

September 20, 2023

Response to the ECHA Public Consultation of the Restriction on the manufacture, placing on the market and use of PFAS in the EU

Part 1/7 General remarks and proposals

Our Key Messages

- *BASF is committed to safe and sustainable products and supports balanced regulatory measures for PFAS.*
- *To make the future regulation clearer and more concise we propose to implement a science- and risk-based regulation scheme of PFAS that is based on available physical, chemical and (eco)toxicological data instead of chemical structure elements and potentially related properties.*
- *The PFAS regulation needs to be closely aligned with other regulations for example with industrial emissions directive, to avoid contradicting double regulations, e.g., conflicts arising from banning PFAS gasket preventing emissions of hazardous chemicals.*
- *BASF proposes that the use of PFAS in contained industrial applications should be exempt from the restriction proposal, because of the strict control of emissions in the use and in the waste phase. Therefore, industrial uses do not pose an unacceptable risk for humans or the environment. The absence of notable emissions or specific residue thresholds can be laid down and monitored via existing legislations such as the Industrial Emission Directive (IED).*
- *Consideration should be given to the presence of substantial quantities of materials containing fluorine in upcoming waste streams when laying down the residue limits for recycled materials, in order to maintain the feasibility of circularity.*

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1. About BASF

At BASF, we create chemistry for a sustainable future. We combine economic success with a high level of environmental protection and social responsibility. More than 111,000 employees in the BASF group contribute to the success of our customers in various sectors and over 90 countries. Our portfolio comprises six segments: Chemicals, Materials, Industrial Solutions, Surface Technologies, Nutrition & Care and Agricultural Solutions. BASF generated sales of €87.3 billion in 2022. Its shares are traded on the stock exchange in Frankfurt (BAS) and as American Depositary Receipts (BASFY) in the United States. Further information can be found on www.basf.com.

1.1 How we manage regulatory requirements at BASF and strengthen sustainability through the value chain

We achieve long-term business success by creating value for our shareholders, our company, the environment, and society. Our products play a crucial role in making positive environmental impacts. They contribute to climate protection, conserve resources, avoid waste, strengthen circularity and are safe to use. With products from chemistry, we pave the way for climate-smart mobility. With our programs for carbon management, circular economy, sustainable water, and energy management we tackle the big transformation challenges in the chemical industry – upstream as well as downstream for consumer products.

For example, we have developed our own Sustainable Solution Steering Method (TripleS) to evaluate the sustainability performance of our products consistently and transparently and manage our portfolio accordingly. TripleS was introduced at BASF with the aim of increasing our portfolio of innovative and sustainable solutions and the sustainability performance of related value chains. BASF has further strengthened TripleS in 2023, by enabling the early identification of safe-and-sustainable chemicals. With the update, BASF is fostering developments in transformation topics linked to carbon management like Climate Change & Energy, Resource Efficiency and Circular Economy. Further, we aim to identify at an early stage of a product cycle those solutions that are likely to be affected by regulations and/or a negative market perception.

We are committed to doing business in a responsible, safe, resource-efficient, and respectful way. We are guided here by our corporate values and our global Code of Conduct. Our actions are based on the applicable laws and regulations. Some of our voluntary commitments go above and beyond these. We want to ensure that we act in line with the applicable laws and uphold our responsibility to the environment and society with our comprehensive management and monitoring systems. Our Responsible Care Management System does this for environmental protection, health, and safety.¹ We rely on a systematic, integrated, risk-based approach and established monitoring and management systems. BASF is also active in initiatives such as Together for Sustainability (TfS) and Responsible Care®, which promote sustainability in the supply chain.²

¹ BASF Report 2022 p100

² BASF Report 2022 p123

1.2 The use of PFAS in BASF

In this document and subsequent BASF submissions, the term "PFAS" is employed according to the definition outlined in the PFAS restriction proposal. It should be noted, however, that our use of the definition is not intended to explicitly state or implicitly infer agreement with this definition.

BASF, along with the entire chemical industry, utilizes specific PFAS in its industrial plants and processes to establish a productive and efficient infrastructure for example, in various applications such as electrolysis and filtration membranes. Seals and gaskets are used to minimize gaseous and liquid emissions and to ensure the safety of production workers. To achieve durable and dependable installations reactors are coated and pipelines lined. Many of these safety targets are legally required and indispensable for the license to operate and are in line with EU objectives and legislation.

1.2.1 General remarks on the industrial use of PFAS

In a safe industrial context, suitable alternatives for critical applications must be available before restrictions or bans enter into force. Most industrial applications utilizing PFAS lack viable alternatives with necessary technical capabilities and ensuring an equivalent level of safety. Consequently, any proposed restriction of PFAS must address the potential disruptions to value chains as well as unintended effects on the environment and health arising from *regrettable substitution* of existing PFAS materials with alternatives that show lower safety performance.

The PFAS restriction proposal has a notable drawback. The Dossier Submitters failed to identify relevant uses at industrial sites. They also did not comprehensively analyze alternative regulatory management options (e.g., RMOA), particularly in the industrial sector. Prior to proposing a ban of most PFAS, a thorough analysis of their industrial applications could have revealed sector specific risk management options. These options would effectively limit PFAS emissions into the environment as efficiently as a ban while being more practical, less burdensome and without *regrettable substitutions* for industry and society (see Chapter 3: Assessment of the restriction proposal).

1.2.2 Overview on concrete uses and use cases at BASF

BASF, along with its subsidiaries, manufactures products for the semiconductor industry that either contain PFAS or are formulated with PFAS to meet customer specifications and attain specific properties.³ BASF also depends on various solvents and materials containing PFAS for the use in analytics.⁴

Consequently, BASF supports a constructive, and proportionate, regulatory approach for industrial uses of PFAS in a contained environment.

³ BASF submission Part 2/7: Uses of PFAS for the production of electronic materials.

⁴ BASF submission Part 7/7: PFAS uses in analytics.

Further details regarding the highly specific applications of PFAS in chemical production facilities can be found in subsequent BASF Submissions, including requests and proposals on necessary derogations and exemptions:

- Part 2/7: Uses of PFAS for the production of electronic materials
- Part 3/7: PTFE coated conveyor belts for the production of thermoplastic material.
- Part 4/7: Request for the addition of an exemption of an industrial process aid under strictly controlled conditions including raw materials.
- Part 5/7: The use of Trifluoromethane sulphonic acid (TFMSA) as catalyst.
- Part 6/7: Broad uses of PFAS in chemical production plants.
- Part 7/7: PFAS uses in analytics.

1.3 What BASF aims for

In general, BASF seeks for its use of PFAS:

1. **The use of PFAS in contained industrial applications should be exempt from the restriction proposal, because of the strict control of emissions in the use and in the waste phase. Therefore, industrial uses, do not pose a risk for humans or the environment.**
2. **Exemptions where use of PFAS is essential to meet legal requirements, especially regarding safety and emission regulations, and where the use of PFAS provides better environmental and employee protection compared to other materials.**
3. **A maximum limit of 0.1% of PFAS residues to be considered acceptable in recycled materials if efficient sorting is not possible and there are significant amounts of PFAS contamination in major waste streams. However, it's important to note that other regulations may still require lower levels of specific regulated PFAS.**
4. **A science- and risk-based regulation scheme of PFAS that is based on available physical, chemical and (eco)toxicological data instead of chemical structure elements and potential related properties.**
5. **Close alignment of PFAS restriction proposal with other regulations, e.g., Industrial Emissions Directive 2010/75/EU, to avoid double regulations.**

2. General remarks and observations

2.1 PFAS Restriction Proposal can conflict with EU headline objectives

The current PFAS restriction proposal contradicts the EU Green transition objectives and jeopardizes much needed progress. The EU is dedicated to pursuing both the green and digital transitions simultaneously, with a focus on sustainable economic growth, combating climate change, and promoting digital innovation. In various "key strategic technologies and sectors" identified by the Net Zero Industry Act⁵ PFAS play a crucial role, as they are used in essential components throughout the value chains. These include but are not limited to solar photovoltaic technologies, onshore and offshore renewable

⁵ NZIA, March 2023

energy technologies, battery/storage technologies, electrolyzers and fuel cells, and Carbon Capture and Storage (CCS) technologies. All the above technologies will need to be scaled up rapidly to meet the EU's 2050 climate targets. (Table 1)

As a result, the restriction proposal anticipates a rise in the utilization of PFAS (section 1.3.2.12). The PFAS restriction proposal would affect downstream sectors directly or indirectly through their suppliers which use PFAS in their own processes. This would disrupt the development and deployment of these as well as many other technologies. The Digital Transition equally relies on electronic devices, semiconductor manufacturing, and telecommunications infrastructure, all of which use PFAS in certain processes. A full ban of PFAS without viable alternatives readily available would impede the EU's digital objectives. These concerns are reflected in the subsequent BASF submissions.

Table 1 Technology-specific Objectives and Targets

EU Objective/Strategy	Target	PFAS component
EU Hydrogen Strategy & Fit for 55	Reach 2x40 GW of electrolyzer capacity by 2030 in 1) EU and 2) neighborhood	Among other processes, electrolyzers and fuel cells rely on fluoropolymers. These fluoropolymers are manufactured and used responsibly in contained industrial environments. They are also verified to not pose a risk to human health or the environment as for example described in the submission by Hydrogen Europe (4114, 17/05/2023). There are no known alternatives today nor are there any foreseen in the near future.
EU Chips Act	Increase the EU's production capacity (from 10%) to 20% of the global market by 2030: more than double the current production capacity	The microchip industry relies on many processes and applications involving PFAS as defined by the current restriction proposal (e.g., photolithography, high purity water distribution systems,). As detailed by the submission of ESIA (4449, 02/06/2023), most uses have no known alternatives making substitution timelines highly insecure.
- CO₂ emission performance standards for cars and vans - EU Batteries Regulation and EU Battery Alliance	- From 2035, all new cars that come on the market must not emit any CO₂. - Supporting European battery cells manufacturing and a full competitive value chain at scale in Europe	Lithium-ion battery cells can currently and in the foreseeable future not be produced without the use of PFAS since there are no suitable alternatives available, as for example detailed in the Tesla submission (4402, 31/5/2023).
Trans-European Energy Network regulation [Q4 2023: Industrial Carbon Management Strategy]	5th list of Projects of Common Interest already includes 6 CO ₂ trans-European infrastructure projects	PFAS are integral to different steps in the CCS value chain, from seals used in the process of compressing CO ₂ over valves and seals used in pipes during the transportation phase and sensors using cables which are insulated using PFAS.

