SOCIO-ECONOMIC ANALYSIS AND ANALYSIS OF ALTERNATIVES of the potential restriction of the per- and polyfluoroalkyl substances (PFAS) used in the manufacturing of razor blades for shaving

SUBSTANCE: **Per- and polyfluoroalkyl substances (PFAS)**
FROM: **Razor Blades Manufacturers**
USE: **In Manufacturing of Razor Blades for Shaving**
DATE: **21 September 2023**

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The views expressed in this report are, unless otherwise stated, those of the authors and do not necessarily represent any official view of Razor Blades Manufacturers and/or any other organization mentioned in this report.

Contents

Abbreviations

CAR	Competent Authority Report
EBIT	Earnings Before Interest and Taxes
ECHA	European Chemicals Agency
EEA	European Economic Area
EiF	Entry into Force
EU	European Union
EUR	Euro (currency)
FTE	Full Time Employee
NPV	Net Present Value
OECD	Organization for Economic Co-operation and Development
PFAS	Per-and Polyfluoroalkyl Substances
PMT	Persistent, Mobile, and Toxic
PTFE	Polytetrafluoroethylene
RAC	Committee for Risk Assessment
RO	Restriction Option
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SVHC	Substances of Very High Concern
vPvM	Very Persistent and Very Mobile

1. Summary of the Socio-Economic Analysis

1.1. Purpose and methodology

On 13 January 2023, the Competent Authorities (CAs) of the Netherlands, Germany, Sweden, Denmark, and Norway submitted a joint proposal to ECHA for a broad restriction under REACH of a group of substances, specifically Per- and polyfluoroalkyl substances (PFAS) (proposed restriction).[1] The proposed restriction entails a full ban on the use, manufacturing and placing on the market of PFAS, and on the marketing of substances, mixtures and articles containing PFAS, within the European Economic Area (EEA) unless a derogation is granted. The proposed restriction aims to limit the risks to the environment and human health arising from the manufacture and use of a wide range of PFAS due to their persistent/very persistent (P/vP) and bioaccumulative properties. All PFAS in scope of the proposed restriction are either P/vP themselves or degrade to other P/vP substances. Following standard timelines, the proposed restriction is anticipated to enter into force in 2025 and become effective in 2026/2027.

In the proposed restriction, PFASs (Per- and Polyfluoroalkyl Substances) are defined as any substance containing at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any hydrogen, chlorine, bromine, or iodine attached to it). The definition is based on the OECD definition of PFAS published in 2021 and covers over 10,000 PFAS, including some fully degradable subgroups (which would also be restricted under the current draft of the proposed restriction, unless a derogation is granted).

The proposed restriction[2] highlights two potential restriction options (ROs), referred to as RO1 and RO2:

- RO1 entails a full ban on PFAS, covering their use, manufacturing, and placing on the market in the EU, with no derogations and a transition period of 18 months (from the entry into force of the restriction).
- RO2 covers the same scope of restriction while introducing a number of specific and time-limited derogations. In addition to the 18-month transition period, it would allow for either a 5- or 12-year derogation period.

PFAS have been produced in large quantities and used in a variety of industrial, commercial, and consumer applications since the late 1940s.[3,4,5] Manufacturers of razor blades use PFAS when manufacturing manual blades in the wet shaving category. In particular, **Polytetrafluoroethylene (PTFE) is used to create a low friction-blade coating on the blade edges that significantly improves**

[1] See https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea.

[2] See https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea.

[3] Banks, R.E., Smart, B.E., Tatlow, J.C., 1994. Organofluorine chemistry: Principles and commercial applications. New York (NY): Plenum. 670 p. ISBN 978-1-4899-1202-2.

[4] Kissa, E., 2001. Fluorinated Surfactants and Repellents, 2nd Edition, CRC Press. ISBN 9780824704728.

[5] Buck, R.C., Franklin, J., Berger, U., Conder, J.M., Cousins, I.T., de Voogt, P., Jensen, A.A., Kannan, K., Mabury, S.A., van Leeuwen, S.P., 2011. Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins. *Integr. Environ. Assess. Manag.* 7, 513–541.

shaving performance. Furthermore, razor blades manufacturers use additional PFAS in equipment parts and as process chemicals in the manufacturing processes.

This document sets out a socio-economic analysis (SEA) of, and analysis of alternatives (AoA) for specific PFAS used for blade edge coatings on razor blades in the EEA. It has been performed by EPPA[6] at the request of four major manufacturers of razor blades for shaving: **BIC, Edgewell, Harry's** and **Procter & Gamble** (hereinafter Participating Manufacturers). It aims to provide regulators with strong, evidence-based findings on the expected social and economic impacts should these substances be restricted for use in razor blades under REACH.

This analysis has been **conducted in accordance with the existing official guidance from ECHA under REACH,**[7] and it is based on aggregate information and data gathered from the Participating Manufacturers, who each use PFAS in their manufacturing processes. **The entire EEA market size for the PFAS-containing razor blades is estimated at 2.5 billion EUR (based on retail sales value).**[8] **The Participating Manufacturers together hold a market share of 90 to 95% of the EEA razor blades market.**

This analysis uses technical and economic information to describe — in both qualitative and (if feasible) quantitative terms — the significant socio-economic impacts that the ban of PFAS is expected to have on the razor blades market, as well as on EEA supply chains, and on European society at large. In particular, the SEA describes the crucial technical function of polymeric PFAS used in razor blades, as well as the importance of PFAS used at different stages of the manufacturing process of razor blades. This analysis also provides an AoA, and shows the current lack of available, technically suitable, and economically feasible alternatives.

1.2. Main findings and derogation request

- The Participating Manufacturers are major players in the EEA, as well as in the global, razor blades markets. They have an aggregate revenue related to the sales of razor blades of more than 1.3 billion EUR in the EEA market alone. The Participating Manufacturers have various manufacturing plants for razor blades in the EEA, specifically in the Czech Republic, France, Germany, Greece, and Poland. **These EEA sites produce more than 11 billion[9] cartridges and disposable razors each year with approximately 50% being exported out of EEA.**
- In light of the high potential for, and consumer impact of, skin-related issues, **high-performance razors are essential to minimise the risk of skin damage, irritation, and discomfort – both during and after shaving**. In particular, inferior razors may result in or worsen issues such as sensitive skin, inflammation, redness, ingrown hairs, and razor bumps (pseudofolliculitis barbae). Modern razors are engineered with consumers' safety and comfort in mind, and significant advancements have been made to improve the shaving experience while minimizing skin-related concerns.

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[6] www.eppa.com.

[7] The ECHA Guideline for SEA for the restriction proposals is available at: https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d.

[8] Rounded value of ECB exchange rate on 8 May 2023 (1 EUR = 1.1037 USD), based on one of the Participating Manufacturer's estimate of 3 billion USD.

[9] Four

- **All modern multi-blade wet shaving products depend heavily on some of the most common PFAS. In particular:**
    - <u>Polytetrafluoroethylene (PTFE) is used in blade manufacturing to create a low friction coating on the blade edge; and</u>
    - <u>PFAS are used in materials and mixtures that are necessary to manufacture the razor blades for shaving</u>, such as oils, inspection equipment, material handling equipment, sintering ovens, magazines, spraying systems, lubricants, seals, and gaskets. Given the complexity of the PFAS definition and very large scope of the proposed restriction, the Participating Manufacturers are currently assessing the presence of PFAS to understand the full impact of the potential ban.

- **The performance of modern multi-blade wet shaving products without PTFE would be set back by around 50 years to single-blade products (currently containing PTFE) that are acceptable for only 1-2 shaves. However, generally, it is the low-cut force that allows multi-blade razors' functionality. Without a low cutting force, the addition of multiple blades leads to an excessive increase in resistance during a shaving stroke, resulting in an unusable product.** Before PTFE was introduced in 1964, the coatings used in razor blades products were based on cured silicone oil, which had poor durability and was only suitable for one or two shaves. Silicone oil is not suitable for use in modern, multi-blade shaving products, as the additional blades increase the discomfort that results from silicone oil's poor durability. **Prolonged use of inferior products that use silicone oil rather than PTFE could lead to skin irritation, damage, and discomfort.** Furthermore, it leads to substantially additional waste as the blades need to be replaced more frequently resulting in 10 times more consumer waste at end-of-life disposal.

- **There is currently no evidence of any technically suitable, economically feasible, and readily available alternatives to PTFE-based coatings for razor blades that can provide comparable product performance benefits for shaving products and that could be deployed in the next 15 years. Dossier Submitters (DSs) have identified the presence of PFAS substances in the components of the powered, dry shaving products (such as membranes, batteries, and electronic circuit board). Therefore, it is unrealistic to anticipate that the market would transition towards powered, dry shaving products as these technologies would also be facing PFAS substitution challenges. Lower performing edge coatings, such as silicone oils and silicone-like materials are widely available. However, the performance of such coatings on a blade edge is significantly inferior, especially in terms of durability of performance (1-2 shaves only)**. Additionally, the processes used to coat blades using these silicone oils and silicone-like materials are typically non-durable and sensitive to changes in the processing conditions or substrate material, leading to widely variable edge performance. If consumers wanted a similar experience from products that do not contain PTFE, they would need to replace their razor blades products at more than 10 times the current average rate. As a result, there would be a significant increase in consumer waste and disposal of over 10 times more products, which could be an unintended negative consequence of the restriction on PTFE.

- The Participating Manufacturers would support the phase-out of the use of PFAS where technically suitable and economically viable alternatives are available. However, as discussed above, such technically feasible and economically viable alternatives do currently not exist. Substitution, in the event that an acceptable alternative is identified, developed, and/or validated, is a highly time-consuming process due to the complexity of the affected products. In any event, it will not be possible to find alternatives and substitute them for PFAS in razor blades in the proposed 18-month transition period.

- **If a suitable alternative coating to PTFE is found, current manufacturing equipment would need to be discarded and replaced with completely new equipment. Staff would need to be newly trained to operate it. Therefore, it is estimated that it could take at least 15 years, and cost more than 132 million EUR, to develop and launch PFAS-free products that use an alternative to the PTFE coating.**
- In the case of a restriction on PFAS (PTFE) used in the production of razor blades, the cost per kg of avoided PFAS (PTFE) emissions is estimated to be at least 149,541 EUR/kg for all releases for over 30 years (temporal scope chosen by DSs) under a conservative estimation on the emissions. **This cost-effectiveness ratio is considered high enough to justify a time-limited derogation of at least 12 years (with an additional 18-month transition period, adding up to 13.5 after the entry into force) for the use of critical PFAS, such as PTFE in razor blades and their production.**
- The coating process of razor blades are automated. Due to the closed system and use of appropriate personal protective equipment (PPE), worker exposure is avoided. In addition, all residual PTFE in plant (not captured by the coating) is collected either as solid waste or as aqueous dispersion in liquid form for expired materials and is subject to thermal recycling in a municipal waste combustor. There are no extensive studies available regarding the release, if any, of PFAS during product usage. The PTFE coating on the blades is designed to be well-adherend due to the strong chemical bonds with the surface of the blades. This ensures that the amount of PTFE that might potentially be released (if any) during the use-phase is limited. According to studies, when incinerated under representative European municipal incinerators conditions, **fluoropolymers do not generate any measurable levels of PFAS emissions at their end of life during incineration**.[10] Furthermore, as PTFE is chemically, thermally, and biologically stable, **PTFE coated razor blades are not expected to lead to dispersive non-polymeric PFAS when disposed of in a landfill**.[11] Therefore, at the end-of-life stage, PTFE coated razor blades are not expected to lead to PFAS emissions.

[10] Aleksandrov, K., Gehrmann, H.J., Hauser, M., Mätzing, H., Pigeon, D., Stapf, D. and Wexler, M., 2019. Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per-and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. *Chemosphere*, *226*, 898-906.

[11] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management,* 19(2), 326-354.

