SOCIO-ECONOMIC ANALYSIS

Legal name of applicant(s):	A.L.P.A. -Azienda Lavorazione Prodotti Ausiliari S. p. A. Caffaro Industrie S.p.A.
Submitted by:	A.L.P.A. -Azienda Lavorazione Prodotti Ausiliari S. p. A.
Prepared by:	Danger&Safety s.r.l.
Substance:	Trichloroethylene (TCE), EC 201-167-4, CAS 79-01-6
Use title:	Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers
Use number:	1
Report status	Public Report
Report date	05/10/2014

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DECLARATION

We, A.L.P.A. -Azienda Lavorazione Prodotti Ausiliari S. p. A., request that the information blanked out in the "public version" of the Analysis of Alternatives is not disclosed. We hereby declare that, to the best of our knowledge as of today (15/10/2014) the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature:

Date, Place:
15/10/2014

20010 Pregnana Milanese – Milano (ITALY)

FABIO ZAPPETTINI QUALITY RESPONSIBLE

LIST OF ABBREVIATIONS

AfA	Application for Authorisation
ATEX	ATmosphères EXplosibles (1999/92/EG & 94/9/EG)
CAS	Chemical Abstracts Service
CBA	Cost Benefit Analysis
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
CSR	Chemical Safety Report
DU	Downstream User
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
ES	Exposure scenario
EU	European Union
LE	Legal entity
LoA	Letter of Access
LR	Lead Registrant
OC	Occupational Condition
PPE	Personal Protection Equipment
PPM	Parts Per Million
RAC	Risk Assessment Committee
RCR	Risk Characterization Ratio
REACH	Registration, Evaluation, Authorisation & restriction of CHemicals
RMM	Risk Management Measures
SVHC	Substance of Very High Concern
SEA	Socio Economic Analysis
TCE	Trichloroethylene

1. SUMMARY OF SOCIO-ECONOMIC ANALYSIS

1.1. Executive summary

A.L.P.A. S.p.A. and Caffaro Industrie S.p.A. are applying for authorisation for the continued use of trichloroethylene (TCE) as a solvent in the synthesis of crosslinking agents for fluoroelastomers at their facilities. The aim of this report is to assess whether the socio-economic benefits of the applied for use of TCE outweigh the risks to human health and the environment.

A screening analysis of all impacts has been performed: human health, environmental, economic, social and wider impact have been analysed in their main points and the combined assessment demonstrates that the benefits to society of continuing this use of TCE outweighs the risks to human health and the environment. The applicants are therefore proposing a 10 year review period to evaluate if potential alternatives can be applicable. This should enable the company to find a valid substitute, if it would exist, and have the approval of the customers, as described in the Analysis of Alternative document.
The applicants will implement all described needing risk management measures (RMMs) to minimize emissions of TCE as described in the Chemical Safety Report (CSR)). For more than 20 years Research & Development (R&D) has focused on seeking an alternative solvent in order to have the same application properties with a less hazardous solvent. As a result of extensive research a limited number of possible alternatives have been identified which could lead to a suitable alternative being available within 10 years (see Analysis of Alternatives - AoA); up to now no valid alternative is available.
Authorisation would allow for the additional time needed to establish technical feasibility of the alternative through proper testing and implementation. It would also improve the economic feasibility of the alternative by allowing implementation to proceed while the applicants can produce and enter the potential market.

1.2. About the Applicants

1.2.1 A.L.P.A.

A.L.P.A. S.p.A. is a medium sized company with registered capital of € 1,040,000, focused on the Leather industry and specialized in providing specific solutions and services for the tanneries. In particular, the company develops and manufactures auxiliary products that cover all stages of leather processing. In 2013, the total value of sales 36,904,000 euro and exports (over 24 million euro) accounted for two thirds of the total. In Tuscany sales exceed 5 % of the national turnover. China and India are the driving forces and together reach 30% of the total turnover. A.L.P.A. share on the world market is of 1.2 %, 4,3 % in Italy

The Leather industry has developed in different countries. Italy is the undisputed leader in terms of fashion, quality and high technology, and is, with China and India, the largest producer. The Italian Leather industry has faced and will continue to face competition from countries in the developing world, with the following difficulties / disadvantages:

- 93 % of the raw material used is imported from outside Europe;
- Many countries in the developing world hold large part of the raw materials and apply protectionist policies;
- High cost "anti-pollution" (3-4 % of sales),
- High costs of labor and social costs;
- High global taxation;
- Strong Euro, which penalizes exports, compared with competitors, which are almost all in areas of weaker euro coins, however, and they tend to depreciate over time.

The recent global economic crisis has had serious consequences in the Leather industry and consequently for those companies involved in the production of "auxiliary products of the tanning sector."

A.L.P.A. suffered a strong impact, and on several occasions there have been staff reductions and from 2006 to 2014 there has been a reduction of organic from 76 to 42 units. (almost 50 %).

Given the nature of business and ethical values and management typical of small businesses where the relationship has a strong human component, a situation like the present leads to non-conservative investments but also investment in technology, therefore A.L.P.A. decided to evaluate new opportunities outside its traditional context for the following reasons:

- To avoid further staff reductions, due to the new economic difficulties due to declining sales
- Diversification of the business, to increase the chances of having a source of alternative income
- Technical Investment, to optimize the production from the qualitative point of view and increase the professionalism of the staff

Among the business priorities, A.L.P.A. always put the environmental protection as outmost priority. And it has developed production processes with low environmental impact.

In 1993, A.L.P.A. was the first Italian chemical company producing auxiliaries for the leather industry obtaining the ISO 9000 certification; the next step in the medium term is the acquisition of ISO 14000 certification.

A.L.P.A. has always pursued a “green” policy, using as much as possible products and clean technologies, for example by promoting water-based products and technologies or “metal free” tanning agents

The headquarters are located in Pregnana Milanese (MI), at a site of about 20,000 square meters. Production is divided into seven main types of products:

- Pre-dispersed pigments in water
- Casein binders
- Fat liquors
- Syntans (Synthetic tannins)
- Water based polyurethane resins
- Solvent based Dyes
- Compound and top finishing

The production site of A.L.P.A. is divided into 5 departments and 6 pilot plants that currently cover a productivity of 20,000 tons

1.2.2 Caffaro Industrie S.p.A.

Caffaro Industrie S.p.A. is one of the most important manufacturing company in the industry of fine and base chemicals in the North East of Italy with more than 25,000 tons of products per year. The company is placed in the industrial area of Torviscosa (Udine), founded in 1938 as a manufacturing site of SNIA VISCOSA. Here there are, in addition to the chlorination plants for the production of chlorinated paraffins (since 1998), the facility for the production of TAED (Tetraacetylethylenediamine) and fine chemicals and intermediates plants (multipurpose facility). The industrial complex covers an area of 1,205,000 square meters of which about 300,000 square meters belonging to Caffaro Industrie S.p.A. As it is today Caffaro Industrie has spare capacity for toll manufacturing in its fine and intermediates plant and the synthesis of the phosphonium salt contributes to saturate the productivity of the plant in order to ensure an increase in turnover and full employment.

Today, Caffaro Industrie employees in the Torviscosa plant are 143. The production is focused on two areas: the chlorination and the fine chemical / specialties areas.

Caffaro Industrie has a number of resources dedicated to toll manufacturing, taking advantage of the deep know-how acquired in over 70 years of experience and existing structures. Currently the area of fine chemicals is active in the production of ketones, esters, organic carbonates, surfactants as the granulation of TAED (Tetraacetylethylenediamine) and other specialties. The production capacity of this area is approximately 6,500 tons for the specialties and 5,000 tons for detergent products (TAED).

