SOCIO-ECONOMIC ANALYSIS OF THE CONTRIBUTION OF FLUOROPOLYMERS TO THE EUROPEAN SEALING INDUSTRY

Proposal

For: European Sealing Association

Ricardo ref. ED17523 Issue: 1 18 November 2022

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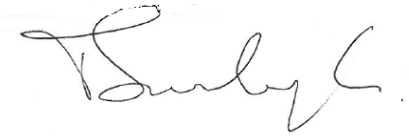

Ricardo ref:
ED17523

Date:
18 November 2022

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1. INTRODUCTION

Ricardo Energy & Environment ("Ricardo") is delighted to submit this proposal to support the European Sealing Association (ESA) for the study "*Socio-economic Analysis of the contribution of fluoropolymers to the European Sealing Industry*".

The Study comprises an independent socio-economic analysis (SEA) that would evidence the potential consequences of a universal restriction of per- and polyfluoroalkyl substances (PFAS) on the sealing industry in the EEA.

Ricardo is well placed to deliver this project for ESA, combining our chemical regulatory subject matter experts, who have over 40 years' experience in supporting the chemical industry on chemical safety and compliance, and our economics and policy team, who have decades of experience in conducting social, economic and environmental assessments in line with the European Commissions' Better Regulation Guidelines. This experience is key to a high level of credibility when engaging with the European Commission and its agencies.

Ricardo has recently deployed this experience in several projects, including:

- Leading an assessment of the economic impacts of the European Commission's Chemical Strategy for Sustainability (CSS) on the chemicals industry for the European Chemical Industry Council (Cefic) and other business associations (e.g. the International Fragrances Association (IFRA), the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E));
- Ongoing projects supporting the European Commission with the revision of EU chemicals legislation (e.g. Study to gather further information to be used in support of an Impact Assessment of potential options, for the update of REACH Annexes for inclusion of data requirements on endocrine disruption; Technical and Scientific Support to the Commission's Impact Assessment for the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP); Study to support the impact assessment on a possible revision of Regulation (EC) No 1223/2009 - Cosmetic Products Regulation);
- Ongoing assessments for other business associations to understand the impact on their members and the economy of emerging chemicals policies under consideration in the EU (including at least two other SEAs in the context of the universal PFAS restriction).

This means we have the technical knowledge, the deep understanding of the context and the practical experience of working with similar organisations to provide a robust, defendable and accurate SEA to support ESA in their engagement with the European Chemicals Agency (ECHA), the European Commission and Member States.

This document responds to a request for proposal during a call with ESA on 04/11/2022 and sets out how we propose to help ESA in achieving its objectives for this Study. The proposal is structured as follows:

- The remainder of this section 1 provides background and motivation, the assignment objectives and its scope and why Ricardo is best placed to support ESA in achieving their objectives.
- Section 2 provides the project structure, where we have proposed key tasks that would be required to deliver this Study.
- Section 3 details our proposed methodology for specific tasks where we felt a more detailed outline would be of value to ESA. This focuses on the stakeholder consultation and the economic and societal analysis.
- Section 4 lists the assumptions that we have made to scope and price this proposal.
- Section 5 outlines the proposed project team.
- Section 6 summarises our proposed project management and communication principles.
- Section 7 provides an indicative project timeline.
- Section 8 contains our commercial offer, split into a core offer that would meet the requirements specified by ESA, and additional optional packages for ESA's consideration.

1.1 BACKGROUND AND MOTIVATION

Fluoropolymers play a key role in the manufacture of sealing products. The market for fluoropolymers in the EEA is substantial, interlinked with the wider industry, and has a crucial role in the manufacture and performance of widely used consumer goods. The level of regulation that currently applies to fluoropolymers is limited, but an EU-wide restriction on the use of PFAS has been proposed that would be a significant change

to the regulatory framework and would disrupt the fluoropolymers' market in the EEA, its supply chain, including the sealing industry, and the consumer experience. The ESA would like to investigate the impact of such a change by performing an SEA for submission to ECHA.

1.1.1 Overview of the EEA's fluoropolymers' market

Based on a 2022 analysis of market data for the SEA of the European fluoropolymers industry[1], it is estimated that in 2020 40,000 tonnes of fluoropolymers were sold in the EEA. The EEA was a net exporter, with 15,000 tonnes of fluoropolymers being imported into the EEA and 24,000 tonnes being exported. A comparison between the 2020 and 2015 European fluoropolymer markets show a decrease in production (-4%), import (-30%) and sales (-23%) over this time period, while exports increased by 17%. This can be considered a result of the COVID-19 pandemic and fluoropolymer producers have anticipated strong market growth in the medium (to 2025) and longer term (to 2050). Growth opportunities are expected to expand the global fluoropolymers market with a compound annual growth rate (CAGR) of 6.5% from 2020-2027[2].

In 2020, the EEA's fluoropolymer market (in basic form) is estimated to generate an annual revenue of around €750 million, whilst the EU-28 market was estimated at €740 million. Approximately a billion euros of fluoropolymers are produced annually in the EEA, while the value of exports is twice as high as imports (€550 million and €270 million respectively).[3] Employment related to fluoropolymers has been estimated to be around 10% of total employment within the ESA member companies (approximately 4,500), with indirect and induced employment related to fluoropolymers estimated at 4,800.

Fluoropolymers have a number of highly desirable properties, such as chemical and flame resistance; thermal stability; cryogenic properties; low coefficient of friction, surface energy and dielectric constant; and high volume and surface resistivity, which has led them to be used in a broad range of industries.

This evidence will be further reviewed, tailored to the needs of this study, and complemented by the information gathered from the rapid evidence review and stakeholder engagement proposed for this project.

1.1.2 The role of fluoropolymers in sealing devices

Sealing devices are used to prevent media, such as powders, gas, and liquids from escaping from process and storage equipment. There are two types of seals: static seals for non-moving equipment, and dynamic seals for moving equipment, such as pistons, bearings, and gearboxes. The media being contained can often be hazardous, toxic, flammable, corrosive, and reactive chemicals, meaning high performance seals are required for them to be used safely and efficiently. The environment within which seals are used are often hostile, including exposure to wear, abrasion, radiation, strong acids, and temperature and pressure extremes[4].

Industrial sealing device are made from different materials depending on specific requirements of their application. The materials must be softer than the surrounding hardware to prevent physical damage, so graphite, plastics, and elastomers are preferred. The unique physical and mechanical properties of fluoropolymers, such as high chemical resistance and thermal stability, low permeability and surface energy, strength, and softness mean that they are a favoured material. For many sealing applications, fluoropolymers are the only material that can achieve the necessary performance and no alternative technology exists for their replacement[4].

ESA represent the majority of European sealing device manufacturers, who have a combined turnover of 2.6 billion and employ 12,500 people. ESA covered five main product types: packings, mechanical seals, flange gaskets, expansion joints, and elastomeric and polymeric seals. The fluorinated gasket market alone has been recently estimated to be in the region of €100 million - €1.1 billion globally per annum[4,5].

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[1] Wood (2022) Update of market data for the socio-economic analysis (SEA of the European fluoropolymer industry

[2] Allied Market Research "Fluoropolymers Market - Global Opportunity Analysis and Industry Forecast, 2020-2027", August 2020.

[3] Ibid footnote 1

[4] European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry

[5] Suko (n.d.) Teflon Gaskets See Significant Growth Potential Due To Growing Demand From Emerging Markets. Available at https://ptfe-machinery.com/teflon-gaskets-see-significant-growth-potential-due-to-growing-demand-from-emerging-markets/

1.1.3 The role of sealing devises in the EEA's industry

Fluoropolymer-based sealing devices have applications in a wide range of sectors. Case studies from the oil and gas, aerospace, chemical, and power generation sectors are provided below, which highlight the importance of fluoropolymer-based sealing devices to the EU economy and security, and valuable services upon which many EU citizens rely.

Chemical sector

Chemical processing uses a range of corrosive substances and require sealing devices that can withstand extremes of pH. Seals must also be chemically compatible with substances used in refining and production processes. Ensuring equipment is sealed prevents harmful leaks and emissions, which deliver a high level of protection for human health and the environment[6]. The properties of fluoropolymers, such as creep resistance, stress retention, low friction coefficient, and high permeability resistance, mean that they are the preferred material. Non-PFAS alternatives may not have the same performance and safety standards in chemical processing applications[7].

Aerospace sector

Aircraft are essential for national defence and provided a means of transport for nearly 4 billion people in 2020[8]. Passenger numbers have increased 400% in the last 30 years and are expected to grow annually by 3.6% over the next 20 years[9]. Gas turbine engines have helped increase engine efficiency and reduce emissions by operating at higher temperatures. This has been made possible by fluoropolymer-based sealings, which are the only material solution able to withstand exhaust temperatures of over 200°C and prevent fuel loss[10].

Oil & Gas sector

Natural gas is of key importance to Europe's energy security and transition towards a cleaner and more sustainable energy system. Its usage is predicted to increase between now and 2025, with an average annual growth in demand of 1.5%[11]. It has been estimated that between 20 – 43% of global gas reserves are sour gas[12][13], which is natural gas that contains measurable amounts of hydrogen sulphide (H_2S). Hydrogen sulphide is highly toxic and can be fatal if inhaled[14]. Sour gas is highly corrosive and high operating temperatures are required on gas fields. Extremely low temperatures are then required for the handing of sour gas and transport of natural gas once it has been cooled to reduce its volume for shipping and storage. Fluoropolymers are the only material that can withstand these harsh conditions and are therefore critical to Europe's energy industry and the safety of workers[15].

Power generation sector

Fluoropolymer-based sealings prevent leaks and emissions, which helps increase efficiency and levels of environmental protection[16]. No other material is able to offer the same level of safety and efficiency due to the high operating temperatures and weather extremes[17]. This includes green energy technologies, such as solar and wind power, which are crucial to meeting the EU's legally binding commitments under the Green Deal[18].

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[6] Ibid footnote 5

[7] Ibid footnote 5

[8] Statista (2022) Number of scheduled passengers boarded by the global airline industry from 2004 to 2022

[9] Airbus (2022) Global Market Forecast: 2022 – 2041. Available at: https://www.airbus.com/en/products-services/commercial-aircraft/market/global-market-forecast s

[10] Ibid footnote 5

[11] IEA (2020) Gas 2020. Available at: https://iea.blob.core.windows.net/assets/555b268e-5dff-4471-ac1d-9d6bfc71a9dd/Gas_2020.pdf

[12] Kearney Energy Transition Institute (2014) Introduction to Natural Gas. Available at: https://www.energy-transition-institute.com/documents/17779499/17781903/Introduction+to+Natural+Gas_FactBook.pdf/cb59da84-42b6-936b-83dc-7f04688654e4?t=1561052377799

[13] Bamforth (2019) Addressing the sour gas challenge. Available at: https://www.digitalrefining.com/article/1002383/addressing-the-sour-gas-challenge#.Y3YVsXbP2Uk

[14] https://echa.europa.eu/substance-information/-/substanceinfo/100.029.070

[15] Ibid footnote 5

[16] Plastics Europe (n.d.) Chemical and Power Sector: Driving the transition towards a more sustainable future for the chemical and power sectors. Available at: https://fluoropolymers.plasticseurope.org/index.php/Applications/chemical-and-power-sector s

[17] Adtech (n.d.) The use of fluoropolymers in green technology. Available at: https://adtech.co.uk/about/news/use-fluoropolymers-green-technology

[18] European Commission (2019). Delivering the European Green Deal. Available at: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal/delivering-european-green-deal_en s

Food and Beverage sector

The food and drink industry relies on a range of equipment, such as filling machines, heat exchangers, and valves, all of which require sealing devices that must meet various specifications, such as the ability to withstand high temperatures and pressure, aggressive cleaning agents, acids, and greases. They must also preserve flavour so must not transfer any taste or aroma[19]. Fluoropolymers can meet this requirements and hygiene standards, such as those under Regulation EC 1935/2004 on food contact materials[20].

1.1.4 Current regulatory framework and the restriction under consideration

Fluoropolymers are not directly regulated within the EU, although some PFAS[21] are regulated by the EU Regulation 2020/784 restricting the use of persistent organic pollutants (POPs). This Regulation specifically restricts the use perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds and came into force in July 2020. Some fluoropolymers (e.g., fine powder polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF)) have been manufactured, in the past, using PFOA as a processing aid during the emulsion polymerisation process. Since the restriction of PFOA, alternatives have been developed, many of which have a comparable fluorinated structure. Some of these fluorinated alternatives have been reported to be toxic, such as PFBS and HFPO-DA, which has led to their restriction under REACH.[22] Due to growing to regulatory pressures, there has been recent investment in the development of non-fluorinated processing aids.