2.2 Disrupting the global level playing field

A full ban on PFAS within the EU is likely to result in the relocation of affected industries to regions with less stringent regulations, leading to an overall increase in global PFAS emissions. There are so far no other jurisdictions planning a full ban on PFAS technology. This could also reduce the EU's strategic autonomy. The restriction proposal has already created uncertainty in various industries as companies are (re-)considering their investment (plans) in Europe. This is further compounded by international initiatives such as the American Inflation Reduction Act (IRA) challenging the EU as a business location.

In most cases the use of PFAS in an industrial setting does not lead to any residue (above the proposed concentration limits) in products and often leads to a safer and more cost-efficient production process compared to the use of potential alternatives. Therefore, companies outside of the EU would still be able to export products which were created using PFAS in the industrial production process to the European market (no residues = no ban). A trade ban on those products cannot be enforced as those products would be indistinguishable from products created by other (PFAS-free) processes. An unbalanced regulation that excludes European companies from the market, while global PFAS production and use remains the same, would unfairly disadvantage European companies.

3. Assessment of the restriction proposal

The universal PFAS restriction proposal is an Annex XV restriction under Regulation (EC) 1907/2006 ("REACH"). Article 68(1) REACH provides that substance(s) can be restricted only if they pose an unacceptable risk to human health or the environment. This unacceptable risk must be proven by conducting a full risk assessment that follows the rules set forth and is consistent with Annex XV of REACH (and cross-referenced in Annex I and Annex XIII).

According to Annex XV, a full assessment of an unacceptable risk comprises (a) hazard identification and characterization, (b) exposure assessment and (c) risk assessment (= assessment of hazard x exposure).

The first step to develop an Annex XV restriction dossier is the definition of the hazard, which starts with the specific identification of the chemical substance, mixture, or article that poses a risk to human health or the environment. Afterwards, information needs to be gathered on hazardous properties, exposure scenarios, and the extent of the risk.

As the group of PFAS is very large and only limited information is available the Dossier Submitters chose to take a case-by-case approach to evaluate the risk. Thereby they use the available information on a small group of already regulated substances and extend the conclusions to the whole group of PFAS.

By following their case-by-case approach, the Dossier Submitters introduced certain deficiencies or made invalid extrapolations. These shortcomings will be further detailed in the following discussion. At this point, we can only say that a different approach would have been more sensible, namely, to define and analyze multiple risk management measures in order to select the option that achieves the desired goal with minimal impact on both society and industry.

3.1 Scope of the restriction proposal does not fit to the definition of hazard

The basis of all Annex XV restrictions is the definition of the hazard. The PFAS restriction proposal defines the hazard as the combination of persistence with one or more additional concerns, such as bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects (see restriction proposal, page 23 figure 4 and chapter 1.1.4.10 Concerns triggered by combinations of properties).

In other words, the hazard is defined as a combination of persistence with a second concern.

The Dossier Submitters acknowledge that the group defined as PFAS is a very large group and therefore they define the scope as:

“All PFASs in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment. This is the key hazardous property common to all PFASs in this restriction proposal (restriction proposal, page 22).”

Consequently, the scope of the restriction proposal is based solely on the property of persistence. As a result, even substances that do not contribute to the defined hazard are included in its scope, creating a mismatch in the regulation. This mismatch significantly increases the burden on industry and society and leads to regulation that is not efficient, as the desired reduction of hazard is reached by an unnecessary large scope (and impact).

Persistence is a quality that exists for a continuous or prolonged period of time. Persistent chemicals can become a problem when they end up accumulating where they shouldn't. But in many use-cases persistence is a desirable quality in a substance because it makes objects that contain it, resistant and durable. Persistent is the characteristic that makes chemical substances resistant and durable over extended periods of time.⁶

In other words, persistence is a necessary attribute and much sought after in many applications. For instance, some pharmaceuticals need to be persistent to remain effective over time. In these cases, the persistence of the substance is essential for its intended purpose.

As acknowledged by the Dossier Submitters, persistence is a modifier of other hazards, as it can exacerbate or attenuate the risks associated with the substance's other properties. This viewpoint recognizes that persistence alone does not make a chemical harmful; rather, it is the combination of persistence and other hazardous properties that contribute to the overall risk. However, not all persistent chemicals are toxic. Some chemicals may remain in the environment for extended periods without causing significant damage to ecosystems or human health. The same is true for many so-called natural substances, such as precious metals or many minerals. On the other hand, some non-persistent chemicals can be highly toxic, posing immediate risks to humans and the environment. In this context, persistence is not a sufficing indicator of a substance's potential harm.

Persistent substances that also have a second hazard are already regulated under REACH including a tonnage-based prioritization. The REACH Regulation aims at minimizing human exposure to and environmental release of PBT/vPvB and substituting PBT and vPvB substances where technically suitable and economically viable alternatives are available. Under REACH, a PBT/vPvB assessment is required for all substances for which a chemical safety assessment is carried out. A chemical safety assessment is required for substances manufactured or imported in amounts of 10 tons or more per year unless exemptions apply. Annex XIII to the REACH Regulation sets criteria for substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

The same principle could be applied to the PFAS restriction proposal. Not one, but a combination of criteria (e.g., bioaccumulating and persistent) would be needed to justify restricting a substance. On the

⁶ ECETOC

other hand, if a substance would be persistent but would e.g., not bioaccumulate or would not show any hazardous effects, would it scientifically be justified to conclude that persistence alone is a sufficient 'hazard' criterion for banning of the substance? (see also Chapter 3.5 on the 'non-threshold nature of the hazard')

The same logic is also partially used in the PFAS restriction proposal. For example, the authors state on page 48 "Analogously, a specific case for excluding a PFAS from the scope of the restriction proposal could be made if sufficient evidence is provided that the specific PFAS is not very persistent itself and does not degrade into a very persistent PFAS." Accordingly, persistent substances which do not show a hazard could be excluded from the restriction proposal. We therefore **propose to limit the scope to substances that are persistent in combination with a second criterion, such as bioaccumulation or toxicity.**

Another shortcoming of the restriction proposal is that the scope is based on persistence, but its definition is based on chemical structure elements such as presence of a $-CF_3$ group or a fully fluorinated $-CF_2-$. Therefore, there is an inconsistency between the scope (persistence) and the chemical definition of the scope (CF_3 , CF_2). Although the Dossier Submitters exempt a few structures because they are known to be degradable, e.g. $-O-CF_3$, the property of degradability is not used to define out-of-scope substances. The exclusive definition by structure leads to inconsistencies in those cases when substances were proven experimentally to be degradable, but do not possess a structural feature that is exempt from the restriction proposal.

Therefore, all non-persistent PFAS that do fully degrade in nature or are proven to not be persistent should be out of scope. This would be consistent with the microplastics restriction where polymers can be exempted if proven to be degradable according to certain criteria. (see Chapter 5: Improvement of the proposed restriction by inclusion of alternative risk-based decision logic).

3.2 Lack of evaluation of other Risk Mitigation Options (RMOs).

The Dossier Submitters failed to prove that a ban of all PFAS is the most appropriate measure to fulfill the defined goal in terms of effectiveness, practicability and monitorability. This could only be achieved by (a) identification of possible other risk management options and (b) comparison of the ban to the other RMOs.

Risk management options are strategies or approaches that are used to mitigate or manage defined risks associated with a particular activity and substance.

There is a multitude of alternative RMOs that could have been evaluated, to elucidate their potential to fulfill the goal of the restriction proposal to reduce the emission of PFAS into the environment.

The Dossier Submitters mentioned on page 83 that "Many RMOs directly related to REACH processes are not considered manageable for the whole group of PFAS" without substantiating this claim. Just to name a few examples of alternative RMOs:

1. Existing legislations could be applied to limit exposure to or emissions of PFAS (see Chapter 4, "Other regulations that conflict with restriction proposal").
2. Product stewardship measures and Extended Producer Responsibility (EPR): EPR requires manufacturers and importers of chemicals to take responsibility for the management of their products throughout their lifecycle, including disposal and recycling. For example, the EU's Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU requires producers to finance the collection, treatment, and recycling of electronic waste containing hazardous substances.

EPR and stewardship principles could be extended to high value goods containing PFAS, such as electric vehicles or lithium-ion batteries. Similar approaches could also be applied for “industrial use” articles containing PFAS, such as pumps or valves in a way that used parts are collected and adequately recycled (or disposed of) at the end-of-life stage.

3. Use or sector specific authorization allowing the use of PFAS only in contained or close-loop systems while avoiding emissions into the environment. This option had been used already successfully in the Montreal Protocol.⁷
4. Tracking systems: At BASF in Ludwigshafen, we have set up an IT based tracking system in our chemical plants in a way to direct material into the suitable waste or recycling stream that avoids emissions into the environment. We plan to extend this tracking system to PFAS containing parts.

Further analysis is required to see whether those examples or other RMOs will suffice to reach the defined goal in terms of effectiveness, practicability and monitorability, but to develop an Annex XV restriction, a detailed and thorough analysis of such alternative options is a prerequisite to justify a potential ban.

