Socio-Economic Impact Assessment regarding the use of PFAS substances in the European Sealing Industry

Proposal

prepared for

European Sealing Association e.V.

15 November 2022

RPA
Risk & Policy Analysts

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1 Introduction

1.1 Introduction to the proposal

This document is being submitted by Risk & Policy Analysts Ltd (RPA) in response to a request for a service offer from Mark Neal at the European Sealing Association (ESA) e.V. made on 20 October 2022. The proposal sets out the consultancy support services that RPA can provide to ESA in relation to a 'Socio-Economic Impact Assessment regarding the use of PFAS substances in the European sealing industry'.

Based on the initial information, it is understood that ESA is looking to develop a socio-economic assessment (SEA) of the potential restriction of PFAS substances used in sealing devices. The basis for concern is the upcoming PFAS restriction proposed in the EU by 5 European countries (Germany, Denmark, Netherlands, Sweden, Norway) to ban the manufacture, placing on the market and use of all PFAS substances. A future restriction may result in severe impacts on the sealing industry and with far reaching impacts on the performance of sealants, and in consequence, vital products to society dependent on functional seals.

This proposal outlines the scope of the project and timeframe, whilst also highlighting areas of uncertainty and potential for adjustment based on future progression.

This proposal also describes in detail RPAs' proposed approach to the socio-economic assessment to be undertaken. Following ESA's assessment of this proposal, RPA are happy to have additional discussions with ESA for any suggested clarifications or refinements of the proposal to ensure the work would reach the desired expectation.

1.2 Background

1.2.1 ESA and sealing devices

This short background is extracted from the ESA March 2022 position paper.[1]

The European Sealing Association (ESA) represents most Sealing Device manufacturers in Europe. The ESA has over 50 members, with a combined turnover of Euros 2.6 billion, and employs some 12,500 people. PFAS are critical to global industry in their use as sealing elements. Seals made from fluoropolymers (fluoroplastics, fluoroelastomers) are irreplaceable in certain industries and that a severe restriction on PFAS required for the sealing industry will have a profound negative impact on society (health, welfare, and standard of living). No suitable alternatives to PFAS substances lead to high socio-economic costs when trying to replace them. Larger molecular weight materials, such as polymers and cross-linked rubbers are non-bioavailable.

In its position paper, the ESA asks that PFAS fluoropolymer (fluoroplastic and fluoroelastomer) materials are exempted from the proposed restriction.

Polymers (plastics and elastomers) are manufactured from monomers which react together to form the repeating unit of the polymer. Fluoropolymers are manufactured from low molecular weight PFAS monomers and in some cases using PFAS process agents. It is an important consideration that a class

[1] https://www.esaknowledgebase.com/wp-content/uploads/2022/03/ESA-Position-Statement-on-proposed-PFAS-regulation-March-2022-1.pdf

ban on low molecular weight PFAS is in effect also a ban on fluoropolymers (fluoroplastics and fluoroelastomers).

Industrial seals are used to contain media (powders, gas and liquids) inside hardware (process or storage equipment). Media within non-moving equipment are secured by "Static Seals" such as gaskets, whereas pistons and rotating equipment such as bearings and gearbox use "Dynamic Seals".

Hazardous, toxic, flammable, corrosive and reactive chemicals are media found in different industries all of which require high performance seals to be used efficiently and safely. Seals are used in aggressive environments where they can be exposed to conditions, such as, wear, abrasion, radiation and extremes of temperature.

Seal materials must:

1. Withstand the environmental conditions of the application, including, media, temperature, pressure, speed, and abrasion
2. Not damage other equipment (hardware) in which the seal is housed
3. Be compliant with the counter surface to maximize sealing efficiency

1.2.2 EU PFAS restriction

The PFAS restriction was first proposed to the European Chemicals Agency (ECHA) on 15 July 2021 by the member states Germany, Denmark, Netherlands, Norway, and Sweden. The basis for this restriction relates to the persistence of PFAS chemicals in the environment which may relate to 'irreversible environmental exposure and accumulation'[2]. Additionally, some PFAS substances pose a risk to human/environmental health[3] providing extra justification for restriction. To mitigate these risks the current proposal suggests a ban on the placing on the market, manufacture, and use of all PFAS chemicals in the EU. For clarification, the PFAS restriction defines PFAS chemicals as any substance with at least one perfluorinated methyl group (-CF_3) or perfluorinated methylene group (-CF_2-).

Derogations from an implemented restriction may be granted in cases where a strong socio-economic and risk assessment demonstrates disproportionate impacts between the benefits of substance restriction and the socio-economic costs of its restriction. The restriction dossier is expected to be submitted on 13 January 2023[4] and will subsequently be analysed by both ECHA's Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC).

1.2.3 Considerations

The purpose of this project is to provide ESA with a high level SEA which can be used in communications to make a case for a derogation of certain sealants under the proposed PFAS restriction. Further discussion of the exact intentions of the project can be raised in subsequent meetings with ESA, before the kick off meeting. In a best-case scenario for ESA a derogation would allow import of PFAS containing sealing devices into the EU and for continued manufacture of sealants using PFAS substances (monomers) at current facilities within the EU.

