BISPHENOL AF

Consortium

Initial input into public consultation on the restriction of BPA and Bisphenols of Similar Concern

Brussels, 21 June ,2023

The Bisphenol AF and related substances REACH registration Consortium groups the registrants of Bisphenol AF in Europe, both manufacturers and importers. Members of the Bisphenol AF and related substances REACH registration Consortium are; Central Glass Europe, Chemours Netherlands BV, Daikin Chemical Europe GmbH, Solvay Specialty Polymers Italy SpA.

ETRMA is the voice of tyre and rubber goods producers to various European institutions. ETRMA activities focus on the following key interdependent areas: representation, coordination, communication, promotion and technical liaison. The primary objective of ETRMA is to represent the regulatory and related interests of the European tyre and rubber manufacturers at both European and international levels. ETRMA is the sole interlocutor, specifically designated by the European tyre and rubber producers to carry out this critical task.

During this submission we will focus on the following topics:

- Restriction conditions and settings : updated comment
- Test method : residual content investigation
- Socio economic impacts in case of non use
- Emission estimates

Warning : Development of an harmonized test method for BPAF and its salts residual content is ongoing. It is therefore at this moment not possible to fix a limit for BPAF and its salt content in articles and to fully assess impacts on industry. We are aiming to provide more result at a later stage of the Echa opinion making process.

1. Restriction conditions and testing

Do you consider that the restriction conditions (including derogations listed in Appendix Y) and the conditions and methods for migration testing (as described in Annex Z) are clear? Are there conditions that require further clarification? Do you consider that the conditions and methods for migration testing as described in Annex Z are representative to assess migration during the entire article service life? If not, can you propose a more reliable testing?

We would like to refer to the previous BPAF consortium comment of 25 January 2023 and further specify it.

Although it is clear from the restriction dossier that the dossier submitters intends to derogate applications of fluoroelastomers containing residual BPAF, the wording of the restriction actually does not allow the use of fluoroelastomers since it derogates mixtures and articles where BPAF is covalently bound to any type of matrix (e.g. via functioning as a crosslinker) but does not allow the placing on the market of the mixtures (pre- and full compound fluoroelastomers) containing > 10 ppm of uncured BPAF used in industrial premises to produce cross-linked cured fluoroelastomer articles.

Those mixtures are not yet crosslinked and covalently bound.

During the formulation stage Bisphenol AF is incorporated in solid mixtures in dedicated facilities. This greatly reduces the risk of exposure and release to environment by focusing this activity in dedicated facilities, and avoiding the handling of Bisphenol AF in powder form. The solid mixture takes the form of sheets in most cases, sometimes pellets or stripes.

The current restriction wording would prevent these operations to take place. This would force the downstream article producers to handle Bisphenol AF in pure form (i.e. powder form), which increases the risk or makes the operation impossible because the article producers are not equipped to handle Bisphenol AF safely.

In this paper we demonstrate that the releases into the environment are according to our assessment much lower than those estimated by the dossier submitter (see section 10) and document significant socio-economic impact both on upstream supply chain and in critical downstream uses. We would therefore question the proportionality of the current restriction proposal. For the sake of ensuring the proportionality of the restriction proposal and also with a view to simplify the restriction and facilitate its enforcement we therefore would suggest the following adaptations to be made to the restriction conditions.

Proposed modification :Main restriction text(in bold) :

"Bisphenols, HO-(R1)-R2-(R3)-OH with R1 and R3 being phenylene groups bearing any substituents at any ring position and R2 being a methylene group being unsubstituted or bearing any substituents or another bridging unit bearing unspecified substituents, which are listed in Appendix X and their salts.[...]

1. Shall not be placed on the market in mixtures and articles in a concentration equal to or greater than 10 ppm (0.001 % by weight). This limit value refers to the sum of all substances subject to this Annex XVII entry which are present in the respective mixtures and articles.

