Forum for Exchange of Information on Enforcement

Advice on enforceability of the Annex XV restriction proposal regarding:

“Per-and polyfluoroalkyl substances (PFAS)”

Version	Basis for the advice	Adoption
1.0	The Forum advice is done on the basis of the Annex XV report proposing a restriction published on ECHA´s website on 22 March 2023	23.10.2023

Advice of the Forum on the enforceability of a proposed Annex XVII restriction

1. Preface

According to Article 77(4) of the REACH Regulation, the Forum shall examine proposals for restrictions with the view to advising on enforceability.

This advice was elaborated according to the Working Procedure for developing Forum advice on enforceability of the Annex XV proposals for restriction and the Activity Plan of the Forum Working Group (WG) on enforceability of the proposed restriction. In March 2023, the Forum received the Annex XV report submitted by Denmark, Germany, the Netherlands, Norway and Sweden, concerning the proposal for a new entry in Annex XVII.

2. Proposed restriction

Brief title: *Restriction on Per- and polyfluoroalkyl substances (PFAS)*

Column 1: Designation of Substance, of the group of substances or of the mixture	Column 2: Conditions of Restriction
Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the restriction: CF_3-X or X-CF_2-X', where X = -OR or -NRR' and X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).	1. Shall not be manufactured, used or placed on the market as substances on their own. 2. Shall not be placed on the market in: a. another substance, as a constituent; b. a mixture, c. an article in a concentration of or above: i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification) iii. 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 4. By way of derogation, paragraphs 1 and 2 shall not apply to a. active substances in biocidal products within the scope of Regulation (EU) 528/2012 b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009 c. active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information: i. the derogation that the intended use belongs to; ii. the identity and quantity of the active substance placed on the market The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii) 5. By way of derogation, paragraphs 1 and 2 shall not apply to:

	a. polymerisation aids in the production of polymeric PFASs until 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM. b. textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c), until 13.5 years after EiF; c. textiles used in personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF; d. impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EiF; e. textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence until 6.5 years after EiF; f. refrigerants in low temperature refrigeration below -50 °C until 6.5 years after EiF; g. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF; h. refrigerants in refrigerated centrifuges until 13.5 years after EiF; i. maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist until 13.5 years after EiF; j. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives; k. industrial precision cleaning fluids until 13.5 years after EiF; l. cleaning fluids for use in oxygen-enriched environments until 13.5 years after EiF; m. clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EiF; n. diagnostic laboratory testing until 13.5 years after EiF; o. additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry until 13.5 years after EiF; p. refrigerants in mobile air conditioning-systems in combustion engine vehicles with mechanical compressors until 6.5 years after EiF; q. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF; r. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EIF; s. lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF;

	t. calibration of measurement instruments and as analytical reference materials. *The following potential derogations are marked for reconsideration after the Annex XV report consultation:* u. [textiles for the use in engine bays for noise and vibration insulation used in the automotive industry until 13.5 years after EiF]; v. [hard chrome plating until 6.5 years after EiF]; w. [foam blowing agents in expanded foam sprayed on site for building insulation until 6.5 years after EiF]; x. [industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiF]; y. [industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiF]; z. [propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF]; aa. [preservation of cultural paper-based materials until 13.5 years after EiF]; bb. [cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiF]; cc. [membranes used for venting of medical devices until 13.5 years after EiF]; dd. [use as refrigerants and for mobile air conditioning in vehicles in military applications until 13.5 years after EiF]; ee. [the semiconductor manufacturing process until 13.5 year after EiF]. 6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in: a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF; b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF; c. tubes and catheters in medical devices until 13.5 years after EiF; d. coatings of Metered Dose Inhalers (MDIs) until 13.5 years after EiF; e. proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF; f. fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF. *The following potential derogations are marked for reconsideration after the Annex XV report consultation:* g. [non-stick coatings in industrial and professional bakeware until 6.5 years after EiF]; h. [hernia meshes until 13.5 years after EiF];

