

This document contains RAC's evaluation of sector-/use-specific aspects. It should be read in conjunction with the Committee's evaluation of the general elements of the proposed restriction, which is documented in the *RAC Opinion*.

Committee for Risk Assessment (RAC)

Evaluation of sector-/use-specific aspects of the opinion
on an Annex XV dossier proposing restrictions on
Per- and polyfluoroalkyl substances (PFAS)

Cosmetics

Date: 2 March 2026

RAC
COMMITTEE FOR RISK
ASSESSMENT

RAC EVALUATION OF SECTOR-/USE-SPECIFIC ASPECTS OF THE
OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON
PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

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R-0. Overview of the sector

This sector covers specific uses of PFAS related to cosmetics including:

- Cosmetic products containing PFAS¹
- Use of TFA in the synthesis of peptides as cosmetic ingredients²

R-1. Emissions and exposure

Relevant sections of the Background Document:

The uses, volumes and emissions of PFAS in the “Cosmetics” sector have been summarised in Annex A.3.7 and B.9.7 of the Background Document.

RAC conclusion(s):

- The scope of the assessment is sufficiently well defined for RAC to evaluate the volumes/emissions.
- RAC notes that there are moderate uncertainties related to the estimated volumes of PFAS used in cosmetic products due to: (i) the lack of representativeness of the market data as a result of the low number of products analysed in the underpinning study (KEMI 2021), and (ii) the limited scope of the overall methodology which targets only PFAS that are intentionally added to cosmetic products and listed as an ingredient. This may result in an underestimation of the volumes in use.
- Despite the above-mentioned uncertainties regarding the estimated volumes of PFAS used in cosmetics products and considering that there is no further information available to allow for a better estimation, RAC considers that the volume estimates of PFAS used in the “Cosmetics” sector (ca. 400 t/y) are an acceptable basis for the emission estimate.
- Particle emissions are likely to occur but have not been quantified due to lack of data.
- Regarding emissions, RAC notes that the Dossier Submitter estimated the release of PFAS resulting from the manufacture of cosmetic ingredients based on the volume of TFA used to manufacture peptides. RAC notes that the Dossier Submitter took into account (i) emissions of residual TFA in cosmetic products resulting from the manufacture of peptides and (ii) emissions from the waste management of TFA after peptide synthesis. RAC estimates emissions of approx. 0.1 t/y from residual TFA in cosmetic products resulting from the manufacture of peptides and of 7.2 t/y from the waste management of TFA after peptide synthesis.

¹ In some parts of the Background Document and the RAC Opinion, this use is also referred to as ‘Uses of PFAS in cosmetic products’ or just ‘Cosmetic products’.

² In some parts of the Background Document and in the RAC Opinion, this use is also referred to as ‘Manufacturing of cosmetic ingredients’

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- RAC notes that there are several uncertainties in the calculation of emissions, mainly due to: (i) lack of consideration of formulation phase, (ii) lack of consideration of solid waste management and (iii) uncertainties regarding the PFAS volumes in cosmetic products.
- Nevertheless, RAC considers that the estimated emissions (midpoint estimate ca. 40 t/y) provide an acceptable basis for risk characterisation.
- RAC also refers to the RAC Opinion regarding specific considerations around waste stage emissions (see section 3.1.2 of the RAC Opinion). Emissions related to the production of PFAS are covered under the PFAS manufacturing sector. These are considered to be an important source of PFAS to the environment. RAC notes that there is no monitoring data available to support the emissions estimations.
- RAC notes that operational conditions and risk management measures have not been described for this sector in the Background Document, nor provided as part of the Annex XV report consultation (i.e. for manufacturing of cosmetic ingredients).
- RAC notes that some PFAS are prohibited for use in cosmetics due to human health grounds under the Cosmetic Products Regulation (Regulation (EC) No 1223/2009). However, RAC considers the Cosmetic Products Regulation is not addressing the environmental risk of PFAS.

Key elements underpinning the RAC conclusion(s):

R-1.1 Scope and Uses

According to the Dossier Submitter, the scope of the assessment of the “Cosmetics” sector covers two applications: (i) the manufacturing of cosmetic ingredients and (ii) the end-use of PFAS in cosmetic products. It should be noted that the following related uses are assessed under different sectors in the Background Document: cosmetics manufacturing equipment (sealing applications), packaging of cosmetic products, and analytical equipment in the “Cosmetics” sector.

Table 1: Overview of uses described within the sector

Use(s)	Sub-use(s)	Remarks
Use of PFAS (TFA) in manufacturing of cosmetics ingredients	Peptide synthesis using TFA	Covered by Dossier Submitter’s assessment for the “Cosmetics” sector <i>Added as a result of the Annex XV report consultation - includes TFA used in peptide synthesis; no information has been provided regarding the use of other PFAS in manufacturing of cosmetic ingredients.</i>
	Residual TFA in cosmetic products	

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Use(s)	Sub-use(s)	Remarks
Cosmetic products containing PFAS	Decorative cosmetics	Covered by Dossier Submitter's assessment for the "Cosmetics" sector (i) PFAS intentionally added and reported as cosmetic ingredients, and (ii) residual TFA. Not covered by Dossier Submitter's assessment for the "Cosmetics" sector: <i>PFAS contaminants in "PFAS-free" cosmetics products (cosmetic products not listing PFAS among ingredients).</i>
	Skin care	
	Hair care	
	Toiletries	
	Perfumes and fragrances	
Manufacturing of PFAS substances used in cosmetics	Not applicable	Not covered by Dossier Submitter's assessment for the "Cosmetics" sector. <i>Covered under the PFAS manufacturing sector.</i>

Based on literature and a review of several databases (e.g. CosIng, CosmEthics, Kemiluppen, ToxFox), the Dossier Submitter concluded that PFAS are used in cosmetics due to their functions as emulsifiers, antistatics, stabilizers, surfactants, film formers, viscosity regulators and solvents; PFAS can be found in different product groups: skin care, toiletries, hair care, perfumes and fragrances, decorative cosmetics (including make-up, nail varnish and remover, lipstick and lip balm). An overview of the main PFAS substances and their identified properties in the "Cosmetics" sector is shown in Table A.31 in Annex A of the Background Document. The Dossier Submitter identified six specific PFAS substances of the type PFAA and PFAA precursors commonly used in cosmetic products. In addition, they identified two specific polymeric PFAS, of which PTFE is the most common due to its use as a bulking agent, microbeads or micropowder in leave-on products such as mascara and rinse-off products (hair bleaches as slip modifier, binding agent, skin conditioner).