A recent proposal has been made to ECHA for a universal restriction of PFAS due to concerns about their persistence in the environment. The first call for evidence by Germany, Denmark, the Netherlands, Sweden and Norway was launched in May 2020, with a second call for evidence launched in July 2021. This is part of a wider global effort to reduce the use of PFAS.

The definition of PFAS used within the restriction intention would include small molecules, as well as polymeric PFAS (i.e. fluoropolymers):

"*substances that contain at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I atom attached to it)."*[23]

This definition is similar to the OECD definition, derived in 2021, which reads as: *'PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS.'*"[24]. Substances meeting the chemical scope definition for this restriction proposal will also meet the OECD PFAS definition.

Fluoropolymers are typically defined as a polymer consisting of a carbon backbone and multiple carbon-fluorine bonds. They may sometimes be categorised as perfluoropolymers in order to distinguish them from partially fluorinated polymers (fluoroelastomers) or other polymers that contain fluorine.[25]

A formal definition of PFAS is expected with the publication of the Annex XV dossier under REACH in January 2023, which will be followed by a public consultation led by the Committees of ECHA. Stakeholders have been invited to provide any relevant information to the Dossier Submitter and to the Committee consultations.

In this context, ESA plans to submit a robust SEA with scientifically based arguments and facts following ECHA's official guidance, such as the preferred content and structure of SEAs[26]. This engagement will be supported by the tasks and outcomes of this proposed Study.

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[19] Freudenberg (n.d.) Hygiene and Process Reliability. Available at: https://www.fst.com/sealing/markets/process-industry/food-and-beverage/

[20] See: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:en:PDF

[21] For example, as noted in an evidence synthesis written by one of our experts Emma Pemberton in 2021: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012230/Poly-_and_perfluoroalkyl_substances_-sources_pathways_and_environmental_data_-_report.pdf

[22] ECHA (2019) Registry of SVHC intentions until outcome. Available at: Registry of SVHC intentions until outcome - ECHA (europa.eu)

[23] ECHA, n/a. Registry of restriction intentions until outcome. Available from: https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b

[24] Registry of restriction intentions until outcome - ECHA (europa.eu)

[25] Ebnesajjid. S. (2021) Introduction to Fluoropolymers: Materials, Technology and Applications. Second edition. Elsevier, UK

[26] ECHA, 2008, Guidance on Socio-Economic Analysis- Restrictions. Available from: https://echa.europa.eu/documents/10162/2324906/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

1.2 OBJECTIVES OF THE ASSIGNMENT

We understand that the main general objective of this assignment is to **deliver a Study that supports ESA** in providing evidence to ECHA as they consult on the proposed restriction, by considering the socio-economic impacts of a universal restriction of PFAS in the EEA on the sealings industry and the knock-on economic implications. More specifically, this assignment will seek to:

1. **Identify and assess the social and economic contribution** of fluoropolymer-based sealing products in the EEA and qualitatively assess any associated human health or environmental risks, including from their production and/or placing on the market, their supply chains, their use in downstream products by European citizens and in industrial processes and their disposal.
2. **Identify and assess the availability, suitability, technical and economic feasibility of alternatives to fluoropolymer-based sealing devices for the sealing sector as well as** current downstream users of these devices, and consider their costs and benefits when compared to the baseline.
3. **Evaluate (ex-ante) the potential impacts of a universal restriction of PFAS** on the sealings industry, their downstream users and the wider socio-economy. This includes all actors in the supply chain: manufacturers, importers, and downstream users (where possible).

A range of tasks (or activities) will be undertaken to deliver a study that achieves these general and specific objectives in around seven months (January 2022-July 2023). This is aligned with the discussion with ESA. These tasks, further specified in the rest of this document, include:

- A literature review and data-gathering exercise from publicly available sources and stakeholders consulted during this project on the sealing products market in the EEA and their supply chains; followed by a review and confirmation of the methodology and scope for this Study.
- Stakeholder consultation, including with ESA members and other stakeholders that may be relevant (with the approval of ESA). The latter might include, for example, members of the sealings value chain such as downstream users, and potentially alternatives manufacturers. Consultation with companies that are not members of ESA shall be discussed and agreed with ESA prior to the consultation.
- Socio-economic analysis of the contribution of the sealings industry to the EEA economy and a qualitative assessment of the human health and environmental risks in the baseline, including from their production and/or placing on the market, their supply chains, use and disposal. Of particular concern is emissions of fluoropolymers and their degradation and incineration products during the end-of-life stage.
- Analysis of the potential consequences of a universal restriction of PFAS on the sealings industry (in scope), the downstream users (or industries), and the wider socio-economy (taking into account whether or not there are alternatives to fluoropolymer in sealing products, and their costs and benefits). This would include assessing, for example, economic Gross Value Added, capital and operating costs (one-off and recurring), investment in R&D, competitiveness, etc.

1.3 SCOPE OF THE STUDY

This study shall include a quantitative analysis of the economic impacts of a universal restriction of PFAS on the fluoropolymer-based seal market, their supply chains, their use in downstream products by European citizens and industrial process, as well as their disposal, and a qualitative assessment of the human health and environmental impacts. Quantification of human health and environmental impacts shall depend on availability of data, including emissions during the lifecycle of fluoropolymers, and empirical evidence of links between these emissions and effects on human health and the environment.

Three Study scoping dimensions are considered below: geographical scope, stakeholders in scope and chemical scope.

1.3.1 Geographical scope

It is proposed to perform an analysis at the EEA level, given REACH is a legal text with EEA relevance and the restriction proposal is to be submitted by selected EU Member States + Norway. Should the scope of the restriction be limited to the EU-27 when the restriction proposal is published, the geographical scope of this study can be reviewed.

1.3.2 Stakeholders in scope

It is proposed that the analysis is focussed on the effects of the potential restriction on manufacturers and importers of fluoropolymer-based sealing products. Whilst all industrial downstream users will be considered, due to time and budget restrictions, the scope of quantitative assessment of the impacts on industrial downstream users of fluoropolymer seals would require refinement. Following discussion with ESA, it is suggested that downstream users of focus are selected based on:

1) Volume/value of sales of sealing devices to these downstream sectors, based on feedback from members (80:20 rule, i.e., 20% of sectors which purchase 80% of the volume/value)
2) Criticality of the sectors in our socio-economy (e.g., the power sector, etc.)
3) Level of buy-in from downstream businesses to engage with consultation and ultimate participation in the survey

This would require insight into the market of fluoropolymer-based sealing products at an early stage, and will be discussed with ESA and ESA's members in the inception phase. Quantitative analysis of all downstream user sectors is not possible in the time and budgetary constraints of this study, so a limited number of 5 or so sectors will be prioritised for any quantitative assessment and agreed with ESA during the project inception phase. It is advised that ESA engage members on scope refinement before the project starts so that the timeline for delivery is not affected.

The effects on consumers and public authorities will not be of focus. The Study will, however, consider how the health of EU residents may be affected qualitatively. The feedback loop with regard to the use of fluoropolymer-based sealing products would also be considered qualitatively e.g. the potential knock-on effect of wider manufacturing activities should sealing products no longer be available for industrial use.

1.3.3 Chemical scope

The documentation received from the ESA shows that eight fluoropolymers are used across different seal types, as shown in the table below.

Table 1-1: Fluoropolymer use in sealing types

Fluoropolymer	Packings	Mechanical Seals	Flange Gaskets	Expansion Joints	Elastomeric & Polymeric Seals
PTFE					
FKM					
FFKM					
FEP					
FEPM					
PCTFE					
PFA					
PVDF					

It is proposed that these fluoropolymers will form the list of substances in scope on this study, but this will be reviewed, discussed and agreed with ESA during the project inception phase.

The uses of fluoropolymer seals are also multiple and diverse, which means there is a wide range of downstream sectors that could be included in the scope of this Study. In order to deliver a cost-effective SEA, it is proposed that sectors for analysis refined as outlined above (Section 1.3.2). From the data received from ESA, there are six sectors that consume products made from the widest range of fluoropolymers, as presented in the table below.

Table 1-2: Fluoropolymer use by sector

Fluoropolymer	Chemical	Food & Beverages	Pharmaceutical	Aerospace & Defence	Power Generation	Oil & Gas
PTFE						
FKM						
FFKM						
FEP						
FEPM						
PCTFE						
PFA						
PVDF						

Some use sector-specific analysis will be important because we would expect that:

- data and/or evidence of potential alternatives to fluoropolymer seals may vary by sector (e.g., for some applications, the use of a fluoropolymer may be substitutable and for others not)
- the socio-economic implications (e.g., turnover losses, additional regulatory costs, or deterioration of performance in use) of the different fluoropolymer-based sealings at different life cycle stages will also vary.

Any grouping of fluoropolymer seals will be confirmed, reviewed and iterated with ESA during the inception phase and different stages throughout the project. Sectoral analysis would be based on the availability of data and consultation responses from the downstream users, noting that low response rates would affect our ability to carry out any sectoral analysis robustly.

1.4 WHY RICARDO

This project is perfectly suited to Ricardo as this work combines the principles that underpin all Ricardo work; policy, data (market) analysis, and implementation. We have very recently completed and are working on projects that put us at the forefront of the chemicals policy analysis that this Study would be seeking to influence, including for Cefic, other industry associations and for the European Commission.

We summarise our deep expertise, skills, and knowledge in three areas required for this Study: Chemicals policy and technical expertise; Consultation, data gathering and SEA experience; and policy implementation.

Chemicals policy and technical expertise: Ricardo's chemical regulatory consultancy team has significant experience in the REACH Regulation (EC) No 1907/2006. We have been involved in REACH legislation since initial conception and were completing pre-Registrations by 2008 and undertaking Registrations by 2010.

- Our REACH team includes dedicated Environmental Chemistry and Toxicology experts who have expertise in PFAS and combine scientific expertise with regulatory insights to provide service such as biodegradation and persistence testing; regulatory compliance and chemical safety assessments; and regulatory technical research, training and advocacy, giving us the technical 'substance' knowledge to understand PFAS substances, and their alternatives.
- Our experience also extends to REACH-related impact assessments for the EU Commission, including the DG Environment study concerning the introduction of standard information requirements under Annex VII-X for endocrine disruption, so we understand how to create and deliver robust analysis to the Commission's standards.
- Ricardo has extensive experience in undertaking studies of specific economic sectors and the potential socio-economic implications of environmental policies, including with regards to PFAS, their uses and substitutes. This includes decades of work with the UK government on HFC emissions as part of the National Atmospheric Emissions Inventory (NAEI), analysis of the market sizes of PFAS, such as F-

gases, and impact assessments of regulatory proposals for the European Commission. We are also working on a number of studies that explore the socio-economic implications of the proposed PFAS restriction, including with regards to the implications on the F-gases market for the European FluoroCarbons Technical Committee (EFCTC) and the fluoropolymer market for Home Appliances Europe (APPLiA).

Consultation, data gathering and SEA experience: Ricardo holds extensive experience in conducting consultations and data gathering exercises and delivering socio-economic impact assessments, based on robust and evidence-based methodologies aligned with international best practice. These experiences include:

- Our ongoing work to carry out an independent economic assessment for the European Chemical Industry Council (Cefic) on selected actions from the EU Chemicals Strategy for Sustainability (CSS) includes SEAs for upstream (Cefic) and downstream user associations (International Fragrance Association (IFRA), International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.), and others). Our approach focuses on the likely impact to businesses, including impact on revenues (as contribution to GDP), regulatory burden, exports, employment, innovation / Research and Development, capital and operating expenditures, and other structural impacts. This means that we already have credibility within the Cefic membership with regards to SEAs, which can help with engagement during the consultation phase.
- We have undertaken a large number of impact assessments, in particular for the European Commission, which have considered and analysed in detail the economic, social and economic impacts of policy options. Our experience covers conducting review studies for DG Environment and DG GROW alongside numerous other DGs (DG Energy, CLIMA, MOVE, FISMA). This means that not only are our impact assessments technically robust, but they are aligned with the Commission's expectations, ensuring that the SEA delivered for ESA will be seen to be robust and credible when used as supporting evidence for ECHA's upcoming consultation. As noted above, we are also well versed in performing SEAs following ECHA's Guidance on Socio-economic Analysis for restrictions[27].
- We have a vast experience in conducting stakeholder consultations to gather new evidence in support of impact assessments and SEA. This includes developing and delivering surveys to chemicals businesses including in our recent work for Cefic, IFRA and A.I.S.E.. We have also led and delivered numerous consultations in our work for the European Commission, seeking evidence and views from EU citizens, public authorities, non-governmental organisations, as well as businesses. We know the best way to ask questions to gather meaningful data from ESA's members, and the upstream manufacturers (plus the network to access these manufacturers) to ensure the SEA analysis is robust.
- We have also carried out detailed data analysis on specific elements of the fluorinated gas sector, which employed relevant methodologies for this project. For example, we conducted an SEA of the impact of a potential ban on the use of HCFC-22 as a precursor for certain processes in the upstream chemical industry, including elements such as the size of the impacted market, substitution costs, innovation requirements, energy savings/costs, and risks of structural economic effects (such as offshoring of production in response to substance or process bans).

