ANALYSIS OF ALTERNATIVES

and

SOCIO-ECONOMIC ANALYSIS

Non-Confidential Version

Legal name of applicant(s):	Chemetall GmbH **Chemetall PLC**
Submitted by:	Chemetall GmbH
Date:	1st July 2019
Substance:	4-Nonylphenol, branched and linear, ethoxylated
Use title:	Use 1: The formulation of a hardener component containing NPE in Aerospace two-component sealants. Use 2: Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1% w/w of NPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a).
Use number:	1 and 2

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LIST OF ABBREVIATIONS

AfA	Application for Authorisation
AOA	Analysis of Alternatives
CSR	Chemical Safety Report
DU	Downstream User
EAAC	Ethoxylates in Aerospace Authorisation Consortium
EASA	European Aviation Safety Agency
EEA	European Economic Area
MRO	Maintenance, Repair & Overhaul
N/A	Not Applicable
NPE	Nonylphenol ethoxylate
NPV	Net Present Value
NUS	Non-Use Scenario
OEM	Original Equipment Manufacturer
OPE	Octylphenol ethoxylate(s)
PBT	Persistent Bio accumulative and Toxic
SEA	Socio Economic Assessment
SME	Small or Medium sized Enterprise
vPvB	Very Persistent and Very Bio accumulative

LIST OF DEFINITIONS

Term	Definition
Adhesion promotion	Enhancement of the tendency of dissimilar constituents or surfaces to cling to one another (for example adhesion of sealant to substrate, adhesion of paint to sealant and/or substrate).
Aerodynamic/aero smoothing	Exterior sealing to achieve aerodynamic smoothness is important as it reduces the drag of the aircraft as it flies and thus reduces the amount of fuel used. Typical exterior areas where aerodynamic sealant is applied include fuselage, rudders, windows, wings and antennas.
Aerospace	Business sector of companies producing products and services for aerospace and their associated supply chains relating to aircraft (both civil and military incl. helicopters), etc., that fly or operate in the atmosphere.
Aircraft on Ground	Aircraft (incl. helicopters) not in an airworthy condition, therefore not authorized to fly, typically at an airport gate.
Alternative	A candidate alternative that has been tested, qualified, fully industrialised, and certified by the aerospace OEM. This definition is used only for the final classification of evaluated alternatives.
Approval	Written acceptance by an authorized representative of the customer or authority that a product/service/person or organization is suitable and accepted.
Assembly	Procedure of fitting together several components, or subassemblies of a product to make an identifiable unit capable of disassembly, such as equipment, a machine or an aircraft. *NOTE 1: An assembly also is the resulting product of fitting components together*

Term	Definition
Base	The larger quantity component of a 2-part sealant that contains the sealant polymer. When the sealant base and hardener are mixed together, the sealant starts to cure (polymerize).
Candidate Alternative	Potential alternative provided to the aerospace OEM for their evaluation and will have already been evaluated in the labs of the formulator.
Certificate	Document attesting that a formulation/service/organization conforms to specified requirements.
Certification	The procedure by which a party gives written assurance that all components, equipment, products, service or processes have met or exceeded the specific requirements, defined in the Certification Specifications, documented in technical standards or specifications.
Chemical resistance	The ability of solids to resist damage by chemical exposure.
Civil aerospace	Subsector of 'aerospace' relating to non-military aircraft.
Compatibility (with substrate/or other coatings)	Suitability of formulations, processes or services for use together under specific conditions to fulfil relevant requirements without causing unacceptable interactions (ISO Guide 2:2004)
Competent authority	The authority or authorities or bodies established by the EU Member States to carry out the obligations arising from the REACH Regulation
Compliance verification	Confirmation by the approving agency that all documentation provided to demonstrate fulfilment of requirements is satisfactory. *NOTE 1: See also Part 21 Subpart J Design Assurance System GM No. 1 to 21A.239(a)(b) 3.1.3*
Component	Hardware or software product, sub-assembly or assembly which is uniquely identified and qualified. *NOTE 1: Hardware components may be further divided into lower tier products (sometimes given names such as subassemblies), components, processes, and data. software components may be further divided into additional components and/or software units (adapted from MIL-STD499C and MIL-STD-973)*
Components list	List of components, usually issued by the Design Organization, necessary to manufacture, assemble or maintain a product
Configuration	Interrelated functional and physical characteristics of a product (hardware/software) defined in product design or build information.
Corrosion	The process of an unwanted chemical reaction between an item and its environment, for example, oxidation of a metal part leading to loss of constituents.
Corrosion resistance	The resistance an item offers against reaction with adverse environmental factors that can degrade it.
Design	Mixture of a set of information that defines the characteristics of a product. (adapted from EN 13701:2001)
Design parameters	Those dimensional, visual, functional, mechanical, and features or properties, which describe and constitute the design of the article as specified by Drawing requirements. These characteristics can be measured, inspected tested, or verified to determine conformance to the design requirements.
Development	Process by which the capability to adequately implement a technology or design or requirement is established before series production. NOTE 1: This process can include the building of various partial or complete models of the products and assessment of their performance. (adapted from EN 13701:2001)
Downstream processes	Those processes occurring after an activity e.g. the transport of a manufactured product from a factory to customer, end user or distributor cf. upstream.

