufacture and innovate more environmentally preferable products, especially reducing global warming potential (GWP). Hydrofluoroolefin (HFO) technology has been recognized for its minimal global warming potential, low to non-flammability, zero ozone depletion, and also quickly degrades in the environment.³ HFOs are a compound consisting of hydrogen, fluorine, and carbon. Some HFOs have a fully fluorinated carbon, which would unfortunately result in these propellants being captured by the bill's definition of PFAS as currently proposed in HF 372. The use of such a broad definition could needlessly impose new requirements on products and technologies deemed safe and environmentally beneficial.

Conclusion

The safety of human health and the environment is a top priority for HCPA and our member companies. HCPA supports efforts to address the release of PFAS into the environment; however, we believe HF 372 is redundant of federal efforts and includes an overly broad definition of PFAS, capturing products that are not persistent, bioaccumulative, or toxic. For the reasons outlined above, HCPA respectfully opposes HF 372 and asks the Legislature to consider the points set forth in this letter.

Thank you for your consideration of this request and for your leadership on these issues. I welcome any opportunity to discuss these concerns and can be reached at cfinarelli@thehcpa.org.

Sincerely,



Christopher Finarelli
Director, State Government Relations & Public Policy - Western Region

³ The Intergovernmental Panel on Climate Change:
https://www.ipcc.ch/site/assets/uploads/2018/02/WG1AR5_Chapter08_FINAL.pdf
HFO-1234ze(E) has an atmospheric lifetime of 16.4 days (see p. 732).



January 31st, 2023

TO: House Environment and Natural Resources Finance and Policy Committee

FROM: Andrea Lovoll, Legislative Director, Minnesota Center for Environmental Advocacy

RE: PFAS Legislation

Chair Hansen and Members of the Committee:

Thank you for your service to the people of Minnesota and thank you for the opportunity to testify on HF 372 (Hollins). Minnesota Center for Environmental Advocacy (MCEA) is a nonprofit organization with almost 50 years of experience using law and science to protect Minnesota's environment and the health of its people.

MCEA supports the disclosure of PFAS in products as defined in HF372. This proposed bill will collect vital information for MPCA to learn about intentionally added PFAS in products offered for sale in Minnesota. PFAS are widely dispersed across Minnesota's land and water resources, and these chemicals pose severe risks to public health, including increased risk for and incidence of cancer, reproductive issues, decreased immunity, and kidney functioning. Requiring manufacturers to disclose the function and amount of PFAS in their products to MPCA is an essential step to better understanding how and where these toxic chemicals are entering our environment.

This disclosure bill will provide critical information to MPCA for the agency to better understand what PFAS compounds are entering Minnesota. This information will help improve the agency's response to the PFAS crisis by enhancing testing capabilities and improving risk assessments for a broader array of PFAS. Because the federal Toxic Substances Control Act has been unable to compel this exchange of information to regulators, we need this disclosure requirement at the state level to know what potentially fatal chemical compounds enter our borders.

I want to emphasize the importance of how this proposed legislation defines PFAS. By requiring disclosure of any substance containing at least one fully fluorinated carbon atom, this will prevent manufactures from avoiding disclosure by using alternatives to the more commonly used and better known PFAS, like PFOA and PFOS. In response to broad public outcry about the public health risks of specific PFAS compounds like PFOA and PFOS, we have already seen alternative fluorinated chemical compounds (such as GenX) enter the market. However, the health risks of these alternatives have already been demonstrated.¹ Therefore, the broad

¹ *Fact Sheet: Human Health Toxicity Assessment for GenX Chemicals*, The United States Environmental Protection Agency (Oct. 2021),

definition of “perfluoroalkyl and polyfluoroalkyl substances” in this bill is critical to ensure we capture the full range of these chemical compounds that enter our state. Furthermore, the emphasis on the manufacturer of the product or product component will help to protect independent retailers because the disclosure notice obligation falls on the “person that manufactures a product or whose brand name is affixed to the product.” This bill will also hold large manufacturers like 3M accountable to their recent promises to phase out the use of these compounds in their products and product components.