R-1.1.1 Additional uses

It should be noted that the definition of what kind of products are covered under the "Cosmetics" sector has been interpreted differently by some stakeholders. For instance, during the Annex XV report consultation, submitters reported some additional uses within the "Cosmetics" sector not included in the restriction proposal. Several comments (#6150, #8521 and #7820) mentioned the general use of fluoropolymers in the sector, listing examples such as dental floss, dip tips in perfume bottles and hair irons.

Comment #8283 pointed out the use of PFAS in sunscreen products e.g. for making the product more waterproof. Several comments (#7756, 8490, #8987, #9404) highlighted that TFA is used in the manufacturing process of synthetic peptides used as active ingredients in the cosmetic industry (mainly skin care), where TFA remains as an impurity (up to 1% of 50ppm) in the finished product.

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RAC notes that the key study underlying the Dossier Submitter's assessment (KEMI, 2021) is focused on emissions from use and end-of-life of cosmetic products containing intentionally added PFAS such as makeup, creams, shampoos etc., and does not cover packaging of these products, nor articles that are not cosmetic products in the scope of the Cosmetic Products Regulation. Consequently, RAC notes that the scope of the "Cosmetics" sector as defined by the Dossier Submitter can differ from the interpretation of the submitters to the Annex XV report consultation and therefore leads to uncertainties when considering information (e.g. volumes) submitted for additional uses. Furthermore, RAC highlights that some additional uses reported under the "Cosmetics" sector during the consultation, belong under different sectors described in the Background Document i.e. under consumer mixtures and miscellaneous consumer articles for dental floss and perfume dip tips, and electronics (household electrical appliance) for hair irons.

R-1.2 Volumes

R-1.2.1 Summary of volumes and emissions

The scope of the Dossier Submitter's assessment for the "Cosmetics" sector is summarised in Table 1 above. The Dossier Submitter considered only the use of PFAS in cosmetic products as part of their initial assessment. Volume estimates for cosmetic products are summarised in Table A.34 of Annex A of the Background Document. Due to new information submitted during the Annex XV report consultation, the Dossier Submitter updated their assessment to also include the use of PFAS in the manufacturing of cosmetic ingredients (primarily the use of TFA in peptide synthesis).

RAC notes that the Dossier Submitter's assessment does not cover the releases from the formulation of cosmetic products, likely resulting in an underestimation of emissions. The potential emissions from PFAS residues in "PFAS- free" cosmetic products have not been estimated, either. In addition, RAC notes that the Dossier Submitter was not able to disaggregate the PFAS volume estimates.

according to PFAS type (namely whether PFAAs and PFAA precursors, polymeric PFAS or fluorinated gases), which does not allow to identify which PFAS type has a more significant contribution to volumes for this sector.

Furthermore, several comments (#8521, #6150, #9312) reported a higher tonnage for PFAS (mainly fluoropolymers) in cosmetic products than estimated by the Dossier Submitter. A volume of 100-1000 t/y (exact figure confidential) of fluoropolymers used in the "Cosmetics" sector was explicitly mentioned in comment #8521 and #6150. This volume is significantly higher than the estimates of the Dossier Submitter, who highlights this discrepancy in the Background Document but does not assess it further due to limited information. RAC agrees that the information provided does not allow for a full assessment and notes that it introduces an uncertainty pointing to a likely underestimation of the volumes.

Volumes and emissions calculated by RAC for the "Cosmetics" sector are summarised in Table 2 below.

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Table 2: Overview of volumes and emissions

Application		PFAS Volumes ¹ (t/y)	Release factor ²	PFAS Emissions (t/y)
Use	Life cycle stage	PFAAs and PFAA precursors for manufacturing / Total ³	Compartment/Waste treatment	Total
Cosmetic Products – Skin Care	Waste stage (end-of-life)	L: 0.014 M: 25 H: 49.9	Wastewater: 1 <i>Fraction going to wastewater in low scenario: 0.658</i> <i>Remainder going to solid waste.</i>	L: 0.009 M: 25 H: 49.9
Cosmetic Products – Toiletries	Waste stage (end-of-life)	L: 0.002 M: 1.25 H: 2.5	Wastewater: 1 <i>Fraction going to wastewater in low scenario: 0.796</i> <i>Remainder going to solid waste.</i>	L: 0.002 M: 1.3 H: 2.5
Cosmetic Products – Hair Care	Waste stage (end-of-life)	L: 0.003 M: 2.3 H: 4.6	Wastewater: 1 <i>Fraction going to wastewater in low scenario: 0.815</i> <i>Remainder going to solid waste.</i>	L: 0.002 M: 2.3 H: 4.6
Cosmetic Products – Decorative cosmetics	Waste stage (end-of-life)	L: 0.01 M: 3.55 H: 7.1	Wastewater: 1 <i>Fraction going to wastewater in low scenario: 0.178</i> <i>Remainder going to solid waste.</i>	L: 0.002 M: 3.6 H: 7.1
Cosmetic Products – all uses	Waste stage (end-of-life)	L: 0.005 M: 0 H: 0	Landfill: 0.036 <i>Assuming 38.2% of the remainder waste (i.e. after emissions to wastewater) goes to landfill.</i>	L: 0.0002 M: 0 H: 0
Cosmetic Products – all uses	Waste stage (end-of-life)	L: 0.009 M: 0 H: 0	Incineration(non-hazardous): 0.02 <i>Assuming 61.8% of the remainder waste waste (i.e. after emissions to wastewater) goes to incineration.</i>	L: 0.0002 M: 0 H: 0
<i>Total</i> ⁴				L: 0.03 M: 32.1