Over the years Caffaro Industrie specialized in the transfer of production processes from original producers into the site of Torviscosa. The process is highly personalized and consists of a series of steps, namely:

- technical assessment, feasibility transfer, chemical process
- sharing of know-how
- production and development in laboratory
- industrial scaling

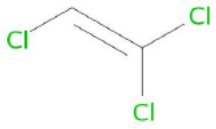
Currently Caffaro Industrie collaborate, through this mechanism, with some of the most important chemical companies worldwide.

1.3. About TCE

1.3.1 Chemical structure and properties

TCE is a non flammable liquid, with low water solubility and high vapour pressure. In Table 1 the main identification details:

Table 1. Substance identity

EC number:	201-167-4
EC name:	trichloroethylene
CAS number (EC inventory):	79-01-6
CAS name:	1,1,2-trichloroethene
IUPAC name:	1,1,2-trichloroethene
Annex I index number:	602-027-00-9
Molecular formula:	C_2HCl_3
Molecular weight range:	131.3883
Purity	99.9%
Structural formula:	

1.3.2 Known uses of TCE

The supporting final background document for TCE's inclusion on Annex XIV, ECHA (2011) reports that the registration dossier indicates that about 50,000 to 100,000 tonnes of TCE per year are manufactured or imported into the EU and no information on export is available. The larger part (volume) is used as an intermediate in the manufacture of other substances such as fluorinated compounds. According to disseminated registration information (ECHA 2011), the substance is still used in industrial settings in the following applications where opportunity of exposure arises:

- Formulation;
- Surface cleaning (closed and enclosed systems);
- Heat transfer (mainly in closed systems);
- Process chemical (e.g. in purification);
- Textile scouring;
- Adhesives; and
- Laboratory chemicals

According to the ECHA Annex XV report (2010), the major non intermediate use of TCE is for hot vapour degreasing of metal parts (surface cleaning) It is used for the removal of substances such as oils, greases, waxes and buffering compounds, or soils. The substance has high solvent power while not being flammable under working conditions. Closed systems, including closed supply and take) back systems in safety containers are today standard in some countries like Germany and Austria.

Given the small volumes purchased each year by the applicants, the main supplier of TCE [redacted].[1]

1.3.3 Regulatory status of TCE

TCE has been registered in 2010 for a tonnage band > 1000 tons/year by 5 companies and it has been included in the Authorisation list in the amendment of Annex XIV of REACH (Authorisation List), published on 18 April 2013 in the Official Journal. The sunset date has been established as 21/04/2016 and the latest application data at 21/10/2014. The Annex XIV entries for substances recommended for inclusion in Annex XIV may include a specific exemption for the use of the substance in product and process oriented research (PPORD) up to a defined quantity. The inclusion has been based on the recommendation of the European Chemical Agency (ECHA) of 20 December 2011 for the inclusion of substances in Annex XIV, due to its carcinogenic properties (category 1B meeting the criteria of Article 57 a). At the 22nd meeting of the Committee for Risk Assessment (RAC) in September 2012, the ECHA Secretariat presented a proposal to set DNELs and dose response relationships for substances prior to receiving applications for authorisation (AfAs). This was approved by RAC as a trial exercise and the document "RAC/28/2014/07 rev 2" was published on April 2014. The document concluded that due to the genotoxic potential trichloroethylene should be evaluated as a non-threshold carcinogen with respect to risk characterisation. As a consequence for this Application for Authorisation (AfA), the applicants submitted a CSR that demonstrate minimisation of emissions and also a Socio Economic Analysis as indicated in the guidance of Application for Authorisation, under the 'socio-economic' route.

1.4. About the USE

TCE is used by the applicants as solvent to produce an aminophosphonium salt used as crosslinker for fluoroelastomers. Fluoroelastomers are synthetic polymers designed for demanding service application in hostile environments, thanks to their resistance to flame, chemicals and oxidative attack. These are widely used when sealing capabilities in corrosive and high temperature environments are needed, as it is often the case in aircraft, automotive, aerospace, chemical, petroleum and energy industry. Their most important properties are related to the structure of the backbone (high bond energy of C-F bond) and to the crosslinking network. The fluoroelastomers are solid at room temperature and liquid when the temperature increases, for this reason they need to be crosslinked. The most common crosslinking system is the so called "Bisphenolic system" that includes an accelerating agent (generally phosphonium and amino phosphonium salts) and a crosslinking agent (generally aromatic polyhydroxylic compound, such as bisphenol AF). Amino phosphonium salts have been revealed the most performing substances because the fluoroelastomers articles produced by them exhibit an excellent resistance to permanent set and to compression, a minimum tendency to scorching as a function of the storing time and temperature or of the temperatures of particular processing technologies, such as for example the extrusion, and also a high resistance to thermal ageing; furthermore, they can be bonded to metal substrates of different types, to which they exhibit a considerable adhesion even at high temperatures. Besides the vulcanizable compositions, including the additives cited hereinbefore, do not give rise to tackiness or soiling phenomena of the molds, wherefore production rejections are practically absent, so allowing high production standards and highly regular processing cycles. (US Patent n°4,501,858)

The product PS (Phosphonium Salt) has been developed and it is used only by [redacted][2] as accelerant to crosslink a consistent part of its proprietary fluorinated rubber (brand name Tecnoflon) and will be produced at industrial scale by the two applicants A.L.P.A. S.p.A. and Caffaro S.p.A..

Other competitors use for their polymer curing other type of accelerants like $Ph_3(Bz)PCl$ (DuPont): PS is definitively more reactive in similar curing composition due to the presence of the [redacted][3] on Phosphorous atom. The performance has been established as the best one between all existing similar substances.

The project started in 2009 and involved an total investment of [redacted][4] of euro in Research & Development, and about 1 Mio of euro in industrialization

The fluoroelastomers are mainly used to produce fuel hoses, shaft seals, o-rings, diaphragms, etc, items primarily used in high end cars and in the aerospace industry, as said before thanks to their high performance. The automotive and aerospace end users, before introducing any items in their production line, are forced to homologate them.

Prior to marketing and sales of motor vehicles, automotive systems and their components need to have type approvals according to the official standards of their destination countries. These standards aim at improving active and passive car safety, environmental protection as well as the quality of products and production process. The approval process is very long and consists of several steps:

- Component approval (lamps, mirrors, tires etc)
- Component fitting to the vehicle (electric/electronic sub assemblies, car audio systems etc)
- System approvals (breaking, exhaust emission etc)
- Whole vehicle type approval (WVTA)

For each item, the European authority chosen by the manufacturer will issue a system approval according to each applicable directive. Those approvals are based on test reports prepared by an officially recognized testing organisation. Once all approvals are collected, the testing organisation issues the report for the approval as a basis for the homologation certificate.

Costs to homologate a new car are around [redacted][5] of euros and timing can go up to three years.

For this reason the end users, once obtained the approval of the finished items, are no longer willing to change any of the ingredients which form part of the finished item, since the replacement of only one of them, would result in a new approval and again very long time and additional costs. Besides if they are not supplied, they cannot use a different product without approval, which means the production lines blocked, with large economic loss and the risk of leaving workers without jobs.