Policy implementation: Ricardo works closely with industry to understand the implications that regulations have on individual organisations, and to manage their response. This ranges from regulatory strategy development and planning, through to detailed compliance activities such as substance- testing and assessment, regulatory submissions, and dedicated third party support. This includes:

- 48 years of experience working directly with the chemical industry on all matters of chemical safety and compliance, providing this to hundreds of companies throughout Europe, including downstream users under REACH (as well as CLP). We have also supported the industry to understand the importance of REACH dossier quality through a joint project with Cefic and their membership. This means that we have the experience of not just the downstream industry, but how they use chemicals, achieve their regulatory obligations, and maintain their supply chains.
- We are leaders in chemical safety within Europe, (through Ricardo's Chemical Risk business, which is also known as the National Chemical Emergency Centre (NCEC)) where we provide emergency

[27] ECHA (2008) Guidance on Socio-economic Analysis – Restrictions. Available at: https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

response support to over 650 chemical manufacturers and users across the world (including some of ESA's members).

- Carrying out detailed site-based case studies on the impact of EU legislation on the physical and financial operation of industrial installations.

For ESA, this would mean:

- ✓ You can be confident that the Study (data gathering exercise and SEA) will be aligned with ECHA's guidance to ensure the evidence collated will be effectively taken into account in the REACH policy process. We understand what an SEA needs to contain and are comfortable working within this expectation.
- ✓ A multidisciplinary team of consultants working for you –covering chemical risk, industry, policy and socio-economic analysis experts– with experience working together for a number of Industry Associations and the European Commission. This would lead to report of high quality on chemicals policy understanding, technical expertise and economic and social analysis and can stand up to the scrutiny of external stakeholders. Several examples of outputs from this and similar teams from Ricardo have already been mentioned. These include our work with the European Commission on impact assessments for the CLP Regulation, on endocrine disruption, Cosmetic Products Regulation, ODS and F-gas Regulations for the European Commission; services to Cefic, A.I.S.E., IFRA to assess the implications of the EU Chemicals Strategy for Sustainability; and SEAs in the context of the proposed PFAS restriction for EFCTC and APPLiA. These latter projects provide evidence-based and effective support the clients' engagement with the European Commission and ECHA.
- ✓ Our subject matter expertise is based on the most recent understanding of policy developments, both on PFAS and the wider context of the state and ambition of the REACH Regulation.
- ✓ Our connections and experience in the industry (both in research pieces with Cefic, Concawe and others, as well as our global chemical industry customers) bring us credibility in the market. This is reinforced by the support of our corporate entity, with ISO 9001 and ISO 27001 accreditation, which provides industry with the confidence their data will be secure with us. We are used to working to different organisational Statistical Rules, which ensure that the data cannot be 'reverse engineered' to a particular company, whilst maintaining statistical relevance. This means we can start gathering the data more quickly with the selected industry members.
- ✓ Our entire business is built upon the basis of scientific targets and implementation. As an organisation, all our work demonstrates a science and evidence-based approach, which will be extended to this project. This means that all assumptions (e.g., determining how substances may be categorised in the future) will be supported by as much evidence as possible, to ensure they are as accurate as they can be. This is critical to the robustness of this Study, as it will need to be accepted by third parties.

2. PROPOSED PROJECT STRUCTURE

This section outlines our proposed project structure and deliverables for a core offer; identifies some tasks that could be considered for an 'extended offer'; and, for the avoidance of any doubt, clarifies a range of tasks that would be out of scope from this proposal.

The proposed task structure and content can be adjusted based on feedback from ESA and its members, which we would welcome, and it would be further considered and agreed during the project's inception phase.

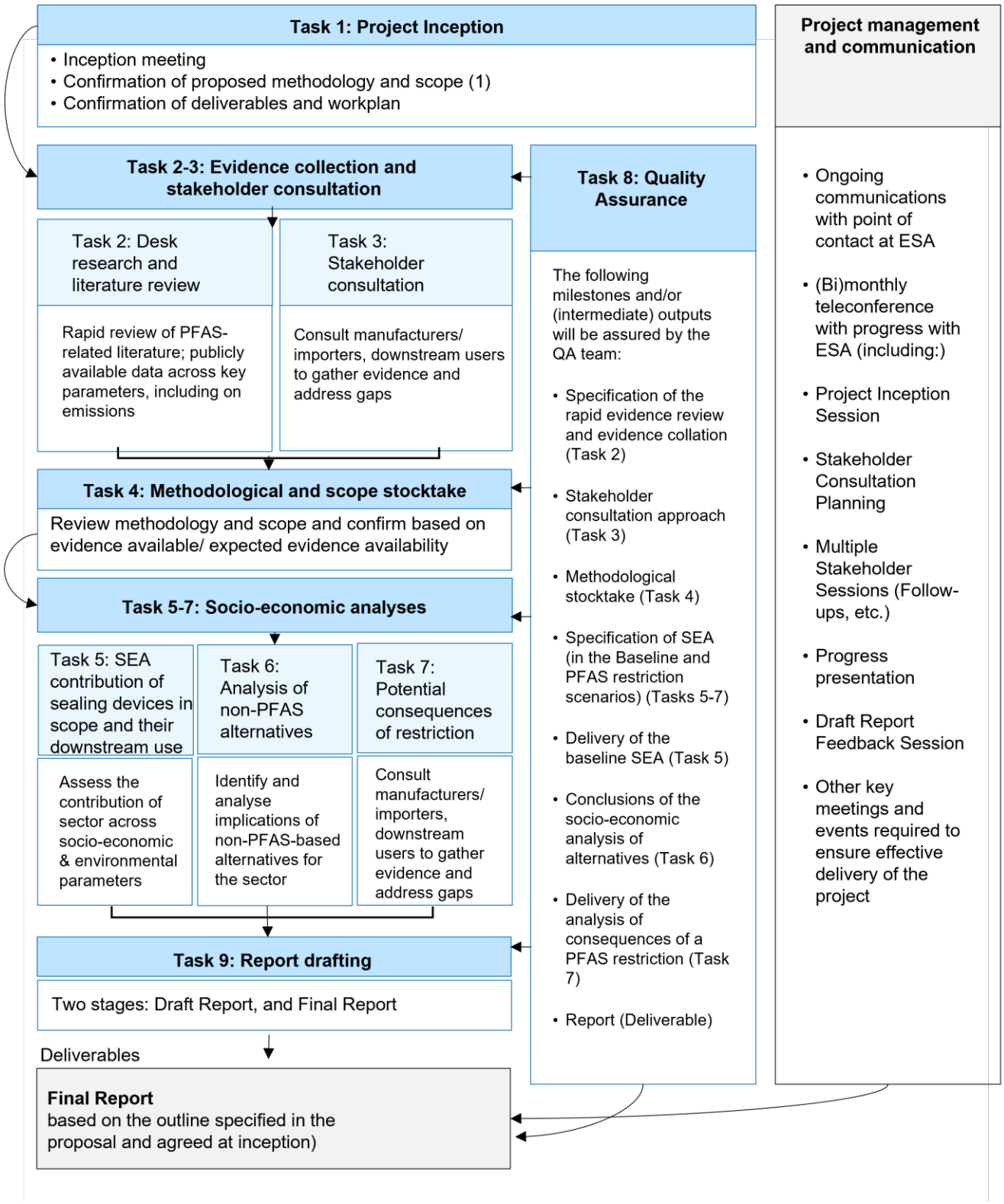
2.1 PROPOSED PROJECT STRUCTURE

To deliver the general and specific objectives of this proposed Study within the aforementioned scope, we propose to structure the work in nine tasks to be delivered in around 6 months until end of July 2023.

Table 2-1 summarises the core tasks (i.e. core offer) proposed for this Study, which are described further in this and the following sections.

An optional and extended offer is also described in this section. The extended offer sub-tasks could be delivered as additional to the core offer if agreed by ESA. These are not included in Table 2-1 but are described in this and the following sections in boxes.

Table 2-1 Proposed task structure for the project



The proposed project would primarily focus on assessing the socio-economic contribution of sealing products containing fluoropolymers in the EEA; and considering the economic, social and environmental consequences of a universal REACH restriction of PFAS, following ECHA's guidance for SEAs and according to ESA's needs (as discussed in the call on 04/11/2022). The assessment of economic impacts shall be quantitative, with a qualitative assessment of human health and environmental impacts (with quantification where possible). The nine tasks proposed to achieve this are outlined below and, when required, more detail is provided in Section 3.

Task 1: Project inception – The inception would include a review and confirmation of the proposed methodology and scope for the SEA; deliverables; and proposed workplan.

The fluoropolymers in scope as well as the structure (fluoropolymer and sectoral groupings) will be reviewed, discussed and agreed during the project inception and subsequently reviewed and confirmed as part of the methodological stocktake (Task 4). The geographical scope (EEA or EU-27) and prioritisation of downstream sectors shall be discussed with ESA at project inception.

For the SEA, we propose to follow ECHA's own guidance and templates (RESTRICTIONS SEA template), whilst adapting to the timescales and agreed budget with ESA. From our experience working with other industry associations and the European Commission, it is very important to follow the guidance and SEA structure to ensure the document is taken into consideration by ECHA. It has been our experience that documents deviating from this template may not have the desired impact.

Task 2: Desk research and rapid literature review – This offer will include desk research and a review of PFAS-related literature. This review will focus on the manufacture of sealing products containing fluoropolymers and their use in scope and identify and review the most recent and important scientific/agency papers on the matter. Thematically, the research and literature review will seek to collate the latest evidence on the social, economic and environmental implications of the manufacture and use of sealing products containing fluoropolymers in scope.

Ricardo has an extensive team of chemists and REACH experts who can help characterise current literature and understanding of PFAS; substance-specific uses; potential substitutes or alternatives for the fluoropolymers in scope (at the sector group or higher level); emissions to air, water and soil; and human health and environmental risks and/or implications.

In the core offer (sub-task 2.1), we will review and extract evidence and data from public data repositories, from sources known to Ricardo and ESA, assessing which information is available and which is still required from other sources, such as the stakeholder consultation activities, for the SEA. Primary data sources include, but are not limited to:

- The 2020 ECHA Analysis of the derogations included in the restrictions on the manufacture, placing on the market and use of perfluorocarboxylic acids (PFCAs), their salts and related substances and perfluorocarboxylic acid (PFOA), its salts and related substances
- The EEA's report on Fluorinated polymers in a low carbon, circular and toxic-free economy[28]
- ESA and ESA members' data and library of publications (for example, the evidence underpinning ESA's statistical reports[29] and relevant technical documents[30])
- Additional industry sources, especially for evidence on fluoropolymers (e.g., Plastics Europe, AGC Chemicals Europe[31], etc.)

[28] EEA (2021) Fluorinated polymers in a low carbon, circular and toxic-free economy: Technical Report. Available at: https://www.eionet.europa.eu/etcs/etc-wmge/products/etc-wmge-reports/fluorinated-polymers-in-a-low-carbon-circular-and-toxic-free-economy

[29] ESA (2020), ESA Statistical Report, ESA-statistical-report-2020.pdf (ESA-europe.eu)

[30] ESA (2022) Sealing devices and the need for PFAS. Available at: https://www.esaknowledgebase.com/wp-content/uploads/2022/06/PFAS-Article-Valve-World-May-2022.pdf

[31] AGC Chemicals Europe. Fluoroplastics: Dielectric Properties for Digitalization, Electro Mobility and Autonomous Driving. https://www.agcce.com/fluoroplastics/

- Academic publications (e.g., Lohman et al (2020)[32]; De Silva, et al. (2021)[33]; Ebnesajjad, S (2021)[34]; Henry et al. (2018)[35]; Meng et al. (2021)[36]; Tansel, B. (2022)[37] , Small, G. (2014)[38] etc.)

