Comments of the Chemical Users Coalition on
Proposed 06-096 C.M.R. ch. 90, Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

CUC acknowledges the efforts of the Department to address comments that CUC previously submitted (enclosed), as well as those of many other stakeholders. However, CUC recommends that the Department address a number of remaining issues to ensure that the regulation is clear and easily understood and will not unduly burden the regulated community. Our comments on specific provisions in the Proposed Rule follow.

06-096 CMR 90 (2) - Definitions

The Proposed Rules define "Alternative" as a substance that when used in place of PFAS results in a functionally equivalent product. The intent of the Department is unclear. If PFAS is being restricted and an alternative to PFAS is required, the CUC recommends that the alternative should indeed function in every respect as did the PFAS in the product, and therefore the product itself should function in every respect as it did prior to the substitution. Otherwise the Alternative would not be a true equivalent. CUC requests that the Department clarify if that is indeed the intent of the definition.

The Proposed Rule defines "PFAS" as substances that include any member of the class of fluorinated organic chemicals containing at least one fluorinated carbon atom. The breadth of this very expansive definition presents many questions and the opportunity for errors and omissions when manufacturers of products are attempting to determine whether they are subject to the reporting (notification) requirements. This is especially true for members of the regulated community that may not have sophisticated chemistry capabilities in-house, and the many users of chemical products and complex formulations (and components of articles) who might receive (if they receive information at all) little information from their suppliers, which may (at best) include one or more Chemical Abstract Service (CAS) numbers identifying chemical components in a product or formulated mixture. Given that 38 MRS §1614 requires the notification of PFAS in a product to be made by referencing the CAS number, CUC recommends the Department publish a list of CAS numbers of all PFAS that are within the scope of the PFAS definition in the underlying law. This will provide greater clarity and transparency and ease with compliance for all affected entities.

The Proposed Rule defines "Manufacturer" as the person that manufactures a product or whose brand name is legally affixed to the product. There are circumstances when two different entities meet that definition: one may manufacture the product and the other may legally affix their name to the product. In such a circumstance, it is not clear who the "manufacturer" is and therefore which entity has the notification requirement. The Department should clarify which entity has the primary obligation to report.

06-096 CMR 90 (3) - Notification

(A) - The Proposed Rule sets forth the obligations of a "Manufacturer" of a product intended for sale in Maine that contains intentionally added PFAS to submit a notification to the Department.

CUC recommends that the Department clarify how the notification requirements apply to multiple businesses in the supply chain for finished products that will be distributed with multiple PFAS-containing components. The proposed regulations do not make sufficiently clear whether the responsibility falls upon the maker of the PFAS-containing components, the brand owner, a brand licensee, an importer, or the company that is distributing the finished product when multiple parties fit into the definition of manufacturer.

For example: With regard to a finished product containing PFAS as one [or more] of the components, clarification is needed concerning who is subject to the reporting requirement, the company actually selling the finished product or the company(ies) whose PFAS component(s) is(are) used in the finished product? As "product" is defined to include "product components," it is not clear in this section if the Department intends for the burden of reporting to be on the manufacturer of the complete finished product, or on the manufacturer of the component of a finished product.

Complex finished products may contain a multitude of complex components. For example, a passenger automobile/vehicle could have an air conditioning system that is charged with a PFAS refrigerant or refrigerant blend. In such a case, which party is subject to the reporting requirement: the automotive company whose name appears on the vehicle, the entity that manufactured the refrigerant/refrigerant blend itself, or the automobile dealership that actually sells the automobile? If the same automobile also contains a windshield with a PFAS-based coating that is supplied by a third party, does that supplier also have a reporting obligation in Maine?

Used products

The Proposed Rule states that notifications are not required for "used" products. CUC recommends that the Department also exempt previously manufactured products (existing stocks produced before the final rule's effective date), and spare/replacement parts for existing products. These parts often are not newly manufactured. Rather, when a new product is manufactured, spare and replacement parts are manufactured and maintained in accordance with either contractual or regulatory requirements so that the product can be continuously used and need not be replaced solely because a replacement part is not available. If these parts are not newly manufactured, it may be difficult for the entity selling the parts in Maine to ascertain PFAS content due to the lapse of time since manufacture. The availability of spare/replacement parts would also allow for the continued use and maintenance of existing products, thereby preventing the accumulation of unnecessary waste including e-waste.

The notification requirement

Manufacturers may not know if PFAS is contained in the products they sell. As discussed later, testing all products to determine if PFAS is in the product is not viable or even possible. Consequently, many manufacturers will be turning to component suppliers (who will in turn also ask their upstream suppliers) for information concerning PFAS content. First, CUC asks that the Department adopt a "reasonably ascertainable" standard for determining if any obligation to report exists. If a manufacturer can reasonably ascertain, via supplier communications or proven and economical testing, that PFAS is present in the product, they have an obligation to report. If a manufacturer cannot reasonably ascertain whether or not a product contains PFAS, the rule should state that a manufacturer has no obligation to report.

Furthermore, even with due diligence, manufacturers may only be notified concerning the presence of PFAS in their products after the notification deadline has passed. CUC asks that manufacturers not be penalized in such cases as long as the manufacturers have made a good faith effort to reasonably ascertain the use of PFAS prior to selling the product into Maine after the effective date. Article manufacturers work within complex supply chains composed of potentially thousands of suppliers, and it is anticipated that some time and resources will be needed for upstream suppliers to become aware of the use of PFAS.

Timing

The Proposed Rule addresses the notification requirements for products that are in commerce at the time the notification requirement becomes effective. CUC thinks that clarification is needed to address the

situation of when notification is required for products containing PFAS that are first introduced into Maine subsequent to the reporting deadline.

(A)(1)(a)(ii) - The Proposed Rule provides that the notification must include the "general type" of the product. CUC requests greater clarity as to what "type" means. Does it refer to consumer vs. commercial, retail vs. wholesale, or product category such as toy/consumer electronic/furniture etc.?