1.5. SEA method

The SEA analysis has been performed according to the ECHA guidance on the preparation of a socio-economic analysis as part of an application for authorisation: data have been collected following the proposed check lists that recommend to:

- Identifying in-house expertise (skills);
- Identifying the relevant supply chain and individual contacts;

- Establishing contact and agreeing involvement with each key person;
- Organising a start-up/inception meeting or briefing;
- Developing a work plan based on the stages and steps as set out in this guidance;

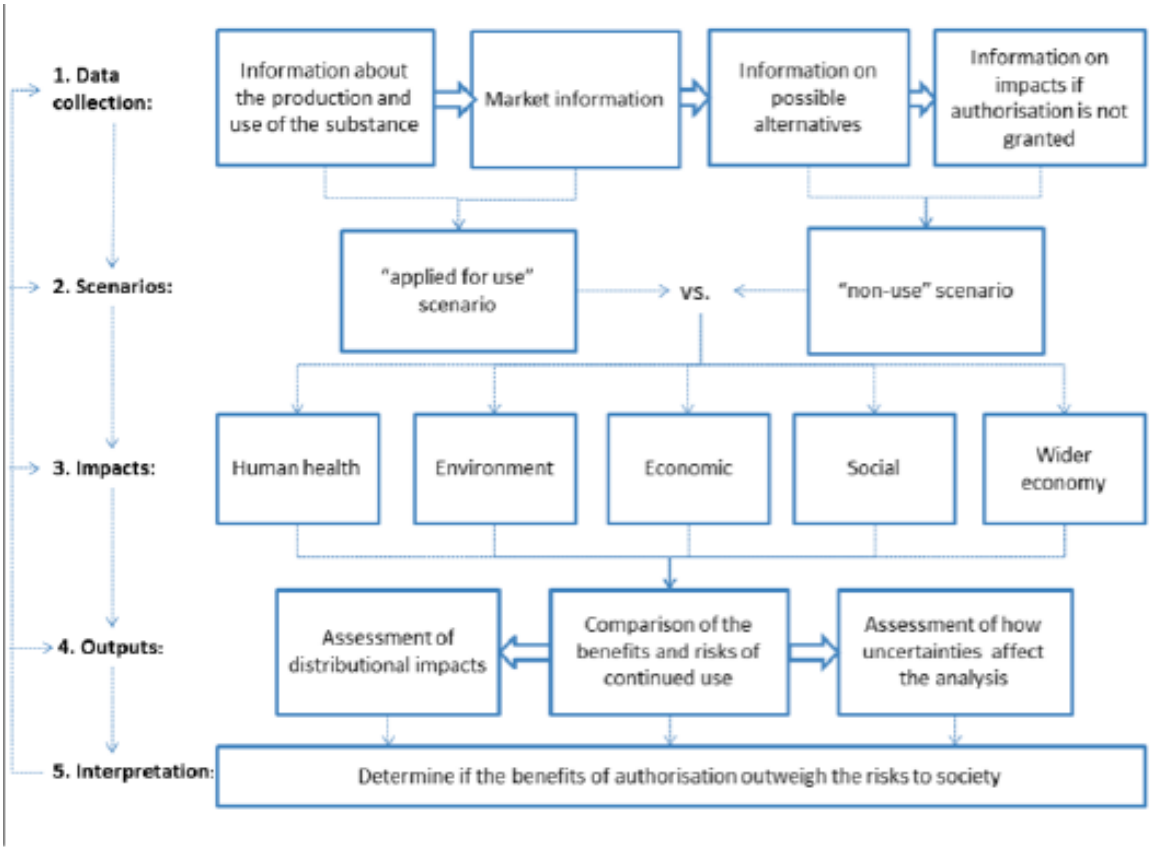
The primary source of information for the SEA has been information and data provided by the applicants and the customer who developed the product with surveys and physical meetings within the companies. This includes information relating to production and sales processes and market forecasts. This is supported by a confidential report provided by the [redacted] [6]. The report includes significantly relevant data on the automotive market and competitors. The net impacts are assessed in accordance with ECHA (2011b) SEA guidance.

Several impacts were identified in an initial screening process (See Section 4.2) and significant impacts have been assessed in detail in Section 4.

Finally, a cost benefit analysis (CBA) has been performed (section 5), and conclusions have been drawn

Where monetisation of impacts is possible, the results are presented in 2016 evaluation, at the time of the sunset date. The final comparison of costs and benefits is provided within a CBA framework. An overview of the SEA approach used is summarised in Figure 1 below (Authorisation SEA 'roadmap', September 2012, Nickel Institute).

Figure 7. **Practical overview on how to undertake an Authorisation SEA**



2. "APPLIED FOR USE" SCENARIO

2.1. Introduction

This chapter describes all steps of the supply chain from the manufacturer of TCE to the users of the final articles and the impact on all economical aspects of all stages. Finally, exposure assessment are summarized for workers, consumers and man via the environment

2.2. The supply chain

2.2.1 Manufacturer/Importer

The Manufacturer/Importer does not need authorisation, but if TCE will not be authorised for this use, the supplier in theory will lose a business or a market, therefore his market share has to be taken into account. In Europe TCE is produced only by few big players, that own the 80 % of the market share.

In the European Union, this solvent is produced by Dow Europe, Ineos Chlor and Chimcomplex Borzesti (Romania). Sales in 2006 in the EU 25 plus Norway, Switzerland and Turkey totalled 25,000 tonnes, down by 16.7% on 2005 sales (28,000 tonnes) and less than half the figure recorded in 2002 (52,000 tonnes)(ECSA, November 2011).

The 40 tons/year used by the applicants are about 1/1000 of the European production. With a price of [redacted][7] €, no influent on its business at all.

Furthermore it has to be considered that the product cannot be substituted at the moment and if it is not produced in Europe anymore for regulatory reasons, it will be produced not far, with no economical impact for the supplier.

Expected trend

No forecast available on market trend in case the product will be soon available on the market.

Due to the high performance it can be expected with a reasonable uncertainty that the actual quantities can double in a few years.

2.2.2 Downstream user 1: The applicants

The applicants are the first downstream user for TCE. As described in the introduction and in more details in other documents (Chemical safety Report and Analysis of Alternatives) they are using it as a unique solvent to produce a special crosslinker for fluoroelastomers with outmost applicative properties.

In fact the product PS (Phosphonium Salt) has been developed and it is used only by [redacted] [8] as accelerant to crosslink a consistent part of its proprietary fluorinated rubbers ([redacted]).

To build the plant for this production the following investment has been made by each applicant:

Table 2: ALPA investments [9]

Machinery	Material	volume in L	m^2	n°	value in K€
Reactor	enamel	[redacted]		1	[redacted]
Condenser	CSi		[redacted]	1	[redacted]
Tank	AISI 316	[redacted]		2	[redacted]
Filter plate	AISI 316	[redacted]	[redacted]	1	[redacted]
TCE tank	AISI 316	[redacted]		1	[redacted]
Vacuum condenser with liquid N_2	AISI 316	[redacted]	[redacted]	1	[redacted]
Chiller	AISI 316			1	[redacted]
Carpentry				1	[redacted]
Electrics				1	[redacted]
Piping + valves				1	[redacted]
Segregation system filter plate	Insulation panels			1	[redacted]
TOTAL (K€)					[redacted]

This investment and the production costs (raw materials, workers and maintenance) will be well compensated by the sales of the product.

The annual turnover of A.L.P.A. (about 37,000 k€), in the case of potential uses of trichlorethylene will changes significantly as production has been currently agreed with the customer from a minimum of [redacted] corresponding in terms of sales to a value ranging between [redacted] €.

These values will result in an increase in percentage of sales variable from [redacted] %.[10]

On these values, the margin ranges from [redacted]

To this it has to be added that together with the production of the crosslinker, also the production of the crosslinked polymer has been commissioned to A.L.P.A. In this respect further [redacted] € of investment have been made to set on the new reactor, which will also bring further profit to the company.

