Maisons-Alfort, le 18/08/2023

# ANSES COMMENTS ON THE PROPOSAL FOR RESTRICTION RELATED TO PFAS (ANNEX XV RESTRICTION REPORT)

## GENERAL COMMENTS ON THE CONTENT

**ANSES fully supports the work performed in regard to the proposal to restrict PFAS to protect the environment and the human health of current and future generations. PFAS and/or their degradation products are very persistent, exceeding by far Annex XIII criterion for persistence of the REACH Regulation. PFAS and their degradation products have been demonstrated to persist in the environment longer than any other man-made chemical. Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. PFAS enter the environment via emissions during manufacture, the use phase, and the waste stage. The continuous release of these substances has led to increase the environmental stock concentration as their degradation (mineralisation) is almost inexistent under natural conditions. By contaminating every environmental compartment, PFAS and their degradation products contaminate biota, including humans as demonstrated by biomonitoring studies and threaten human health. PFAS exposure has been demonstrated to lead to adverse effects through interaction of certain PFAS with the hormone system, adverse immune effects, organs impairments, potential carcinogenicity and reprotoxicity. In that respects, Anses fully supports the work performed with the objective to decrease to the maximum extent the emission and exposure of the environment and human health to PFAS in Europe.**

The dossier is well structured, well documented and easily readable, with a substantial bibliography providing a comprehensive overview of PFAS and the PFAS restriction is argued in depth.

Some remarks can be made regarding the main annex XV document and the annexes and will be developed along this document. The main and fundamental remarks concern :

***Regarding the proposed legal text:***

It is unclear why paragraph 1 of the proposal does not ban the manufacture of substances which have PFAS as constituents.

In the column 2 of the proposed restriction, the paragraph 2 indicates “shall not be placed on the market in:

A. Another substance as a constituent,

B. A mixture
C. An article”

It may also be included that PFAS may be present as impurities or contaminants and that needs to be forbidden as these quantities can be quite important and that the whole objective of the restriction is to decrease as far as possible the emission and release of PFAS to the environment. This is especially the case as it is argued that some PFAS are used as polymerization aids to form fluoropolymers that are not included in the restriction proposal. These polymerization aids may be still present in the fluoropolymer formulation to quite a large extent and contribute to the dissemination and contamination with PFAS.

Paragraph 5 includes derogations for (n) diagnostic laboratory testing and (t) calibration of measurement instruments and as analytical reference materials. It is not clear whether these uses would fall under the category for “Scientific Research and Development”, which are exempt from restriction under REACH. The implication on these slight differences in consideration and in wording is important and needs to be clarified to ensure the proper application as targeted by the restriction.

In the paragraph 7 of the proposed entry, the wording “formulator” is used while it is not defined in REACH nor in the proposed entry. It should be very clear what is intended by “formulator” to avoid any misunderstanding. According to the explanation provided in page 12, it is indicated that only the first formulator will be impacted by the restriction. Anses is of the view that all the formulators and the supply chain should be integrated in this restriction. Indeed, during the formulation, some PFAS could be added through the process to the article and/or the substance and /or the mixture. It could be also important to define this word in the proposal to ensure the full clarity of what is intended.

Regarding paragraph 8 of the proposed legal text concerning site-specific management plan. No further information is provided in the dossier. The Dossier Submitters (DS) are recommended to provide an explanation on what this requirement is intended to achieve and to detail it more in the annex XV dossier.

- ***Scope of the restriction proposal:***

According to the Dossier Submitters, there are a few specific PFAS subgroups with certain structural elements that are fully degradable and cannot form persistent PFAS arrowheads. These substances contain the following structural elements: CF3-X or X-CF2-X’, where X = OR or -NRR’ and X’ = methyl (-CH3), methylene (-CH2-), 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 (-CH2-), an aromatic group or a carbonyl group (-C(O)-). The underlying hypothesis is that complex molecules attached to a degradable moiety will degrade into the corresponding non-persistent substances. This hypothesis is not sufficiently substantiated and uncertainties remain on these possibilities. DS does not explain how different chemical structures (branching and alkyl chain length) would affect degradation rates and pathways of different substances. The DS could clarify why X’, R, R’, R’’, R’’’ do not include other structural carbon atoms besides methyl and methylene and this can impact the whole degradability of the structure. Generally speaking, how the determination and exclusion criteria for degradable PFAS have been defined needs to be substantially detailed as it is not sufficiently clear in the text and has to be done to ensure a common acceptance of exclusion criteria of some structures. Neither hydrolysis data alone without assessing the hazards of the degradation products, nor rapid degradation in one compartment or degradation under very specific conditions are sufficient to consider a substance automatically as non-persistent in all environmental compartments

