Memo

To:	ECHA
From:	AEGIR-Marine
Date:	1 June 2023
Subject:	**Submission Public Consultation ECHA PFASs restriction proposal 22 March 2023**

AEGIR-MARINE - SUBMISSION

To be summarized in survey and full report uploaded in section 4

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- On behalf of a company: AEGIR-Marine
- country: the Netherlands
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Memo

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EXECUTIVE SUMMARY - MAIN OUTLINE OF THE REQUEST FOR A 12- 15 YEAR DEROGATION

- **Request for a 12-15 year derogation by AEGIR-Marine**

  AEGIR-Marine fully supports the initiative to restrict the use of certain PFASs which are a risk to human health or the environment.
  AEGIR-Marine asks for a 12-15 year derogation, to find fundamental solutions as an alternative for the current - essential - use of the fluoropolymer (fluoroelastomer) FKM in its seals/ sealing applications. In addition, AEGIR-Marine also aims to prevent issues related to the persistency of FKM by taking responsibility in relation to the end-of-life stage of its seals/sealing applications. Reasons for the need for (at least) a 12-15 year derogation are the lead times for legally required class type approval, the required docking intervals for seagoing vessels (5 year period) and the lead times of our 4 R&D programmes, with a timeline of 12 – 15 years, that aim for two solutions:
  - To find an adequate alternative material to the fluoropolymer FKM;
  - To realise a full circular solution, by collecting the used seals and re-cycle them or incinerate them controlled >850 ^{0}C (short term) and to start in parallel a R&D program on breaking the crosslinks in FKM by de-vulcanizing (long term).

- **AEGIR-Marine welcomes a ban for certain PFASs, except for Fluoropolymers**

  AEGIR-Marine acknowledges the need for measures to ban these PFASs, because of the high risks for health and environment; *except for fluoropolymers / fluoroelastomers and in particular for FKMs, of which the 'unacceptable risks to human health and the environment'* are not evidenced in the restriction proposal. On the contrary, these fluoropolymers meet the 13 OECD-criteria of 'polymer of low concern (PLC)' as they are non-toxic, non-bio-accumulative, non-bioavailable, and non-mobile. The OECD (2009) defined 'polymers of low concern' as: *"Polymers are those deemed to have insignificant environmental and human impacts. Therefore, these polymers should have reduced regulary requirements."*[1]

[1] OECD, Environment Directorate, Joint meeting of the Chemicals committee and the Working party on Chemicals, pesticides and biotechnology data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern, 27 -Jan-2009, ENV/JM/MONO(2009)1, p.10

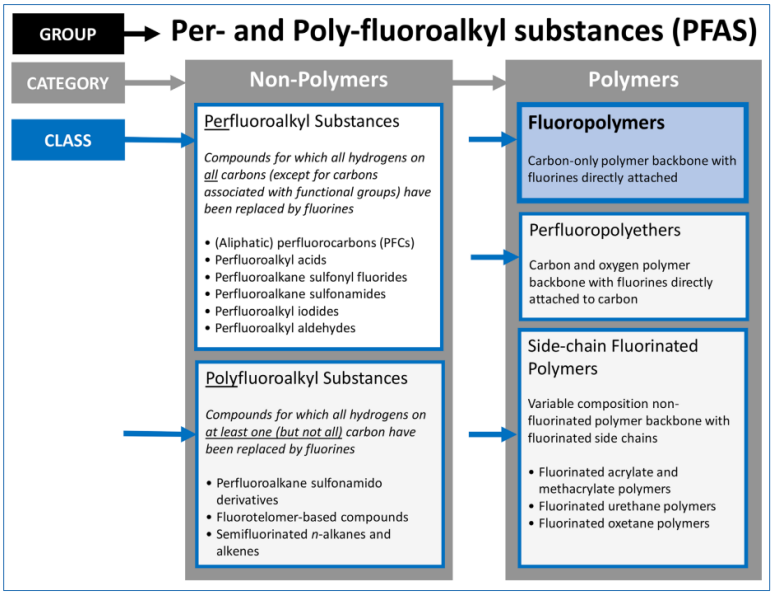

Figure 1: *Per-and poly-FluorAlkyl Substances (PFAS) categorised in 5 classes*[2]

Figure 1 visualises that the class of per-and polyfluoralkyl substances (PFAS) consists of non-polymers and polymers. Non polymers have short chains (gases and vapours) and polymers have long chains (solids and liquids).
Short chains are very hazardous because they are toxic, bioavailable and bio-accumulative (they build up in our body), hence a restriction seems justified.
AEGIR-Marine agrees and fully supports the restriction proposal to ban substances in the 'white boxes' of figure 1: Perfluoroalkyl Substances, Polyfluoroalkyl Substances and Side-chain Fluorinated Polymers.

The fluoropolymers, visualized in **Figure 1,** in the blue coloured box in the upper right quadrant includes fluoroelastomers, like FKM, which are non-toxic, non-bio-accumulative, non-bioavailable, and non-mobile, hence non-hazardous.

- **Fluoropolymers should be fully exempted from the restriction. Fluoropolymers are safe to use and shouldn't be banned.** Why?
  Fluoropolymers have very long chains. The fluoropolymer FKM is a fluoroelastomer and a '*polymers of low concern*'.
  Lohman[3] (2020) et al. criticized the PLC status of all fluoropolymers because, the PLC-status is based on a mass-based (molecular weight) cut-off related to cellular uptake, and they brought 2 relevant elements into the debate:

[2] Henry, B. et al*, A critical review of the application of Polymer of Low Concern and regularly criteria to fluoropolymers, 2018.*

[3] Lohmann R., Cousins I.T., DeWitt J.C., Glüge J., Goldenman G., Herzke D., Lindstrom A.B., Miller M.F., Ng C.A., Patton S., Scheringer M., Trier X., and Wang Z. (2020): *"Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?"* Environ Sci Technol 54 (20), 12820-12828. DOI: 10.1021/acs.est.0c03244.

- They argued that Henry et al. analysed a data set that was restricted to only a few polymers substances;
- The study of Henry et al. is focused on the use-phase, while the whole life-cycle of fluoropolymers should be taken into account (also disposal end-of-life).

These elements add an important nuance to the study of Henry et al. (2018).

To AEGIR-Marine, the study of Korzeniowski et al. (2022), does apply due to the very high number average molecular weight of the fluoroelastomer it uses. Fluoropolymers have in addition to long chains, a very high number average molecular weight (Mn).

Based on sound scientific research, the OECD[4] reported the importance of the 'number average molecular weight' (Mn), which determine the bioavailability and warn of potential hazard (details and references see section 5). The OECD states: *"The most significant and commonly used criterion for establishing a PLC is its Mn range of >1000 Da."* And a second indicator mentioned was: *"Another commonly used criterium for establishing PLC is its oligomer content, and this may be determined for <1000 Da and <500 Da species."*
From this research the main findings were that from a point of view of health and ecotoxicology, safe polymers (PLC) had the following characteristics:

- **Mn values are >2000 Da;**
- **<1000 Da oligomer contents are <5%;**
- **<500 Da oligomeric species are <2%.**

Korzeniowski et al. also mentioned that molecular weight is an important predictor of biological effect, because **large molecules (>1000 – 10.000 Da), are too large to penetrate cell membranes and because they cannot enter the cell, such as the reproductive system, they are not bioavailable.**[5]

For the seals/sealing applications of AEGIR-Marine, the findings of OECD on molecular weight and oligomeric content, are very relevant. And also the study of Korzeniowski et al. who specifically investigated the properties of the FKM Fluoroelastomers, is applicable to the products of AEGIR-Marine.
From the findings of these thorough studies can be concluded that on health and ecotoxicological effects, the **FKM fluoroelastomers** used by AEGIR-Marine **meet the Safe norms of the OECD, with a broad bandwidth, and that there is no concern for health, nor for the environment.**

[4] OECD, Environment Directorate, Joint meeting of the Chemicals committee and the Working party on Chemicals, pesticides and biotechnology data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern, 27 -Jan-2009, ENV/JM/MONO(2009)1, p.10 and p.21-30; p37.
[5] S.H. Korzeniowski, R.C. Buck, R.M. Newkold, A. El kassmi, E. Laganis, Y. Matsuoka, B. Dinelli, S.Beauchet, F. Adamsky, K. Weilandt, V. Kumar Soni, D. Kapoor, P. Gunasekar, M. Malvasi, G. Brinati, 0. Musio; "*A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*", Integrated Environmental Assessment and Management—Volume 19, Number 2—pp. 326–354326, Accepted: 7 June 2022, p11.

Special issue: vulcanized FKM matrix/network is far too large to penetrate cell membranes

Another relevant point to mention here is that Henry, Lohman and Korzeniowski researched on level of (stand-alone) molecules. The FKM used by AEGIR-Marine is a result of **vulcanization** which means that FKM is a **network structure** *(there are no stand-alone molecules anymore)* **in which molecules are cross-linked together in a matrix/network.** *(it is like baking flour and cake, the network/matrix structure is comparable to the cake in this example and the stand-alone molecules are the flour).*

This means also that the crosslinked FKM matrix/network more stable is than the FKM polymer itself. And this means that:

- a (stand-alone) **FKM molecule is too large** to penetrate cell membranes;
- **FKM as matrix/network is far too large** to penetrate cell membranes.

Criterium	Safe norm PLC according to OECD[6]	FKM Value	Conclusion
Number average molecular weight (Mn)	>2000 Da	**30,000 – 340,000 Da**	**No concern**
% Oligomeric content of <1000 Da	<5%	**<1%**	**No concern**
% Oligomeric content of <500 Da	<2%	**<1%**	**No concern**
Water solubility	Insoluble	**Insoluble**	**No concern**

Table 1: *Overview of FKM values compared to Safe norm PLC according to OECD.*

From the above-mentioned **investigations was concluded:**

- The FKM fluoroelastomers used by AEGIR-Marine satisfy the widely accepted polymer hazard assessment criteria and thus are 'polymer of low concern (PLC)' according to these OECD criteria.
- The fluoroelastomers used by AEGIR-Marine are not bioavailable, not hazardous for humans, thus of no concern for health and environment, due to:
    - The very high number average molecular weight of FKM, falls - with a broad bandwidth - within the Safe norm of the OECD;
    - The FKM value of the oligomeric content of <1000 Da, falls - with a broad bandwidth - within the Safe norm of the OECD;
    - The FKM value of the oligomeric content of <500 Da, falls - with a broad bandwidth - within the Safe norm of the OECD;
    - The fluoroelastomer (FKM), with a **very large molecular matrix structure due to vulcanization, cannot penetrate into cells membranes, thus is safe.**

[6] OECD, Environment Directorate, Joint meeting of the Chemicals committee and the Working party on Chemicals, pesticides and biotechnology data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern, 27 -Jan-2009, ENV/JM/MONO(2009)1, p.10 and p.21-30; p37

To further substantiate the before-mentioned conclusions, it is **widely acknowledged that FKM fluoroelastomers are safe in use:**

- Fluoropolymers are safe for use, hence used for eye lenses, kidney dialysis, stents and heart valves etc.
- The Health and Safety Executive (HSE) i.e., **the agency for UK REACH**, gave a **full exemption:** *"The restriction(s) set out above need not apply to low hazard groups or low risks uses, for example fluoroplastics or fluoroelastomers. These could be highlighted as derogations to any restriction proposal."*[7]

- **There is no alternative for fluoropolymer FKM, which plays a critical role in the vital propulsion system of seagoing vessels.** Every container vessel, oil- and gas tanker or cruise ship depends heavily on FKM (fluoroelastomer rubber is part of the fluoropolymers 'family') were it plays a critical role in the vital propulsion system of a seagoing vessel. FKM is used as a fluoropolymer seal rubber to seal against leakage and spill of oil from the oil bath of the shaft propeller bearings unto the environment / sea water. These seals perform under extreme heavy conditions, which require -for example- resistance to continuous high temperatures - between **130 °C** and **150 °C -** chemical resistance and mechanical strengths and a low friction coefficient, for a safe use of at least 5 years. This is the period between 2 scheduled major overhauls for which dry-docking is needed (see for an overview **table 2**).

Substance FKM-Fluoroelastomers	
A potential alternative substance for FKM for use as seals and/or in sealing applications in marine shipping; must fulfil – at least - the following cumulative requirements: **a) continuous high temperature as from 130 °C and much higher degrees;** **b) long-term chemical resistance to oil;** **c) long-term chemical resistance to (salt)-water;** **d) sufficient mechanical properties: such as tensile and tear strengths, fatigue strength, abrasion resistance;** **e) sufficient static modulus or hardness to carry axial force exerted by the Garter spring;** **f) low compression set at different temperatures between 0 °C and operating temperatures for various durations;** **g) brittleness temperature in marine applications ≤ -5 °C; and** **h) need to perform safely for a duration of 5 years (dry-docking)**	
Potential Alternative substance	**Suitable alternative?**
H-NBR	**No, because H-NBR does not fulfil requirement(s) a), b), c) and h).**
FVMQ	**No, because it fails severely on c) and d), and so on h).**
ACM	**No, because it fails on a), d), g) and h).**
High CAN NBR	**No, because it fails on a), d), g) and h).**

Table 2: *Overview potential alternatives for FKM for use as seals and/or in sealing applications in marine shipping.*

[7] HSE, Analysis of the most appropriate regulatory management options (RMOA), Poly-and perfluoroalkyl substances (PFAS), March 2003, p.174.

Currently there is no alternative for FKM, as is scientifically evidenced by the study conducted by Noordermeer and Masen (2023)[8]: *"**FKM is by far the highest temperature resistant elastomer, with excellent material properties and water/oil resistance with a duration of at least 5 years**. There is **no alternative rubber material available** which can match its properties to meet the required high-performance standards for the safe use of these seals in the **marine transport sector.** Experience over the past decades shows that no alternatives exist that match the combination of characteristics required to substitute FKM. **Replacing FKM in propeller shaft seals is hardly realistic and will require at least many years of research."*** (More details and references: see section 4 and the attached study conducted by prof. J. Noordermeer[9] and ass. prof. M. Masen).

- **The European maritime industry is of strategic importance for the EU economy but will be hit hard.**
  The maritime industry plays a vital role in the global economy, more than **80% of the world trade is transported by shipping.** Of all goods that are imported/exported **to and from the EU 77%** are transported by sea. Shipping industry is **the aorta of global and European trade** and the most efficient and environmental-friendly way of transportation.
  The maritime sector contributes on European level 149 billion GDP (Gross Domestic Product) annually. With 23,400 vessels the EU fleet amounts to 39,5% of the world fleet[10]. Based on research from the Oxford Economics Institute the total number of jobs in the maritime industry in the EU in 2020 amounts to 2 million. There is estimated that due to the restriction a substantial part (it is assumed between 30%-50%) of the maritime activities will leave the EU/EEA to Asia, the UK or the Middle East. On EU level this could lead to a reduction between 30% to 50 % and will than cost around 45 - 70 billion GDP and will have serious social impact between 600,000 to 1,000,000 jobs. (For more details and references see chapter 4 and 10).

- **The restriction proposal leads to an uneven level playing field: the maritime industry will leave EU/EEA.**
  With the upcoming restriction, there is no level playing field in the EU anymore to compete effectively with global players. Firstly, as mentioned, at the other side of the Canal, the UK will give a full exemption to fluoropolymers, **so it is easy to dock ships in UK.** Secondly, ship owners mention that they **will leave for Asia or the Middle East** for dockings, thus the EU will lose a substantial part of the maritime business. The effects will be dramatic, because on the long-term maritime companies will withdraw not only their operational activities but also their research and development activities from the EU/EEA. The maritime innovation in the EU will stifle seriously and knowledge will drain out of the EU/EEA. (For more details and references see section 10).

- **There are enormous difficulties to control and enforce the prohibition on a running ship.**
  Because the propulsion system is part of the underwater machinery, authorities are not able

[8] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 15. (ANNEX 1).
[9] For resumes of prof J. Noordermeer and ass. Prof. M. Masen see ANNEX 4 and ANNEX 5.
[10] Oxford Economics Institute, 2020. https://www.ecsa.eu

to control whether a certain material for a seal is actually used. Thus, adequate enforcement of a ban will be extremely difficult and in fact impossible.

- **AEGIR-Marine's way forward is to intensify and extend their current R&D activities** which entail 4 programs:
  - **Firstly, intensify the current R&D activities in search for alternatives,** with a new focus. After years of research the focus has been changed from (searching for improvement of basic compounds) to focus on decreasing friction, to lowering of the temperature, and whether other materials can be used in a changed setting:
    - AEGIR-Marine currently runs 2 different R&D projects now on decreasing friction and temperature; these showed potentially promising first results, but positive Duration tests results will be crucial for actual success in the coming years.
    - Timeline of these 2 projects – including Class Type Approval – will be between 12 and 15 years (for more details see section 10).
  - **Secondly, closing the loop for persistent FKM.** AEGIR-Marine acknowledges the persistency of the fluoroelastomers used in their process and is therefore creating a circular solution to collect all the used seals and to re-cycle these seals. Focus will be on the end-of-life phase of the seals, by closing the loop; this is needed because of the persistency of the fluoroelastomer FKM. **Philosophy of AEGIR-Marine: no FKM seal of AEGIR-Marine will end up in the environment.**

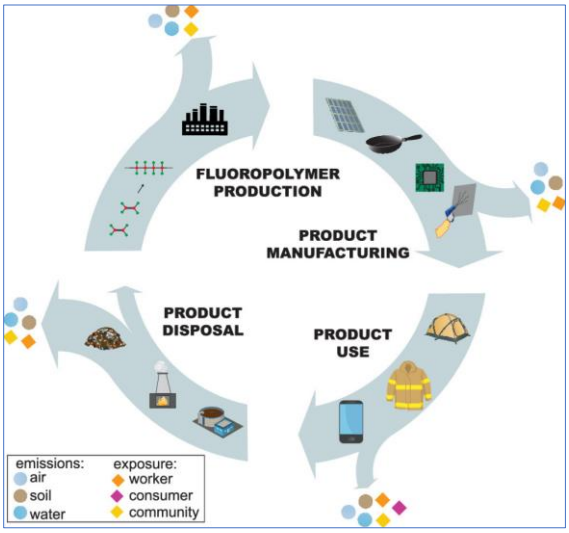

Figure 2: *Conceptual diagram of PFAS emissions during fluoropolymer production, product manufacturing and disposal. Source: Lohman et al, 2022*

AEGIR-Marine has enrolled the "AEGIR-Marine Circular Collection Program"; which entails a collection program to assure that all used seals come back to the Netherlands in a special container. The next step is under research, but one thing is clear: it will be a controlled next step.

- **Thirdly, AEGIR-Marine initiated a 3rd R&D-project** to investigate the best way (i.e. most **environmentally sustainable and economically** feasible) to approach the re-collected seals at their **end-of life**. Currently the two options are:
  - Incinerate controlled at > 850 ^{0}C;

- Re-cycle in a new life-cycle (4th R&D-project).

- **Fourthly AEGIR-Marine initiated a 4th R&D-program on de-vulcanisation** of fluoro-elastomers with the aim to re-cycle the material (preferably to fully recycle the material to re-use it for new seals):
  - This R&D-program is currently running with potentially promising first results, but it is still at an early stage and thus still a long way from implementation in actual seals (keeping in mind that the test-phase will - by definition - require a solid test/trial-phase; due to safety and environmental risks when seals are installed in the ships.

Conclusion and request.

- Due to the before mentioned points, AEGIR-Marine requests for a 12-15 year derogation in order to get the time needed to find the suitable and sustainable solutions.
- AEGIR-Marine will intensify the current R&D projects; and is already minimizing the persistency related issue during this time by collecting the used seals, but the time for the derogation is needed and will support that the (after)market for repair & maintenance and overhaul of marine ships stays in the EEA, instead of moving to countries outside the EEA, without environmental gain.
- The timeline of 5 years derogation is definitely much too short. Only the development and testing / validation phase will last 6-7 years and after that serious testing (inner/outer seal) and Type approval must also being performed, before Market Introduction can start safely.
- These projects – including Class Type Approval – will take between 12 and 15 years, as is shown in the below **figure 3** (for details and references see section 10).