Although the Dossier Submitters state that “diverse risk management options (RMOs) were analyzed to identify the most appropriate risk management measure to address the risk” (restriction proposal, page 76), there is no evidence that a detailed analysis of RMOs other than a restriction was performed, especially considering risk and socio-economic impacts. With the immense impact on industry and society in view, it is indispensable to put all measures under scrutiny.

We propose to perform sector and PFAS subtype specific analysis whether better and less burdensome risk management options exist, to fulfill the goal to drastically reduce the emissions of PFAS into the environment. Alternatively, the development of a proposal for a more specific risk management system that fulfills the goal of this restriction proposal could also be done by the individual sectors on request of the legislators.

The use of PFAS in an industrial setting: At BASF we have a comprehensive overview over the use of PFAS in industrial applications, such as seals, gaskets, pipe lining, chemical reactor coatings, pumps, valves, and membranes. More detailed information can be found in the submission “Part 6/7: Broad uses of PFAS in chemical production plants”. As all materials and parts in industrial plants are contained, during the use and the end-of-life phase, the use of PFAS in an industrial setting does not lead to notable emissions, neither into the product nor into wastewater or air. All PFAS containing materials used in chemical production can be tracked from installation to disposal. By ensuring that all PFAS containing materials are subjected either to recycling (if possible) or to high temperature incineration, leading to mineralization of PFAS to inorganic fluorine, the goal of the restriction proposal to limit PFAS emissions into the environment has already been fulfilled. **Therefore, the use of PFAS in industrial processes does not need to be restricted and should be exempt from the restriction proposal.**

⁷ <https://www.umweltbundesamt.de/publikationen/1987-2017-30th-anniversary-of-the-montreal-protocol>

Conclusion:

We propose an exemption from the restriction proposal for uses of PFAS in contained industrial applications, because of the strict control of emissions in the use and in the waste phase. Therefore, those industrial uses, do not pose a risk for humans or the environment. The absence of notable emissions or concentration thresholds can be laid down and monitored via existing legislations such as the industrial emission directive (IED).

3.3 Grouping not based on criteria set forth in REACH

The grouping approach in chemical regulation under REACH is a method used to manage and assess the safety of numerous chemical substances more efficiently. Nevertheless, grouping approaches require a strict methodology to avoid oversimplifying the complex and diverse properties and risks associated with individual chemicals within a group.

In case of the PFAS restriction proposal, all substances that fall under a very generic "PFAS" definition are grouped together ("scope") and are intended to be restricted as a single class. This very broad grouping violates Article 68(1) of REACH. Moreover, the "case-by-case approach" used for risk assessment is not representative for the entire group (see Chapter 3.4, Case-by-case risk assessment approach not representative).

The definition of PFAS as used in the restriction proposal (and in all BASF's responses to the public consultation, although we do not necessarily agree with the definition), is based on an OECD publication⁸, which was developed as a chemical definition but not a regulatory or toxicological definition. This is supported by the Dossier Submitters who acknowledged on page 19 that the definition of PFAS is only based on chemical structure and does not consider any hazardous properties or risks.

Scientifically and legally valid grouping rules have been established by ECHA based on the concept of "category approach" and "read-across" (RAAF, Read Across Assessment Framework).⁹ The RAAF has been developed by ECHA as a tool providing a framework for a consistent and structured assessment of grouping and read-across approaches under REACH. To make use of those concepts, the substances of matter need to share similar physicochemical, toxicological, or ecotoxicological properties. Only if sufficient data are available to substantiate the grouping hypothesis, read-across techniques can be used to predict the unknown properties of data-poor substances in the grouping domain. (see Article 4.2.3 and Section 1.5 of Annex XI of the REACH Regulation). The term "category approach" is used when read-across is employed between several substances that have structural similarity. These substances are grouped together based on defined structural similarity and differences between the substances. As a result of the structural similarity, the toxicological, ecotoxicological and/or environmental fate properties will either all be similar or follow a regular pattern. Predictions should cover all parameters as required in the respective REACH information requirements. For PFAS, the category hypothesis is related to structural elements and persistence as major concern, but, given that the group of PFAS is larger than 10,000 substances, the number of available data substantiating the category hypothesis is very limited and therefore not sufficient to substantiate the grouping.

⁸ OECD 2021: Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. OECD Environment, Health and Safety Publications, Series on Risk Management No. 61. Organisation for Economic Co-operation and Development.

⁹ [614e5d61-891d-4154-8a47-87efebd1851a \(europa.eu\)](https://doi.org/10.1002/chem.201900001)

3.4 Case-by-case risk assessment approach not representative

The generation of an Annex XV restriction dossier requires a risk assessment to evaluate and manage the potential risks posed by chemical substances to human health and the environment. As stated by the Dossier Submitters, there is only limited data on exposure levels based on a few substances such as PFOA and PFOS. Therefore, the Dossier Submitters used a case-by-case approach in which they attempted to demonstrate that the emission of PFOA, PFOS and a few other fluorotelomers poses a risk for humans and the environment.

While contemplating other PFAS compounds as the foundation for the restriction proposal, it has been deemed challenging to extrapolate findings from a limited subset of substances to a significantly larger and highly diverse group of substances.

There is a body of literature cited in the description of hazard and exposure that almost exclusively references fluorotelomers. Almost all those substances are already restricted either under REACH and/or under the POP Regulation (EU) 2019/1021 or have been identified as SVHCs. Although there are no specific indications on hazardous properties for most fluoropolymers or most F-gases, they are also in scope of the restriction proposal. Physicochemical and toxicological properties of fluoropolymers have been analyzed and reviewed intensively¹⁰ and stated that fluoropolymers have documented safety profiles, are thermally, biologically, and chemically stable, negligibly soluble in water, non-mobile, non-bioavailable, non-bioaccumulative, and non-toxic¹¹.

To establish a scientifically valid base for risk evaluation, we recommend the data supporting the risk of specific PFAS to be considered representative for the targeted group of substances (=scope of the restriction). In practice, this might lead to **splitting the restriction proposal into separate restriction proposals, each focusing specifically on one group of PFAS**. Such specific restrictions are better suited to assess and define the risks and to evaluate the best possible method to minimize exposure to humans or the environment without introducing unnecessary regulatory burden.

There are plenty of well documented approaches on how to group PFAS (based on OECD nomenclature) into meaningful subgroups that can be used for environmental and human health risk assessment.¹²

3.5 PFAS as non-threshold substances

In their conclusions, the Dossier Submitters stated: *“In conclusion, the ongoing releases of PFASs are causing the environmental pollution stock and subsequent exposures to increase over time. Combined with the non-threshold nature of the hazard, this warrants an urgent need for minimization of the releases.*

¹⁰ e.g., Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed, Oscar Hernandez (2018) A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Integrated Environmental Assessment and Management Volume 14, Issue 3, Pages 316-334.

¹¹ Stephen H. Korzeniowski, Robert C. Buck, Robin M. Newkold, Ahmed El Kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli, Severine Beauchet, Frank Adamsky, Karl Weilandt, Vijay Kumar Soni, Deepak Kapoor, Priyanga Gunasekar, Marco Malvasi, Giulio Brinati, Stefana Musio (2023) A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers; Integrated Environmental Assessment and Management, Volume 19(2) Pages 326-354

¹² US National PFAS Testing Strategy: Identification of Candidate Per- and Polyfluoroalkyl Substances (PFAS) for Testing (2021) grouped PFAS primarily by their structure and then by secondary categories, such as volatility. More background on the usefulness of the grouping approach to inform toxicological testing can be found in Grace Patlewicz, Ann M. Richard, Antony J. Williams, Richard S. Judson, Russell S. Thomas (2022) Towards reproducible structure-based chemical categories for PFAS to inform and evaluate toxicity and toxicokinetic testing, Computational Toxicology, Volume 24, 2022, 100250).

“(restriction proposal, page 48) or “due to the non-threshold nature of the hazards” (restriction proposal, page 50) or “Information to derive a robust Predicted No Effect Concentration (PNEC) as well as a Predicted Environmental Concentration (PEC) is currently insufficient. Therefore, it is not possible to conclude whether risks are adequately controlled, either now or in the future. Even though not all PFASs are PBT substances, the concerns raised for them compare with the concerns for PBT/vPvB substances. Additional concerns regarding mobility and long-range transport potential of PFASs justify a non-threshold approach. The Dossier Submitters therefore conclude that PFASs should be treated as non-threshold substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk.” And consequently: “The need for the restriction of PFASs is based on the following considerations: - Risks of PFASs are of a non-threshold nature.” (restriction proposal, page 190).

This generalization is not supported by scientific data. There may be single candidates that are acting for single (eco)toxicological endpoints via non-threshold mechanisms. However, there is no scientific evidence that there are endpoint-specific non-threshold modes of action for all PFAS candidates, yet. A precautionary approach is therefore not suitable for justifying a broad restriction of all PFAS as non-threshold substances. Furthermore, it is not sufficient to draw a general conclusion about the mode of actions and risks of all PFAS candidates in terms of their (eco)toxicological profiles.

3.6 The restriction proposal is disproportionate

A valid Annex XV restriction must strike a balance between its benefits and costs, ensuring that the restriction is proportionate to the risk it aims to address. This principle of proportionality requires that the restriction is necessary, reasonable and that there are no less restrictive measures that could achieve the same objective with similar effectiveness. The least burdensome approach needs to be chosen to accomplish the goal. A reasonable way must consider the socio-economic impacts on all stakeholders, including industry, consumers, and public authorities.

BASF concludes that the PFAS restriction proposal in its current form is disproportionate and not reasonable.