The impact on employment is not currently in consideration because the company is still trying to recover and to resist to the unemployment generated by the crisis and actually it would be more correct to define it as "consolidation of employment." The prospect of being classified as a "producer" by an international group as [redacted], for A.L.P.A. is an opportunity not negligible as [redacted] [11] has lately chosen a strong politic of " outsourcing of production" therefore the optimization of their production programs, puts us in a prime condition for obtaining other productions that will help in recover the investment could lead to interesting developments in all aspects both business related and employment related. The global situation of Caffaro Industrie S.r.l. is very similar. Caffaro Industrie has spare capacity for toll manufacturing in its fine and

intermediates plant and the synthesis of the phosphonium salt contributes to saturate the productivity of the plant in order to ensure an increase in turnover and full employment. The Caffaro investments amount to about [redacted], with a global income of about [redacted] / year. Based on the total income of [redacted] €, this project weights of about [redacted]

2.2.3 Downstream user 2: The first customer

As described before the product PS (Phosphonium Salt) for which TCE is used, has been developed and it is used only by [redacted] as accelerant to crosslink a consistent part of its proprietary fluorinated rubbers ([redacted]®). The Research & Development to finalise this process started in [redacted] [12] in 2009 and the Reaserch costs amount to [redacted] plus [redacted] [13] € of industrialisation costs. [redacted]s investments also involve the subsequent phase of homologation, that will be described in the next section, where the administrative workload for [redacted] [13b] consists of about [redacted] €. In return the sales for [redacted] of fluoropolymers produced with the use of PS amounted in 2013 at about [redacted] €, with a medium price for product of [redacted] €/Kg.

2.3. Automotive application

The fluoroelastomers are mainly used to produce fuel hoses, shaft seals, o-rings, diaphragms, etc, items primarily used in high end cars and in the aerospace industry, as said before thanks to their high performance. The automotive and aerospace end users, before introducing any items in their production line, are forced to homologate them. Prior to marketing and sales of motor vehicles, automotive systems and their components need to have type approvals according to the official standards of their destination countries. These standards aim at improving active and passive car safety, environmental protection as well as the quality of products and production process. The approval process is very long and consists of several steps:

- Component approval (lamps, mirrors, tires etc)
- Component fitting to the vehicle (electric/electronic sub assemblies, car audio systems etc)
- System approvals (breaking, exhaust emission etc)
- Whole vehicle type approval (WVTA)

For each item, the European authority chosen by the manufacturer will issue a system approval according to each applicable directive. Those approvals are based on test reports prepared by an officially recognized testing organisation. Once all approvals are collected, the testing organisation issues the report for the approval as a basis for the homologation certificate. Costs to homologate a new car are around [redacted] € and timing can go up to three years.

To have an overview of the impact of the homologations of articles produced with the [redacted] polymers, crosslinked with PS the following data can be considered:

Table 3. Costs for homologation [15]

Homologation costs per item (fuel hoses, shaft seals, o-rings, diaphragms, etc)	[redacted]
Number of different formulations produced with PS	[redacted]
Number of customers	[redacted]

Table 4: 2013 homologation cost analysis [16]

Customer	Formulation	item/formulation	€
1	[redacted]	[redacted]	[redacted]
2	[redacted]	[redacted]	[redacted]
3	[redacted]	[redacted]	[redacted]
Total small customers			[redacted]
Total costs for homologation			[redacted]

On the basis of these assumptions, it is estimated that the entire re-homologation of the items produced with PS is not less than [redacted] € formulated or 5 Mio €. Moreover, as the maximum value of the re-homologation (assuming [redacted] the mean number of items to be delivered) can be calculate as [redacted] €.

The point value estimated by 'analysis on customers is [redacted] €, with an average value of customer impact of [redacted] €.[17]

2.4. Risks from continued use

This exposure/risk assessment is generated in function of ALPA and Caffaro Industrie authorisation application dossier for the following use as downstream user:

– USE 1: Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers

Article 62.4(d) of REACH stipulates that the authorisation dossier shall contain a Chemical Safety Report (CSR) covering the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV, i.e. carcinogenicity Cat. 1B.

The complete analysis has been performed within the CSR, that focuses on the carcinogenicity endpoint, whereas in the Analysis of Alternatives (AoA) other endpoints are also considered for the comparison of potential alternatives.

In April 10, 2014 ECHA published the „Reference Dose Response Relationship for carcinogenicity of Trichloroethylene“13, which constitutes the opinion of the Risk Assessment Committee (RAC) that trichloroethylene is considered to be a non-threshold carcinogen. As a result, demonstrating adequate control is not possible and the SEA route is applicable.

The applicants, ALPA and Caffaro, performed the risk assessment in accordance to the Reference Dose Response Relationship as proposed by RAC.

In the CSR, the applicants demonstrate **minimization of emissions.** The related exposure levels are compared to the dose response curves provided by RAC, demonstrating minimization of risks for the uses applied for. The applicants demonstrate that the risks related to the continued use of TCE will be minimized as far as technically and practically possible.

In addition, the excess risk levels for the different activities have been ranked. The ranking of these excess risk levels is used solely in the context of evaluating the relative risks of the different activities described in the CSR. Based on this relative risk ranking, priorities for improvement and further minimization of emissions have been identified and implemented (or scheduled to be implemented before Sunset Date).

The applicants calculated the excess risk levels % for inhalation, dermal exposure and combined exposure for all performed activities indicating that the **maximum excess risk level is set at 4.324 $\times 10^{-3}$ %.**

Trichloroethylene is classified as a Chronic Aquatic Toxicant Category 3. This endpoint is not specified in Annex XIV of the REACH Regulation. Therefore the effects and risks to the environment resulting from the endpoint for water are not evaluated in detail. Nevertheless, in the context of exposure of "man via the environment" a detailed environmental exposure assessment was performed leading to the identification of excess risk levels for the general population. The overall tonnage taken into account for the exposure/risk assessment was 20 T/yr. The results of the environmental exposure and risk assessment indicate that **there is no risk to the environment as a consequence of the use of TCE for the described use.**

2.5. Possible changes or trends

The following possible changes or trends have been evaluated:

- Possible technological development that reduces or increases the need for the Annex XIV substance
- Future changes due to forthcoming legislation
- Future changes in demand for the end use product

Technological development

This is the focus of the Analysis of Alternatives: two possible scenarios can contribute to the reduction of the use of TCE: new products (new system crosslinker/polymers) will be developed with better performances by the customer or applicants R&D or by competitors or an Alternative solvent or solvent system will be found with the same properties, but a less demanding hazard profile. The process is still on-going, but the outcome will need to pass the homologation step and not less than 10-12 years will be necessary to have the new system implemented.

Future changes due to forthcoming legislation

Legislation about TCE developed with the time and no further development seem to be expected in the near future. Regarding local/national legislation the tendency is to go toward a more strict control within the companies and induce all chemical producers to officially apply regular controls

referring to external and/or national authority representatives. This will ensure that minimisation of emission will be implemented properly.
Between the alternative to be studied, the solvents without a classification as potential CMR (CMR cat 2) will be preferred to the others.

Future changes in demand for the end use product
Since the articles have an outmost performance, the end use sector is in continuous development (automotive) and the articles produced with this crosslinker already pass all the homologation process, the previsions are of sure increase of the demand, at least for the next 5-10 years, the timing for the competitors to generate similar performing systems and have them approved.