	i. [wound treatment products until 13.5 years after EiF]; j. [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF]; k. [Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF]; l. [PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF]; m. [PTFE in ophthalmic solutions packaging until 13.5 years after EIF]; n. [packaging of terminally sterilised medical devices until 13.5 years after EIF]; o. [applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF]. 7. Manufacturers and importers of PFASs or PFAS containing articles as well as formulators of PFAS containing mixtures making use of any of the derogations according to paragraphs 5 b)-d) and f) – t) [and u), w)-ee)],and 6 b)-d) and f) [and h)-o)], shall from (EiF + 18 months) provide by 31 March of each calendar year a report to the Agency containing: i. the derogation that the intended use belongs to; ii. the identity and quantity of the substances placed on the market in the previous year. The Agency shall forward the information to the Commission by 30 June every year; 8. Without prejudice to paragraph 7, manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any of the derogations in paragraphs 5 or 6 shall establish a site-specific management plan which shall include: i. information on the identity of the substances and the products they are used in; ii. a justification for the use; iii. details on the conditions of use and safe disposal. The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request. 9. Paragraphs 1 and 2 shall apply without prejudice to the application of any restrictions set out in this Annex or to other applicable Union legislation.

3. Forum's advice on the enforceability of the proposed restriction

3.1 *Scope of the proposed restriction*

The proposal covers per- and polyfluoroalkyl substances (PFAS), defined by structural criteria using the OECD definition: "any substance that contains at least one fully fluorinated methyl (CF_3) or methylene (CF_2) carbon atom (without any H/Cl/Br/I attached to it)." Other provisions have been added by the dossier submitter to define exclusions from the scope of the restriction (see column 1).

The proposal is to restrict the manufacturing, the placing on the market and the use of PFAS as substances on their own and the placing on the market of PFAS in another substance (as constituent), in a mixture and in an article, in a concentration of or above:

- 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFAS excluded from quantification)
- 250 ppb for the sum of PFAS measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFAS excluded from quantification)
- 50 ppm for PFAS (polymeric PFAS included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFAS or non-PFAS.

Manufacturing, use and placing on the market are proposed to be restricted from 18 months after entry into force unless a derogation applies.

The proposed restriction is not applicable to active substances in biocidal products, active substances in plant protection products and active substances in human and veterinary medicinal products. However, manufacturers and importers of the above-mentioned active substances will have to report to ECHA every two years information related to the intended use, identity and quantity of substances placed on the market.

Several derogations have been proposed by the dossier submitter, applicable to all PFAS (see paragraph 5) or only fluoropolymers and perfluoropolyethers (see paragraph 6). Derogations are proposed for an additional 5 years (i.e., 6.5 years in total), 12 years (i.e.,

13.5 years in total) or an unlimited duration. Manufacturers and importers of PFAS or PFAS-containing articles and formulators of mixtures containing PFAS making use of some derogations would have to report to ECHA annually information related to the intended use, identity and quantity of substances placed on the market.

Furthermore, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any of the derogations listed in paragraphs 5 and 6 would have to set up a site-specific management plan, to be made available to enforcement authorities upon request.

Finally, the dossier submitter proposes to apply the restriction without prejudice to other restrictions set out in Annex XVII or other applicable Union legislation.

Issues for enforceability related to the proposed scope

Substance identification

In column 1, substance identification is based on structural criteria only. There is no reference to a list of substances or CAS numbers. The Forum considers this proposal challenging for enforcement authorities.

Scope of the restriction

The Forum interprets paragraphs 1 and 2 this way:

	Manufacturing	*Placing on the market*	*Use*
Substances	Covered	Covered	Covered
Mixtures	Not relevant	Covered	**Not covered**
Articles	Not relevant	Covered	**Not covered**

The current formulation of paragraph 2 does not cover the use of mixtures and articles. If it is the intention of the dossier submitters to cover the use of mixtures and articles, Forum suggests changing the wording as to be in line with the wording in entry 68 (C9-C14 PFCAs).

Therefore, as examples:

- when already in use, the use of a fluorinated gas containing a single PFAS will be banned, but a mixture of two PFAS will not;
- when a mixture has been placed on the market and bought before the entry into force, the mixture could still be used. If that was the intention of the dossier submitters, a clear mention could be added in the dossier.