- **The total monetised impact of a PFAS restriction is calculated as more than 2.8 billion EUR in a 4-year horizon for the manufacturers of razor blades.** This sum includes approximately 43 million EUR of economic impact driven by substitution costs for the manufacturers of razor blades; 2.5 billion EUR of economic impacts (EBIT losses) and 288 million EUR of social impact deriving from unemployment. **This is a conservative (lower boundary) estimate. The actual cost may be significantly higher as the PFAS restriction may lead to other costs for the manufacturers of razor blades in the EEA.**

- As discussed above, the proposed restriction on the manufacture, use and marketing of PFAS and the marketing of mixtures and articles containing PFAS would effectively prohibit manufacturing of razor blades in the EEA. This is because the PTFE used is an integral component of razor blades and its manufacturing. Moreover, this restriction may prevent PTFE-coated blades (non-compliant with the restriction scope) manufactured outside the EEA from being placed on the EEA market for use in cartridge assembly plants, thereby forcing all wet shaving manufacturing operations to be relocated outside of the EEA. Therefore, from an EEA macroeconomic standpoint, the broad restriction of PTFE and the marketing of mixtures and articles containing PTFE in the EEA will have impacts on the competitiveness of the EEA markets for razor blades, on competition in the EEA, on innovation, and on the overall EEA trade balance. Non-EEA manufacturers would not be subject to a restriction of PFAS used in manufacturing equipment and production processes. As a result, **the attractiveness of the EEA for investment in innovation and R&D would be jeopardised**. Section 4.3 provides a discussion on the wider macroeconomic impacts and consequences on European society at large.

- **Based on the highly representative survey and the detailed SEA and AoA, the report concludes that a broad restriction without a long-term derogation for the use of PFAS in the manufacturing of razor blades for shaving will have disproportionate negative impacts on the European economy and society. Hence, this report reasonably justifies the following request:**
  - **a derogation for the placing on the market of razor blades containing PFAS until 13.5 years after the entry into force,**
  - **a derogation for the manufacture, marketing, and use of PFAS and the placing on the market of substances, mixtures and articles containing PFAS to manufacture razor blades for shaving until 13.5 years after the entry into force.**

Therefore, we request the following text to be included in the restriction:

- By way of derogation, paragraphs 1 and 2 shall not apply to: Coatings in razor blades used for shaving until 13.5 years after the entry into force.
- By way of derogation, paragraphs 1 and 2 shall not apply to: The manufacture of razor blades used for shaving until 13.5 years after the entry into force.

2. Aims and Scope of the SEA

2.1. Purpose, scope and methodology of SEA

According to the standard process for developing a new restriction under REACH, ECHA's Risk Assessment Committee (RAC) must give its opinion as to whether the proposed restriction demonstrates a risk to human health or the environment, and whether the proposed restriction would be effective in reducing that risk. At the same time, ECHA's Committee for Socio-Economic Analysis (SEAC) must prepare an opinion on the socio-economic impacts and proportionality of the proposed restriction. The opinion-development phase at ECHA takes 12 – 15 months. After this, the proposed restriction and the opinions of RAC and SEAC are forwarded to the European Commission for decision making. Following the standard timelines, the proposed restriction could enter into force in 2025 and become effective in 2026/2027.

Many PFAS are efficient surfactants or surface protectors because of the perfluoroalkyl moiety's high chemical and thermal stability as well as its ability to repel water and oil. As a result, they have been produced in large quantities and used in a variety of industrial, commercial, and consumer applications since the late 1940s.[12, 13, 14] In May 2017, the German authorities proposed criteria for identifying PFAS in the regulatory context of EU REACH Regulation (EC) No 1907/2006.[15,16,17,18] Some substances meeting these criteria are referred to as either persistent, mobile, and toxic (PMT) or very persistent and very mobile (vPvM) substances.

Fluoropolymers are distinctly different from other polymeric and non-polymeric PFAS due to their thermal, chemical, photochemical, hydrolytic, oxidative and biological stability. They have high molecular weights and are not subject to long-range transport.[19] Based on available studies, the molecules of these fluoropolymers are believed to be too large to cross cell membranes and are

[12] Banks, R.E., Smart, B.E., Tatlow, J.C., 1994. Organofluorine chemistry: Principles and commercial applications. New York (NY): Plenum. 670 p. ISBN 978-1-4899-1202-2.

[13] Kissa, E., 2001. Fluorinated Surfactants and Repellents, 2nd Edition, CRC Press. ISBN 9780824704728.

[14] Buck, R.C., Franklin, J., Berger, U., Conder, J.M., Cousins, I.T., de Voogt, P., Jensen, A.A., Kannan, K., Mabury, S.A., van Leeuwen, S.P., 2011. Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins. *Integr. Environ. Assess. Manag.* 7, 513−541.

[15] Neumann, 2017. Proposal for criteria and an assessment concept for the identification of Persistent, Mobile and Toxic (PMT) substances to protect raw water for the production of drinking water under the EU regulation REACH [in German]. Zbl. Geol. Paläont. Teil I 1, 91-101.

[16] Neumann, M., Schliebner, I., 2017. Protecting the sources of our drinking water: A proposal for implementing criteria and an assessment procedure to identify Persistent, Mobile and Toxic (PM or PMT) substances registered under REACH. German Environmental Agency (UBA), Dessau, Germany. ISBN: 2363-8273.

[17] Neumann, M., Schliebner, I., 2017. Protecting the sources of our drinking water - A revised proposal for implementing criteria and an assessment procedure to identify Persistent, Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM) substances registered under REACH. German Environmental Agency (UBA), Dessau, Germany. ISBN: 2363-8273.

[18] Neumann, M., Schwarz, M.A., Sättler, D., Oltmanns, J., Vierke, L., Kalberlah, F., 2015. A proposal for a chemical assessment concept for the protection of raw water resources under REACH. 25th annual meeting of the Society of Environmental Toxicology and Chemistry (SETAC Europe), Barcelona, Spain.

[19] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, *14*(3), 316-334.

therefore believed to pose less risk to human and ecological health relative to non-polymer PFAS.[20,21] Contrary to other PFAS, fluoropolymers are considered to be non-mobile in the environment, not bioaccumulative and unable to bioconcentrate. Stability studies reported fluoropolymer stability in terms of light, hydrolysis, heat, oxidation, and biodegradation.[22]

Despite that for particular PFAS, like PFOS and PFOA, severe health consequences have been disclosed by toxicological and epidemiological studies, potential risks of polymers (i.e., PTFE) to human health are still under estimation. In fact, certain studies demonstrated that polymeric PFASs are not toxic or exhibit low toxicity.[23,24,25] For instance, studies have shown that for PTFE, PVDF, FEP, FKM, and PFA, their polymer composition, molecular weight, ionic character, structural similarities, ratio of residual monomers, solubility and the octanol–water partition coefficient (K_{ow}), particles size, and stability meet the PLC criteria.[26,27]

Methodology

This ex-ante Socio-Economic Analysis (SEA) aims to identify and to assess in both qualitative and (when feasible) quantitative terms the socio-economic impacts that are expected to occur in the event of a REACH restriction of this group of substances. The current SEA is not limited to the use of PFAS in razors and blades, but also covers the importance of PFAS used at different stages of the manufacturing process of razors and blades in the EEA. **A detailed questionnaire has been provided to the Participating Manufacturers** to gather information and data on PFAS and the impact of the proposed restriction on razors and blades in the EEA.

[20] Ibid.

[21] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management,* 19(2), 326-354.

[22] Ibid.

[23] Ebnesajjad, S., Khaladkar, P.R., 2017. Fluoropolymer applications in the chemical processing industries: the definitive user's guide and handbook. William Andrew.

[24] Ebnesajjad, S., 2015. Fluoroplastics, volume 2: Melt processible fluoropolymers-the definitive user's guide and data book. William Andrew.

[25] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management,* 19(2), 326-354.

[26] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, *14*(3), 316-334.

[27] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management,* 19(2), 326-354.

The Participating Manufacturers have provided data for the SEA with a view to extrapolating, given their large total market share, the impacts for the whole market. This conservative approach is further detailed below. The market share covered by the Participated Manufacturers (and, therefore, by this survey) represents **90 to 95%** of the EEA market, measured as a percentage of the total revenues in the wet shaving razor blades industry. **The estimates reported in this socio-economic analysis should be considered as a minimum (lower bound) of the expected impacts of a restriction for European manufacturers of razors and blades produced with PFAS.**

The assessment has been conducted in accordance with the existing official guidance from ECHA under REACH. ECHA has developed a solid methodology for conducting socio-economic assessments in the context of the REACH Regulation, with the support of a dedicated committee (SEAC). More specifically, this methodology is consistently applied for REACH applications for authorization of Substances of Very High Concern (SVHC), and for REACH restrictions, with a view to forecasting the impacts of the different regulatory options.

From a geographical perspective, this analysis focuses on the territory of the EEA, comprising the European Union (EU-27), Iceland, Liechtenstein, and Norway. For assessing the producers' surplus (one part of the economic impacts), it has been decided to use **a 4-year time horizon**, which is the time period suggested by SEAC when there is no "suitable alternative available in general" (referred to as "SAGA" in ECHA documents).[28, 29]

Moving beyond the costs to the Participating Manufacturers alone, this SEA also accounts for the costs to European society in terms of unemployment, innovation and international economic competitiveness, in the event that PFAS substances are prohibited from being manufactured, used, and placed on the market, and/or for the socio-economic costs of a complete ban (REACH restriction) starting from the year 2027 (year of the entry into force of the proposed restriction plus 18 months of transition period).

Future monetary values have been estimated by using the concept of net present value (NPV), adopting a 3% annual discount rate, which is the standard discount rate adopted by the European Commission and European agencies (e.g., ECHA) in impacts assessments.[30] **All monetised values have been adjusted to a base year, assumed to be 2027**. Information and data have been aggregated and anonymised. Statements and estimations from the Participating Manufacturers are as close to real data or perception of future changes as possible.

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[28] See https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1 for a discussion of the SAGA concept.

[29] See https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138 for a discussion of SEAC's approach to assessing changes in producer surplus.

[30] European Commission, 2021. Better Regulation Guidelines and Toolbox. https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=br_toolbox-nov_2021_en.pdf.

2.2. General overview of razor blades market and their value chain

Razor blades have been developed as essential tools for shaving and personal hygiene for centuries, and their importance continues to evolve with technological advancement. Razor blades play a fundamental role in the personal care product sector, by offering products for a variety of purposes, including shaving and personal hygiene.[31] The total EEA market size for razor blades products containing PFAS is estimated at 2.5 billion EUR.[32] The importance of razor blades lies in their ability to remove unwanted hair, which not only contributes to a cleaner and more polished appearance, but also has significant health benefits. For instance, shaving can reduce the risk of skin infections as well as improve hygiene.[33,34]

In addition to the benefits, the use of razor blades has been linked to improved mental health outcomes. By enhancing an individual's physical appearance, shaving practices can enhance and contribute to the development of a positive social identity, boosting self-esteem and confidence. According to a study published in the Journal of Cosmetic Dermatology, people who shaved regularly reported feeling more confident and attractive than those who did not.[35] In addition, the act of shaving has been shown to have a calming effect, which can help reduce stress and anxiety.

It is clear from the information provided by the Participating Manufacturers that the razor-blades market's ability to adapt to evolving consumer needs and meet consumer preferences is key to its continued growth and success in the market. A proposed restriction that threatens this ability threatens the EEA market as a whole.

2.2.1. Overview of the participating manufacturers

This socio-economic analysis has been written at the request of the Participating Manufacturers. The Participating Manufacturers are major **world leaders in razor blades**, and other shaving products in the wet shaving category, and they are also major players in the EEA as well as the global razor blades markets. The Participating Manufacturers' aggregate annual revenue related to the sales of razor blades in the EEA market is more than 1.3 billion EUR.

The Participating Manufacturers have various manufacturing plants in the EEA, namely in Czech Republic, France, Germany, Greece, and Poland. **These sites produce more than 11 billion cartridges and disposable razors per year with approximately 50% being exported out of EEA.**

The Participating Manufacturers have over 4,000 employees in the EEA that are directly engaged in the manufacturing and supply chain for razor blades containing PFAS. The Participating Manufacturers have indicated that all (100%) of their razor blades use PTFE coatings on the blade edges, and would

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[31] Sturrock, F., Pioch, E., 1998. "Making himself attractive: the growing consumption of grooming products", *Marketing Intelligence & Planning*, Vol. 16 No. 5, 337-343.