3. "NON-USE" SCENARIO

3.1. Introduction

To assess the possible "non-use"scenarios a screening of the possible impacts and reactions of the different actors along the supply chain, in case the use of TCE would not have been allowed anymore after the sunset date to the applicants, has been analyzed

This screening process is summarized here:

Table 5. Possible responses to a refused authorisation [17]

Supply chain	Possible response	Likelihood
Upstream suppliers	Shutdown production	**Very unlikely** - As set out in section 2.2.1, the volume of TCE supplied to the applicants is relatively small compared to other users of the raw material
	Reduce production	**Possible response by suppliers of the other raw materials involved** in the synthesis or connected services- If in fact no alternative is found and the production will be completely stopped, the impact will be also on the other raw materials suppliers, and services to the production
	No significant change in activity	**Likely for most suppliers** - The use of TCE in this application is really small compared to the other application and counts for 1/1000 of the total production. Furthermore it is possible that the production is moved outside Europe, but still very near and the TCE producers still go on in supply the same quantity to different companies
The applicants	Produce until the sunset date, then stop	**Likely for both applicants**. It will be too costly for the market to homologate a new product, unless it will demonstrate itself with higher performances respect to the existing or the market will not find a substitute in the competitors products. If there will be no available competitor solution the customer will delocalise production outside Europe, where no Authorisation is needing and production costs are lower. This will have as a consequence that the investment will not be recovered, the workers will be left without work and the development plan related to the new structure will fail.

	Produce until the sunset date, while finding an alternative solvent with major investment to adapt the plant	**Unlikely** - The Analysis of Alternatives demonstrated that no technically feasible or valid alternative is available for the time being, but also more research can be done to evaluate all existing possibility. In case the alternative exists that requires major modification to the plant after two years, the balance between those modification and the cost for the homologation of the new product is difficult sustainable, unless technical performances will highly overcome the previous ones.
	Produce until the sunset date, while finding an alternative solvent with minimal investment to adapt the plant	**Unlikely** - The Analysis of Alternatives demonstrated that no technically feasible or valid alternative is available for the time being, but also more research can be done to evaluate all existing possibility. In case the alternative exists that requires minor modification to the plant after two years, the balance between those modification and the cost for the homologation can be evaluated, but will always be so high that only higher performances or the contingent lack of competitor products on the market will make the sector go for this route
The customer	Support the ri-homologation of a new raw material	**Unlikely** - Costs for homologation are too high [redacted] either in terms of monetary costs and in terms of timing.
	Find a producer outside Europe	**Likely** - Even the possibility to invest in a new plant outside Europe and bear the logistic and administrative workload doesn't overcome the big investment already performed on homologation and the great added value in selling the product. Investments can be covered in two years
The automotive field	Invest on new ri-homologation	**Unlikely** - Costs for homologation are too high [redacted]) either in terms of monetary costs and in terms of timing. Only higher performances or the contingent lack of competitor products on the market will make the sector go for this route
	Use competitors products already homologated even if with less performances	**Likely** - It would be the best compromise for downstream users and the amount of investment involved in this field. This will really have serious consequences on the two subjects above, the applicants, and also the customer, who will lose a business of [redacted] €

The impacts (costs and benefits) associated with the most likely responses are assessed in Section 4.

It is important to note that the AoA shows there are presently no ‘suitable’ alternatives available to the applicant.

In the following the detail loss for the actors for which a likely scenario is proposed

4. ANALYSIS OF IMPACTS

4.1. Introduction

The analysis of impacts has been assessed in the following order:

- Human health and environmental impacts;
- Economic impacts;
- Social impacts; and
- Wider economic impacts (which includes trade, competition and economic development).

The assessment of impacts has been focused on the "non-use" scenario considering that the impact is not present in case of applied for use. The SEA is partly based on assumptions, projections and predictions about the likely behavioural response of actors in relevant supply chains, on their future usage (of the substance or an alternative substance) and the significance of each impact under the relevant scenarios.
The assessment of the health and environmental impacts of the reduced/abandoned manufacture, use or placing on the market of the Annex XIV substance under the "non-use" scenario will mean, in the first place, reduced adverse effects caused by that substance. The starting point for assessing these impacts have been information contained in the applicant's CSR.
Economic impacts comprise the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole. "Net costs" have taken into account additional costs to actors if an authorisation is not granted and possible costs caused by the transfer to alternatives. Social impacts are taken to include all relevant impacts which may affect workers, consumers and the general public that have not been analysed under human health and environmental impacts and economic impacts.

4.2. Identification of impacts

Human health

Table 6 lists the main types of human health impacts expected, based on the most likely responses to a refused authorization (as set out in Section 3). Only the main impacts are assessed in detail within the SEA

Table 6. Screening of human health impacts

Supply chain	Potential impact	Significant	Reasons
Applicants worker exposure	Exposure to TCE	**Yes**	This is the reason why TCE has been put into the Authorisation list, therefore it is the first impact to be assessed
General population around the site	Exposure to TCE	**Yes**	Man via the environment has been assessed since TCE has been placed on the Authorisation list for its risks to human health
Consumer	Exposure to TCE	No	Final products as well as resulting articles are completely free from TCE, therefore no exposure is possible and the assessment is not applicable

Environment

Table 7 lists the main types of environmental impacts expected based on the most likely responses to a refused authorization (as set out in section 3). Only the main impacts are assessed in details within the SEA

Table 7. Screening of environmental impacts

Supply chain	Potential impact	Significant	Reasons
Applicant production	Reduction of TCE in air emissions	No	Despite the low risk profile, the classification as Aquatic Chronic 3 imposes to maintain the emission level as low as possible, below the permitted limits. This will actually not have an impact, since the companies already run a number of productions which require this emission control if not much worse
	Reduction of TCE in water emissions	No	There are no emission into the wastewater
	Reduction of TCE in soil emissions	No	There are no emission into the soil
	Reduction in physico-chemical risks	No	Since TCE is not classified for physico-chemical hazards
	Impact from alternative process	**Yes**	Despite not technically satisfactory, some alternatives can be used, but they will require more energy (longer distillation process) or more risk (flammable substances). No quantification is possible up to now

Economic

Table 8 lists the main types of economic impacts expected based on the most likely responses to a refused authorization (as set out in Section 3). Only the main impacts are assessed in detail within the SEA

Table 8. Screening of economic impacts [19]

Supply chain	Potential impact	Significant	Reasons
Raw material supplier	Low sales/profit of TCE for [redacted]	No	As demonstrated in section 2.2.1 the impact of this use on the total production has a 1/1000 of incidence
Applicant	Change in operating costs (stop production, then time, energy consumption)	**Yes**	Applicants will stop production until a valid alternative is found
	Change in operating costs (modify production, then time, energy consumption)	**Yes**	Applicants will increase costs of production in case an alternative is used
	Change in capital costs (non used equipment)	**Yes**	The equipment is not used and the investment is not recovered
	Change in capital costs (new equipment)	**Yes**	New investments have to be made in case of alternatives
	Change in sales revenue/profit	**Yes**	Sales will stop and revenues/profit will be set to zero

	Changes in employments	**Yes**	Stop production will generate unemployment for the people dedicated to the plant
	Changes in trends	**Yes**	This production is like an approval and scouting production that will allow the customers in developing more new products and with high added value with the applicants
Customer	Change in costs for R&D	**Yes**	A lot of new investments will be needed in R&D to find suitable alternatives
	Loss of the market	**Yes**	Giving time to competitors or ask for new homologations can involve the loss of the market for this kind of fluoropolymers
Final users	New investment in ri-homologations	**Yes**	Any alternative will need to be ri-homologated unless they will use already approved products from competitors

Social

Table 9 lists the main types of social impacts expected based on the most likely responses to a refused authorization (as set out in Section 3). Only the main impacts are assessed in detail within the SEA

Table 9. Screening of social impacts

Supply chain	Potential impact	Significant	Reasons
All	Changes in employment at an EU level	No	The employment at risk are the applicants workers
All	Any likely to be changes in employment outside of the EU	No	
Applicants	Are there any likely to be changes in employment at a MS level	**Yes**	It will contribute to the unemployment tendency within the specific member state

Wider

Table 10 lists the main types of macroeconomic impacts expected based on the most likely responses to a refused authorization (as set out in Section 3). Macroeconomic impacts refer to any responses by the applicant that could result in noticeable impacts in EU level. Some impacts listed below, even if in a qualitative manner, can be considered of great importance in respect to others listed before.