Finally, we need MPCA to initiate a rulemaking to develop rules to connect the disclosure notice to other areas of PFAS regulation under the PFAS Blueprint. For example, the rulemaking could help to ensure that the disclosure requirements include sufficient information for the agency to monitor for new chemical compounds as they enter the state, as well as to determine how the public will access information about these disclosures, such as through product labels. The origin story of PFAS begins here, in Minnesota. We therefore have an obligation to lead on this issue. Enacting laws that help equip our state agencies with critical data to aid their public health and environmental response is common sense. For decades, products containing PFAS have been produced and shipped around the world, and the irreversible impacts of these chemical compounds on our land, water, and the health of Minnesotans is firmly established. We need this disclosure law to close the regulatory information gap and be able to effectively protect our public and environmental health.

Thank you,

Andrea Lovoll
Legislative Director
Minnesota Center for Environmental Advocacy
alovoll@mncenter.org

Carly Griffith
Water Program Director
Minnesota Center for Environmental Advocacy
cgriffith@mncenter.org

January 31st, 2023

Attn: Environment and Natural Resources Finance Policy Committee

Dear Chair Hansen and Members of the Environment and Natural Resources Finance and Policy Committee:

The American Chemistry Council (ACC) is an organization comprised of a diverse membership of companies engaged in the business of chemistry. Chemistry is essential to life in general but also to our economy and plays a vital role in the creation of ground-breaking products that make our lives and our world healthier, safer, more sustainable and more productive. We are at the heart of innovation and in fact, more than 96% of all manufactured goods are directly touched by the business of chemistry.

On behalf of the members of ACC, we respectfully oppose HF 372.

About per- and polyfluoroalkyl substances (PFAS)

While we can appreciate the intent behind this bill, we want to raise several questions and concerns including:

- An overly broad definition of PFAS that does not consider the very different health/safety profiles, uses and potential for exposure for this broad and diverse class of chemistry.
- Overlap and redundancy with new reporting requirements underway at the federal level by the U.S. Environmental Protection Agency (USEPA).
- Lack of clarity on how this information will be presented to the public to ensure information is presented in an unbiased, scientifically sound manner that does not cause unnecessary concern.
- Lack of protections for confidential business information/trade secret protections.
- Impractical implementation timeline, costs to the state and diversion of limited state resources.

Background

Today's PFAS are essential to modern life and an important enabling technology for thousands of critical uses and important products.

- PFAS are integral to many more products that we use every day and are an important enabling technology for key sectors of the economy including aerospace, autos, semiconductors, electronics, alternative energy, healthcare, building and construction, pharmaceuticals, and agriculture.
- This also includes critical uses that rely on PFAS technology like semiconductors; advanced material defense applications; high-capacity batteries for electric vehicles and energy storage; alternative energy sources, like solar, wind and green hydrogen; and 5G and smart device technologies just to name a few.
- PFAS are used in many applications that are critical to some of our society's biggest challenges and opportunities. And for many of these applications there are simply no alternatives or no alternatives that provide equivalent functionality and performance.

Broad Range of PFAS Substances That Have Very Different Properties – It is Not Scientifically Accurate or Appropriate to Group All PFAS Together.

- The diversity of uses is driven by the diversity of PFAS chemistry. It's critical to understand that PFAS are a diverse universe of chemistries with different physical, chemical, and toxicological properties as well as uses.
- Unfortunately, there are a lot of misconceptions about PFAS and this presents many challenges as we consider various regulatory approaches and policies.
- Overly broad definitions and regulatory approaches have the potential to pull in thousands of products and would include many unrelated substances with a history of safe use.
- It is neither scientifically accurate nor appropriate to group them together for the purposes of regulation.
- And there is growing recognition of this fact in the scientific and regulatory community.

The proposed legislation would be duplicative of reporting requirements at the federal level.

- As mandated by Congress, the U.S. Environmental Protection Agency (EPA) has initiated rulemaking under the Toxic Substances Control Act (TSCA) that would require those who manufacture (including import) any identified PFAS to report information regarding PFAS uses, disposal, exposures, hazards, and production volumes.¹

Additional Reporting and Notification Requirements Would Be Duplicative and Divert Limited State Resources from Priority Issues.