(A)(1)(c) - The Proposed Rule requires that the notification contain the amount of each PFAS as a concentration by name and CAS number. CUC has significant concern with this requirement. The Proposed Rule presumes that it is possible to identify all PFAS in a product. At this time, testing is not available to specifically identify all PFAS. Consequently, the only other way to ascertain PFAS content is from suppliers. However, if PFAS content information – such as the CAS number of the specific PFAS in the product and the amount contained – cannot be obtained from others, due to trade secret concerns or simply refusal to cooperate, a manufacturer will not be able to provide the required notification. CUC recommends that the Department address this extremely likely scenario. Utilizing a "reasonably ascertainable" standard, as discussed earlier, is an option the Department should seriously consider, and it should be within the Department's discretion to provide such clarification and guidance.

Additionally, CUC suggests that the final rule allow for reporting the amount of PFAS either by concentration or by weight. The same components which contain PFAS can be used in multiple products, and that would result in different PFAS concentrations in the overall product. To simplify reporting, we believe that a "weight" option be made available as well.

To address the situation where PFAS content information cannot be obtained from a supplier due to trade secret concerns, CUC suggests that the Department authorize and implement a joint submission system. Such a system would allow manufacturers to submit their suppliers' contact information when such suppliers were reluctant to provide chemical substance information to the customers due to confidentiality concerns. The system would directly contact the upstream suppliers so that those suppliers could submit the needed information directly to the Department. The duty to report would then lie with the suppliers, and the reporting manufacturers would have fulfilled their notification obligation by providing the supplier contact information.

The Proposed Rule allows for reporting PFAS quantity using a Department-approved range. However, the rule does not provide any ranges for any PFAS, nor has any indication been given as to the process the Department will use for establishing ranges, including as to whether they will be substance-specific or general. This information is needed well in advance of reporting so that reporting entities can obtain information from suppliers. Consequently, CUC recommends that provisions addressing these issues be included in a final rule.

The Proposed Rule states that manufacturers of complex products can refer to notifications filed by component manufacturers in satisfaction of their notification requirements. However, it is not clear how a product manufacturer will know whether a component manufacturer filed and whether such information is available. While in concept this provision appears to provide assistance to manufacturers of complex products, it remains to be seen whether this allowance will aid manufacturers of complex items in practice, especially if reporting is required by the manufacturers of finished products and their components by a single deadline.

Furthermore, the Notes in Section 6 of the Proposed Rule states: *Notifications are required only for products or product components offered for sale or distributed for sale in the State Maine. Product components that are incorporated into a complex product which are offered or distributed for sale in*

Maine are not subject to the notification requirement, even when information regarding the product components is provided as part of that product's notification submission. This note appears to state that complex product manufacturers need not report PFAS content of constituent components. However, that is not the implication from other provisions in the Proposed Rule, such as 06-096 CMR 90 (3)(A)(1)(c): why would the complex product manufacturer ever need to rely on notifications submitted by component manufacturers if it has no obligation to notify for components? The Department must clarify the extent of the notification requirement and whether complex good manufacturers need to notify about PFAS in constituent components.

(A)(1)(d) - The Proposed Rule contains a "note" which states that claims of confidential business information ("CBI") may be asserted at the time of reporting and that such information will be handled as confidential if it is information the courts would find to be "privileged." CUC thinks that this standard is substantially inadequate for purposes of trade secrets and other commercially sensitive information that might be required by the final Chapter 90 rules. Procedures for asserting claims must be provided, and the Department must have procedures in place for maintaining the security and confidentiality of the information it collects before the reporting period commences.

Additionally, CUC has concerns about the potential use by the Department of the Interstate Chemicals Clearinghouse (ICC) Platform. That platform is run by a third-party non-governmental organization, and there is no public accountability for the handling and treatment of data that resides on their platform. It is entirely unclear what steps, technologies, processes, or tools the ICC Platform uses to protect CBI, and how Maine Freedom of Access Law can be imposed on a third-party database. Moreover, if the CBI is accessed inappropriately, what penalties or remedies are available to the Department and impacted companies? The lack of clear, predictable, and transparent CBI rules presents concerns for manufacturers that must survive in highly competitive fields with technologically sophisticated products and competitors. In a final rule, the Department must establish internal procedures and data security capabilities to reliably ensure that any CBI submitted will not be disclosed.

(A)(2) - The Proposed Rule permits the Department to waive all or part of the notification requirement if substantially equivalent information is publicly available. CUC recommends that a final rule contain more detail as to how the waiver process will work. Specifically, more clarity is needed as to how a manufacturer will file, with whom the manufacturer should file, what information needs to be in a filing, when a waiver filing should be made, how long the decision-making process on a waiver application will take, whether there will be an appeals process from denied waiver applications, and what degree of compliance with the general notification requirements is expected while the Department is considering the waiver application.

(C) - The Proposed Rule provides that manufacturers may propose a category for reporting multiple products or components. The CUC recommends that a final rule contain more details concerning the process for proposing a category for reporting multiple products. Aside from the procedural elements of how a manufacturer formally proposes a category, the Department should elaborate on the criteria the Department will use to determine whether the proposed category is reasonable. Clarity is also needed on the compliance status of a manufacturer that has proposed a category: if an entity is not providing all listed information while the Department is reviewing a category proposal, how is a notification accomplished using just the other pieces of information required by the Proposed Rule?

Additionally, CUC would like the Department to clarify what is meant by "substantially similar amount" of PFAS for categorical reporting purposes. CUC requests that "substantially similar amount" be in the form of ranges, as many products are composed of complex chemistries, and no one product is identical

to another. Consequently, ranges would best meet the goals and accomplish the efficiencies that are meant to be conferred by categorical reporting.

(D) - The Proposed Rule requires a manufacturer to update notification information whenever there is a significant change in the reported information. CUC recommends that the final rule should state that an update of information in a notification should occur when the filer **becomes aware** of a significant change, not merely when there is a significant change. A filer may not become aware of changes when they occur, and only find out later, especially with regard to product components.

The Proposed Rule also provides that the update must include the date after which the prior formulation will not be sold, offered for sale, or distributed. This requirement creates compliance complexities. Manufacturers often sell to distributors, and those distributors then control when the product is actually sold. Consequently, the manufacturers may often not be able to provide a date as to when the prior formulation will stop being sold.