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Application		PFAS Volumes ¹ (t/y)	Release factor ²	PFAS Emissions (t/y)
Use	Life cycle stage	PFAAs and PFAA precursors for manufacturing / Total ³	Compartment/Waste treatment	Total
				<i>H: 64.1</i>
Manufacture of non-PFAS cosmetic ingredients – peptide synthesis using TFA	Waste stage (end-of-life) ⁵	L: 0.13 M: 0.13 H: 0.13	Wastewater: 1 Emissions of residual amounts of TFA in peptides in cosmetics	L: 0.13 M: 0.13 H: 0.13
	Waste stage (end-of-life) ⁶	L: 366 M: 366 H: 36.6	Assumed that >99% goes to incineration Worst-case scenario assumed, i.e., Air: 0.02 (non-hazardous waste incineration).	L: 7.24 M: 7.24 H: 7.24
<i>Total</i>				<i>L: 7.37 M: 7.37 H: 7.37</i>
Total		L: 366 M: 398 H: 430		L: 7.45 M: 39.6 H: 71.6

L: low, M: mid, H: high

1 Volumes presented in the RAC Opinion are based on estimations for year 2020. It is important to note that some sections of the Background Document present volumes and emissions estimations for year 2023

- Manufacturing of cosmetic ingredients (based on 4% growth rate): 366 t/y
- Cosmetic products (based on 0% growth rate): 0.028 – 64.2 (mid 32.1) t/

2 For wastewater treatment, the high estimate assumes a release factor of 100% for all categories

3 No disaggregation by type of PFAS for “Cosmetic Products” was provided by the Dossier Submitter; PFAAs and PFAA precursors for “Manufacturing of non-PFAS cosmetic ingredients”

4 For cosmetic products, the emission estimates for the solid waste are not included, because the volumes were considered negligible for the assessment even though it is likely that this results in an overall emissions underestimation or cosmetic products. RAC notes that the impact of this uncertainty on the assessment is minor

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5 According to the Background Document, 23 tonnes of peptides were produced for use in cosmetics in the EU in 2023. Assuming an annual growth rate of 4% and back calculating for 2020, results in 21.2 tonnes of TFA. From these, approximately 60% are obtained in synthetic processes using TFA. TFA residuals of up to 1% by weight remain in the synthetic peptides used as cosmetics ingredients: $21.2 \text{ tonnes} * 60\% * 1\% = 0.13 \text{ tonnes}$ per year of residual TFA in cosmetic products

6 According to the Background Document, more than 99% of the amount of TFA used in the manufacture of synthetic peptides (366 t in 2020) is collected as waste after the manufacturing process and the waste is primarily treated by incineration

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R-1.2.2 Manufacturing of cosmetics ingredients

Several comments submitted to the Annex XV report consultation (#8490, #9404, #8987, #7756) introduced that TFA is used in the manufacturing process of synthetic peptides used as active ingredients in the cosmetics industry (mainly skin care). TFA functions as a reagent for cleavage and deprotection reactions in solid-phase peptide synthesis (SPPS), and as a co-solvent for the washing and purification steps. RAC notes that this use was not reported in the restriction proposal and that the claimed volume (366 t/y) is significant compared to the initial volume (maximum 64 t/y) estimated by the Dossier Submitter for the whole "Cosmetics" sector. No information was provided regarding the use of other PFAS in manufacturing of cosmetic ingredients.

In order to extrapolate the total volume of TFA used in the manufacture of peptides for cosmetics, the comment submitter (#8490) estimated the portion of peptides synthesised from TFA (based on information from a peptide manufacturing company) and the projected volume of peptides placed on the EU market in 2023. The Dossier Submitter agreed with this approach and incorporated it into the Background Document. The 2023 volume (411 t/y) was back-calculated to 2020, to align with other sectors, using a growth rate of 4%, yielding 366 t/y. RAC considers this approach as appropriate given the available data.

R-1.2.3 Cosmetic products

The Dossier Submitter commissioned a detailed study (KEMI, 2021) to assess the presence and emissions of PFAS in the "Cosmetics sector". As reported in the study, the Dossier Submitter developed a specific empirical methodology to assess PFAS volumes and emissions related to cosmetic products. A detailed overview of the approach and results can be found in the Background Document, literature (Pütz et al., 2022) and the study itself (KEMI, 2021). See also Figure 1 for a visual overview.