We consider it likely the stakeholder consultation will be a key (and potentially main) source of evidence used to gather economic data and information on alternatives to the fluoropolymers within scope, given the limited evidence that may be readily accessible.

In an extended offer, a sub-task 2.2 is proposed that would provide Ricardo with access to additional information sources that cost a significant fee, if upon discussing with ESA there is evidence that is additional to what they might hold inhouse. These are expected to hold evidence of the production, use and market value of the substances in scope.

As noted earlier, this and other tasks will follow a fluoropolymer-centric approach and will be complemented by sector -specific analysis.

Task 3: Stakeholder consultation – The study will develop a brief consultation strategy, covering a mapping and prioritisation of ESA members and other stakeholders within ESA and Ricardo's network (e.g., downstream users and alternatives manufacturers). This strategy will partly depend on the conclusions and findings (or gaps) from tasks 1-2.

We will engage with all ESA's 51 direct member companies. The targeted consultation activities will primarily take the form of a survey of all 51 ESA members and selected businesses in its network (50-100 businesses to the extent that it is possible and as agreed with ESA). The sample will cover manufacturers and importers of the sealing products containing fluoropolymers in scope, as well as members of the supply chain, especially across the industries selected of focus.

In order to ensure sufficient responses from downstream users of fluoropolymers, engagement activities with the supply chain of ESA members will be required. It is suggested that ESA members notify their supply chain of SEA activities and to encourage them to register their interest in participating in the consultation. Engagement documents such as presentation materials and a letter of cooperation can be provided to ESA members in order to facilitate them in actively recruiting members of their supply chain to participate in consultation activities. A webinar is also suggested to allow ESA and the study team to provide the supply chain with details on the consultation and the rationale behind the study.

The queries that will be explored in the survey will cover quantitative questions on sales revenues and volumes, and employment from manufacturing sealing products containing fluoropolymers; regulatory costs faced; the volume of sealing products containing fluoropolymers placed on the market and used; and qualitative questions on the life cycle of the product; emissions to air, water and soil in key life cycle stages; exposure to fluoropolymers; evidence of environmental and/or human health impacts from these emissions/exposure; etc.

Task 4: Methodological and scope review and confirmation – We will take stock based on the literature reviewed and evidence gathered, including through engaging stakeholders, and review the methodology and scope following the close of the consultation and data cleaning. This will include considering whether there are any specific uses or sectors that may be missing from the scope outlined in Section 1.3 and that should be incorporated into the analysis, as well as any approaches or methodological considerations that may need to be revisited. This will result in the final confirmation of the methodology and scope with ESA, taking into account the evidence gathered up and until this milestone. As the project will have potentially started prior to the

[32] Lohman et al., (2020), Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS? | Environmental Science & Technology (acs.org)

[33] De Silva, et al. (2021). PFAS exposure pathways for humans and wildlife: a synthesis of current knowledge and key gaps in understanding. Environmental toxicology and chemistry, 40(3), 631-657.

[34] Ebnesajjad, S (2021) Introduction to Fluoropolymers, 2nd ed.; Ebnesajjad, S., Ed.; William Andrew Publishing: Norwich, NY, USA. Available from: https://doi.org/10.1016/C2018-0-04702-7

[35] Henry et al. (2018) A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035

[36] Meng et al. (2021) The occurrence of per- and polyfluoroalkyl substances (PFASs) in fluoropolymer raw materials and products made in China, Journal of Environmental Sciences, Volume 107, https://doi.org/10.1016/j.jes.2021.01.027

[37] Tansel, B. (2022) PFAS use in electronic products and exposure risks during handling and processing of e-waste: A review. Journal of Environmental Management, 316, 115291.

[38] Small, G. (2014). Outstanding physical properties make PEEK ideal for sealing applications. Sealing Technology, 2014(4), 9-12.

publication of the restriction proposal, this methodological and scope review shall be used to ensure alignment with the restriction proposal.

Task 5: Socio-economic analysis of the contribution of sealing industry (products containing fluoropolymer) and their role in downstream industries to the EEA and qualitative consideration of human health and environmental risks – This task will focus on the analysis of the socio-economic contribution of the products in scope within the baseline and their role in downstream uses, and it will also include qualitative considerations of human health and environmental risks, given ECHA's guidance and ESA's requirements. That is, the work will estimate social and economic contributions of the industry if the universal REACH restriction of PFAS were not to be introduced and characterise the human health and environmental risks (where evidence is available) in the baseline.

This task will, therefore, include the quantitative and qualitative characterisation of the sealing industry in terms of:

- Volume of sealing devices containing fluoropolymers (in scope) manufactured and sold (manufactured + imported – exported) per year and sector in the EEA. This may include an exploration of any stock/ inventory of such products in the EEA at any given point in time.
- Estimation of the lifecycle emissions of fluoropolymers from sealing products to the environment in the EEA, in tonnes per year (where data is available).
- Annual turnover/ revenue from placing sealing products containing fluoropolymers on the EEA market (direct, manufactured in the EEA or otherwise)
- Annual turnover/ revenue 'facilitated by' sealing products placed in the EEA market (direct and indirect, manufactured in the EEA or otherwise, and including associated revenue streams in the supply chain through the life cycle of the products in scope). Different approaches will be explored during the design of the survey to collect data from downstream users of sealing devices, including their role and the extent to which their economic activity could happen without the sealing devices so to understand the scale of their economic contribution downstream. Data would be collected at a sector level and proportion of revenue from sales of fluoropolymer-containing sealing products will be estimated based on evidence from the stakeholder consultation.
- Employment (direct and indirect, associated with the supply chain through the life cycle of the products in scope)
- Operating, capital and Research and Development (R&D) expenditures in the EEA (primarily focussed on direct contributions), including devoted to developing new non-PFAS alternatives as a response to baseline legislative developments and associated business implications (costs of substitution, product and supply chain adjustments, etc.)
- Other user or social considerations will be explored, where evidence is available or collected through the stakeholder consultation, including the useability, accessibility and performance of the fluoropolymer-containing products in the baseline. This is likely to be primarily a qualitative consideration.
- Environmental and human health risks/ impacts associated with emissions of fluoropolymers throughout the product life cycle, considered primarily qualitatively and quantitatively where possible based on available evidence. Given the very limited evidence available, it is unlikely that a quantitative analysis of the human health and environmental risks would be feasible.

Task 6: Identification and analysis of non-PFAS alternatives to fluoropolymers (and their polymerisation aids) for use in the sectors in scope – This task will focus on the identification and analysis of potential non-PFAS alternatives that businesses may explore as a result of the potential introduction of universal and/or other restrictions of PFAS.

Alternatives would range from non-PFAS substitutes to fluoropolymers that are currently used in baseline sealing devices and/or new or existing products that do not contain PFAS and perform similar functions to those that do contain PFAS. Based on discussions during the inception phases, this analysis would be carried out at either a sectoral level, depending on data availability and number of products affected, or at product-cluster level for the selected sectors.

Once alternatives are identified, the analysis would consider their technical and economic feasibility, and explore the potential costs and benefits (social, economic and environmental) of their use at a high level – using the sectoral approach that is agreed as part of the scoping discussions during project inception – in comparison to the baseline.

This task would build on the evidence collected and developed under Task 5 to better understand the consequences of a universal PFAS restriction (see below). To note, it is unlikely to be possible to perform an analysis of alternatives for all sealing products containing fluoropolymers in use due to the sheer scale of products containing such substances and the variability in their sectoral usage. The scope of this task shall be discussed with ESA and refined in the inception and methodological review tasks.

Task 7: Analysis of the potential consequences of a universal restriction of PFAS on the sealing industry and the wider socio-economy – the direct consequences of a universal restriction of PFAS would be that sealing products containing fluoropolymers would require substitution of the fluoropolymer content (should an exemption not be granted), with implications in terms of costs, accessibility and useability of products containing fluoropolymers by industry and EU residents and, more broadly, potential social, economic and environmental implications.

This analysis will be carried out based on the work performed under tasks 5-6, and findings will be iterated with ESA. We will seek to develop insights into whether the socio-economic benefits from fluoropolymers in sealing products would outweigh the human health and environmental risks that may arise from the use and exposure to fluoropolymers, based on the available evidence. Although the quantitative impact on downstream users shall be limited to key sectors, qualitative consideration of all sectors will be included in the report to explain to the audience that the impact presented in the report would likely be greater in reality.

Please note that as quantitative analysis may not be always possible, a qualitative scoring framework will be specified and agreed with ESA during the first half of the project, which will serve to present the quantitative and qualitative evidence in a way that evidences the conclusions reached.

Task 8: Quality Assurance– The evidence collected, analysis carried out and outputs developed will be quality assured by experts in Ricardo from across a range of specialisms: chemicals and chemicals policy, PFAS, data gathering and socio-economic analysis. A proposed approach for Quality Assurance is in Section 3.5 or ESA's review and agreement during the inception phase, if possible.

Task 9: Report drafting and communication – It is suggested to have one reporting deliverable within this project as the study shall span 6 months.

The Final Report and its annexes will be the main deliverables of the project (please see Section 3.6 for more detail on this), which will be shared with ESA for feedback. This report shall be delivered in draft form for commenting by ESA and in final form.

The Final Report will bring together the findings from the assessment of the socio-economic contribution sealing products containing fluoropolymers, and insights into potential consequences of a universal REACH restriction of PFAS, following ECHA's guidance for SEAs and according to ESA's needs. The main report would also describe the methodology employed, and the report's annexes will at least capture a synopsis of the consultation activities and key technical assumptions or hypotheses. The report would also be reviewed by the Project Director and relevant sections will be Quality Assured by the group of experts proposed for the project team to ensure that it meets our high-quality standards and the specifications agreed with ESA.

Underpinning all of this work, our proposed Project Manager will be the point of contact for ESA and other key stakeholders to ensure that there is effective, ongoing communication; that the project runs smoothly; and that it meets ESA's needs.

Ricardo also acknowledges and understands ESA's desire to complete the project to enable their contribution to the SEAC consultation (expected summer 2023) so that the content can feed into discussions related to the proposed restriction. We also appreciate that it would be equally important for the final Study to be robust, stand up to scrutiny, be evidence-based and draw from the consultation of businesses and other stakeholders as relevant, and, ultimately, be useful to progress ESA's objectives in representing the fluoropolymer industry.

In an extended offer, a sub-task 9.2 is proposed in which Ricardo actively support ESA in their interactions with the Commission, ECHA and Member States by attending meetings with them to present the findings of this study and answer questions on methodology or results. Ricardo has extensive experience in presenting the outcomes of private sector assessments to the European Commission and ECHA.

2.2 CLARIFICATION ON TASKS OR ACTIVITIES THAT ARE OUT OF SCOPE

As noted in Section 1.3, it is proposed that our work is, where possible, substance-specific and that this is complemented by some sector-specific analysis. This means that all of the tasks undertaken in this project will be carried out or at least presented at this level of granularity.

This means that the following tasks would be out of the scope of our **core** offer:

- Three sub-tasks considered for the extended offer, including:
  - Sub-task 2.2: access and use of paid information services.
  - Sub-task 9.2: active support from Ricardo during ESA's interactions with the Commission, ECHA and Member States, including attending meetings, etc.
- In addition, other tasks will be out of scope of the core and extended offers:
  - A cost-benefit analysis (CBA) of individual non-PFAS alternatives for each of the individual fluoropolymer-containing products in EEA (instead, see Task 7 for what is included). Availability of alternatives will be covered by the ECHA Committees and will be considered in the REACH restriction. Due to the large number of sectors (with varying needs), and the time and data available for this study, it is not possible to perform a CBA for all alternatives that may be identified in Task 6.

Ricardo are, however, happy to explore adding elements of these (or other areas) into the scope (for an additional price) in discussion with ESA, as needed following the submission of this proposal.