(E) - The Proposed Rule states that for imports from outside of the United States, the person who imports into Maine must provide the notification. CUC notes that identification of the responsible notifying party is more specific than "manufacturer of product for sale," and perhaps is an overall better and clearer criterion for which party is responsible for reporting.

(F) - The Proposed Rule states that notification is not effective until the Department has received payment of the fee. CUC asks that the Department clarify whether that simply means that the fee has been submitted, or must the Department acknowledge processing of the fee? If something more than mere transmittal of the fee is required, it is unclear how long that process takes. Consequently, those who notify need to understand the exact timing so the appropriate amount of time can be budgeted for submission of the notification.

(G) - The Proposed Rule states that the Department may require evidence "sufficient" to demonstrate the accuracy of the reported information. CUC request clarification as to what evidence the Department will consider "sufficient."

06-096 CMR 90 (4) - Exemptions

38 MRA 1614 (4)(A) simply states that a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority is exempt from Section 1614. However, in the Proposed Rule, the Department has added a significant amount of language that is not regulatory. Rather, it borders on inserting legal opinion in substantive regulatory provisions. Accordingly, CUC recommends that the Department remove the entire "note" from this provision, so that the regulatory provision aligns with the underlying statutory text.

CUC asks that the Department consider situations where a manufacturer is compelled to use PFAS, such as to comply with a performance standard established by a federal agency. Product manufacturers may need PFAS to meet requirements imposed by the Federal Aviation Administration or a United States Military Standard used by the Department of Defense. In these cases, federal agencies would essentially be requiring the use of PFAS in certain products, which would conflict with the prohibition requirements in Section 5. The Department should address these situations clearly, so that the compliance obligations of manufacturers in these situations is clear.

38 MRA 1614 (4)(B) exempts from the notification requirements a product subject to the food packaging laws in Title 32 chapters 26-A and 26-B. The statute makes no distinction as to whether the food packaging exempted from the notification requirements is being sold as a product or as part of food packaging. The food packaging laws in 26-A and 26-B apply to the commodity of food packaging, and not solely food packaging when used with food. Accordingly, the provision in the Proposed Rule that restricts the statutory exemption and subjects commodity packaging to the notification requirements does not comport with the statute.

06-096 CMR 90 (5) - Prohibition on Sale of Products Containing Intentionally Added PFAS

As discussed above, the CUC recommends that the prohibition on sale should not apply to spare/replacement parts.

06-096 CMR 90 (6) - Fees

The "Note" in this section that states that components incorporated into a product are not subject to reporting adds clarity. However, this note establishes the substantive scope of the reporting requirement. Consequently, this provision should not be a note; CUC recommends that this should be incorporated as a substantive provision as part of the reporting requirements.

06-096 CMR 90 (7) - Failure to Provide Notice

38 MRS 1614 (5)(D) states that "Effective January 1, 2030, *a person may not sell, offer for sale or distribute for sale in this State any product that contains intentionally added PFAS, unless the department has determined by rule that the use of PFAS in the product is a currently unavoidable use.* The department may specify specific products or product categories in which it has determined the use of PFAS is a currently unavoidable use. This prohibition does not apply to the sale or resale of used products."

Proposed 7(A)(2) states that "The Department may exempt a product f*rom the prohibition under this subsection* if the Department has determined that the use of PFAS in the product is a currently unavoidable use." §2(F) defines "current unavoidable use" as "a use of PFAS that the Department has determined by rulemaking to be essential for health, safety, or the functioning of society and for which alternatives are not reasonably available."

While the above cited MRS provision states that the Department may exempt products from the general prohibition on sale, the Proposed 7(A)(2) seems to indicate that the exemption will only be from the prohibition on sale of products for which notification was not received, as that provision is in the subsection that discusses that specific prohibition. CUC requests that that the Department clarify as to whether that was the Department's intent, or did the Department intend to restate the general exemption provision found in the above cited MRS provision?

Additionally, CUC recommends that the Department provide more details as to how it will make "unavoidable use" determinations. As a first step, CUC suggests that the Department exercise its rulemaking authority under sections 5 and 10 of the underlying law at the present time to affirmatively identify uses of PFAS which are "currently unavoidable" and explicitly exempt them from both the Section 2 notification requirements and the Section 5 product prohibition measures before finalizing the Chapter 90 notification rules. Second, the final rule should articulate a procedure whereby a manufacturer may request an affirmative determination that a specific PFAS/Use combination is a currently unavoidable use, including specified deadlines for decision-making. In connection with the procedural elements for requesting an unavoidable use determination, the Department must establish clear and

transparent criteria to as to when they will make a determination that specific products that contains intentionally added PFAS are an unavoidable use. Lastly, the Department should exempt any applicant for an unavoidable use determination from both notification and prohibition requirements until the Department issues a final determination on the request.

Conclusion

CUC appreciates your consideration of these, as well as our previously submitted, comments. CUC looks forward to additional opportunities during the regulatory process to discuss the concerns mentioned both in this letter and in our prior submission.

ATTACHMENT

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November 10, 2022

VIA EMAIL PFASPRODUCTS@MAINE.GOV

Kerri Malinowski
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333

Re: Comments on Revised Concept Draft Rule for PFAS in Products Program

Dear Ms. Malinowski:

The Chemical Users Coalition (CUC) is providing comments on the Revised Concept Draft Rule for implementation of the PFAS in Products program.[1] CUC submitted preliminary comments on the initial Concept Draft Rule[2] and appreciates the opportunity to provide comments on the Revised Draft in advance of the proposed rule. CUC reserves the right to comment further, to address additional issues to be covered, and to expand on these initial comments, at later dates.

CUC is an association of companies from diverse industries interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.[3] CUC encourages the development of chemical-regulatory policies that protect human health and the environment while simultaneously fostering the pursuit of technological innovation in the context of international markets and the global economy.

The CUC appreciates your consideration of these comments. If you have any questions relating to this submission, please feel free to contact me.

Sincerely,

Lawrence E. Culleen

Enclosure

[1] The regulations will implement Maine's *Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution*. MRS Title 38, Section 1614.