[32] Rounded value of ECB exchange rate on 8 May 2023 (1 EUR = 1.1037 USD), based on one of the Participating Manufacturer's estimate of 3 billion USD.

[33] Sturrock, F., Pioch, E., 1998. "Making himself attractive: the growing consumption of grooming products", *Marketing Intelligence & Planning*, Vol. 16 No. 5, 337-343.

[34] Lanzalaco, A., Vanoosthuyze, K., Stark, C., Swaile, D., Rocchetta, H., Spruell, R., 2016. A comparative clinical study of different hair removal procedures and their impact on axillary odor reduction in men. Journal of Cosmetic Dermatology, 15(1), 58-65.

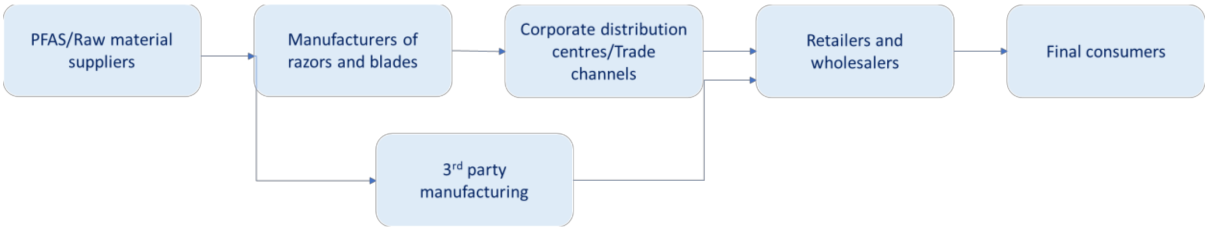
[35] Luebberding, S., Kreger, N., Kerscher, M., 2014. Shaving of unwanted facial hair influences perception of age, health and attractiveness. Journal of cosmetic dermatology, 13(4), 329-333.

therefore be adversely affected by a potential REACH restriction.

2.2.2. Supply chain overview

The typical supply chain of the Participating Manufacturers for manufacturing of razor blades is as follows:

Figure 1: Typical supply chain of the Participating Manufacturers



- **PFAS and raw materials (such as steel and plastics) are globally sourced from third-party suppliers.**
- **The raw materials are then processed** to obtain the necessary components and compounds that are used in the razors and blades manufacturing process.
- **Razors and blades can be directly produced by the Participating Manufacturers themselves** ("integrated manufacturers") or **third-party manufacturers**. The manufacturing of razors and blades involves several processes, such as assembly and packaging. The specific manufacturing steps differ across the participating companies.
- **After the blades have been assembled into cartridges, they are packaged for distribution both within and outside the EEA.** Some Participating Manufacturers sell their razor blades as finished products for sale, whereas others ship cartridges to packaging sites outside the EEA for final packaging and distribution.
- Finished razors and blades are then sold to the final **customers** via **trade channels** (i.e., retailers and wholesalers). **These retailers and wholesalers then distribute the finished razor blades to local stores across the EEA that ultimately sell them to consumers**. **The Participating Manufacturers supply their products to more than 100 retailers and wholesalers in the EEA alone.** These retailers and wholesalers subsequently further distribute the products to more than 50,000 local stores across the EEA, which ultimately sell them to consumers.

Globally, the Participating Manufacturers' facilities support over 180 countries. Furthermore, the Participating Manufacturers export more than 50% of their produced value out of the EEA. Therefore, this supply chain is not limited to the EEA only.

2.2.3. Market trends and developments

This section aims to highlight the advancements in the performance of wet shaving products throughout the history of the shaving industry, encompassing innovations from the 1900s to the present day. These milestones underscore the significant progress made in enhancing the overall shaving experience, and the central role of PTFE, a PFAS impacted by the proposed restriction.

The primary function of a wet shaving product is to safely and efficiently remove, shape or otherwise style facial and body hair. Product designers work to balance key performance vectors including **comfort** (low tug and pull while cutting hair), **safety** (avoiding nicks, cuts, and irritation) and **efficiency** (fast and easy removal of unwanted hair). Product evolution has been driven by improving one or more of these vectors over time versus previous products or in response to a competitive development. Given the growing disposable income of EEA households over the last decade and increased expectations by consumers regarding razor blades as personal care products, the shaving industry has been adapting to consumers' demands, always taking into account the product's comfort, safety, and efficiency during innovations.[36,37]

Over the course of wet shaving product development history, the largest step-change in wet shaving was the introduction of low-friction coatings for blade edges. The technical effect of these coatings was to reduce hair cutting force by approximately 70% versus an uncoated blade edge. **This cutting force reduction significantly reduced dermal irritations** by reducing the feeling that the hair was being pulled out, thereby significantly improving shaving comfort and consumer safety. Without a low-friction coating, the discomfort level after even a few shaving strokes would be too high and would result in severe skin irritations, making it impossible to shave efficiently, safely, and comfortably. Therefore, modern multi-blade products offer greater levels of comfort, safety, and efficiency compared to older style single-bladed products. **PTFE coatings were first commercialized in 1964, and became the gold standard for low-friction coating**. This opened the door to modern multi-blade shaving products and significantly improved consumer comfort in shaving. All major manufacturers of wet shaving products now use PTFE coating on blade edges.

Building on the foundation of low-friction PTFE coatings, modern multi-blade wet shaving product innovations have most recently focused on:

- The addition of more blades to multi-bladed cartridges. More blades:
  - distribute skin pressure across more blades to reduce incidence of nicking and cutting;
  - reduce the number of strokes required to achieve the desired shave; and
  - increase shaving closeness via the hair cutting hysteresis effect — the rapid, sequential cutting of hairs by trailing blades before the hair retracts into the follicle after a cut, enabling below-skin level closeness.
- Improved blade edge designs that further reduce hair cutting forces by delivering thinner edge cross-section to further reduce resistance of cutting through hair.
- More and better lubrication on the cartridge via lubrication pads or a reservoir that supplies hydrated lubricants during the shave to provide glide and protection.

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[36] Sturrock, F., Pioch, E., 1998. "Making himself attractive: the growing consumption of grooming products", *Marketing Intelligence & Planning*, Vol. 16 No. 5, 337-343.

[37] Eurostat, 2023. Adjusted gross disposable income of households per capita. Available at: https://ec.europa.eu/eurostat/databrowser/view/sdg_10_20/default/table?lang=en (Accessed in August 2023).

- Improved cartridge geometry and features: the addition or modification of blade positioning (blade spacing, blade presentation angle to skin, blade responsiveness (contouring to skin); rinsing features; a trimming blade; elastomeric components for skin stretching; and blade stabilization.
- Improved razor handle ergonomics: the addition of elastomeric grips, cartridge pivot for contouring, pivot location and aspect ratios.

All blade edge advances over the past decades were built on the same foundation of the PTFE coating, which still represents the state of the art in low-friction blade coatings. **Even with the subsequent innovations in shaving technologies, the absence of a PTFE coating would set the performance of modern multi-blade wet shaving razor blades back by roughly 50 years. The next section provides a more detailed overview of the technical performance of the PTFE coating, as well as identified potential alternatives.**

3. Analysis of Alternatives

This section provides a closer look at the **use and function of PTFE in razor blades, and outlines performance requirements** for a suitable substitute. It has been written under the guidance of ECHA, and it illustrates the potential alternatives and their **technical feasibility and economic viability**. **In addition**, the alternative must not result in additional **safety** concerns in terms of its **hazard properties**. Furthermore, the typical timeline for discovering and implementing an alternative will be described. This analysis of alternatives (AoA) concludes that **there are currently no suitable alternatives** that could substitute PTFE in blade coatings.

3.1. Function and technical performance of PFAS in razor blades

Fluoropolymers, as a subgroup of PFAS, are prevalent in the shaving market. Fluoropolymers have unique physical and chemical properties that set them apart from other members of the PFAS family, resulting in specific toxicological and environmental characteristics. Fluoropolymers as a group have negligible residual monomer and oligomer content and low to no leachables. With a molecular weight well over 100,000 Dalton (Da), fluoropolymers cannot cross the cell membrane.[38]

The Participating Manufacturers use PTFE to obtain a thin coating on the razor blade edges. To achieve this thin layer of PTFE, the Participating Manufacturers spray a PTFE material onto the blade edges. The specific technique and solution of the PTFE used differs between the Participating Manufacturers. **To ensure there is a well-adhered, continuous coating on the edge of the blade, the blades are heated to sinter the PTFE particles.**

The key characteristic of the PTFE coating on the blade edge is **its low coefficient of friction**. This contributes to a reduction in hair cutting force, which ultimately translates in a more safe, comfortable, and smooth shaving experience. This is due to less tugging and pulling compared to a non-coated blade edge**.** The next section illustrates the difference in performance of a PTFE-coated blade edge versus a non-coated blade edge in further detail.

With the potential restriction on the use of PFAS, finding a viable alternative has become a priority for the Participating Manufacturers. Nevertheless, the technical challenges of the task must be understood, and must not be underestimated. **Merely finding and applying a low coefficient of friction coating or treatment to a blade edge will not be sufficient for success. A suitable alternative to the PTFE coating on the blade edges must meet other stringent requirements, including:**

- **Highly Inert**: The mechanism for reducing hair-cutting force requires an extremely non-reactive surface, which has an extremely low surface energy. To reduce friction, any potential chemical bonding at the cut interface between the blade edge coating and the cut hair surfaces must be eliminated.
- **Durable**: The coating must adhere to the blade via a strong bonding mechanism to remain in place for multiple shaves. A graphitic-type slipping, or material sloughing is not a suitable friction reduction mechanism, as it will deplete rapidly with use. A strong, well-adhered

[38] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, *14*(3), 316-334.

coating on the blade will allow the blade to remain comfortable for many uses (i.e., more than 10 shaves).

- **Thin**: The residual, conformal coating should be thinner than 100 nm; otherwise, it will increase the apparent geometry of the edge and interrupt or degrade cutting performance.
- **Cost-effective material and processes**: As the Participating Manufacturers (like other razor blade manufacturers) are active in global operations, any material and process must be cost-effective, available, reproducible, and scalable to a global operation.

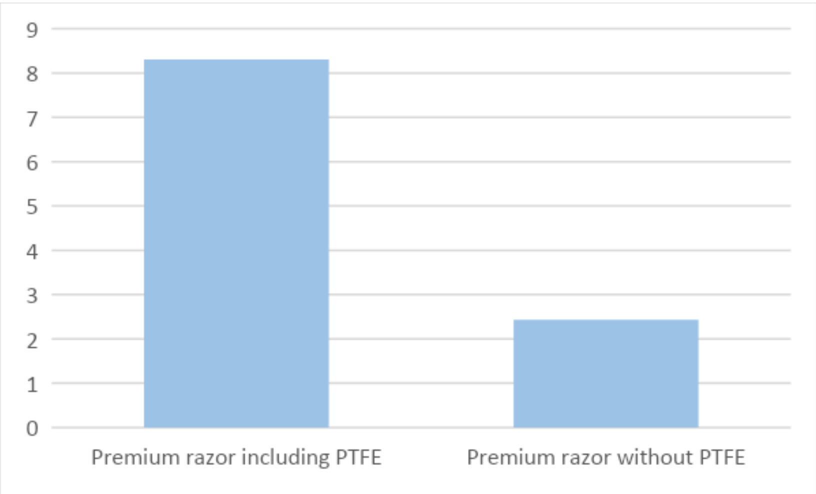
While PTFE is used for the thin layer on the blade edge, **there are additional PFAS present in processing aids and the fixed manufacturing equipment**, such as the spraying systems, the magazines, sintering ovens, inspection equipment, compressors, and releasing agents. Even though this section focuses on the availability of potential alternatives for the PTFE coating on the blade edges, it is important to keep in mind that all PFAS-containing manufacturing equipment would also be within the scope of the proposed restriction. Additionally, suppliers cannot offer any PFAS-free alternatives at this point in time, and the discovery of the presence of PFAS in the supply chain is still ongoing but not promising.