Applicability of the restriction to articles

As PFAS have a huge variety of functions, they can be found in articles or parts of articles (i.e.: coatings). If it is the intention of the dossier submitters that the concentration limits should apply to, for instance, the coating of a frying pan, the legal text needs to be written differently. If it is the intention of the dossier submitter, a reference to the concept of "homogeneous material" (as made in the RoHS directive) could be an option.

With the current wording for an article that is coated with PTFE, the concentration of PFAS will be calculated on the whole article and not only on the concentration in the coating. From an enforcement perspective it would be easier to assess the compliance in the coating, providing the desired function to the article, rather than the whole article.

Derogations (paragraphs 5 and 6)

A lot of derogations have been proposed by the dossier submitter. The Forum urges the legislator to make the legal text as clear as possible to avoid unnecessary difficulties to enforcement authorities.

Management plans (paragraph 8)

The Forum considers that it is not clear enough what is the scope of products proposed to be covered under paragraph 8 (substances, mixtures, articles) for which importers and downstream users shall establish a management plan. For example, an importer of a fluoropolymer is clearly in the scope once the fluoropolymer is a substance. However, it remains unclear to which extent the importer of mixtures or articles containing fluoropolymers above 50ppm is affected by the provisions of paragraph 8, creating legal uncertainty for companies and inspectors.

Also, companies who refill substances or mixtures and which are considered as downstream users, will in most cases not have the information necessary to draft a "site-specific management plan".

Overlapping with existing legislation

The Forum understands that paragraph 9 is not designed to exempt already restricted PFAS (Annex XVII of REACH, other Union legislation like the POP Regulation or F-Gas Regulation) from the proposed PFAS restriction but to apply the proposed restriction in parallel ("without prejudice") in an overlapping manner and irrespective of any existing restriction or other applicable Union legislation.

Fundamental concepts of existing restrictions under REACH, POP or F-Gas Regulation are that much different, that it is difficult to assess which of the rules for a given PFAS is actually the strictest. Furthermore, the "strictness" of a rule also strongly depends on the individual context (product, use). This will to a great extent generate non-harmonised interpretations about the applicable rule for a set of PFAS/product/use which cannot be clarified by just writing additional guidance.

Examples of wordings making the enforcement difficult

The Forum draws the attention to some wording that could make the enforcement difficult, because Forum finds no legal definition in REACH or in other legislation or no common definition in reference documents. So, the exact extent of these wordings shall be not clear enough for legal enforcement. Forum gives following examples:

- "Impregnation agent" (paragraph 5d): The Forum thinks that it is unclear what properties should be expected from an impregnation agent.
- "High performance" (paragraph 5e): The Forum doesn't find any statement what minimum performance is considered as high.
- "Precision" for cleaning fluids (paragraph 5k): It is unclear for the Forum for what kind of systems to be cleaned it is applicable.
- "Drop-in alternative" (paragraph 5i): The Forum states that it is not clear what should be considered to say that is a drop-in alternative.
- "Where current alternatives damage the assets to be protected or pose a risk to human health" (paragraph 5m): The Forum has the opinion that the inspector in charge will have difficulties on judging which are the assets to be protected or which pose a risk to human health.

- "Harsh conditions" (paragraph 5s): It is unclear for the Forum what kind of physico-chemical parameters should be considered and what limit values should be defined.
- "Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required" (paragraph 5z): The Forum states that the inspector will have difficulties to judge what is a high technical performance and what level is required.
- "Cultural paper-based materials" (paragraph 5aa): It is unclear for the Forum what kind of materials should be considered.

3.2 *Sampling, sample preparation and analysis of substances*

3.2.1 Sampling and sample preparation

General remarks on sampling

Since this is a very broad restriction proposal that covers a large range of articles and many chemical products, it is hard to say if specific sampling and preparation methods are necessary and available. The number of matrices in an analytical meaning is particularly high. As a high number of polymeric analytes on articles can be expected, it remains unclear if proper sample preparation could be achieved to enforce the current restriction proposal effectively. This suspicion is supported by the limited number of laboratories, which possess the equipment for conducting these analyses and the accreditation for the procedure.