[2] http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/CUC%20Comments%20on%20Maine%20PFAS%20in%20Products%20Program%20Reporting%20Rules%20with%20Cover%20Letter%20071822.pdf

[3] The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, the National Electrical Manufacturers Association, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

Before the Maine Department of Environmental Protection

Maine's Second Concept Draft in Advance of Proposed Rules for Notification Requirements and Sales Prohibitions for Products Containing Intentionally Added PFAS Under Maine's *Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution*, 38 M.R.S. § 1614

Comments of the Chemical Users Coalition

Introduction

Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments in response to the Maine Department of Environmental Protection's ("DEP" or "Department") recent revised Concept Draft for its forthcoming proposed rule for notification requirements and sales prohibitions for products containing Intentionally Added PFAS under Maine's *Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances [PFAS] Pollution*. CUC Members will likely be affected by the proposed changes being considered.

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.[1] CUC has consistently supported measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. CUC Members produce and distribute highly complex materials and products, including critical microscopic circuits to major devices, appliances, and intricate equipment. To thrive in a competitive global economy, our Members depend on the availability of certain existing substances as well as products that incorporate such substances. CUC Members also rely on a reliable pipeline of innovative new chemistries and products upon which the consumer, commercial, industrial, health care, defense, space, and transportation sectors consistently rely. Consequently, our Members encourage the Department when implementing PFAS related restrictions or requirements to develop regulatory approaches that responsibly take into account existing (and developing) products and technologies on which the US economy and the departments of the US government depend. The availability of such products and the development of new technologies will be unintentionally and adversely restricted if DEP does not develop certain implementation strategies that provide exceptions and varying compliance schedules to enable the continued distribution and use of such materials and products. The failure to do so will cause producers of numerous critically important products to cease distribution in Maine and discourage innovation of new alternative chemistries that might be defined as "PFAS" under Maine law, but may actually have a comparatively favorable health and environmental profile compared to existing substances.

[1] CUC Members include Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

Comments

CUC provided preliminary comments addressing several specific provisions in the initial Concept Draft.[2] CUC incorporates its preliminary comments by reference. CUC appreciates DEP's efforts to respond to stakeholder comments on the initial Concept Draft. However, CUC still has significant concerns about the revised Concept Draft and believes that compliance will be difficult, even impossible, if the revised Concept Draft is finalized as is.

Notification Requirements Should Be Phased in and the First Deadline Should Be No Less than One Year Following the Rule's Effective Date

The information which will be required to be included in notifications is extensive, and for entities such as CUC Members that have complex supply chains and which use and distribute products comprised of numerous components, meeting a January 2023 notification deadline will be impossible. We reiterate CUC's recommendation that the deadline for filing notifications be at least one year following the effective date of any final regulation.

CUC understands that DEP interprets the statute to require that notifications be submitted by January 1, 2023, unless DEP has granted a manufacturer's extension request. CUC disagrees with this interpretation and considers the statute to afford DEP the flexibility to phase in the notification requirement, based on the use of the phrase "[b]eginning January 1, 2023" rather than, for example, "by January 1, 2023." The statutory "requirement" to prepare a notification can be reasonably interpreted as beginning on January 1, 2023, while the *deadline* for submitting such a notification can be established as a later date (e.g., one or more years following the effective date of any final rule).

A January 1, 2023 deadline is unworkable and significantly burdensome. It will be incredibly difficult for companies that manufacture complex products to gather the required information by that date due to their international, multi-tiered supply chains, particularly in light of the statute's broad definition of PFAS and DEP's newly proposed definition of "Fully Fluorinated Carbon Atom." The implications of failing to meet the deadline—a prohibition on sale and distribution of a PFAS-containing product—are substantial both for manufacturers and for the Maine marketplace, including end-use consumers.

With fewer than two months remaining until the deadline, it still remains unclear what the format for the "preliminary" notification will be. Requiring submission of a preliminary notification by January 1, 2023, and then submission of a "final notification" to the online notification system after the rule is promulgated increases the administrative burden. Furthermore, it is unclear as to how confidential business information (CBI) will be protected. It is unclear what advantages Maine will accrue by obtaining the preliminary notifications early on and then receiving the final notifications at a specified date "x" months later. It seems likely that the preliminary notifications would absorb Department resources that could be used to develop the final notification process and data systems more efficiently.

[2] http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/CUC%20Comments%20on%20Maine%20PFAS%20in%20Products%20Program%20Reporting%20Rules%20with%20Cover%20Letter%20071822.pdf

CUC also notes that it is important that the online notification system be launched at the same time that the final rule is adopted.

Establishing an inflexible deadline of January 1, 2023 conflicts with the statute's provision (38 MRS 1614(7)(A)) granting authority to DEP to exempt products that are "currently unavoidable uses" from the prohibition on the sale, offering for sale, or distribution for sale of products for which the manufacturer has not submitted a notification. A January 1, 2023 deadline makes it impossible for manufacturers to avail themselves of this statutory exemption, which will not be articulated until DEP undertakes and eventually completes its separate rulemaking.

In addition, given the complexity of supply chains, it is very possible that manufacturers who submit preliminary notifications will receive new, previously unknown information about the content of their products before they submit their final notifications (or, potentially, even after that time). The rule should provide a safe harbor for manufacturers to submit different and updated information with their final notifications if they receive new information from their upstream suppliers.

CUC again recommends DEP consider a "phased in" approach whereby different product categories be considered for initial notification during intervals occurring between one year after the final rule's effective date and the 2030 prohibition date. Section 5 of the underlying statute (38 MRS 1614) encourages DEP to consider products by category or use on the basis of the category's likelihood to cause contamination of the environment in Maine. Notification requirements should be phased in and sequenced on such a basis. Moreover, this "staggered notification" approach will reduce reporting and administrative burdens on both the entities subject to the final regulations and DEP personnel; this also will encourage more orderly and complete notifications.

CUC recommends repair and replacement parts for products manufactured prior to the effective date of the rule should be exempt from notification indefinitely. In addition, CUC urges DEP to include an exception to the sales prohibition for sale of spare parts to maintain products that were manufactured prior to the sales prohibition date. Such an exception would keep PFAS-containing products out of the waste stream.