- Testing for and identifying what is defined as PFAS is already a complex process. Additional and different reporting requirements at the state level will lead to multiple testing requirements with multiple definitions of PFAS. At a minimum, Minnesota can utilize data from existing federal efforts to better inform and prioritize any necessary policy options. We urge policy makers to avoid the redundant use of state resources and support the EPA's efforts to comprehensively identify PFAS substances.
- The chemical industry supports a comprehensive approach to managing per- and polyfluoroalkyl substances that helps to ensure protection of human health and the environment. This includes appropriate, science-based policies and regulations.

Other States Have Opted Not to Pursue Duplicative Reporting Requirements and/or Are Having to Assess How to Implement Such Policies

- Presently, the Maine Department of Environmental Protection (DEP) is undertaking the arduous task directed by their legislature for similar reporting structure. Despite having over a year to construct a rule-making, they have to formalize it while the first reporting requirement has already passed. Maine DEP has received over 2,000 requests for reporting extensions and no formal submission process for those that did not receive the extension.
- California's Governor vetoed similar legislation in 2022. In his veto letter, the Governor cited ongoing federal reporting requirements and a burdensome and steep fiscal note outlining significant start-up costs in the millions along with on-going costs for implementation.

¹ <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0001>

For these reasons, we respectfully oppose HF 372.

Thank you for your consideration and we look to work with the Committee and bill sponsors on this legislation.

Sincerely,

Robert J. Simon
Vice President, Chemical Products and Technology
American Chemistry Council



AdvaMed

Advanced Medical Technology Association



1301 Pennsylvania Avenue, NW
Suite 400

Washington, D.C. 20004

P :: 202.783.8700

F :: 202.783.8750

W :: AdvaMed.org

January 31, 2023

Representative Rick Hansen
Environment and Natural Resources
Finance and Policy Committee, Chair
407 State Office Building
St. Paul, MN 55155

Representative Sydney Jordan
Environment and Natural Resources
Finance and Policy Committee, Vice Chair
553 State Office Building
St. Paul, MN 55155

RE: HF 372, Products Containing PFAS Notice Required

Dear Chair Hansen, Vice Chair Jordan, and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed) submits this letter to provide comments on House File 372. AdvaMed is the largest national trade association representing nearly 450 of the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. The Medical Alley Association is our State MedTech Alliance member, the leading Minnesota healthcare industry association that supports and advances the industry globally. Medical devices made by AdvaMed and Medical Alley members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment. Minnesota is the second-biggest med tech center nationwide in revenue, jobs and payroll – generating an \$8 billion dollar industry and creating over 26,000 high-paying jobs in the state.

Cognizant of the complexity and extensive supply chain involvement that goes into the manufacturing and approval of FDA regulated medical devices and medical products, we request that HF 372 be amended to exempt medical devices.

Background

PFAS are a broad class of 12,000 chemistries, characterized by the strong bond between fluorine and carbon. Because of this strong bond, PFAS provides products with strength, durability, stability, and resilience required for the safe functioning of a broad range of products including medical devices and technology. PFAS are defined based on small chemical structural elements with such diverse properties and effects that it is not scientifically accurate to regulate them as a single class. The very distinct physical and chemical properties of PFAS demonstrate how varied they are and how imposing a new reporting requirement regardless of these differences would be inappropriate.



Federal Action

Congress and the Biden Administration recently authorized significant legislation with new rules regulating PFAS.³ Subsequently, under the Toxic Release Inventory (TRI) program companies or federal facilities that release 100 or more pounds of the 179 identified PFAS substances must collect and publicly report information on the amount that is released into the air, water, or land, and the quantities managed through disposal, energy recovery, recycling, or treatment. Additionally, the EPA is undergoing rulemaking under the Toxic Substances Control Act (TSCA) Section 8 that would require those who manufacture (including import) any identified PFAS to report information regarding PFAS uses, disposal, exposures, hazards, and production volumes.⁴

The EPA's recent PFAS Roadmap recognizes the broad class of PFAS and outlines additional efforts to define, subcategorize, assess, and regulate this important class of compounds. The Administration and EPA agreed to a targeted approach and to regulate by groupings of chemicals rather than regulate as one big class.