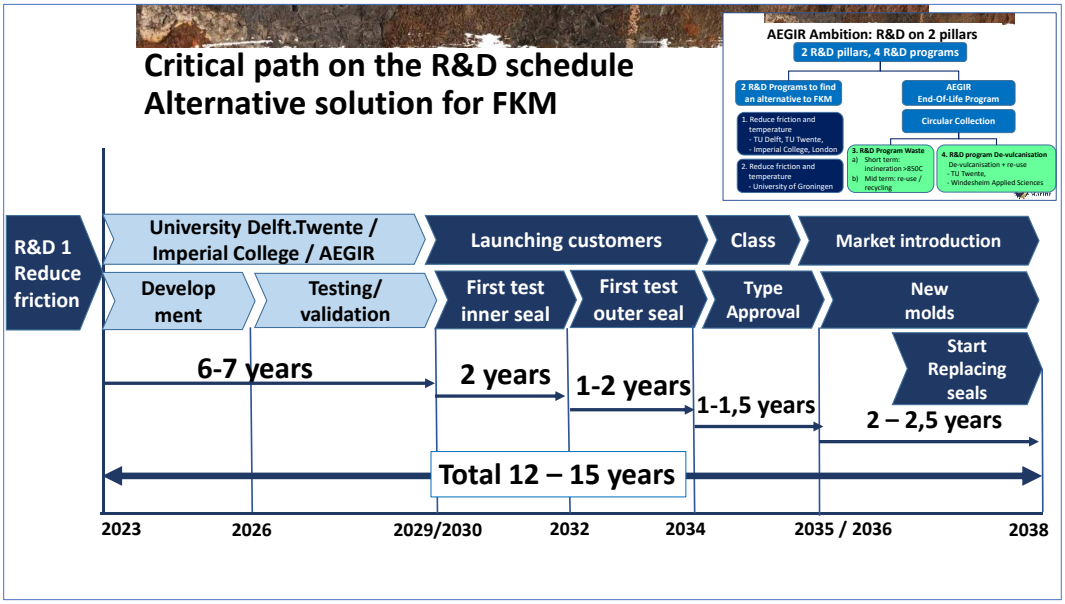

Figure 3*: Critical path on R&D schedule in search for an alternative for FKM rubber*

- AEGIR-Marine is an innovative, healthy and fast growing company with significant growth potential, many very satisfied clients, turnover of 40 million euros and 180 highly motivated and involved people.

Two scenarios have been shown:

Scenario 1

- **Risk Management Option A, a ban + 18 months transition and/or a 5 year derogation** showed the seriously negative impact of a ban. In case of a ban without derogation, AEGIR-Marine will stop to exist in Europe as of Spring 2026; the effect will be a turnover downturn for AEGIR with 28 million euro's; 90 colleagues (50%) will have to be dismissed in Europe. Even though there is no hazardousness for human health or the environment, because the used material (FKM) is a fluoropolymer (polymer of low concern) and FKM possess a matrix/network structure, so this structure is far too large to penetrate cell membranes (see section 5 for more details). Because there is no alternative for FKM yet, use of inadequate alternative substances will result in an environmental burden of marine waters, which is estimated to increase from 50 million litres to 75 to 100 million litres oil leakages annually (see the whole overview in **table 3**).

IMPACT	Current Baseline	Risk Management Option A: ban + 18 months
Economic impacts	Growth 40 million '22 to approx. 80 million '33	**Turnover drop (54%) from 52**[11] **million euro's in '25 to 24 million euro's in '26** and growth to 34 million euro's in 2033
Environmental risks	FKM: very persistent	Drop of volume FKM
	Disposal of used seals, approx. 12.000 kg/year	End-of-Life policy: collection and controlled incineration of used seals at 850^{0}C
Human Health risks	**No risk** for use FKM fluorpolymer of low concern	**No risk**
Social impacts	Growth from 180 colleagues '22 to 330 in '33	**90** colleagues dismissed in '26
Wider economic impacts on EU/EEA level	NA	**30%-50%** shipowners **will leave** EU/EEA
Wider economic impacts on EU/EEA level	NA	**Loss of 45-70 billion GDP** level EU/EEA **Loss of 600,000 – 1,000,000** maritime jobs on level EU/EEA
Wider environmental risks	NA	**25-50 million litres oil more spilled** in the sea annually
Conclusion:		**Dramatic negative effects on environment, social and economic aspects**

Table 3: *Overview of impact of a ban + 18 months transition period*

[11] These figures result from the detailed explanation in the next sections of this report, in particular section 10.2.

Scenario 2

- **Risk Management Option B, a 12- 15 years derogation,** shows an option to a sustainable future via high R&D efforts:
  By giving a derogation of 12 - 15 years there is an option to find a **real alternative** for the use of FKM; and there is an option for **de-vulcanisation of used seals**, to re-use the substances again. The environment in marine waters will be polluted less by lubricants (25-50 million litres less spilled oil) and AEGIR-Marine will take a large step towards a Circular Economy.
  By giving a 12–15-year derogation there will remain a level playing field between parties active in the EU and global market players; the 12-15 years will be used to build a stronger, more innovative, sustainable and safer economy in EU/EEA, with behold of 30%-50% shipowners that will stay in the EU. A downturn with 45-70 billion GDP on EU level will not happen and on the social side 600,000 – 1,000,000 jobs will be saved.
  By giving a 12–15-year derogation, AEGIR-Marine will continue its activities, 180 colleagues will keep their jobs and they have also the possibility to contribute in a positive and innovative way to create a solution for the persistency of FKM (see for an overview **table 4** below).
  Above all: on EU level it will be possible to strengthen the Green Economy (Hydrogen, electric cars etc) for with FKM - fluoropolymers are being used and for which alternatives have to be found.

IMPACT	Current Baseline	Risk Management Option B: 12-15 years derogation+ 18 months
Economic impacts	Growth 40 million '22 to approx. 80 million '33	Turnover AEGIR-Marine will grow to approx. **80**[12] **million** in 2033
Environmental risks	FKM: very persistent	Due to our **2 R&D** programs, there will be **a safe alternative solution.** FKM will be changed for non-PFAS material
	Disposal of used seals	Due to our **2 R&D** programs there will be: - de-vulcanization of used seals; - re-cycled + re-used again as Circular solution
Human Health risks	No risk for use FKM fluoropolymer of low concern	**No risk**, AEGIR-Marine **will use other materials** for seals than FKM, due to R&D activities
Social impacts	Growth from 180 colleagues '22 to 330 in '33	Growth from **180** colleagues in '22 to **330** colleagues in '33
Wider economic impacts on EU/EEA level	NA	Innovative climate in EU will strengthen the Green Economy (**Hydrogen, electric cars** etc.) **No brain drain** out of EU/EEA
Wider economic impacts on EU/EEA level	NA	**Behold of 30%-50% shipowners,** who will stay in EU/EEA **No turndown of 45-70 billion** GDP level EU/EEA **No loss of 600,000 – 1,000,000** jobs
Wider environ-mental risks	NA	**25-50 million litres oil <u>less</u> spilled** in the sea annually, than in scenario RMO A
Conclusion		**Positive outcome on all factors on level of AEGIR and EU/EEA**

Table 4: *Overview of the impact of a 12-15 years derogation*

[12] These figures result from the detailed explanation in the next sections of this report, in particular sections 10.3-10.5.

Request AEGIR-Marine:

- Please honour the request to execute Risk Management Option B by granting a derogation of 12–15 years.

3. Importance of Restriction proposal, its concerns & legal considerations

AEGIR-Marine recognises and supports the importance of restricting the use of certain PFASs that poses a risk to human health or the environment and welcomes and fully supports the initiative of restriction proposal of the five Member States in that respect. For many individual PFASs-substances **it is clear that they pose a risk to human health or the environment** and this results from the restriction proposal and the evidence provided. However, for **Fluoropolymers** and in particular **for the Fluoroelastomers - part of the Fluoropolymers - 'FKM[13]', the risks are not clear and is not adequately evidenced in the restriction proposal.** Considering that also the RAC and SEAC-Committees operate within the context of Regulation No 1907/2006[14] (hereinafter "REACH") and EU-rules in general, AEGIR-Marine provides some legal considerations in relation to the use of fluoroelastomers in the maritime shipping sector.

The (revised) general OECD (2021) definition of PFASs, used in the restriction proposal, is based on a coherent and consistent approach across compounds (the compounds share the same trait for having a fully fluorinated methyl or methylene carbon moiety), based on the chemical structure which makes it easier to distinguish between PFASs and non-PFASs. However, it is important to notice that the OECD definition[15] never concluded that all PFASs have the same properties, uses, exposure and risks. This is also explicitly acknowledged in the restriction proposal "*The OECD definition of PFASs is based on chemical structure. Hazardous properties or risks are not part of it.*"[16] In the restriction proposal - in addition - a concern-based scope is chosen as it aims to cover all PFASs that are **very persistent**, to address the concerns associated with this persistent nature.[17] Targeting PFASs in that way entails the risk that substances that are persistent, but not hazardous, are included in the scope of the restriction proposal. The procedure for restrictions, incorporated under Title VIII REACH, requires that the Member States show that the manufacture, placing on the market or use of FKM in an article **poses a risk** to **human health or the environment** that is **not adequately controlled** and **needs to be addressed.[18]** "*Very persistent*" - as such – without showing an 'unacceptable risk to human health or the environment' for fluoroelastomers does not meet the threshold required under REACH for a restriction proposal (more explanation in chapter 5 'Hazardousness' below).

[13] PFASs Restriction proposal 22 March 2023, p.ix, FKM is defined as "*Family of Fluorocarbon-based Fluoroelastomer Materials*"

[14] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p.1

[15] OECD , www.oecd.org/chemicalsafety; ENV/CBC/MONO(2021)25, p.18 and p.25

[16] PFASs Restriction Proposal, 22 March 2023, p. 19

[17] PFASs Restriction Proposal, 22 March 2023, p. 19

[18] Note that REACH aims not only at ensuring a high level of protection of human health and the environment, but also aims at the free circulation of substances on the internal market while enhancing competitiveness and innovation; see Article 1(1) REACH.

In addition, the approach of the Member States – PFASs as group of over 10.000 compounds banned (under RO1 or RO2), based on their very persistent nature - implies that the burden of proof in this restriction proposal can be reversed to 'the downstream user and/or manufacturer'[19] (as defined under Article 3 REACH).

Indeed, the 'downstream user' who uses fluoroelastomers FKM in its seals in maritime shipping has not been provided with evidence that the very persistent nature of the seals poses a risk to humans or the environment, nor that such risk would not be adequately controlled and needs to be addressed. Nevertheless, under the restriction proposal the use will be banned and by providing evidence one can - at best - obtain a derogation under RO2 to stay for a longer period on the internal market. That the use of FKM in maritime shipping has not been assessed adequately under REACH, results also from the fact that the restriction proposal does not provide justifications for the worldwide market of maritime shipping – as required under Annex XV REACH – in particular the effectiveness, practicability and monitorability of a ban in this worldwide sector is lacking.

For the reasons indicated above**, AEGIR-Marine is of the opinion that there is no legitimate legal basis for a ban of fluoroelastomers, and in particular a ban of FKM, under the REACH restriction process, and it will exceed the powers provided for in the Regulation (REACH)**. The restriction proposal 1) does not establish that fluoroelastomers pose a risk to human health or the environment and 2) does not established that such risk (if it would exist) is not adequately controlled and needs to be addressed in the maritime shipping sector. There is no legal basis to reverse the burden of proof for use in maritime shipping by stating that fluoroelastomers are persistent without showing hazardousness.

The position of AEGIR-Marine is confirmed by the **Analysis of PFASs conducted by the Health and Safety Executive (HSE) i.e., the agency for UK REACH in March 2023**. Without further ado the HSE provides a full exemption for fluoroelastomers from any ban, based on the fact that these are polymers of low concern: *"***The restriction(s) set out above need not apply to low hazard groups or low risks uses, for example fluoroplastics or fluoroelastomers. These could be highlighted as derogations to any restriction proposal.[20]"**

Having said that, in the remaining part of this submission AEGIR-Marine follows the procedure with the objective to obtain at least a 12-year derogation under the restriction proposal, for the reasons substantiated in this submission.

[19] Downstream user and manufacturer are defined under Article 3 Reach.

[20] HSE, Analysis of the most appropriate regulatory management options (RMOA), Poly-and perfluoroalkyl substances (PFAS), March 2003, p.174.

4. Sectors, uses and benefits

Introduction of AEGIR-Marine and the maritime sector

AEGIR-Marine delivers sealing applications and provides services to the maritime industry, specifically propulsion systems and propeller shaft seals (or stern tube sealings). The main types in the ship repairing market are container ships; bulk carriers; oil and chemical tankers; general cargo; gas carriers; offshore vessels; ferries, mega yachts and passenger ships. The world market of these vessels amounts approximately 80.000 ships.

AEGIR-Marine was established in the year 2000 by two partners and is fast growing. Nowadays the firm has 180 people employed. AEGIR-Marine is based in the Netherlands, headquarters at Wijk bij Duurstede. AEGIR-Marine has currently affiliates in Shanghai, Singapore, Dubai, Walvis Bay, Panama, Fort Lauderdale, Tuzla.
The role of AEGIR-Marine in the production/supply chain of maritime seals is visible in **Figure 4**.

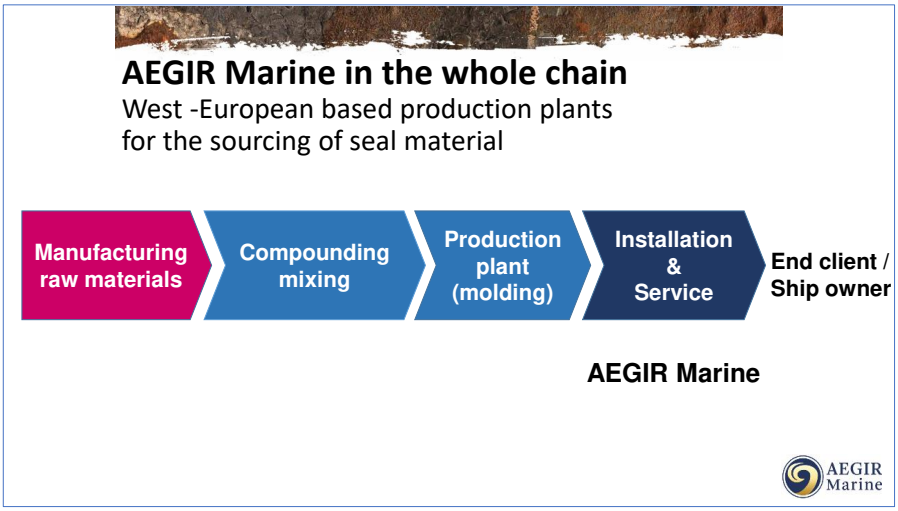

Figure 4. *Production/supply chain of marine seals in maritime sector & role of AEGIR-Marine.*

The maritime sector

The shipping industry is vital to the world-wide and EU-economy, **more than 80% - 90% of the global** trade is transported by ship[21,22] by volume roughly 11 billion tonnes annually. Around 77% of the goods that are imported/exported to and from the EU are transported by sea.[23]
Sea transport is the aorta of the world economy and the European economy. The incident with the cargo vessel '*Ever Given'* in the Suez Canal in 2021 made the huge importance and impact of this shipping transport system crystal clear.
Thereby is maritime shipping - in comparison - a very environmentally friendly way of transport. The **emissions of CO2** per tonne kilometre (tkm) of **cargo transported by ships are very low**. Research on emissions was done in 2022 on marine shipping, air cargo and heavy goods vehicles (HGV), and showed that **marine shipping had the lowest emissions with 7 gCO2/tkm compared to** HGV with 137 gCO2/tkm and air cargo with 1,036 gCO2/tkm.[24]

The EU has a significant impact on the worldwide maritime sector with 23,400 vessels the EU fleet amounts to **39,5% of the world fleet.**[25] On **European level the contribution of the maritime sector is 149 billion GDP annually.** Based on research from the Oxford Economics Institute amounted in the European maritime industry in **2020 in total number of jobs of 2 million**.

Due to the crucial role of sea transport, the capacity of ships has been grown in the last decades. Maritime shipping companies are incited to use the largest containerships possible on their shipping routes because of the benefits of economies of scale. This led to an increase of performance standards in time. To give an example. Around 1970, a containership could transport 1,500 TEU (Twenty foot Equivalent Unit); in 2000 the capacity was grown to approx. 7,000 TEU and nowadays the capacity for a containership is approx. 24,000 TEU.[26] Thereby has the speed increased in these years from 33 km/hr (18 knots) to 45 km/hr (25 knots). This means that the performance requirements for propulsion of cargo vessels have changed severely over time and that the **requirements of one decade ago do not meet the required standards of performance for parts and equipment of today**.

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[21] R. Grynspan, "Review of the maritime transport 2022", UNCTAD, 2022. https://unctad.org/system/files/official-document/rmt2022_en.pdf

[22] Website chilternmaritime https://www.chilternmaritime.com/why-is-the-maritime-industry-so-important/
" The maritime industry is vital for global trade and economic growth for a wide range of reasons that encompass almost every aspect of modern life. As a result, answering the question "why is the maritime industry so important?" isn't easy. To do it justice, we've broken down our answer into three key points:
- Essential for global trade
- A major source of employment
- It's important for environmental protection"

[23] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, p. 93, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

[24] Fraunhofer ISI and CE Delft, 2020. https://www.eea.europa.eu/publications/rail-and-waterborne-transport

[25] Oxford Economics Institute, 2020. https://www.ecsa.eu

[26] J.P. Rodrigues, The geography of Transport Systems, New York, 2020. Evolution of Containerships | The Geography of Transport Systems (transportgeography.org)

This is true for cargo vessels but applies equally to virtually all vessels (e.g. cruise ships, fishing boats etc.) as the size and speed increased significantly (see **figure 5**).

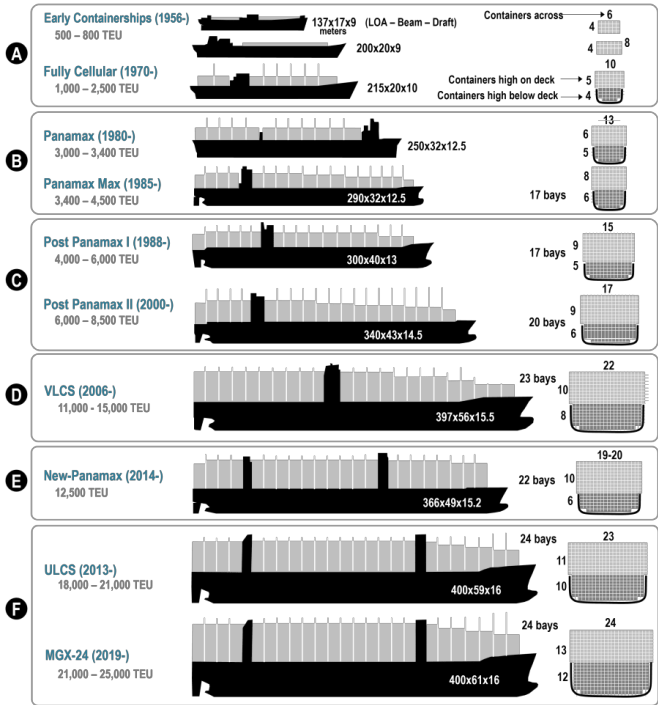


Figure 5: *The evolution of Containerships*
(The geography of Transport Systems, J.P. Rodriques, New York, 2020)

Type of fluoropolymer used for stern tube seal in vessels.