CUC Members understand that DEC interprets the notification requirement and prohibition to apply based on the date a product is sold or distributed in Maine. However, CUC encourages DEP to apply these requirements based on the manufacture date of products. A "date of manufacture" approach is more practical, and is well understood by the makers and distributors of both commercial use and consumer use finished products.

DEP Should Articulate Due Diligence Standards

DEP also must provide guidance on the level of diligence that is required when product manufacturers and assemblers are seeking information from suppliers (both in the US and abroad) with respect to the PFAS content of components and parts. Entities that are required to submit notifications should be allowed to reasonably rely on information provided by their suppliers.

CUC Members recommend DEP make clear that manufacturers may reasonably rely on information provided by their suppliers, provided they can document that inquiries have been made to suppliers and reasonable efforts have been made to obtain information regarding the use of PFAS.

Key places in the regulations where DEP should clarify the level of diligence required include 3(A)(1), where the rule should specify that manufacturers' notifications should be "*based on reasonably ascertainable information*," and 3(G), where the requirement to provide information to DEP upon request should be revised to require that a manufacturer provide "evidence sufficient to demonstrate the accuracy, *to the best of the manufacturer's knowledge*, of information reported." These recommended changes are further discussed later in these comments.

CUC Supports Excluding Non-Functional Byproducts and Contaminants from "Intentionally Added PFAS," Urges Other Changes to Limit Scope of Key Terms

CUC supports DEP's efforts to narrow its definition of "intentionally added PFAS" to avoid unnecessary and burdensome reporting and to seek information of greatest importance to the policy objectives. Accordingly, CUC supports the revised definition's exclusion of manufacturing byproducts and impurities that do not serve a functional purpose yet might remain unintentionally present in a product. CUC also supports the definition's explicit exclusion of PFAS that is present in a final product as a contaminant. CUC notes that it may be challenging or impossible to validate that PFAS is "intentionally added" where its presence in a product originates from a source that could be multiple tiers up the supply chain. For this reason, CUC believes it would be appropriate to add the italicized text to the definition: "Intentionally added PFAS" means PFAS *known to have been* added to a product or one of its product components in order to provide a specific characteristic, appearance, or quality or to perform a specific function. Intentionally added PFAS also includes any degradation byproducts of PFAS serving a functional purpose or technical effect within the product or its components. Products containing intentionally added PFAS include products that consist solely of PFAS. Intentionally added PFAS does not include PFAS that is *reasonably believed to be* present in the final product as a contaminant.

Although CUC understands that DEP views itself as constrained by the statute, CUC reiterates its position the definition of PFAS used in the Concept Draft as "containing at least one fully fluorinated carbon atom" is overly comprehensive, is not at all well understood in the regulated community, and will create reporting requirements that are unnecessarily burdensome. CUC recommends that a more limited definition of PFAS be implemented for notifications during a first cycle of reporting for all categories of products, and that the scope of the definition be revisited thereafter. As noted above, CUC believes that DEP may implement a phased system of notifications. By limiting the scope and breadth of PFAS for which notification requirements are initially imposed, DEP can provide a more reasonable and practical opportunity for suppliers of products and components that are incorporated into complex articles to determine the presence of PFAS in the supply chain and to seek opportunities to phase out certain uses of PFAS where possible. This also will permit the development and submission of more accurate notifications. Notwithstanding that the statute employs the broad definition carried over into the Concept Draft, CUC considers the statute to enable DEP to exempt fluoropolymers and recommends that DEP

implement such an exemption.[3] These are substances of low hazard and low risk to human health and can readily be excluded from the PFAS definition without creating a new or increased risk to product purchasers and users. Moreover, the ubiquitous nature of fluoropolymers in commercial and consumer products makes their presence in those products "currently unavoidable"—at least until substitutes can be affirmatively identified, tested, and confirmed to be effective alternatives and after reformulation of existing products can occur and be fully phased in.

In addition, CUC recommends DEP create a list of specific PFAS that are of concern for health or environmental effects and require notifications only for products containing listed PFAS. Such a list should include the Chemical Abstract Services (CAS) registry number and the specific chemical identity using CAS nomenclature for each substance for which notification is required. The use of CAS numbers enables businesses throughout the value chain and across global marketplaces to understand which substances must be reported.

CUC also requests that the final rule incorporate a de minimis threshold level for PFAS content in manufactured articles, beneath which level no notification would be required. For example, the selection of a commonly-referenced de minimis threshold, such as 0.1% by weight of the finished product, would align with the European Union restrictions on chemicals designated pursuant to REACH as substances of very high concern when such substances are present in articles.[4] However, CUC would not advocate that a de minimis level should replace the Department's exclusion of contaminants and impurities from the definition of intentionally added PFAS, as those features also are critical to our Members.

Notwithstanding the statutory definition of the term "product," CUC recommends DEP narrow the term to include solely consumer products, as this is more consistent with the legislative intent of the statute and will minimize reporting burdens. The definition of "consumer" in the Concept Draft is overly broad, which results in the definition of "product" being overly inclusive, extending well beyond what would reasonably be considered consumer products. The unreasonably broad definition of consumer also makes the scope of the definition of "fabric treatment" unclear. "Consumer" should not include, for example, manufacturers of highly complex products that are not typically used by "consumers" or in "households."

Additional Changes Are Needed to Clarify the Party Responsible for Notifications and to Eliminate Duplication

[3] DEP also should exempt gaseous and volatile forms of PFAS from the notification requirements and sales prohibition. Many of these gaseous/volatile forms of PFAS are currently subject to hydrofluorocarbon (HFC) phasedown requirements under the American Innovation and Manufacturing (AIM) Act. Furthermore, several of the replacements materials for HFCs, including selected olefin chemistries, may still be considered PFAS under the DEP regulations yet be approved for usage under the Clean Air Act's Significant New Alternatives Policy (SNAP) rules.

[4] See, e.g., ECHA Guidance on requirements for substances in articles, "Article 7(2) of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a Candidate List substance of very high concern, is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article." https://echa.europa.eu/documents/10162/2324906/articles_en.pdf.