The Dossier Submitters started to perform a proportionality analysis (restriction proposal, page 159), but the published analysis is only fragmentary. First, the Dossier Submitters concluded that due to the lack of a safe concentration for PBT/vPvB chemicals, the emission reduction needs to be used as a proxy. The Dossier Submitters used this comprehensible argument to make a direct step to a ban of all PFAS as the most appropriate restriction option without analyzing any other options that could be used as a proportionality check. Most likely this logical analysis could not be done due to lacking data. Dossier Submitters state that they only assessed 14 sectors in detail (restriction proposal, page 3), but they could identify at least 30 specific sectors (including firefighting foams, which are addressed in a separate restriction, restriction proposal Annex A, page 5). Therefore, the Dossier Submitters recommended a far-reaching restriction based on the analysis of only half of the impacted sectors. To improve this analysis, Dossier Submitters and RAC/SEAC need to take all information into account that is collected on the remaining sectors via the public consultation and add this information to the proportionality analysis.

We support the goal to limit PFAS emissions into the environment. However, the extremely broad scope of the restriction proposal limits a detailed and thorough analysis of the environmental impact of PFAS emissions and the socio-economic consequences of a ban. For example, it has been reported that fluoropolymers hardly contribute to PFAS emissions,¹³ but the socio-economic impact of a ban of fluoropolymers would be huge. Unfortunately, corresponding studies take a backseat amidst a bulk of publications on environmental and safety data on already regulated PFAS. If any environmental or health risk is posed by PFAS, it is posed by a small group of PFAS, but a lot of cost and burden on society and industry will be conferred by the restriction of fluoropolymers (for more details on EU wide business impact see the Cefic¹⁴). A more detailed analysis (which requires more detailed data) would reveal that the restriction as published overburdens some sectors that hardly contribute to the purported hazard.

As the assessment of proportionality is a key step of any Annex XV restriction (see 2.4.4), we **propose to break down the environmental and socio-economic analysis of the current proposal to individual groups of PFAS and individual sectors** to avoid disproportionate burden on individual sectors without minimizing the “unacceptable risk” that forms the basis of the restriction proposal. A similar sector specific approach has been taken for example in the case of the microplastics restriction.

3.7 Limited evaluation of alternatives

In order to prepare an Annex XV restriction, the evaluation of alternatives is required (REACH Art 68(1) and further elaborated in Guidance to Annex XV (06/2007, page 68-69). The evaluation of alternatives performed by the Dossier Submitters is limited to only half of the sectors impacted by the restriction proposal. For about 15 of the 30 sectors identified by the Dossier Submitters (see table A.1 annex 1), no systematic analysis of alternatives has been performed. This further limits the validity of the conclusions stated in the restriction proposal.

Given significant uncertainty in terms of the availability of alternatives and potential emissions, **we propose to include all sectors in the current evaluation. A review period after a certain time should be established to discuss novel developments. This will also serve to exempt certain uses for which no alternatives will become available** or if it can clearly be demonstrated that a specific use does not interfere with the goal of the restriction proposal.

¹³ Barbara J Henry, Joseph P Carlin, Jon A Hammerschmidt, Robert C Buck, L William Buxton, Heidelore Fiedler, Jennifer Seed, Oscar Hernandez (2018) A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Integrated Environmental Assessment and Management Volume 14, Issue 3, Pages 316-334.

Stephen H. Korzeniowski, Robert C. Buck, Robin M. Newkold, Ahmed El Kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli, Severine Beauchet, Frank Adamsky, Karl Weilandt, Vijay Kumar Soni, Deepak Kapoor, Priyanga Gunasekar, Marco Malvasi, Giulio Brinati, Stefana Musio (2023) A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers; Integrated Environmental Assessment and Management, Volume 19(2) Pages 326-354

¹⁴ In publication: Cefic “Economic analysis of the impacts of a REACH Restriction on the manufacture, placing on the market and use of per and polyfluoroalkyl substances.

4. Other regulations that conflict with the restriction proposal

The global chemical industry sector is regulated by multiple standards, norms, and legislation, which allow it to operate legally and safely under Standard Operating Procedures SOPs. Operating under standards and norms assures high product quality, which is a prerequisite to stay competitive.

The proposed PFAS restriction will severely impact the supply with gaskets, sealings, lances, hoses, and lubricants containing fluoropolymers and PFAS, jeopardizing the fulfillment of existing requirements for the chemical industry. If you cannot comply with safety regulations due to lack of proper equipment, the license to operate can be lost. Consequently, the safety level on production sites may decrease and it may no longer be possible to meet customer requirements.

Chemical companies rely on certain PFAS to keep fugitive emissions low, to enhance efficient and robust production, and, above all, to ensure safe working conditions for employees. Many of these aspects are governed by regulations and are necessary for companies' license to operate. To meet increasingly strict emissions regulations, modern production plants use state-of-the-art equipment that is fitted with many more valves, gaskets, and pressurized vessels. This results in increasing use of fluoropolymers, and it is currently not possible to operate most chemical plants safely without PFAS-based sealings. Consequently, BASF supports a constructive regulatory approach for industrial uses of fluoropolymers and fluoroelastomers.

We found the restriction proposal directly and indirectly contradictory to already existing comprehensive and protective frameworks for chemicals in the EU, namely:

EU regulations

Industrial Safety Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances.¹⁵ The Directive provides a framework on risk management measures to prevent major accidents and limit their consequences and applies for the industrial applications across Europe. Safety of a chemical installation is ensured, among others, by its tightness and protection against leakages. That is assured by chemically durable fluoropolymers gaskets and sealings.

Industrial Emissions Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control).¹⁶ The Directive aims to achieve a high level of protection of human health and the environment. The integrated approach of the directive covers emissions to air, water, land as well as prevention of accidents. As already mentioned above, tightness and chemical resistant installations sealed with fluoropolymers gaskets play a crucial role.

Chemical Agents Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.¹⁷ The Directive requires that employer must take appropriate technical measures to reduce or eliminate the risk of occupational exposure caused by hazardous substances.

To ensure safety and health of workers, technical installations must withstand harsh process condition e.g., protection against high pressure and heat in combination with chemical substances. That is provided by gaskets, sealings and coatings using PFAS materials.

¹⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0018>

¹⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0075>

¹⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0024>

Based on the above legislations it is necessary to guarantee chemical and physical durability of the industrial installation during its use. Insufficient sealing of chemical installation or fastening the installation with chemical materials with insufficient resistance and durability increases the leakage potential and the risk of releasing substances into the environment. Fluoropolymers provide excellent leak tightness and chemical resistance for various temperatures and pressures.

As the alternatives do not cover the range of the properties of fluoropolymers, it will no longer be possible to comply with the above-mentioned legislations. Moreover, it will bring additional risk to the operations of the chemical industry across the EU.

Responsible Care® by ICCA.

The voluntary initiative implemented by the chemical industry globally engages chemical companies in safe chemical management to achieve excellence in environmental, health, safety, and security performance.¹⁸ To achieve this target, it is necessary to secure essential sealing components in chemical installations. This is done by using fluoropolymer sealings and coatings.

Using substitutes which do not have the same level of chemical and physical persistence will stop the continuous improvement potential in safe chemicals management and jeopardize achieving excellence in environmental, health, safety, and security performance.

European Norm for sector specific industry, e.g.:

DIN EN 13555:2021 - Flanges and their joints - Gasket parameters and test procedures relevant to the design rules for gasketed circular flange connections.

DIN 51503 Lubricants - Refrigeration oils - Part 1: Minimum requirements.

DIN EN 1514-2, Spiral wound gaskets for use with steel flanges, e.g., Non-metallic PTFE gaskets.

EN 1514-3, Non-metallic PTFE envelope gaskets.

The listed norms are standardized requirements for gaskets and sealing in industrial installations. Those examples of EN standards demonstrate the necessity to use materials with high chemical, thermal and pressure persistence in industrial facilities. These standards guarantee tightness of chemical installations by using fluoropolymer components. So far, alternatives do not offer the unique combination of properties which can comply with the listed norms: There are no alternatives that comprise all required properties in one go, e.g., thermal stability and pH stability and abrasion resistance.

¹⁸ <https://icca-chem.org/focus/responsible-care/>

ISO Standards

Integrated management system consisting of ISO 45001, 14001 and 9001- occupational health and safety, environmental protection, and quality.

Industry specific norms

ISO 13856-3:2013 Safety of machinery - Pressure-sensitive protective devices - Part 3: General principles for design and testing of pressure-sensitive bumpers, plates, wires, and similar devices.

ISO 14123-2:2015 Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 2: Methodology leading to verification procedures.

ISO/TR 10358:2021 Plastics pipes and fittings for industrial applications - Collection of data on combined chemical-resistance.

ISO 4433-4, Thermoplastics pipes - Resistance to liquid chemicals - Classification - Part 4: Poly(vinylidene fluoride) (PVDF) pipes.

ISO 18752:2022 Rubber hoses and hose assemblies - Wire- or textile-reinforced single-pressure types for hydraulic applications - Specification.

ISO certification for the chemical industry assures safe operations, high product quality and fulfilling customer requirements. Recognizing context of the organization and defining risks and chances allows to implement the best solutions during production processes. Additionally, industry specific standards list necessary parameters which need to be met in accordance to process and product safety, continuous improvement, production efficiency and avoiding poor quality related costs.

In summary, it can be said that the restriction proposal will negatively impact the safety of chemical processes and jeopardize continuity of operations under the current regulatory frameworks. PTFE seals can deliver the high level of safety and performance required by industrial standards and norms. Using alternatives, if available at all, will lead in many cases to leakages, poor product quality and batch failures. Compliance with the standards will no longer be maintained. That in fact could lead to the loss of the license to operate in chemical operations.

As PFAS in industrial plants make it possible to achieve the objectives of standards and norms and to comply with the already existing comprehensive and protective framework for chemicals in the EU, the restriction is disproportionate.