3.1.1. Performance comparison of a PTFE coated and a non-coated blade edge

This subsection provides a more thorough comparison of PTFE-coated blade edges and uncoated blade edges, illustrating how the PTFE coating creates a significantly more comfortable consumer experience compared to an uncoated blade edge.

Compared to non-coated blades, blades with the PTFE coating demonstrate a reduction of up to 70% in cutting force versus those without the PTFE coating. These findings suggest that the use of PTFE coating significantly enhances the performance and safety of hair cutting blades.

Figure 2: Consumer shave testing – overall liking scores



Source: Consultation with one of the Participating Manufacturers, 2023

In consumer testing performed by one of the Participating Manufacturers, it was concluded that the non-PTFE-coated blade edge resulted in an unacceptable level of discomfort and pain and was not perceived as acceptable for use. For blades without a PTFE coating, participants even discontinued using the razor blades, scoring the performance of the razor 2.43 out of 9, compared to a razor blade with PTFE coating scoring 8.31 out of 9. These test scores are also illustrated in Figure 2. Over 25 years of research and thousands of studies, the company has indicated that these have been the **lowest scores that have ever been reported in consumer tests.** Some examples of consumer comments included:

- "*Medieval torture, pulling"*
- *"Worst ever, it HURT"*
- *"Pulling, tugging, red, a lot of burning"*
- *"Brutal"*
- *"Horrible, couldn't shave properly"*

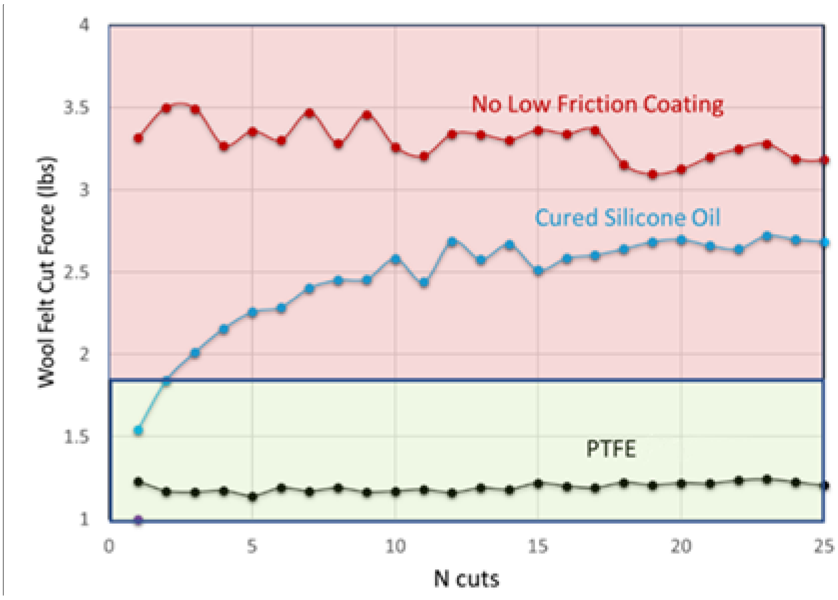
In an additional randomized split-face clinical study, 10 adult men were required to shave with PTFE-coated blade edge razors and uncoated blade edge razors daily for five days. Results indicated that on the fifth day of the study, 90% of the subjects rejected future use of the non-PTFE coated razors. **The subjects experienced severe pain and discomfort**. The non-coated razor felt rough on skin, did not glide properly, the shave was painful, and the subjects felt like it irritated their skin. Subjects shaving with the uncoated razor also showed skin barrier disruption objectively measured by bioinstrumentation. **The subjective level of discomfort was confirmed with objective measurements of skin barrier disruption**. Therefore, in terms of safety and corresponding comfort level, non-coated blade edge razors are not feasible.

Based on the technical assessment of the cutting forces, there is a significant variation in the performance of blade edges and the shaving products that use them. During **cantilevered cutting experiments with single fiber cutting**, a cut force difference of 10% or more was noticeable to consumers, who reported experiencing higher "tug and pull" and less comfort during usage testing. Moreover, during these experiments, blades without the PTFE coating cut with 120% higher cutting force and significantly further away from the hair follicle than PTFE-coated blades, which can lead to reduced ability to engage and cleanly cut through the hair. The result is an increased duration of the blade-hair cutting event during shaving, leading to a significant reduction in comfort.

In compressive cutting (wool felt cutting), cutting forces above 1.75-lbf (pound-of-force) are considered uncomfortable, and would not be suitable for multi-bladed shaving products. Cutting forces greater than 2-lbf, which is approximately 50% higher than the average cutting force of PTFE-coated blades, are unsafe due to corresponding skin issues and should therefore be rejected. Uncoated blades typically cut at over 3.25-lbf, going way beyond the range of 2-lbf, and would therefore be considered impossible to safely shave with. Ultimately, **the technical assessment suggests that PTFE-coated blades offer superior performance, comfort and safety compared to non-coated or poorly coated blades.**

Figure 3 represents performance tests with different low-friction coatings as explained above, highlighting that a cutting force greater than 1.75-lbf results in skin damage, irritation, and discomfort. Whereas PTFE-coated blade edges provide a consistent cutting force of just over 1-lbf, even after twenty cuts, this is not the case for the two researched alternatives. Figure 3 illustrates that the absence of a low friction coating is deemed unacceptable in terms of the cutting force. Regarding the alternative of cured silicone oil, the next section will analyse the technical performance and feasibility of this alternative in further detail.

Figure 3: Blade substrate technical performance tests with different low friction coatings.



Source: Consultation with one of the Participating Manufacturers, 2023

These clinical and consumer tests prove that there is a significant difference in performance when comparing a PTFE-coated blade edge to a non-coated blade and have shown **a non-coated blade edge is not feasible and not desirable in terms of technical performance**. The next section continues to identify known and potential alternatives to the PTFE coating, keeping into consideration the aforementioned technical and functional requirements that the coating should meet.

3.2. Identification of known alternatives to the low-friction blade coating

Of great relevance to the current situation, one of the Participating Manufacturers faced a supply risk for PTFE in 1994. Therefore, over the past decades, that Participating Manufacturer undertook a comprehensive exploration of alternatives. Others have also done the same. For instance, one Participating Manufacturer has stated that it worked with 33 external companies and tried 41 different materials, but that all researched alternative materials failed to reach the technical performance of PTFE. Generally, the challenge in the identification of a feasible alternative is the lack of an alternative that meets PTFE's low coefficient of friction required for functionality. This section provides a closer look into the identification and shortcomings of known alternatives for PTFE in manufacturing and specifically coating razors and blades.

As described above, a feasible alternative to the PTFE coating on blade edges, in terms of technical performance, must have a low coefficient of friction, must be highly inert, durable, and thin.

Furthermore, it must be cost-effective and its safety and hazard properties should be taken into consideration.

3.2.1. Cured silicone oil

In the mid-1950s, the discovery of **cured silicone oil** as a low friction blade coating revolutionized the shaving market by significantly improving shaving comfort compared to the status quo at the time. Before the implementation of PTFE coating, cured silicone oil was used as a friction-reducing coating on double-edged blades. Research revealed that controlled heating of the cured silicone oil could reduce the hair cutting force by up to 50% compared to an uncoated blade, resulting in a breakthrough for the users of double-edge blades.

However, the cured silicone oil coating had a major shortcoming, namely that it **poorly adhered to the blade**. This means that while the coating could reduce cutting forces, it would rapidly wipe away during the first or second shave, leaving the blade uncoated and resulting in high levels of tug and pull and nicks. The curing process was also susceptible to minor deviations in blade surface conditions or variations in the process ambient condition, resulting in a range of coatings with varying levels of adhesion and durability. In some cases, the overcured vitreous film coating degraded cutting performance by exaggerating the blade cross-section.

Thus, while cured silicone oil can reduce initial cutting forces to a degree, it is still not comparable to PTFE, and it is **far less durable and typically lasts for one or two shaves at best**. In contrast, the PTFE coatings have proven to be much more robust, lasting at least 10 shaves. This **durability allows for a consistently smooth and comfortable shaving experience for users, greatly reducing the need for frequent blade replacements of multi-use razors, and the plastic pollution generated by single-use razors**. This is also highlighted in Figure 3, where after two cuts, cured silicone oil shows marginally acceptable initial cutting force that deteriorates within approximately two cuts (less than one shave), making it **unsuitable for multi-bladed products** (appearing in the "red zone" of Figure 3 for acceptable performance). If blades were coated with cured silicone oil, final consumers would need to replace their products at more than ten times the current average rate of replacement. The unintended consequence is a **dramatic increase in consumer waste and end of life disposal of ten times more products**.

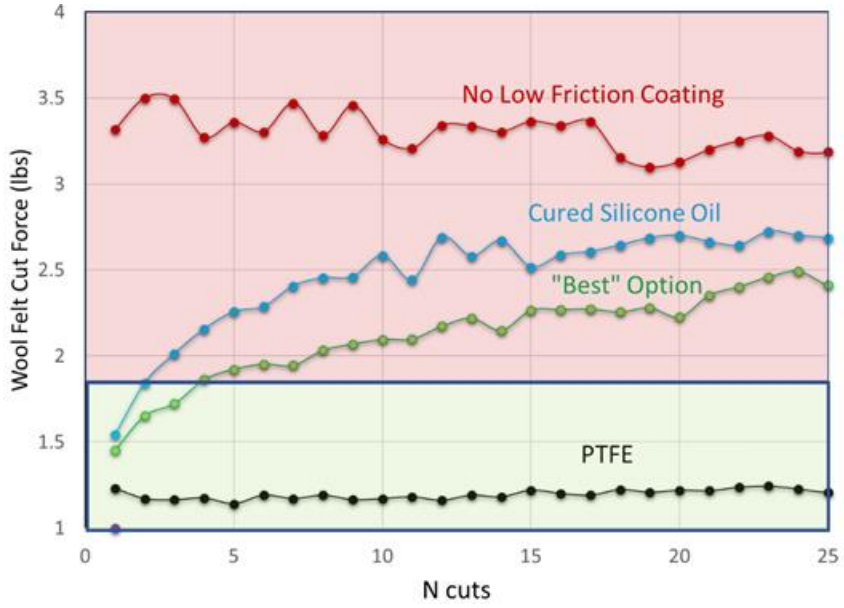
3.2.2. Silicone-like materials

Additional potential **candidates for substitution, such as non-fluorinated silicone oils, silicone-like, and siloxane-related materials**, have also been examined in the search for a PFAS-free alternative for the coating on the blade edges, with a renewed focus on addressing the known technical challenges related to adhesion. The test coatings were compared to the then-best PTFE system qualitatively and quantitatively, using visual inspections, informal shave tests, and cut force testing. **Out of more than 40 siloxanes that have been tested, even the best-performing coatings amongst these were unable to match the cut values of PTFE**. The worst performers could not even form a cohesive or durable film.

Figure 4 shows the performance of the best-researched, non-fluorinated, silicone-like coating option, alongside data from other coating materials for comparison. **Figure 4** depicts the cutting force of wool felt as a function of the number of cuts. For reference, 50 cuts through wool felt are approximately equivalent to one full shave, and cuts 1-5 would represent the first few strokes of a typical shave. The “best” option is a **silicone-like coating that exhibits marginally acceptable initial cutting force that**

deteriorates within approximately five cuts. This coating is unsuitable for multi-bladed products, as it is appearing in the "red zone" of Figure 4 for unacceptable performance, which would be uncomfortable and possibly lead to safety issues.

Figure 4: Premium blade substrate with different low friction coatings



Source: Consultation with one of the Participating Manufacturers, 2023

Therefore, despite more than a decade of advanced research in improving adhesion for non-fluorinated, silicone-like materials for blade edges, the improvements have been only marginal. At best, **sufficient improvements in these most promising coating options are more than 10 years away from commercial product usage**.

3.2.3. Lower fluorine concentration

In the search for the best coating material, researchers have turned their attention to understanding the **role of fluorine in reducing friction**. They explored blade coatings made from non-fluorinated "base" polymers with 2% fluorinated additives. Researchers attempted to lower the surface energy of six different non-fluorinated polymer coatings. Although the addition of fluorinated additives did reduce cutting forces compared to the non-fluorinated polymer coating alone, the lowest cutting force values achieved by the resulting coatings was still more than twice the cutting force values of PTFE. Therefore, **low-fluorine content polymer blended coatings were deemed insufficiently promising to pursue any further study**.