Testing for and identifying what is defined as PFAS is already a complex process. Additional reporting requirements at the state level will lead to multiple testing requirements with multiple definitions of PFAS. At a minimum, Minnesota can utilize the TRI data to better inform and prioritize any necessary policy options. We urge the committee to avoid the redundant use of state resources and support the EPA's efforts to comprehensively identify PFAS substances.

Use in Medical Technology

FDA considers human health and safety risks, optimal product quality, and assessment of who will be utilizing the device (practitioner or patient) in their approval processes for medical devices and medical products. The health risks of these medical devices are thoroughly assessed by the FDA before they make it on the market and must undergo multiple tests to prove biocompatibility in compliance with the international biocompatibility standard, ISO 10993.

As part of FDA's regulatory process for medical devices coming to market, materials of the product as well as the packaging may be considered a component of the device itself or it could be a part of the final design specifications of the device as it's meant to be sold and distributed. Some devices like surgical tools, implantables, and syringes that need to be sterilized, require all their packaging and the product itself to withstand melting, breaking, becoming brittle or otherwise degrading during the critical sterilization process. FDA must validate these products as safe, non-toxic, and resilient enough to withstand sterilization, transport, storage, and normal use so that it can function as intended without any damage or harm to the patient.

A few examples of the numerous FDA regulated medical devices and medical products or packaging that include PFAS:

- Circuit boards, leads, foil in large equipment such as MRI, CT, and mammography machines.
- Instruments and equipment (shears, cutters, staplers) used in minimally invasive, endoscopic surgical procedures



- Blood collection bags, suction devices used in respiratory therapy and for anesthesia, IV solution bags, Peritoneal Dialysis solutions, premixed drugs (drugs that are in a plastic bag ready for infusion in the hospital setting/no need for compounding, diluting, etc.), enteral nutrition.
- Wireguides and delivery systems used in minimally invasive procedures to navigate through a patient's anatomy.

Supply Chain Concerns

Due to the complexity of the supply chain (8-10 layers deep for complex medical systems), it can take years for information to propagate upstream for suppliers to become aware of the occurrence of newly regulated substances by the medical device manufacturer. Manufacturers are beholden to the information that their suppliers provide, which is not always a consistent or standard read out of the materials in the product.

Even with already established environmental regulations discussed above, it may take device manufacturers upwards of several years to even identify where in the supply chain regulated substances occur before they can attempt to mitigate and change their processes. There is no "commercially available" technique that can assess for all 12,034 chemicals at one time. Analytical techniques can only assess what can be extracted out of a device, it becomes near impossible to identify what is present rather than what can leach out. Substitutions or changes require extensive and costly compatibility studies to ensure no cross contamination, bleed-through or residuals are present. Any changes in the device or the package would then subject the item to re-submission to the FDA, further restricting patient access to proper healthcare and preventing providers from treating their patients appropriately.

In 2022, California passed a near identical bill that exempted medical devices, but ultimately was vetoed by the Governor due to high implementation costs and other complications. With this complexity in mind and the vast array of life-saving products that would fall under the reporting of this bill, we request the following amendment:

This article does not apply to any of the following:

- A product regulated as a drug, medical device, or dietary supplement by the United States Food and Drug Administration.**
- A medical equipment or product used in medical settings that is regulated by the United States Food and Drug Administration.**
- A product intended for animals that is regulated as animal drugs, biologics, parasiticides, medical devices, and diagnostics used to treat or are administered to animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).**



Conclusion

AdvaMed and Medical Alley respectfully request that the committee consider all of the reasons discussed above. Given the complexity and extensive supply chain involvement that goes into the manufacturing and approval of FDA regulated medical devices and medical products, we respectfully request to amend HF 372 to exempt medical devices. We look forward to working with you on this important matter. AdvaMed appreciates the opportunity to provide these comments. Please contact me at rkozyckyj@advamed.org if you have any questions.