The potential PFAS regulation needs to be closely aligned with other regulations for example with industrial emissions directive, to avoid contradicting double regulations.

5. Improvement of the proposed restriction by inclusion of alternative risk-based decision logic

Innovations based on chemistry can help to overcome many of the challenges of our time – from climate change and resource scarcity to feeding the world's growing population. Products, solutions, and technologies from BASF enable and accelerate the transformation to a sustainable future in all these areas.¹⁹

A broad and general restriction of PFAS would hamper innovation in the EU (e.g., identification of safe and sustainable fluorinated substances incl. substances falling under the PFAS definition). We therefore propose to exempt R&D and related use case-specific options and thereby enhance the restriction proposal. The following proposal to introduce an alternative risk-based decision logic for R&D and the innovations complements the proposals from other chapters or parts of the submission.

5.1 Exemption of process and product related research and development (PPORD) and alternative decision logic for development and exemption of safe and sustainable fluorinated substances

The main goal of the EU Green Deal and the Chemicals Strategy for Sustainability (CSS) is to increase the protection of human health and environment. This may be achieved by restrictive regulatory measures. However, another goal of the CSS is to boost innovation on the EU market to develop safe and sustainable new substances which contribute to the zero-pollution ambition of the CSS.

In the current EU proposal, the definition includes over 10,000 substances. The EU universal PFAS restriction proposal will be the broadest REACH restriction ever. Per and polyfluoroalkyl substances (PFAS) are a class of thousands of chemicals that have in common the presence of carbon-fluorine (CF) bonds. Some PFAS and their degradation products may persist in the environment and the human body. This has led to concerns and, as a result, PFAS substances are subject to restrictive regulatory measures.

However, there is only a small set of data-rich substances for which data e.g., on persistence, degradation products, bioaccumulation or associations to effects is available. For most of the fluorinated substances, which fall under the universal restriction proposal, no data is available. The restriction proposal is driven by the precautionary principle based on very generic assumptions which were extrapolated to a very large group of fluorinated substances. Such a regulatory approach is unprecedented and would hamper innovations in fluorochemistry in Europe.

While BASF supports the overall goal of the CSS, a balanced regulatory approach and transition time to transform the Chemical Industry are required. In the context of the current restriction proposal, the potential risk level is neither well defined nor sufficiently supported by data. We acknowledge the political goal to ban very harmful substances in order to reduce the risk of potential exposure and potential risk to humans and the environment. However, a restrictive grouping approach that mainly relies on few data-rich substances but is applied to thousands of substances without providing guidance on potential exclusions from restriction is not in line with current EU regulations and guidelines e.g., on grouping of substances (ECHA, 2017). There may also be applications in which fluorinated substances (incl. PFAS)

¹⁹ BASF-Report 2022:2

can be used without exposure or emission and for which a general restriction would not be justified and proportionate. Furthermore, there may be technical applications or needs (e.g., in industrial settings) in which substitution of fluorochemistry (incl. PFAS) is not possible and the development of new fluorinated substances (incl. PFAS) would be required. If sufficiently investigated, such newly developed candidates (incl. fluorinated substances and, potentially, PFAS) could combine technically equivalent characteristics but also safe and sustainable properties and, thus, could be ideal candidates for substitution of existing PFAS. However, the innovation and development of safe and sustainable substances (incl. potential fluorinated candidates) with the required technical performance is laborious and takes many years. An innovation chain process, for example, consists of separate phases characterized by specific activities and these innovation phases are separated by gates. Typically, the innovation chain process starts with an ideation/opportunity field phase, is followed by a business case phase, a lab phase, a pilot phase, and a launch phase (innovation chain or phase-gate process). A gate is a 'go' or 'stop/kill' decision point, guarding entrance into a (new) phase of the innovation chain process. The innovation process should not be seen as a linear process as innovation activities often have feedback loops within a phase. Also, activities from earlier phases may be continued or even completely revisited, if needed. Therefore, if, in the future, fluorochemistry would be generally banned while being required to achieve the necessary technical performance, an early decision would be essential in the innovation processes whether under an ongoing "universal PFAS restriction" the respective innovation process can be continued or not.

In the current restriction proposal, the proof of non-persistence, would be the only criterion to establish future exemptions from the restriction, which would not be balanced and a potential roadblock for innovation. There may be conditions (e.g., in industrial settings under closed or contained conditions and appropriate waste management) under which a substance can be safely and sustainably manufactured, handled and/or applied without exposure of humans or environment. In addition, there may be fluorinated substances in the large group of PFAS that do not show bioaccumulative properties and do not fall under the same characteristics as recently regulated PFAS chemicals. To account on these conditions a guidance for industry would be required that describes a decision logic including the expectations from a regulatory point of view. If clear guidance would be provided under which conditions a derogation/exemption would likely be successful for safe and sustainable fluorinated substances, this would mitigate uncertainty, strengthen the development of unique substances and, hence, in line with the goal of the CSS, the overall innovation capacity of the EU.

Within an innovation process, limited amounts of new and potentially fluorinated substances falling under the generic PFAS definition are synthesized and manufactured in the early development phase. Such so-called 'scientific research and development' (SR&D) is exempted from REACH restrictions in accordance to REACH Article 67(1): "[...] *This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. [...]*". Scientific research and development (SR&D) is defined according to ECHA guidance (V2.1, 2017) as "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 ton per year (Article 3(23) of the REACH Regulation). Examples of SR&D may include any experimental research or analytical activities at a laboratory scale such as synthesis and testing of applications of chemicals, release tests, etc. as well as the use of the substance in monitoring and routine quality control or in vitro diagnostics at a laboratory scale under controlled conditions. The total quantity of the substance to be considered as used in experimental research or analytical activity covered by SR&D definition applies per legal entity that manufactures or imports the substance (not per laboratory or per analysis).*" However, after early development, up-scaling is required in order to test the characteristics of a new substance in more detail.

Reaching quantities of about 1 ton per year and more in the course of Product and Process Orientated Research and Development (PPORD) is anchored as PPORD process in the REACH regulation. According to ECHA Guidance (V2.1, 2017) product and process orientated research and development (PPORD) is defined as *“any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance (Article 3(22) of the REACH Regulation). Any scientific development of a substance consisting of, for example, campaign(s) for the scaling-up or improvement of a production process in a pilot plant or in the full-scale production, or the investigation of the fields of applications for that substance, falls under the definition of PPORD.”* Furthermore, in line with REACH Article 67(1): “[...] Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.” ECHA assesses a PPORD notification and may impose conditions to a PPORD exemption. The manufacturer or importer of the substance must comply with the imposed conditions and must inform relevant customers involved in the PPORD exemption. If a substance used for PPORD is subject to a restriction or authorization, the respective decisions will specify how they apply to PPORD. They will also define the maximum quantities of the substance that can benefit from a PPORD exemption.

In conclusion, an option to exempt PPORDs in the universal PFAS restriction proposal needs to be anchored in the proposed Annex XVII entry to avoid i) a roadblock for innovation and ii) a contradiction to the CSS goal to boost innovation in the EU.

5.2 Alternative decision logic as guidance for development of safe and sustainable fluorinated substances

In the current restriction proposal on PFAS the (potential) persistence of a substance is the major “risk” driver and sole descriptor to achieve a full exemption from restriction. Based on the current proposal and the precautionary principle, persistent substances could enter the environment and/or accumulate in the food chain and, thus, be a constant exposure-source for humans. For some PFAS the biological half-life in the human organism is months to years, but there are also examples which show much lower biological half-lives (e.g., PFBA). Knowledge about causal relationships and availability of data is limited. Hence, persistence remains the main modulator of the overall concern, which is in combination with the precautionary principle, the basis for the universal restriction proposal.

However, due to the lack of sufficient data on PFAS the overall risk level is undefined, the number of potential fluorinated substances included in the current restriction proposal is high and there is no guidance on future innovations and, so far, no derogation option for development of innovative substances (PPORDs) in the proposed Annex XVII entry. Therefore, based on the current proposal the uncertainty is high whether there are options to develop fluorinated substances (including PFAS) in the future that may have unique technical and non-harmful properties (e.g., no bioaccumulation, low exposure, no adversity in regulatory studies) although they may have some persistent characteristics.

If the focus of the restriction proposal would be kept as broad and generic as currently proposed and would not be narrowed to a limited group of sufficiently investigated fluorinated substances with known characteristics, an alternative decision logic would be required for the large ‘PFAS-Chemical Universe’ to enable and facilitate future innovation/developments and exemptions/derogations for safe and

sustainable fluorinated substances including substances falling under the generic PFAS definition. As end-to-end (E2E) product development life cycles for alternatives require many years, including periods >13.5 years, early decision points need to be identified and implemented in such a decision logic. These decision points need, of course, alignment and anchoring in the restriction proposal as a guidance for industry and future innovation. In the later innovation phase an up scaling and tiered testing of the innovation candidates would be required. Here, the REACH regulation provides an appropriate legal framework for tiered testing of potential candidates in the late development process.

In conclusion and in line with the above PPORD exemptions, an option for case-specific assessments, i.e., science- as well as risk-based exemptions, needs to be anchored in the restriction proposal in order to avoid roadblocks for innovation and development of safe and sustainable fluorinated candidates that are sufficiently investigated to perform application-specific risk assessments.

As a proposal and starting point for further discussion, we provided an example how such an alternative logic could be designed (see below figure and description).