The seal material used for vessels is a fluoroelastomer, e.g., FKM, which belongs to the family of fluorocarbon-based fluoroelastomer materials. 60% or more of the fluoroelastomers (e.g., FKM) produced, are used in sealing applications in the transport sector[27]. AEGIR-Marine delivers sealing applications and services to the marine sector, specific for the propulsion systems and shaft propellers of vessels (container ships; bulk carriers; oil and chemical tankers; general cargo; gas carriers; offshore vessels; ferries, mega yachts and passenger ships), where these fluoroelastomers (FKM) are used.

The majority of ocean-going ships operate with oil-lubricated propeller shafts and use lubricating oils in on-deck and underwater (submerged) machinery e.g., the propulsion system.[28] (see **figures 6a and 6b**).

[27] PFASs Restriction Proposal, 22 March 2023, Annex A, p 95

[28] European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry, Le Biot, France, 2022, Case study, p3. (ANNEX 2)

Figure 6a: *Overview of a vessel with (under deck) the engine and propulsion system.*

Vital part of a ship is the propulsion system, consisting of the propeller shaft, which is supported by white metal sliding bearings. These bearings function within an oil bath; the elastomeric rubber sealings are used to seal the oil bath.[29] **Since 2013, the environmentally allowed oils/lubricants have changed from mineral oils to primarily ester-based oils (EALs), which are much more acid (if combined with sea-water). This requires that seals are more acid-resistant than in the past.**

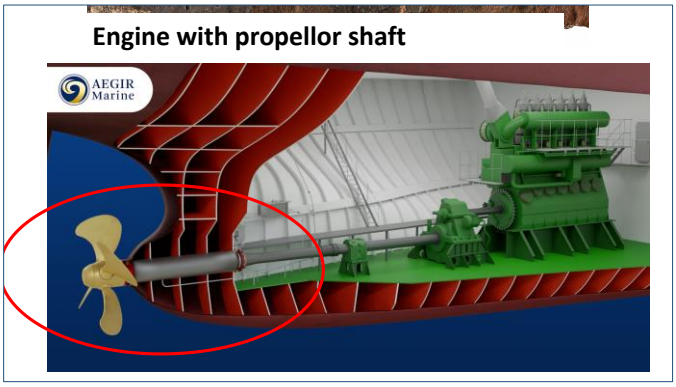


Figure 6b: *More detailed view of the propulsion system.*

One of the important functions of these elastomeric seal rubbers is to separate oily environments in ships from the (sea-)water, in order to avoid environmental spillage of oil from the oil bath into the sea and vice versa and function also to guarantee the hull integrity (see also the attached scientific study of prof J. Noordermeer et al, 2023).[30]

Key functionalities of fluoroelastomers (FKM)

Key functionality of the fluoroelastomer seal rubber is to seal under extreme high temperature (> **130 ^{0}C)** against leakage and spill of oil from the oil bath unto the environment / sea-water and also functions to guarantee the hull integrity.

[29] J.W.M. Noordermeer and M.A Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 3. (ANNEX 1).

[30] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 7. (ANNEX 1).

It is the **combination of** the following four properties that are essential for these elastomeric seals (non – exhaustive list):

- long-term high temperature (**130 ^{0}C – 150 ^{0}C**);
- long-term chemical resistance (**aggressive chemicals, salt water and ester-based oils[31] (EALs**);
- long-term sealing properties (mechanical strength, tensile and tear strengths, fatigue strength, abrasion resistance; low compression set, pressure resistance, **low friction coefficient**);
- durability of **at least 5 years**; this is the period between two standard scheduled dry-dockings needed for a major overhaul.

Fluoroelastomers are typically used for sealing applications because of the above-mentioned properties.[32] FKM has these unique required material features, such as mechanical and abrasion properties, and the resistance to acids and steam generated from the ester-type oils in combination with the high temperatures encountered by the seals.

In 2023 J. Noordermeer and M. Masen[33] defined material requirement criteria for seals and reviewed different types of alternative materials. One of these basic material requirements is the safe performance and endurance of maritime seals for at least 5 years.
In their study Noordermeer and Masen concluded: ***"FKM is by far the highest temperature resistant elastomer, with excellent material properties and water/oil resistance with a duration of at least 5 years; there is no alternative rubber material available which can match its properties to meet the required high performance standards for the safe use of these seals in the marine transport sector. Experience over the past decades shows that no alternatives exist that match the combination of characteristics required to substitute FKM. Replacing FKM in propeller shaft seals is hardly realistic and will require at least many years of research."***[34]

Class societies & type approval requirements

Goal of this section is to elaborate on specific requirements applicable in the maritime industry that needs to be taken into account when developing a new type of seal material: for reasons of safety **type approval requirements** must be complied with. The United Nations Convention on the Law of the Sea (UNCLOS) is an overarching convention concerned – amongst others with the granting of registration of a ship by a State. Once a ship is registered by a State, the convention imposes certain duties on this flag State.

[31] European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry, Le Biot, France, 2022 ((ANNEX 2).
[32] PFASs Restriction Proposal, 22 March 2023, Annex A, p 95
[33] For an overview of requirements see J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 8. (ANNEX 1).
[34] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 1. (ANNEX 1).

Under Article 94 UNCLOS, the flag State has the duties to "*effectively exercise its jurisdiction and control in administrative, technical and social matters over ships flying its flag*" and to take "*such measures for ships flying its flag as are necessary to ensure safety at sea with regard, inter alia, to: (a) the construction, equipment and seaworthiness of ships*."

Under guidance of IMO, International Conventions have set out uniform statutory requirements which cover – amongst others - aspects of the ship's design, its structural integrity, essential propulsion and steering equipment. The International Convention for the Safety of Life at Sea (SOLAS Convention, 1974) is generally regarded as the most important international treaty regarding the safety of (merchant) ships. *The main objective of the SOLAS Convention is to specify minimum standards for the construction, equipment and operation of ships, compatible with their safety. Flag States are responsible for ensuring that ships under their flag comply with its requirements, and a number of certificates are prescribed in the Convention as proof that this has been done*.[35]

Chapter II-1 SOLAS Convention titled "*Construction – Subdivision and stability, machinery and electrical installations*" includes requirements for machinery and electrical installations to ensure that services which are essential for the safety of the ship, passengers and crew are maintained under various emergency conditions. The SOLAS Convention also requires that ships are designed, constructed and maintained in compliance with the structural, mechanical and electrical requirements of a Classification Society which is recognised by the Administration of a Flag State.

According to IACS (the International Association of Classification Societies): "*More than **90% of the world's cargo carrying tonnage is covered by the classification design, construction and through-life compliance Rules and standards set by the Member Societies of IACS"***[36]. "*The objective of ship classification is to verify the structural strength and integrity of essential parts of the ship's hull and its appendages, and the reliability and function of the propulsion and steering systems, power generation and those other features and auxiliary systems which have been built into the ship in order to maintain essential services on board. Classification Societies aim to achieve this objective through the development and application of their own Rules and by verifying compliance with international and/or national statutory regulations on behalf of flag Administrations."*[37]

[35] Source website IMO; https://www.imo.org/en/About/Conventions/Pages/International-Convention-for-the-Safety-of-Life-at-Sea-(SOLAS),-1974.aspx

[36] IACS 2020, latest update March 2022, *Classification societies – what, why and how?, p.1* https://iacs.org.uk/media/8871/classification-what-why-how.pdf

[37] IACS 2020, latest update March 2022, Classification societies – what, why and how?, p.3 https://iacs.org.uk/media/8871/classification-what-why-how.pdf

All Classification societies (often referred to as Class of class societies) – in particular in their role of recognised organisations of Flag States – must carry out their duties to issue approval certificates while being strictly independent, with highly specialised technical competence, whilst applying a rigorous quality management. **A Class Society can suspend or withdraw ship from class and will notify the relevant flag Administration.** The latter will generally invalidate the statutory certificates concerning construction and equipment, which basically will mean that the ship cannot operate and will not be insured.

AEGIR-Marine and type approvals from class: timeline
Stern tube seal arrangements and its complementary seal rings are critical parts for the technical functioning and safety of a vessel. As of 2005, AEGIR-Marine specializes in stern tube seals and produces its own stern tube seal arrangement. These seals are essentially based on the patent-free design of another manufacturer of such arrangements, which has been further developed and improved by AEGIR-Marine in the course of the years. AEGIR-Marine supplies (replacement) seals for all type and brands of type approved Stern Tube seal Arrangements. The stern tube seal arrangements of AEGIR have been Type Approved by a Class Society and also type approval for individual seal rings of AEGIR-Marine have been issued. In **Annex 3** examples are provided of Type approval-certificates obtained by AEGIR-Marine.

In Practice it can take up quite some time to obtain a type approval: For one type of seal the time required for the whole **approval process is between 1 and 1,5 year** as is proven in the past.

5. Hazardousness

Goal of this section is to answer the question what the hazardousness of the fluoroelastomer FKM is in its use by AEGIR-Marine.
The restriction proposal states that the key hazardous property common to all PFASs in the restriction proposal is that they are either very persistent themselves or degrade into very persistent PFASs in the environment (arrowhead).[38.]

Fluoropolymers are distinctly different from other polymeric and non-polymeric PFAS (Henry et al., 2018).[39] Due to their high molecular weight, narrow molecular weight distribution and negligible oligomer content and organic and inorganic leachable, **fluoropolymers have unique properties that constitute a distinct class in the PFAS group.**

[38] PFASs Restriction Proposal 22 March 2023, p.22.
[39] Henry, B.J., J.P. Carlin, J.A. Hammerschmidt, R. Buck, L.W. Buxton, H. Fiedler, J, Feed and O. Hernandez, 2018. "*A Critical Review of the Application of Polymer of Low Concern and Regulary Criteria to Fluoropolymers*", Integrated Environmental Assessment and Management 14(no 3), DOI: 10.1002/ieam.4035, pp. 316-334.

Based on their review and assessment of fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal and biological data, Henry et al. concluded that fluoropolymers satisfy the widely accepted criteria of *"polymers of low concern" (PLC).*
The OECD defined PLC as: *"Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements."*[40]

Lohman[41] et al. (2020) criticized the article of Henry et al. and mentioned that fluoropolymers are a too divers group to warrant a blanket exemption and consider them all as PLCs, because the low concern mass-based (molecular weight) as this relates to cellular uptake. Lohman et al. brought 2 relevant elements into the debate:

- They argued that Henry et al. analysed a data set that was restricted to only a few polymers substances;
- The study of Henry et al. is focused on the use-phase, while the whole life-cycle of fluoropolymers should be taken into account (also disposal end-of-life).

These elements add an important nuance to the study of Henry et al. (2018).

Building also on the prior study of Henry et al. (2018), Korzeniowski et al.[42] executed in 2022 a very detailed study to a range of 14 different polymers, including fluoroelastomers, one of which FKM.

Figure 7 below, with the subtitle "Figure 1 OECD polymer of low concern," derives from this study of Korzeniowski et al. (2022) and gives an overview of the 13 criteria of the OECD that -if all met – results in the conclusion that the substance fulfils the PLC-criteria.

[40] OECD, Environment Directorate, Joint meeting of the Chemicals committee and the Working party on Chemicals, pesticides and biotechnology data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern, 27 -Jan-2009, ENV/JM/MONO(2009)1, p.10 and p.37

[41] Lohmann R., Cousins I.T., DeWitt J.C., Glüge J., Goldenman G., Herzke D., Lindstrom A.B., Miller M.F., Ng C.A., Patton S., Scheringer M., Trier X., and Wang Z. (2020): *"Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?"* Environ Sci Technol 54 (20), 12820-12828. DOI: 10.1021/acs.est.0c03244.

[42] S.H. Korzeniowski, R.C. Buck, R.M. Newkold, A. El kassmi, E. Laganis, Y. Matsuoka, B. Dinelli, S.Beauchet, F. Adamsky, K. Weilandt, V. Kumar Soni, D. Kapoor, P. Gunasekar, M. Malvasi, G. Brinati, 0. Musio; "*A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*", Integrated Environmental Assessment and Management—Volume 19, Number 2—pp. 326–354326, Accepted: 7 June 2022

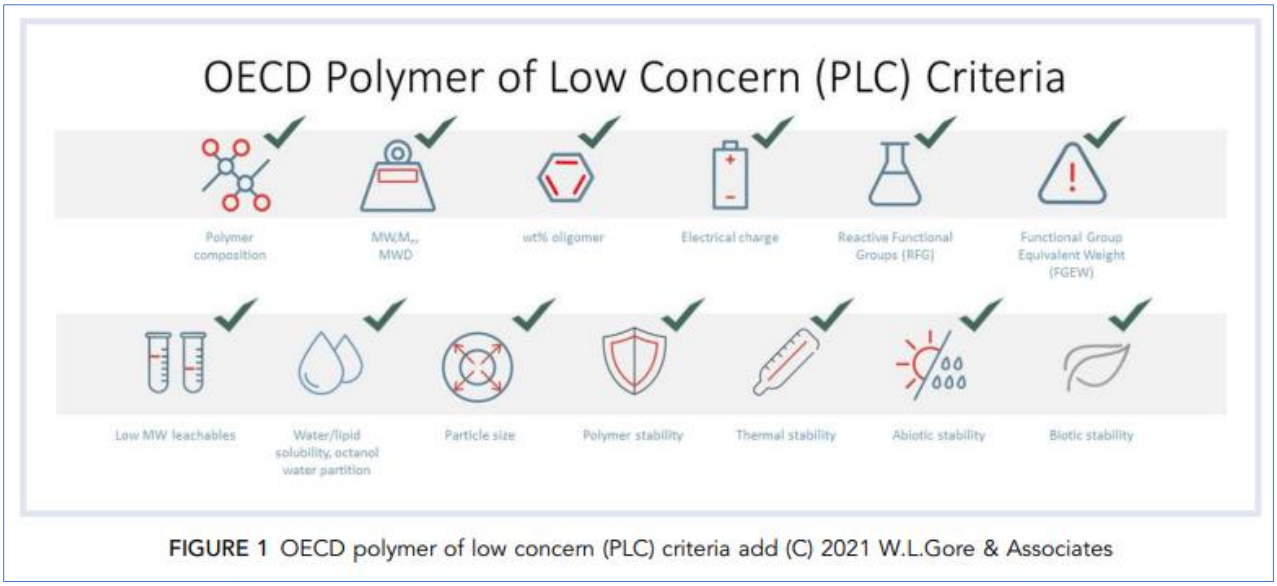


Figure 7: *OECD Polymer of low concern, Korzeniowski et al. (2022) p. 335.*

Relevant findings from the study of Korzeniowsky[43] et al. are that fluoropolymers are insoluble in water and are not subject to long-range transport; they are not bio-available, not bio-accumulative, non-toxic and – as such - **do not meet the PBT criteria under REACH** (Persistent, Bio accumulative and Toxic) (Henry et al., 2018).
This means fluoropolymers only meet the property of 'very high persistence' and none of the other seven properties listed in figure 4 of the restriction proposal,[44] i.e. long-range transport potential, mobility, accumulation in plants, bioaccumulation potential, ecotoxicity, endocrine activity and effects on human health.

Based on this review and assessment of fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal and biological data, **Korzeniowski et al. concluded that fluoropolymers satisfy the widely accepted criteria of "polymers of low concern" (PLC).**

Hazardousness of fluoroelastomer FKM
In the next section the focus will be on the findings of the OECD study and Korzeniowski et al. specifically on the hazardousness of FKM.

[43] S.H. Korzeniowski, R.C. Buck, R.M. Newkold, A. El kassmi, E. Laganis, Y. Matsuoka, B. Dinelli, S.Beauchet, F. Adamsky, K. Weilandt, V. Kumar Soni, D. Kapoor, P. Gunasekar, M. Malvasi, G. Brinati, 0. Musio; *"A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*", Integrated Environmental Assessment and Management—Volume 19, Number 2—pp. 326–354326, Accepted: 7 June 2022, under "*Fluoroelastomers (FKM)*"p. 9
[44] PFASs Restriction Proposal 22 March 2023, p.23.

The study of Korzeniowski et al, 2022[45], clarifies that these FKMs fluoroelastomers, are used mainly in fabricated parts (e.g. O-rings, gaskets, seals used in aerospace, automotive, pharmaceuticals and maritime industry) and are indeed thermally, biologically and chemically stable, insoluble in water and are non-mobile. Why? These molecules are too large to migrate into the cell membrane making them non-bioavailable, non-bio-accumulative and non-toxic. The Korzeniowski-study includes in **Column 3** (criteria descriptions), and in **Column 5 the characteristics of the fluoroelastomer FKM**, the relevant parts of **Table 5** are copied below for clear insight.

Column 3	Column 5
Supporting Information Data: Chapter	4.11 FKM
	1-Propene,1,1,2,3,3,3-hexafluoro-polymer with 1,1-difluoroethylene copolymer and terpolymers
PLC assessment criterion[a]	9011-17-0, 26425-79-6, 25190-89-0
Structure	Supporting Information
Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to carbon)	Yes
Molecular weight[b] (Mn >1000 Da and oligomer content <1%)	30 000–340 000
Molecular weight distribution Mw[c] ÷ number average M_n	1.2–2.4
Wt% oligomer (Figure MWD) (<5% for <1000 Da oligomers, <2% for <500 Da oligomers)	Negligible to <1%
Ionic character	Neutral
Reactive functional groups (RFGs)[d]	None and N/A
Functional group equivalent weight (FGEW; typical value)	$>10^4$–10^5

Table 5: *Source: Korzeniowski et al., 2022. p, 342-344*

[45] S.H. Korzeniowski, R.C. Buck, R.M. Newkold, A. El kassmi, E. Laganis, Y. Matsuoka, B. Dinelli, S.Beauchet, F. Adamsky, K. Weilandt, V. Kumar Soni, D. Kapoor, P. Gunasekar, M. Malvasi, G. Brinati, 0. Musio; "*A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*", Integrated Environmental Assessment and Management—Volume 19, Number 2—pp. 326–354326, Accepted: 7 June 2022, under "*Fluoroelastomers (FKM)*"p. 9

Column 3	Column 5
Supporting Information Data: Chapter	4.11 FKM
Low molecular weight leachables	<0.4 ppm to <1 ppm
Residual monomers	<50 ppt to <5 ppm
Ratio of residual monomers to molecular weight (typical value)	$>10^{-10}$–10^{-13}
Structural similarities to RFG of concern	None
Reference standard	ASTM D 1418
Physical–chemical properties	
Water solubility and octanol/water partition coefficient, K_{ow}	Insoluble/practically insoluble and N/A
Particle size (median mass aerodynamic diameter, aerodynamic diameter, MMAD, should be >5μm)	Sheet or block; powders 300–350 μm stability increased/enhanced when cross-linked
Stability	
Hydrolysis, light (hν), oxidation, biodegradation (aerobic and anaerobic)	Stable

Table 5: *Source: Korzeniowski et al., 2022. p, 342-344*

Column 3	Column 5
Supporting Information Data: Chapter	4.11 FKM
Thermal stability at normal foreseeable use maximum continuous Temp (°C)	180 °C
Meets[a] PLC criteria (Yes or No)	Yes
Fluorinated polymerization aid (PA) used? (Yes or No)	Yes and No
Recommended processing/ application (use) temperature (T°C)	Melt processing: <300 °C 160 °C–320 °C (cross-linking temperature)

Table 5: *continued Source: Korzeniowski et al., 2022. p, 342-344*

Before we conclude this section, the **correlation between health and environmental risk and molecular weight** has to be elaborated.

No penetration in cells possible because of large molecules

The study of Korzeniowski (2022), does apply to the seals/seal applications used by AEGIR-Marine due to the very high number average molecular weight of the fluoroelastomer it uses. Fluoropolymers have next to long chains, a very high 'number average molecular weight' (Mn).

Based on sound scientific research the OECD[46] reported about the importance of the number average molecular weight (Mn), as it determines the bioavailability and thus forms a warning for potential hazard.
The OECD stated (p.20): *"The most significant and commonly used criterion for establishing a PLC is its Mn range of >1000 Da. This criterion is based on the expectation that smaller molecules will more easily cross biological membranes to cause toxicity. Therefore, as the Mn of a polymer increases, a reduced incidence of potential health concern effects might be expected."*

Health concern and ecotoxicological concern.