Sincerely,



Roxolana Kozyckyj

Director, State Government & Regional Affairs



Michael C. Morton

Senior Advisor, Policy & Advocacy

Medical Alley





January 30, 2023
The Honorable Rick Hansen
Chair, Environment and Natural Resources Finance and Policy
Saint Paul, MN 55155

RE: HF 372 - Products containing PFAS notice required
Position: Oppose

Dear Chair Hansen:

The Alliance for Automotive Innovation (Auto Innovators) is writing to express our concerns with the provisions of HF 372 which raise serious challenges for automakers, including unrealistic timelines, overly broad definitions, and failure to provide consideration for trade secret and intellectual property issues. HF 372 will also unnecessarily duplicate efforts at the federal level.

The Alliance for Automotive Innovation is the leading advocacy group for the auto industry, representing 39 innovative manufacturers and value chain partners who together produce nearly 98 percent of all light-duty vehicles sold in the United States. Members include U.S. and international motor vehicle manufacturers, original equipment suppliers, technology and other automotive-related companies and trade associations.

While Auto Innovators recognizes the growing attention paid to products containing PFAS, we have concerns that the implementation of this legislation will place a substantial and difficult burden on auto manufacturers for compliance. Our concerns are further detailed below.

Redundant Data Collection Effort

Currently the U.S. Environmental Protection Agency (EPA) is proposing reporting and recordkeeping requirements for PFAS under the Toxic Substances Control Act (TSCA). That proposed rule, when finalized, will require manufacturers (including those who import) to report information regarding uses, production volumes, disposal, exposures, and hazards for any level of PFAS in products. HF 372 would implement redundant state-level reporting that would replicate the data elements that will be federally required under TSCA Section 8(a)(7). Considering that implementation of HF 372 would be extraordinarily costly for the State, the auto industry, and other regulated entities, if Minnesota wants this sort of information it should instead leverage the data that will be collected under federal efforts to inform PFAS management policy.

Proposed Timelines are Unachievable

HF 372 requires reporting no later than April 1, 2025. The bill also calls for rulemaking to address the notice reporting. This aggressive timeline and lack of clear standards, which are essential elements for the regulated community to develop complete compliance plans, make HF 372 challenging from a compliance standpoint. The auto industry produces complex consumer goods. Vehicles contain thousands of complex components, with multiple subcomponents (up to 30,000 at the lowest component

level). Additionally, the automotive global supply chain has a very complex structure. The automotive original equipment manufacturer (OEM) is often up to ten tiers removed from the raw material supplier.

Collecting the required data to report under HF 372 would be a tremendous resource and financial burden, one that the auto industry likely would struggle to complete within the timeframe provided for in the bill.

Specific PFAS Should Be Regulated Based on Risk

By definition, the universe of PFAS chemicals requiring disclosure under HF 372 is tremendously wide, capturing over 10,000-plus unique chemical substances. This appears to be without discernment regarding the actual levels of risk and concern to humans and the environment of these thousands of chemicals. HF 372 explicitly ignores that the broad use of the term PFAS incorporates exceptionally different physical, chemical, environmental, and biological properties. Not all PFAS chemistries are the same, and they should not be managed under a single regulatory reporting class. This bill is overly broad, lacks scientific justification, and imposes an extremely onerous obligation on the automotive industry with no apparent or obvious benefits to the public.

Because there is no standard definition for PFAS chemicals, current legislative efforts default to this basic definition which could, according to recent National Institute for Occupational Safety and Health (NIOSH) data include over 9,000 synthetic chemicals¹² including hydrofluorocarbons (HFC), PFOA, PFOS and high molecular weight fluoropolymers to give a few examples. EPA's Toxcast database increases that estimate to 12,034 chemicals.³ When defaulting to this definition no distinction is made between chemicals that are harmful and those that are not.