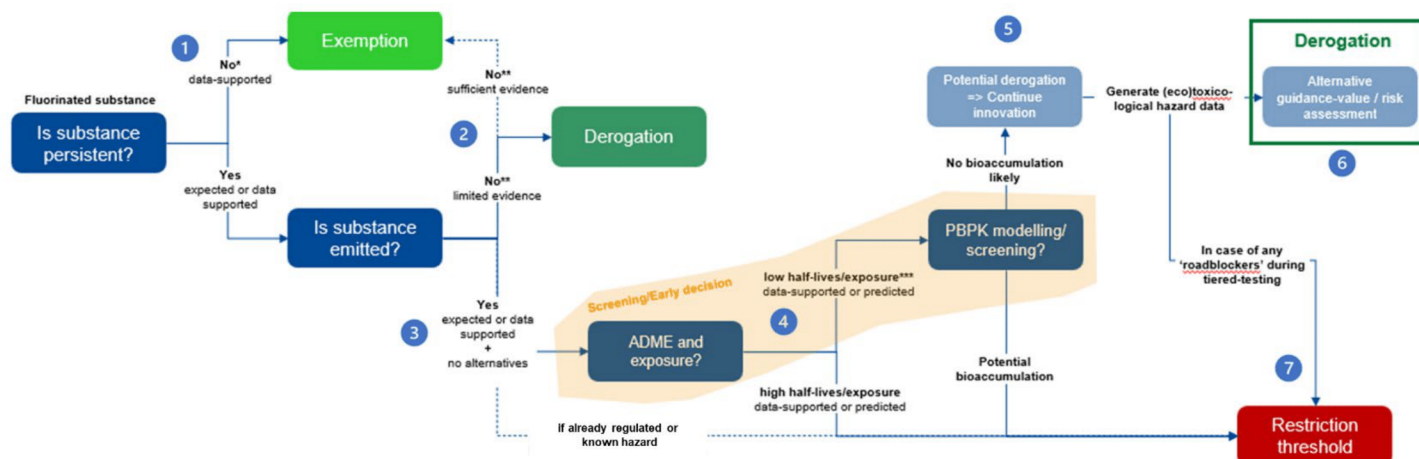


Figure 1. Proposed decision logic for future development of safe and sustainable fluorinated substances. Footnotes and abbreviations: *, perfluorinated moiety is fully degraded at a rate which indicates them to be not persistent, resulting in a substance/substances which is/are not a PFAS (in accordance to exemption criteria in restriction proposal); **, based on holistic view on potential emission throughout the complete life-cycle including waste streams; ***, half-lives and external exposure as initial grouping criteria/guiding principle; e.g. half-life <1 week = low/short (e.g. Dawson *et al* (2023), *Toxics*, 11(2);98) and low external exposure (e.g. substance as impurity, concentration below 1% or limited migration) and no/low continuous exposure (e.g. no daily application) or only industrial/professional application of fluorinated substance; screening assessment should consider uncertainties and potential bioaccumulation and/or metabolism (e.g. PFAS-metabolites with bioaccumulative potential); ADME, Absorption, Distribution, Metabolism and Excretion. ADME studies are designed to investigate how a chemical is processed by a living organism; PBPK, Physiological-based pharmacokinetic modeling and simulation (PBPK) is a computer modeling approach that incorporates blood flow and tissue composition of organs to define the toxicokinetics of substances.

- 1 In line with the current restriction proposal and the political ambition to reduce the environmental burden triggered by persistent substances, persistence should remain the first modulator to decide about general exemptions. If a substance is not persistent in line with the definition included in the restriction proposal, an exemption should be granted.

- 2 If a parent substance is persistent, the next decision level should be the emission of the substance. Particularly in industrial settings including manufacture, persistent substances could be used under closed and/or contained conditions. Also, any waste streams may be 'decontaminated' from persistent substances, e.g., by incineration. Therefore, and depending on the conditions in the industrial processes a time-limited derogation or even exemption should also be possible for such industrial applications.
- 3 If, however, the parent substance may be emitted to a certain degree, further information would be required in an early point of time. As a first step, information on alternatives would be required. If there is no potential substitute and if the potential exposure profile is low, environmental release as well as environmental degradation products would be another important information requirement. If the result of initial testing of environmental degradation would be that already restricted PFAS, such as certain perfluorocarbonic acids (PFCA), would be liberated, no exemption from restriction should be granted (see 7). The same would be true if PFAS degradation products with known critical characteristics are released to environment (see 7). For all other cases the next step could be an option.
- 4 If there is an emission and a limited external exposure of humans, a potential internal exposure in humans needs to be extrapolated as an early decision criterion in the innovation chain process for further development. Testing or prediction (e.g., QSAR or machine-learning tools (e.g., Dawson et al, 2023)) for determination of biological half-lives and further PBPK modelling or screening could support the decision on further development of the respective candidate. Exposure levels (incl. all potential routes) and toxicokinetic examinations (ADME) may further substantiate extrapolations about potential bioaccumulation. If it is indicated that the parent or degradation products bioaccumulate, or if there are indications about long biological half-lives those would be 'stop-criteria' for further development (see 7).
- 5 If initial tests incl. predictions indicate that there is a low internal exposure and/or low biological half-life of the substance or its degradation products, development could be continued. As this is related to up-scaling and a PPORD exemption (see above), the REACH regulation provides a comprehensive framework for further tonnage-based tiered (eco)toxicological testing. Application of different integrated testing regimen including screening tests (e.g., metabolomics) or new approach methodologies (NAMs) is not excluded. The main goal is identification of potential harmful characteristics. If there are any roadblocks indicating that the internal exposure likely exceeds safe thresholds (e.g., DNELs), development needs to be canceled and no exemption is granted (see 7).
- 6 However, if the substance appears to be safe in the (eco)toxicological testing program there should be the option to grant an exemption from restriction including a substance- and application-specific threshold (e.g., DNEL) and risk assessment.

6. Other comments

6.1 Balanced communications and clarifications needed:

Paragraphs or statements in the restriction proposal tend to generalize findings on PFAS and need clarification.

For example, the Dossier Submitters state on the topic of environmental degradation or persistence: *“All PFASs in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment. This is the key hazardous property common to all PFASs in this restriction proposal.”* (restriction proposal, page 22). This statement emphasizes that only persistent PFAS and their persistent degradation products (“arrowhead compounds”) fall under the scope of the restriction. However, the statement that persistence is common to all PFASs included in the very generic definition is generalized or even incorrect since degradation of PFAS candidates was only investigated to a very limited extent. Furthermore, the restriction proposal includes statements about perfluorinated moieties, such as *“Common for all the PFASs is that they have perfluoroalkyl moieties present. These moieties resist environmental and metabolic degradation due to the very stable C-F bonds.”* (restriction proposal, page 23). This, again, is very generic and, in accordance with the arrowhead approach, there are counter-indications that e.g. -CF₃ residues are not necessarily as stable as postulated and that they are rapidly and completely defluorinated and oxidized to CO₂ under environmentally relevant conditions. In a 28-day study the defluorination of 14C-labelled trifluoromethoxy benzoic acid at 20°C in three different soils originated from Germany was investigated under field application rate conditions of 250 g active substance per hectare. Treated soils were incubated in closed containers and trapping systems were attached to the test containers to capture evolving volatiles. Soil samples were taken in duplicates at day 0, 1, 2, 3, 6 or 7, 10, 14 and 28 days after treatments and radioactivity was analyzed in the volatile trapping solutions and soil remainders. The degradation times for the test substance, i.e., the labelled -CF₃ moieties, were between 1 and 3 days for 50% degradation and 3 and 9 days for 90% degradation. This may only be one example challenging the very general assumptions that have been used as basis and the related proportionality of the restriction proposal.²⁰

6.2 Exemption of precursors and manufacturing processes/plants for exempted fluorinated substances

If certain substances, such as active ingredients, are exempted from the restriction, it is insufficient to exclude only the products of complex manufacturing processes. In the ECHA Q&A, it was clarified that the exemption should also apply for source materials, educts, and intermediates, but it is still unclear if the exemption would also apply for all materials needed for the manufacturing process. Therefore, **it needs to be clearly stated that the exemption comprises all materials for the entire manufacturing processes including e.g., processing aids, catalysts, technical materials, as well as all raw materials or solvents required for synthesis of the active ingredients.**

²⁰ Defluorination of 14C-Trifluoromethoxy Benzoic Acid in Soil”, Ebert et al, SETAC, 2023

7. Emissions in the end-of-life phase and Waste Management

Chemical plants typically produce multiple waste streams, e.g., liquid waste and wastewater and different classes of solid waste. BASFs waste management is in compliance with legal requirements, such as:

- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
- Waste Incineration Directive 2000/76/EC
- Commission implementing decision (EU) 2019/2010 (under Directive 2010/75/EU) for establishing the Best Available Techniques (BAT) conclusions, for waste incineration.

For all incineration plants in the European Union, the EU reference document on waste incineration (WI BREF) is setting binding minimum performance standards (Best Available Techniques [BAT]) for these installations and the related waste management operations, aiming to minimize the negative impact that waste treatment can have on the environment (for details see below).

Waste Management at EU regulated BASF Sites

To organize the proper treatment of various waste streams, BASF has established an IT based waste management system according to the BAT-conclusions. This system is designed to efficiently manage the proper segregation, collection, transport, storage, disposal or reuse or recycling of waste materials – either in own facilities or third-party plants - to reduce their impact on the environment. In an industrial setting, waste management systems ensure the tracking of the waste materials to be disposed according to applicable laws, to reduce emissions as far as technically possible and to rule out inappropriate disposal methods and misuse. This system could be extended to track also various PFAS materials.

Waste Treatment of EU regulated BASF-Wastes

BASF's hazardous wastes are finally treated by high temperature incineration - either in own facilities or third-party plants – with BAT-compliant installations. Some streams are chemically and physically treated in advance for proper conditioning or to separate and recover recyclable materials.