- Regarding **health concerns** several groups with Mn ranges were investigated by OECD. **Main observation** was that there is an inverse correlation between Mn and health concerns: polymers with **Mn <2000 Da correlate with more potential health concerns.**
- The correlation between **Mn and ecotoxicological concern** was also investigated and there was concluded that **high ecotoxicological concern polymers have an Mn value of <2000 Da**.
- For both **ecotoxicological and health concerns** the conclusion is also**: the higher the Mn the lower the concern**!

The OECD[47] report (2009) **concluded on the importance of the high molecular weight** in relation to **hazardous properties**: *"Both ecotoxicological and health concerns appeared to inversely correlate with number-average molecular weight – the higher the Mn, the lower the concern. From the available health concern data, it appears **that polymers with a Mn <2000 Da have a higher incidence of potential health concern.** Similarly, a **direct relationship between decreasing Mn and increasing severity of ecotoxicological concern** was observed." [emphasize added]*

Korzeniowski et al. also mentioned that molecular weight is an important predictor of biological effect, because **large molecules (>1000 – 10.000 Da), are too large to penetrate cell membranes and because they cannot enter the cell, such as the reproductive system, they are not bioavailable.[48]**

[46] OECD, Environment Directorate, Joint meeting of the Chemicals committee and the Working party on Chemicals, pesticides and biotechnology data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern, 27 -Jan-2009, ENV/JM/MONO(2009)1, p.10 and p.21-30.
[47] OECD, Environment Directorate, Joint meeting of the Chemicals committee and the Working party on Chemicals, pesticides and biotechnology data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern, 27 -Jan-2009, ENV/JM/MONO(2009)1, p.37
[48] S.H. Korzeniowski, R.C. Buck, R.M. Newkold, A. El kassmi, E. Laganis, Y. Matsuoka, B. Dinelli, S.Beauchet, F. Adamsky, K. Weilandt, V. Kumar Soni, D. Kapoor, P. Gunasekar, M. Malvasi, G. Brinati, 0. Musio; "*A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*", Integrated Environmental Assessment and Management—Volume 19, Number 2—pp. 326–354326, Accepted: 7 June 2022, p11.

Oligomer content

The OECD report investigated another indicator for establishing that a polymer is of low concern, which is also relating to molecular size: *"Another commonly used criterium for establishing PLC is its oligomer content, and this may be determined for <1000 Da and <500 Da species. As described for Mn, this criterion is based on the expectation that* ***smaller molecules will more easily cross biological membranes to cause toxicity.*** *Therefore, it was expected that as the oligomer content increased, a higher incidence of polymers with potential health concern would be observed."*

From this investigation the **main findings** were that from a point of view of health and ecotoxicology, safe polymers had the following characteristics:

- **Mn values are >2000 Da;**
- **<1000 Da oligomer contents are <5%;**
- **<500 Da oligomeric species are <2%.**

The results of the before mentioned investigations are displayed in below overview and compared to the FKM values. The above-mentioned findings on molecular weight and oligomeric content are **very relevant for AEGIR-Marine,** because Korzeniowski specifically investigated the properties of the **FKM Fluoroelastomers** (for an overview see **table 6**).

From these findings can be concluded on health and ecotoxicological effects:

- The FKM fluoroelastomers used by AEGIR-Marine do have a very high number average molecular weight of approximately Mn 30,000 - 340,000 Da, which is far above the Safe norm of >2000 Da. There is no concern for health, nor for the environment;
- Regarding the oligomeric content of <1000 Da, the FKM value is with <1% far below the Safe norm of the OECD of <5%. There is no concern for health, nor for the environment;
- The FKM value of the oligomeric content of <500 Da, is with <1% below the Safe norm of the OECD of <2%. There is no concern for health, nor for the environment;
- The water solubility of FKM was also researched and complied with the OECD Safe norm because it is insoluble. There is no concern for health, nor for the environment.

Special issue: vulcanized FKM matrix/network is *too large to penetrate cell membranes*

Another relevant point to mention is that Henry, Lohman and Korzenieowski researched on the level of (stand-alone) molecules.

The FKM used by AEGIR-Marine is a result of **vulcanization** which means that these **molecules are cross-linked together in a matrix structure** (like baking flour and the cake), thus the size of these molecules is much larger**, but it also means** that **the crosslinked FKM as a matrix is more stable** is than the FKM polymer itself. And this means that:

- as a (stand-alone) FKM molecule is **too large** to penetrate cell membranes;
- FKM as a **matrix/network** is **far too large** to penetrate cell membranes.

Criterion	Safe norm PLC according to OECD[49]	FKM Value	Conclusion
Number average molecular weight (Mn)	>2000 Da	**30,000 – 340,000 Da**	**No concern**
% Oligomeric content of <1000 Da	<5%	**<1%**	**No concern**
% Oligomeric content of <500 Da	<2%	**<1%**	**No concern**
Water solubility	Insoluble	**Insoluble**	**No concern**

Table 6: Overview of Safe norm criteria and FKM values

Conclusions on hazardousness of FKM

From the above-mentioned can be concluded:

- the FKM fluoroelastomers used by AEGIR-Marine comply with the widely accepted polymer hazard assessment criteria and thus are 'polymer of low concern' according to the OECD criteria.
- The fluoroelastomers used by AEGIR-Marine are not bioavailable and of **no concern to health nor to the environment**, due to:
    - The very high number average molecular weight of FKM, that falls -with a broad bandwidth- within the safe norm of the OECD;
    - the FKM value of the oligomeric content of <1000 Da of <1%, that falls -with a broad bandwidth- within the Safe norm of the OECD;
    - The FKM value of the oligomeric content of <500 Da of <1%, that falls -with a broad bandwidth- within the safe norm of the OECD;
    - the fluoroelastomer (FKM) has a very large molecular structure, and with crosslinks **due to vulcanization, cannot penetrate cells membranes, thus is safe.**
    - The fluoroelastomer (FKM) is insoluble in water.

With regard to potential environmental emissions of the marine seals, more details are provided in Chapter 6 below and with regard to the disposal-stage more details are provided in Chapter 9 below.

[49] OECD, Environment Directorate, Joint meeting of the Chemicals committee and the Working party on Chemicals, pesticides and biotechnology data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern, 27 -Jan-2009, ENV/JM/MONO(2009)1, p.10 and p.21-30; p37

6. Environmental emissions during production and use of the product

The restriction proposal, seems to focus on two main sources of emission during production and use of the *product*:

- Emissions due to degradation, possibly resulting in microplastics;
- Emissions due to manufacturing of the products.

Firstly, one should clearly identify the PFAS concerned, because the particular characteristics of PFASs vary distinctively. Therefore, to define the actual PFAS involved and its characteristics, is crucial for the exposure assessment. In respect of the fluoroelastomer FKM the characteristic of **very high persistency** is an important reason to use FKMs, because they endure extreme use-conditions. It also means that FKMs practically **not degrade during use**. Indeed, FKM does not degrade.

Degradation of these strongest chemical bonds in organic chemistry[50] - in durable applications, such as in seals for marine shipping – is hardly applicable in the use-phase, as is acknowledged in the restriction proposal[51]. The long use-phase of the marine seals does not alter this, due to the high persistency quality. In the restriction proposal the relation between persistency and lack of degradation is confirmed; "*Even though fluoropolymers are a large group of polymers with different properties, there are no indications that fluoropolymers will degrade in particular as one of their key properties are their thermal and weather stability for the uses as described (Dams and Hintzer, 2017).* ***Therefore, persistence can be concluded*****."** [emphasize added]

The risk related to micro- and/or nano-plastics resulting from products that contain fluoro-elastomers FKM has not been sufficiently substantiated in the restriction proposal. The examples and monitoring data seem to relate predominantly to side-chain fluorinated polymers and do not relate to the fluoroelastomers FKM.
Arguments related to the **occurrence** of the fluoroelastomer FKM (Paragraph B.7.6 of Annex B) cannot be identified, so no relation between FKM (fluoroelastomers) and the generic conclusion can be identified. **To conclude:** based on the information in Korneziowski et al., and the lack of support in the Annex B to conclude otherwise, as far is known today, **FKM does not degrade in the environment under ambient conditions.**

[50] Website chemours: https://www.chemours.com/en/about-chemours/global-reach/dordrecht?_ga=2.135289075.395688877.1682523731-1117443820.1680163008
[51] PFASs Restriction Proposal 22 March 2023, p.39 "*For durable applications, e.g. PFAS applications in electronics and automotive, the environmental release is very slow in the use phase and most PFAS load enters the waste stage."*

As a general comment AEGIR-Marine would like to point at its efforts to limit exposure to the environment as much as possible by taking control over the end-of life phase of the products concerned, thus reducing the exposure time in environmental circumstances considerably after use.

Exposure / emissions during manufacturing and use
Goal of this section is to focus on the impact of the restriction on exposure/emissions on health and environment.

Position of AEGIR-Marine.
In the study of **Lohman et al. (2020[52]) criticism has been expressed that the study of Henry et al.** (2018) focuses too much on the use-phase, while not only the use-stage but **the whole life-cycle of fluoropolymers should be taken into account,** thus including the production and disposal-phases. **AEGIR-Marine agrees that the full life-cycle should be taken into consideration.**

AEGIR-Marine's role in the whole supply chain (see **figure 8**) is delivering and installing FKM seals as already was mentioned.

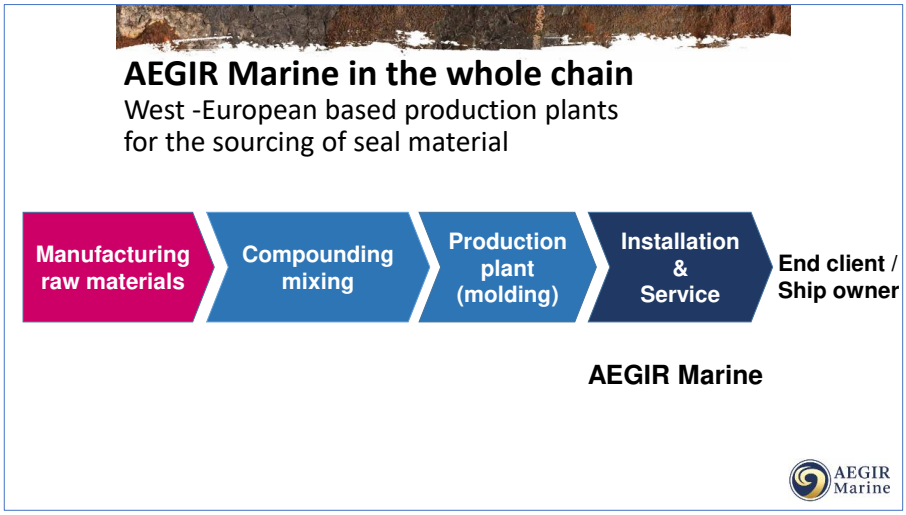


Figure 8: *Production/supply chain of marine seals in maritime sector & role of AEGIR-Marine.*

[52] Lohmann R., Cousins I.T., DeWitt J.C., Glüge J., Goldenman G., Herzke D., Lindstrom A.B., Miller M.F., Ng C.A., Patton S., Scheringer M., Trier X., and Wang Z. (2020): *"Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?"* Environ Sci Technol 54 (20), 12820-12828. DOI: 10.1021/acs.est.0c03244.

With regard to the manufacturing stage (raw materials) is referred to the restriction proposal under Table 8 "RO1"- "manufacture (Annex E.2.1.)" "sector as a whole" and under Table 9 "RO2" – "manufacture (Annex E.2.1.)" "sector as a whole", according to which 'sufficiently strong evidence' exists that technically and economically feasible alternative exists for non-polymeric PFAS as polymerisation aids in the production of FKM.[53] Thus, in the production stage, **fluoroelastomer FKM apparently can be produced without the use of PFAS as processing aids.** In addition, the manufacturer of the substance -used by AEGIR-Marine- has committed to 'Responsible Manufacturing- principles' (detailed in footnote).[54]

AEGIR-Marine's vision is to take the whole life-cycle into consideration.
Exposure/emissions of substances are **primarily** at stake in the phase of manufacturing of raw materials. As of 2018, the manufacturer announced that it would reduce its air and water process emissions of **fluorinated organic chemicals by at least 99%** across the board:

1. **Phase 1** of that goal has by now been completed. The substances that are used as a **polymerization aid in the production process,** are filtered out of the wastewater and air streams. **By investing €75 million this manufacturer has reduced these emissions by more than 99% compared to the 2017 baseline levels;**
2. **Phase 2** is ongoing and involves the reduction of process emissions of other fluorinated organic compounds by at least 80% by 2024.
3. **Phase 3** concerns the last step: reducing **all process emissions of fluorinated organic compounds by at least 99%** compared with the 2017 baseline. This goal is to be achieved as soon as possible after Phase 2 is completed, but no later than 2030. To this end, the manufacturer invests in research and technology to continuously improve its processes.

Ultimately, the manufacturer wants to realize a **net-zero operations by 2050.**

As mentioned, exposure/emissions of substances are **primarily** at stake in the phase of manufacturing of raw materials, but not in the installation phase.

[53] ANNEX E to PFASs Restriction Proposal 22 March 2023, p.10 and p.12.
[54] Position paper, Fluoropolymer Products Group, *FPG perspectives accompanying the Regulatory Management Option Analysis (RMOA) for fluoropolymers (FPs)*, Brussels September 2021.https://fluoropolymers.plasticseurope.org/application/files/3116/3339/9286/FPG_perspectives_accompanying_the_Regulatory_Management_Option_Analysis.pdf
Responsibility Manufacturing Principles: "*all FPG Members have committed voluntarily to responsible manufacturing principles in term of continuously improve and/or develop best available techniques in the manufacturing process, management of environmental emissions, development of R&D programs for the advancement of technologies allowing for the replacement of PFAS-based polymerization aids, and/or the increase recyclability and reuse of its products in line with the objectives of circular economy. The implementation of the Voluntary Industry Initiative to address concerns related to FPs (RMO 3) will strengthen the already on-going efforts performed by fluoropolymer industry in ensuring responsible manufacturing practices. FPG Members are committed to working with EU authorities to establish and implement the technical actions that may be required to guarantee an adequate control of the risks derived from the manufacture and use of FPs, and remove such risks wherever possible, with a strong emphasis on R&D for a continued improvement of the polymerization process. This will be done with a clear schedule and following transparency principles and agreements to monitor progress.*"

AEGIR-Marine is installing completed seals as 'products' in which no machining operations and/or chemical operations are performed. Therefore, the **exposure of substances during activities of AEGIR-Marine is ZERO.**

Made in Europe, waste and End-of-Life

AEGIR-Marine delivers sealing applications and provides services to the maritime industry, specifically propulsion systems and propeller shaft seals. The delivered and installed parts must comply with the highest standards demanded by the customers. This is certified by "Made in Europe"- certification. This means that the whole supply and production of parts is performed in Western Europe.

Looking again to the whole life-cycle, below **table 7**, gives an overview of the produced volume and the waste % in different production steps in the year 2022. In total a volume of 12.433kg in total and a waste% of 39% in total.

	Raw material manufacturing	Compoun ding	Manufact. 1	Manufact. 2	Manufact 3	AEGIR	Total
Volume	12.433	12.433	6363	3240	2830	7884	**12.433**
Waste %/ yr	NA	2%	38%	28%	50%	ZERO	**39%**
Waste kg/yr	NA	249	2386	784	1415	ZERO	**4834**

Table 7: *Overview of volume and waste in different production steps in 2022.*

Goal is to reduce the waste drastically.

7. Baseline and Baseline assumption

Goal of this paragraph is to give an overview of the Baseline and the used assumptions regarding the activities of AEGIR-Marine. Core activity of AEGIR-Marine is delivering of sealing and propulsion applications, which consists for 100% of fluoroelastomers (FKM). AEGIR-Marine is a healthy and fast-growing company, that grew from the start with 2 owners in the year 2000; where now (2023) 180 employees are employed. The volume of sold and installed fluoroelastomer seals in 2022 amounted approximately 12,000 kg's annually, the turnover in 2022 amounted 40 million euros, as visualized in **Figure 9** and **Figure 10**.

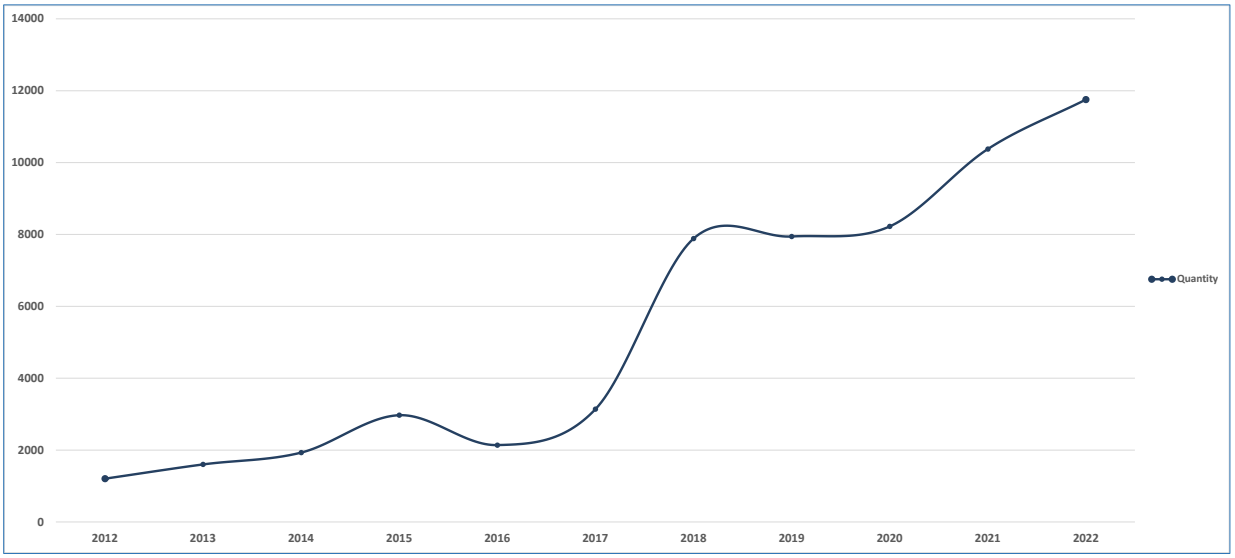


Figure 9: *History. Baseline volume development as of 2012 - 2022*

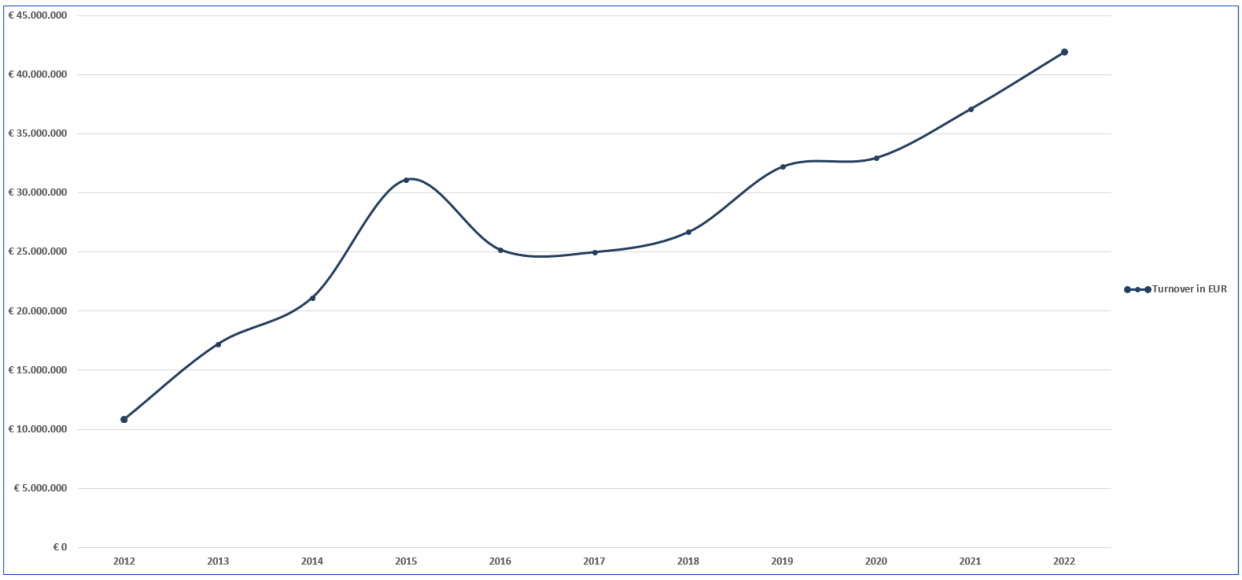


Figure 10: *History. Turnover development as of 2012 - 2022*

Analysis showed that without the ban, further growth will be realised. The market share of AEGIR-Marine is estimated at approximately 8-10%, and the market research performed by AEGIR-Marine, indicates that there is room for high quality independent service providers like AEGIR-Marine. In this submission report we work with the (realistic) assumption of 8% growth annually. The baseline is also addressed in the SEA-analysis in chapter 10 below.