One single clear statutory definition of the sample preparation step for the purpose of the proposed restriction is key to ensure harmonised laboratory checks for PFAS concentrations. In this moment no such one single clear statutory definition of this sample preparation step is available in the proposed restriction. The Forum notes that the definition and clarification of this important step in the legislation is necessary, especially for the extraction method to be applied. One approach could be to refer to the very recent CEN standard EN 17681-1:2022-09 and EN 17681-2:2022-09 for textiles.

Sampling of fluorinated gases (F-gases)

Sampling of PFAS which are F-gases is a challenge, since it will require external specialists that may have to be certified and able to extract F-gases from equipment.

Sampling of an article, part of an article and coatings

Sampling needs to be aligned with the exact legal impact of the article definition and the related concepts as outlined e.g., in the existing ECHA Guidance on requirements for substances in articles[1]. This Guidance always applies to all articles, but the challenge in the application of this Guidance for the proposed restriction lies in the articles with a coating or in articles where a part of the article contains PFAS and other parts do not.

3.2.2 Analysis of substance(s)

About the limit values in paragraphs 2(i), (ii) and (iii)

- **The exclusion of polymeric PFAS:**
  A clear legal statement is missing regarding what limit values need to be applied for products that contain polymeric PFAS and for products that do not contain polymeric PFAS. The remark "*polymeric PFASs excluded from quantification*" in paragraph 2(i) and 2(ii) leads to the conclusion that any presence of polymeric PFAS can be disregarded for the related limit values of 2(i) and 2(ii) (25 ppb, 250 ppb PFAS). The Forum points out that in the current form, only the limit value of 2(iii) (50 ppm) can be enforced for polymeric PFAS.

  If all the limit values apply in case of mixtures and articles at the same time, the Forum suggests to clearly state this in the restriction text
  (See also below Recommendations on the wording, subtitle: Are the limit values to be applied in a cumulative manner?).

[1] ECHA, Guidance on requirements for substances in articles, June 2017, version 4.0

- **The option of prior degradation of precursors (limit of 250 ppb for sum of PFAS):**

  The limit of 250 ppb is set with an option: *"optionally with prior degradation of precursors"*. Leaving an option (of analysis with total oxidizable precursor assay (TOPA)) is always a difficult point for enforcers. Both methods (targeted analysis of the individual PFAS on the one hand or TOPA with degradation of precursors on the other hand) can give different results.

  But even more importantly, the Forum points out that the precursor itself is subject to the restriction and not the degradation product(s) produced from an intentional laboratory degradation process. The basic principle in Annex XVII is that any restriction is focused on the substance/mixture/article in the form placed on the market or used. While degradation is a fully applicable concept in restrictions like PFCAs (REACH) or PFOA (POP) due to the concept of "related substances", this concept seems intentionally not applied in the PFAS restriction proposal.

- **The limit value of 50 ppm for PFAS (polymeric PFAS included):**

  In the explanatory notes it is stated that this limit value "shall apply if targeted analysis is not applicable, e.g., in the case of fluoropolymers". The Forum points out that this needs to be clarified. Does this mean that inspectors would have to analyse for the PFAS where there are available targeted analytical methods before or in parallel to using the total fluorine method?

  This limit value requires an exact knowledge of the detailed composition of substance constituents, mixtures or articles, especially for the polymeric PFAS components, in order to assess compliance with this limit value. For mixtures with polymeric PFAS components or for mixtures with polymeric PFAS and non-polymeric PFAS (non-polymeric PFAS below the limit values of paragraphs 2(i) and 2(ii)) a clear-cut concept for compliance control is missing. This is especially relevant once total fluorine is 50 mg F/kg or below, in which case no specific information requirement by the manufacturer/importer/downstream user is stipulated.

  As polymeric PFAS are not accessible to analytical determination to check this limit value of 50 ppm, PFAS enforcement independent from documentary evidence provided by the manufacturer/importer/downstream user is not possible (see section E.4.1.4.2 in Annex E of the dossier). Additional documentary evidence on the type of polymers present will always be needed.

- **The criterion for applying "targeted analysis":**

  The criterion to decide which limit value(s) apply(-ies) is the availability of targeted PFAS analysis. The Forum considers this criterion as too unspecific to create legal certainty and enforceability. This criterion strongly depends on the development of new analytical reference standards for more and more PFAS and therefore is subject to continuous transformation ("moving target"). Substances, mixtures or articles which were considered compliant with the limit value of paragraph 2 (iii) by an inspector on day X, could become non-compliant with paragraph 2(i) or 2(ii) the next month, if a targeted PFAS analysis was validated or applied during that month.