It is understood that a manufacturer, "the person that manufactures a product, or whose brand name is affixed to the product," is the party responsible for completing the notification when they have a presence in the US. The revised Concept Draft is still unclear as to how a manufacturer who does not directly sell their product into Maine (i.e., sells through distribution), is made aware that they have a notification obligation.

Further, 3(A)(1)(c) states: "For product components for which the Department has previously received notifications which are used in more complex products containing the reported components the manufacturer may report total PFAS in the product including its components, or may refer to the notifications for product components and any PFAS in the remainder of the product." In the next iteration of the rule, DEP should provide more details regarding how the "previously received" notifications will be collected, formatted, or made available for use in downstream notifications.

To Ensure Compliance and Streamline Notifications, DEP Should Limit the Information Required in the Notification to What Is Required by the Statute

CUC recommends that DEP make the inclusion of a product code an option rather than a requirement of the notification. Failure to include a product code should not be a violation. The statute does not require the use of such codes in the product description, and there are many cases in which the Global Product Classification brick categories and codes would not provide good options for products. For example, they may not be used in the manufacturing process or in various types of products, such as business-to-business products. If DEP decides to continue to require that notifications include product codes as part of the product description or provides a voluntary option for inclusion of such codes, DEP could consider allowing use of alternative code systems, including the Harmonized Tariff Schedule,[5] which is widely used around the world. HTS will not, however, be an adequate replacement for all products since it is not required for products shipped domestically within the US and manufacturers therefore may not have this data readily available. An HTS determination is a complex process that requires detailed knowledge of both product and tariff schedule.

The revised Concept Draft's requirement that manufacturers provide estimated sales volumes is not provided for in the statute and adds significant extra burden to the notification requirement. It is difficult to forecast the estimated sales volume in a country, let alone at the state level, since manufacturers often cannot control where products are sold in the United States. Moreover, estimated sales volumes are considered CBI by many companies, raising additional concerns regarding the workability of this component of the notification. In addition, it is not clear what value this additional information would add and why DEP views it as necessary to implement the requirements of the statute. Although DEP stated during the stakeholder meeting that estimated sales volume will be used to understand the volume of PFAS entering the state, it is not apparent that estimates provided only at the time of first notification would be helpful in assessing the volume of PFAS entering the state with any accuracy. However, if DEP decides to proceed with a requirement to provide information about sales volumes, it would be appropriate to allow manufacturers to base state sales volumes on proportional estimates, using national volumes and

[5] https://hts.usitc.gov/current

state populations. Other states, including California and Massachusetts, allow this method of calculation.

Section 3(A)(1) should be revised to state "A manufacturer of such a product must submit to the Department a notification that includes, *based on reasonably ascertainable information*,"[6] the specified components. There is significant difficulty in obtaining information from upstream suppliers regarding the use of PFAS. Suppliers may declare that intentionally added PFAS is contained in their products, but may be reluctant to share CAS registry numbers and quantity/concentration information. This reluctance is due to the information being proprietary, and because a supplier further upstream (many tiers up) may be the party which has incorporated the PFAS. This creates significant complexity in communicating and gathering information, because direct upstream suppliers may need to further consult their own upstream suppliers.

The requirement for providing the amount of PFAS as a concentration should be clarified in the rule to indicate that the concentration should be based on a component, not the finished product as a whole (as was stated to be the intent in the stakeholder meeting on October 27). In addition, clarity is needed on how this will be instituted in the notification mechanism. If multiple components (could be multiples of the same component or different components) within an end product contain intentionally added PFAS, how should that be disclosed?

DEP should consider allowing an alternative to the CAS registry number where the CAS registry number is not known.

DEP should provide more information about how the concentration ranges will be determined well in advance of the final rule. Also, we request that manufacturers be allowed to report concentration ranges based on supplier declarations.

As discussed below, in many cases, it may not be possible to publicly report the purpose for which PFAS are used in a product, particularly if a product is for a defense (military) or national (including State of Maine) security purpose.

The term "responsible official" should be more clearly defined.

As noted above, CUC highly recommends the requirement in 3(G) to "provide, upon request by the Department, evidence sufficient to demonstrate the accuracy of information reported" be revised to required that a manufacturer provide "evidence sufficient to demonstrate the accuracy*, to the best of the manufacturer's knowledge,* of information reported." This qualifier is necessary to reflect the dependency of manufacturers of highly complex products on the information provided by their suppliers (and the suppliers of their suppliers, etc.).

More Clarification Is Needed on the Statutory Exemptions, Which DEP Appears to Construe Too Narrowly

[6] DEP may consider using EPA's proposed definition of the similar phrase "known to or reasonably ascertainable by" in its proposed TSCA Section 8(a)(7) reporting rule. The proposed definition is "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." *See* 86 Fed. Reg. 33926, 33928 (June 28, 2021).

More clarification is needed on the exemption for a "product for which federal law or regulation controls the presence of PFAS in the product in a manner that preempts state authority." CUC also believes that the second part of 4(A)(1) ("For this purpose, the provisions of this Chapter are severable, and if any phrase, Section or Subsection is preempted by federal law or regulation, the validity of the remainder of this Chapter shall not be affected") should be removed to align the provision with the statutory text. Furthermore, CUC believes that there currently are products—such as those subject to military, national security, and/or space specifications (i.e., MilSpec or equivalent or similar), product requalification to conform with MilSpec or equivalent and ITAR[7] requirements, and Federal Aviation Administration certification, including aqueous film forming foam—that should fall into this exemption. In addition, there may be other products that are subject to specific federal regulatory requirements that make use of PFAS unavoidable (e.g., certain products regulated by the US Food and Drug Administration). For such products, the federal regulation "controls" the presence of PFAS even if there is not an applicable PFAS specification. Such products should fall within the scope of the exemption.