8. Information on alternatives

Finding alternatives for FKM has been an ongoing process for AEGIR-Marine. FKM is an expensive substance, hence there has always been a strong incentive to look for alternatives. As of 2014, **R&D activities at AEGIR-Marine were initiated.** Also test equipment was built and installed. First aim was to improve H-NBR for which 2 PhD students of the University Twente were deployed for years, but the H-NBR tests failed due to delamination and swelling issues. Studies were also done on the improvement of FKM for the use of (ester-based) Environmentally Acceptable Lubricants (EALs) that became mandatory in large vessels. Nevertheless, the past decade **no alternatives were found that could safely and adequately replace the use of FKM.**

Scientists J. Noordermeer and M. Masen also concluded in their study[55] that finding alternatives for FKM is highly challenging and it is not certain at all, that this can be achieved. The required key functionalities for seals are very complex, because they need to perform under extreme circumstances. Key functionality of the fluoroelastomer seal rubber is to seal (against leakage and spill of) the oil bath to the environment / sea water.
As mentioned before, it is the **combination of** the following four properties that are essential for these elastomeric seals (non-exhaustive list):

- Long-term high temperature (**130 ^{0}C – 150 ^{0}C**);
- Long-term chemical resistance (**aggressive chemicals, salt water and ester-based oils[56] (EALs)**;
- Long-term sealing properties (mechanical strength, tensile and tear strengths, fatigue strength, abrasion resistance; low compression set, pressure resistance, **low friction coefficient**);
- durability of **at least 5 years**; this is the period between two scheduled dockings.

To conclude this section.
Noordermeer and Masen investigated the properties of FKM, which have to perform under extreme circumstances with an endurance of a period between two dockings of 5 years. Their conclusion is that there is **no alternative for FKM**, which is the one and only fluoroelastomer seal **that is sufficiently safe as seal for vessels**; due to the combination of properties that can match the complex requirements of this seals (high temperature, chemical resistance (EAL oils and sea water) and mechanical properties (see attached article prof J. Noordermeer).[57]

[55] Noordermeer J.W.M. and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 8. (ANNEX 1).
[56] European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry, Le Biot, France, 2022. (ANNEX 2)
[57] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 8. (ANNEX 1).

At AEGIR-Marine is a R&D agenda developed, consisting of two pillars **(see Figure 11)**. The first pillar consists of two R&D programs, both with the aim to find an alternative for FKM by **reducing friction** thus resulting in a reduced temperature. This would lower the extreme temperature requirement for the material.
This is a different approach than followed in the past. Instead of improving materials to meet the high temperatures (130^0C – 150^0C) , this approach focusses on lowering friction and thus temperatures, so that other materials can be used.

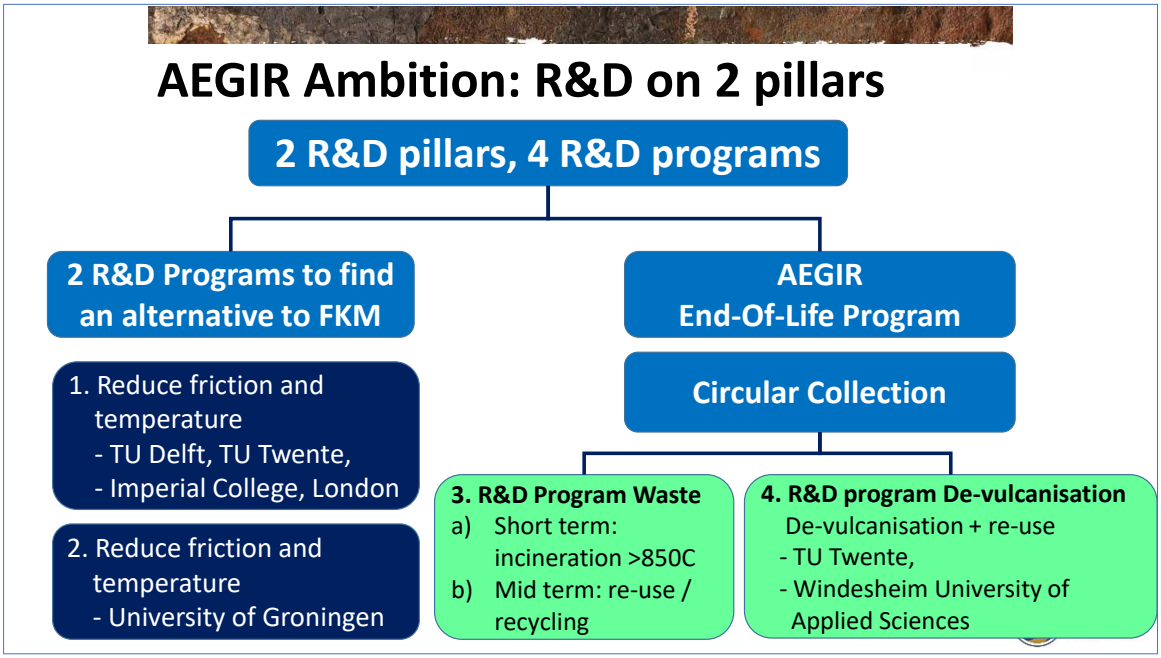


Figure 11: *AEGIR-Marine, internal document, 2023*

The two R&D projects under the first pillar on 'alternatives' are the following:

- **First R&D program:**
    - R&D efforts to find alternatives for FKM (by reducing friction and as a result a reduced temperature) are executed in conjunction with:
        - the Technical University of Delft;
        - University of Twente;
        - Imperial College in London.
    - R&D phase: Testing
    - Timeline: 5-6 years of development and pilot-tests, and after that Type Approval, before market introduction
    - Costs estimation: approx. 500,000 euro

- **Second R&D program:**
    - Another R&D program to find alternatives for FKM (by reducing friction and as a result a reduced temperature) is started in conjunction with the University of Groningen;
    - R&D phase: Project Initiating Phase
    - Timeline: 4-6 years of development and pilot-tests, and after that Type Approval before market introduction
    - Costs estimation: approx. 700,000 euro

More information on the current R&D activities can be supplied, if needed.

9. Emissions in the end-of-life phase & control

Goal of this End-of-life paragraph (hereinafter EOL) is to elaborate the AEGIR-Marine Approach on EOL of FKM seals.
The Restriction Proposal contains a very clear overview of the main property-related concerns to PFASs in Figure 4.[58] It is expressed clearly that one of the main concerns of member states that submitted the restriction proposal is the very high persistence of PFASs. The fluoroelastomer FKM indeed has a very high persistence, without being hazardous. **AEGIR-Marine would like to address this specific property-related concern of the high persistency of FKM.**

The restriction process activated AEGIR-Marine to focus on the EOL phase and this led to a renewed policy on waste, and it gave an impetus to our R&D process: the EOL pillar (see section 8). AEGIR-Marine provides seals, sealing applications and services (installing and replacing of seals and propulsion parts) for vessels (see **table 8**).

- There is no emission on delivering services (installing seals): **ZERO**
- The real issue in this phase is the EOL of used seals. Currently AEGIR-Marine deals with an amount of approx. **12.000 kg of used seals annually**. Until last year these used seals were removed to the waste disposal on the dockyard, where the docking of a ship took place. In fact this was an uncontrolled EOL process.

Current figures on emissions of AEGIR-Marine:

AEGIR-Marine	Installing/Services	End-of-life phase
Annually emissions (2022)	ZERO	12,000 kg FKM

Table 8: *Emissions at AEGIR-Marine in EOL phase*

[58] PFASs Restriction Proposal, 22 March 2023, Figure 4., p 23

AEGIR-Marine developed a Waste Policy:

- AEGIR-Marine developed a **Waste Policy and started a R&D program** (**see figure 12)** which encompasses the research to the best way, *i.e. most environmentally sustainable and economically feasible way,* of dealing with 12 tonnes of used seals.

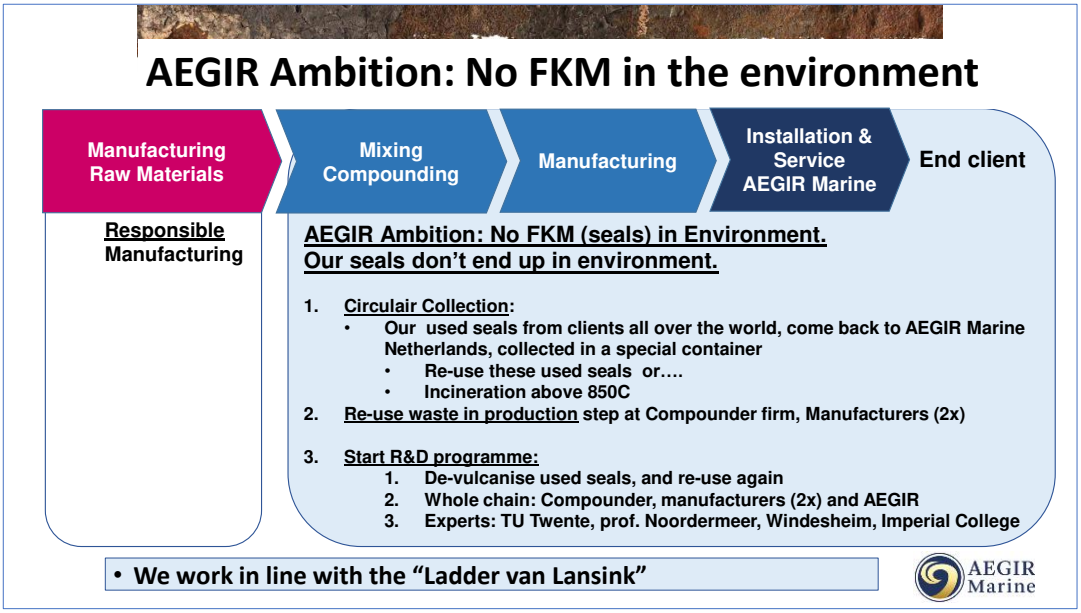


Figure 12. *AEGIR-Marine, internal document, 2023*

Main goal of our **AEGIR-Marine Ambition** is that we truly want to achieve **that no AEGIR-Marine FKM will ever end in the environment again!**

- Our Waste policy consists of the following steps:
  - **Circular Collection (this has currently already been implemented)**
    - All our used seals (average weight of a seal is between 7-9 kg) return to our homebase in the Netherlands;
    - These old seals are collected in a separate Seal Waste container.

  - **R&D research on EOL is ongoing now on two fields:**
    1. **R&D on safest way of Incineration** of used seals; which should be (at minimum) above >850 °C, at a special controlled incineration[59] installation (e.g. Indaver Antwerp);

[59] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 19. (ANNEX 1).

2. **R&D to Re-cycle the used seals again**; this is a tough matter and acknowledged as mentioned in the Restriction proposal: "*Recycling of fluoropolymers is hardly possible/cost effective*.[60]
   - Approx. 400.000 -600.000 euro

AEGIR-Marine makes and wants to make **fast and transparent progress** on this important issue, but the **most important aim is a long-term solution of recycling,** as detailed below.

AEGIR-Marine Long-term approach EOL

At AEGIR-Marine EOL is one of the two pillars of R&D, which is visualised in **figure 13.** The **short-term** aim is to find the safest way of incineration, but the **long-term aim is to find a solution for the de-vulcanisation issue**. If there is a breakthrough, the way is open to re-cycle the material again and to make a huge step towards a Circular Economy for seals/sealing applications, without waste.

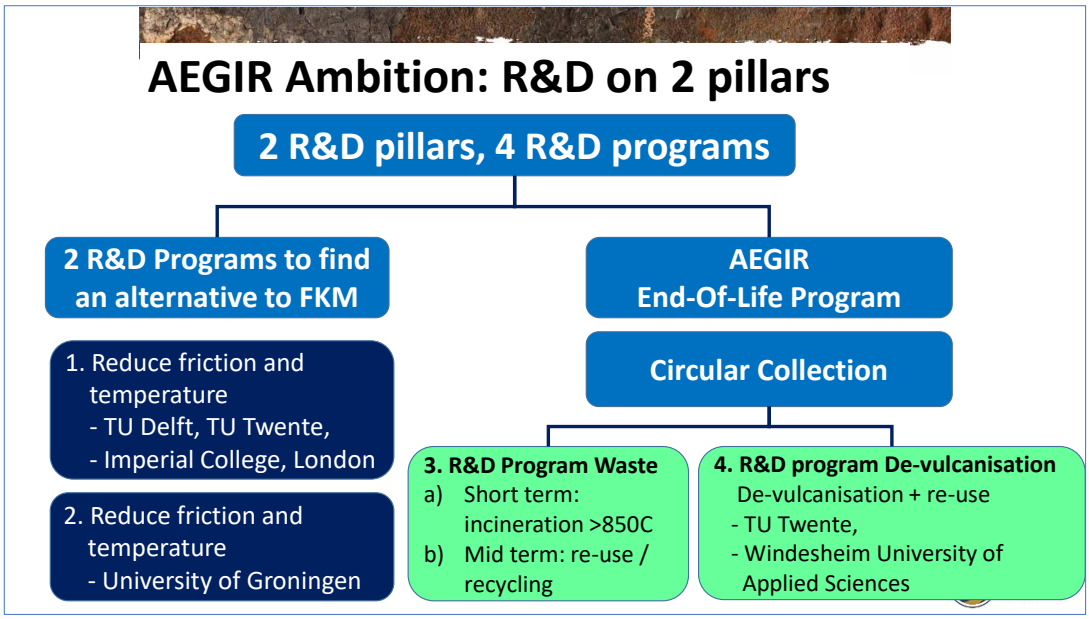


Figure 13: *AEGIR-Marine, internal document 2023*

AEGIR-Marine R&D program on De-vulcanisation:

- The AEGIR-Marine Approach is to involve the full vertical supply chain (from manufacturing, compounding/mixing, production, to installation & services) in these R&D activities, because this is really a tough matter for which we have to bundle forces and disclose all knowledge and experience available on this issue.
- As part of the team, highly regarded experts[61] from different universities will give scientific input on this complex issue:

[60] PFASs Restriction Proposal, 22 March 2023, Annex B, p 313.

[61] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 20. (ANNEX 1).

- University Twente (Netherlands), professor (em) J. Noordermeer and associated professor W. Dierkes, both more than 20 years' experience on fluoroelastomers, rubber waste & recycling;
- Windesheim University of Applied Sciences, Netherlands, where next to knowledge, the required equipment is installed;
- Imperial College London, associated professor, department of Mechanical Engineering, M. Masen.

- The R&D program on De-vulcanisation consists of three phases, below visualized in **Figure 14.**
  - First phase: De-vulcanising post-cured seals (production seals);
  - Second phase: De-vulcanising post cured seals and inlays, which are made from aramide fibres;
  - Third phase: De-vulcanising used seals.

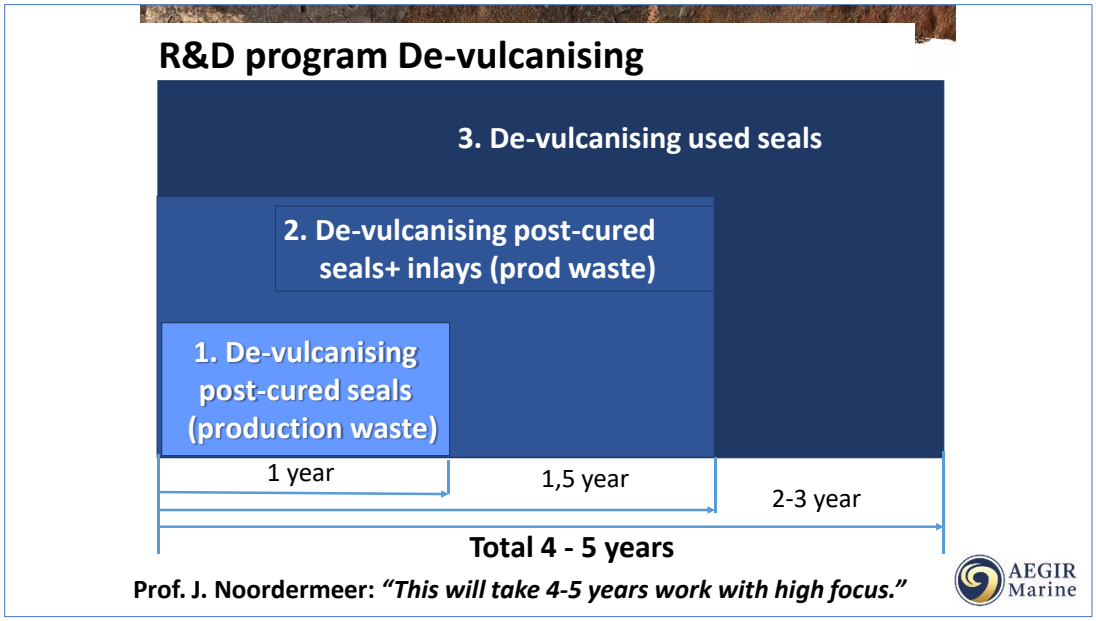


Figure 14: *AEGIR-Marine, internal document, 2023*

- Timeline: 2023 – 2028.
  - All the 3 phases will endure in total 4-5 years as of now (May 2023)
  - July 2027 we aim to have de-vulcanisation of used seals implemented; to be followed immediately with pilot tests (which must contain durability tests) and afterwards type approval and market introduction.
- Estimated Costs:
  - Approx. 500.000 – 800.000 EURO

Overview of AEGIR-Marines policy on waste and EOL

The below **table 9** gives summarized an overview of the volumes, the waste approach and End-of- Life approach.

AEGIR-Marine	2022	2023	2028
Volumes FKM	12,000 kg	12,500 kg	15,000 kg
Policy / measures	-	EOL policy	EOL policy / R&D effort
Waste approach	Shipyard waste disposal	Circular Controlled Collection to homebase	De-vulcanisation of used seals
EOL last journey	unknown	Controlled Incineration (>850C)	Re-cycle used material again

Table 9: *overview of the policy on waste and EOL by AEGIR-Marine*

10. Socio-Economic (SEA) Analysis

Aim of SEA: give clear picture of impact measures

Why this SEA? Because of the huge impact of the Restriction Proposal on the EU/EEA maritime shipping sector and on the sealing business of AEGIR-Marine. AEGIR-Marine needs time to develop, test and implement alternatives that are safe for the persons and goods transported, for the people operating the ship and for the environment.

Summary

This SEA Analysis underpins an innovative, healthy and fast growing company, that grew from the start in the year 2000 with 2 owners, till now with 180 employees, Volume of 12,000 kg's annually, 40 million euro's turnover.