3. METHODOLOGY

This section outlines our proposed methodology for the following tasks, where we believe further specification is required:

- Task 3: Stakeholder consultation
- Task 5: Socio-economic analysis of the contribution of the sealings industry to the EEA economy
- Task 6: Identification and analysis of non-PFAS alternatives to fluoropolymer-based sealings in scope
- Task 7: Analysis of the potential consequences of a universal restriction of PFAS on the sealings industry (in scope) and the wider socio-economy
- Task 8: Quality Assurance
- Task 9: Report Drafting

3.1 TASK 3: STAKEHOLDER CONSULTATION

We will develop a brief consultation strategy, including a mapping and prioritisation of ESA members and stakeholders within ESA's network, as well as other key stakeholders, especially downstream users of fluoropolymer-based seals and associated businesses. Task 2 is expected to be partially undertaken prior to finalising the preparation of the questionnaires/survey, so that the latter will address any data gaps identified in the early stages of the desk research and literature review. The consultation strategy will be divided in two parts.

3.1.1 Part One - Engagement with ESA's 51 direct member companies

Data, evidence and opinions gathered through engaging with ESA's members will be a priority in the consultation strategy. The consultation for ESA members will aim to gather valuable evidence associated with the socio-economic contribution of fluoropolymer-based seals. Member engagement will also be key to estimate the potential consequences of a PFAS restriction as well as to address the evidence gaps identified in Task 2. Table 3-1 includes a preliminary list of the data and evidence expected to be covered in the questionnaires/survey for ESA's members.

Table 3-1- Data and evidence of interest in the questionnaire/survey for ESA's members.

Economic data	Social and environmental evidence
• The number of different fluoropolymer-based seals that are manufactured or imported and placed on the EEA market by the stakeholder's organisation. • The percentage or mass of fluoropolymer content per product manufactured and sold in the EEA. • The volume (and market value or cost) of the fluoropolymer-based products sold in the EEA. • The associated operating, capital and R&D expenditures. • The total regulatory costs faced by the stakeholder due to their manufacture or import of fluoropolymer-based seals. • Key markets, supply chain actors and downstream users for fluoropolymer-based sealing products; as well as gathering evidence as to the economic role of the sealing devices in these sectors. • Any known alternatives to fluoropolymers across these key markets. • An estimation of how the fluoropolymer-based seal market in the EEA would evolve over time without any further regulatory action that has not already been adopted.	• The employment attributed to the manufacture or import of fluoropolymer-based seals in the EEA. • Evidence of the fluoropolymer-based seal manufacturing processes currently in place. • Evidence of developments regarding any expected changes in the manufacturing process. • Data on emissions (to air, water and soil) of fluoropolymers from the manufacture and use of fluoropolymer-based seals, quantitative data included where credible. • Evidence of relevant human contact and/or any other environmental exposure/impacts. • Evidence on the extent of fluoropolymer recycling or recovery during manufacture • Data on emissions (to air, water and soil) of fluoropolymers and degradation products from sealings EOL.

3.1.2 Part Two - Engagement with the associated supply chain, including selected downstream users.

Building from the stakeholders identified in in the inception phase and from feedback from ESA's members a number of downstream users will be invited to complete a complementary survey. ESA's members will also be invited to contribute to this survey if vertically integrated. Table 3-2 includes a preliminary list of the data and evidence expected to be covered in the survey for downstream users. As mentioned in Section 1.3.2, a limited number of DU sectors will be selected based on a prioritisation exercise agreed with the ESA.

Table 3-2- Data and evidence of interest in the survey for downstream users.

Economic data	Social and environmental evidence
• The volume (and market value or cost) of the fluoropolymer-based sealing products used within each sector. • The total regulatory costs faced by the stakeholder due to their use of fluoropolymer seals. • The proportion of equipment using fluoropolymer-based seals that could be adjusted or for which there is, or could be, an alternative that does not contain PFAS. • An estimation of the economic activity that could be disrupted in these sectors if all or a proportion of sealing devices were not accessible. • An estimation of costs of switching to non-PFAS alternatives.	• The employment attributed to the use of fluoropolymer-based seals in each sector in the EEA. • Evidence of relevant human contact and/or any other environmental exposure/impacts. • Evidence on the extent of recycling or recovery of fluoropolymers in seals at EOL. • Data on emissions (to air, water and soil) of fluoropolymers and degradation products from fluoropolymer-based seals EOL.

Both questionnaires seek to develop an economic, social and environmental baseline, with no PFAS restriction, against which a comparison can be made. The assessments of the socio-economic contribution and any potential consequences of a universal PFAS restriction are expected to include a degree of qualitative analysis, for which the views of relevant stakeholders will be highly beneficial.

In sum, it is proposed that the following activities are taken forward as part of the core offer:

- **An online survey** to be completed by the 51 full and associate member companies of ESA.
- **An online survey** for downstream users with respondents sourced by ESA, ESA's members and Ricardo.

Given the budget constraints on this study, an online survey is deemed to be the most effective way for the project team to collect as much evidence as possible whilst ensuring that ESA's members and downstream users can express their views through a structured dialogue. The survey questionnaire is expected to have between 30-50 questions, and 6 weeks will be given for participants to respond.

This approach will be discussed with ESA at the project inception and feedback will be sought to ensure that the consultation approach is aligned with ESA's vision for the consultation activities and that buy-in is secured from ESA's members for their engagement in the consultation exercises.

We will aim to cover the largest possible share of the market of fluoropolymer-based seals and thus will engage with all ESA's members. ESA members would be expected to identify relevant stakeholders within their supply chain who would be willing to participate in the downstream user consultation. To supplement this, Ricardo will undertake research of the relevant players in the supply chain to ensure the list is comprehensive and effective for this project. We will iterate this and other lists with ESA during the inception phase and ahead of the launch of the consultation activities. Collaboration between Ricardo and ESA to secure buy in from these additional companies will benefit the total engagement with the online survey.

Finally, as noted earlier, we have expertise and experience in engaging with industry stakeholders and gathering data and evidence in a way that remains private and anonymous (including but not only through developing and agreeing to Non-Disclosure Agreements) and is aligned with different organisational statistical rules. All data in the report is aggregated, and no one outside of Ricardo will have access to consultation and individual company data. The intention is to gather as much data as needed to inform the depth and breadth

of the analysis, whilst ensuring that none of this data can be used to reverse-engineer or identify any individual organisation. This is reinforced by the support of our corporate entity, with ISO 9001 and ISO 27001 accreditation, which provides industry with the confidence their data will be secure with us. This means we can start gathering the data more quickly with the selected industry members.

3.2 TASK 5: SOCIO-ECONOMIC ANALYSIS OF THE CONTRIBUTION OF FLUORPOLYMERS TO THE EEA ECONOMY

This task will focus on the analysis of the socio-economic contribution of the fluoropolymer-based seals market within the baseline; that is, the social and economic contributions of the industry if no additional REACH restriction were to be introduced. This will include the quantitative and qualitative characterisation of the fluoropolymer-based sealings industry and the relevant downstream sectors. The Table below presents an initial overview of the key parameters that will be considered.

Table 3-3 Illustration of parameters for the SEA of the direct contributions in the baseline

Type of parameter	Specific parameters
Volume of business activity	• **Number and volume (tonnes) of fluoropolymer-based sealing products** that are manufactured and sold (manufactured + imported – exported) per year in the EEA • **Volume (tonnes) of fluoropolymers used in fluoropolymer-based sealing products** that are manufactured and sold (manufactured + imported – exported) per year in the EEA
Economic footprint of this business activity	• Annual direct **turnover/ revenue** from manufacturing and placing fluoropolymer-based sealing products on the EEA market • Annual **turnover/ revenue** related to the downstream use of fluoropolymer-based sealing products in certain sectors in the EEA and the role of these sealing products • Overall **operating, capital and R&D expenditures** in the EEA (direct contributions), including devoted to developing new non-PFAS alternatives as a response to baseline legislative developments and associated business implications (costs of substitution, product and supply chain adjustments, etc.)
Social and environmental footprint of this activity	• **Employment** (direct and, to the extent that is possible, indirect and induced) • **Product useability, accessibility and performance**/ how users would/might feel about their products and the value they might extract from them • **Environmental emissions of fluoropolymers** during manufacture, use and EoL of fluoropolymer-based sealing products. Qualitatively and fluoropolymer specific where possible. • **Environmental and human health risks**/ impacts associated with fluoropolymer emissions during manufacture, use and EoL of fluoropolymer-based sealing products. Qualitatively and fluoropolymer specific where possible.

Volume of business activity

ESA's own data and publications and consultation with ESA's members will be key sources for this work, coupled with the second survey for downstream users to illustrate further sector breakdown.

If relevant data is collected for one Member State (or a collection of Member States), an extrapolation approach will be used to determine the EU-wide estimates. This approach will be based upon two criteria depending upon which is considered most appropriate. 1) Member State population sizes; 2) Proxies for the relevance of business activity within a given Member State (e.g. number of companies that may be of relevance, sectoral sales, or other metrics).

As a result of this work, the project will produce estimates, in the baseline policy landscape, of:

- **Number and volume (tonnes) of fluoropolymer-based sealing products** that are manufactured or imported in the EEA.
- **Volume (tonnes) of fluoropolymers used in fluoropolymer-based sealing products** that are manufactured and imported into the EEA
- **Volume (tonnes) of fluoropolymers emitted per year** during manufacture, use and EoL of fluoropolymer-based sealing products.

Economic footprint of this business activity

During the methodological and data stocktake (Task 4), the public data sources of economic data (from Task 2) will be reviewed and used to construct a final database for analysis, including information from Eurostat, ESA's own estimates and publications and other available and recent publications.

For additional granularity of evidence, engagement with ESA's members (Task 3) will be helpful to address any gaps in the evidence and estimate the potential evolution of the market size and economic footprint of the fluoropolymer-based sealings industry.

Based on this work, further insights will be drawn on other parameters such as employment and investment. The use of Input-Output multipliers will also be useful to identify the indirect and induced economic footprint that could be associated with the manufacturing or import of specific fluoropolymer-based sealing products in the EEA.

As a result of this work, the project will produce estimates, in the baseline policy landscape, of:

- Annual **turnover/ revenue** from the manufacture and import of fluoropolymer-based sealing products in the EEA market
- Annual direct **turnover/ revenue** related to the economic activity facilitated by the use of fluoropolymer-based sealing products in certain downstream user sectors
- **Employment** (direct and indirect)
- Overall **investment and Research and Development** (R&D) in the EEA, including devoted to developing new non-PFAS alternatives as a response to baseline legislative developments and associated business implications (costs of substitution, product and supply chain adjustments, etc.).

Social and environmental footprint of this activity

In line with ECHA's guidance, a balanced socio-economic assessment should consider the broader social and environmental implications of the manufacture, import, use and disposal of fluoropolymer-based sealing products in the EEA. From previous studies we have carried out, Ricardo is acutely aware of the volume of relevant data available on the human health and environmental impacts of fluoropolymer exposure, and is prepared to adapt the analysis approach as necessary. In our core offer, it is proposed that these implications in the baseline are considered qualitatively, unless accessible and credible literature is available that outlines the quantitative social and environmental footprint of the sector in scope.

Firstly, the project team will consider, especially through the literature review and stakeholder engagement, the social implications of the manufacture, import, use and disposal of fluoropolymer-based sealing products.

Secondly, a primary concern surrounding the use of PFAS, including fluoropolymers, is related to their properties. In particular, that they do not degrade but rather persist and accumulate in the environment. There is limited evidence as to the effects of long-term exposure from fluoropolymers to humans and the environment. For example, Lohman et al (2020)[39] noted that environmental emissions of the fluoropolymer itself is probably mostly dictated by EOL (e.g., if the product goes to landfill, etc.). Although emissions are not the same as risks, emissions could become a proxy indicator for non-threshold substances (e.g. PBT substance authorisation is assessed based on characterisation and minimisation of emissions, and we see the approach employed for PBT a sensible start for considering the implications and way of assessing fluoropolymers).

The studies that have quantified the monetised benefits of the PFAS restriction that may underpin this REACH restriction (pending release of the restriction dossier) focus on long-chain PFAS with established persistence, bioaccumulation and/or negative human and environmental health effects. The environmental and human health impacts associated with fluoropolymers have not been widely or clearly established. Data on emissions of the fluoropolymers in scope from fluoropolymer-based sealing products to air, water and soil will be gathered

[39] Lohman et al., (2020), Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS? | Environmental Science & Technology (acs.org)

and/or estimated, depending on evidence available, stakeholder input, and the broader health and environmental implications will be reviewed also as part of Tasks 2-3.

As a result of this work, the project will characterise in the baseline policy landscape, to the extent that evidence is available:

- **Product useability, accessibility and performance**/ any evidence or data as to how users might feel about their products (or product groups) in scope and the value they might extract from them.
- **Environmental and other (e.g., human health) risks**/ documentation of any or the absence of scientific evidence of impacts associated with emissions of specific fluoropolymers in scope from fluoropolymer-based sealing products. This will be considered primarily qualitatively.