(water, water-sediment and soil) for relevant conditions. These environmental issues and the results of the corresponding studies presented clearly show that it is absolutely essential to continue research on these chemicals, as their behavior in the environment is multifactorial. Regarding the use of modeling in e-fate studies, the document highlights that abiotic degradation prediction is of low reliability for all analyzed PFAS in water, sediment and soil and consequently, cannot be used in support to the decision. The document also looks at the degradation products PFAS compounds, regarding them as a class of chemical compounds that absolutely must be monitored and studied within the various environmental matrices.

- ***FFF fire-fighting foams:***

A restriction was just approved by RAC and SEAC and it could have been useful to include some descriptive elements into the universal restriction proposal on PFAS in order to have a full view on these substances, there uses, hazards and risks and how they are managed. Moreover, by providing data on FFF, the reader will have a better representation on the concerned tonnages and the multifactorial implication of such a ban proposition. The proposal on FFF could have been discussed as it was done for PPP, BP or MP.

- ***Regarding PPP, BP and MP:***

A full derogation is not acceptable as specific authorisation processes are available under their respective regulations and strictly related to the use of these substances in specific conditions. It is also observed that these regulations (especially MP regulation) do not fully consider risks related to the persistence of the compounds in the environment and that this critical hazard will remain through time. As this parameter (persistence) is the main justification of the restriction proposal it seems inconsistent to promote a time-unlimited derogation for active substance who are persistent. This is particularly important as one of the major metabolite of PFAS is TFA and that TFA is known to be extremely persistent in the environment. Allowing a permanent derogation can potentially give the opportunity to promote the use of these substance and indirectly allow the entrance of new PFAS in the market of PPP, BP or MP and later promote their misuse. Moreover, several alternatives are available for fluorinated PPP and BP and this should have been more substantiated in the annex XV report. It should be more clearly stipulated that these active substances, under their specific legal text approval, are assessed and that authorisation of uses is granted for a certain period of time and that reassessment occurs. It should be made clearer in the text that this permanent derogation do not correspond to a permanent derogation as such but to a derogation under REACH that does not preclude the control by dedicated regulations. It should be also made clearer that this derogation means that derogation of production and manufacturing applies if these substances are used as active substances under any of these respective regulations. It could be also made clearer what amount and how many products containing PFAS it involves.

- ***Regarding the Concentration limits :***

The values determined by the DS for the concentration limits are not sufficiently explained, and the rationale for their selection need to be improved and substantiated. Precision in regard to the objects in which it is measured (articles, mixtures, substances …) needs to be clearer and better explained. Regarding the last value of 50 mg F/kg, this value is really higher than the two previous ones and it should be more substantiated how it will be technically possible to ascertain that it can be directly related to F of PFAS and not to other substances. Moreover, the possible misidentification linked to analysis and the non availability of standardized

methodology needs to be more substantiated and detailed for a proper full application by enforcement authorities.