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[2] ECHA, (2022), https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b, Accessed: 09/08/2022

[3] As an example, Pentadecafluorooctanoic acid (PFOA) has a harmonised classification as toxic to reproduction, PBT (Persistent, Bioaccumulative and Toxic), POP (Persistent Organic Pollutant) and is suspected as being carcinogenic.

[4] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b

At this point, it is suggested that the scope of this study should would only include a high level assessment of PFAS emissions associated with the manufacturing operations sealants using PFAS in the EU. High level information on emissions during manufacture and human exposure will be used for monetisation of human health impacts. Further discussion on this point should be held in the upcoming meetings/kick off meeting.

It is RPA's assumption that ESA have actively been engaging with its members on this proposed SEA as this will allow for the data collection and consultation to be conducted fast will result in higher response rates. It is suggested that a workshop is hosted by RPA before the consultation opens to ensure respondents fully understand the data requirements and consultation approach.

The remainder of this proposal sets out RPAs' approach to the socio-economic assessment. **Section 2** presents the proposed approach to the study to be performed in four main tasks; and **Section 3** sets out the project team, the costs, and the envisaged timeline.

2 Approach

2.1 Overview

In order to meet the desired outputs for ESA the approach will consist of a socio-economic impact assessment coupled with a high level assessment of emissions and exposure. This combined approach will provide ESA with data which can be used in communications and to provide justifiable input to upcoming public consultations on the PFAS restriction proposal. These approaches are further outlined in sections 2.2 and 2.3.

The restriction proposal from the five countries is expected to be provided to ECHA in January 2023. Following this, ECHA will initiate an internal assessment of the proposal and to launch a six month open public consultation. This consultation will be open until around August/September 2023 (depending on the exact submission date and length of ECHA checks). This timeline will impact the duration of the projects, and RPA foresees a final delivery ensuring submission during the open public consultation. However, the aim would be for initial SEA results to be available earlier to allow ESA time to provide their input to the consultation. Timelines for this study are further elaborated on in section 3.3.

The following actions are proposed as a general approach to the delivery of this project:

1. Review initial documents and information from SEA regarding PFAS substances used in sealants, their functionality in specific end uses, their production process and emissions, the quantities and values manufactured and imported in the EU, availability of alternatives, and information regarding the wider supply chain
2. Open a consultation with ESA and their members following the sharing of initial information. This will involve ESA's and members participation in a questionnaire to gather data relating to the socio-economic impact assessment, emissions and exposure.
3. Map out the supply chain and identify additional key stakeholders and conduct a consultation to gather downstream user data.
4. Identify potential impacts arising from a restriction for both ESA's members and their downstream supply chain.
5. Generate qualitative and quantitative estimates (to the degree possible) of the socio-economic impacts arising from the restriction of PFAS in the EU; this can be represented by the loss of profits/revenues in relevant markets, associated job losses at ESA's members and throughout the supply chain, societal impacts, improvements in human/environmental health arising from a restriction.

The overall approach will consist of a brief literature review but will centre around an in-depth consultation of ESA's members and relevant stakeholders at different levels of the supply chain. In addition to desk-based research, questionnaires will be developed for circulation to collect relevant information (the consultation phase). In addition to questionnaires, follow up interviews will be conducted to gather data and clarify consultation responses directly with a number of respondents. Assistance from ESA's members would also be requested throughout the consultation, as engaging via pre-established routes will likely increase the response rate. Alongside this any information ESA and its members hold regarding markets, products, and alternatives would be important to RPA in conducting the analysis.

2.2 Socio-Economic impact assessment approach

The SEA approach considers a holistic overview of relevant supply chains with reference to issues surrounding competition and competitiveness. Key elements of a typical SEA may include:

Setting out the reaction of the supply chains in the event of a regulatory action: the SEA needs to explain what the responses of actors along the supply chains will be in the event of a particular regulatory development. In an SEA there may be more than one scenario depending on the options available to different stakeholders. In this project however only one restriction scenario will be considered.

Assessment of human health impacts: This assessment links the exposure of workers and consumers to hazardous substances via patterns of exposure over time and the number of exposed individuals. This may be covered in brief in the current study.

Assessment of environmental impacts: Environmental impacts may relate to direct emissions of hazardous substances to the environment or to changes which would adversely affect efforts to improve environmental sustainability. The analysis of emissions can be conducted at a deeper level by sub-consultant. Discussions on the use of an external sub-consultant and the importance of emissions analysis can be discussed in future meetings (this would be at an additional cost, RPA has strong working relations with several suitable environmental impact consultants)

Assessment of economic impacts: This is the core part of the SEA and aims to assess the direct and indirect economic impacts of the adverse regulatory developments to both the client and along the relevant supply chains. Consideration is also given to the impacts on the markets for alternatives. When impacts are quantified, the focus is typically on the loss of profit rather than turnovers; however, where information availability is limited, the size of the relevant markets can be used as a proxy to estimate economic losses. In this section arguments will be strengthened if they can be supported by actual data. Where actual data cannot be gathered, data gaps may be filled via the use of national statistical data on average company size, average turnover, average net margins, etc. This data can be sourced directly from Eurostat using relevant NACE and PRODCOM codes.