3.2.4. Other chemical options: non-stick options and polyethylene materials

As part of its effort to develop a new blade coating, one of the Participating Manufacturers **explored a range of non-stick options commonly used for other applications**, such as cooking utensils, cutlery, machine parts, and medical devices. These options include **diamond-like carbon, amorphous diamond, ceramics, non-fluorinated polymers, and metal oxides**, which are known for their low coefficients of friction and high durability. However, the Participating Manufacturers found that these coatings often **perform poorly under the wet conditions** present during shaving or fail to exhibit **low cutting force behaviour** during technical assessments. This poor cutting is likely due to unacceptable chemical reactivity at the cutting interface between the coating and the hair. Additionally, these coatings tend to be too **thick** (> 500 nm), brittle, or have **poor adhesion with blade substrates, rendering them not effective** for wet shaving.

Additional non-PTFE solutions, in particular **polyethylene** materials, have been evaluated and researched for decades. **Polyethylene-based** materials, which have a low coefficient of friction, still fall short of the performance that PTFE provides. Furthermore, polyethylene-based materials do not have the unique mechanical properties that allow thinning of the coating, and therefore would require chemical etching or some other technique during manufacturing to remove excess coating material.

After trying and testing various alternatives, **despite ongoing efforts, to date, no breakthrough alternatives to the PTFE coating have been found**.

3.2.5. Critical analysis of Aculon's contribution to the public consultation (razor blade coating)

In the public consultation, there has been a submission by Aculon,[39] stating they have created a PFAS-free alternative to coatings for razor blade edges. The Participating Manufacturers are aware of Aculon's purported low friction, non-fluorinated coatings being developed for blade edges. However, there is currently insufficient supporting data that demonstrates a shave-capable alternative to PTFE from Aculon that would be considered technically or commercially ready within several years.

The data in the submission regarding cutting forces, both wet and dry, are related to hair engagement force. However, the reported data is highly correlated to the blade edge tip geometry in a region of less than 1 micron from the ultimate blade edge tip. Therefore, this data is not sufficiently indicative of the coating's friction reduction and does not capture the related hair cutting forces that drive the consumer-perceived sensations as if the hair is tugged and pulled out, resulting in post-shave skin irritation. A much stronger technical measure to reflect shaving performance is Single Fiber Cutting. To date, no data or evidence of acceptable Single Fiber Cutting (or similar measure) values has been reported to warrant a more focused investigation.

The blades with Aculon's best non-PFAS material have an average cutting force which is about ~44% higher than PTFE coated blades as measured by dry felt cutting test and ~22% higher as measured by wet felt cutting test. Such differences in blade performance in the above lab tests would be noticeable and negatively perceived by the user in actual shaving leading to an unsatisfactory and uncomfortable shave.

The second key measure of the performance tests was related to the coating's durability. A suitable alternative blade coating must conform to the minimum technical standard of performance of less than 2.3 lb_f after 500 cuts, which is equivalent to withstanding 10 shaves.[40] **The extremely limited data**

[39] ECHA10, 4184.

[40] PTFE coated blade edges have a performance of 1.7 lb_f after 500 cuts.

set supplied by Aculon does not support durability of the coating over extended use and much more testing and evidence is required.

The recently shared data from Aculon regarding its PFAS-free alternatives lacks technical support for the achievement of the minimum standards of performance or safety for acceptable consumer performance. Moreover, we note that in its submission Aculon does not provide any information on the risks to human health or the environment related to the manufacture or use of its material. Accurate evaluation of blade performance requires significant testing of the product on the intended subject of use (i.e., human skin).[41] Aculon's submission states that their coating still needs to be evaluated on humans, suggesting that safety assessments on the coating have not been done yet. Therefore, it is not possible to establish if the proposed coating is regulatory viable or could be a regrettable substitution. Aculon's submission also lacks data on the economic feasibility, availability in sufficient volume to meet the market demand, the time needed to develop and validate the alternative in the future and the time needed to adapt product design and production process.

The Participating Manufacturers estimate that at least 12 years of coating development, process scaleup, safety assessment and significant capital investment would be needed to make Aculon's coatings potentially viable as PTFE alternative coatings on an industrial scale. **Therefore, it can be concluded that Aculon's material cannot yet be considered as an available technically suitable and economically viable alternative to PTFE.**

3.2.6. Ceramics

Ceramic is known for its low coefficient of friction and high durability. Ceramic coatings are typically produced via sol-gel processes from solutions (the application of ceramic coatings does not involve the use of PFAS,) and require adhesion layers, sintering, and drying, making them **too thick** to be applied to razor blades. A blob of coating at the tip of the blade would make it impossible to shave effectively, while an uncovered tip would have the same result. Furthermore, during the drying process, **shrinkage** may occur, leading to film cracking that shavers can easily detect (e.g., via nicks). As shavers can pick up even the smallest differences in blade edges, coatings need to be contiguous to avoid any problems with shaving performance.

3.3. Typical innovation process and timing

The Participating Manufacturers have stated that the typical innovation cycle for a razor blade with known coatings takes 7 to 15 years. The typical innovation cycle for a new razor blade innovation to be developed in the razor blades sector consists of the main following phases. A blade-coating innovation would likely take longer, as there is higher complexity during this process.

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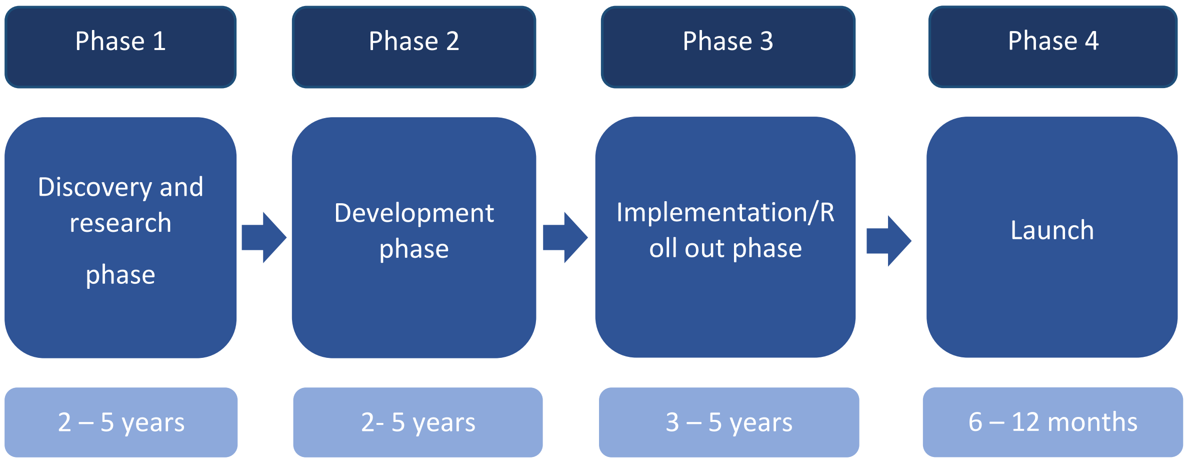
[41] Aziz, H.A., 2017. Comparison between field research and controlled laboratory research. Archives of Clinical and Biomedical Research, 1(2), 101-104. Available at: https://www.researchgate.net/publication/316543113_Comparison_between_Field_Research_and_Controlled_Laboratory_Research (Accessed in September 2023).



<u>Phase 1 - Discovery and Research Phase</u>

If an available alternative is found, the discovery phase of a product development process typically lasts 2 to 5 years. During this phase, several steps are taken to ensure that the product opportunity, technical challenge, and success criteria are clearly defined. This involves extensive research via literature search, intellectual property (IP) search, consultation, and external collaboration, partnerships, or outsourcing. Patent applications are also filed to protect intellectual property, and freedom to practice is assessed to determine any potential legal barriers to market entry. The next step is to demonstrate proof of principle by developing prototyping methods and equipment and producing samples for analytical and consumer testing. This process is highly iterative and continues until the product meets the defined success criteria. The final step is to define the target product characteristics that meet the performance success criteria, which will guide the development process moving forward.

<u>Phase 2 - Development Phase</u>

The development phase typically overlaps with the end of the discovery phase and lasts between 2 to 5 years. This phase involves translating proof-of-concept solutions and prototyping methods into scalable products and processes that meet appropriate product-and process-specification limits. This phase also involves developing test methods and testing the performance of the new products against established targets to ensure they meet the desired quality standards. This involves a lab-scale process validation, where there are established process settings at a lab scale. Once the product performance has been tested and validated, companies specify and design equipment and processes required to manufacture the product at scale. They will also build pilot equipment and lead lines, which are used to debug and demonstrate the scalability of the new process.

To successfully move beyond the Discovery Phase and into the subsequent Development phase, the candidate blade edge coating will need to have demonstrated both adequate cutting forces relative to a PTFE coated blade edge and sufficient coating durability. During the Development phase, a significant set of required and essential evaluations will be required to gauge and progress the performance, safety and scaleup potential. An abbreviated summary of these evaluations is included below:

Table 1: Summary of assessments that need to be performed during the development phase.

Property	Assessment	Purpose
Hair Peak Cutting Force	Single Fiber Cutter (U.S. Patent # 9,255,858)	Quality, comfort and safety of product in use
Quality of Hair Cutting	Single Fiber Cutter	Quality of hair cutting and closeness post-use
Coating Durability	Wool Felt Cutting (U.S. patent # 10118304)	Product longevity and life cycle prediction
Edge Strength and Durability	Edge strength, mechanical durability testing	Product longevity and life cycle prediction and safety
Consumer related attributes	Multiple consumer use assessments	Direct consumer performance assessment
Safety and Environmental	Multiple Health and Toxicology Profile, Exposure Limits Measures	Safety and hazard identification and assessment: Product material, process materials, byproducts, waste streams, decomposition materials
Process and Manufacturing Scaleup	Material Transformation and Process Development Models and Measures	Equipment/process complexity, raw material and conversion costs, energy consumption
Manufacturing compatibility	Multitude of assessment techniques	Quality measures and controls, process capability, factory space conversion (HVAC, controls, ...)
Stability testing	Multitude of assessment techniques	Shipping, storage, in-use and end of life

Source: Consultation with one of the Participating Manufacturers, 2023

Of particular interest and consideration will be the safety profile of the coating material, the process materials used and/or process related waste streams. These include the volume or mass of byproducts, waste disposal methods, safety requirements for processing, storage, and shipping. It is important to note that extensive data is available in detail in these areas for the current coating material (PTFE) indicating a high confidence in usage of this material.

If the Development phase is successfully completed, the Implementation and Launch phases still remain to be completed in order to achieve industrial scale. Given the range of products and the scale of operations that would be affected across the Participating Manufacturers, these phases alone could take five or more years, significant capital investment and extensive process operator re-training.

Phase 3 - Implementation/Rollout Phase

The implementation phase typically overlaps with the development phase and lasts between 3 to 5 years. This phase involves the final specification, ordering, installing, and building of equipment required for large-scale production. Once the equipment has been ordered and built, it is installed and debugged to ensure that it operates efficiently and effectively. This involves a series of validation tests to ensure that the equipment meets the necessary performance standards. After the equipment has been installed, validated, and tested, the production startup phase begins. This involves confirming the product performance against the established targets from the production equipment, using methods such as the manufacturing system test.

Phase 4 - Launch Phase

The launch phase typically lasts between 6 to 12 months and consists of pre-building a volume of inventory based on expected market demand, followed by shipping the product to distribution centres or customers.

Whereas the above illustrates a typical innovation process for an innovation for the coating of a blade edge, it should be taken into account that, to date despite almost 30 years of research, no feasible alternative to the PTFE coating has been identified. Importantly, if a suitable alternative coating to PTFE is found, current manufacturing equipment would no longer be suitable and the existing equipment would need to be discarded and replaced with completely new equipment and staff would need to be newly trained to operate it. Therefore, it is estimated that the total development time and launch of PFAS-free product could reasonably take at least 15 years for a large and successful product or process.