- ***Regarding SEA:***

The DS have made choices in their estimations that lead to underestimate the benefits of the restriction and overestimate the economic impacts for the industry (see i.e. Main report § Summary / socio-economic analysis *The emissions during the waste phase, […] are not accounted for […], it can be assumed that emission estimates are severely underestimated*). When DS make choices as a basis for calculation, they lead to favor the industry. (see i.e. Annex E § E.2.2.1). In the baseline scenario, the use of PFAS in the TULAC sector is growing according to the previous trend, i.e; 2%/year. The DS do not consider that the industry could limit the use of PFAS because of NGOs pressure (as observed in the sector of outdoor wear) § E.2.1.4.1. Economic impacts: Producer surplus losses: *[…] the closure of all production facilities in the EU-27 is taken by the Dossier Submitters to estimate an upper boundary of the potential producer surplus losses;* § E.2.9.1. Medical devices*: The market for PFAS applications in the medical sector is assumed to grow considerably in the short- and medium term. For instance, the use of prescribed PFAS-pharmaceuticals in the EU in 2019 is estimated to increase with 3.4%/y by the Dossier Submitters. For European anesthesia drugs a growth of 5.5% is expected between 2020 and 2025107. Furthermore, positive growth rates are expected for fluoropolymer invasive use as well as medical packaging (mainly fluoropolymers). For other PFAS applications in this sector, there is no reliable information about market trends. As a conservative approach a yearly real growth rate of 5% was assumed at sector level for assessing emissions under the baseline, and under the different restriction options.*). Thus, the evaluation of economic impacts for the industry can be seen as conservative.

The DS do take into account a disutility for the consumer if the quality of the product gets lower without PFAS. However, they do not consider the value a consumer is prone to give to a PFAS-free product. The examples of the communication of the German company for outdoor equipment Vaude about its commitment to eliminate PFAS[1], or the results of the Greenpeace campaign on the reduction of hazardous chemicals rejections[2], suggest that consumers give value to sustainable products. Therefore, the restriction could have a positive impact on consumers' utility while providing PFAs-free products (even with a potential lower functionality) and at least a share of the consumers gives value to the availability of these products.

Linked to the previous comment: In the description of the baseline, the DS do not consider that today most consumers are not aware of the large use of PFAS and their adverse effects on health and environment. We could state that in the absence of any restriction, the knowledge of the effects of PFAS would increase, making the consumers of PFAS-based products more aware of the risk to their health and the environment, thus decreasing their utility and willingness to pay for such products. Thus, the baseline situation would be worse than expected, reducing the negative impact of the restriction.

The DS do not take sufficiently into account the cost of depollution of sites or environment in their assessment. These costs could increase if more PFAS are used i.e. if PFAs uses are not restricted further. Thus, a restriction might reduce the cost of depollution. Moreover, the ecosystemic services to support human health are not assessed in regard to the impact of

[1] PFAS in outdoor products: What you need to know! (vaude.com)
[2] https://www.greenpeace.org/international/publication/17612/destination-zero/

PFAS, for example in soil health and ability to provide good growth support to plant and the potential impact in decreasing production linked to landfilling of contaminated sludges.

**On the basis of the comments above, we suggest to more broadly integrate the cost of inaction (i.e. the impacts of PFAS without a restriction) in the baseline to permit a more comprehensive view of the impacts of the restriction proposal.**

## DETAILED COMMENTS ON THE CONTENT

### MAIN REPORT

The EBITDA and EOR definitions are lacking in the abbreviation list.

The term durable is used in the manuscript, which is confusing as it gives the impression that the concerned sector and material are “greener” than they actually are. The term long life, or long service life….could be considered.

Some numbers in the corresponding tables which are normally linked, table 1, table 3, table 8-9, table 11, are not always corresponding and some mistakes seem to be present. This has to be checked.

Page 39: the paragraph related to PFAS formed as by products should be more explained. The DS indicate that these PFAS formed as by-products are not taken into account in this restriction but a more thorough explanation is necessary. Indeed, these PFAS could be a huge source of contamination in the environment and for human health and at least, a qualitative estimation could be useful.

Page 41: 1.1.5.4, Table 1: Even if the DS consider that a permanent derogation is necessary for PPP, BP and MD, it could have been useful to estimate in the table what represents this derogation in term of annual emission. It could have been useful to do the same for FFF in order to be able to have a full global view and estimates of the problem of PFAS.

Page 42: 1.1.5.5. Emissions from waste management. Are destruction processes established for any equipment (consumers, professionals...) in parallel to the restriction report?