“High temperature incineration” refers to a thermal treatment process in which hazardous and non-hazardous wastes are converted into gases and incombustible solid residues that are being landfilled. The incineration process thus detoxifies the waste by destroying the organic compounds and reduces the volume of the residing waste. To ensure sufficient destruction of the organic compounds in the waste, a minimum temperature within the incinerator is maintained at a minimum residence time of 2 seconds: above 850°C for non-hazardous waste incineration and above 1100°C for hazardous waste incineration (the Industrial Emission Directive enables derogations and thus the approval of slightly lower minimum temperatures as long as the complete destruction of organic components has been scientifically proven). According to the current state of knowledge PFAS organic compounds (composed of carbon, hydrogen, and fluorine) are thermally converted to inorganic HF, CO₂, and H₂O. HF and other potentially contaminants efficiently be removed by the flue gas cleaning (see below).

The main advantages and efficiency of the combustion of waste streams can be summarized as follows:

- Effective and controlled destruction of the hazardous components in the waste streams through the combination of high temperature incineration and highly efficient flue gas cleaning
- Use of the energy content of the hazardous waste streams and substitution of natural gas or other primary resources for steam or power production
- It minimizes the amount of waste residue which must be disposed.

Studies on PFAS in the incineration

For waste streams containing PFAS, BASF is currently working on a study to assess the incineration conditions regarding the guidance for firewater and foam concentrate disposal in PFAS restriction Report in Firefighting Foams, Annex XV.

In the last few years, other studies have been carried out on the incineration of PFAS and the resulting emissions via the cleaned flue gas, as well as the effluents and slags and ashes, at various industrial waste incineration plants and published.^{21,22,23} The incineration temperatures during these measurements varied between 850 to 1100°C at a residence time of 2 seconds, according to the requirements of the Best Available Techniques which are used as a reference to set permit conditions for industrial installations, including the emission limit values (ELVs). These Studies have shown that high-temperature incineration (>1000°C) can effectively destroy PFAS compounds with destruction efficiencies greater than 99.99%.

Further measurements have been carried out in the meantime but not yet been published completely. But unofficially communicated results seem to confirm the existing data. In addition, further measurement campaigns are being planned.

Conclusion: By following the applicable regulations and by using the best available technology it can be ensured that incineration is an accepted technology to degrade PFAS without generating considerable PFAS containing emissions.

Further research and data collection is ongoing, and results will only be presented after the end of the consultation period.

Best Available Technology approach

BASF's hazardous waste incineration plants, as well as third-party plants that BASF uses, operate according to the "Best Available Technology", BAT, described in the reference document for waste incineration (WI BREF) and adopted by the European Commission. BREFs cover the descriptions of a range of industrial processes as well as the techniques, emission levels, applicable alternative processes that can be applied. In accordance with the BAT-Conclusions to the WI BREF of Nov. 12th, 2019, general environmental and exhaust parameters were established in 5 aspects:

- a. Determination of the types of waste that can be incinerated in a specific facility.

²¹ Emission of Per- and Polyfluoroalkyl Substances from a Waste-to-Energy Plant Occurrence in Ashes, Treated Process Water, and First Observation in Flue Gas, Sofie Björklund, Eva Weidemann and Stina Jansson*, Environ. Sci. Technol. 2023, 57, 27, 10089–10095

²² ZYS-inventarisatie AVR Duiven., Houben T. and Boerleider R. (2020). ZYS-inventarisatie AVR Duiven. Royal HaskoningDHV reference number BH2652I&BRP001F01, 2 June. In Dutch.

²³ 3. Per- and polyfluoroalkyl substances and the contribution of unknown precursors and short-chain (C2-C3) perfluoroalkyl carboxylic acids at solid waste disposal facilities, Wang B. Yao Y. Chen H. Chang S. Tian Y., and Sun H. (2020), Science of the Total Environment, 705, 135832.

- b. Procedures for waste characterization and pre-acceptance which aim to ensure the technical (and legal) suitability of waste treatment operations for a particular waste prior to the arrival of the waste at the plant.
- c. Procedures for waste identification and acceptance which aim to confirm the characteristics of the waste, as identified at the pre-acceptance stage at the time of delivery to a facility.
- d. Waste tracking system and inventory which aims to track the location and quantity of waste in the plant. In the case of hazardous waste, the tracking covers the complete process until the final disposal/destruction (end-of-waste).
- e. Waste segregation which ensures that wastes are kept separated depending on their properties in order to enable easier and environmentally safer storage and incineration.

Principal measures in accordance with BAT conclusions are implemented at BASF and at disposal companies employed by BASF to ensure safe and proper hazardous waste management.

8. Impacts on Circular Economy and the Recycling Industry

One of the main goals of the European Green Deal is the transition to a circular economy. Therefore, the European Commission adopted the new circular economy action plan in March 2020. In order to fulfill those goals, a steep increase in recycling of plastic waste from various sources is required.

Today, mechanical recycling (MR) is the most commercially used technique, while chemical recycling (CR) and solvent based recycling (SBR) are treating only small amounts of plastic waste in Europe (Plastics Europe 2019). Several studies predict that CR technologies (i. e. pyrolysis, gasification, depolymerization) and SBR technologies (i. e. dissolution-precipitation, deinking, delamination) will play a significant role in the future plastic waste treatment in Europe.²⁴²⁵²⁶²⁷ These technologies are regarded as more efficient in dealing with complex waste streams.²⁸²⁹ In an extensive material flow analysis Lase et al. 2023³⁰ conclude that combining improved MR with CR and SBR results in the highest rates for plastic waste recycling. This clearly indicates that the complementarity of different technologies is needed to achieve ambitious plastic recycling targets. There are only very few studies that measured PFAS impurities in different waste streams. Those studies show a wide range of PFAS (or total fluorine) concentrations in various waste streams. For example, Roosen et al. 2020³¹ analyzed in detail the

²⁴ Crippa, M., De Smet, M., Mats, L., Rudy, K., Doorsselaer, K.V., Costas, V., De Wilde, B., Ritschkoff, A-C., Leysse, J., Wagner, M., Muncke, J., 2019. A Circular Economy for Plastics - Insights from Research and Innovation to Inform Policy and Funding Decisions. Publication Office of the European Union, Luxembourg.

²⁵ Hann, S., Connock, T., 2020. Chemical Recycling: State of Play Report for CHEM Trust.

²⁶ Man'zuch, Z., Akelyt' e, R., Camboni, M., Carlander, D., 2021. Chemical Recycling of Polymeric Materials from Waste in the Circular Economy - Final Report Prepared for The European Chemicals Agency. Plastics Europe, 2019. The Circular Economy For Plastics – A European Overview.

²⁷ Simon, J.M., Martin, S., 2019. El Dorado of Chemical Recycling - State of Play and Policy Challenges.

²⁸ Arena, U., Ardolino, F., 2022. Technical and environmental performances of alternative treatments for challenging plastics waste. Resour. Conserv. Recycl. 183, 106379.

²⁹ Cardamone, G.F., Ardolino, F., Arena, U., 2022. Can plastics from end-of-life vehicles be managed in a sustainable way? Sustain. Prod. Consum. 29, 115.

³⁰ Lase, I.S., Tonini, D., Caro, D., Albizzati, P. F., Cristóbal, J., Roosen, M., Kusenberg, M., Ragaert, K., Van Geem, K. M., Dewulf, J. De Meester, S. 2023. How much can chemical recycling contribute to plastic waste recycling in Europe? An assessment using material flow analysis modeling. Resour., Conserv. Recycl. 192, 106916.

³¹ Roosen, M., Mys, N., Kusenberg, M., Billen, P., Dumoulin, A., Dewulf, J., Van Geem, K. M., Ragaert, K., De Meester, S. 2020. Detailed Analysis of the Composition of Selected Plastic Packaging Waste Products and Its Implications for Mechanical and Thermochemical Recycling. Environ. Sci. Technol. 54, 13282.

composition of plastic packaging waste components and the total fluorine levels determined were between 0 and 46 ppm (LOD<1 ppm). A study by Arcadis “PFAS in products and waste streams in the Netherlands”³² found levels of 539 µg/kg PFAS (=0.5 ppm) in rubber. In Annex A of the restriction proposal the Dossier Submitters analyzed the use of PFAS in generic plastic packaging and plastic food packaging, which constitutes a large fraction of municipal waste. On the other hand, based on a stakeholder consultation, the Dossier Submitters estimate that PFAS polymer processing aid concentrations in various plastics normally range between 500 – 1000 ppm. This quantity is carried over from production into the product (restriction proposal Annex A page 43).³³

To the best of our knowledge, there are no efficient technologies available to completely remove PFAS from waste materials. Analytical methods are limited and usually the exact composition of the waste streams is not known as well as potentially changing over time. Also, the Dossier Submitters acknowledged in Annex A page 20 that “...in recycling, PFASs currently cannot be removed.”³⁴

Since there are many different uses of PFAS, there will be also PFAS-containing waste streams in the future – given the planned restriction with decreasing overall PFAS concentrations. Additional R&D efforts are required to improve PFAS analytics and removal technologies.

Emissions of PFAS from recycled plastics are unlikely to occur, as these small amounts are almost ‘hidden’ in the plastic’s matrix.

The PFAS restriction with the very low limit values would be a threat to the circular economy regardless of the type of recycling (MR, CR or SBR): Current recyclates and intermediates from plastic waste recycling could not be usable anymore – resulting in (i) a push for incineration of plastic waste and (ii) the manufacture of plastics and chemicals from fossil feedstocks.

In order to allow a healthy and growing recycling industry, we propose to:

- 1. exclude F-polymers from the PFAS restriction proposal (as it is already excluded from registration under REACH) or**
- 2. set the limit for residual PFAS/fluoropolymers according to the rules set forth in the regulation EC No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) leading to a sum of all PFAS or fluoropolymers of 0.1% max. However, it's important to note that other regulations may still require lower levels of specific regulated PFAS, like for PFOS or PFHxA**

Those exemptions or limits are required, as long as efficient sorting is not possible and there are significant amounts of PFAS contamination in major waste streams.