Table 10. Screening of macroeconomic impacts

Potential impact	Significant	Reasons
Changes to competition within the EU. (e.g. changes in the number of products available to downstream users and consumers)	No	Just the customer will be affected, but competition will still high and the available products to the consumer will not change
Changes to competitiveness outside of the EU. A refused authorisation will give an advantage to manufacturers outside of the EU.	**Yes**	At the crosslinker (applicant) producer level
Changes to international trade. (e.g. trade flows between EU and non-EU countries)	No	International trade will no sensibly affected
Changes in investment flows. Customer will decide to locate the supplier outside of the EU	**Yes**	At the crosslinker (applicant) producer level
Changes to the labor market. Specialist skills, job migration outside of the EU	**Yes**	The production of the cross linker is a high quality production, bound with patented applications and a specific high level plant conduction. Those skills will be transferred outside Europe

4.3. Human health impacts

As described in the CSR, applicants workers are potentially exposed to minimal levels of TCE mainly during the transfer operations, which would either continue in the applied for use scenario or cease in the non-use scenario. To estimate the value of the associated health impacts, dose response relationships, developed in April 2014 by the RAC of ECHA, are used. The assessment is based on there being no threshold for effects of TCE for renal (kidney) cancer using a presumed exposure of 8 hours per working day over a working life of 40 years.

Table 11 summarizes the range of estimated impacts using ECHA's dose response relationship. These are modeled based on inhalation and dermal exposure of TCE for the applicants workers. It shows that the total value of impacts on workers are estimated to be up to [redacted]8, with a best estimate of between €[redacted] [20]

Table 11: Summary of the estimated total value of worker health impacts of TCE exposure [21]

Sensitivity analysis	Description	Low estimate (€)	High estimate (€)
Best estimate	Based on the actual situation	[redacted]	[redacted]
Sensitivity 1	This assumes that the excess risk is pro-rated to reflect the 10 years assessment period	[redacted]	[redacted]
Sensitivity 2	This assumes that any possible cancer is fatal	[redacted]	[redacted]

Note: all prices have been reported to 2016 prices considering the Harmonized Indices of Consumer Prices and the fact that the ECB defines price stability as an annual increase in the HICP for the euro area of close to but below 2 %, therefore a representative value of 2 %/year has been considered to report all prices to 2016

In the following the explanation of the calculations.

4.3.1 Types of health impacts relevant from TCE exposure

A very good review of the epidemiological studies has been prepared and published by the Germany Federal Institute for Occupational Safety and Health (BAuA) and their Committee on Hazardous Substances (AGS) (BAuA – "The risk-based concept for carcinogenic substances developed by the Committee for Hazardous Substances - From limit-value orientation to an action-oriented approach". And – "Exposure-risk relationship for trichloroethylene in BekGS 910").

The report analyses all the previous toxicological literature and the relevance in three cancer forms: renal cancer, hepatic cancer and non-Hodgkin lymphomas (NHL)and concludes that Supported by a unit risk based on epidemiological data; uncertainty whether TRI is a hepatic carcinogen for humans, as well as it is uncertain the TCE induces NHL in human.

Therefore only the renal cancer will be considered within the scope of the assessment

4.3.2 Excess risks of developing renal cancer from TCE exposure

Exposure-risk relationships (ERR) are established by the Committee on Hazardous Substances (AGS) and published by the Federal Ministry of Labour and Social Affairs (BMAS) in the Technical Rule for Hazardous Substances 910 "Risk-related concept of measures for activities involving carcinogenic hazardous substances" (TRGS 910). This approach is well consistent with the document developed by RAC, where the excess risk has been estimated as percentage excess cancer risk per unit of concentration

The non-linear equation for inhalation exposure risk is set in a tiered way as follows:

- Excess risk (%) for the first 6 ppm = 0.0067 x concentration (ppm)
- Excess risk (%) for the range of ppm beyond 6 ppm = 0.0720 x concentration (ppm)

Due to lack of valid data for dermal absorption rates, ECHA applied a "route – to – route" extrapolation from worker inhalation to dermal exposure.
From worker inhalation to general population inhalation different factors such as duration of exposure and breathing volume of the person were taken into account for the derivation of the inhalation dose response curve.
For extrapolation from the worker inhalation dose response curve to the oral general population dose response curve duration of exposure was taken into account in combination with a "route-to route" extrapolation.

As a result the following is derived for dose/response relationship:

Inhalation exposure

Workers

At 33 mg/m^3 and above:
Excess risk = 1.3 × 10^{-4} (mg/m^3)$^{-1}$ × concentration (mg/m^3) – 0.0039

Below 33 mg/m^3:
Excess risk = 1.2 × 10^{-5} (mg/m^3)$^{-1}$ × concentration (mg/m^3)

General population

At 6.2 mg/m^3 and above:
Excess risk = 6.9 × 10^{-4} (mg/m^3)$^{-1}$ × concentration (mg/m^3) – 0.0039

Below 6.2 mg/m^3:
Excess risk = 6.4 × 10^{-5} (mg/m^3)$^{-1}$ × concentration (mg/m^3)

Dermal exposure

Workers

At 4.72 mg/kg bw/d and above:
Excess risk = 9.09 × 10^{-4} (mg/kg bw/d)$^{-1}$ × dose (mg/kg bw/d) – 0.0039

Below 4.72 mg/kg bw/d:
Excess risk = 8.4 × 10^{-5} (mg/kg bw/d)$^{-1}$ × dose (mg/kg bw/d)

General population

At 2.05 mg/kg bw/d and above:
Excess risk = 2.09 × 10^{-3} (mg/kg bw/d)$^{-1}$ × dose (mg/kg bw/d) – 0.0039

Below 2.05 mg/kg bw/d:
Excess risk = 1.9 × 10^{-4} (mg/kg bw/d)$^{-1}$ × dose (mg/kg bw/d)

4.3.3 Risk for applicants workers to develop cancer

The excess cancer risk for workers on the applicants sites as a result of inhalation and dermal exposure to TCE has been calculated within the CSR (Conclusions, Table 35)

Table 12. Excess risk level for combined exposures

Exposure pattern	Excess risk level
Man via Environment (Inhalation + Oral)	**4.34 ×10^{-6} %**
PROC 8b (TCE transfer)	**5.7 ×10^{-4} %**
PROC 1 (Synthesis)	**3.01 ×10^{-4} %**
PROC 15 (Sampling)	**2.218 ×10^{-4} %**
Combined	**4.324 ×10^{-3} %**

Therefore the additional renal cancer cases are calculated multiplying the excess of risk for the number of exposed workers (4 workers)

Additional renal cancer cases = 4.324×10^{-5}* 4 = **0.00017296**

The final result corresponds to the number of additional cancer diagnoses from a working lifetime exposure of 40 years. From this calculation continued use even for a working life-time exposure of 40 years, is not expected to result in a very low risk of cancer diagnoses (1/10000).