CUC believes that DEP's interpretation of the statute's exemption for a "product *subject to* Title 32, chapter 26-A or 26-B" (Reduction of Toxics in Packaging and Toxic Chemicals in Food Packaging) is erroneous. Although it appears that DEP interprets "subject to" to mean that DEP has taken action to prohibit or restrict a specific product, CUC's view is that a more straightforward interpretation would read the exemption as applying to any product that would fall within the statutory definitions in those two chapters (e.g., the definition of "package" as "a container used in marketing, protecting or handling a product," including a unit package and a shipping container defined by the American Society for Testing and Materials in its annual book of standards as ASTM, D996; a food package; and unsealed receptacles such as carrying cases, crates, cups, pails, rigid foil and other trays, wrappers and wrapping films, bags and tubs"). Because CUC believes DEP's current interpretation of the exemption's scope is erroneous, we request that DEP remove packaging from the definition of "product component."

The Concept Draft provides that retailers are exempt from the prohibition on selling products for which notification has not been provided unless they have received a notification from the manufacturer. The Concept Draft should clarify that the term "retailer" does not include a distribution center or warehouse.

Fees Should Be Assessed on a "Per Manufacturer" Basis

CUC reiterates its position that imposing the notification fee on a "per product" or "per notification" basis will encourage manufacturers and retailers to limit the number of products that are offered for distribution or sale in Maine and that this will unfairly penalize consumers and commercial product users who reside in Maine. CUC recommends fees should be assessed on a "per manufacturer" basis.

It is difficult to assess the fairness of the proposed fee amounts (i.e., $250 for the first three notifications submitted and an additional $50 for each additional notification). To provide a basis

[7] International Traffic in Arms Regulations (22 C.F.R. Parts 120-130), established by the Directorate of Defense Trade Controls within the United States Department of State.

for the proposed amounts, DEP should present the analysis of its "reasonable costs" for developing rules and administering the program, and its estimates regarding the number of product notifications it expects. DEP also should provide examples of how the fees will be assessed especially in instances where similar products might be included in the same notification. This is especially unclear in the absence of guidance concerning how and whether reporting by "category" will be permitted and whether notifications can be submitted or aggregated when a manufacturer produces a variety of similar products that might have minor differences not affecting PFAS content. Clarification is needed on reporting by a manufacturer when it produces identical products for several entities—each of which might differ only by model numbers (or SKU codes).

Clarification also is needed regarding whether fees will be associated with components or end products. With the need to submit notifications for both components and end products that use a component, it would be more reasonable to require a fee that is associated with the components reported, and there should be no charge for the entity reporting for the end product. This approach would be in furtherance of the revised Concept Draft's "linking" intention.

The final rule should provide for a dispute resolution process regarding the amount of fees assessed. It would also be beneficial to include a fee ceiling or cap (i.e., the fee paid by each manufacturer could not exceed "x" dollars).

The Process and Criteria for Category- or Type-Based Notification Must Be Spelled Out in More Detail

The notification process for categories or types of products remains unclear. Based on the language in the revised Concept Draft, it appears that, in order for a group of products to be reported together by category, a manufacturer must first submit information for each individual product "through the notification system," after which DEP will make a determination regarding whether "reporting as a category or type is feasible and consistent with the purposes of the program." Such a process would not provide any of the intended efficiencies. Instead, the manufacturer should be entitled to make the determination of product grouping based on the regulatory criteria and submit the information for the grouping in its notification, subject to review by DEP.

The ability to submit notifications by category is important for containing the costs of reporting. Given the proposed fee of $250 for the first three notifications and an additional $50 for each additional notification, the total fee will grow fast if assessed at individual product level. Not only will the fee increase, causing significant financial impact, but the administrative burden associated with handling payment will also increase significantly if each product must initially be reported individually.

The Rule Should Provide More Detail on the Availability of Waivers

CUC requests additional clarification on the waiver process under 3(A)(2). The final rule should clarify whether fees are required if a full waiver is granted. In addition, the final rule should specify whether spare parts are included within the scope of a waiver. The procedures for requesting and issuing waivers should be set forth in more detail in the final rule, including

expected timelines for the waiver processing, and the expected timing required for DEP to answer waiver requests. The regulations also should provide that the notification is not required during the period when a waiver request is being processed.

CUC also requests that waivers not be limited to instances where "substantially equivalent information is publicly available." DEP should exercise its discretion to issue regulations to allow manufacturers to request full or partial waivers (or extensions of time for notification submission) for other reasons, including because manufacturers may not receive specific information in regards to the PFAS used in their products for a variety of reasons (including proprietary reasons, etc.).

Additional Changes to the "Significant Change" Provisions Are Needed

CUC remains concerned that the Concept Draft suggests that changes in personnel (i.e., "responsible official") or their contact information at a particular reporting entity should trigger a notification of a "significant change." The identity of corporate officers and directors, as well as their contact information, can change frequently, and requiring notification for each such occurrence is burdensome and should not be considered a "significant" change. In addition, our Members continue to be concerned that the Concept Draft would consider the removal of a PFAS as a trigger for a "significant change" notification. These types of changes are not pertinent to what CUC understands to be the underlying policy objectives of the reporting requirements (i.e., to identify products that contain PFAS and to identify which PFAS are contained in products). CUC suggests DEP should minimize unnecessary reporting such as these changes. Thus, CUC recommends that the definition of "significant change" should not include the removal of a specific PFAS or a change in responsible official or contact information. CUC recommends that there be an option to provide notification of the removal of PFAS, but that such notification should be voluntary. In addition, CUC recommends that "PFAS" be changed to "intentionally added PFAS" in the definition of "significant change."

CUC continues to recommend, as we advocated in our preliminary comments, that a significant change should be defined as the addition of one or more PFAS not previously reported or the material increase (i.e., one which reflects an increase of at least 10% by weight or greater) in the concentration of a previously reported PFAS that is present in a product. Notification of the removal of PFAS content or an immaterial increase or decrease should not be required. Since CUC submitted its comments on the initial Concept Draft, some CUC Members have raised the issue of whether a 10% increase in PFAS content is the appropriate way to define "significant change" when one considers that PFAS content can be as small as the parts per million level in a product. A change of 10% is almost never discernible with analytical test methods, as the measurement uncertainty is often greater than 10% (most international test standards accept up to a 30% error as limit for the validity of the result). We recommend that DEP consider a material increase in PFAS content of perhaps even greater than 10% be incorporated in the final regulation as the threshold for increases considered significant.