2. Paragraph 1 shall not apply to mixtures and articles where the bisphenols listed in Annex X are either covalently bound to any type of matrix (e.g. via functioning as a crosslinker), **are used or formulated in uncured mixtures used at industrial sites such as masterbatches, pre-compounds, compounds, uncured elastomers sheets,** or are used as intermediates in the manufacture of polymers, and for which

i. contact to aqueous media in any form can be excluded during their reasonable and foreseeable use throughout their service life or

ii. the migration limit in the respective mixtures and articles does not exceed 0.04 mg/L over the entire service life. Conditions for migration testing are described in Annex Z below. "

In addition, we would like to suggest a revised wording for the exemption for fluoroelastomers:

Appendix Y :

Use	Proposed derogation	Reason
Cured fluoroelastomer-based articles	**Concentration limit 150 ppm[1] (for 10 years), conditional on the results of ongoing development of harmonized test method**	**BPAF reacts and gets covalently bound to the fluoroelastomer backbone during curing. Residual (unreacted) BPAF levels are below 150 ppm. Harmonized residual test method under development.**

Justification : The term fluoroelastomer is not specific enough as there are several categories of fluoroelastomers.

As such, before curing the term fluoroelastomer refers to a substance (the base polymer) or a mixture (precompound or full compound), while after curing, cured fluoroelastomers already meet the definition of article of REACH. For this reason, we suggest using the terms "cured fluoroelastomer-based articles". To note, fluoroelastomers (base polymers) do not contain any BPAF.

For a full description of the different steps in the supply chain we refer to our answer to question in our submission of 25 January 2023 (sections 1.1 and 1.5).

Also, with regards to the proposed threshold of 150 ppm, it is aimed at ensuring the proportionality and enforceability of the measure. Moreover there is yet uncertainty on the actual BPAF and its salts residual levels and this cannot be confirmed before the development of an harmonized test method (ongoing).

[1] Please refer to Warning on p. 1

2:

Which analytical methods exist for your sector to test:

a. the **content** of BPA and BoSC in article or mixtures that are covered in the scope of the restriction?
b. **migration** of bisphenols from your articles, part of articles and/or mixtures?

Residual content of BPAF

We are performing more tests on residual content and develop an harmonized method so as to be able to determine the actual residual level of BPAF in FKM based articles (or cured FKM) in a repeatable manner with an independent lab. The new method in development aims at extracting not only BPAF but also its salts in the scope of the restriction proposal. It investigates what is the most efficient solvent to meet this aim (too mild solvent would lead to incomplete extraction, too harsh would lead to a degradation of the FKM matrix). The method investigates the extraction efficiency of each solvent/setting as well as precision, stability and robustness of the method. We can unfortunately not yet conclude on the most suitable method at this moment and also therefore not provide harmonized results regarding residual concentration of BPAF and its salts in cured articles.

5: The Dossier Submitter assessed the impacts of the examined restriction options (See Annex E and section 2.4 of the Annex XV report). Please provide additional information on the economic impacts of the proposed restriction. Please consider both the restriction conditions as described in paragraph 1 and 2, as well as the derogations described in Appendix Y. If the derogations are relevant for your sector, please also describe the economic impacts you would expect in case the derogations are removed.

5.1. Introduction

Before describing economic impacts, we would like to highlight that , our estimate of releases is several orders of magnitude lower than the submitted dossier (see section 10). We would therefore question the proportionality of the proposed measure, given the potential actual impacts. In case ECHA recommends to proceed with the restriction of BPAF, we would recommend the restriction option 2 to be applied (limit of 150 ppm) in the case of BPAF), conditional on the results of ongoing development of harmonized test method. For a proposal of rewording of the restriction and its derogation see answer to question 1.

5.2. Supply chain description

We refer to previous BPAF consortium submission dated 25 January 2023.

5.3. No satisfactory Alternatives

There are currently no satisfactory alternatives to the Bisphenol AF based systems.