3.3 TASK 6: IDENTIFICATION AND ANALYSIS OF NON-PFAS ALTERNATIVES

This task will focus on establishing which fluoropolymers in scope would be 'possible' to replace in fluoropolymer-based sealing products in the event of a universal PFAS restriction; that is, establishing whether the associated economic activity could remain with adjustments despite the restriction.

This task will include reviewing the evidence gathered in task 2 and engaging with experts and stakeholders (task 3) to identify **whether:**

- **There are reasonable product substitutes** that are not based on fluoropolymers across the use sectors.
- **There are non-PFAS alternatives** that could be used to manufacture reasonable materials, product component and/or altogether product substitutes. For example, a 2017 report for Plastics Europe established that there are some alternatives with similar performance to fluoropolymers "for a particular parameter or property, [although less so for the]…combinations or ranges of properties required for the applications".[40]
- **Economic activity would cease** for all fluoropolymer-based sealing products.

Where alternatives are identified, the project team, with input from experts and stakeholders, will

- carry out a high-level analysis of the costs and benefits (social, economic and environmental) of the alternative and compare the substances and their properties e.g., technical, economic and environmental and/health implications, and
- establish the extent to which the resulting products would be reasonable substitutes of those that would have been manufactured in the baseline (considering price, performance and availability).

The evidence collated throughout the project will be employed to develop scenarios in which fluoropolymer-based sealing products would no longer be used unless in cases where exemptions were secured. These scenarios will be characterised so that the business, economic and user implications are understood as quantitatively as possible, e.g., differences in their operational and capital costs attributed to these products (including but not only capturing substitution costs as pertinent), and other socio-economic dimensions such as product useability, product performance, etc.

As a result of this work, the project will conclude on the chance of there being non-PFAS alternatives for a sector and a high-level consideration of their technical and economic feasibility, costs and benefits (social, economic and environmental).

3.4 TASK 7: ANALYSIS OF THE POTENTIAL CONSEQUENCES OF A UNIVERSAL RESTRICTION OF PFAS ON THE FLUOROPOLYMER-BASED SEALINGS INDUSTRY AND THE WIDER SOCIO-ECONOMY

The evidence and analysis carried out under tasks 5-6 will be brought together to characterise the potential consequences of a universal PFAS restriction on the sealings market in scope, and its supply chain in the EEA.

These consequences will be **measured against each of the key socio-economic and environmental parameters** that were used to describe the baseline in Task 5 (See Table 3-3), especially to quantify and/or

[40] Final_SEA_Fluoropolymers_summary2017_3.pdf (plasticseurope.org)

characterise qualitatively how a universal PFAS restriction **may lead to changes in the volume of business activity in the EEA, which would have economic, social and environmental implications.**

As an illustration, a fluoropolymer-based sealing product which has no substitute or alternative without PFAS would no longer be marketed as a result of the universal PFAS restriction. This would affect:

- Sealing product manufacturing/ importing businesses by reducing their activity, source of revenue and employment attributed to said product, having knock-on economic and social implications;
- Industries that require these sealing devices to operate their machinery and/or perform their economic activity, having further knock-on economic and social implications;
- EU citizens/ residents as they may not be able to access and use products that contain fluoropolymer-based sealing products, or services that rely on such products. In cases where such products are valued and/or needed, this could also have an impact in the day-to-day life of EU citizens;
- Emissions of fluoropolymers into the environment might be reduced, which could have some implications on public health and the environment.

The economic impacts on the fluoropolymer-based sealings industry and downstream users will also have knock-on implications on the EEA economy. These will also be assessed, where appropriate, using an Input-Output (or Leontief) model that depicts the interconnectedness of different economic sectors and, thus, offers a solid approach to estimate the scale of the potential ripple effects throughout the whole economy.

This work will produce an evidence-based picture of how the fluoropolymer-based sealings market in the EEA may be affected -especially as a result of whether fluoropolymers may need to be substituted, or where downstream applications may need to be adjusted and/or discontinued without a substitute-, and the key social and economic implications that may result from this, including but not only in terms of the costs of doing business and the effects on product accessibility, useability and performance for EU citizens.

This task will also bring together the evidence that is available on the potential environmental and human health risks that may arise from exposure to fluoropolymers during the manufacture and the life cycle of fluoropolymer-based sealing products, and products containing them, and consider the extent to which this may affect EU citizens. The available evidence of these risks and implications, if any, will be weighed against the evidence of the socio-economic impact that may arise from the universal PFAS restriction. For example, a restriction may lead to the reduction of economic activity where products cannot identify reasonable substitutes and this could affect the lives of the EU citizens who are interested, value and/or need to use products containing fluoropolymer-based seals in their day-to-day.

As noted, as quantitative analysis will not always be possible, a qualitative scoring framework will be specified (e.g., framework that classifies impacts as strongly positive, positive, weakly positive, limited/none, weakly negative, negative or strongly negative impacts) and agreed with ESA during the first half of the project, which will serve to present the quantitative and qualitative evidence in a way that evidences the conclusions reached.

The findings will be iterated with ESA, experts and stakeholders where possible and agreed, before finalising and publishing the Final Report.

The result of this task will be:

- First, the production of evidence around the socio-economic implications of a potential PFAS restriction on the EEA fluoropolymer-based sealings market and any considerations of their environmental and human health risks
- Second, insights into whether the socio-economic benefits from the use of fluoropolymer-based sealing products (in the baseline) might outweigh the potential environmental and human health risks that may arise from exposure to fluoropolymers during the lifecycle of fluoropolymer-based sealing products, based on the available evidence.

3.5 TASK 8: QUALITY ASSURANCE

The evidence collected and analysis carried out will be Quality Assured by experts in Ricardo across chemicals and chemicals policy, PFAS, data gathering and socio-economic analysis.

Our proposed project team is multidisciplinary and includes a range of experts who will also be providing Quality Assurance (QA) throughout the project, including Brais Louro (Project Director), Inge Kukla (Project Manager/ Senior Economist/ SEA expert), Becca Johansen (Chemicals Policy and REACH expert), Sabino

Del Vento (PFAS expert), and Emma Pemberton (PFAS expert).There are other experts within Ricardo that will be brought in as and when needed throughout the project to ensure the most effective QA.

The following eight (intermediate) outputs and/or milestones were identified (alongside the project timeline - see Section 7) to ensure there is ongoing and effective QA throughout the project:

1. Specification of the evidence review and evidence collation (Task 2)
2. Stakeholder consultation strategy (Task 3)
3. Methodological stocktake (Task 4)
4. Specification of SEA (in the Baseline and restriction scenarios) (Tasks 5-7)
5. Delivery of the baseline SEA (Task 5)
6. Conclusions of the analysis of alternatives (Task 6)
7. Delivery of the analysis of consequences of a universal PFAS restriction (Task 7)
8. Progress and Final Reports (Deliverable)

The QA team has different types and depths of expertise and thus will be brought in to help at different stages for their feedback. The QA team will test the proposed approaches and the project team shall seek their steer to ensure the project progress in line with needs and remains on a path to delivering the highest possible quality outputs. In more detail:

Table 3-4 Quality Assurance Plan

QA milestones/ (intermediate) outputs	The QA team will:
Specification of the rapid evidence review and evidence collation (Task 2)	• Check that the specification will meet the needs of the project • Identify any gaps • Provide suggestions • Approve final specification
Stakeholder consultation strategy (Task 3)	• Review the approach proposed, including key questionnaires, identified stakeholders, sample size • Provide feedback
Methodological stocktake (Task 4)	• Review the reflections and conclusions outlined by the project team • Provide feedback
Specification of SEA (in the Baseline and restriction scenarios) (Tasks 5-7)	• Test the specification against their expert knowledge • Identify any gaps and/or provide suggestions • Approve final approach
Delivery of the baseline SEA (Task 5)	• Check and verify any of the analyses/ models developed (to ensure they are working correctly) • Review outputs • Contrast with publicly available sources • Sense-check their validity against their expertise and knowledge
Conclusions of the analysis of alternatives (Task 6)	
Delivery of the analysis of consequences of a universal PFAS restriction (Task 7)	
Progress and Final Reports (Deliverable)	• Review reports, especially to ensure that the evidence collated is employed and supports the conclusions drawn effectively • Challenge those conclusions against their expertise and knowledge and test their validity • Provide feedback

These reviews will be complemented by an iterative internal process, within Ricardo, as well as with ESA and its members.

The project manager will maintain an effective engagement throughout the project with their counterparts at ESA and seek their feedback alongside these milestones as agreed. This approach will maximise our collective success in delivering an output that meets ESA's needs at the highest possible quality.

3.6 TASK 9: REPORT DRAFTING

The Final Report will be drafted following ECHA's SEA guidance to the extent that is pertinent and supporting the needs of ESA.

It is proposed that a first full Draft Final Report at the end of June 2023; and a Final Report in July 2023. ESA will be given time to review and provide comments on the Draft Final Report.

There are risks that this timetable is not deliverable especially as much of the work will rely on the evidence collected through consultation activities from ESA members and other pertinent stakeholders. This type of evidence-gathering exercises are complex, even when there are resources and commitment from businesses.

A proposed (Final and Draft) Report structure will be reviewed at the project inception and will be expected to include (with approximate numbers of pages):

- Section 1: Summary of SEA
- Section 2: Introduction, aim and purpose of the SEA, structure outline (<5 pages)
- Section 3: Definition of the baseline scenario (fluoropolymer-based sealings industry and the policy landscape) and proposed restriction scenario; time and geographical boundaries of SEA (20 pages)
- Section 4: Study methodology and limitations (5 pages)
- Section 5: Analysis of impacts (20-40 pages)
    - 5.1 – economic impacts, including availability of alternatives
    - 5.2 – environmental risks
    - 5.3 – human health risks
    - 5.4 – social impacts
    - 5.5 – wider economic impacts
- Section 6: Comparison of scenarios (5-10 pages)
    - 6.1 – key assumptions
    - 6.2 – results of uncertainty analysis
    - 6.3 – results of SEA
- Section 7: Conclusions (5 pages)
- Section 8: References
- Annexes: data collection approach and data sources, consultation synopsis, further detail on methodology and assumptions

4. ASSUMPTIONS AND LIMITATIONS

Assumptions

To deliver this project for the proposed fee, Ricardo has made the following assumptions:

- The work is focused on gathering economic, social and environmental data and producing an SEA in line with ESA's needs and the ECHA guidelines and does not consist of other campaign-related activities for ESA that are not related to the SEA.
- The SEA will be based on publicly available data, a review of the available literature, and data gathered through the consultation activities for this project on the manufacture and sales of sealing products containing fluoropolymers (production + imports - exports) in Europe or as available in specific countries; ESA to provide more detailed data if available to them.
- ESA will provide contacts for consultation of members. Ricardo will suggest and work with ESA on who to contact across the supply chain of the sealing industry.
- ESA will provide support and coordinate efforts in the stakeholder consultation to ensure there is sufficient engagement with and from members and stakeholders in their network to contribute to all information gathering exercises, as well as any activities needed to ensure independent consultation responses to ECHA do not contradict the outcome of the SEA and/or other evidence gathered.
- The Final Report will be issued in draft form with provision made for one revision following ESA's comments prior to the final report being delivered.
- ESA will provide feedback with a turnaround that is aligned with the timetable that is agreed at the start of the project. Feedback will be provided as one consolidated set of comments in track changes within the report itself. Meetings can be held to discuss feedback.
- The project meetings and sessions will be held by videoconference.
- Additional meetings to support ESA in their interactions with the Commission, ECHA or Member States would be on a time and materials basis and not included in the fixed price as these are an additional option.

Limitations

This project may be primarily limited by a lack of evidence and data at the granularity that is required across the breadth of dimensions of interest: social, economic and environmental. This will be mitigated to the extent that is possible through the use of our expertise and stakeholder engagement. In more detail:

- The availability of data will be critical to any quantitative assessment, specifically its robustness, which will vary especially at the level of granularity required for this study (substance and sector specific). We will prioritise the sectors that are most relevant in terms of their application and sales across the EU. A simple first criteria is to look at the sales value/ volume of fluoropolymer-based products. It is noted that fluoropolymers-based seals may be used for critical applications in low volumes and these would be considered. We will also collect and collate information in a substance-centric format as required and possible.
- The literature review will also aim to collect data as far as is available regarding socio-economic parameters outlined in earlier sections. Where gaps exist, we will seek to fill these through the stakeholder engagement. Where this is not possible, we will look to use techniques to derive estimates or insights based on the data collected (e.g., combining price and volume data to estimate revenues). As such, we will focus our resources on addressing gaps in the existing evidence based on the relevance of the fluoropolymers in scope.