4.3.4 Evaluation of the additional cancer diagnosis

To monetize the cancer diagnosis it is has been assessed the probability that cancer is going to be fatal or non-fatal, as they are valued differently from a monetary point of view. Data on Italy-specific incidence, for kidney tumor, focused on males were obtained from the IARC database (http://globocan.iarc.fr). The probability that a cancer is fatal for males is 36 %, therefore 64 % are non fatal.

A review of literature sources provides different valuation for a statistical life that can be applied and the followings are taken as a reference:

Table 13. Values for preventing a fatal cancer

Source	Value (in 2016 prices, Mio€)
EC (2000). Recommended Interim Values for the Value of Preventing a Fatality in DG Environment Cost Benefit Analysis	2.08 (1.360-05.21)
OECD (2012). Mortality risk valutation in environment, health and transport policies	3.60 (1.80 – 5.40)

As a consequence the following two values for minimal and maximal estimate are considered:

- **Low estimate: 1.360 Mio€**
- **High estimate: 5.40 Mio€**

The economic value of reducing the risk of non-fatal cases is much smaller than that of reducing the fatal risk and it is more related to the Willingness To Pay and a number of cost voices related to the medical costs, absence from the working place and so on. The reference evaluation is the HSE (Health and Safety Executive) uplifted to 2016 estimations to be consistent with the previous estimations and it amounts to €362,509.

Based on the monetized values for fatal and non fatal cancer registrations, the process of estimating the value of the impacts of workers exposure to TCE is the following:

% of fatal cases * value of fatal case (minimum/maximum) + % of non fatal case* value of non-fatal case = Benefit of preventing cancer

The results are reported in table 11

4.3.5 Man via the environment

Based on table 12, the excess risk level for men via the environment is 4.34 $\times 10^{-6,}$ three order of magnitude below the excess risk level for workers. It means that up to 1000 people potentially exposed the value of the estimation is the same than for workers.

Reporting the excess risk estimated for workers on a 40 year timeframe to a 70 years the following additional estimation can be performed:

Table 14. Estimated total value of men via the environment health impacts of TCE exposure

Description	Low estimate (€)	High estimate (€)
Estimation based on the on the actual situation reported to 70 year	218.42	658.63

4.4. Environmental impacts

Trichloroethylene is classified as a Chronic Aquatic Toxicant Category 3. This endpoint is not specified in Annex XIV of the REACH Regulation. Therefore the effects and risks to the environment resulting from the endpoint for water are not evaluated in detail. Nevertheless, in the context of exposure of "man via the environment" a detailed environmental exposure assessment was performed leading to the identification of excess risk levels for the general population. The overall tonnage taken into account for the exposure/risk assessment was 20 T/yr.

The emission levels are minimized and there is no release to the water and to the soil. The results of the environmental exposure and risk assessment indicate that there is no risk to the environment as a consequence of the use of TCE for the described use.

TCE is not classified for physicochemical hazards, being a non-flammable solvent. It has to be noticed that between the potential alternatives that will be evaluated (Analysis of Alternatives) there are two categories for which an environmental impact has to be considered:

- High boiling point substances (longer distillation timing, higher energy consumption)
- Flammable substances (higher risk for the environment)

The overall impact cannot be quantitatively estimated since a valid alternative has not been identified yet.

4.5. Economic impacts

In case after the sunset date the Applicants must cease their use of TCE, two different scenarios are evaluated:

1. **Scenario 1: Stop production (the customer will bring the production outside Europe)**
2. **Scenario 2: An alternative is found**

The two scenarios have two very different economic impacts

4.5.1 Investment and sunk costs

Investment costs refer to the purchase of capital equipment such as plant and machinery. 'Sunk costs' refer to investments which have already been paid for, and cannot be recuperated by selling the investment. Thus, sunk costs no longer figure in the decision making process of the company. For example, once an unpatented product is brought to the market, research and development costs are sunk costs.

While for scenario 1 the impact is just the loss of the investment made for the plant (about [redacted] € minus the quantity repaid in the two years 2014-2016 until the sunset date), scenario 2 will be possible with a big global investment in R&D, industrialisation and ri-homologation (about [redacted]€):

Table 15. Investment and sunk costs [22]

Investment and sunk costs		
	Scenario 1: Stop production (Mio €)	**Scenario 2: Valid alternative (Mio €)**
Change in innovation and R&D costs		[redacted]
Change in performance testing costs		[redacted]
Change in equipment costs	[redacted]	
Change in modification costs		[redacted]
Change in general site and operations costs	[redacted]	[redacted]
Equipment down-time costs		
	[redacted]	[redacted]

4.5.2 Operating and maintenance costs

In case of scenario 1 all the costs will be zeroed; an estimation of the operating costs is of a total from [redacted]€/year, instead will surely vary in direct proportion to changes in output, such as raw materials, components, labour and energy used in manufacturing (i.e. variable costs), but there will also be fixed operating costs.
The implementation of a new technique can lead to changes in the production process, which might lead to increasing costs, for instance, a reduction in system effectiveness or inferior product quality. A clear assessment cannot be performed yet since a technical valid alternative has not been identified.

Table 16. Operating and maintenance costs [23]

Operating and maintenance costs		
	Scenario 1: Stop production	**Scenario 2: Valid alternative**
Change in electricity costs		Not evaluated yet
Change in petroleum products costs		Not evaluated yet
Change in auxiliary costs, such as chemicals, water		Not evaluated yet
Change in environmental service costs, such as waste treatment and disposal services		Not evaluated yet
Change in operating costs, supervisory costs and maintenance staff costs		Not evaluated yet
Change in training costs of the above staff.		Not evaluated yet
Change in sampling, testing and monitoring costs		Not evaluated yet
Change in insurance premium costs		Not evaluated yet
Change in marketing costs, license fees and other regulatory compliance activities		Not evaluated yet
Change in emergency provision costs		Not evaluated yet
Change in other general overhead costs (e.g. administration)		Not evaluated yet
TOT	[redacted]	

4.5.3 Revenues, avoided costs and benefits

Revenue refers to value received in the market for the quantity of the product sold. Scenario 1 can be well identified in the total loss of the potential revenue coming from selling the product at the agreed market price with the customer (from [redacted]€). The potential implementation of a new technique (scenario 2) will lead to changes in the production process, but it would be very difficult that the alternative could bring lower costs, for instance, a rise in system effectiveness or improved product quality.

Table 17. Revenues, avoided costs and benefits [24]

Revenues, avoided costs and benefits		
	Scenario 1: Stop production	**Scenario 2: Valid alternative**
Change in sales	[redacted]	Not evaluated yet
Change in production efficiency / downtime		Not evaluated yet
Change in interest on working capital		Not evaluated yet

4.5.4 Others

Two further considerations have to be taken into account, even if it not possible to quantify yet.

For the applicants this production is like an approval and scouting production that will allow the customers in developing more new products and with high added value with the applicants. As can be in fact seen by the number of scheduled batch and timing for production, the plant will not be

at a full usage. Such a plant presents the big advantage to have the possibility to work in completely close process, with nitrogen pulmonation, with complete emission control, with distillatory. A number of high value process can be studied to fill the plant capacity with high value products.

Finally it has to be considered that in market like Automotive, with the very highly required quality standards and high investment, it is very easy that generating a problem will have as a consequence that the complete business of those fluoropolymers will be completely lost in favour of the competitors (actually very skilled big companies like Du Pont/ Daikin / Dyneon). The business bound to polymers for which PS is used is actually of about [redacted] €.[25]

4.6. Social impacts

The scenario for which a social impact is to be noticed is the “non-use” scenario without alternative, if the production is re-located outside EU. The affected subjects will be the applicants, while skilled people who can be relocated in the new production plant will not be taken from the applicants, but from the R&D and development group within [redacted] , the exclusive customer.[26]

For the applicant side it can be reported here the data already reported in section 2.2.2: the companies are still trying to recover and to resist to the unemployment generated by the crisis and actually it would be more correct to define it as "consolidation of employment."