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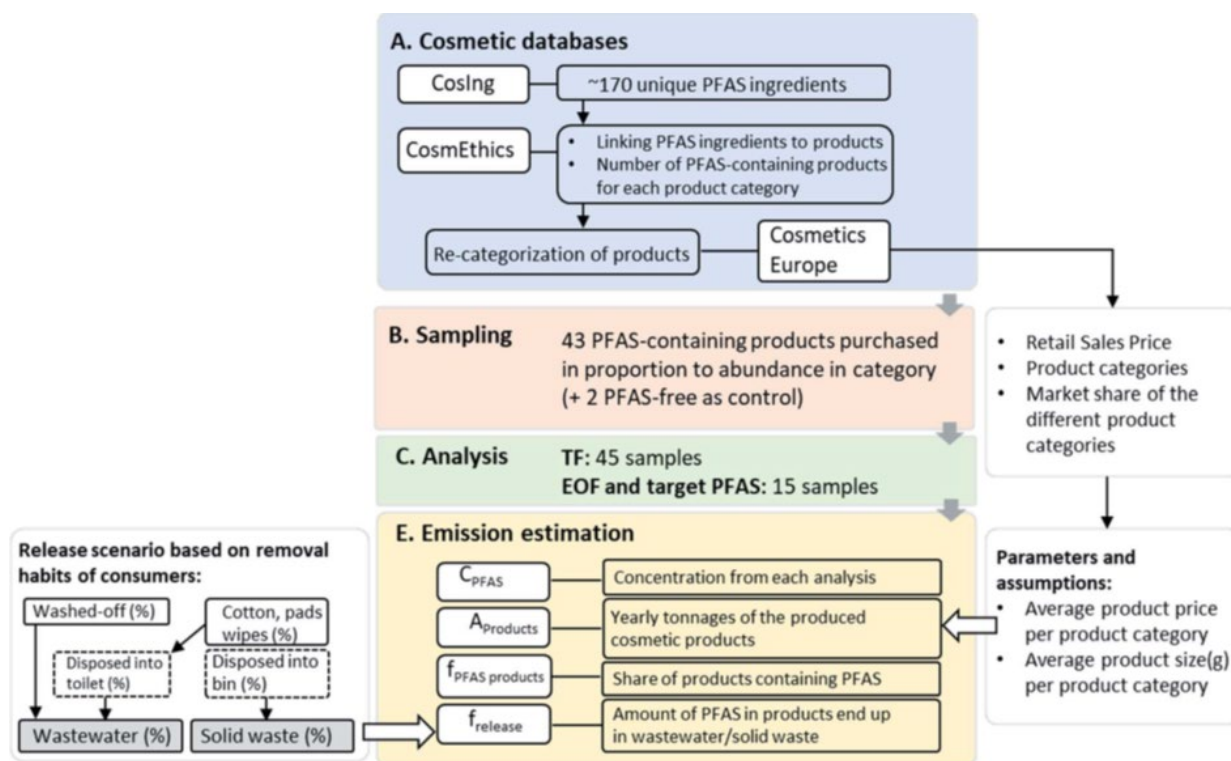


Figure 1: Methodology to assess the emissions in “Cosmetics” sector (From Pütz et al., 2022)

Cosmetic databases: As a first step, the EU Commission CosIng database was consulted to identify cosmetic ingredients likely to contain PFAS (e.g. International Nomenclature Cosmetic Ingredient (INCI) names containing “fluoro”, resulting in 170 INCI assumed by the Dossier Submitter as representative of PFAS ingredients). These PFAS INCI names were then linked to specific products in the CosmEthics database, to calculate the number and share of PFAS-containing products per product category. The CosmEthics categories were then grouped to match the Cosmetic Europe categories in order to associate the identified cosmetic products with sales statistics. The result of this exercise is summarised in Table A.32 in Annex A of the Background Document.

The Dossier Submitter concluded that PFAS are mainly used in decorative cosmetics where 3.67 % of them contained PFAS. RAC notes that less than 1% of products used for hair care, perfumes and fragrances, skin care and toiletries contained PFAS. Furthermore, RAC notes that the Dossier Submitter considered the occurrence of PFAS in “perfumes and fragrances” negligible (only 1 out of 3 637 products listed a PFAS ingredient) and did not derive volume/emission estimates for this category.

Sampling and analysis: In order to determine the typical concentration of PFAS in different cosmetic products, 45 products were analysed for total fluorine (TF) content (Table 19 from KEMI, 2021). A subset of 15 products was also analysed for extractable organic fluorine (EOF) and individual PFAS via targeted analysis (21 substances, mainly PFCAs, perfluoro sulfonates and perfluoro phosphates). However, according to the Dossier Submitter, the results of EOF and targeted PFAS analysis were neither detailed nor representative enough to disaggregate

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estimated volumes per PFAS type and were therefore not considered further in this assessment. RAC agrees with the Dossier Submitter that the available information is not sufficient to calculate separate volume/emission estimates for polymeric vs non-polymeric PFAS.

RAC considers that the above approach results in the following moderate uncertainties:

- The number of analysed products compared to the vast number of products placed on the market is low and therefore the representativeness of the analysis is questionable. Similarly, there are uncertainties in the representativeness of the Swedish market covered by the KEMI study to the whole EU.
- The lack of analysed products from the toiletries category could lead to an underestimation of the emissions.
- The overall methodology targets only products which list PFAS as ingredients and are thus intentionally added; therefore, it does not take into account potential PFAS contaminants in cosmetic products that are not listing them as an ingredient (supposedly “PFAS-free” products). Considering that PFAS were found in many PFAS-free products (as described in KEMI 2021), this methodology is likely to lead to an underestimation of the total PFAS volumes placed on the market. This is further supported by a comment submitted to the Annex XV report consultation (#7146) by a Swedish NGO providing confidential information on measured PFAS concentrations in 25 different cosmetics products, highlighting that seven products did not list PFAS on the INCI-label even though they were measured in detectable amounts.
- Some inorganic cosmetic ingredients (mica, synthetic fluorophlogopite) contain fluorine and it is unclear how much they could contribute to the measured total fluorine concentrations resulting in a possible overestimation. RAC notes that the targeted methodology of cosmetics identification and measurement of total fluorine concentrations lead to additional uncertainties regarding the volume estimates. However, RAC was not able to determine whether this uncertainty could have a significant impact in the results.

Despite the limitations listed above, RAC considers that the Dossier Submitter’s methodology is sufficiently representative to estimate the share of cosmetic products containing PFAS and their average concentration.

Tonnage estimation: Due to lacking data, the yearly tonnage of cosmetic products per category was indirectly derived from data on market value per product category and assumptions on price per kg of product. These estimates were used together with data on the share of products per category that contain PFAS, and PFAS concentrations from TF analysis to estimate annual PFAS volumes. RAC considers that moderate uncertainty is introduced from using the average product size and average product price. The calculations are further detailed in the KEMI 2021 study and Annex A of the Background Document, and summarised below as follows:

1. Retail sales price (KEMI Table 5) / Product price (KEMI Table 6) = # packaging sold
2. # packaging sold x Product weight (KEMI Table 7) = Estimated tonnage of cosmetic

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products sold in 2019 in the EEA (KEMI Table 4)