Peroxide cure grades are the best for the application where chemical resistance is needed. On the other hand, bisphenol cure grades, which need BPAF, are the best for the application where heat-resistance up to 230-250 °C is needed. As consequence, peroxide cure grades are not suitable for the applications where bisphenol cure-grades are currently used.

Another substitute of BPAF is the amine curing system which was the predecessor of BPAF curing system. The amine curing system lacks chemical resistance, shows poorer compression set and are associated to odour nuisance, insufficient processing and vulcanization properties, higher reject rates and insufficient heat resistance.

5.4. Impacts in case of non use

5.4.1 Where and why are FKM using BPAF as crosslinker used?

The FKM portfolio of the BPAF REACH Consortium covers the full range of fluoroelastomers for BPAF curing, mainly comprising copolymers of vinylidene fluoride, hexafluoropropylene and, optionally tetrafluoroethylene or other monomers. A series of fluoro-thermoplastic elastomers, F-TPV, offer a unique combination of low permeation, low modulus (high flexibility), and excellent processability. The progressive polymerisation method allows linear or branched polymers with controlled molecular weight distribution. These grades provide optimal flow-ability and compression set.

Their characteristics:

- Oil resistance
- Fuel resistance
- Low fuel permeation
- Chemical resistance
- Highest heat resistance (~230°C-250°C)
- Excellent sealing performance

Applications

FKM polymers are used in automotive, aerospace, defense, robotics, energy, semiconductors, healthcare & medical devices, pharma, food processing industry, construction, oil& gas and chemical processing applications, where a combination of heat and chemical or oil resistance are needed from a single component, such as a seal or hose. FKM are ideal for applications that require resistance to fuel mixtures and solvents, such as fuel hoses and seals used in chemical processing. Injection and compression moulding grades, extrusion grades and lower temperature grades are available.

Focus : Fluoroelastomer products in the automotive sector

BPAF is used for production of pre-compounds containing FKM, which are designed to achieve the highest requirements in extreme environments, e.g. in the automotive sector. This includes **high temperatures in combination with contact to fuel, diesel, oil and all kinds of media. The very low permeation rate of the pre-compounds containing FKM allows components to meet current environmental regulations, which without BPAF would not be possible, the automotive sector would be unable to operate without FKM products**. FKM are also used in the **design of novel electric engines** where similar heat resistance is also key.

The reason for this is that the sophisticated polymer design of FKM, thanks to BPAF, allows stable extrusion and moulding processes for all kinds of technical rubber articles like O-rings, seals and fuel / turbo charge hoses. In short, FKM parts used in the automotive industry rely on BPAF, so without BPAF the entire automotive sector would face technically difficult situations (shortage of materials, low performance of raw materials/car components).

When it comes to car parts, for example, FKM products used for sealing provide excellent high temperature and aggressive fluid resistance when compared with other elastomers.

They are the only materials available that combine all the necessary properties and performance criteria – such as heat and chemical resistance as well as low-permeability – that the downstream industry requires in its applications.

They also combine the most effective resistance to chemicals and fluids such as oil, diesel or ethanol mix. With their low permeation rate, FKM allow downstream users to meet stringent automotive regulations on gas emissions by significantly reducing leakage.

The main fluoroelastomer applications inside an automotive engine are:

- Turbocharger hoses: improve thermal efficiency
- Particle filter hoses/Differential pressure hoses: reduce emission
- Fuel hoses/filler neck hoses: transport fuel without evaporation to the environment
- Seals and gaskets: prevent fuel/oil leakages - safety

Turbocharger hoses improve the heat efficiency of an internal combustion engine. The hose which connects with the turbocharger is called a turbocharger hose. For air with high temperature and pressure to pass in the hose, fluoroelastomer material is used for the inner layer. The acid resistant function is also requested by EGR (exhaust gas recirculation).