Analysis showed that without the ban, this grow will develop further, because of market absorption due to excellent service by AEGIR and a market share of approximately 8-10%.

Without a ban (baseline) in 2033 the facts are:

- 330 employees, a volume of 24,000 kg's of FKM and 80 million euros turnover.

With the ban on fluoroelastomers (FKM), and/or 5 year derogation the facts in 2033 are:

- As of July 2026, AEGIR Marine has to close the business in EU and move to UK, Middle East or Asia.
- In effect 90 colleagues will be dismissed, drop of volume with 53,3% (15,000 kg -> 7,000 kg's) and a drop in turnover (54%) from 52 million euro's in 2025 to 24 million euro's in 2026

Derogation of 12-15 years requested

An underpinned derogation of 12-15 years is asked, to support AEGIR Marine in building a EU future oriented business with safe (tested) products for clients and to develop and create real breakthroughs to ZERO emissions to the environment and safe products for humans.

10.1 Baseline scenario (10 years): No Restriction

- Current volume is **12,000 kg** FKM annually, which will double – following the trendline - within 10 years to 24,000 kg's, as visualized in **Figure 15;**
- the turnover is currently 40 million and will also follow the trendline and double to a turnover of approx. 80 million euro in 2033, as visualized in **Figure 16;**
    - This is estimated by market research (AEGIR-Marine report P. Grizell.[62])
- Employment will also grow from 180 → 330 in 2033
- R&D investments: currently approximately 1,000.000 euro annually, which will grow to approximately 2 million.

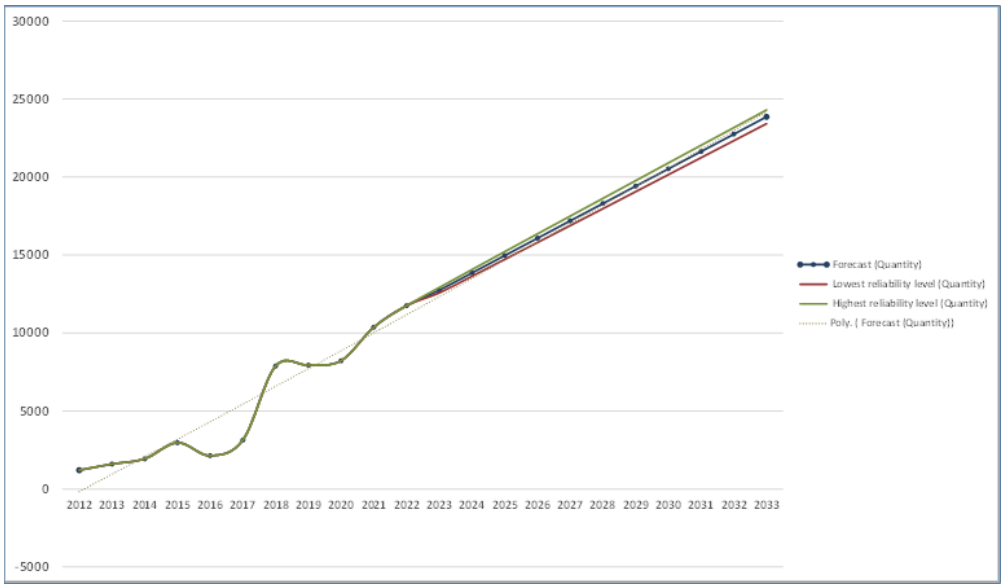


Figure 15: *Volume Development in Baseline scenario: 2023 – 2033 no restriction*

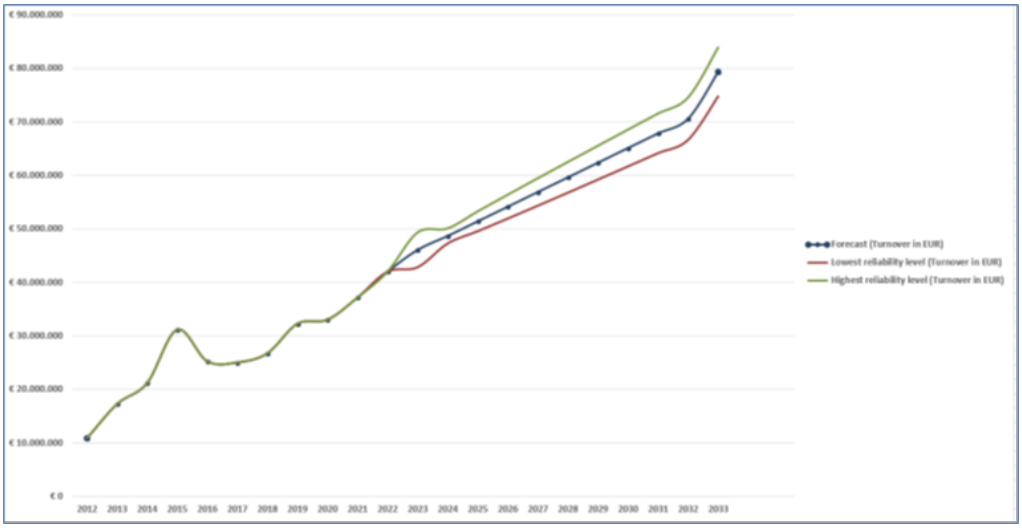


Figure 16: *Turnover Development Baseline scenario 2023 -2033: no restriction*

[62] Grizell, P., AEGIR Marine, internal market report May 2023

AEGIR-Marine	2000 (est)	2022	2033
Turnover (EUROs)	100,000	40 million	80 million
Volume FKM	100 kg	12,000 kg	24,000 kg
Employees	2	180	330
R&D investments annually	0	1 million	2 million
EOL / waste	100 kg	Incineration (controlled at >850C)	De-vulcanisation and Re-cycling

Table 10: *No-restriction-scenario: key figures of AEGIR-Marine*

10.2 Socio-Economic impact of Risk Management Option A: a ban with 18 months transition period and/or a derogation for 5 years for AEGIR-Marine

- As of July 2026, there is no alternative seal-application for FKM ready for launching to customers, which is scientifically evidenced by the study conducted by Noordermeer and Masen[63];
- Even if an alternative could be found within 5 years after EiF, it is impossible for AEGIR-Marine to have its seals/sealing applications ready on the market for use by customers, within a derogation period of 5 years after Eif. This is mainly due to the need of a severe testing phase for safety purposes and due to type approval requirements. This is substantiated in detail in chapter 10.3 (10.3.1-10.3.2) below.
- The consequence will be a reduction of sales in EU/EEA with 95%-100%[64]; in which case AEGIR-Marine will move out of EU as of Spring 2026[65] to **UK, Middle East or Asia.**
- Clients have already mentioned that they will replace seals outside the EU/EEA area and go for aftermarket services to the Middle East or Asia.[66] The assumption is made that 50% or more of the maritime shipping aftermarket will leave EU;
- The below graphs **(figure 17 and figure 18)** show the impact of the Risk Management Option A:
    - Volume drop with **(53,3%)** from **15,000 kg's to 7,000 kg's;**
    - Economic downturn of AEGIR-Marine Europe with **(approx. 54%)** from **52 million euro's** (2025) to **24 million euro's** beginning as of Spring 2026 and closing Europe activities mid 2026;
    - This will have a huge social impact: **90 dismissals (approx. 50%)** in Europe.

[63] Noordermeer, J.W.M., M. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 1. (ANNEX 1).
[64] Risk Management Team Meeting AEGIR Marine, date May 10th 2023.
[65] Risk Management Team Meeting AEGIR Marine, date May 10th 2023.
[66] Interviews with MCS, MAERSK, CMA/CGM

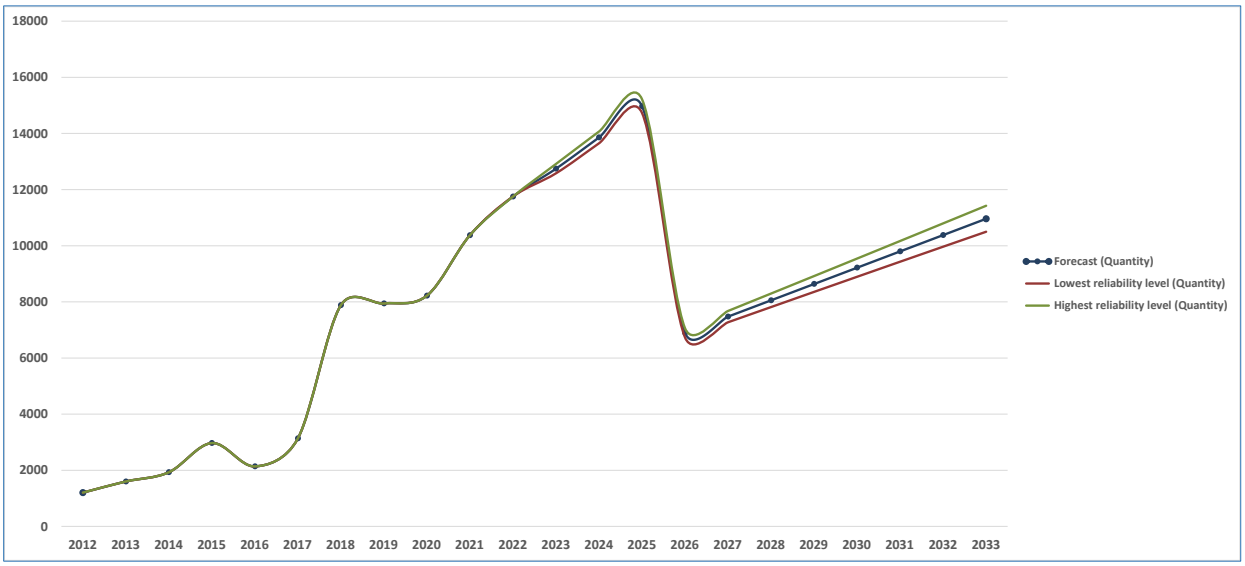


Figure 17: *RMO A: Volume development as economic impact of the ban / RO2 at AEGIR-Marine*

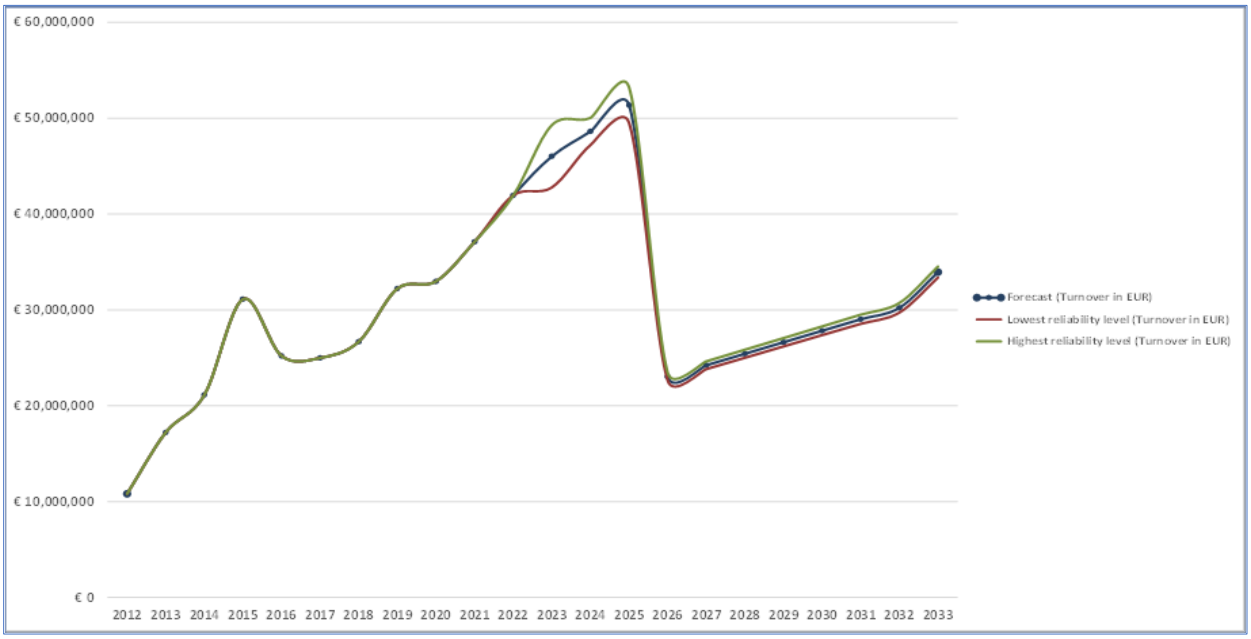


Figure 18: *Turnover development: economic impact of the ban / RO2 at AEGIR-Marine*

There is not only a positive effect on the environment related to a ban of fluoroelastomers, but instead sever adverse consequences for the environment are more likely. If the fluoroelastomers can't be used anymore and one has to go back to use substances with lower qualifications and less reliability the number of leakages and unplanned dockings will increase enormously.

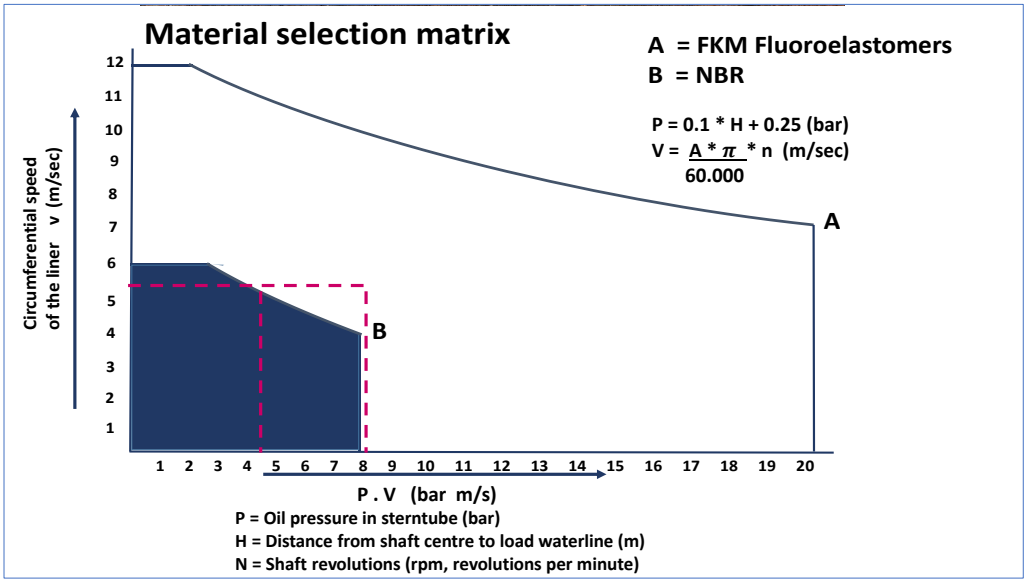
Estimates are (interviews with shipowners MSC, MAERSK and CMA/CGM) that the number of spills will **double** and the **unplanned dockings** will increase with **40-50%.**

In the box below an example is shown of what the consequences will be of a choice for an alternative material that will not meet the stringent requirements.

Consequences of a choice for an alternative that will not meet the requirements

As shown in the below PV diagram, FKM (A) has far wider tolerances when compared with the first available alternative, Nitrile rubber (NBR). Stern tube sizes vary from roughly 200 mm to 1200 mm. The vast majority of the ocean-going merchant fleet has shaft sizes between 300 and 800 mm. The propellers of these vessels will rotate with a speed between 100 and 250 revolutions per minute (RPM). If we take an average of 600 mm shaft size at 175 rpm, this means a circumference speed of **5,5 meter / second.** If we take this figure at the vertical axial, it means that the water pressure at the center of the propeller shaft **should not exceed 0,54 bar**, in order to stay within the operational limits of NBR. Practically this means a max waterhead / draft of just over 5 meters. This is well below what is realistic. Drafts in this example **will exceed at least 8 meters in average, thus Nitrile will fail.**

As Nitrile is the first material that will be considered as an alternative to FKM, it can be expected that seals made from that material, based on the above data, **will fail well within the 5 years dry-dock interval, causing environmental damage (unforeseen leakages and spills) as well as unplanned downtime and costs.**



P V Diagram – AEGIR-Marine

Box 1: *Example of effects of using an alternative material that doesn't meet the stringent requirements*

The European Sealing Association reports that the amount of lubricant spilled in marine waters in 2010 was 50 million.[67] Assumptions are made that the spills[68] will increase with 50% - 100% as the use of FKM will be banned, because:

- the alternative used substances cannot meet the requirements of continuous high temperatures (130-150C); (see for an example the box of the previous page)
- the alternative used materials by far cannot meet the requirement of a safe endurance of at least 5 years.

This means a rise as of 2026 of spills and leakages. See below the increase of spills in **figure 19**.

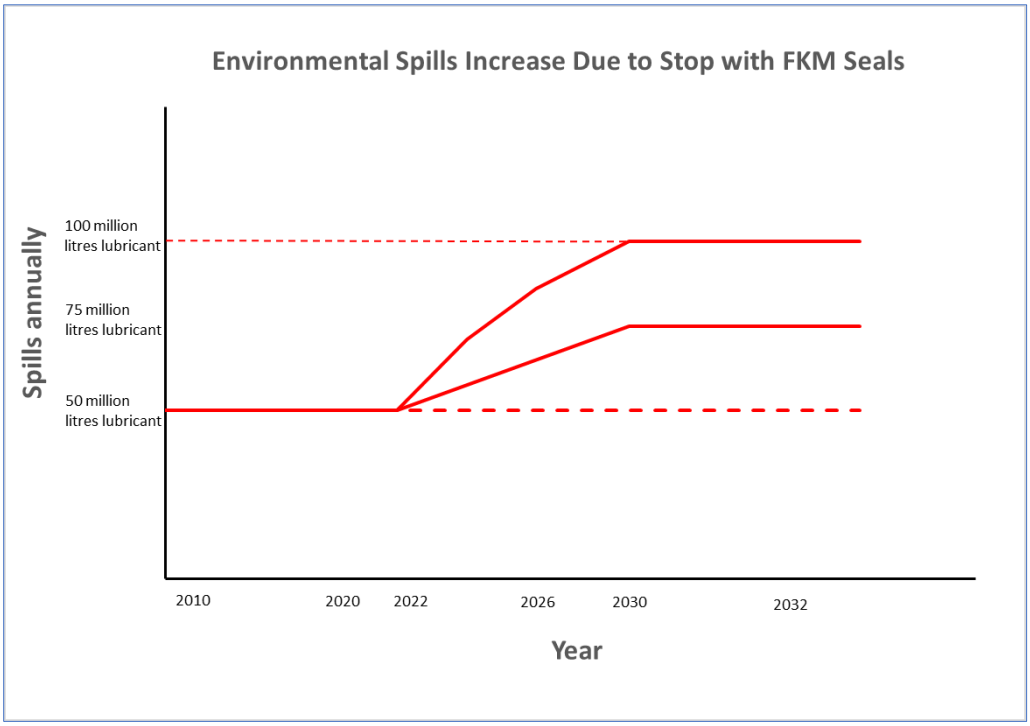


Figure 19: *Increase of lubricant spills due to stop with FKM seals*

To conclude: the Risk Management Option A has a dramatic impact at AEGIR-Marine.
An innovative, healthy and fast-growing company with high growth potential, **will stop to exist in Europe** as of medio 2026. This will lead to a downturn in turnover with 28 million euro's (54%). The social implications are serious, 50% of the colleagues (90 employees) have to be dismissed. Thereby will the exposure of lubricants into marine waters with an increase from 50 million litres to between 75 and 100 million litres annually, which also will have dramatic impact on the environment.