5. PROPOSED PROJECT TEAM

For this proposal, we have brought together a bespoke team who can deliver strongly against the core themes of this work: REACH restrictions, Socio-economic impact analysis and PFAS (fluoropolymers), their uses and substitutes.

In particular, given some similarities between this proposed Study and our ongoing work undertaking impact assessments for Cefic, downstream user associations such as IFRA, A.I.S.E., EFCTC, APPLiA and others, we propose a team that is made up of professionals also engaged in these recent and relevant chemicals projects.

Our proposed project team comprises the following structure:

- A **project leadership team**, comprising:
  - **Project manager** (and senior economist/ SEA Technical lead) – **Inge Kukla**
  - **Project director** – **Brais Louro**, who will also have a leading Quality Assurance role
- **Subject Matter Experts and/or Quality Assurers:**
  - Becca Johansen (Chemicals policy and REACH expert/ Technical lead)
  - Sabino Del Vento (PFAS expert)
  - Emma Pemberton (PFAS & chemicals/ Environmental risk expert)
- **Support team of chemicals policy researchers and economists** (Ricardo), including Jack Dubey (Economics/SEA Technical Support), Jacob Sendall (Economics/SEA Technical Support), Chris Stone (REACH and chemicals Technical Support), and Graham Pattle (REACH and chemicals Technical Support).

The project leadership team, Subject Matter Experts/Quality Assurers and support team are all very experienced in leading and conducting stakeholder engagement with businesses, EU citizens and other agents, of different types, including online surveys, workshops, focus groups, meetings, and others.

We provide a short overview of the experience of the proposed team members.

INGE KUKLA: PROJECT MANAGER AND SEA TECHICAL LEAD

Inge is a Senior Economist at Ricardo Energy & Environment working on environmental policy and climate change economics. She has over 7 years of experience in policy analysis and research. Prior to joining Ricardo in 2021, Inge worked as an energy and environment consultant at KPMG Spain, providing policy-oriented economic analysis to international utilities, investors, sector associations, professional service providers and public agencies, among others.

Inge has taken part and led a wide range of environmental policy related projects for various areas including chemicals, energy, decarbonisation and environmental policies across sectors such as the chemical industry and various subsectors within, and the road and maritime transport sectors. Inge is also the project manager for two ongoing assessments related to the potential universal PFAS restriction.

Inge's technical skills include market analysis, cost-benefit analysis, impact assessment, data analytics and quantitative analysis techniques, economic modelling, econometrics and forecasting, as well as deep understanding of causal inference and its applications for policy/ regulatory design and evaluation.

BRAIS LOURO: PROJECT DIRECTOR

Brais is a Principal Economist and Project Manager and Director with over 12 years of international experience in delivering projects on public policy, strategy and socio-economic and environmental analysis for public and private sector clients, including the European Commission (DG ENV, DG GROW), national public authorities (the UK government, UK regulators and Agencies, Spanish Agencies, Belgian Regulators, etc.), and private sector clients (the European Chemical Industry Council, the International Fragrance Association, Cosmetics Europe, International Association for Soaps, Detergents and Maintenance Products, Home Appliances Europe, etc.).

Brais has an excellent command of ex-ante impact assessment methods and Socio-Economic Analyses, including qualitative and quantitative approaches, the Commission's latest Better Regulation Guidelines and ECHA's SEA guidance. Brais currently manages and/or contributes with economic and technical leadership to several ex-ante impact assessments and related work, including of the revisions of the Industrial Emissions

Directive (DG ENV), the Cosmetic Products Regulation (DG GROW) and REACH annexes for the inclusion of data requirements on Endocrine Disruption (DG ENV/ DG GROW). Brais has led the economic analysis of commitments within the EU's Chemicals Strategy for Sustainability for European Chemicals Industry Council and provides technical leadership and assurance to ongoing projects supporting other business associations, e.g., on how their members and the broader economy may be affected by a potential universal PFAS restriction, especially with regards to the use of fluoropolymers.

In his project work, Brais has also led consultation activities, including survey and interview design and implementation, and engaged with stakeholders from across the European Commission, European agencies, trade associations, Member States and businesses. During the five years Brais worked in the UK government, he also led multiple Programme Management Offices and managed multiple programmes of work with responsibility for steering strategic policies in the UK. Examples include managing and servicing an Inter-Ministerial Working Group on Renewable Energy and a National Prevention Programme in England. In his four years at Deloitte, Brais also managed multiple economic analysis projects with private and public sector clients internationally.

BECCA JOHANSEN: CHEMICALS POLICY AND REACH EXPERT

Becca is a Principal Chemicals Policy Consultant, leading the Chemicals Policy Team at Ricardo. Having previously worked for Risk & Policy Analysts Ltd, she has over 7 years' experience in EU chemicals policy intervention and regulation. Becca's experience includes data generation, collection and analysis for numerous socio-economic analyses, impact assessments and policy evaluation studies for both the European Commission, European Agencies, National Governments and industry.

Key projects for the European Commission and its Agencies have included the study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation in accordance with the European Commission's Better Regulation Guidelines; providing scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles: with a view to improve the implementation and enforcement of Article 33 of REACH; a feasibility study into tools to manage information flows from product supply chains to waste operators; legislative mapping and preparation of policy briefs under HBM4EU; the study to assess the impacts of adding standard information requirements to Annex VII-X of REACH for endocrine disruption; and the CLP Impact Assessment.

Work for private sector clients includes being the project manager and technical lead for the Cefic economic analysis of the impacts of selected actions from the EU Commission's Chemicals Strategy for Sustainability (CSS), recently published (here); the project director and technical lead for the related IFRA, Cosmetics Europe and A.I.S.E. studies on the CSS; the Cefic REACH Landscape Study; socio-economic analyses for EFCTC and APPLiA in the context of a universal PFAS restriction, the TiO_2 socio-economic assessment for TDIC; and assistance in Applications for Authorisation under REACH. Becca has also led and developed the methodology for impact assessments in order to provide justification for derogation under Article 5(2)(c) of the Biocidal Products Regulation, which lead to presenting at the Chemical Watch Biocides Symposium 2019.

EMMA PEMBERTON: PFAS EXPERT

Emma is a Chartered Chemist (CChem) and Fellow of the Royal Society of Chemistry with over 23 years' experience in collating, interpreting, and communicating evidence on chemical risk and water quality. She is an experienced project manager, having successfully led a broad range of R & D projects centred on interpreting evidence on environmental risk from chemicals. She previously worked for the Environment Agency, providing specialist knowledge and technical leadership on the environmental fate, behaviour and ecotoxicological impacts of chemicals to inform policy development. She has written several narrative syntheses, describing the evidence base on UK sources, pathways, and environmental levels of chemicals of national concern. These have included a recently published evidence synthesis narrative on PFAS (see Environment Agency, 2021). Emma was an active member of the UK Water Framework Directive Technical advisory group Chemistry Task team from 2015 to 2020.

SABINO DEL VENTO: PFAS EXPERT

Sabino Del Vento is a Principal Consultant at Ricardo, working primarily in the area of emission inventories. He combines an academic research background in environmental chemistry with environmental consultancy and regulatory affairs (REACH/CLP). Sabino is a core member of the NAEI team, responsible for the development and compilation of the inventory of Persistent Organic Pollutants (POPs) and of the waste sector for the Greenhouse Gas (GHG) and Air Quality Inventory. He has strong understanding of the process and data management required to support inventory development and linkage of emission output to support wider policy work.

Sabino acted as project manager and technical lead for updating the multi-media POPs emission inventories for the UK, Ireland and Gibraltar, providing estimate emissions for air, land, water, product and residue, which are required for submission to the POPs Stockholm Convention and the EU POPs Regulation. As part of the update of Ireland's POPs inventory in 2018, the first multi-media inventory for Pentachlorobenzene for Ireland was developed. During his academic career, he gained in-depth knowledge of the occurrence and environmental fate of PFAS and POPs, particularly, concerning emissions and analytical analysis. He has extensive laboratory and field experience gained through working in international research institutes and several sampling campaigns (both in Antarctica and in the Arctic). He has been involved in analysing trace-level organic pollutants, including PFAS, in different environmental matrices and analytical techniques.

JACK DUBEY: ECONOMICS/SEA TECHNICAL SUPPORT

Jack is a Consultant at Ricardo, having joined in January 2020. Since joining Ricardo he has undertaken cost-benefit analysis and impact assessments of environmental policy options, including assessing the impact of policies on air quality both in the U.K and internationally. He has supported the DG CLIMA evaluation and impact assessment of the current F-gas Regulation, including employing economic analysis to determine to determine potential monetary costs associated with proposed policy options. He has experience in stakeholder engagement, helping to draft the Open Public Consultation questionnaire for the assessment of the F-gas Regulation, and has significant experience in analysing stakeholder feedback across a number of topics. Jack also has experience in conducting stakeholder interviews and undertook targeted interviews with LIFE Programme beneficiaries to support the development of the LIFE Programme (2021-2027) monitoring and evaluation framework. Before joining Ricardo, he gained 1.5 years of professional experience in environmental campaigning at UK100 Cities Network, supporting campaigns relating to improving air quality in UK cities and increasing investment in local energy projects. Jack is an Economics graduate with an MSc in International Public Policy from University College London.

JACOB SENDALL: ECONOMICS/SEA TECHNICAL SUPPORT

Jacob is an Economist at Ricardo. Having previously worked for EHS projects and Agri-Ideas Limited, he has 2 years' experience in environmental consulting. Jacob's experience includes conducting economic analysis to support policy development, implementation and evaluation. Jacob is also heavily involved in the delivery of projects, contributing to desk-based research, literature reviews, data analysis/modelling and stakeholder consultations. His consultancy experience includes supporting local, national and international public institutions, alongside private sector clients.

Key projects for the Chemicals industry have included the impact assessments for the chemicals, detergent and fragrance industry, relating to the EU Chemicals Strategy for Sustainability towards a toxic-free environment. In particular, how the application of a Mixture Assessment Factor may affect EU businesses and the wider industry.

Work on European Commission impact assessments and policy evaluation studies includes providing economic inputs for the Urban Waste Water Treatment Directive Impact Assessment, Amending Regulation (EC) No 1005/2009 on Substances that Deplete the Ozone Layer Impact Assessment and Evaluation of the Sewage Sludge Directive.

CHRIS STONE: REACH TECHNICAL SUPPORT

Chris is an expert in EU chemical regulations, in particular Article 45 of CLP (poison centres), SCIP, Cosmetics, and REACH, with years of experience working with hundreds of private sector chemical manufactures, importers and exporters. While working with global chemical customers, Chris has been responsible for

producing and submitting tens of thousands of chemical mixture notifications to 28 different EU member states. Chris has recently supported European Commission Impact Assessments on both the CLP Regulation and the Cosmetic Products Regulation, providing technical and written support. Chris has also supported multiple socio-economic assessments, in particular on the topic of PFAS. Having a strong scientific and data analysis background he has excellent information processing and written communication skills. Chris has produced several excel data processing tools for formatting large datasets to increase efficiency and reduce human error in submitting chemical regulatory data to governing bodies.

GRAHAM PATTLE: REACH TECHNICAL SUPPORT

Graham is a Senior Chemicals Policy Consultant at Ricardo with 6 years' experience of EU chemical policy and global chemical regulations, having previously worked at Risk and Policy Analysts Ltd, and Yordas Group, who are a leading provider of global chemical regulatory, sustainability and product stewardship consultancy services. Graham's experience includes various socio-economic and impact assessments for the European Commission and industry associations, and the provision of regulatory services to industry in relation to REACH, CLP, and other EU chemicals legislation.

Key socio-economic assessment experience includes technical lead and support roles for Cefic's economic analysis of the impacts of selected actions from the EU Commission's Chemicals Strategy for Sustainability (CSS); and the related IFRA and A.I.S.E. studies on the CSS, and most recently, an ongoing RMOA study investigating the implications of a restriction.

Key impact assessment experience includes a number of projects for the European Commission, such as: the ongoing impact assessment on the revision of the CLP Regulation where Graham is acting as internal project manager for Ricardo's input on the areas of self-classification, simplification of labelling, and poison centres; the impact assessment on the revision of the Cosmetic Products Regulation; and the recently completed impact assessment of potential options for updating REACH annexes with data requirements on endocrine disruption, where he has been supporting the data collection and analysis of impacts.