3. Estimated tonnage of cosmetic products sold in 2019 in the EEA (KEMI Table 4) x share of PFAS-containing products (KEMI Table 8) = Tonnage of PFAS-containing products t/y
4. Tonnage of PFAS-containing products (t/y) x PFAS concentration = Estimated annual PFAS volume in cosmetic products (Annex A Table A.34)

The Dossier Submitter estimated that **annual PFAS volumes in cosmetic products range from 0.028 – 64.12 t/y, with an estimated midpoint of 32.11 t/y**. RAC notes the large range between the low and high volume estimates presented by the Dossier Submitter. The large range is explained by the Dossier Submitter as a result of the wide difference in measured PFAS concentrations, where the highest concentrations are up to >1 000 times higher than the lowest per subcategory. They further explained that individual (extremely) low measurements therefore substantially impact the low estimate. RAC notes that the Dossier Submitter did not consider the average of all measured concentrations in their estimation but rather presented a midpoint estimate (arithmetic mean of best-case and worst-case estimate). RAC considers this calculation is not the most appropriate because the arithmetic mean of all measured values is more representative of the whole dataset than the arithmetic mean of the minimum and maximum value only.

Based on the information above, RAC considers that the low volume estimate is not reliable and is likely a significant underestimation. Consequently, RAC notes that the midpoint value might not be fully representative of a precise estimate but is nevertheless a reliable indicator that emissions do occur in this sector. Therefore, despite the uncertainties and taking into account the limited data available, RAC considers the midpoint estimate an acceptable basis for further evaluation of emissions by RAC and impacts by SEAC.

R-1.2.4 Conclusion on volumes

RAC thus estimates the **total volume of PFAS used in the “Cosmetics” sector** in 2020 to be between **366-430 t/y, with a mid-point estimate of 398 t/y**. Overall, RAC agrees with the methodology and estimation presented by the Dossier Submitter and considers it acceptable for emission estimations. Nevertheless, RAC notes several uncertainties described in the previous sections and considers the calculated volume figures as likely underestimated. Furthermore, due to the unreliability of the low estimate, it is likely that the midpoint estimate is more reflective of the minimum volume and therefore emissions expected for the “Cosmetics” sector.

R-1.3 Emissions

R-1.3.1 Manufacturing of cosmetics ingredients

According to submissions (#8490, 9404) during the Annex XV report consultation, more than 99% of the TFA tonnage estimated to be used for manufacturing of peptides, is collected as waste after the manufacturing process and is primarily incinerated. Based on the stakeholder information, the Dossier Submitter derived PFAS emission estimates for (i) residual TFA in

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cosmetic products resulting from the manufacture of peptides and (ii) the waste management of TFA after peptide synthesis. RAC assumes that this means that only a negligible proportion of TFA is emitted during the peptide manufacturing process and that most of the emissions occur in the subsequent waste stage. RAC questions whether this is realistic and notes that sufficient information on operational conditions or risk management measures was not provided to support the claim that there are no direct emissions to the environment occurring at the manufacturing site(s). However, due to lack of data, RAC accepts this claim but notes it introduces an uncertainty in the assessment.

TFA residuals of up to 1% by weight remain in the synthetic peptides used as cosmetic ingredients. According to the sector organisations, 23 tonnes of peptides were produced for use in cosmetics in the EU in 2023. From these, approximately 60% were obtained from the synthetic processes using TFA, leading to the amount of **residual TFA** in cosmetic products of **0.13 tonnes per year** (back-calculated to 2020). RAC agrees with this estimation but notes that there may be possible double-counting of emissions for TFA residuals potentially captured under the analysis of cosmetic products (see below section on cosmetic products); RAC notes that the impact of TFA residuals on total emissions is however very minor.

Based on information provided by stakeholders, the Dossier Submitter considered that more than 99% of the TFA tonnage used in peptide synthesis is collected as waste after the manufacturing process and is primarily treated by incineration. Due to lack of information in the submitted comments, the Dossier Submitter assumed the worst-case scenario that this TFA waste stream is incinerated as non-hazardous waste. RAC assumed a 98% efficiency for non-hazardous waste incineration and applied a release factor of 0.02 (see section 3.1.2 of the RAC Opinion), resulting in **7.24 tonnes of PFAS emissions to air** from this use of TFA.

R-1.3.2 Cosmetic products

The Dossier Submitter assumes that the end-use of cosmetic products does not result in any direct emissions to the environment, and that all releases will go either to wastewater or solid waste management. Low and high emissions were estimated by applying a release factor (per product category) to the low and high volume estimates summarised in Table A.34 in Annex A of the Background Document. RAC notes that the applied release factors (shown in Table 2) reflect release to wastewater only; the portion of releases expected to end up in solid waste are not factored into the calculation for emissions. The resulting RAC emission estimates are summarised in Table 2 and range between 0.03-64.1 tonnes of PFAS emitted per year from end-use of cosmetic products, **with a midpoint estimate of approx. 32.t/y**. According to the results, skin care products are the largest contributor to emissions related to cosmetic products. RAC notes the large range between low and high emissions that results from the large range and related uncertainties in the underlying volume estimation (see previous section on volumes). Therefore, RAC considers that the low end of the range is likely a significant underestimate and considers the midpoint value of 32.1 t/y as more reflective of a minimum.

The Dossier Submitter assumes that the total quantity of PFAS contained in cosmetic products will be emitted to wastewater or end up in solid waste. Release factors are calculated by the Dossier Submitter based on the relative proportion of emissions to wastewater and solid waste, according to a survey of consumer behaviour (Kantar TNS, 2018, commissioned by

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Cosmetics Europe). Results of the survey are provided in Table 9 in KEMI (2021). In the high emissions estimate it was considered that 100% of the volumes of all product categories would go to wastewater treatment and the release factor to wastewater applied to all product categories is 1. In the low emissions estimate, the Dossier Submitter considered that, for each product category, only a fraction of the total volumes would end up in wastewater. More specifically, the following fraction values were applied by the Dossier Submitter: Decorative cosmetics - 17.8%; Skin care - 65.8%; Hair care - 81.5%; Toiletries - 79.6%. For this low volume/low emission scenario for wastewater, a release factor of 1 was used for all product categories. The remaining fraction of the waste stage volume in the low scenario for each of these categories is considered to go to solid waste (see Table 2 for more detail). The resulting releases are summed up respectively to derive overall "low" and "high" end emissions of PFAS from cosmetic products to wastewater. The Dossier Submitter did not derive releases to individual environmental compartments. RAC finds this approach acceptable considering the available information and considers that the selected release factors are reasonable.