CUC requests that DEP provide additional information in the next iteration of the rule regarding the impact of a significant change to a category or type notification. For example, if a significant change is made to only a portion of products covered by a category or type notification,

what is the impact to the notification? Is the manufacturer required to submit and will it be charged for new notifications?

CUC also requests clarification regarding whether a notification can be withdrawn if sale of a product is discontinued.

CUC appreciates the addition of information in the revised Concept Draft regarding the timeframes for updating notifications in the event of a significant change but believes that the proposed timeframes may not be workable. In addition, it is not clear what is meant by "start of sales" in 3(D)(1)(c). CUC suggests that an across-the-board 90-day timeframe for providing an updated notification after a significant change would be reasonable.

Confidential Business Information Must Be Protected

CUC Members produce and distribute highly complex products. The content of such products and their many individual components is regarded by CUC Members as commercially sensitive. For this reason, CUC Members consider it to be imperative that DEP establish a process (and the necessary accompanying data security and protection capabilities within DEP) by which claims to protect confidential business information can be asserted for notifications that are submitted. Such claims for confidentiality can be accommodated by requiring reporting entities asserting such claims to provide a "non-confidential" (redacted) copy of each confidential notification for purposes of any "public records" or a confidential submission that is required under the law.

The Revised Draft's note that "Claims of Confidential Business Information may be made at the time of reporting and will be managed under the Uniform Trade Secrets Act 10 M.R.S. §1542(4)(A)&(B)" does not provide sufficient guidance on a number of issues related to the protection of CBI. More detail should be provided about how CBI claims should be made, and how they will be processed. The notification system must include a secure way to submit CBI, equivalent to the US Environmental Protection Agency's Central Data Exchange (CDX). DEP must provide additional information about data security measures as well as details about whether all notification contents will be made publicly available, or whether DEP intends to make information available based on user profile (consumer, DEP staff member, manufacturer, etc.) to protect and secure CBI.

For "preliminary" notifications, submission via email will not provide adequate assurance of confidentiality, and an alternative submission method should be established if the preliminary notification requirement is retained.

For highly complex products such as those produced by CUC Members, suppliers at one or more tiers of the supply chain may refuse to provide information on the basis that it constitutes CBI. Ideally, the notification system will provide a mechanism through which such information can be submitted securely and confidentially

The rule should address how confidentiality claims will be handled for information that cannot be shared (e.g., the purpose for which PFAS are used in a product cannot be shared because

it is military-related or the sharing of information about the material composition of a product would pose a risk to national security by potentially providing information to adversaries that could be used for reverse engineering).

DEP Should Continue to Look for Ways to Achieve Administrative Efficiencies

DEP should seek and achieve administrative efficiencies. For example, CUC recommends that DEP should consider the extent to which existing reporting systems and databases used in Maine can be expanded for purposes of this new program. Similarly, when other states in the US are implementing similar reporting requirements, there are likely to be efficiencies that can be gained by using the same databases and by sequencing and harmonizing reporting deadlines and the information being gathered whenever possible.

To ensure such opportunities for efficiencies are optimized, CUC highly recommends DEP not establish the details of its reporting format and the technologies that will be used for notifications until the US Environmental Protection Agency has issued its reporting regulations pursuant to Section 8(a)(7) of the Toxic Substances Control Act (TSCA). The TSCA reporting rule is due to be issued in final form before the end of calendar year 2022.

Furthermore, in the event of future legislative amendments—including but not limited to any changes in the law that take effect immediately—DEP will need to make timely revisions to their regulations.

Additional Comments on the Revised Concept Draft

- The definition of "commercially available analytical method" would seem to allow use of methods that have not been sufficiently vetted. CUC recommends that the definition be clarified to include methods that have been "validated" by at least one federal and state regulatory authority (e.g., US EPA) in *addition* to being commercially available.

- CUC recommends that the definition of "distribute for sale" be clarified to state: "'Distribute for sale' means to ship or otherwise transport a product with the intent or understanding that it will be sold or offered for sale by a receiving party *in the State of Maine* subsequent to its delivery."

- The last sentence in the definition of "essential for health, safety, or the functioning of society" should be modified to add references to "defense or national security" in addition to "public transport" and the other items listed.

Preliminary Comments on "Currently Unavoidable Use"

CUC understands that the interpretation and application of the term "currently unavoidable use" will be subject to a separate rulemaking. In advance of that rulemaking, CUC has the following preliminary comments:

- The interpretation of the phrase "alternatives are not reasonably available" should take into account that certain products, including but certainly not limited to products and components in the aerospace and defense sector, are often subject to batteries of qualifications tests, customer approvals, and "Type Certifications" with various regulatory bodies such as the Department of Defense or Federal Aviation Administration. Therefore, alternatives that appear initially to be available may not be reasonably available because they must be subjected to these processes that may take months or even years to complete.

- The interpretation of the phrase "alternatives are not reasonably available" should also take into consideration that in many sectors there are often no readily available substitutes due to safety concerns. While a substitute (including a non-PFAS alternative) may exist on the market, it may be the case that such a substitute is more flammable, toxic, or otherwise unsafe—leading to an unwanted regulatory outcome.

- The exemption for "currently unavoidable use" should include a security or military exemption similar to what is in the EU's Waste Electrical & Electronic Equipment (WEEE) Directive, which provides for exemptions for "equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes" and for "equipment which is specifically designed and installed as part of another type of equipment that is excluded from or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment."[8]

- As noted above, in certain products regulated by the US Food and Drug Administration, use of PFAS is a currently unavoidable use.

- Maine DEP should also consider aligning exemptions with international regulations such as the Stockholm Convention[9] and EU REACH.[10]

Conclusion

CUC appreciates the opportunity to submit the foregoing comments and reserves its right to submit additional or modified comments at a later date. We would welcome the opportunity to meet with DEP staff to address our comments and to assist in refining the Concept Draft.

[8] https://echa.europa.eu/en/web/guest/legislation-profile/-/legislationprofile/EU-WEEE
[9] http://chm.pops.int/Implementation/Exemptions/SpecificExemptions/tabid/1133/Default.aspx
[10] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R1297&from=EN