A similar issue might occur also in battery recycling. Also in this waste stream very low thresholds might pose a risk for recycling and circularity. Modern high-performance batteries often contain fluoropolymers

³² Arcadis study 2021 PFAS in products and waste streams in the Netherlands – focus on soluble PFAS.

³³ Annex A page 43: PFAS polymer processing aids are used in the manufacturing of generic plastic packaging and plastic food packaging. It is likely also used in the production of rubber and non-plastic packaging uses especially in cases where thermoplastics are used (Glüge et al., 2020). Polymer processing aids enable polymers such as PP, PE, and polyolefins to be processed (e.g., extruded) at higher rates and can also reduce energy consumption. Polymer processing aids are based on fluoropolymers (fluoroelastomers or fluorotherm), => 500 – 1000ppm in product

³⁴ AnnexA page 20: In waste treatment landfilling and incineration are the most important final waste treatment methods. Recycling can extend the lifetime but eventually for almost all substances, mixtures or articles only landfilling and incineration apply. In recycling, PFASs currently cannot be removed. It therefore can be present in recycled articles like paper or plastics.

(PVDF or PTFE) as binders. Theoretically, battery recycling processes remove PFAS, nevertheless, we can currently not exclude low level residues. All types of PFAS used in batteries are fully dissociated into fluorine compounds at the high temperatures used in the pyrometallurgical processes. Hydrometallurgical processes involve lower temperatures; however, fluorinated compounds are captured in the waste fractions, which are incinerated afterwards at sufficiently high temperatures to assure quantitative decomposition of the PFAS and prevent unintended or uncontrolled emissions. For detailed information on PFAS in batteries, please refer to the comments submitted by RECHARGE.

9. Analytical methods

For full enforceability of such a broad restriction, it is a prerequisite that a sufficient number of analytical methods is available and that these analytical methods are ready for comprehensive implementation and are accepted by authorities. So far, there is a lack of analytical methods (1) for quantitative targeted analysis (limited to approx. 40 substances for which reference standards are available), and (2) for complex sample matrices such as consumer products, reactive mixtures, and intermediates, (3) which are harmonized and standardized, and (4) available in sufficient testing capacity.

Therefore, a sufficient transition time is needed until reliable, robust, and standardized analytical methods are developed, established, and accepted by authorities. For cases where, despite the best efforts, it is not possible to develop a suitable targeted analytical method for the very low limit values proposed, the limit value of 50 ppm for total fluorine should apply.

(1) Availability of reference standards

The availability of reference standards and analytical methods with required sensitivity (proposed limit for single/targeted substances: 25 ppb) is very limited. More than 10,000 PFAS are potentially in scope, however, only a limited number of analytical reference standards (*"today ca. 40 different substances"* (restriction proposal Annex E, page 521)) is available for targeted analysis. The Dossier Submitters admitted that this is *"a key limitation of this method"* (restriction proposal Annex E, page 521): *"To quantify a specific PFAS reliably (e.g., for enforcement), an analytical reference standard for the specific PFAS must be available. Laboratories can currently quantify around 40 different PFAS, and this number is increasing as more reference standards become available."* (REACH Annex XV, page 183). Even if the number of reference standards will significantly increase the time to cover >10,000 potential PFAS is considerably long.

Therefore, for cases where, despite best efforts, no targeted analytical method is available or where it is not possible to develop a suitable targeted analytical method, the limit value of 50 ppm for total fluorine should apply.

(2) Availability of methods for complex and diverse products

For the applicability of an analytical method, the nature of the sample matrix plays a crucial role, for example with regards to the solubility of the sample matrix (e.g., solubility in water vs. organic solvent) and interferences by other substances. Taking this into account, the sum of available methods for different matrices in the low 3-digit range (Appendix E) is small. Broken down to

single groups of matrices, there are groups for which currently no analytical method is available and groups, such as waste, for which a 2-digit number of different methods are currently available. However, even within the groups of matrices, the nature and therefore the requirements for a suitable analytical method can differ significantly. For example, a method which was developed for wastewater cannot be directly applied to plastic waste. So far, method development focused mainly on environmental samples, waste, textiles, and food contact material. However, applicability of these methods to other sample matrices such as consumer products, reactive mixtures, and intermediates is limited and needs to be checked for every sample matrix. The combination of a very huge number of analytes (>10,000 PFAS) in diverse matrices from the various use fields of PFAS makes the evaluation of suitable analytical methods highly complex. Therefore, a high level of scrutiny is required by the regulators when evaluating published data. The application of methods on incompatible products/matrices will result in unreliable data. Thus, the suitability of an analytical method for a specific analyte (both a specific PFAS as well as total fluorine) in a specific sample matrix needs to be sufficiently controlled for every case as analytical data can otherwise not be used to justify any action.

Therefore, a sufficient transition time is needed until reliable, robust, and standardized analytical methods are developed, established, and accepted by authorities.

(3) Availability of standardized methods

To enforce such a broad restriction, a sufficient number of harmonized and standardized methods plays a crucial role. Up to now, the total number of standardized methods for targeted analysis is very limited. The available standardized methods focus on environmental samples (water, soil, etc.) and textiles, and thus only cover a very small part of relevant sample matrices. For untargeted analysis “*So far, there is no standardized total fluorine analysis available*” (restriction proposal Annex E, page 521).

Furthermore, even if a sensitive method was developed and would be available for single PFAS, such a method would not be ready for comprehensive implementation on the EU market, e.g., for border controls to enforce potential placing of PFAS on the EU market. In the current proposal it is stated (restriction proposal page 139): “*Enforcement authorities will incur costs for enforcing the restriction, which includes administrative and analytical or testing costs. Administrative costs thereby consist of incremental costs for staff salaries, materials, equipment, and overhead costs, while analytical costs consist of the cost for developing testing methods and conducting tests for various products to determine whether they meet the requirements of the restriction.*” The extrapolated annual administrative costs per sector are 55,000 €, which would be considered too low focusing on the potential large number of PFAS. Hence, a strong collaboration and joint investment of scientists, industry and authorities within the EU is proposed to make the analytical part of the restriction fit for purpose. A roadmap focusing on prioritization on method development and implementation is required.

All new legislations are dependent on the ability to be enforced and the enforcement is dependent on the availability of relevant data. Therefore, a potential PFAS restriction would be dependent on the availability of methods to detect and quantify the level of PFAS in products, waste streams and the environment before it enters into force.

Therefore, sufficient time is needed before a restriction can enter into force, until reliable, robust, and standardized analytical methods are developed, established, and accepted by authorities, and thus, a sufficient toolbox of standardized methods is available.

(4) Availability of testing capacity and level playing field

For full enforceability of such a broad restriction, it is required that there is a testing capacity available on a sufficient scale. Especially the targeted analysis of PFAS can be highly complex (including the specialized equipment, the comprehensive measurement, and the expert evaluation). Such highly specialized equipment and analytical expert knowledge can often not be provided by smaller, but also medium-size companies. As they do not have broad analytical capabilities on their own, they have to rely on commercial testing labs. However, the Dossier Submitters already touched on the testing capacity issue that *“For more complex questions like non-target screening, commercial labs are most often not sufficiently equipped”* (restriction proposal Annex E, page 525) and *„CIC instruments [...] are not widely distributed“* (Annex E, restriction proposal page 525). This can result in a distortion of competition when required analytical methods and capacities are only available for large companies.

Therefore, a sufficient transition time is required until testing capacity is sufficiently expanded, or simpler methods are available.

Based on these considerations, it is difficult to understand why the Dossier Submitters concluded that *“Enforceability of both RO1 and RO2 is considered to be sufficient. [...] The enforceability is partly dependent on the availability of sufficiently efficient and effective analytical methods for monitoring, which are in rapid development. [...] The broad chemical scope proposed in this dossier is beneficial to enforcement, since all PFASs are covered by the scope of the restriction proposal, excluding only a few substances which fully degrade under environmental conditions. This is beneficial in avoiding discussions on applicability of the restriction and legal uncertainties when PFASs are being found during enforcement activities. The proposed restriction may be broad, the manageability however is sufficiently practical.”* (REACH Annex XV, page 181).

For full enforceability, a sufficient time is required until reliable, robust and standardized analytical methods are established, accepted by authorities and testing capacities on a sufficient scale are build up. For cases where, despite the best efforts, it is not possible to develop a suitable targeted analytical method for the very low limit values required, the limit value of 50 ppm for total fluorine should apply.

Additional information:

PFAS chemicals and PFAS in consumables play an important role for analytical methods themselves, e.g., as solvents, additives, reagents, calibrants or for equipment components where high chemical, thermal and electrical stability is required. Therefore, a time-unlimited exemption of the use of PFAS in analytical laboratories is required to ensure high quality and safety of products and chemicals. The importance of PFAS containing substances and materials in analytical laboratories is discussed in more detail in BASF's submission Part 7/7: Uses of PFAS in analytics.

10. Specific use cases and proposals for exemption/derogation

Besides the above general remarks and proposals, BASF will submit case/sector specific responses, which will allow a more detailed and adapted discussion of the technical background, potential emissions, and available alternatives.

This submission is submission part 1 of 7 of BASF. BASF submitted 6 additional documents including confidential business information giving detailed insights in specific use cases of PFAS and requesting exemptions and derogations for those use cases.

Please find following submissions of BASF:

- **Part 2/7:** Uses of PFAS for the production of electronic materials.
- **Part 3/7:** PTFE coated conveyor belts for the production of thermoplastic material.
- **Part 4/7:** Request for the addition of an exemption of an industrial process aid under strictly controlled conditions including raw materials.
- **Part 5/7:** The use of Trifluoromethane sulphonic acid (TFMSA) as catalyst.
- **Part 6/7:** Broad uses of PFAS in chemical production plants.
- **Part 7/7:** PFAS uses in analytics.

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