Filler neck hoses are another example, they connect between the fuel tank cap and a fuel tank. For fuel to pass, the excellent low fuel permeability of FKM is used.

Finally, a last example of why fluoroelastomers are critical for the safe and efficient functioning of the engine is particle filter hose to ensure low particle emissions, while monitors made with fluoroelastomers are used to assess when the filter needs replacing.

5.4.2. Essential use

Fluoroelastomer (FKM) articles are essential for the functioning of society as they are used in sealings, O-rings, stators for pumps and engines, gaskets, turbocharger hoses, particle filter hoses/Differential pressure hoses, fuel hoses/filler neck hoses, pressure hoses, pumps, sealing used in automotive engine (fossil and electric), transport (ship, train), healthcare & medical devices, pharma, food processing industry, semiconductors, aerospace. In industrial applications: mainly valves and seals for oil and gas lines, hose lines, pneumatic cylinders, pumps, sealing plates and hydraulic systems.

5.4.3. Quantification of Impacts in case of non use

The **estimated turnover related to FKM production at formulation stage is between 150 and 250 millions €**.

At **converting stage** this turnover would reach around **500 millions €.**

The impacts further downstream are even greater as proper ground or aerial transport could not be ensured with same degree of reliability as today in the sectors of transport, aerospace, oil and gas.

10: Emission estimates are provided in Annexes B8 and H. Please provide any additional information regarding the emission estimates. For example, information on release from the use of hardener as an additive in epoxy resins would be appreciated.

We are currently running tests on the residual content of BPAF in cured fluoroelastomers and their migration in aqueous media in line with the worst case conditions defined by the dossier submitter. We would however already like to provide more information on potential releases based on industry and international guidelines references.

10.1. Industrial emissions

BPAF uses at all industrial stages (manufacturing, formulation or re-packing, substance formulation and pre-compounding, converting of articles involving curing or post curing) do not involve any contact with aqueous media. **Emissions from the industrial stage are considered to be comparatively low by the dossier submitter** (see Annex E.4.7, p. 248, Annex XV dossier) and **this was confirmed in the BPAF consortium submission of 25 January 2023** .

10.2. Volume of FKM articles containing residual BPAF

A recent study made by Conversio on behalf of ProK **(**Source Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams Final report made on behalf of pro-K, Conversio (July 2022) , (https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf)) estimates the amount of FKMs manufactured in Europe to be 3200 tonnes. When incorporating imports those would amount to 4160 tonnes of FKMs[2]. Our previous estimates are based on a detailed survey at formulators level in 2021. Based on this survey the tonnage of FKM formulated (including imports) would be between 6 and 12 kT. Previous ETRMA estimates based on a survey across their membership in 2020 were between 3,4 and 14 kT. Based on our current knowledge we would estimate 9 kT as a best conservative estimate.

10.3 Residual content

We are performing more tests on residual content and develop a harmonized method so as to be able to determine the actual residual level of BPAF in FKM based articles (or cured FKM) in a repeatable manner with an independent lab. We can unfortunately not yet conclude on the most suitable method at this moment and also therefore not provide harmonized results regarding residual concentration of BPAF and its salts in cured articles.

In our release scenarios we consider as starting value 150 ppm being the limit foreseen in Restriction Option 2.

Warning : development of an harmonized test method for BPAF and its salts residual content is ongoing. It is therefore at this moment uncertain to fix a limit for BPAF and its salt content in articles and to fully assess impacts on industry. We are aiming to provide more result at a later stage of the Echa opinion making process.

10.4 Estimating leaching during service life and end of life

Regarding leaching rates, the dossier submitter estimates that any residual BPAF contained in FKM that ends up on landfills will eventually be released in the environment over a period of 20 years. This is not correct.