Assessment of social impacts: Social impacts include employment impacts and impacts on local and wider communities as a result of the adverse regulatory development. An approach often taken is to use multiplier effect methodologies (for example based on the approach developed for the ECHA's Socioeconomic Analysis Committee (SEAC)) to assess how many jobs would be affected across the EU from the closure of production facilities, should these arise, accompanied by consideration of any particular local or regional impacts.

Assessment of wider and competition effects: The importance of wider economic, competition and innovation effects will be assessed. This will aim to aggregate impacts within the supply chains with the aim of demonstrating likely impacts on intra-EU competition and on the competitiveness of EU businesses against their non-EU peers.

The final report will be based on the above elements with a focus on restriction impacts on sealing devices in EU. This analysis will be conducted by the comparison of two scenarios highlighted below.

1. The baseline (or 'continued use') scenario. The baseline scenario assumes that business would continue as normal and highlights the current benefits and drawbacks of the sealing devices to society.
2. The restriction (or 'non-use') scenario. This scenario meanwhile presents the social and economic impacts that would be observed as a result of restricting PFAS substances in sealing devices in the EU.

The outcomes of these different scenarios will be compared and conclusions will be presented to highlight the range of potential impacts arising from restriction.

Additionally, the impacts of an SEA can vary significantly depending on the availability and suitability of alternatives. As such the approach proposed will include a high level analysis of alternatives (AoA) for the specific end uses deemed in the scope of this study. This will involve analysing the requirements of the end use which are met by the PFAS substances and considering whether other substances could realistically be used as an alternative based on functionality, availability, hazard properties and economic factors. The AoA can then be used to predict the extent to which impacts highlighted in the SEA would be felt by ESA's members and their downstream users in the event of the non-use scenario.

Throughout the supply chain the following costs of the non-use scenario will be considered: revenue/profit loss, jobs, exports, imports, and alternatives development (R&D). By assessing these factors in relation to the baseline scenario the socio-economic impacts of restriction can be presented and identified for different levels of the supply chain.

Examples of aspects to be considered for the assessment of costs include, among others:

- Employment
  - Cost of unemployment due to job losses
  - Cost of retraining workers to use a new alternative (safety, process changes, etc…)
- Market impacts
  - Cost to EU market
  - Imports
  - Exports
  - Internal market share
- Research and development cost
  - Cost of finding suitable alternatives
  - Costs of validating new alternatives
  - Cost of adapting manufacturing process
  - Prices of alternatives and impact on the overall cost of manufacturing products

An example of the data to be collected during this task is set out in Table .

Table 2-1: Data collection categories

Category	Information targets
Alternatives identification	Functions of PFAS within the application of use Alternatives to PFAS in specific end uses Substitution timeframe per alternative available Market availability of alternatives Hazard classification of alternatives and existing regulatory measures Research and development costs in switching to/identifying a new alternative Identification of obstacles and incentives for use of alternatives Certification processes, associated costs and timeframe
Market analysis	For all relevant end uses and for identified alternatives for relevant uses: Market share per end use Market share of alternative based products Annual EU production tonnage volumes Annual EU import, export volumes Future trends regarding production, import, export (volume/year) Average market price per product (preferably per year) Current number of producers/importers/users

Table 2-1: Data collection categories	
Category	**Information targets**
	What products are being imported? What is the market share from imports? Profits and turnover per end use Supply chains of selected relevant products and supply chain of alternatives
Environmental impact assessment	Increase in consumption of resource from production change (energy, water, raw materials)
Economic impact assessment	Lost profits incurred by a restriction of PFAS Future losses in terms of net present value (NPV) Economic impacts from production changes Substitution costs per end use: affected market actors in the supply chain, cost difference in the end product Technical costs per end use (e.g. for additional testing, investment in RMM, technical installations etc.) Organisational costs per end use (e.g. training of workers, occupational safety measures, regulator costs) Associated research and development costs Lost profits from switching to alternatives
Human/social impact assessment	Worker exposure to PFAS (if applicable) Cost of human health impacts (if applicable) Human exposure via the environment (if possible) Number of impacted downstream users Number of workers employed in the supply chain Potential employment effects due to substitution (i.e. retraining, redundancy, recruitment) Additional economic, social, and wider impacts monetised where possible

Downstream user workshop

Based on RPAs' previous experience in conducting socio-economic analyses it is recommended that a workshop is arranged before the start of the consultation with EAS's members. In this workshop the data requirements of an SEA (as indicated in Table above) can be fully explained and their importance to the overall analysis highlighted. RPA typically find this improves both the quantity and quality of responses from the respondents. Further discussions on this workshop can be held in subsequent meetings or the kick off meeting.