Both companies, for different reasons, suffered a strong impact for the economical crisis, and on several occasions there have been staff reductions.

The prospect of being classified as a "producer" by an international group as [redacted], is an opportunity not negligible as [redacted] has lately chosen a strong politic of " outsourcing of production". Therefore the optimization of their production programs, puts the applicants in a prime condition for obtaining other productions that will help in recover the investment and it could lead to interesting developments in all aspects both business related and employment related.

Actually it has been estimated that the implementation of the project bound to the production of PS can relocate between 10 to 15 persons for the two plants and the development of new projects bound to the success of this one can estimate for other 10 units.

4.7. Wider economic impacts

For what it concerns wider economic impacts the followings can be taken into considerations:
In case of non use scenario and also no possibility to outsourcing outside Europe, or even in case this will have a delay due to reassessment of the production overview, this will have a great impact on the competition process. [redacted], in fact, with the crosslinker and the system “polymer/crosslinker” is in a market with very high competitiveness. Competitors like Daikin or Du Pont have already their alternatives proposed on the market. It is highly possible that a delay in providing the product to the market will give the competitors the possibility to better establish their systems, even if possible with less technical performances.
Furthermore the disappearing of a competitor on the market will bring the remaining in having the possibility to make higher prices

In the case of outsourcing outside EU both elements have to be considered: the investment flow will be directed outside Europe (and this element has already been considered in the economic impacts), but also the skills are bought outside Europe, in another country. Not only because skilled labours will be transferred in the new plant temporarily, but because further people will learn how to conduct a critical synthesis with high added value, determining an external flow of expertise.

5. COMBINED ASSESSMENT OF IMPACTS

5.1. Comparison of impacts

Table 17 summarises the key benefits and risks associated with continued use of TCE in Use 1 over the period 2016-2026. By comparing the economic benefits of continued use ([redacted]€) against the value of risks to human health (up to ca. €[redacted] as a worst case), it is evident that EU society benefits significantly in net terms from the continuation of Use 1 over this period. Social, environmental and macroeconomic impacts have been assessed and they also have a bearing on this CBA outcome. This demonstrates the benefits of the authorisation of Use 1, which would enable the use of TCE to continue past the Sunset Date, outweigh the risks by several orders of magnitude, and therefore that this authorisation is clearly justified from a societal perspective. This conclusion is strongly robust to reasonable sensitivity analysis.

Table 18. Comparison of impacts [27]

Type of impact	Benefit of authorisation	Cost of authorisation	Net impact
Human health	None	Risk of TCE exposure of applicants workers valued between € 125 and € 934 calculated on 40 year exposure	Total human health impact is up to € 1593
		Risk of TCE exposure of men via the environment valued between € 218 and € 658 calculated on 70 year exposure	
Environment	Risk to use alternatives with physicochemical risks and a higher energy request	Risk of TCE released into the air minimised	Inconclusive
Economic	Avoided lost of capital investment in machinery: [redacted]€	None	A net economic benefit to the EU of about [redacted]€ due to the avoided lost of investments made
	Avoided lost of business for the applicants [redacted]€	None	

	Avoided lost of new investment in R&D: [redacted] €	None	
	Avoided lost of business for the customer: [redacted] €	None	
	Avoided lost of capital investment in customer approval: [redacted] €	None	
Social	Avoided short term unemployment impact and implement the development plan of the applicants	None	It is possible to have a non yet quantifiable benefit from the authorization
Macroeconomic	Avoided outsourcing outside EU and competitors assessing the market and make prices higher	None	Inconclusive

5.2. Distributional impacts

At a first analysis, applicants are the main involved either in benefit for continued use of the substance than in risks for the human health. In fact the customer can find an alternative bringing production outside Europe and no risk is associated to the final product. If the comparison of risks and benefit are just focused on applicants the following is resulting (Table 19):

Table 19. Impact on applicants [28]

Type of impact	Benefit of authorisation	Cost of authorisation	Net impact
Human health	None	Risk of TCE exposure of applicants workers valued between € 125 and € 934 calculated on 40 year exposure	Total human health impact is up to € 1593
		Risk of TCE exposure of men via the environment valued between € 218 and € 658 calculated on 70 year exposure	
Economic	Avoided lost of capital investment in machinery: [redacted] €	None	A net economic benefit to the EU of about [redacted] € due to the avoided loss of investments made
	Avoided lost of business: [redacted] €		

Social	Avoided short term unemployment impact and implement the development plan of the applicants	None	It is possible to have a non yet quantifiable benefit from the authorisation

In this case by comparing the economic benefits of continued use [redacted] [29] against the value of risks to human health (up to ca. €[redacted] as a worst case), it is evident that the net impact in still in favour of the authorisation.

The impact on customers and articles producers can be none in case the substance will be produced outside Europe

5.3. Uncertainty analysis

A number of impacts can be revised in case a valid alternative will be found. In this case the risks for human health will be lowered, a consistent investment will need to be made for the approval of the new product, but a quick and consistent revenue will result in a recovery in income in about two years.
The whole process would take not less than 6-8 year

6. CONCLUSIONS

The objective of this Socio-Economic Analysis (SEA) is to determine whether the benefits of continued use of Trichloroethylene (hereafter referred to as TCE) as a solvent in the synthesis of crosslinking agents for fluoroelastomers outweighs the risks to human health and the environment. The use that A.L.P.A. -Azienda Lavorazione Prodotti Ausiliari S. p. A. & Caffaro Industrie S.p.A (also referred to as the "applicants" within this report) are seeking authorisation for is:

- **USE 1**: Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers

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By comparing the economic benefits of continued use (€ against the value of risks to human health (up to ca. €1,600 as a worst case), it is evident that EU society benefits significantly in net terms from the continuation of Use 1 over this period. Social, environmental and macroeconomic impacts have been assessed and they also have a bearing on this CBA outcome. This demonstrates the benefits of the authorisation of Use 1, which would enable the use of TCE to continue past the Sunset Date, outweigh the risks by several orders of magnitude, and therefore that this authorisation is clearly justified from a societal perspective. This conclusion is strongly robust to reasonable sensitivity analysis.

6.1. Information for the length of the review period

This application demonstrates the case for the granting of an authorisation for Use 1. This is based on the following findings:

- The emissions of TCE have been minimized (as shown in the CSR)
- The risk has been minimized (as shown in the CSR)
- There are no suitable alternatives (as shown in the AoA); and
- The benefits of authorisation significantly outweigh the risks by orders of magnitude (as shown in this SEA).

The applicants consider a review period of 10 years to be appropriate. This is based on the factors suggested by ECHA and SEAC (SEAC/20/2013/03 of 13th of September) as to be considered relevant to the assessment of review periods:

Research and development efforts already made, or just started, did not lead to the development of an alternative that could be available within the normal review period. At least still 3-4 years of Research have to be planned, with consequent studies for industrialisation (1-2 years).

After this process it starts the homologation process by automotive, that will last at least 3 years.

It has to be considered also that the remaining risks are low and the socio-economic benefits are high, and there is clear evidence that this situation is not likely to change in the next decade.

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

Blanked out item reference	*Page number*	*Justification for blanking*		
		Demonstration of Commercial Interest	**Demonstration of Potential Harm**	**Limitation to Validity of Claim**
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