OECD Emission Scenario Document

Residual BPAF is expected to be firmly bound within the FKM matrix. As a worst case one could consider the release rates foreseen for service life outdoor for plasticisers in the OECD emission scenario document on plastic additives (OECD, 2009) : 3,2% over 20 years; 0,16% per year for soft PVC plastisol. Whilst FKM rubber matrixes are soft, unlike soft PVC they are also crosslinked. One should therefore expect the leaching from such matrixes to be much reduced. Reference to the OECD Exposure Scenario Document therefore constitute a very conservative worst case assumption.

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[2] Being calculated as follows : Quantity manufactured FKMs (p.29) x Quantity fluoropolymer placed on the EU market (p. 31) DIVIDED BY quantity fluoropolymers manufactured in Europe (p.30).

Migration modelling

A migration model has been developed to simulate the release of BPAF from cured fluoroelastomers in an environmental scenario.

The kinetic constants (partition coefficient and diffusion coefficient) for the migration modelling have been derived from data of laboratory migration tests performed according to regulation EU 10/2011 with modified PH. Results from this migration modelling may be found in Appendix 1 : “Ap1_Preliminary Investigation Report Modelling on BPAF migration from FKM materials”. Two scenarios have been developed 1) modelling leaching in landfill 2) modelling leaching article O-ring.

In both cases, the FKM material is exposed to rain in outdoor conditions. In Central Europe, this translates into 700mm/year rain with alternating wet and dry periods, dry periods being longer in Summer. Overall, this discontinuous contact with water is assumed to be 91 days per year in total in both scenarios.

For both scenarios as well leaching has been modelled over 20 years.

In both cases the initial BPAF residual concentration was set at 100 ppm. It should be noted although BPAF is poorly soluble in water, leaching from the FKM matrix is very slow meaning that we don’t reach saturation levels into water. It may be assumed that leaching will be proportional to the migrant initial concentration. We may therefore approximate conservatively extrapolate other release by increasing/decreasing the leached value proportionately to the migrant initial concentration.

Margin of safety modelling

Since we are still developing harmonized methods on residual content and given the limited number of migration results available, we apply at this stage an additional Margin of Safety of 10 on the modelling results.

Modelling leaching during service life

In order to estimate leaching we have started from a typical end application, an O-ring being exposed to rain in the above mentioned conditions. The O-ring dimensions were as follows (internal diameter 10 cm, outer diameter 11cm, cross section 1 cm). We also assumed that only the outer part of the O-ring is exposed to rain.

After 20 years, only **0,17%** of the initial BPAF residual content will have leached out of the article. This would translate into **1,7%** of the initial BPAF residual content when applying our modelling Margin of Safety for uncertainty.

Modelling leaching from landfill

In the case of landfill, we calculated the surface that a stack of automotive shredder residues composed only of FKM containing in 1 m^3 would have and modelled leaching into rain water into the conditions defined above.

We assumed that the thickness of FKM material would be 5 mm. This is a worst case estimate providing the largest surface in contact with water. Indeed, rubber and plastics in Automotive Shredder Residue are found mainly in fraction above 11 mm but also in 2 to 11 mm fraction (see Margarido Noguera et al. 2011 Characterization of ASR : https://repositorio.lneg.pt/bitstream/10400.9/1352/1/Margarido-Nogueira_Characterisation%20of%20Automotive%20Shredder%20Residue_fullpaper-192_Wastes%272011.pdf).

We consider in the landfill an "installed stock" (IS) of FKM "layers/sheets of $V_p = 1 m^3$ volume, filled to 65% with"layers/sheets (that means about 1170 Kg of FKM ASR with a total surface of about 260 m^2).

After 20 years, the released fraction from the initial BPAF concentration would be maximum **0,039%**.

10.5. Exposure during service life is unlikely

In our view, the annex XV dossiers overestimates potential releases of BPAF from fluoroelastomers finished articles as it was previously described that there are hardly any outdoor applications for fluoroelastomers based material containing BPAF. A recent ETRMA internal survey confirmed this. We refer to our previously submitted document on exposure based waiving (see ap2_2023-01-25_BPAF use description for exposure based waiving). We therefore expect that applications with contact to aqueous media (outdoor) do not exceed 10%.