Generally waste need to be considered in more details in the assessment especially as the approach is a stock based approach and that the main risk arises from the vP properties of the substances. Recycling is evocated in the section dealing with waste, but if this occurs, the material is no more considered as a waste. The sentence is not sufficiently clear in this situation. Moreover, as detailed before, it brings the question on how to manage second hand articles or recycling products, whose answer is not sufficiently substantiated in the report. An important point of the restriction concerns waste management. First, there is the problem of landfills and the presence of PFAS at very high concentrations in leachate. These high concentrations pose downstream treatment problems at wastewater treatment plants, since the processes currently present do not allow efficient treatment. On the second hand, the document highlights the difficulty of fully degrading PFAS via the mineralization process in waste incineration plants, since the vast majority of waste treatment plants by incineration - with the exception of certain hazardous wastes- are not equipped with ovens capable of rising to temperatures close to 1800 to 2000°Celcius. The Annex XV report therefore highlights here

a major present and future environmental problem, which must therefore be taken into consideration regarding the ban on PFAS in Europe. The DS may have taken into consideration these problems to make some proposal in the restriction proposal or to highlight it clearer to the decision maker for further action to tackle this problem.

Page 48: 1.1.6.1. It could be made more explicit that it is possible to exclude a PFAS from the scope of the restriction only based on sound evidence that the specific PFAS is not very persistent itself and does not degrade into a very persistent PFAS.

Page 51: 1.2. More emphasis could be made on the fact that the restriction is useful but that there is a need to go farther and act more globally to solve this problem.

Page 54: 1.3. Information on how market growth is estimated need to be provided and explained in more details in order to agree on the proposed numbers.

Page 57: 1.3.2. Even if the DS consider that PFAS in PPP, BP and MP should be providing a permanent derogation for manufacturing and uses, indications on emissions and growing market inside UE are important informations to provide and detail. It will help to properly estimate the impact of granting such a derogation.

Page 63: 2.2. It could have been mentioned here that the Stockholm Convention is the most efficient regulation to manage PFAS and that the current work is a good starting point to later try to obtain the inclusion of all PFAS into the convention.

Page 65: 2.2.1.3. These data allow to identify that it is a huge problem for global warming that this type of chemical (CFC 113 and HCFC 22) are not covered by the Montreal protocol. It could have been of huge interest that this restriction proposal proposes to remove this gap by including them into the scope of covered substances, especially as they share common structures and properties. Especially knowing the huge impact that these chemicals cause in global warming. It also could have been a proposal for the decision makers to have a closer look to these chemicals and to propose some specific management measures as the DS identify the problem linked to the release of these substances.

Page 66: 2.2.1.4; An update of the MAC directive could be useful for guiding manufacturers to find better solution for air cooling and avoid the use of refrigerant gases with really high GWP.

Page 72: 2.2.3. The impact of a permanent derogation of PFAS in PPP, MP and BP should be more detailed and assessed. The derogation can potentially promote the market for this type of active substances and increase the market. Moreover, a substance with a market authorisation can be misused for its other properties (such as grease repellence) and it will have an important impact in market flow and utilization. As specific authorisation procedures exist, why not combining specifically PPP, BP and MP regulations to this restriction proposal by allowing a specific time derogation linked to derogation already being possible under these regulations. Moreover, lots of alternatives are already available (as demonstrated in the annexes) and allowing a permanent derogation will not favor R&D to find better solutions to these substances in any of the concerned regulations. Moreover the derogation regime available in these regulations may allow the possibility to continue to use substances that fulfill exclusion criteria on the basis of especially alternative availability and socio-economic considerations. Inclusion of PFAS in Stockholm convention will increase R&D and be an important driver for substitution of these chemical in PPP, BP and MP.

Page 77/78: Details should be provided on the choice of a 5- or 12-years derogation time. Moreover the difference between the 5- or 12-years derogation time proposed in the text and

the fact that it corresponds to a 6.5- and 13.5-years derogation time in the legal text should be substantiated and clearly detailed.

*Table 8. RO1 / Professional apparel (including PPE) (p.83). (Professional apparel). For most uses (except some PPE), there is sufficiently strong evidence that technically and economically feasible alternatives exist*. However, the expected impact is "*high producer surplus losses as a result of business closures [sufficiently strong evidence]*". Does that mean that firms are more likely to end their activities than substitute? Why such an expectation since alternatives seem to exist? Is it due to the prohibitive costs of alternatives? Please provide more detailed justifications.