[67] European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry, Le Biot, France, 2022, Case study. (ANNEX 2)
[68] Risk Management Team Meeting AEGIR Marine, date May 10th, 2023

10.2.1 Socio- Economic Impact on EU/EEA-level

Management Option A: a ban within 18 months and/or a 5-year derogation

- **10.2.1.1 Introduction**

In regard of the Socio-economic effect, key considerations are:

1) the lack of alternatives to components containing fluoroelastomers, like FKM, and the extreme likelihood that no genuine alternatives become available in time within 5 years after EiF of the proposed ban on PFAS; and
2) that sealing/sealing applications (such as stern tube seals) within shipping and shipping transport are crucial to the safety of any ship/vessel, for the transported goods and passengers and for operators/employees involved.[69]

Risk Management option A will have a significant impact on the **whole maritime transport sector in the EU/EEA, on the directly related marine equipment aftermarket, but also on the blue economy in the EU/EEA and on the wider economy due the strategic importance of shipping transport.** Below the **strategic relevance of shipping transport sector and the interrelation with a wide range of other sectors in the EU/EEA** is substantiated. **Facts and figures** are provided from reliable sources. Keeping in mind the lack of alternatives in the area of sealing/ sealing applications within this timeframe, a ban within 18 months or 5 years (after EIF) of fluoroelastomers, will cause a **cascade of negative socio-economic impacts** in the EU/EEA, with far-reaching economic impacts on the whole EU/EEA in terms of decline of employment, of innovation and of the economic position of the EU/EEA in the global economy.

- **10.2.1.2 Global and EU maritime shipping transport is strategic sector, based on ship building, repair and maintenance**

Maritime transport is a key mode of transportation (the aorta) of goods and people, both worldwide and at an EU level and is of strategic relevance to the EU.

The importance of maritime transport was recently expressed by the Secretary-General of UNCTAD (the United Nations Conference on Trade and Development):

> *"Rarely has the importance of maritime logistics for trade and development been more evident than during the last year. Historically high and volatile freight rates, congestion, closed ports and new demands for shipping following COVID-19 and the war in Ukraine have all had measurable impacts on people's lives.* ***With ships carrying over 80% of volume of global trade, higher shipping costs and lower maritime connectivity lead to higher inflation, shortages of food, and interruptions of supply chains – all of which are among the features of the current global crisis."***[70]

[69] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 4.

[70] Report United Nations "*Review of Maritime Transport 2022*", United Nations Conference on Trade and

On the official website of DG COMP of the European Commission is stated[71]:

> *"The carriage of goods by sea is generally regarded as a key sector for trade within the EU as well as globally. There is overwhelming economic evidence on the relevance of maritime transport for global trade and its impact generally on economic growth. According to an UNCTAD Report, the share of international trade carried by sea is around* ***80%, in terms of volume, and over 70% in terms of value.*** *For less developed economies, the share is even higher.*
>
> *Broadly, the maritime freight sector consists of two categories - bulk shipping which involves the carriage of mainly commodities, such as for example coal and steel in bulk, and container liner shipping which involves the carriage of all varieties of goods in containers of varying sizes. (…)*
>
> *As regards carriage of passengers by sea, it is estimated that some 400 million passengers travel through EU ports annually. Passenger transport within the EU is provided mainly by national and intra-EU services with Italian and Greek ports accounting for some 74 and 70 million passengers respectively and handling a combined share of 35% of total number of passengers travelling through EU ports in 2017."*

In the 'EU Blue Economy report 2022[72]' the European Commission shows the interrelation between different sectors in the blue economy and establishes 7 sectors and their subsectors (see **Table 11**):

Table 2.3 The Established Blue Economy sectors and their subsectors

Sector	Sub-sector
Marine living resources	Primary production
	Processing of fish products
	Distribution of fish products
Marine non-living resources	Oil and gas
	Other minerals
	Support activities
Marine renewable energy	Offshore wind energy
Port activities	Cargo and warehousing
	Port and water projects
Shipbuilding and repair	Shipbuilding
	Equipment and machinery
Maritime transport	Passenger transport
	Freight transport
	Services for transport
Coastal tourism	Accommodation
	Transport
	Other expenditure

Table 11: *Overview of interrelations between 7 sectors and their subsectors* in the EU.

Development (UNCTAD), Foreword Secretary-General of UNCTAD Rebeca Grynspan, p. xv, available at https://unctad.org/system/files/official-document/rmt2022_en.pdf

[71] https://competition-policy.ec.europa.eu/sectors/transport-tourism/maritime-transport_en

[72] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, Table 2.3 p. 23, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

In the report the Commission emphasizes the specific contribution and multiplier effect of the sector 'Shipping and repair' for the other (sub) sectors of the blue economy and the rest of the economy: "*Although only the direct contribution of the Blue Economy Sectors is considered here, all sectors have indirect and induced effects on the rest of the economy. For example, in* ***Shipbuilding and repair most of the value is added from upstream and downstream activities****. This means that* ***beyond its specific contribution, it has important multiplier effects on income and jobs in many sectors of the economy***.[73]" [emphasize added]

Table 0.1 EU Blue Economy established sectors, main indicators, 2019

Indicator	EU Blue Economy 2019
Turnover	€667.2 billion
Gross value added	€183.9 billion
Gross profit	€72.9 billion
Employment	4.45 million
Net investment in tangible goods	€6.1 billion
Net investment ratio	3.3 %
Average annual salary	€24 739

Notes: Turnover is calculated as the sum of the turnover in each sector; it may lead to double counting along the value chain. Nominal values. Direct impact only. Net investment excludes maritime transport and coastal tourism. Net investment ratio is defined as net investment to GVA.

Source: Eurostat (SBS), DCF and Commission Services.

Table 12: *Overview of European sectors and their main indicators*

In **table 12,** above, Table 0.1 of the Blue Economy report[74] is shown with the established sectors of the EU Blue Economy directly employed close to 4.45 million people and generated around €667.2 billion in turnover and €183.9 billion in gross value added. Since 2009, **one of the two sectors that have seen the largest growing** trends in terms of EU Blue Economy's Gross Value Added (GVA) was **Shipbuilding and repair** (+39 %).

[73] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, p. 24, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

[74] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, Executive Summary Table 0.1 p. vi, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

- **Relevant figures EU**

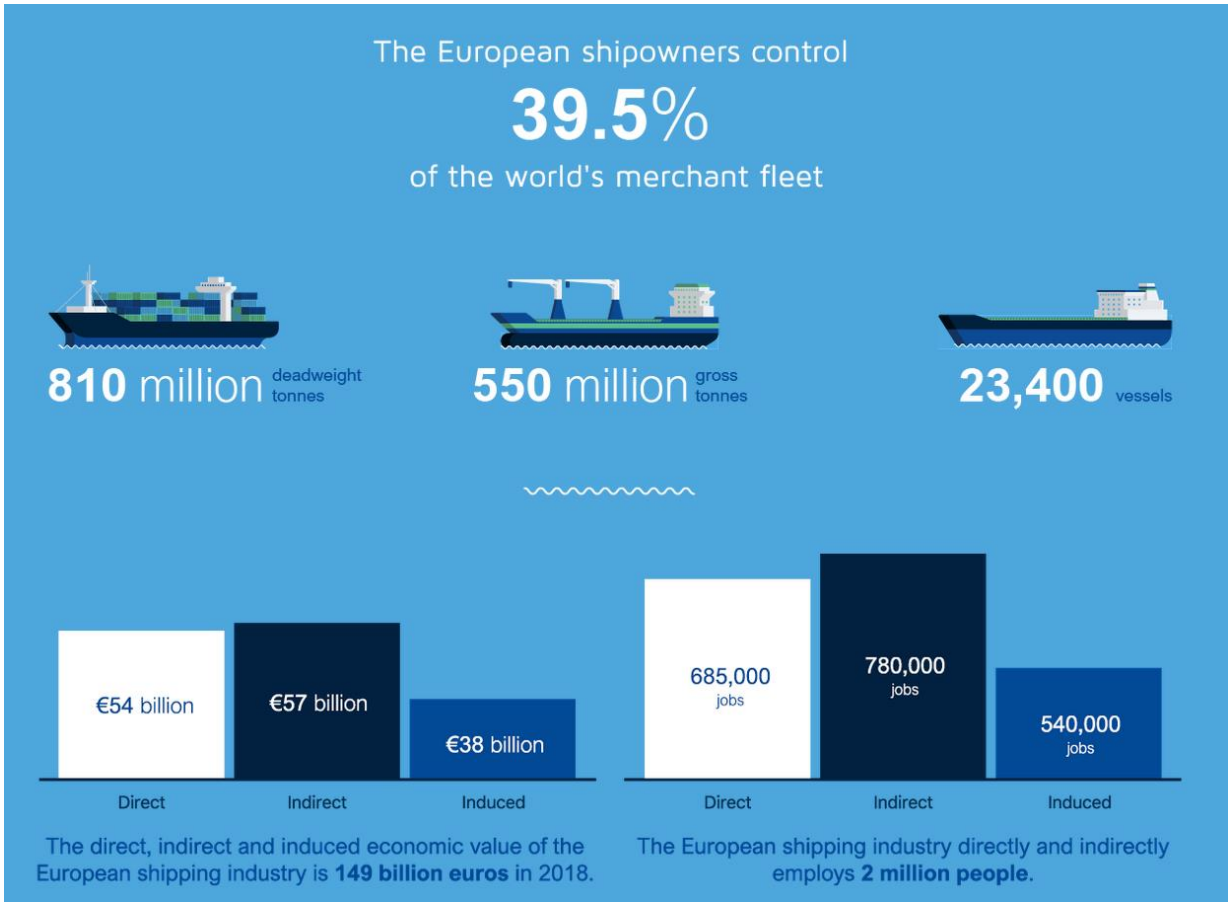


Figure 20: *Impact of the European shipping industry*[75]

The above visualized **Figure 20,** makes clear that the impact of the shipping sector on the EU huge is: **149 billion euros economic value** in 2018 and (directly and indirectly) **employs the shipping industry 2 million people.**

Around 77% of goods that are imported/exported to and from the European Union are transported by sea.[76] The maritime sector generated a turnover of EUR 163.4 billion in 2019, with 59% coming from freight transport, 27% from services for transport, and 14% from passenger transport.[77]

[75] *Oxford Economics Institute 2020, https://www.ecsa.eu*

[76] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, p. 93, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

[77] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, p. 95, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

As to **vessel ownership**, measured in commercial value in million USD, 10 out of the top 25 countries are part of the EU/EEA region. The total commercial value of shipowners from the EU/EEA region amounts to 506,281 million USD, out of a worldwide total of 1,358,270 million USD.[78]

In terms of **vessel registration by flag state**, measured in **dead weight tonnage (dwt),** 11 out of the top 35 flags belong to countries in the EU/EEA. The total amount of vessels registered under EU/EEA flags is and their total dead weight tonnage is 506,281 thousand dwt, out of a worldwide total of 2,199,107 thousand dwt.[79]

Labour-wise, the maritime transport supported more than **2 million jobs** in 2018, including directly, through its supply chain and through workers' spending. Moreover, for every job directly employed by the shipping industry, a further 1.9 jobs are supported, showcasing the vast employment impact of shipping.[80] The total of wages and salaries of people directly employed in maritime transport for 2019 comes up to EUR 15.9 billion.[81]

Focusing on the **marine equipment sector in the EU**, in order to give in idea of its size, there are some key statistics to consider:

- The European Union is the **largest supplier** of services and equipment, with an average production value of **EUR 71.3 billion** between 2010 and 2014.
- The European Union is also the **largest exporter** of marine equipment. Around **24%** of marine equipment worldwide has its **origins in the Union**.
- The **European Union is the largest exporter of marine diesel engines** with net exports of around **USD 12.9 billion** between 2019 and 2020.
- Out of 11,493 marine equipment suppliers worldwide in 2013, **6,539 (57%) were located in Europe.**[82]

[78] Report United Nations "*Review of Maritime Transport 2022*", United Nations Conference on Trade and Development (UNCTAD), Table 2.4, p. 39, available at https://unctad.org/system/files/official-document/rmt2022_en.pdf

[79] Report United Nations "Review of Maritime Transport 2022", United Nations Conference on Trade and Development (UNCTAD), Table 2.6, p. 44, available at https://unctad.org/system/files/official-document/rmt2022_en.pdf

[80] Oxford Economics, *The economic value of the EU shipping industry 2020 Update*, 2020, p. 19, available at https://www.ecsa.eu/sites/default/files/publications/Oxford%20Economics%20-%20The%20Economic%20Value%20of%20EU%20Shipping%20-%20Update%202020.pdf

[81] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, p. 94, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

[82] Working Party on Shipbuilding, *Analysis of the marine equipment industry and its challenges*, Organisation for Economic Co-operation and Development (OECD), 2022, pages 9-12, available at https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=C/WP6(2022)15/FINAL&docLanguage=en

- **10.2.1.3 Uneven level playing field between EU/EEA and global players**

Seals/ sealing applications are essential for the safe operation of any ship. A total ban of Fluoroelastomers within 5 years after Eif, will distort the level playing field of the global market completely. Many shipowners from the EU/EEA are already registering their vessels under foreign flags.[83]

Important costs for maintenance of a ship relate to overhaul, maintenance and repair to components and systems below the waterline of the vessel (incl. seals) which require dry docking[84] of the ship. For example, a 2018 estimate of daily cost of dry docking for large passenger cruise ships comes out to **an average of USD 2.0 million per day**.[85] Thus, minimising the dry docking as such and limiting the time spent on dry docking is crucial for shipowners as it has a considerable effect on the overall operational costs for the vessel, thus on their profitability and competitiveness.

Costs of docking
The cost of dry-docking a commercial vessel for a 5-year class renewal can vary widely depending on a variety of factors such as the size of the vessel, its type and age, the extent of the work required, and the shipyard where the work is being carried out. However, to give a rough estimate, the average cost of dry-docking a commercial vessel for a 5-year class renewal can range from hundreds of thousands to several million dollars.

For example, a small tanker vessel of around 20,000 DWT(Dead Weight Tonnage) might cost around $500,000 for a 5-year class renewal dry-docking. A larger vessel might cost between $2 million to $4 million for a similar dry-docking.
This turnover will leave the EU/EEA.

Box 2: Costs of docking

Replacing FKMs with NBR will result in more docking as the seals/sealing applications **will not last for 5 years** (see study Noordermeer et al., 2023, attached). A competitor that uses FKM seals/sealing applications, will not be forced to dock as much and will have an enormous **competitive advantage, with less risks** (leakage, safety issues etc.). These increasing risks of incidents and pollution and high costs related to the need for more dry-docking in the global market, will lead to **a structural and irreversible imbalance in level playing field** between the EU/EEA and the global market. In addition, it is common knowledge that on a running ship **no enforcement/check of seals or sealing applications is reasonably possible**.

[83] Table 2.5, United Nations Conference on Trade and Development (UNCTAD), *Review of Maritime Transport*, United Nations, 2022, p. 40, available at https://unctad.org/system/files/official-document/rmt2022_en.pdf
[84] United States Department of Labor, Occupational Safety and Health Administration, *Process: Dry-docking and launching, available at* https://www.osha.gov/ship-building-repair/dry-docking
[85] Cruise Industry News, *Cruise Ship Drydocking Infographic*, 2018, available at https://cruiseindustrynews.com/cruise-news/2018/06/cruise-ship-drydocking-infographic/

The foreseeable result will be that these circumstances will chaise the shipbuilding and repair and maintenance activities related to shipping outside of the EU/EEA. On the global shipping market, it is relatively easy to dock ships elsewhere. Shipowners already mention that they will **leave to Asia or the Middle East.** Moreover, considering the **full exemption for fluoroelastomers in the UK[86], shipowners only have to go to the other side of the channel to escape the ban on fluoroelastomers**. Even without taking enforcement risks, the UK is likely to become a global hub, to change ships before goods/ persons enter into the EU. Thus, the **EU will lose a substantial part of the maritime business, which is estimated by some shipowners as between 30%- 50%** of the maritime activities that will leave the EU/EEA to Asia, the UK or the Middle East. On EU level this could lead to a reduction between 30% to 50 % and will than cost around the **45 - 70 billion GDP** and will have serious social impact between **600,000 to 1,000,000 jobs**. This will clearly have a direct impact on the marine equipment market if such substantial activities leave the EU/EEA. But the impact will be much bigger, due to the well-acknowledged strategic relevance of the maritime shipping sector and the interrelation of the (sub)sectors (detailed above), also other activities will escape from the EU/EEA. On the longer-term, maritime companies will not only withdraw their operational businesses but also their research and development activities, which will mean that maritime innovation in the EU/EEA will stifle. This will indeed have a strategic negative impact on the EU/EEA economy.

- **10.2.1.4 Likely negative environmental impact**

Moreover, it is **even likely that such a ban within 5 years (after EIF) will overall have a negative impact on the environment**. Firstly, Shipping is the most carbon-efficient mode of transportation with the lowest carbon dioxide emissions per distance and per carried weight[87], and as such is one of the most environmental-friendly ways of transportation.

Secondly, FKMs are much more expensive than its potential replacement substances, e.g. NBR, and that there has been a strong incentive to look for alternatives over the past decade, without success. The lack of proper alternative for FKM will inevitably result in more safety risks and leakages of seals, spills and pollution, as detailed under section 10.2 above, **(75 million -100 million litres annually)** while also the environmental impact of docking every 2nd year instead of ones every 5th year should be considered as it entails a lot of extra activities and energy loss and use of products such as replacement of lubricants etc.

[86] HSE, Analysis of the most appropriate regulatory management options (RMOA), Poly-and perfluoroalkyl substances (PFAS), March 2003, p.174.

[87] European Commission, *The EU Blue Economy Report*, 2022, Publications Office of the European Union, Luxembourg, p. 93, available at https://oceans-and-fisheries.ec.europa.eu/system/files/2022-05/2022-blue-economy-report_en.pdf

As detailed above the competitive advantage of FKM is such that it is likely that ships will remain using these fluoroelastomers. If dry-docking takes place outside the EU/EEA, EU/EEA authorities will lack the ability to properly enforce a ban on FKM seals. Under these circumstances the repair and maintenance of shipping and related (blue) economy will - to a significant extend - leave the EU/EEA, without any aimed positive effect on the environment, without abilities for maritime (sustainable) innovation in the EU/EEA and even with the risk that the EU/EEA on the longer run will not be able to impose relevant environmental friendly rule on maritime shipping because the impact of the EU/EEA sector has become too low, in global perspective.

To conclude on Risk Management Option A:

- **The overall environmental impact in case of a ban within 18 months and/or a 5-year derogation is likely to be both negative for the environment, and substantially negative for the economy in the EU/EEA.**

10.3 Risk Management Option B: Derogation for 12-15 years

This section will elaborate the need for a 12-15 years period of derogation. To find a reliable alternative for FKM, perform an endurance test for 5 years and to realise the Type Approval requirements, is impossible to complete within 5 years.
On **page 60** is shown how the AEGIR trajectory goes. Timelines are built on realistic assumptions.

Derogation, why?

- There is **no alternative for FKM. This is scientifically concluded by Noordermeer and Masen.[88] FKM** is the **one and only fluoroelastomer seal that is unbeaten as seal for (container)vessels;** due to the combination of properties that can match the complex requirements of this seals (high temperature, chemical resistance (EAL oils and sea water) and mechanical properties (see attached article prof J. Noordermeer[89]).
- R&D efforts are ongoing and promising, as shown in Chapter 9 above.
    - our two R&D projects to find an alternative for FKM;
    - our End-of-Life R&D project to find the safest way of incineration;
    - Our End-of-Life R&D project efforts to find a radical Circular waste solution to really built a EU-future oriented business.

[88] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 21. (ANNEX 1).
J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 21. (ANNEX 1).

10.3.1 Socio Economic effects

There is expected that it is possible to find an alternative solutions for the use of PFAS, FKM within 12-15 years.

This scenario will be presented further on underpinned with realistic lead times and deadlines.

Under these assumptions the economic effects will unfold, as presented in **Figure 21.** AEGIR-Marine will grow further and also the number of colleagues will grow. Moreover: this is only one example of what in the whole EU will happen if the issue of the fluoropolymers will be approached in a way that the persistency will be solved.