6. PROJECT MANAGEMENT AND COMMUNICATION

This section demonstrates our ability and vision on managing the project. It provides a brief synopsis of important items relevant for a dynamic, efficient and effective project management set-up between ESA and Ricardo.

The project demands sound coordination mechanisms and feedback loops, as well as clear guidance for individual teams and team members in order to deliver high-quality results against the multidisciplinary team-set up, timeframe and complex nature of the analysis.

The proposed **Project Manager** would be the main point of contact for ESA and its members and be responsible for:

- Overall responsibility for day-to-day management of the project, including being responsible for the dissemination and implementation of the approach and providing workplans for the supporting team and SMEs
- On communication: ensuring good communication between the ESA's lead contact(s) and the team (and on behalf of the team). This includes being in contact with them (e.g., by conference call or phone biweekly or otherwise) to give an update of the progress and discuss any relevant issues for the tasks at hand
- On direction: taking the final decisions, together with ESA and the Project Director, on the focus and direction of the study
- On timing: ensuring that the various assignments progress according to agreed plans (see Section **7**) and completed in due time
- On QA: working with the QA team to ensure deliverables produced are in line with the agreed terms, and providing deliverables and reports to the quality reviewers in ample time
- On continuity: responsibility to find suitable replacements for every member of the study team in case he or she becomes unavailable due to unforeseen circumstances.

The following sessions and approaches are suggested at this stage for this project, and other key events or meetings may be required for the effective management and delivery of the project:

- (Bi)monthly teleconference with progress updates for ESA (which might include some of the following discussions where separate sessions are not necessary)
- Project Inception Session
- Stakeholder Consultation Planning Working Session
- Multiple Stakeholder Sessions (Interviews, Follow-ups, etc.)
- Progress Report Review Session
- Draft Report Feedback Session
- Project close down following submission of the Final Report.

Please note that we are we are assuming that all of these meetings and sessions will be held remotely by videoconference. As noted in the extended offer, Ricardo can offer support to ESA in their interactions with the Commission, ECHA and Member States on a time and materials basis, as has been done for other private sector clients.

The **Project Director** will:

- Have a critical mind and a good understanding of the substantive issues, to provide real value added to the project
- Be available for quality control according to the agreed timeline, carry out the quality control of all deliverables, being responsible for finalising editing
- Provide a second more senior point of contact for the customer
- Deal with any potential performance issues related to the project team
- Follow up on the progress of the overall project

The **supporting team** will be responsible for:

- Ownership of the timely execution and according to the set quality standards of the respective tasks
- Identifying (and communicating to the Project Manager as relevant) the need for a replacement of a project expert in case they become unavailable due to unforeseen circumstances

- Liaising with the Quality Assurers to ensure the output(s) from their tasks meet high quality standards and arranging any necessary feedback loops with the project team when necessary.

Subject Matter Expert and Quality Assurance team will be responsible for

- Providing timely input based on their expertise across all of the tasks, in line with the project's specifications and upon the Project Manager's request
- Reviewing and providing feedback on / verifying and validating (intermediate) outputs and other content or work that requires their assurance, based on their expertise and knowledge.

In addition to their individual experience and expertise, the proposed team members have a track record of working together in projects for the chemicals industry as well as other private and public sector clients and delivering high-quality outputs working closely and constructively with these clients.

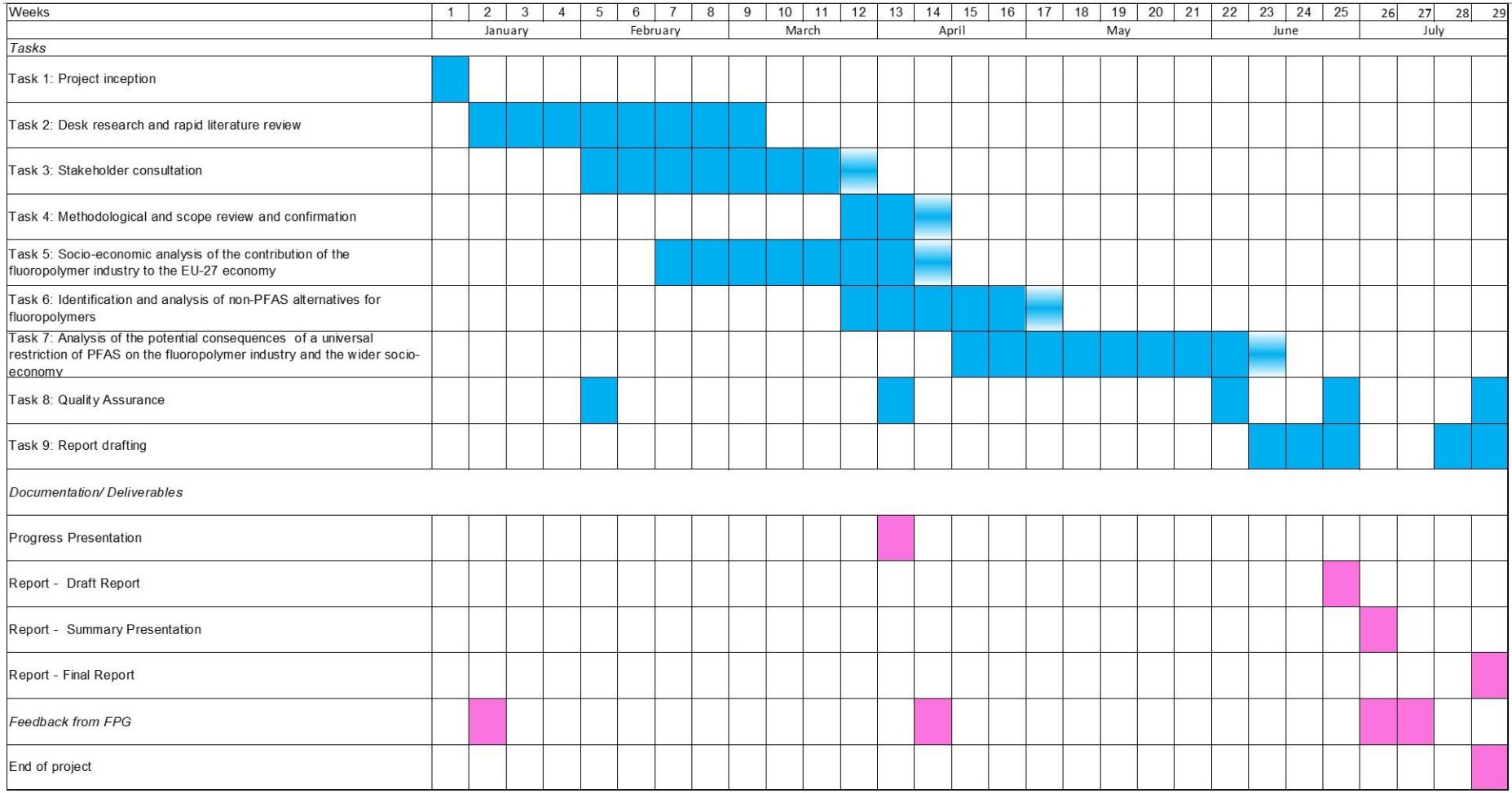
7. PROJECT TIMELINE

ESA have proposed a reasonable timeline for the project of 6 months. We have used this to propose a draft work plan (See Figure 7-1). This does not include resources or scheduling of sub-tasks that would be delivered under the extended offer and would be one of the key agenda items for review and agreement during the inception meeting and project phase.

A presentation of progress would be given to ESA members (early April) which would facilitate feedback and confirm the actions from the methodological stocktake (Task 4). Following the feedback from ESA, by mid-April, Ricardo will progress with Tasks 5-7.

The Draft Final Report would be expected late-June with a presentation of the findings to the ESA members the following week to ensure engagement and understanding. ESA would be provided 2 weeks to offer comments and feedback on the Draft Final Report. This feedback should be in the form of one consolidated set of comments in track changes in the report. The Final Report will be delivered at the end of July 2023 and will take into account any comments or feedback received on the Draft Final report.

Figure 7-1 Project timeline or high-level workplan (2023)



NB 1 Please note that the part-shaded cells represent potential project contingency, due to any iterations required based on feedback from ESA members and the complexity of the evidence-gathering tasks especially, which may suffer from delays. Delays would impact the timeline for the delivery of the Final Report.

8. COMMERICAL OFFER

8.1 PRICE

Our **proposed core offer** responds to ESA's RfP to deliver a socio-economic analysis study for a fixed price of **€ 97 716** (ninety seven thousand, seven hundred and sixteen euros). Face-to-face meetings or support in interactions with the Commission, ECHA or Member States would be additional if requested.

The price of this offer is constructed assuming that all 'core offer' tasks as listed in Section 2 are carried out for the fluoropolymers and uses in scope at a reasonable level of detail (e.g., following a prioritisation exercise for downstream users in scope). ESA may want to further prioritise between substances and sector in scope, which would lead to modifications to this core offer.

Beyond the core offer described in section 2, optional packages covering additional research, data gathering and consultation activities could make an **extended offer**. If ESA is interested, these tasks can be discussed and further developed during contract negotiations, the project inception or at any stage during the project. These tasks are:

- **Sub-task 3.2 / Data gathering: paid data services** – in the event that the desk research, literature review, and consultation of ESA members and other businesses does not yield sufficient evidence of the volume, value and emissions of fluoropolymers, Ricardo may need access to paid information services, which hold some evidence of the production, use and market value of the substances/products in scope.
  For example, on fluoropolymers, there are reports available that could be useful, although these tend to be global and are unlikely to get into the level of detail scoped out for this project. These may include Grand View Research's "Fluoropolymers Market Size, Share and Trend Analysis Report…"[41], Report Ocean's "Fluoropolymers Market Share, Size, Trends, Industry Analysis Report by Product Type, by Application…"[42], IHS Markit "Fluoropolymers" Chapter of the Chemical Economics Handbook[43], and others (indicative price of €5 000 - €10 000 for each report).
- **Sub-task 9.2** where Ricardo actively support ESA in their interactions with the Commission, ECHA and Member States by attending meetings with them to present the findings of this study and answer questions on methodology or results would be on a time and materials basis. Ricardo has extensive experience in presenting the outcomes of private sector assessments to the European Commission and ECHA. In case additional work is required outside of the defined scope, or on completion, Ricardo will agree the scope, price and invoicing of the additional work with ESA, based on the capability of the individuals required.

All pricing is quoted in EURO and our offer is valid for 1 month from the date of submission, 18 November 2022. Our payment terms are 30 days. Please note as the UK exited the EU VAT regime, Customs Union and Single Market as of 1st January 2021, VAT is not applicable to the pricing quoted.

8.2 PROPOSED INVOICING SCHEDULE

- Upfront payment upon contract signature - €29 314.80 (30%)
- Interim payment (progress presentation) – €29 314.80 (30%)
- Final Payment upon acceptance of the Final Report – €39 086.40 (40%)

8.3 TERMS AND CONDITIONS

Our offer to undertake the work described in this proposal is subject to the agreement of terms and conditions, and we propose that Ricardo Energy & Environment's standard terms and conditions apply to any contract between us, as submitted in a separate .pdf attachment titled "REE_FPA_FRM650A_Law of England and Wales".

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[41] Fluoropolymers Market Size | Global Industry Analysis Report, 2022 (grandviewresearch.com)

[42] Fluoropolymers Market Share, Size, Trends, Industry Analysis Report By Product Type (PTFE, PVDF, FEP, PCTFE, PVF, and Others), By Application (Electrical & Electronics, Automotive, Construction, Industrial Equipment, Chemical Processing, and Others), By Regions, Segments & Forecast, 2018 - 2026 (reportocean.com)

[43] https://ihsmarkit.com/products/fluoropolymers-chemical-economics-handbook.html

Our offer is made on the basis of current guidance in relation to the current pandemic. Although the ongoing situation and government advice changes cannot be foreseen, this is a desk-based study and no issues affecting delivery due to COVID-19 disruption are anticipated. As soon as we become aware of anything that could impact on delivery we would look to discuss and agree with you at the earliest opportunity how to proceed. The parties will agree to each take such steps as are reasonable to conclude the work whilst delivering value in full or part to you as our client. In the event it is concluded the value is compromised to the extent the work should not proceed further, the contract will be terminated for convenience without fault or breach on either party.

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