Page 148: 2.4.3.3.g. As there is evidence of viable alternative, the proposed derogation seems not acceptable.

Page 159: 2.4.4. Depollution and remediation costs could be more taken into consideration in regard to the costs to society and the benefice of the restriction in regard to the potential decrease of this burden for society. Often, it is not the industry at the origin of a pollution who later pays for the depollution but society. In that respect, the advantage of the restriction proposal in regard to the huge costs of depollution should be more compared and detailed.

Page 187: Uncertainties. The technical stock, and the stock in general need to be more considered in general, and especially in the uncertainties.

One of the main uncertainty is related to the derogation regime. The derogations were proposed solely on the criteria of an absence of a sound alternatives without considering other factors such as hazards, emission, costs, performance and combination of all these factors. One of the possible factor to judge on the necessity of a derogation could have been the essentiality of uses and the consideration of all other cited parameters.

## ANNEX A

Page 9, Table A2: regarding HFC 365mfc, it is said that tonnage is confidential and a number was indicated in the following text. Moreover, in the table we are not sure if it represents 10 000 or 100 000 tpa. Later, page 14, the EEA is the only region that produces HFC-365mfc, with 15 000 t produced per year (Stemmler et al., 2007). This needs to be clarified.

A.3.12.1. Uses : line 4, a P is lacking to Properties

As many values are estimates, central bond estimates are provided but it could be useful to provide lower and upper bond estimates also. (table A50 and A51, A55 and A56, A58).

Table A.61. Main PFAS uses in petroleum industry. In fact it is not a list of PFAS but a list of their applications.

A.3.17.2.Volumes of PFAS in PPP

Estimation is based on NL volumes of pesticides and there is no direct numbers. Why focusing on NL? Why not another country that potentially use more PPP to be more representative of a worst case? This may lead to underestimation of volumes and should be justified and discussed.

Especially as no data is available for BP, a more strict assessment needs to be done to ensure the right scale of the obtained value.

In table A109, you provide the date of approval; The date of end of approval could be also provided for knowing when dossier is expected to be updated and when it will go back to ECHA for reapproval.

When reading the battery analysis of WEEE, what comes in mind is that there is a need to deeply recommend modification of legislation so that batteries are not fixed or sealed to make easier their replacement.

What is observed is that also many directives are outdated and need to be updated, such as WEEE, waste framework directive, WWTP, ELVs, …

**ANNEX B**

In this part, no inconsistencies or gaps were identified requiring modification or additional information. On the contrary, it is important to emphasize that this part of the document is extremely well written and full documented, with a recent bibliography highlighting the environmental issues underlying PFAS and the latest findings in the scientific literature. This link between environmental issues and the results of the corresponding studies presented clearly shows that it is absolutely essential to continue research on these chemicals, as their behavior in the environment is multifactorial. Regarding the use of modeling in e-fate studies, the document highlights that abiotic degradation prediction is of low reliability for all analyzed PFAS in water, sediment and soil and, consequently, cannot be used in support to decision. The document also looks at the degradation products of PFAS compounds, regarding them as a class of chemical compounds that absolutely must be monitored and studied within the various environmental matrices.