Table 1. Estimate releases into the environment Service Life

	Leaching over 20 years related to products placed on the market during one year	**Cumulated releases installed stock over 20 years**	**Emissions to environment after waste water treatment plant**
Tonnage FKMs placed on market	**Best conservative estimate BPAF consortium- ETRMA :** 9 kT/year **Annex XV dossier :** 50 kT/year	**Best conservative estimate BPAF consortium-ETRMA:** 180 kT/20 years **Annex XV dossier :** 1000 kT/20 years	
Residual concentration	**R02 :** 150 ppm **Annex XV dossier :** 50 ppm	**R02 :** 150 ppm **Annex XV dossier :** 50 ppm	
Emissions	**RO2 (OECD ESD) :** release 20 year OECD (2009) : 3,2% x 150 ppm x 9kT x 10%= 4,32 kg/20 years **RO2 modelling**: Modelled release 20 years : 0,17% x10 (MOS)x 150 ppm x 9 kT x 10% = 2,3 kg	**RO2 (OECD ESD)** year OECD (2009) : 3,2% x 150ppm x 180kT x 10%= 86,4 kg/20 years **RO2 modelling :**Modelled release 20 years : 0,17%x10(MOS) x 150 ppm x 180 kT x 10% = 45,9 kg	**RO2 (OECD ESD) :** 86,4 kg x 39% = **33,7 kg** **RO2 modelling:** 45,9 kg x 39% = **17,9 kg**
	Annex XV dossier : 20% unprotected uses x 50,000tpa FKM x 50ppm x 25% emitted during service life = 125 kg/20 years	**Annex XV dossier :** 20% unprotected uses x 50,000tpa FKM x 50ppm x 25% emitted during service life x 20 years = 2500 kg cumulated emissions	**Annex XV dossier** 2500 kg x 39 % = **975 kg**

From the above, one can see that under Restriction Option 2, releases are 30 times lower than assumed by the dossier submitter based on OECD Exposure Scenario Document on plastics additives. Modelling results based on current tests integrating a Margin of Safety of 10 would be 50 times lower than assumed by the dossier submitter.

10. 6. Exposure resulting from end of life

The main releases of BPAF to water would therefore only be at the end of life stage, when FKMs could end up in landfill.

Table 2 : Fluoropolymer applications End of Life in selected end applications relevant for FKMs

	Collected FP waste (kT)	Energy Recovery (kT)	% share	Landfill (kT)	%share	% share excluding metal fraction	Metal recycling (kT)	FP recycling (kT)	% share
Automotive (including ASR)	3,5	2,5	71,43%	0,8	22,86%	24,24%	0,2	0	0,00%
Aerospace	0,3	0,24	80,00%	0,04	13,33%	13,79%	0,01	0,01	3,33%
CPI	9,4	7,1	75,53%	1,05	11,17%	11,35%	0,15	0,35	3,72%

Source : Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams Final report made on behalf of pro-K, Conversio (July 2022)

(https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf)

A recent study made by Conversio on behalf of pro-K looks into the end of life treatment of fluoropolymers. From this study it may be seen that less than 22,9% of automotive waste, 13,3% of aerospace waste and 11,2% of waste used in industry is landfilled in Europe. 23,3% of waste in Automotive shredder residue would end up in landfill. Since the main application of FKMs is in automotive, we will take a worst case rate of 24% of FKMs going to landfill (plastics fraction of automotive waste fluoropolymers).