  The Forum also signals the following problem: targeted analysis for new substances based on new reference standards have to be validated or accredited; there is a long process before new methods/standards get published and implemented in the laboratories; so, it is very probable that the application of a targeted analysis on a "new" PFAS will not start on the same moment in the different Member States. This delay in accreditation may even increase the issue of moving targets as targets could be altered before the accreditation process is finished.

<u>Limit values higher than the lowest limit of detection (LoD) or limit of quantification (LoQ)</u>

Appendix E4 of the dossier summarises many available analytical methods and their LoDs for several PFAS in several sectors of use. Despite this impressive amount of literature in the dossier there is no general clarity that the limit of quantification (LoQ) is lower than the limit values in paragraph 2, for the relevant analytical methods. Also, it is important to highlight that only the LoQ is relevant when checking for compliance.

For the parameter total fluorine (TF) it is likely that LoQ is not much lower than the limit value, certainly for screening the limit values of 2(i) or 2(ii) with the TF analysis. As there is no clear definition of the concept of TF and no clarity on the specified analytical method to be used for determination of TF, no final conclusion for LoQ << limit value 50 mg F/kg can be drawn.

<u>Standardised analytical methods necessary and available?</u>

In Appendix E4 of the dossier, very few of the listed methods are standardised ones. Even for the total fluorine analysis, for the application of the limit value of 2(iii), there are currently no standardised methods available.

There is a strong need for developing standardised methods, certainly for TF in different types of matrices. Also, for targeted PFAS analysis more standards are required.
For TF it is not clear if total fluorine (inorganic + organic) or total organic fluorine must be measured. The proposed legal text mentions "total fluorine" while in other parts of the Annex XV dossier "total organic fluorine" is mentioned.

Analytical methods to analyse various forms of TF content (inorganic, organic, adsorbable, extractable) are available but the restriction needs to clearly define which method or methods are acceptable for which type of sample, to ensure comparable results for this generic parameter.

Certain problems with analytical methods are not addressed in the dossier:

- Reference materials are not commonly available or may require special techniques of analysis (e.g., headspace gas chromatography–mass spectrometry (GC-MS) for e.g., F-gases).
- The TF content may be measured after combustion. However, especially polymeric PFAS may require very high to extreme temperatures to fully combust, which may exceed the technical limitations of conventional combustion equipment in laboratories.
- Extraction methods for the differentiation of the organic and inorganic fluorine may be very cumbersome and difficult in the case of some polymers and require special chemicals.

For the targeted analyses only approximately 100 PFAS can be determined, ca 1% of the estimated 10 000 PFAS covered by the proposed restriction. CEN standard EN 17681-1 for PFAS in textiles and textile articles, gives an overview which PFAS substances can be analysed with it. However not all PFAS substances can be analysed with this method.

It is also unclear how the sum of PFAS via targeted analysis (polymeric PFAS excluded) should be determined for compliance check, due to the lack of standardised analytical methods.

For the information requirement in 2(iii), the Forum points out that there is a need for guidance to evaluate the proof provided by a duty holder (manufacturer, importer or downstream user).

In sum, the Forum points out that:

- for the enforceability of the restriction proposal a general strategy of analysis must be developed and must become available.
- there is a strong need for developing standardised analytical methods and methods for sample preparation.

Available analytical methods carried out by conventional equipment?

Most of the methods mentioned in Appendix E4 of the dossier are using chromatography and/or spectrometry (such as GC-MS, LC-MS, GC-MS/MS, LC-MS/MS, HRMS, LC-HRMS, SFC-MS/MS, PIGE, XPS, CIC, FTIR), which is usual laboratory equipment. But even though this is usual laboratory equipment, a substantial set of such equipment will be required to carry out all these tests.

Nevertheless, these techniques refer to the identification of single substances or measure HF. This leads to the point that the analysis method is limited to the availability of reference materials (single substance analysis) or requires in many cases sample preparation. Coming back to polymeric PFAS, the sample preparation itself may demonstrate the actual problem as many of the restricted compounds/polymers are extremely stable (which is one or the main reason for the restriction).