3.4 Overall conclusion on suitability and availability of alternatives

The applications of PTFE discussed above have demonstrated its critical function and technical performance in coating of the blade. Due to potential restrictions on the use of PTFE as well as past supply risks for PTFE, as experienced by one of the Participating Manufacturers, finding a viable alternative has been and remains a top priority for the Participating Manufacturers. Extensive research has been conducted to find an alternative that offers superior or equal performance and comfort, while also being economically and technically feasible.

Technical assessments have shown that PTFE-coated blades offer superior performance, safety, and comfort compared to uncoated or poorly coated blades. PTFE-coated blades are also more durable and generate less plastic waste (see supra. at e.g., Section 3.1.1. and Section 4.1). An ideal alternative must be highly inert, durable, thin, and cost-effective in terms of material and processes. Furthermore, in terms of safety, it must be safe during use, but the unknown and inadequate alternative materials' hazard properties must also be taken into consideration.

While the discovery of cured silicone oil as a low-friction blade coating revolutionized the shaving market in the mid-1950s, it had the major shortcoming of poor adhesion to the blade, leading to rapid wear and return to high levels of "tug and pull". In contrast, PTFE coatings have proven to be much more durable, allowing for a consistently smooth, safe, and comfortable shaving experience for users, without the need for frequent blade replacements.

Despite ongoing research into improving adhesion for non-fluorinated, silicone-like materials, the improvements have not been fruitful yet, and these coatings are currently unsuitable for modern multi-blade wet shaving products due to their poor adhesion to the blade. Other alternatives like siloxanes, diamond-like carbon, amorphous diamond, ceramics, polyethylene, and metal oxides have been considered. However, these coatings often perform poorly under wet conditions during shaving, have poor adhesion quality to blade substrates, and tend to be too thick or brittle, or exhibit unacceptable chemical reactivity with hair.

In conclusion, the analysis of potential alternatives reveals that the existing alternative substances do not match the minimal required performance characteristics, lacks understanding of safety profile for new materials, and requires further generation of data, validation and qualification. **Therefore, the**

development and implementation of potential alternatives is not feasible without a derogation of at least 12 years.

4. Analysis of Impacts

The sections below provide a general overview of the environmental, social, and economic impacts of the proposed restriction of the PFAS used in razors and blades, considering the PFAS waste during the manufacturing process, business impacts (i.e., at different stages of the value chain), market impacts (i.e., on the product market), substitution costs, broader macroeconomic consequences as well as the cost-effectiveness ratio (the relationship between socio-economic cost and emissions).

4.1. Environmental impacts – avoided releases of PFAS

This section aims to present estimates for PFAS emissions generated at the Participating Manufacturers' razor blades manufacturing plants, as well as the steps taken to manage and mitigate PFAS emissions.

Collectively, the Participating Manufacturers report that they purchase a total of 1,287 kg PTFE annually for their manufacturing of razors and blades in the EEA, of which 944 kg are purchased from EEA suppliers.

Based on the received data and by making use of a weighted average, more than 50% of the purchased PTFE is used during the manufacturing of the blades. The remaining purchased quantity of PTFE remains on the final razor blades.

As the PTFE coating is sprayed on the blades, only a fraction of the quantity used is deposited on blades. The sprayed mist that does not reach the blades and contains PTFE is entrapped in the closed spraying booth and finally is collected either as a solid residual waste or as an aqueous dispersion in liquid form for expired materials. Throughout the manufacturing process, emissions are controlled through the implementation of air filtration systems during the spraying procedure. Additionally, residual materials and empty raw materials containers are managed through cleaning and disposal procedures. Due to the closed system and use of appropriate personal protective equipment (PPE), worker exposure is avoided. These materials are subjected to thermal recycling in a municipal waste combustor. **The Participating Manufacturers have ongoing research into more precision spraying, aimed at reducing the quantity of PTFE that does not reach the blade during spraying and thereby optimizing the transfer efficiency.**

There are no extensive studies available regarding the release, if any, of PFAS during product usage. The PTFE coating on the blades is designed to be well-adherend due to the strong chemical bonds with the surface of the blades. This ensures that the amount of PTFE that might potentially be released (if any) during the use-phase is limited.

At the end-of-life, the Participating Manufacturers have indicated that consumers dispose their used razor blades as part of their household waste. Razor blades can be therefore assimilated to the so called "Municipal solid waste (bin/trash) disposal" which was defined by the Risk Assessment Committee, in its opinion[42] on the Microplastics restriction proposal, as a pathway to the environment, with low risk of emissions.

[42] See https://echa.europa.eu/documents/10162/a513b793-dd84-d83a-9c06-e7a11580f366.

In the EU, household waste is either incinerated or landfilled. According to a 2019 study, municipal incineration of PTFE does not result in measurable PFAS emissions at temperatures between 860 and 1,020°C.[43] The study evaluated the thermal treatment of a mixture of the four highest volume fluoropolymers - PTFE, PVDF, PFA and FKM, under representative European municipal waste combustor conditions. They concluded that fluoropolymers are converted to inorganic fluorides and carbon dioxide The PTFE degraded mainly into hydrofluoric acid and carbon dioxide. A large majority of samples indicated that long-chain PFAS were below levels of 1 ng/m3 (> 99% of samples associated with 860°C condition and > 98% of samples associated with 1,100°C condition). There were no short chain PFAS detected post incineration. TFA was non-detectable in all samples with a reporting limit of 14 µg/m^3. According to the authors, the results confirm that **when incinerated under representative European municipal incinerator conditions, fluoropolymers do not generate any measurable levels of PFAS emissions at their end of life and therefore pose no risk to human health and the environment**.

Furthermore, no PFAS emissions from PTFE coated razor blades are expected when they are landfilled. **PTFE is chemically, thermally, and biologically stable and therefore PTFE coated razor blades are not expected to lead to dispersive non-polymeric PFAS when disposed of in a landfill**.[44] Other studies have presented results from OECD guideline biodegradation studies, demonstrating that PTFE is stable and does not degrade under environmentally relevant conditions.[45,46] Furthermore, fluoropolymers that meet the criteria to be considered PLC have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing and would therefore not be expected to significantly contribute to landfill leachate.[47,48]

Given the above, coated razor blades are not expected to lead to PFAS emissions at the end-of-life stage.

[43] Aleksandrov, K., Gehrmann, H. J., Hauser, M., Mätzing, H., Pigeon, D., Stapf, D., Wexler, M., 2019. Waste Incineration of Polytetrafluoroethylene (PTFE) to Evaluate Potential Formation of Per- and Poly-Fluorinated Alkyl Substances (PFAS) in Flue Gas. Chemosphere, 226, 898–906.

[44] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., Kassmi, A.E., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S., 2023. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management,* 19(2), 326-354.

[45] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, *14*(3), 316-334.

[46] Ruwona, T., 2021. The fluoropolymer PTFE is stable at environmentally relevant temperatures. In *2021 Emerging Contaminants in the Environment Conference (ECEC21)*.

[47] Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J., Hernandez, O., 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, *14*(3), 316-334.

[48] Ruwona, T., 2021. The fluoropolymer PTFE is stable at environmentally relevant temperatures. In *2021 Emerging Contaminants in the Environment Conference (ECEC21)*.

4.2. Economic impacts

4.2.1. Non-use scenario

The non-use scenario is built on the assumption that the manufacturing, marketing, and use of PFAS and the marketing of mixtures and articles containing PFAS in the EEA will be restricted - starting in 2027. As a result, the Participating Manufacturers alone would be forced to lay off 4,122 FTEs directly involved in the product supply chain within their EEA plants (the remaining business at those plants, to the extent the plants have any other remaining businesses, would continue).

Overall, the total monetised impact of the proposed restriction on PFAS is estimated to be more than 2.8 billion EUR for the razor blades manufacturers in the EEA market (conservative estimates in net losses). This figure, as shown later in this section, consists of social impacts from unemployment in the EEA, economic impact driven by substitution costs and economic impacts (EBIT loss). **The estimates reported in this socio-economic analysis should be considered as a minimum (lower boundary) of the expected impacts.**

4.2.2. Business impacts on razor blades manufacturers

A detailed questionnaire was used to gather SEA data and information from the Participating Manufacturers. If PFAS used in razors and blades is restricted,[49] it is estimated that **the Participating Manufacturers would face a net EBIT loss of approximately 634 million EUR/year. Over four years**, the total impact for the Participating Manufacturers is expected to be approximately **2.4 billion EUR** (NPV, 3% d.r.).[50]

The total market share of the Participating Manufacturers is **90% to 95%** of the whole EEA razor blades market. Therefore, the data on this majority share can be used to extrapolate reliable estimates for the entire market. On that basis, **the total impact for the EEA market is expected to be at least 2.5 billion EUR (2.4 billion EUR x 1/0.95).**

4.2.2.1. PFAS quantities used in production

The Participating Manufacturers purchase the PFAS-containing materials from both EEA and non-EEA, suppliers. The Participating Manufacturers purchase a combined total of **1,287 kg** of PTFE annually to produce razors and blades in the EEA.

4.2.2.2. Business impacts

The PFAS restriction would render obsolete the Participating Manufacturers' current blade making technology and manufacturing processes in the EEA. PTFE was first introduced in 1964; therefore, removing it would essentially regress the technology by more than 50 years. To meet the EEA shaving needs without PFAS, the Participating Manufacturers would need to shift to a single blade edge cartridge that uses a silicone coating, which is significantly inferior to their current multi-blade cartridges that use a PTFE blade coating.

[49] Companies were asked to consider how the revenues (and EBIT) for the year 2027 were impacted under the assumption that a REACH restriction on PFAS used in the production of razors and blades was to be fully adopted in the near future.
[50] Using the Excel function =PV(3%,4,-2538157359,0,0).

With a single blade, silicone-coated blade, customers would perceive a notable reduction in product quality and more discomfort during the shave, leading to increased skin damage and irritation and less safety in using the blades. Since there are currently no PFAS-free alternatives that can match the existing level of performance in razor blades, the restriction would likely cause a substantial drop in sales.[51] Ultimately, as a result of a PFAS restriction, downstream customers would likely phase out all modern multi-blade wet shaving products.

4.2.2.3. Market impacts

PTFE is the lowest coefficient of friction polymer blade coating available, with unique mechanical properties. By restricting use of this substance, the performance of the blade would be significantly degraded, and total removal of the PTFE would render the blades unusable. If the Participating Manufacturers are unable to continue using necessary fluoropolymers, such as PTFE, which is essential for their manufacturing technique, the manufacturing units would be unable to continue operations. The Participating Manufacturers have further indicated that it is not feasible to switch to a different technique within a short period of time, as the facilities are specifically designed for the current process and may not be compatible with other techniques.

4.2.3. Substitution costs for manufacturers of PFAS-containing razors and blades

Dossier Submitters (DSs) have identified the presence of PFAS substances in the components of powered, dry shaving products (such as membranes, batteries, and electronic circuit board). Therefore, it is unrealistic to anticipate the market to transition towards powered, dry shaving products as these technologies will also be facing the PFAS substitution challenges.

As described in Section 3.4., where the typical innovation process and timing has been illustrated, developing and testing alternative PFAS-free ingredients would require approximately 15 years from beginning of a successful discovery phase to production/product rollout. **The aggregate expected costs for the Participating Manufacturers can be conservatively estimated to be approximately 132 million EUR (rounded) in total for the 15-year period of transitioning.** The associated equipment costs would include discovery costs (lab equipment), development costs to identify suitable alternatives (pilot equipment), and rollout and implementation costs (production equipment). These costs would increase due to additional investments in regulatory processes if using existing PFAS ingredients, costs for reformulation and quality assurance, and costs for the transition to a full-scale production using the alternatives or altered formulations. These additional costs will be partly transferred to customers over the next few years after the potential restriction.

By applying the concept of present value, using a discount rate of 3%, we can estimate the economic impact driven by substitution costs over a 15-year period, beginning with 11 million EUR (rounded) for the first year.[52] **The economic impact driven by substitution costs (over 4 years) for manufacturers of razor blades are expected to be 43 million EUR** (rounded, NPV, 3% d.r.).[53]

[51] Even at a higher rate of replacement, blades for safety razors are substantially less expensive than cartridge systems.