Although the Dossier Submitter states that for the "low" emission estimates, the remaining emissions are expected to end up in solid waste, RAC notes that emission estimates for the solid waste have not been provided because the volumes are considered negligible by the Dossier Submitter. RAC therefore considers it likely that overall emissions for cosmetic products may be underestimated but notes that the overall impact of this uncertainty on the assessment is minor.

R-1.3.3 Conclusion on emissions

Considering the **use of PFAS in manufacturing of cosmetics ingredients** and **end-use of cosmetic products**, emissions amount to **approx. 40 tonnes of PFAS per year (midpoint)**. RAC notes that there are several uncertainties, overall likely to result in an underestimation of the relevant PFAS emissions in the "Cosmetics" sector.

Despite the uncertainties, RAC considers that the emissions estimate is sufficiently adequate to conclude that uses in the "Cosmetics" sector contribute to the occurrence of PFAS in the environment and serves as an acceptable basis for further risk characterisation.

R-1.4 Human exposure

There is limited information on the PFAS exposure of humans from cosmetic products and no additional information has been received in the Annex XV report consultation. The dermal route is expected to be the more relevant exposure route for the end-use of cosmetic products but RAC notes that ingestion of PFAS in specific cosmetics like lipstick and lip balm may also occur. RAC concurs with the Dossier Submitter that dermal uptake may be underestimated as a route of PFAS exposure.

RAC notes that the risks resulting from the human health effects of substances in cosmetic products within the scope of the Cosmetic Products Regulation (are outside the scope of the restriction requirements under REACH. However, the Dossier Submitter has not clearly defined the scope of the "Cosmetics" sector so it is not fully clear whether all products

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considered in the assessment of this sector would fall under the exemption from the REACH Regulation (Regulation (EC) No 1907/2006).

R-1.5 Monitoring data

RAC notes that there is no monitoring data available to support the emissions estimations.

R-1.6 Existing operational conditions and risk management measures

RAC notes that no operational conditions nor risk management measures on PFAS implemented in the manufacturing process of cosmetic ingredients have been described in the Background Document or provided during the Annex XV report consultation. Several submitters reported the industrial use of TFA in the manufacture of peptides, implying that emissions are controlled and mainly take place during subsequent waste management, however they did not provide details supporting this statement.

R-1.7 Existing regulatory risk management instruments already in place

The Cosmetic Products Regulation is the main regulatory framework for finished cosmetic products when placed on the EU market. The main purpose of this regulation is to ensure the safety of cosmetic products leading to a high level of protection of human health. Many PFAS (i.e. PFOS, PFOA and PFNA) are already prohibited from use in any cosmetic products under this regulation due to their harmonised classification as Reprotoxicant Cat.1B. It is important to highlight that this regulation covers only human health hazards and does not take into consideration environmental hazards. Therefore, RAC agrees that the Cosmetic Products Regulation is not addressing the risk of PFAS to the environment.

In addition, RAC notes that there are several restrictions under REACH that may (partially) target the use of PFAS in cosmetics. The Dossier Submitter states that one third of the cosmetics products identified in their assessment contain PFAS that are or are about to be restricted (summarised in Table A.116 of Annex A of the Background Document). Five cosmetic ingredients are quoted to be covered by an existing PFAS restriction (mainly PFOS, PFOA or C9-C14 PFCAs restriction). RAC highlights that the quoted restrictions are targeted to specific PFAS, meaning that they allow the substitution of PFOS, PFOA or C9-C14 PFCAs by other PFAS, and therefore do not have an impact on the total release of PFAS in the "Cosmetics sector".

Furthermore, RAC notes that the Dossier Submitter did not assess to which extent the use of fluoropolymers (PTFE) in cosmetic products may be covered by the existing microplastics restriction under REACH. PTFE was identified by the Dossier Submitter as a common cosmetic ingredient that mainly functions as microbeads, micropowder or bulking agent. However, the applicability of the microplastics restriction is dependent on specific properties (e.g. size,

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production process) and function of the synthetic polymer microparticles in cosmetic mixtures. Due to the lack of information, it is not clear for RAC to which extent the microplastics restriction addresses the use of PTFE in cosmetic products.

R-2. Risk characterisation

Relevant sections of the Background Document:

The risk characterisation is available in section 1.1.6 of the Background Document.

RAC conclusion(s):

- As reported in the RAC Opinion section 3.1.3 Risk characterisation, RAC concludes that PFAS should be treated as non-threshold substances for the purpose of the risk assessment in a similar manner to PBT/vPvB substances, whereby releases are taken to be a proxy for risk and, therefore, should be minimised. This conclusion applies also to PFAS used in the “Cosmetics” sector.
- RAC considers that emissions related to the use of PFAS in cosmetic products can be considered significant, giving a significant contribution to the overall PFAS load in the environment (also via consumer exposure).
- Particle emissions are likely to occur but have not been quantified due to lack of data.
- According to the RAC estimations, emissions of PFAS from the sector are **approx. 40 t/y** (midpoint). RAC agrees that PFAS releases from this sector present a risk to humans and the environment and that the risk increases with continued use due to PFAS persistence and other properties of concern the consequent build-up of in environmental stocks over time. RAC concludes that there is no evidence that the release of PFAS from uses in the “Cosmetics” sector is adequately controlled and, therefore, it should be minimised.

Key elements underpinning the RAC conclusion(s):

See section R-1 on emissions and exposure.

In the case of cosmetics, the end-use of cosmetic products is expected to result in high releases to the municipal wastewater stream and eventually to the environment. The manufacturing of cosmetic ingredients also contributes to the build-up of PFAS in the environment, mainly via PFAS emissions to air as a result of non-hazardous waste incineration.