^{19}F-NMR (fluorine-19 nuclear magnetic resonance spectroscopy) may prove a highly valuable tool in the substance identification. But for the moment, it is relatively imprecise.

The Forum considers that it is not clear if the laboratory equipment for the analytical methods for TF and even more for targeted analytical methods to be used for assessing the limit value of paragraph 2(iii) for polymeric PFAS, will be available.

3.3 *Recommendations on the wording to improve the enforceability*

Definition of PFAS

To help enforcement authorities, the Forum suggests the developing of an indicative list of PFAS in a future guidance (with the chemical structure) covered by the restriction.

Derogations

The proposed derogation in paragraph 5n lacks clarity. At first glance, it seems that the derogation focuses on reagents used for *in vitro* diagnostic devices. However, the Annex XV dossier states: "*The derogation for diagnostic laboratory testing includes precision refrigeration (blood bank refrigerator, vaccine storage), ultra-low temperature freezers or cryogenic storage, refrigerated centrifuges for sample separation, process chillers for*

precise temperature control and freeze-drying equipment. Use in in-vitro diagnostic devices is also covered."
The derogation includes reagents used for *in vitro* diagnostic devices and refrigerants in heating, ventilation, air conditioning and refrigeration (HVACR) equipment in diagnostic laboratories. For clarity, two separate derogations could be proposed.

The wording of paragraph 5bb ("cleaning and heat transfer: engineering fluids for medical devices") does not seem clear enough and does not match with the description proposed by the dossier submitter (page 11 of the dossier), where there is no mention of cleaning of heat transfer. The wording "engineering fluids for medical devices" could be used instead.

Limit values

Part of paragraph 2 should be reformulated to get more consistency. For more rigour, the Forum could propose the use of SI units instead of ppm/ppb, even though ppm/ppb has been used in entry 68.

- **Are the limit values to be applied in a cumulative manner?**

It is unclear whether the different limit values in paragraph 2 are to be applied in a cumulative manner or not (limit values linked by a logical "AND" or "OR"?). It is also not clearly stated whether one limit value may take precedence over the other. To clarify that the limit values apply independently of each other, we suggest to link the limit values with "OR".

Proposal for rewording/additions/deletions

Paragraph 4 should include the first date by which information should be given to the Agency, to make it clearer from a legal point of view to manufacturers and importers.

In paragraphs 5 and 6, some derogations are targeting uses, while most of them are targeting products. A coherence should be found for more practicability and legal certainty.

In paragraph 7, "formulators of PFAS containing mixtures" should be replaced by "downstream users formulating PFAS containing mixtures", as the word "formulator" is not defined in REACH Regulation.

The following elements should be modified:

- the reference to "degradation of precursors", in paragraph 2(ii), as it is a non-standardized concept for the laboratories carrying out analysis. Leaving an option (of analysis with TOP assay) is always a difficult point for enforcers. Different methods (with or without degradation of precursors) can give different results;
- the term "total fluorine" should be used in a consistent manner in paragraph 2 (iii);
- acronyms should be written in full, at least once, e.g., "HVACR" in paragraphs 5 (i) and (j).

When appropriate, references to existing regulations could be added (e.g., Food contact material Regulation, Medical Devices Regulation and the *In vitro* Devices Regulation), where relevant in paragraphs 5 and 6, as it has been done in paragraph 4.

Reporting requirements

The Forum backs the idea of making information coming from reporting easily available to enforcement authorities, as it is mentioned in the Annex XV dossier or the recently adopted microplastics restriction.

Even though the wording is considered practical by the dossier submitter, the mentioning of "formulators" is not providing legal certainty to enforcement, as it is not defined in the REACH Regulation.

Management plan

Given the details and aim of the management plan as provided in paragraph 8(i), 8(ii) and 8(iii) it seems that also a distributor is a relevant actor that needs to be covered by paragraph 8 (storage and handling activity). Including also the distributors will enhance consistency of the legislation and will thus support harmonised enforcement of this provision.

Overlapping with existing regulations

The Forum recommends the legislator to find coherence and clarity in the different existing legislations, in particular in the different entries of Annex XVII.