Moreover, an important point of the restriction concerns waste management. First, there is the problem of landfills and the presence of PFAS at very high concentrations in leachate. These high concentrations pose downstream treatment problems at wastewater treatment plants, since the existing processes do not allow an efficient treatment. On the second hand, the document highlights the difficulty of fully degrading PFAS via the mineralisation process in waste incineration plants, since the vast majority of waste treatment plants by incineration - with the exception of certain hazardous wastes- are not equipped with ovens capable of rising to temperatures close to 1800 to 2000°Celcius. The Annex XV report therefore highlights here a major present and future environmental problem, which must therefore be taken into consideration regarding the ban on PFAS in Europe. This is directly linked to the management of waste, which is not the subject of this restriction proposal, for the substances with these properties and this matter is of first importance and really needs to be tackle by the decision makers. Further, part B.4.5.8 of the Annex B presents a situation of concern regarding the treatment of PFAS in wastewater. First of all, several studies showed that conventional wastewater treatment has a limited efficiency in removing, both, short-chain and long-chain PFCAs and PFSAs compounds. The accumulation of PFAAs from precursors in waste water treatment plants is highly dependent on process temperature and treatment type. High rates of accumulation of PFAAs were observed in plants operating with biological processes at longer hydraulic retention times and higher temperatures. Second, as the restriction points out, a major source of PFAS contamination of soil and water originates from the spreading of wastewater treatment plant sludge. Again, the document describes the problem well and specifies that these data must be taken into account. Finally, from an analytical point of view, the document specifies that special attention will be required in the development of sampling of effluents and sludges from wastewater treatment plants.

B.4.5.4. Drinking water treatment

Last paragraph, please correct accordingly (red mark): « It has to be noted though that the experiment was so far only conducted under Lab conditions with a pure PFCA solution and that during the treatment also TFA was formed (Trang et al., 2022)."

B.4.5.8.Wastewater treatment

Sampling strategies, please correct accordingly (red mark): (e.g. sampling at high or low flow periods and seasonal effects (Guerra et al., 2014; Sinclair and Kannan, 2006)).

Regarding emission from the FCM, as a high number of data is lacking, it is recommended to use the HIGh estimate to be closer to the worst case scenario than the middle estimates.

Estimating the same amount of uses and releases for PFAS in consumer products is supported as the good way to proceed.

B.9.18.2. Overview of waste stage emissions

Please correct accordingly (red mark): The Dossier Submitters consider waste stage emissions for PFAS uses in the following sectors: TULAC, food contact material and packaging, construction products, transportation, medical applications, HVACR, electronics and semiconductor, and energy. These sectors are given a high priority for the assessment, based on anticipated waste volumes containing PFAS.

Regarding waste, we deeply recommended to add a recommendation to treat waste in incineration system, mainly in hazardous or cement incineration centers to ensure the maximum elimination of PFAS. In addition, it is recommended that the use of PFAS-containing sludge in landfill is further addressed in appropriate regulations.

More generally, the available data contribute to demonstrate that, although important risks will be addressed by the restriction, further risks related to PFAS will remain and warrant further considerations in the appropriate contexts. The following points are identified:

- For water production for human health based on potentially contaminated water, the use of high pressure nanofiltration potentially combined with high energy UV treatment is recommended to remove to a maximum extent PFAS.
- A preconcentration step can be recommended for leachate for example by sorbent in landfill before an incineration, to ensure full elimination of PFAS.
- One of the important learning from this annex is that specific routes for waste management of PFAS should be developed. In particular, it could be recommended that all PFAS waste should be treated in hazardous waste incineration centers or burnt in cement facilities in order to reach sufficiently high temperature to ensure their degradation.
- Moreover, a strong emphasis should be made to stop the landfilling of PFAS as increasing the environmental stock raise problems in the long-term.
- Last but not least, the use of sludge in land as fertilizers should be reconsidered as they are deeply contaminated with PFAS and contribute to the widespread of this pollution and to contaminate remote places, land, food and human.

**Annex E**

Please consider the following comments to refine the assessment.

**PFAS manufacturing.**

E.2.1.4.1. (p.11). *In case of a full ban the Dossier Submitters expect most production facilities in the EU-27 to stop operating after entry into force of the proposed restriction*. Do the local plants only produce PFAS? What would be the opportunity to convert the plant for another type of production?

E.2.1.6. (p.12). *The evidence is sufficiently strong that technically and economically feasible alternatives for PFAS production* ***are unavailable for the quantities required*** *and that the substitution potential is low under RO1 and RO2. Does* the evaluation of the insufficient quantities take into account the restriction (i.e. if PFAS use is restricted, fewer PFAS are needed; and if PFAS are fully banned, no PFAS are needed)?

**TULAC**

E.2.2.2.1. (p.18). The DS consider that a company can either substitute or close. Could we suggest that companies may divert their activity to other productions (i.e. no substitution) or reduce their activity without closing, especially if they do not produce PFAS-based products only?