The automotive industry recommends that:

1. PFAS chemicals should not be combined into one large class of substances for regulatory or reporting purposes. A clear distinction must be made between those chemicals that may cause harm and those that do not.
2. Focus on PFAS of known health concern.
3. Exclude breakdown products and byproducts of PFAS that are not intentionally added.
4. Exclude hydrofluorocarbons, hydrofluoro-olefins, hydrochlorofluoro-olefins, fluoriodocarbons, hydrochlorofluorocarbons, and chlorofluorocarbons that are used refrigerants as define in ISO 817:2014, Refrigerants — Designation and safety classification.
5. Exclude high molecular weight fluoropolymers.
6. Do not include analytical testing as part of a PFAS compliance strategy until such time as the scientific methods for measurement of PFAS in products and product components are generally available.
7. Exclude PFAS that are approved or intended for use as FDA approved drug.
8. Exclude PFAS that are no longer manufactured and have an existing SNUR to prohibit the import or manufacture, including the import or manufacture in articles.

¹ GAO, 2022, TECHNOLOGY ASSESSMENT Persistent Chemicals: Technologies for PFAS Assessment, Detection, and Treatment, Report <https://www.gao.gov/products/gao-22-105088>

² <https://www.cdc.gov/niosh/topics/pfas/default.html>

³ <https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster>

No Consideration for Trade Secret and Intellectual Property Issues

HF 372 calls for the commissioner of the Pollution Control Agency to collect these notices; however, the bill appears to make no consideration for trade secret and intellectual property issues when it comes to the reporting entities. Auto manufacturers sign confidentiality agreements with suppliers contractually protecting confidential information and trade secrets. Without any provisions to enable protection of that sort of information, manufacturers will be forced to choose between compliance with the law and regulations and compliance with their contractual obligations.

Considerations from other States

Other states have struggled with implementing PFAS reporting and notification statutes or have scrapped legislation altogether. Maine, which passed the first major PFAS reporting legislation of this kind, is now struggling to implement it. Despite adding a hire to their Department of Environmental Protection, they failed to have in place an online reporting portal or even an implementing regulation by the statutory start date of January 1, 2023, and it appears those tasks will not be completed for at least a few more months. Considering those circumstances and continuing confusion, Maine has granted around 2,000 extensions of the reporting deadline. And in the state of California, often at the vanguard of environmental regulation, Governor Newsom in September 2022 vetoed AB 2247, a PFAS reporting bill, citing concerns over costs and the duplication of federal efforts.

Conclusion

Though the rationale for such a reporting requirement may appear to be self-evident, the serious compliance obligation creates an unprecedented imposition of cost and burden both to the State and the automotive industry with little to no benefit, as there are federal efforts underway to collect similar data.

Thank you in advance for your consideration of our position.

Sincerely,



Josh Fisher
Director, State Affairs
Alliance for Automotive Innovation

January 31, 2023

Representative Rick Hansen, Chair
House Committee on Environment and Natural Resources Finance and Policy
State Office Building, Room 247
Saint Paul, MN 55155-1232
By email

Dear Chairman Hansen:

On behalf of the Animal Health Institute (AHI), we respectfully oppose HF 372 related to reporting requirements for manufacturers of products containing PFAS, unless amended to exempt animal health products. The Animal Health Institute (AHI) is the national trade association representing the companies that make the animal medicines, vaccines and parasiticides that keep animals and humans healthy.

Veterinary medicinal products are subject to a thorough and rigorous regulatory review by federal agencies. These veterinary products are reviewed by either the U.S. Food and Drug Administration under the Federal Food, Drug and Cosmetic Act, the U.S. Department of Agriculture under the Virus-Serum-Toxins Act, or the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act. They can only enter the market after successful completion of a scientific assessment, including evaluation of safety and an environmental assessment, and approval by the agency. These assessments must be generated for every active pharmaceutical ingredient and final drug product regardless of volume.

This bill appears to be in the interest of protecting water, as it provides that rulemaking may prioritize products based on those that, in the commissioner's judgment, are most likely to contaminate the state's land or water resources or pose a risk to public health. While veterinary medicinal products are essential for animal health and public health, the volumes of active pharmaceutical ingredients used in them are low in comparison to high-volume industrial chemicals. This limited use results in minimal environmental exposure compared to other compounds and uses. Moreover, as a result of the small amount of PFAS in these products, the state would receive large volumes of data on an estimated small amount of PFAS, creating a large and expensive workload that will not benefit consumers. This bill also authorizes the commissioner to charge fees to manufacturers, which, combined with the compliance costs of the reporting requirements, could lead to increased costs for pet owners.