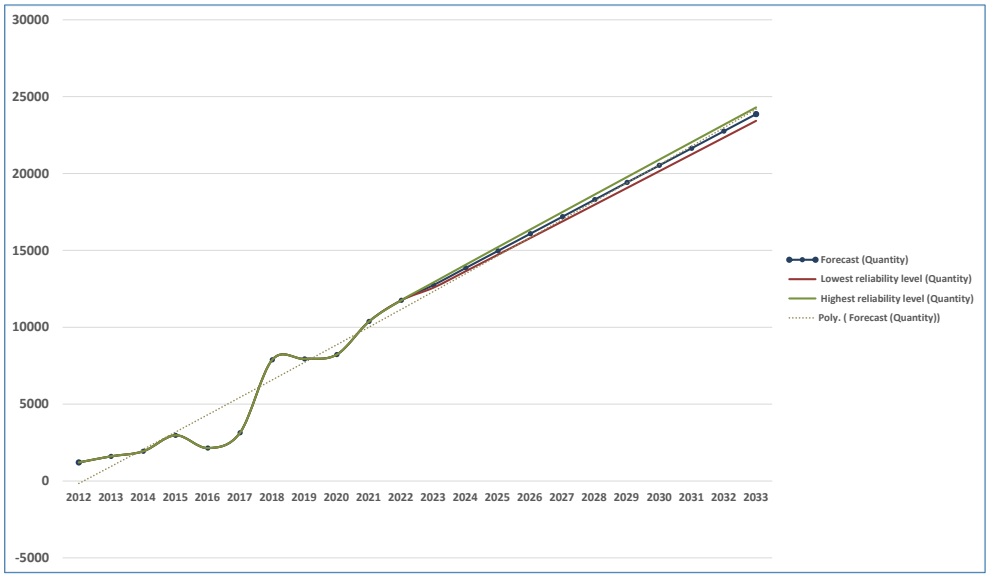


Figure 21: *Impact on Volume: Scenario 18 months and 12 – 15 year-derogation*

10.3.2. R&D schedules for alternatives FKM

Below are the schedules shown for the development of the alternatives for FKM within AEGIR-Marine.

R&D program 1

- R&D program 1 has enrolled in June 2022, we are in the development phase and there are first promising results (more information see Chapter 9). Key is that there is made a shift from searching for improving materials, the focus went to lowering temperatures. This shift seems to deliver results.
- In the development phase the promising result is that **lowering temperature** is realised. Key question is: will the endurance of 5 years in the tests with the new material be reached? This has to be tested thoroughly.

- The endurance tests and validation tests are performed in the Testing and Validation stage; this is an iterative process with the development stage. When the results in the testing stage are below the requirements new technical modifications are developed and the process of testing starts again. This is a time-consuming process.
- When the results out of the endurance test and validation stage are meeting the requirements, launching customers are approached.
- First test on a vessel of a launching customer will be executed on the inner seal (chambers 4 and 5 (see article of prof Noordermeer.[90] This is done to prevent environmental emissions of oil, in case of leakages. When these tests results meet the requirements, then it is possible to test the outer seals (chamber 1, 2 and 3).
- Next stage is replacing outer seals (chamber 1, 2 and 3). This is also a time-consuming process because it is needed to dock the ship and thereafter to do the endurance tests again 'live' (1-2 year).
- After performing the tests and validation of outer seals, the actions are initiated to obtain a Type approval. Type approval (Class certification) will take 1-1,5 year (preparation and paperwork, auditing and reporting), as is already known based on historical information.[91]
- After Class Approval, market introduction can be started.

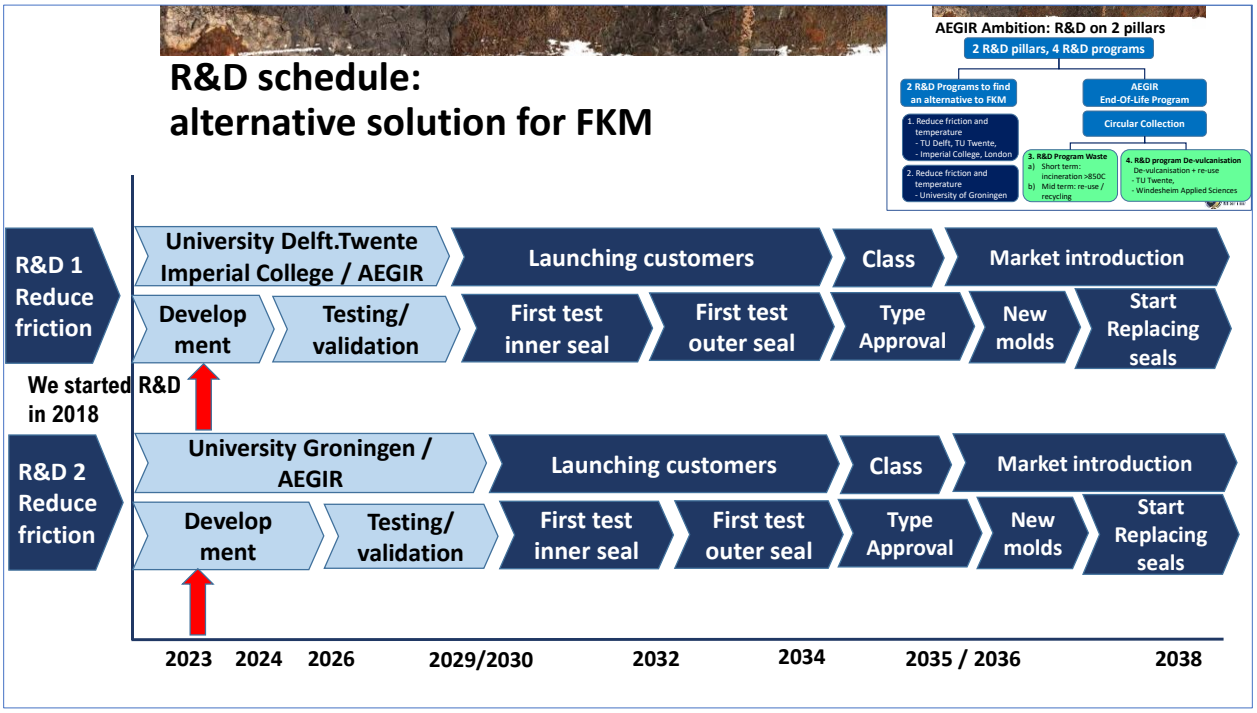


Figure 22: *R&D schedule with 2 programs on Friction Reduction*

[90] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 4. (ANNEX 1).
[91] Historical data of type approval on FKM seal adjustments (source AEGIR)

R&D program 2

- R&D program 2 has enrolled in February 2023, and we are in the first part of the development phase without results yet (for more information see Chapter 9). Key is that here is made - like program 1- a shift from searching for improving materials, the focus went to lowering temperatures.
- In the development phase the **expected result** is that **lowering temperature** will be realised. Key question is: will the endurance of 5 years in the tests with the new material be reached? This must be tested thoroughly.
- The endurance tests and validation tests are performed in the Testing and Validation stage; this is an iterative process with the development stage. When the results in the testing stage are below the requirements new technical modifications are developed and the process of testing starts again. This is a time-consuming process.
- When the results out of the endurance test and validation stage are meeting the requirements, launching customers are approached.
- First test on a vessel of a launching customer will be executed on the inner seal (chambers 4 and 5 (see article of prof Noordermeer[92]). This is done to prevent environmental emissions of oil, in case of leakages. When these tests results meet the requirements, then it is possible to test the outer seals (chamber 1,2 and 3).
- Next stage is to replace outer seals (chamber 1,2 and 3). This is also a time-consuming process because it is needed to dock the ship and thereafter to do the endurance tests again 'live' (1 -2 year).
- After performing the tests and validation of outer seals, the startup is made for a type approval. Type approval (Class certification) will take 1 -1,5 year (preparation and paperwork, auditing and reporting), as it is already known out of historical information.[93]
- After Class Approval, market introduction can be started.

10.3.3 R&D schedule on End-Of-Life programs

The End-Of-Life programs consists of 2 R&D programs:

[92] J.W.M. Noordermeer and M.A. Masen, Material selection criteria for Elastomeric Rotary Propeller Seals for Marine Applications, Nieuwstadt, 2023, p 4. (ANNEX 1).
[93] Historical data of type approval on FKM seal adjustments (source AEGIR)

R&D program 3

Program 3 entails R&D **on Incineration**.

In 2023 AEGIR-Marine developed the Waste policy, which means that NO used seal will end in the environment, but come back to the homebase in the Netherlands.

The R&D program 3 has to deliver the best way of controlled incineration for fluoroelastomers. This program is executed by prof Noordermeer and TU Twente, ass. Professor W. Dierkes (see section 9).

Realistic expectation is that between end of 2023 and mid 2024, the incineration solution is ready for implementation.

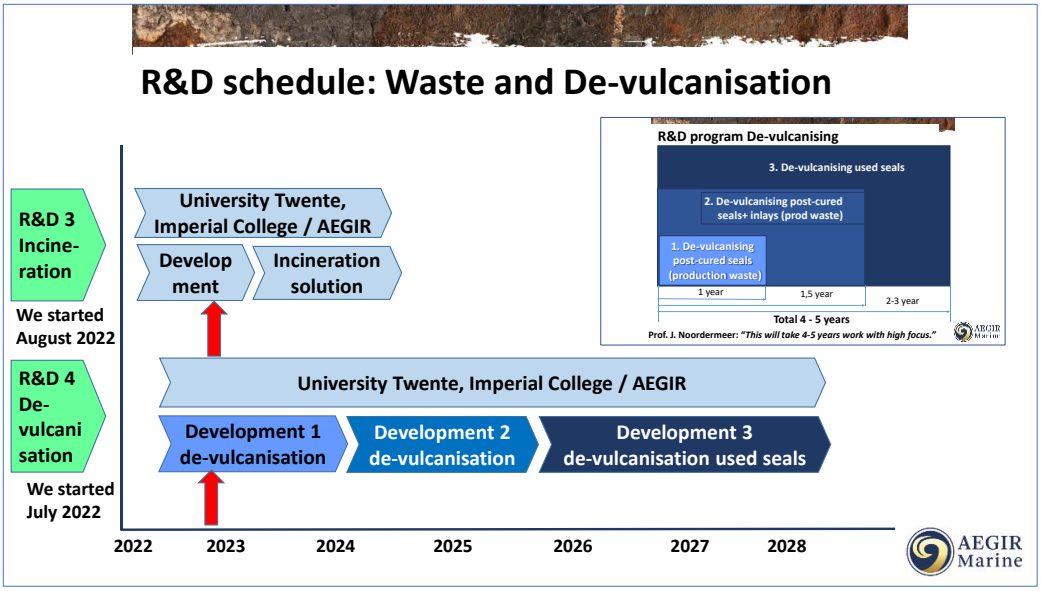


Figure 23: *R&D schedule Waste and De-vulcanisation*

R&D program 4

R&D program 4 entails a very complex issue: **de-vulcanisation** of the strongest chemical bond in nature. As elaborated in Chapter 9, this program consists of 3 development stages:

1. De-vulcanising post-cured (production) seals;
2. De-vulcanising post-cured seals including aramid inlays;
3. De-vulcanising used seals.

Timeline:

- Program 4 was started in July 2022. The whole programme will last at least 4 to 5 years, as estimated by prof. Noordermeer[94]
- End of 2027 we aim to have de-vulcanising of used seals ready for implementation, which means 1-1,5 years Type Approval and after that market introduction.

Total timeline critical path R&D activities

The critical path shows the essential activities needed to realise the desired result in time; in this case that will be the research to alternatives for FKM. In sequence the endurance of the activities will be between 12 and 15 years.

Below the critical path is shown.

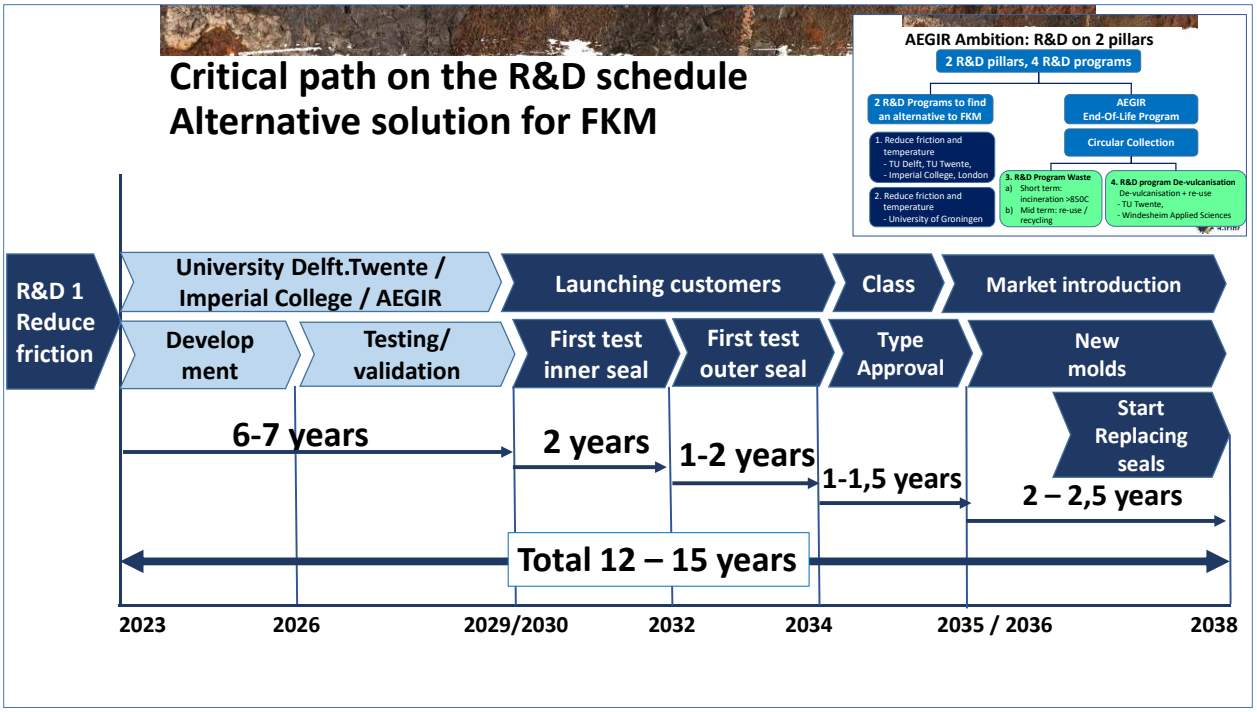


Figure 24: *Critical path on the R&D schedule in search of an alternative for FKM*

[94] Meeting with prof. J.W.M. Noordermeer, 20st March 2023.

10.4 Interpretation and conclusion

- An innovative, relative healthy and fast-growing company with significant growth potential will be seriously negative impacted by a ban.
  In case of a ban without derogation, AEGIR-Marine will stop to exist Europe in Spring 2026; 90 colleagues have to be dismissed. Because there is no alternative for FKM yet, the environment burden of marine waters will increase to 75-100 million litres leakages annually.
- By acting proactive, a series of 4 R&D programs were started which are potentially promising into two directions:
  - Finding an alternative for fluoroelastomer FKM (pillar 1);
  - Finding new ways to change the way waste has been handled to a real Circular economy (pillar 2)
- These programs are running now, and the timelines made are realistic, which gives the impression that a solution will be found within 12 to 15 years.
- A derogation of 12 -15 years will give the required room to transform to a healthy company that delivers sealing solutions with PFAS – free material. That will support ship owners to do business with vessels that are key in our economy.
- During the derogation-period the impact on the environment after end-of-life of the marine seals will be minimized due to the re-collection of these seals.

10.5 Results

Two scenarios have been shown.

- **Risk Management Option A, a ban + 18 months transition period** and/or a derogation for 5 years showed the seriously negative impact of a ban. In case of a ban without derogation, AEGIR-Marine will stop to exist in the EU as of Spring 2026, with the effect of a turnover drop with 28 million euro's/year; 90 colleagues (50%) have to be dismissed in Europe. Because there is no alternative for FKM yet, the environmental burden on marine waters will increase to 75 - 100 million litres oil leakage annually (for an overview see **table 13**).

IMPACT	Current Baseline	Risk Management Option A: ban + 18 months + 5 years
Economic impacts	Growth 40 million '22 to approx. 80 million '33	**Turnover drop with (54%) from 52[95] million euro's in '25 to 24 million euro's in '26** and growth to 34 million euro's in 2033
Environmental risks	FKM: very persistent	Drop of volume FKM
	Disposal of used seals, approx. 12.000 kg/year	End-of-Life policy: collection and controlled incineration of used seals at 850C
Human Health risks	**No risk** for use FKM fluoropolymer of low concern	**No risk**
Social impacts	Growth from 180 colleagues '22 to 330 in '33	**90** colleagues dismissed in '26
Wider economic impacts on EU/EEA level	NA	**30%-50%** shipowners will leave EU/EEA
Wider economic impacts on EU/EEA level	NA	**Loss of 45-70 billion GDP** level EU/EEA Loss of **600,000 – 1,000,000** maritime jobs on level EU/EEA
Wider environmental risks	NA	**25-50 million litres oil more spilled** in the sea annually
Conclusion:		**Dramatic negative effects on environment, social and economic aspects**

Table 13: *Overview of impact of a ban + 18 months transition period + 5 years derogation*

[95] These figures result from the detailed explanation in the previous sections, in particular section 10.2.

- **<u>Risk Management Option B,</u> Derogation for 12-15 years,** showed a way out via high R&D efforts.
    - By giving a derogation of 12-15 years there will be a realistic opportunity to find a real alternative for the use of FKM; and there will be an opportunity to find a solution for de-vulcanisation of old seals, in order to re-used the substance again. The environment in marine waters will not be polluted by leakage from lubricants and AEGIR-Marine will control the end-of life cycle of its products. A step towards a Circular Economy has become more likely.
    - By giving a 12–15-year derogation there will stay a level playing field between the EU and the global market players; the 12 years will be used to build on a strong, innovative, sustainable and safe economy in EU/EEA.
    - By giving a 12–15-year derogation, AEGIR-Marine will continue its operations and activities, 180 colleagues will keep their jobs and they have also the possibility to contribute in a positive and innovative way to create a solution for the persistency of FKM (for an overview see **table 14** below).

IMPACT	Current Baseline	Risk Management Option B: 12-15 years derogation+ 18 months
Economic impacts	Growth 40 million '22 to approx. 80 million '33	Turnover AEGIR-Marine will grow to approx. **80[96] million** in 2033
Environmental risks	FKM: very persistent	Due to our **2 R&D** programs, there will be **a safe alternative solution.** FKM will be changed for non-PFAS material
	Disposal of used seals	Due to our **2 R&D** programs there will be: - de-vulcanization of used seals; - re-cycled + re-used again as Circular solution
Human Health risks	No risk for use FKM fluoropolymer of low concern	**No risk**, AEGIR-Marine **will use other materials** for seals than FKM, due to R&D activities
Social impacts	Growth from 180 colleagues '22 to 330 in '33	Growth from **180** colleagues in '22 to **330** colleagues in '33
Wider economic impacts on EU/EEA level	NA	Innovative climate in EU will strengthen the Green Economy (**Hydrogen, electric cars** etc.) **No brain drain** out of EU/EEA
Wider economic impacts on EU/EEA level	NA	**Behold of 30%-50% shipowners,** who will stay in EU/EEA **No turndown of 45-70 billion** GDP level EU/EEA **No loss of 600,000 – 1,000,000** jobs
Wider environ-mental risks	NA	**25-50 million litres oil <u>less</u> spilled** in the sea annually, than in scenario RMO A
Conclusion		**Positive outcome on all factors on level of AEGIR and EU/EEA**

Table 14: *Overview of the impact of a 12-15 years derogation*

[96] These figures result from the detailed explanation in the previous sections, in particular sections 10.3-10.5.

Request:

- Please honour this request to carry out Risk Management Option B and grant a derogation for 12–15 years.