Considerations with regard to exposure and emissions

Information on emissions and exposure will be used by RPA for monetising SEA impacts. A high level approach to emissions and exposure will be applied to develop estimations of emissions of PFAS used by ESA members during the production, downstream use, service life and end-of-life stage.

The following lifecycle stages have been identified as relevant and would be assessed based on information from the consultation:

1. **Manufacture and Industrial use**. This stage includes all operations that take place in industrial settings manufacturing and processing of sealing devices.

2. **Service life stage**. This stage includes the use of sealing devices. It is expected that emissions during service life will be minimal due to the nature of the products and its applications.

3. **Waste (end-of-life) stage**. After a product reaches the end of its service life and is discarded, it is considered waste, or left in situ underground. Waste can in general be recycled,

incinerated or landfilled, depending on the waste stream and on each Member State's policy (and potential future EU policy regarding SVHCs in recycled waste streams). The breakdown of waste treatment for each of the different uses is not easy to determine due to the different waste management strategies in each MS, and also due to the different legislation that may apply.

This information will be collected during the data gathering stage on material flows from ESA's members (i.e. manufacturers) and along the supply chain will be used to estimate the emissions to the environment and exposure.

The level of detail, the feasibility of calculation of emissions, and the margin of error in each of the three broad lifecycle stages will depend on the available information. If no company specific information is available it is assumed that information found in literature, in relevant guidance documents, relevant sector specific environmental release category documents and from relevant studies will be used.

2.3 Task breakdown

2.3.1 Task 1: Kick-off meeting

RPA proposes a kick-off meeting (KoM) be held with ESA (and other participants based on ESA's discretion) with the purpose of agreeing a collective understanding of the work to be undertaken, identifying data requirements and sources, defining the scope, and refining the approach (if needed).

In addition, the KoM will also be important for discussing the information collection activities that will follow, including any requests for additional support from ESA, as well as establishing deadlines for activities and deliverables, and the appropriate lines of communication and data exchange.

There are several key elements that will be addressed, and these should be discussed and agreed upon:

- Finalisation of the scope of the assessment.
- Clarification of the target audience and the level to which information that is not publicly available can be reproduced in the report.
- Identify data requirements from ESA (e.g. socio-economic data) and contacts throughout the supply chain.
- Discuss the consultation approach and gathering of any supplementary beneficial information which can be used to support the analysis.
- Determining whether the type of questions and data to be collected is sufficient or whether there are gaps.
- Agreeing the specific number of interviews to be conducted.
- How information and data from individual parties should be handled and reported.
- Clarification on the handling and reporting of confidential data, both from ESA and its members.
- Establish communication channels and agree on the responsibilities.
- Confirm the schedule of work, including deadlines for deliverables.
- Answer any questions ESA may have.

To provide a basis for the timelines presented in this document, **RPA have assumed that the study will start in January 2023** and that the kick-off meeting (suggested to be held via Microsoft Teams) will take place as soon as possible after signature of the contract.

RPA will provide written minutes of the meeting (and all subsequent planned meetings with ESA) within one week of the call/meeting. Minutes of the kick-off meeting will also include a list of agreed actions for both parties.

2.3.2 Task 2: Data collection

Overview of sealing devices/end uses

RPA will start by conducting desk-based research into uses of PFAS in sealants and their use in EU. Any documents and information ESA hold relating to sealing devices and end uses would be highly beneficial to review, and we request would be made available to RPA. Typical information which can be found online includes a summary of the key features of relevant PFAS products, data regarding hazards risks and functionalities, EU registration data (tonnages produced in the EU, tonnages imported into the EU), and the value of relevant EU markets. If gaps in these data are identified, these will be raised with ESA and addressed in the consultation phase. RPA would welcome a discussion with ESA to assess the extent to which information already available can be shared with RPA in the initial stages.

RPA understand that there may be sensitivities among manufacturers and along the supply chains as regards the collection of detailed market information. As a result, our suggested approach would be to where possible:

- Rely on information in the public domain and any additional data that ESA can source from reputable sources;
- Where gaps are identified, RPA will aim to fill these via consultation;
- Ensure that any confidential information shared via consultation is aggregated and that ranges are used to protect confidentiality, and that such measures are communicated to the downstream users.

Through the review of available information and assisted by the consultation, RPA will be able to:

- Develop a detailed overview of the existing publicly available information on the sealing devices containing PFSA, market, and end uses;
- Identify specific product-end use combinations which are likely to represent significant impact areas; and
- Identify additional contact persons and establish channels of communication for further information collection (this has already been made significantly easier via efforts from ESA to engage their members and downstream users).

Consultation phase

The consultation phase will gather relevant information from downstream users throughout the uses of sealing devices and their applications. This will be conducted by producing a surveys tailored to ESA's members. The survey will be available online and will be circulated by either RPA or by ESA (to be discussed in the kick off meeting. RPA's preferred approach is for circulation by ESA as this typically improved the response rate). It is proposed that the consultation approach takes place as quickly as possible to capture all of the required information and avoid any potential delays due to respondents' unavailability.