Other states that have passed similar bills, including California and Colorado, have exempted animal medicines for these reasons and we ask you to do the same.

The companies that produce these medications are dedicated to keeping them accessible and affordable. For these reasons, we ask that animal health products not be subject to the requirements of this bill and offer this possible exemption language:

“Drugs, biologics, parasiticides, medical devices, or diagnostics used to treat, or administered to, animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), by the United States Department of Agriculture under the federal Virus-Serum-Toxin Act (21 U.S.C. Sec.

151 et seq.), or by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).”

We urge you to amend HF 372 with exemption language for animal health products. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Ginny Siller". The signature is fluid and cursive, with the first name "Ginny" and last name "Siller" clearly distinguishable.

Ginny S. Siller
Director, Government Affairs



CONSUMER
HEALTHCARE
PRODUCTS
ASSOCIATION

Taking healthcare personally.

January 31, 2023

To: Minnesota House Committee on Environment and Natural Resources Finance and Policy
The Honorable Rick Hansen, Chair
The Honorable Sydney Johnson, Vice Chair

Fr: Carlos I. Gutiérrez, Vice President, State & Local Government Affairs
Consumer Healthcare Products Association

RE: HF 372 – Oppose as Currently Drafted

Dear Chairman Hansen and Vice Chairman Johnson:

On behalf of the Consumer Healthcare Products Association (CHPA), the Washington, D.C. based national trade association representing the leading manufacturers of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices, I'm writing to express opposition to HF 372. This legislation seeks to install a reporting requirement for manufacturers of products containing perfluoroalkyl and polyfluoroalkyl substances (PFAS). While CHPA shares in Representative Hollins' desire to limit use of PFAS chemicals, we cannot support the bill as it is currently drafted.

Definition of PFAS is Too Broad

HF 372 defines PFAS as “any substance that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.” This very broad definition of PFAS is far more expansive than what the federal Environmental Protection Agency (EPA) considers a PFAS chemical. As a result, this legislation runs the risk of falsely branding chemicals that the Food and Drug Administration (FDA) deem safe and effective, as a “dangerous” PFAS containing product. The allergy medication Flonase®, for instance, would fall under the “fully fluorinated carbon atom” definition of PFAS in this proposed legislation. The FDA approved product is a safe and effective OTC used for the treatment of symptoms associated with rhinitis, but its active ingredient – fluticasone – has a “fully fluorinated carbon atom.”

Branding FDA approved products as a “PFAS” may have the unintended effect of discouraging consumers from treating common ailments and illnesses early before they become serious and require intervention of a physician. OTC medicines are the trusted first line of defense against illness for millions of Minnesotans. In fact, research

indicates OTC medications save Americans approximately \$167.1 billion by reducing the need for doctor's visits and prescription medications.¹

Amendment Request

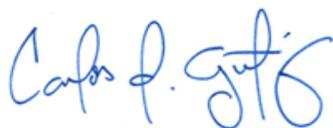
In order to avoid the unintentional inclusion of FDA approved product ingredients in the definition of PFAS, CHPA recommends expressly exempting FDA approved consumer healthcare products from the requirements of HF 372. This can be accomplished with the following language:

"a product that is regulated as a drug, medical device or dietary supplement by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., sec. 3.2(e) of 21 U.S. Code of Federal Regulations or the Dietary Supplement Health and Education Act is exempt."

Conclusion

CHPA and its members are committed to the health and welfare of consumers and the global environment. We applaud Representative Hollins for taking on this important issue, but unfortunately we cannot support the legislation in its current form. We look forward to continued dialogue with her office and this committee in hopes we can come to an equitable resolution.

Respectfully submitted,



Carlos I. Gutiérrez
Vice President, State & Local Government Affairs
Consumer Healthcare Products Association
Washington, D.C.
cgutierrez@chpa.org | 202-429-3521

cc: The Honorable Representative Athena Hollins

¹ <https://www.chpa.org/about-consumer-healthcare/research-data/research-reports/power-otcs-provide-consumer-value>