Table E.21. (p. 59). The table indicates *possible negative implications on share of affected companies opting for substitution.* If shares are lost for companies opting for substitution, we may expect positive implications for the companies gaining market shares (the ones that have already substituted?), which could compensate (or partly compensate) for the negative impact. This positive impact may be taken into account.

E.2.2.4.3. (p. 85-86). *Given the high total number of affected companies in these sub-sectors and the significant share of business closures costs associated with employment losses might be substantial*. Here again, the job losses due to business closures may be compensated by recruitments in the companies gaining market shares and this potential positive impact seems not to be taken into account.

**Metal plating and manufacture of metal products**

Table E.63. (p. 205), line Full ban. *High producer surplus losses due to a significant share of business closures [weak evidence]*. Since evidence is weak, can producer surplus losses be qualified as “high”? We suggest mentioning *producer surplus losses due to a significant share of business closures [weak evidence] without qualifying them as “high”.*

**Cosmetics**

E.2.6.2.1. (p.221). For information, two smartphone applications are available in France to check the composition of cosmetics: quel produit (Appli QuelProduit - Une application gratuite pour choisir ses produits alimentaires, cosmétiques et ménagers - Application mobile - UFC-Que Choisir) and Yuka (https://yuka.io/).

**Applications of fluorinated gases**

E.2.8.4.3. (p.273). The DS mention legacy burdens that *arise through the use of materials that will need to be managed over long (inter-generational) periods*. However, in the circumstances of the evaluation of PFAS, it relates to persistent pollutants that will persist in the environment for decades or centuries, we suggest mentioning legacy burdens for all PFAS uses.

**Medical devices**

E.2.9.2.1. (p. 321). *In most cases these alternatives are more comfortable, softer or cheaper but have not been a useful solution for the user, implying that RGP contact lenses have superior characteristics*. It is not clear what the DS mean by “useful”. For what reasons are the

alternatives not useful given the characteristics mentioned (more comfortable, softer, or cheaper)? Did the consumer have the opportunity to choose between different alternatives?

E.2.9.4.4. (p. 333). *The Dossier Submitters note that the information obtained indicates that a ban on PFAS in these applications would lead to more procedures that are more invasive and/or more painful for the patient*. It is not clear if the alternatives to PFAS would be fewer catheters or more painful catheters. The evaluation of the impacts on public health does not take into account the preferences of patients between more comfort and more toxicity. Therefore, we suggest associating uncertainty with the evaluation of the socio-economic costs.

E.2.9.4.9. (p. 335). *Further justification on the severity of the quality-of-life reductions and the increased costs due to more frequent replacements of eyeglasses is required to conclude on the magnitude of the socio-economic impacts of a ban on PFAS in these applications*. The DS suggest that the ban on PFAs applications would lead to *more frequent replacements of eyeglasses*. Based on this statement, it may be expected that companies selling eyeglasses would increase their turnover (by selling eyeglasses more often) and may increase employment consequently; this impact does not seem to be taken into account. The impact would be negative for consumers though as they would need to buy eyeglasses more frequently. The same comment applies to lubricants that would need to be applied more often (E.2.14.4.3. (p. 488)).

**Suggestions on the content**

Anses suggests an additional condition for the restriction proposed by enforcing a mandatory labelling of any product containing PFAS to inform on the risk of pollution and recommend adequate waste disposal (for an example of such a labelling, see Annex XVII of REACH https://reach-info.ineris.fr/sites/reach-info.gesreg.fr/files/pdf/1_annexe_xvii_2022.pdf page 15, entry 23. Cadmium, condition 4).

**Suggestions on the document format**

Anses suggests providing a navigable detailed table of contents that could be displayed in the margin of the pdf document and numbering the lines of the document to facilitate review.

In Annex E, Anses suggests harmonizing the denomination of the restriction options (in some cases, they are described as RO1 and RO2 like in E 2.1, in other cases they are described as “full ban w/ a transition period of 18 months” and “ban use-specific derogations” like in E.2.2.5).