The survey will include a question to identify respondents willing to be approached for follow-up interviews with the RPA study team. These interviews will aim to clarify responses given in the questionnaire, collect new supporting information and place responses in context in relation to the

information collected through the literature review. Interviews are an effective technique of data collection as they allow a detailed collection of information and an opportunity to get comparable results from different interviews by using the same interview guide template. The number of interviews to be conducted should be discussed at the kick-off meeting, in general RPA would suggest between 8-12 interviews to be conducted as part of the consultation phase.

2.3.3 Task 3: Analysis

Assessment of impacts on ESA's members

Under the first part of this task RPA will analyse the socio-economic impacts on ESA's members as a manufacturer using data generated under task 2. This will help to build a deeper understanding of the impacts on business for ESA's members specifically and may help to contribute to an argument for derogation. The objectives of this analysis will be to:

- Conduct a preliminary assessment of the availability of alternatives and the likelihood of successful substitution;
    - This section will draw on the category 1 data mentioned above to provide an overview of which alternatives are available to replace PFAS in the specific end uses, how these alternatives functionality differs to PFAS, the feasibility of substitution for each alternative and the wider impacts of replacing sealing devices with an alternative (i.e. lifespan reductions, etc)
- Consider ESA's members response to a restriction and the costs, lost profits, and employment impacts for each of the relevant end uses;
    - This analysis will draw on the data gathered around ESA's members manufacturing and sales in/to the EU to highlight the economic consequences of a restriction of PFAS for these specific end uses.

Assessment of emissions

This aspect of the analysis will be reliant on the emissions/exposure data from the consultation. This analysis may be able to be used to support an argument for the continued manufacture sealing devices containing PFAS within the EU alongside assisting with the overall socio-economic assessment.

SEA of impacts on ESA's members

The analysis impact on ESA's members will be conducted by RPA and relates to the socio-economic impacts which will be felt throughout ESA's members. RPA will aim to address the following:

- Consider the various responses to a restriction for ESA's members (i.e. manufacturers/converters/compounders).
    - Analysis of information gathered in the data collection and consultation phase and will highlight how sealing manufacturers would react in the event that sealing devices could not be manufactured due to a restriction of PFAS. This will also include considerations around alternatives and the impact that switching to alternatives may have on ESA's members.
- Quantify to the degree possible the costs associated with a restriction of PFAS enabled sealing devices supplied by ESA's members in specific end uses.
    - This analysis will be based on the economic data gathered via the consultation to illustrate the costs to industry such as costs of lost sales, retraining workers, reinvestment in new production facilities, changes in operational costs, and including other societal costs such as costs of unemployment to society.

    - The analysis will be compared to market data presented in the baseline scenario to indicate the overall impacts of a restriction on the EU market in terms of market shares, value and competition.
- Consideration of wider societal impacts arising from restriction of PFAS containing sealing devices within of ESA's members.
    - This data will be gathered more qualitatively throughout the consultation phase and will indicate wider impacts felt by manufacturers (i.e. increased manufacturing costs, maintenance times/costs, replacement costs, impacts on availability of end products, impacts on location of manufacturing sites, etc).

2.3.4 Task 4: Reporting

Progress reports

Throughout the project, ESA will be kept informed at regular intervals on the progress of the report, either via biweekly (once every two weeks) emails or telephone/video calls. Details on communications will be agreed during the kick-off meeting.

Final report

When presenting the draft final report, RPA propose organising a video conference to allow us to present the key findings of the report, and to gain initial feedback on these and to agree any areas still requiring further work.

We would propose that ESA will have around two weeks to provide additional comments to the draft final report. Once RPA have received comments, the draft final report accordingly to produce the Final Report, at latest, within two weeks of receipt of the comments. It is expected that input to the ECHA open public consultation may be provided with information from a draft report, and not from the final report.

3 The Study Team, Costs and Timeline

3.1 Study team

3.1.1 RPA

RPA is an independent specialist consultancy providing expert advice in the environmental field to both public and private sector clients around the world. RPA has recognised experts with unrivalled experience in AoA and SEA development and chemical risk management, who have the necessary expertise and experience in all of these relevant areas of work. Tables of past SEA work conducted by RPA can be seen in Annex 1. It is noted that over the last 2 years RPA has been involved in four PFAS related projects, one for RIVM, in the Netherlands, and three studies for private clients.

For this study, we have brought together a team of chemical experts and economists, all recently involved in much of the work that RPA does in the chemical field:

Dr David Carlander (DC), RPA Director, will act as the project director and provide support to Robert White. Dr Carlander joined RPA in February 2020, is managing the chemicals department and work on RPA analysis for industry clients relating to all aspects of chemicals legislation including e.g. REACH and CLP as well as international developments. Dr Carlander has a MSc in Biotechnology and a PhD in clinical chemistry.