[52] Using Excel function =PMT(3%,15,-132000000)

[53] Using the Excel function =PV(3%,4,-11057189,0,0).

The Participating Manufacturers of razor blades have indicated that the phasing out of chemicals as a result of regulatory bans can pose significant challenges for companies, especially when viable alternatives are not available. This difficulty was taken into account when discussing transition periods for the recent restriction on microplastics. The dossier submitter (ECHA) initially proposed a 6-year transition period for leave-on products. Additional data was brought by industry during ECHA's stakeholder consultation, confirming the lack of alternatives, the large number of products to reformulate, and the low release to the environment. Based on the opinions of RAC and SEAC, the European Commission decided to extend substantially the transition period: *"Taking also into account the comparatively lower contribution of make-up, lip and nail 'leave-on' cosmetic products to the overall emissions, the Commission considers that a transitional period of 12 years for the ban on placing on the market of such products is justified in order to ensure sufficient time to develop suitable alternatives and limit the costs for industry."*[54]

4.3. Wider economic impacts

It is also important to consider the wider macroeconomic impacts and consequences to the EEA society at large, by focusing on the expected consequences for the EEA market. In particular, there are concerns on the overall EEA trade balance and on the competitiveness of the EEA market.

4.3.1. Impacts on the market – quality and costs

If PFAS are no longer available for manufacturing, marketing, and use of PFAS and the marketing of mixtures and articles containing PFAS, sectors and consumers relying on these goods would be particularly affected. In the EEA, the Participating Manufacturers sell blades and razor products to more than 100 downstream customers. These retailers and wholesalers distribute to more than 50,000 local stores throughout the EEA. Those stores sell to the vast majority of the EEA consumers.

The development of new substances with the same technical function in the razor blades industry as PFAS is currently not technically possible. Indeed, a restriction of this crucial category of chemicals would **require a completely new redesign across the shaving industry and would lead to a loss of functionality and technical performance of razors and blades**. This would have a severe impact on the quality and costs of products in the EEA.

All investments made in manufacturing units today, and future units, will have no value on the market if the proposal of a PFAS ban without any derogations becomes reality. Relocating investments outside of the EEA would incur large costs and will be detrimental to the overall EEA shaving industry. As a result of a decreased availability within the EEA of the razor blades and increased investments outside the EEA as well as transportation costs that would be required by the shaving industry, **consumer prices would significantly increase**. In addition, the total carbon footprint of blades would increase. It is noteworthy that the razor blades market has, in recent years, made significant investments in the EEA with an objective to localize production. This way, carbon footprint is lowered, cost is minimized and supply chains are more resilient.

[54] Comitology Register (europa.eu).

In absence of low-friction coatings for blade edges, users of the razors and blades would experience a **significant discomfort level** after a few strokes compared to the status quo. Ultimately, consumers in the EEA would not have the opportunity to shave with the most comfortable and performing products that would be available outside the EEA. If existing brands and suppliers are not able to deliver the most comfortable and best performing products anymore, consumer choice would be significantly limited. Therefore, poorer performing razors and blades products, serving a lower price, will gain advantage. **This adverse impact on both the quality and costs of razors and blades in the EEA would therefore have widespread social impacts.**

4.3.2. Impacts on the market – competitiveness

The proposed broad restriction of PFAS would considerably disadvantage the EEA-based manufacturing versus non-EEA one. EEA manufacturing sites would be prohibited from using PFAS in the manufacturing process. Non-EEA manufacturing sites would not be subject to that restriction, and would therefore have a considerable advantage compared to EEA manufacturing in international markets. They would be able to supply and place on the global market a wider range of products, currently preferred and purchased by consumers without bearing any reformulation cost. **A broad restriction of PFAS used in the production of razors and blades in the EEA would disadvantage European markets in the competition with the rest of the world** that would have access to a wider range portfolio of products.

As a result, some producers of finished products could even decide to **move outside the EEA** and decide to service the EEA and regional markets with razor blades of different quality, safety, and performance due to lack of available alternatives. The risk is that market players would not be able to find an alternative to PTFE, and may only be able to provide competitive blades from outside the EEA. Market players would rather be uncompetitive in the EEA and produce PFAS-containing products that are marketable outside the EEA, than re-working their portfolios with uncertain outcomes and costly investments to manufacture EEA region-specific products in the EEA (viz., REACH compliant finished products that would serve the EEA market only). This is particularly likely for large companies who operate at a larger scale and who have more resources to be able to do so. Should the Participating Manufacturers of razor blades for shaving move out of Europe to service both the EEA and the rest of the world, it would result in a **significant downsizing in manufacturing, operational expenditures, and innovation in Europe**.

Manufacturers that have already installed blade and cartridge-making capacity in the EEA would have to move and start new capacity outside the EEA, which is both costly and time-intensive, while existing manufacturers that supply the EEA from manufacturing capacity outside the EEA would be less impacted. This would make countries like the USA, China, Korea, Israel and Brazil more competitive in manufacturing. These global competitors, unaffected by the PFAS restriction, would see a **major supply chain advantage** as their primary manufacturing operations would not be directly affected and they could even create large supply stocks ahead of the restriction going into effect.

Thus, compared to the non-EEA market, the EEA razor blades industry would be **subject to significant hurdles**. **The EEA would face a loss of competitiveness compared to the rest of the world, resulting in a significant shift from EEA manufacturing to non-EEA manufacturing**.

4.3.3. Impacts on the market – innovation and R&D

The Participating Manufacturers have invested in **extensive R&D to create safe and efficient shaving products** that meet consumer needs by removing, styling, or shaping facial and body hair. Product designers aim to balance key performance vectors including comfort (low tug and pull while cutting hair), safety (avoiding nicks, cuts, and irritations), and efficiency (fast and easy removal of unwanted hair). Product evolution has been driven by improving one or more of these vectors over time. As a result of this extensive product evolution and R&D, the Participating Manufacturers have continuously been adopting consumer's demands and have been successful in implementing the most safe and efficient hair removal technologies.

Assuming that a company invests in R&D in proportion to its revenue, the loss of sales to the EEA market will have an inevitable negative impact on R&D investments and spending. Moreover, the current R&D efforts and resources would inevitably be redirected towards re-formulating, re-qualifying, and re-certifying companies' existing portfolios. This will require R&D resources to support efforts to redevelop portfolios, stalling innovation and new product development.

More generally, **broad regulatory restrictions, such as the PFAS proposal, have a negative impact on the attractiveness of the EEA for investment**, including investments in innovation and R&D. Typically, innovation is made for global markets, including EEA, and not for specific regions. Given the development costs, and the length and complexity of the development process, the Return on Investment (ROI) for research and innovation around non-PFAS blades and razor products for the EEA only would be rather limited. Blade making operations and manufacturing would likely be relocated outside the EEA to avoid PFAS restrictions. Also, additional innovation and manufacturing of assembled cartridges using blades with PTFE coatings may require relocation. As the production and sales will be affected for the razor blades companies, the level of investment in R&D would also be lowered. **Therefore, R&D support activity related to product and process development in EEA manufacturing plants would be limited or banned due to the restriction on PFAS use and shifted to non-EEA countries.**

4.3.4. Impacts on the market – trade

A broad restriction of PFAS used in the production of razors and blades in the EEA would disadvantage European companies in their trade with the rest of the world. **Currently, the Participating Manufacturers export more than 50% of their EEA production**. The exports from the EEA would be particularly hard-hit by a potential restriction. Thus, the restriction of PFAS used in the production of razors and blades produced in the EEA would reduce the exports of these products to non-EEA markets. This would make countries like the USA, China, Korea, and Brazil more competitive in exporting razor blades. As a result of these factors, **the overall EU trade balance would be severely adversely impacted**.

4.3.5. Impacts on suppliers and sub-contractors

As described in Section 2.2.2, the supply chain for PFAS is extensive. A wide range of actors are involved in the supply chain linked to razor blades. This extensive supply chain is typically global and not limited to businesses located in the EEA.

Ultimately, suppliers of PFAS-containing materials would also be negatively impacted and would stop selling in the EEA. **If the PFAS restriction is implemented, there would be a decreased demand for the services of each actor.** These suppliers are at a risk of losing these sales in the EEA while bearing high reformulation costs to develop new technologies to replace their existing PFAS based products.

More broadly, the entire supply chains of the razor blades manufacturer would require a lengthy transition period in the case of the PFAS restriction. If there are no feasible alternatives found, the razor blades manufacturers would not be able to produce their components and consequently lose business. This would, in turn, impact all customers of razor blades in the EEA.

4.4. Social impacts: unemployment

In general, it is complex to estimate the potential unemployment consequences of the proposed restriction because this depends on whether the end-user market will accept completely different PFAS-free razors and blades. Moreover, the scale of impact on employment is expected to be lower than the impact on EBIT. However, it is estimated that, assuming a REACH restriction is implemented, 4,122 FTEs directly involved in the manufacturing and supply chain of razors and blades will face layoff in the EEA (Germany, Poland, Czech Republic, France, Greece). Table 2 shows an overview of the corresponding reduction in FTEs per country. Here, we monetize and estimate the likely social costs of unemployment for these workers.

Table 2: Overview of FTEs facing unemployment in the manufacturing of razor blades as a result of the PFAS restriction.

Country	FTEs
Germany	1,658
Poland	869
Czech Republic	850
France	95
Greece	650

The average annual salaries across these European workers (including the employer's social security contributions) are reported below.

A well-known guideline in monetizing the social impact of unemployment has been developed by the European Chemicals Agency (ECHA) for evaluating such impact in different regulatory processes. Estimates have been made in accordance with the ECHA document on the evaluation of unemployment (SEAC/32/2016/04)[55] and the paper of Dubourg (2016)[56] endorsed by ECHA. Therefore:

[55] ECHA (2016). The Social Cost of Unemployment. Available at: https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

[56] Richard Dubourg, 2016. Valuing the Social Costs of Job Losses in Applications for Authorization. The Economics Interface Limited.

- Using Table A7 (column G, considering the gross wages including the employer's social security contributions) in Dubourg's paper, the total social cost of unemployment in Germany is equal to 2.18 times the annual gross salary, 1.95 in Poland, 2.04 in Czech Republic, 2.10 in France, and 2.62 in Greece.[57]
- Tables 3, 4, 5, 6 and 7 represent the statistics from Eurostat (data for 2023-Q1) on the average duration of unemployment for both men and women in the age of 15-64 years in Germany, Poland, Czech Republic, France, and Greece, respectively.[58] The weighted average of the average duration of unemployment is consequently aggregated.
- Only 75% of the average duration of unemployment is considered, to reflect the fact that some affected workers are highly skilled and could find employment sooner.

Table 3: Duration of unemployment in Germany.

Duration Grouping	Duration of unemployment (in thousand units)	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	199.8	0.151317782	0.5	0.075658891
From 1 to 2 months	319.1	0.241669191	1.5	0.362503787
From 3 to 5 months	233.1	0.176537413	4.5	0.794418358
From 6 to 11 months	172.4	0.130566495	8.5	1.109815208
From 12 to 17 months	99.0	0.07497728	14.5	1.087170554
From 18 to 23 months	65.4	0.049530445	20.5	1.015374129
From 24 to 47 months	116.0	0.087852166	35.5	3.118751893
48 months or over	115.6	0.087549228	48	4.20236292
Total	1320.4	1		**11.76605574**

The social costs of unemployment for workers employed in Germany would therefore be equal to:

61,400 EUR x 1658 people x 2.18 x 11.76605574/12 x 75% = 163.2 million EUR (rounded).

[57] These values are greater than 1 because they take into account the following components: lost wage, costs of job searching, recruitment costs, the impact of unemployment status on future wages (scarring effect) and employment possibilities, and leisure time (which is a benefit and therefore subtracted from the previous components).

[58] Data extracted from: https://ec.europa.eu/eurostat/databrowser/view/LFSQ_UGAD__custom_5694655/default/table?lang=en

Table 4: Duration of unemployment in Poland.