RAC considers that PFAS emissions of ca. 40 t/y (midpoint) present a risk to humans and the environment and that the risk increases with continued use due to their persistence and the consequent increase in environmental stocks over time.

Overall, RAC concludes that the release of PFAS from uses in the “Cosmetics” sector is not adequately controlled and should be minimised.

R-3. Risk of alternatives

Relevant sections of the Background Document:

The analysis and overview of alternatives for the “Cosmetics” sector are presented in Annex E.2.6.2 and Appendix E.2 of the Background Document, respectively.

RAC conclusion(s):

- RAC notes that there are some alternative substances as ingredients for cosmetic products that are sufficiently characterised for a first comparison of their hazard properties with those of the used PFAS. The following elements have however hindered a more comprehensive assessment of alternatives:
 - The Dossier Submitter does not conclude on the hazard/risk of each alternative individually compared to that of PFAS;
 - For some of the alternatives, the available information regarding their identity (CAS or EC number) and physico-chemical properties, fate and behaviour and (eco)-toxicity is limited;
 - Some alternatives are only listed by generic names and their hazard cannot be assessed properly;
 - The Dossier Submitter did not assess concerns related to the whole life cycle of alternatives.
- RAC considers the approach used by the Dossier Submitter for the analysis of the risks of alternatives acceptable.
- RAC agrees with the Dossier Submitter that based on the limited data available, the three alternatives identified are likely of lower concern.
- No alternatives have been proposed for TFA in the manufacturing of peptides.

Key elements underpinning the RAC conclusion(s):

To identify alternatives, the Dossier Submitter considered information from European cosmetic databases containing consumer data collected via smartphone applications (apps), i.e. CosmEthics (Finnish), Kemiluppen (Danish), ToxFox (German). The Dossier Submitter considers CosmEthics to be the most representative of the EEA market, given the wide geographical spread of their data and the large number of products included. The same conclusion was reached in the REACH restriction proposal for D4, D5 and D6 (ECHA, 2019). Based on this analysis, the Dossier Submitter concludes that cosmetic products containing PFAS make up less than 10% of all of the 108 cosmetic product subcategories in the CosmEthics database.

Considering that (i) less than 10% of cosmetic products in the database contain PFAS, (ii) the Dossier Submitter concludes that PFAS have no critical function in cosmetic products and (iii) submitters (#8577) to the Annex XV report consultation reported that they have phased out PFAS from cosmetics products, it is reasonable to conclude that PFAS alternatives for most cosmetic products exist. This conclusion is also reflected in SEAC’s evaluation of the availability and technical and economic feasibility of alternatives for the “Cosmetics” sector,

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which states that “SEAC agrees with the Dossier Submitter’s assessment that the substitution potential for PFAS-containing cosmetics is high at entry into force of the proposed restriction”.

Nevertheless, the Dossier Submitter has identified a few specific alternatives with unique identifiers: such as synthetic waxes (CAS 822-12-8, CAS 91031-63-9) in decorative cosmetics such as pressed powders. Based mainly on REACH registration data, these alternatives are not classified and no data on PBT/vPvB properties are available. RAC agrees that based on the available information, these substances are likely of lower concern than PFAS but due to lack of data, uncertainties remain. RAC also notes that due to a lack of data on specific operational conditions and exposure the following evaluation is limited to hazard properties rather than risk.

Table 3: Overview of the risk of alternatives

Application		Qualitative assessment of risk/hazards by RAC	Notes/conclusions on sub-use specific alternatives
(Sub-)Use	Alternative		
Decorative cosmetics (Pressed powders)	Synthetic waxes (e.g. magnesium stearate, EC: 292-967-2 CAS:91031-63)-	Not classified; no data on PBT/vPvB properties available. Likely lower concern.	Alternatives that are likely of lower concern are identified.
	Synthetic waxes (e.g. sodium myristate, EC: 212-487-9 CAS: 822-12-8)	Not classified; no data on PBT/vPvB properties available Likely lower concern.	
Decorative cosmetics (lip pencils)	Fats	Insufficient information to make an assessment.	

R-4. Effectiveness in reducing the identified risk(s)

Relevant sections of the Background Document:

The environmental impacts of restriction options relevant for PFAS use in “Cosmetics” are summarised in Annex E.2.6.3 of the Background Document.

RAC conclusion(s):

- RAC agrees that RO1, i.e., a full ban of PFAS for all uses within the scope of this sector is an effective measure to minimise emissions and exposure of humans and the environment. RAC calculates a total emission reduction potential of 93.8%, corresponding to ~1 240 tonnes of emissions reduction over the 30-year period of assessment.
- RAC agrees with the assumptions made by the Dossier Submitter to arrive at a total emission reduction potential of the proposed RO1. However, RAC notes that the

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effectiveness in reducing the risk is underestimated for cosmetic products due to the underestimation of volumes and emissions.

- RAC emphasises that these calculations do not consider emissions arising from the manufacturing of PFAS, which will be covered in a different assessment.
- RAC notes that no derogations have been proposed by the Dossier Submitter.

Key elements underpinning the RAC conclusion(s):

No derogations are proposed under either restriction option for this sector, neither for cosmetic products nor for the use of PFAS in manufacturing of cosmetic ingredients. RAC agrees with the Dossier Submitter's proposal for a complete ban of all PFAS uses in the "Cosmetics" sector.

The Dossier Submitter estimated the baseline and the emission reduction that would be achieved under RO1.

For the use of TFA in peptide synthesis for cosmetics applications, RAC notes that the assessment is based on the assumption that baseline emissions correlate to a 4% annual growth rate for 2020-2030 and a steady state after that. This assumption is based on a comment (#8490) from the Annex XV report consultation in which the respondent provided a projection of annual growth of 4% between 2023-2027. Due to the limited information provided, the Dossier Submitter assumed the same rate as valid for the period from 2020 to 2030.