Dr Carlander's tasks includes activities related to chemicals, nanomaterials, food and managing projects, including e.g. stakeholder consultations and client relations. At RPA Dr Carlander is involved in analysis of uses of chemicals and their possible alternatives under the REACH Authorisation process. Currently Dr Carlander is supporting e.g. the CLP impact assessment and addressing PFAS substances.

Dr Carlander has over 23 years of experience working with science, risk assessment and government policies and regulations related to novel technologies in the life science area such as GMO, novel foods, animal cloning and nanotechnologies, e.g., for Swedish Ministry and National Food Administration and as Scientific Officer at the European Food Safety Authority. Before RPA, most recently Dr Carlander worked as Director General and Director of Regulatory Affairs at the globally active Nanotechnology Industries Association, NIA. Previous experience includes working for the Swedish Ministry negotiating EU regulations (e.g., GMO) and preparing Swedish positions in EU matters. Dr Carlander coordinated the work of the European Food Safety Authority work in the area of nanotechnologies, including writing and supporting publication of several EFSA scientific opinions and guidance documents, and representation at international meetings. Dr Carlander has regularly attended and contributed to work at the OECD, standards work in ISO and CEN, and written reports and policy papers for the nanotechnology sector as well as participating at ECHA accredited stakeholder meetings and contributing to ECHA Guidance 'Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification' published in 2019 as a member of the ECHA Partner Expert Group.

Robert White (RW) is a consultant with RPA and will support Dr Carlander in the day to day management of the project. He is an economist supporting the chemical and environmental teams. Robert joined RPA in 2021 as a researcher after leaving university. Specialising in economics, Robert possesses skills in economic analysis, modelling, socio-economic analysis, game theory analysis, health economics, behavioural economics, and experimental economics. Previous work experience has provided Robert with experience in dealing with clients and colleagues from around the world including in the US and Asia-Pacific regions. Robert is currently working on multiple projects including several EU REACH restriction socioeconomic analysis documents, a REACH Authorisation for

Application, several policy impact analysis reports for DEFRA and the European commission and cost benefit analysis assessments for multiple environmental projects for local authorities in the UK. Additionally, Robert has previously completed a Biocidal Products Regulation (BPR) restriction socioeconomic analysis (SEA), a European Commission policy impact assessment and a natural capital accounting project for the Environment Agency. Robert holds a BSc in Politics and Economics and an MSc in Behavioural and Experimental Economics from the University of East Anglia, where his dissertation project focused on designing and conducting an economic experiment where the primary goal was to assess the impact of digitisation on consumers perception of value for money.

Gillian Federici (GF) is a Senior Consultant at RPA and has a degree in Environmental Biology and a MRes in Aquatic Ecotoxicology. Gillian joined RPA in 2021 and has over 13 years of experience in the EU regulatory world, particularly with REACH. She has experience in public sector projects where she has worked with DG ENV on the development of options for the assessment of polymers, and developed the impact assessment for changes to IUCLID, Chesar, the CSR and REACH guidance documents to strengthen and clarify the use description. She has experience in private sector projects working with multinational companies and industry associations to develop impact assessments in relation to REACH restrictions and availability of biocides. She has successfully managed large projects and overseen the registration of dozens of dossiers under REACH. She has also developed the environmental hazard assessment and REACH registration strategies of CMRs, reprotoxins, UVCBs, amongst others, and has a good understanding of CLP. Previously, she managed a consortium, led breakout sessions in workshops, developed surveys, conducted interviews and interacted with stakeholders on commercially sensitive as well as technically complex topics. She is mother tongue English and Italian and has conversational knowledge of French and Spanish.

Dave Fleet (DF) has more than 15 years consulting experience and holds BA Hons and Masters degrees in Economics from Cambridge University, UK. He has worked as a Technical Director and Principal Consultant at RPA for 11 years and leads RPA's impact assessment and evaluation work at RPA with his extensive experience in conducting economic analysis and skills as a project management practitioner and trainer. David possesses strong skills in socio-economic assessment, regularly applying a range of techniques including cost-benefit and cost-effectiveness analysis to monetise the impacts of policies, and has developed intervention logics and theory of change analyses in collaboration with Commission staff and other clients. He is fully familiar with the EU's Better Regulation guidelines, having applied them in a large number of studies, and has regularly used the Commission's Standard Cost Model, competition assessment tools and assessed impacts on SMEs.

David has managed a large number of study projects for the Commission as well as for other clients. In 2015-16 was Project Manager for DG GROW's Supporting study for a Fitness Check on the Construction Sector – The Second Phase on EU Environment, Health and Safety Legislation. Previously, he was Project Director for the EC Impact Assessment Study concerning the Charging of Electric Vehicles and Co-Project Manager for the EC study on the Harmonisation of mobile Phone Chargers (DG Enterprise & Industry), as well as Project Manager for the study on the potential of impact assessments to support environmental goals in the context of the European Semester for DG Environment. He also worked on RPA's contribution to the Interim Evaluation of the Activities under the Secure Societies Challenge under Horizon 2020, providing an analysis on the overriding situation in the EU regarding the challenges faced in different security areas over the period covered by FP7 and the design and implementation of H2020 security research themes.