Duration Grouping	Duration of unemployment (in thousand units)	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	19.5	0.0390625	0.5	0.01953125
From 1 to 2 months	133.3	0.267027244	1.5	0.400540865
From 3 to 5 months	85.8	0.171875	4.5	0.7734375
From 6 to 11 months	108.5	0.217347756	8.5	1.847455929
From 12 to 17 months	97.8	0.195913462	14.5	2.840745192
From 18 to 23 months	14.5	0.029046474	20.5	0.595452724
From 24 to 47 months	26.2	0.052483974	35.5	1.86318109
48 months or over	13.6	0.02724359	48	1.307692308
Total	499.2	1		**9.648036859**

The social costs of unemployment for workers employed in Poland would therefore be equal to:

59,600 EUR x 869 people x 1.95 x 9.648036859/12 x 75% = 60.9 million EUR (rounded).

Table 5: Duration of unemployment in Czech Republic.

Duration Grouping	Duration of unemployment (in thousand units)	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	18.8	0.135446686	0.5	0.067723343
From 1 to 2 months	30.9	0.222622478	1.5	0.333933718
From 3 to 5 months	24.5	0.176512968	4.5	0.794308357
From 6 to 11 months	26.2	0.188760807	8.5	1.604466859
From 12 to 17 months	12.8	0.09221902	14.5	1.337175793
From 18 to 23 months	5.4	0.038904899	20.5	0.797550432
From 24 to 47 months	11.0	0.07925072	35.5	2.813400576
48 months or over	9.2	0.066282421	48	3.181556196
Total	138.8	1		**10.93011527**

The social costs of unemployment for workers employed in Czech Republic would therefore be equal to:

16,600 EUR x 850 people x 2.04 x 10.93011527/12 x 75% = 19.7 million EUR (rounded).

Table 6: Duration of unemployment in France.

Duration Grouping	Duration of unemployment (in thousand units)	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	355.9	0.162719459	0.5	0.081359729
From 1 to 2 months	490.2	0.224122165	1.5	0.336183248
From 3 to 5 months	415.4	0.189923189	4.5	0.854654353
From 6 to 11 months	362.5	0.165737015	8.5	1.408764631
From 12 to 17 months	178.9	0.081794075	14.5	1.186014082
From 18 to 23 months	95.3	0.04357169	20.5	0.893219642
From 24 to 47 months	163.6	0.07479883	35.5	2.655358449
48 months or over	125.4	0.057333577	48	2.752011704
Total	2187.2	1		**10.16756584**

The social costs of unemployment for workers employed in France would therefore be equal to:

39,800 EUR x 95 people x 2.10 x 10.16756584/12 x 75% = 5.0 million EUR.

Table 7: Duration of unemployment in Greece.

Duration Grouping	Duration of unemployment (in thousand units)	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	20.0	0.038102496	0.5	0.019051248
From 1 to 2 months	49.0	0.093351114	1.5	0.140026672
From 3 to 5 months	101.3	0.192989141	4.5	0.868451134
From 6 to 11 months	71.9	0.136978472	8.5	1.164317013
From 12 to 17 months	54.7	0.104210326	14.5	1.511049724
From 18 to 23 months	41.9	0.079824729	20.5	1.636406935
From 24 to 47 months	67.9	0.129357973	35.5	4.59220804
48 months or over	118.2	0.22518575	48	10.80891598
Total	524.9	1		**20.74042675**

The social costs of unemployment for workers employed in Greece would therefore be equal to:

22,500 EUR x 650 people x 2.62 x 20.74042675/12 x 75% = 49.7 million EUR.

Across the different manufacturing site locations in Germany, Poland, Czech Republic, France, and Greece, the aggregate social costs of unemployment is equal to 298.5 million EUR.

Although companies along the supply chain would face a reduction in sales over the years, we assume for simplicity that the entire workforce will continue working for another three years after the proposed restrictions come into effect. Therefore, we discount the monetized impact derived above by three years due to the assumed delay in the layoff, using a discount rate of 4% per year, as follows: 298.5 million EUR x $(1 + 0.03)^{-3}$ = 273.2 million EUR.

One can use the market share of shaving products to extrapolate the total social impact of the unemployment in the EU across all razors and blades manufacturers to be: 273.2 million EUR x 1/0.95 = **288 million EUR (rounded).**

One can affirm with a high likelihood that the total social impact of a restriction of PFAS used in the production of razors and blades *along the whole supply chain* would be larger than 288 million EUR, once one considers all other economic operators having a business link to blade edge coatings and razors.

4.5. Cost-effectiveness ratio

A potential broad restriction would have disproportionate socio-economic implications on the EEA society. Overall, the total impact of a REACH restriction of PFAS is monetised at 2.7 billion EUR over a four-year horizon (conservative estimates in net losses), consisting of: social impacts from unemployment in the EEA, economic impacts (EBIT loss) and economic impact deriving from substitution costs for the Participating Manufacturers. **The estimates reported in this socio-economic analysis should be considered as a minimum (lower bound) of the expected impacts of a restriction upstream in the EEA supply chain**. This estimate does not cover the downstream users of PFAS-based articles and other companies in the supply chain working with the Participating Manufacturers.

As reported in Section 4.1., more than 50% of the purchased PTFE is used during the manufacturing of the blades. The remaining purchased quantity of PTFE remains on the final razor blades. As shown, there are strict waste management measures in place during the manufacturing cycle. Therefore, it is assumed that there are no major emissions taking place during the manufacturing of the razor blades. Even though there are also no expected emissions at the end-of-life, for the calculation of the cost-effectiveness ratio, this assessment conservatively makes use of the amount of PTFE that remains on the blades as a maximum value of the emissions, which equals 595 kg of PTFE. This is a conservative estimate and is not equal to the final emissions considering approximately 50% of the blades produced are exported outside EEA. In reality, the emissions will be substantially lower than 595 kg.

The cost-effectiveness ratios is:

- 2.7 billion EUR / (595 kg/year x 30 years[59]) = 149,541 EUR/kg.

[59] Based on Annex E of PFAS restriction proposal which projects the baseline tonnage and emission estimates for a time path of 30 years (2025-2055).

Taking into account these total conservatively estimated emissions of PFAS **a theoretical full ban, applying no concentration limit, would be disproportionate.** The total cost for the Participating Manufacturers of the proposed restriction is estimated to be at least 149,541 EUR per kg of PFAS emissions prevented, averaged over 30 years.

This cost-effectiveness ratio can be compared with the benchmark of 50,000 EUR/kg, which is the threshold beyond which a restriction is clearly disproportionate and should not occur (Oosterhuis et al., 2017).[60] This study is always referenced as a benchmark by SEAC in REACH restriction opinions for substances with environmental concerns (e.g., ED, PBT).

Therefore, in the case of a PFAS (PTFE) restriction used in the production of razor blades, the cost per kg of avoided PFAS (PTFE) emissions is estimated to be more than 149,541 EUR/kg for all releases. This cost-effectiveness ratio is considered high enough to justify a time-limited derogation of at least 12 years for the use of critical fluoropolymers, such as PTFE in the production of razor blades. Even under the worst-case scenario where all purchased PTFE (1,287 kg) is emitted on a yearly basis, the resulting cost-effectiveness ratio would still exceed the threshold.[61]

[60] OOSTERHUIS, F., BROUWER, R., JANSSEN, M., VERHOEVEN, J., LUTTIKHUIZEN, C., 2017. Towards a proportionality assessment of risk reduction measures aimed at restricting the use of persistent and bioaccumulative substances. Integrated Environmental Assessment and Management, 13, 1100-1112.

[61] 2,669 million EUR / (1,287 kg/year x 30 years) = 69,091 EUR/kg.

5. Conclusion

This SEA and AoA identifies the main potential negative consequences that European society at large faces from the potential REACH restriction of PFAS used in the production of razors and blades. This analysis has been performed in line with existing ECHA guidance under REACH. The results are based on a detailed questionnaire focused on the EEA industry, with market share coverage of 90% to 95% of the EEA razor blades market.

Based on the highly representative survey and the detailed SEA and AoA, the report concludes that a broad restriction without a long-term derogation for the use of PFAS in the manufacturing of razor blades for shaving will have disproportionate negative impacts on the European economy and society. This report reasonably justifies the following request:

- **a derogation for the placing on the market of razor blades containing PFAS until 13.5 years after the entry into force,**
- **a derogation for the manufacture, marketing, and use of PFAS and the placing on the market of substances, mixtures and articles containing PFAS to manufacture razor blades for shaving until 13.5 years after the entry into force.**

Therefore, we request the following text to be included in the restriction:

- By way of derogation, paragraphs 1 and 2 shall not apply to: Coatings in razor blades used for shaving until 13.5 years after the entry into force.
- By way of derogation, paragraphs 1 and 2 shall not apply to: The manufacture of razor blades used for shaving until 13.5 years after the entry into force.

That conclusion is founded on the following:

- **Razor blades manufacturers are heavily dependent on PTFE. The PFAS restriction would render obsolete current blade-making technology and manufacturing processes in the EEA**. The Participating Manufacturers studied in this analysis have an aggregate revenue related to the sales of razor blades of more than 1.3 billion EUR in the EEA market alone. The Participating Manufacturers have various manufacturing plants for razor blades in the EEA, namely in Germany, Poland, Czech Republic, France, and Greece. **These EEA sites produce more than 11 billion cartridges and disposable razors per year with approximately 50% being exported out of EEA.**
- In light of the high potential for, and consumer impact of, skin-related issues, **high-performance razors are essential to minimize the risk of skin damage, irritation, and discomfort – both during and after shaving**. Inferior razors may result in or worsen issues such as sensitive skin, inflammation, redness, ingrown hairs, and razor bumps. Modern razors are engineered with consumers' safety and comfort in mind, and significant advancements have been made to improve the shaving experience while minimizing skin-related concerns.
- Despite decades of extensive research, **there is no evidence of technically suitable, economically feasible and readily available alternatives** to PTFE in wet shaving products or the manufacturing process for those products, that provide comparable product and manufacturing performance benefits. In particular, there are no alternatives to PTFE for low-

friction blade coatings. Extensive research has demonstrated that, for various reasons, the technical performance of PTFE coating remains unmatched by alternative materials. For instance, cured silicone oil, despite reducing friction, lacks durability and can only last for one or two shaves. Likewise, ceramic, while also providing a low coefficient of friction, is too thick to be used on razor blades.

- In the case of a restriction on PFAS (PTFE) used in the production of razor blades, the cost per kg of avoided PFAS (PTFE) emissions is estimated to be at least 149,541 EUR/kg for all releases for over 30 years under a conservative estimation on the emissions. **This cost-effectiveness ratio is considered high enough to justify a time-limited derogation of at least 12 years (with an additional 18-month transition period, adding up to 13.5 after the entry into force) for the use of critical fluoropolymers, such as PTFE in razor blades production.**

- **The total monetised impact of a PFAS restriction is calculated as more than 2.8 billion EUR in a 4-year horizon for the manufacturers of razor blades.** This sum includes approximately 43 million EUR of economic impact driven by substitution costs for the manufacturers of razor blades; 2.5 billion EUR of economic impacts (EBIT losses) and 288 million EUR of social impact deriving from unemployment. **This is a conservative (lower boundary) estimate. The actual cost may be significantly higher as the PFAS restriction may lead to other costs for the manufacturers of razor blades in the EEA.**

- In terms of **business and market impacts**, a broad restriction would force all companies currently manufacturing razors and blades to cease production and business activities related to products that include PFAS. **It is estimated that the total development and launch to the EEA market of PFAS-free products, with an alternative to the PTFE coating, would potentially take at least 15 years for a large and successful product or process and would cost more than 132 million EUR.**

- **Non-EEA manufacturers that are not subject to the PFAS restriction would have a considerable competitive advantage compared to EEA manufacturers.** Hence, a PFAS restriction in the EEA will have impacts on the competitiveness of the EEA markets, on competition in the EEA, and on innovation. Downstream sectors in the EEA that rely on razors and blades would face large-scale negative consequences. An adverse impact on the EEA razor blades market will adversely affect the trade balance of the region.

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