For cosmetic products, the Dossier Submitter also calculated a range of reduced emissions over 30 years under RO1.

RAC generally agrees with the Dossier Submitter's approach and estimated for RO1 a total emission reduction potential of 93.8% corresponding to an emission reduction of ca. 1240 tonnes over the assessment period. However, RAC notes that due to scarce data and the uncertainties already mentioned in the emissions section, the baseline and therefore estimated emission reduction (mainly for cosmetic products) might be underestimated.

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Table 4: Overview of effectiveness in reducing the identified risk (30-year assessment period: 2025-2055)

Restriction option		PFAS Volumes (tonnes)	PFAS Emissions (tonnes)		PFAS Emission reduction	
Use	Derogation period*	PFAAs and PFAA precursors / Total	Baseline	Restriction Option (RO)	tonnes	%
RO1 Full ban with no derogations						
TOTAL RO1		398.1	1 326	82.4	1 243.6	93.8%
Skin care	Transitional period of 18m. No derogation.	25.0	773.6	49.9	723.7	93.5%
Toiletries	Transitional period of 18m. No derogation.	1.3	38.8	2.5	36.3	93.5%
Hair care	Transitional period of 18m. No derogation.	2.3	71.3	4.6	66.7	93.5%
Decorative cosmetics	Transitional period of 18m. No derogation.	3.6	110.1	7.1	103.0	93.5%
Manufacturing of cosmetic ingredients	Transitional period of 18m. No derogation.	366.0	332.2	18.3	313.9	94.5%

* Each restriction option includes a general transition period of 18 months in addition to the derogation period

R-5. Sector-/use-specific derogations

Relevant sections of the Background Document:

The impact of the restriction in this sector has been summarised in Annex E.2.6.3 of the Background Document.

RAC conclusion(s):

- RAC agrees with a full ban (RO1) of all PFAS for this sector and takes note that no derogations were proposed.

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter does not propose any derogations for this use. The Dossier Submitter instead proposes a complete ban of all PFAS uses in this sector. RAC agrees with this proposal.

R-6. Summary of uncertainties

Relevant sections of the Background Document:

There are some uncertainties described in the tonnage, number of users and emissions in Annex B.9.7 and E.2.6 of the Background document.

RAC conclusion(s):

- RAC concludes that despite their relevance the identified uncertainties have no impact on the overall conclusion.

Key elements underpinning the RAC conclusion(s):

Table 5: Overview of uncertainties

Topic	Uncertainty	Impact (minor/moderate/major)
Volumes	Several additional uses were reported during the Annex XV report consultation. RAC notes that the scope of the assessment of the "Cosmetics" sector as defined by the Dossier Submitter differs from the interpretation of the submitters to the Annex XV report consultation and therefore leads to uncertainties when considering information (e.g. volumes) submitted for additional uses. Nevertheless, the majority of the submissions did not provide further information to allow for a detailed assessment.	Moderate.

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Topic	Uncertainty	Impact (minor/moderate/major)
Volumes	Several assumptions were used in the volume estimation including average product size and average product price.	Moderate.
Emissions	The emission estimates do not cover the whole life cycle of cosmetic products. Emissions from formulation and solid waste management of cosmetic products (due to the volume considered as negligible by the Dossier Submitter) were not considered by the Dossier Submitter. This likely leads to underestimation of emissions.	Moderate.
Volumes/emissions	RAC highlights the relatively low number of analysed products compared to the vast number of products on the market. Furthermore, RAC notes the lack of a representative of "toiletries" among the products analysed. In addition, RAC notes the focus on products listing PFAS ingredients and no consideration of PFAS contaminants in supposedly "PFAS-free" products.	Moderate.
Emissions	A number of cosmetics samples that were analysed for PFAS also listed inorganic ingredients (mica, synthetic fluorphlogopite) that may contribute to total fluorine concentrations. This leads to potential overestimation of PFAS emissions.	Minor/moderate.
Volumes	RAC notes the large range between the low and high-volume estimates presented by the Dossier Submitter. RAC considers that the low volume estimate is not reliable and is likely a significant underestimation. Consequently, RAC notes that the midpoint value is not fully representative of a middle estimate but is nevertheless a reliable indicator that emissions do occur.	Moderate.
Emissions	The fraction of PFAS released to the individual environmental compartments following treatment of wastewater or solid waste was not assessed. Nevertheless, the majority of PFAS from cosmetic products are predicted to end up in wastewater, where they are not degraded and eventually end up in the environment as PFAS.	Minor.

R-7. Practicality, including enforceability

RAC conclusion(s):

- RAC notes that there appear to be (non-standard) test methods available for measuring PFAS in cosmetic products. For a horizontal assessment of practicality refer to section 3.4.2.3 of the RAC Opinion.

Key elements underpinning the RAC conclusion(s):

RAC notes that during the Annex XV report consultation, respondents highlighted the lack of standard methods to measure PFAS in different matrixes (#9059, #9262), including cosmetics. RAC notes that this point is generally emphasised in the Forum advice. RAC and Forum agree that significant improvements are needed in the availability of standardised analytical methods and in supplying additional guidance. Developing standardised methods for total fluorine in different matrixes is a strong need as well as for targeted PFAS. Forum has already recommended to clearly define which methods are acceptable for which type of sample.

The KEMI study underpinning the emission assessment for cosmetic products indicates that available total fluorine (TF), extractable organic fluorine (EOF) and targeted PFAS analytical methods can be used for measuring PFAS in cosmetic products. Furthermore, RAC notes that one comment from the Annex XV report consultation (#9404) provides additional analytical methods not included in Annex E of the Background Document for the determination of TFA.

Overall, while RAC agrees that significant improvements are needed to develop standardised test methods, there is evidence indicating that there are non-standard methods potentially suitable for measuring PFAS concentrations in cosmetic products.

For a detailed evaluation of the practicality of the restriction proposal, see section 3.4.2.3 of the RAC Opinion.

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R-8. References

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Other references are included in the Background Document.