Julianne Oakley (JO) is a researcher at RPA. Julianne graduated with BSc degree in Chemistry and Forensic Chemistry from the University of Rhode Island in 2016. Prior to joining RPA in 2022, Julianne gained five years professional experience working as a laboratory supervisor for Barley Chalu and as an analytical chemist at GSM Metals. Julianne has extensive knowledge in the field of assaying precious metal alloys and has experience of the management, testing and routine maintenance of

chemical pre-treatment lines and wastewater effluent streams. Since joining RPA, she has contributed to multiple projects delivering desk-based literature research and focusing on socio-economic assessments of a potential PFAS restriction.

Walton Mabuto (WM) joined RPA Ltd as a researcher in February 2022. He is an economist at RPA with an in MSc Economics and International Relations from University of East Anglia, he also has a BA (Hons) in Economics for Business from the University of Derby. Prior to his studies, Walton worked as a Bookkeeper for TaxAssist Accountants where he was responsible for bookkeeping and tax advice. During his studies, Walton worked as Business analyst for InniAccounts LTD, a fintech firm, where Walton helped to modernise the business. Prior to the COVID-19 pandemic, Walton was enrolled in Enterprise Rent a Car's Graduate Management Trainee programme. Since joining RPA, Walton has been conducting market research as part of a project for the Department for Business, Energy & Industrial Strategy (BEIS), the project aims to identify the size and overview of the market, the supply chain structures and to provide an overview of how technical information and data flows in each tier of the supply chains process. Walton is also currently working on the socio-economic analyses of the Aerospace and Defence Chromates for Reauthorisation first tranche of renewal applications for authorisation of uses related to chromium trioxide, sodium chromate, sodium dichromate, potassium dichromate and dichromium tris(chromate) for both UK and EU REACH.

Copies of the team members CVs are available on request. In the unlikely event that a team member is unavailable, there are several alternative colleagues within RPA of equal or greater experience that could take the place of the team member. Assistance for this project will also be given by **David Lever (DL),** a principal consultant in the chemicals team, **Nasir Hussain (NH)**, a senior economist, and **Daisy Copping (DC2)**, a researcher economist.

3.2 Costs

Table 3-1 sets out the costs for RPA to conduct the proposed work coming to a total of €**85,900** over **136 workdays**.

These costs and time spend are presented into the individual work packages a part of this project in the table below.

A line for RPA project contingency budget has also been added and represents extra days that may be needed if tasks do not run to time. This contingency budget will not be charged without confirmation from ESA and will only be required in the event that tasks significantly exceed their expected timeframes. Further discussions on the contingency budget would be welcome in subsequent meetings.

VAT will not be charged. Costs do not include travel and meeting expenses (it is assumed that all meetings will be held remotely). Based on the proposed timeline, it is proposed that 40% of the costs will be invoiced shortly after project kick-off and the remaining 40% of costs will be invoiced after submission of the draft final report and the remaining 20% following submission of the final report in Task 4.

Table 3. 1 Cost and time

Team member	**David Carlander**	**Robert White**	**Gillian Federici**	**David Fleet**	**Walton Mabuto**	**Julianne Oakley**	
Level	Director	Consultant	Senior Consultant	Technical Director	Researcher	Researcher	
Rate	€ 1,650	€ 600	€ 700	€ 1,150	€ 450	€ 450	**Total**

Task 1 Kick-off meeting	1	2				1	**4**
Task 2 Data collection	3	15	2	2	10	20	**52**
Task 3 Analysis	3	15	2	4	10	10	**44**
Task 4 Reporting	3	10	2	1	10	10	**36**
Total days	**10**	**42**	**6**	**7**	**30**	**41**	**136**
Total cost	**€ 16,500**	**€ 25,200**	**€ 4,200**	**€ 8,050**	**€ 13,500**	**€ 18,450**	**€ 85,900**

3.3 Timeline

3.3.1 August 2023 delivery

The suggested timeline is based on the assumption that ESA is aiming to submit information developed in the SEA to the ECHA consultation that is expected to start in February 2023, and run for six months until August 2023. Overall, this would allow approximately eight months to conduct the project in (January to August 2023).

In relation to the August deadline, it is essential that the consultation phases of the study is conducted in a timeframe allowing for data to be gathered to fill any gaps which may occur, resulting in a stronger overall SEA.

Further discussions of the above timeframe should take place in subsequent meetings and be decided on no later than at the kick off meeting. An overview of the indicative timelines is provided in Table 3-2.

Table 3-2: Indicative timelines

Task	Working Period 2023
	Jan Feb Mar Apr May Jun July August
Task 1: Kick-off teleconference	
Task 2: Data collection	
Task 3: Analysis	
Task 4: Reporting	Consultation submission
Planned meetings	

Once submitted, this proposal (including its approach, costs and timings) will be valid until 15 December 2023.