Assumptions regarding the occasion for leaching from landfill in the annex XV dossier (total migration) is also overestimating what happens in reality. At the end of its lifetime, the landfill will be covered by a “final cover” preventing further exposure (see for instance Technical guidelines on the environmentally sound disposal of hazardous wastes and other wastes in specially engineered landfill (D5), which sets standards for hazardous and household waste:

Please refer to UNEP-CHW.15-6-Add.5-Rev.1.English.pdf which may be downloaded at : http://www.basel.int/TheConvention/ConferenceoftheParties/Meetings/COP15/tabid/8392/Default.aspx.

Finally, the assessment should be related to a set time horizon. We will therefore consider leaching from landfill for a period of 20 years only. We consider the estimate below as conservative estimates on potential leaching.

Table 3. BPAF consortium-ETRMA estimate of end of life releases			
	Leaching over 20 years related to products placed on the market during one year	**Cumulated releases installed stock over 20 years**	**Emissions to environment after waste water treatment plant**
Tonnage FKMS placed on market	**Best conservative estimate BPAF consortium- ETRMA :** 9 kT/year **Annex XV dossier** : 50 kT/year	**Best conservative estimate BPAF consortium-ETRMA:** 180 kT/20 years **Annex XV dossier :** 1000 kT/20 years	
Residual concentration	**R02 :** 150 ppm **Annex XV dossier :** 50 ppm	**R02 :** 150 ppm **Annex XV dossier :** 50 ppm max	
Emissions	**RO2 (OECD ESD)** : release 20 years OECD (2009) : 3,2% x 150 ppm x 9kT x 24%= **10,4kg/20 years** **RO2 (Modelling)** : release 20 years (modelling) : 0,039% x10 (MOS) 150 ppm x 9kT x 24%= 1,**26kg/20 years** **Annex XV dossier :** 50% of waste in landfill x 50 kT/year FKM x 50ppm x 100% migration = **1,25 tons**	**RO2 (OECD ESD) :** release 20 years OECD (2009) : 3,2% x 150 ppm x 180kT x 24%= **207kg/20 years** **RO2 (Modelling) :** release 20 year (modelling) : 0,039%x10 (MOS) x 150 ppm x 180kT x 24%= **25,3kg/20 years** **Annex XV dossier :** 50% of waste in landfill x 1000 kT/ 20year FKM x 50ppm x 100% migration = **25 tons**/20 years	**RO2 (OECD ESD) :** 207 kg x 39% = **80,9 kg** **RO2 : Modelling :** 25,3 kg x 39% = **9,86 kg** **Annex XV dossier :** 25 tons x 39% = **9,75 tons**

From the above table, one can see that estimates of releases during end of life stage are according to our estimate maximum 80,9 kg under Restriction Option 2 based on the OECD ESD , which is 2 orders of magnitude lower than the dossier submitter estimates. When taking into account our own migration modelling, even considering a margin of safety of 10 to account for uncertainty, the our leaching estimates are 3 orders of magnitude lower than in the annex XV dossier.

10.7. Conclusions

Table 4. Comparison total releases to environment (20 years)
Annex XV dossier: **Best estimate : 8,000 kg (**Annex XV report, Table 19 p. 48)
BPAF consortium-ETRMA: **Restriction Option 2 (OECD ESD): 33,7 + 80,9 = 115 kg** **Restriction Option 2 (modelling): 17,9+9,86 = 27,8 kg**

From the table above, taking into account Restriction Option 2, releases into the environment would be 115 kg based on the OECD Emission Scenario Document. **This estimate is almost 2 orders of magnitude lower than the dossier submitter assumptions (best estimate was 8 T releases over 20 years**). **Based on the modelling** undertaken by FABES, **releases to water are 27,8 kg in 20 years, 2 orders of magnitude below the dossier submitter estimate**, even considering an additional margin of safety of 10. (summary of calculation are made available in appendix 3 as an xls).

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List of appendixes :

ap1_Preliminary Investigation Report Modelling on BPAF migration from FKM materials

ap2_2023-01-25_BPAF use description for exposure based waiving

ap3 calculation of BPAF releases BPAF consortium & ETRMA final