Second-hand articles

Inspection on second-hand market is always difficult for enforcement authorities. For a more efficient enforcement the Forum recommends the dossier submitter to assess whether a derogation for second-hand articles is possible. If it is possible from a risk assessment perspective, we recommend the following wording for a potential derogation: "Shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before xxx".

Use of acronyms

The Forum suggests avoiding the use of acronyms in the wording of the restrictions, unless clearly defined, to avoid misinterpretations.

3.4 *Practicability/Enforceability/Enforcement costs*

3.4.1 Enforceability

The Forum considers that the proposal in its current form will be challenging to enforce. Significant improvements are needed in the availability of standardised analytical methods and in supplying additional guidance. NEAs will require additional expertise, e.g., because of the proposed derogations for specific uses in many sectors of industry.

Analytical methodologies used for monitoring programs are in a high number of cases not sufficient. Especially with the broad field of polymeric PFAS on the horizon this issue marks a serious challenge to enforcement.

Also, certain parts of the proposal require rewording or redefinition, as mentioned above, to make it more enforceable.

A specific problem is detected when enforcing distributors, since following the current text of the proposal, the information requirement in paragraph 2(iii) only applies to manufacturers, importers and downstream users, not to distributors.

PFAS are already regulated in various other legal acts (POPs regulation, F-Gas regulation, CFCs regulation), complicating enforcement. At least the restrictions on PFAS within REACH Annex XVII should be consolidated in the universal PFAS restriction once this restriction enters into force. Also, guidance on the interaction of the restriction with obligations of POPs, F-Gases and CFCs would be useful.

3.4.2 Practicability

The Forum detects important challenges on the practicability:

- it will require a significant amount of manpower, highly equipped laboratories and potential new and substantial guidelines from official agencies to ensure the harmonised enforcement of the proposed restriction;
- the limited number of laboratories, owning the equipment for conducting all the necessary analyses, could be a bottleneck for enforcement;
- even the initial question "PFAS or non-PFAS?" requires expertise and additional new tools for the NEAs in the field (e.g., name to structure converters etc.) are needed;
- sampling, analysis and interpretation of the results may require the additional help of experts, tools, etc.;
- the high number of proposed derogations together with the large number of substances and types of materials, implies that NEAs will require a large amount of research by inspectors; enforcing this restriction will be more time- and resource-consuming than NEA's often have available;
- sampling of F-gases can be difficult.

3.4.3 Enforcement costs

The Forum expects that the overall costs of enforcement will be significantly higher than for usual restrictions with a more targeted scope, because of the very large number of substances, mixtures and articles, their widespread use, the difficult sampling, the expensive analyses and the required manpower and expertise.

In section 2.4.1.2 of the Annex XV dossier there is an estimate of the administrative enforcement cost of around €55 000/annum/sector. The Annex XV dossier does not specify whether the figure of € 55 000 is per EEA state or the figure is for all the EEA states together. In case of the latter Forum has the opinion that this will be a major underestimation of the costs. The Dossier Submitter has confirmed that the €55k value is per sector per year **for the whole EEA**. It represents the average incremental (i.e.,

additional, not total) administrative costs for enforcing restrictions and is based on an average cost per control (inspection) and an average number of controls per restriction (based on numbers of controls over the period 2010-2014 reported by Member States, reporting under REACH art. 117 / CLP art.46). It includes administrative costs of inspections but not testing costs.

There is also a comment in this section 2.4.1.2 about costs for developing analytical methods. The Forum wants to emphasise that it is not the task of the enforcement authorities to develop analytical methods.

3.5 Miscellaneous

Need for decision tree and guidance

Considering the complexity of analysis of products, a decision tree could be helpful. A guidance is also necessary to cover all aspects of the restriction and should be published before the entry into force of the first provisions, if possible. A guidance covering POP and REACH Regulation could also be a valuable option for inspectors.

Need for development of analytical methods

The Forum encourages the legislator to engage in developing new analytical methods.

Recommendation for grouping/ranking the derogations by the transitional period

For greater clarity, a grouping of the different derogations proposed in paragraphs 5 and 6 by the length of transitional period in 3 groups (time-unlimited and time-limited with 6.5 or 13.5 years after EIF) could be considered.