//END

Annex 1 Past SEA and compliance projects conduct by RPA

The following table A1-1 highlights a range of past SEA projects RPA has conducted.

Table A1-1: Past chemical SEA experience		
Client	**Legislation**	**Project**
ECHA	REACH	RPA provided socio-economic analysis (SEA) training to ECHA
Industry Association	EU chemicals legislation	RPA performed a socio-economic impact assessment study for an industry association covering its sector's activities. The report highlighted the sectors contribution to European society
European Commission	Occupational Health and Safety legislation	As part of four projects for DG Employment, RPA collected information for substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments to occupational health and safety legislation including, the Chemical Agents Directive (CAD) and Carcinogens or Mutagens at work Directive (CMD). The studies involved extensive stakeholder consultation across the EU, desk-based research and an assessment of the cost and benefits
European Plastics Converters	REACH – Authorisations	RPA prepared a detailed socio-economic assessment of the impact of the "Potential Restrictions on Four Phthalates" on the Recycling of PVC waste and an SEA to support Applications for Authorisation under the REACH Regulation
Reach Centrum/Acrylates Consortium	REACH – Authorisations	RPA provided analysis to support the consortium's response to the public consultation on the Hexmethylene diacrylate (HDDA) SVHC proposal
ECHA	REACH – Restrictions	Support in preparing a possible Annex XV dossier on the use of cadmium in plastics. The study involved consultation with stakeholders from both the pigment and plastic industries
German Government – UBA	REACH – Restrictions	RPA developed 'Best Practices' and Quality Standards for Socio-Economic Analysis for Restriction Proposals under REACH
Norwegian Environment Agency	REACH – Restrictions	RPA developed emission estimates, AoA and SEA supporting a restriction proposal for PFHxS and PFHxS-related substances. Additional global information was also produced to support the Stockholm Convention process for the same chemicals
Industry Association	REACH – Restrictions	RPA performed a preliminary Analysis of Alternatives for methanol containing screen washes and denatured alcohol. The findings provided by the industry consortium were used to inform RAC/SEAC's deliberations
RIVM	REACH – Restrictions	RPA provided support to RIVM (as the Dutch Competent Authority) in the evaluation of possible restrictions on Short Chain Chlorinated Paraffins (SCCPs). The work included a detailed analysis of current uses as well as a detailed socio-economic analysis of policy options based on various types of potential restriction
Industry associations and Authorities	Regulatory Management Option Analysis (RMOA)	RPA have performed RMOA for private clients to provide an impact assessment of the proposed CLH, one of these projects including a presentation of the analysis to the OECD. For a public sector client, RPA assessed and produced guidance for how RMOA could look, as well as the pros and cons of authorisation and restriction

The following table A1-2 highlights a range of past compliance projects RPA has conducted.

Table A1-2: Past compliance experience		
Client	**Relevant legislation**	**Project**
RIVM	REACH	Compile information on uses and emissions of PFAS monomers & polymers production and processing within the European Union and of PFAS's put on the European market via import to EU. A market analysis setting out the main PFAS used, alternatives for PFAS, main producers relevant for EU market and tonnages (grouped) including an environmental impact assessment, social impact assessment, data gathering description and main data gaps and limitations.
Private clients	REACH	Over the last two years RPA has supported several private clients with PFAS studies.
Private clients	REACH Authorisation	For several private clients RPA has successfully provided assistance in developing a strategy towards potential REACH authorisation obligations and in the preparation of the Analysis of Alternatives (AoA) and Socio-Economic Analysis (SEA) obligations as part of REACH Applications for Authorisation
Private clients	RMOA	Regulatory Management Option Analysis (RMOA) for substances with the aim to identify the best regulatory strategies for companies
Private client	EU chemicals legislation	Several projects covering supply chain mapping and review of Annex XIV substances conducted from 2016 to the present
ECHA	REACH	Review of registration estimations for the 2018 REACH registration deadline
Private client	BPR	Renewal of Active Substance Approval for substance under the Biocidal Products Regulation
Private client	OHS Legislation	Assessment of the compliance costs of a potential OEL for and substance and its compounds
Federal Environment Agency (Germany)	REACH	Study on intermediate uses of PetCo substances
Private client	EU chemicals legislation	Reporting on EU regulatory developments for EU clients and a major non-EU industry association
Private client	EU chemicals legislation	A short study that will evaluate and summarise the trends in EU chemical legislation that may impact an International Metals Association and their members. The presentation was delivered at a Science Task Force meeting, it included anticipated potential regulatory risks and opportunities within several areas of interest
European Environment Agency	EU chemicals legislation	To produce short, individual reports on the current and future regulatory status and regulatory processes relevant to a selection of substances covering over 45 pieces of EU Regulations and Directives describing chemicals
European Commission	EU chemicals legislation	Study on the regulatory fitness of the EU legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation

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