Term	Definition
Downstream user (REACH)	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, during his industrial or professional activities. (A distributor or a consumer is not a downstream user. In addition, an assembler of articles, or a user of articles is not a downstream user as defined in REACH.)
Drawing	Graphical representation of forms or objects with supporting data to provide a design definition.
Endocrine disruptors	Any chemical verified by testing to exhibit endocrine disruptive properties using the proper toxicological methodology and regulated specifically as an endocrine disruptor by a national regulatory agency.
End user	Same as final customer in the complete supply chain
Equipment	Associated assemblies intended to achieve a defined final objective.
Erosion	Gradual breaking down; the gradual destruction or reduction and weakening of something by physical or chemical forces.
Evaluation	Process of appraising the performance of a person, process, product or system.
Exposure pathways	Existing or hypothetical routes by which chemicals in soil, water or other media can encounter humans, animals or plants.
Failure	Termination of the ability of an item to perform a required function. *NOTE 1: After failure, the item has a fault.* *(IEC Multilingual Dictionary:2001)*
Faying surface	Surfaces which are placed in intimate contact with each other when assembled.
Faying surface/interfay sealant	Sealant applied to one or more faying surfaces that will be placed in contact during assembly.
Formulation	Chemical product purchased by aerospace industry member and specified for a specific use on aerospace product
Galvanic protection	With reference to sealants, the ability to protect dissimilar metal junctions from galvanic attack through the combined functions of moisture blocking, adhesion, and active corrosion inhibition.
Hardener	The hardener is one of two components in a sealant kit. The hardener and base components are mixed to together and applied to the area of the part/assembly as a mixed sealant.
Hazardous materials	Formulation posing a risk to health, safety, property or the environmental when handled or worked on.
Health risk assessment	A study prepared to assess health and environmental risks due to potential exposure to hazardous substances.
Identified use	A use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain (including his own use) or that is made known to him in writing by an immediate downstream user.
Implementation	After having passed qualification and certification, the next phase is to implement or industrialise the qualified formulation, component or process in all relevant activities and operations of production, maintenance and the supply chain.
Inspection	Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.
Interchangeability	Attribute of design that enables exchanged products to be installed.
Life cycle (of a product)	All stages of a product's development, from raw materials manufacturing through to consumption and ultimate disposal.

Term	Definition
Maintenance, Repair & Overhaul	Organization/company that performs maintenance and repair activities on aerospace hardware, components and end products. MRO activities include performance of tasks required to ensure the continuing airworthiness of an aircraft or aircraft component, or function of aerospace component/hardware/assembly including any one or combination of overhaul, inspection, replacement, defect rectification, and the embodiment of a modification or repair. NOTE 1: for civil: the overhaul, repair, inspection, replacement, modification or defect rectification of an aircraft or an aircraft component that is performed after completion of manufacturing
Material	Raw, semi-finished or finished purchased item (gaseous, liquid and solid) of given characteristics from which processing into a functional element of the product is undertaken
Mixture	A solution of two or more substances that do not react.
Non-confirming product	Product that does not meet the design, production or maintenance requirements.
Operator	Individual or team who physically performs the process. “Approved Operators” are Self-Verification qualified individuals or teams. These may also be referred to through terminology considered suitable by the organization’s program focus, cultural and customer environment, i.e. “Approved Technicians”, “Certified/Approved process Team Members”.
Original Equipment Manufacturer	Original Equipment Manufacturer (OEM): defines the performance requirements of the components and the materials and processes used in manufacturing and maintenance. OEMs are responsible for the integration and certification of the final product.
Part	Distinct component, possibly consisting of two or more pieces permanently joined together, that can be separated from or attached to an assembly. *NOTE 1: Hardware item that cannot be disassembled without destroying the capability to perform its required function.*
Potential Alternative	A possible alternative being evaluated in the labs of the Formulator.
Product	In this document product means any final aerospace assembly, engine, propeller, airframe part or equipment (within that assembly) to be used in operating or controlling an aircraft in flight or other aerospace vehicle in use. The result of a process, which in the context of this Standard includes finished detailed components and assemblies. It also includes forgings and castings. In the context of this document, products are purchased as components and/or sold as finished goods.
Product acceptance	Acceptance of a product by either customer or authoritative body.
Qualification	OEM validation that the formulation, process or part meets the engineering technical performance requirements detailed in Qualification Specifications, documented in technical standards or specifications. Documented demonstration of the ability to fulfil specified requirements.
Qualification certificate	Certificate attesting the qualified status.
Regulatory authority	Authority responsible for and competent in a specific matter. In the context of this document this refers to Airworthiness and Defence Authorities (e.g. EASA, MoD etc.).
Repair	The restoration of an aerospace product to an airworthy condition to ensure that the aircraft it continues to comply with the design aspects of the appropriate

Term	Definition
	airworthiness requirements used for the issuance of the Type Certificate for the respective aircraft type, after it has been damaged or subjected to wear.
Sealant	A formulation used to fill voids of various sizes providing a continuous film to prevent the passage of liquids or gaseous media. It prevents the passage of fluids along the surface of or through the joints or seams of structures and piping.
Shore A Hardness	A measure of the resistance of a material to the penetration of a needle under a defined spring force. It is determined as a number from 0 to 100 on the scales A or D using a durometer. The higher the number, the higher the hardness (1).
Site (REACH)	A single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared.
Specification	Document stating requirements. NOTE 1: A specification can be related to activities (e.g. procedure document, process specification and test specification), or products (e.g. product specification, performance specification, process specification).
Sub-tier supplier	Supplier not working under a direct purchase order from the prime contractor but performing work on related products at a lower level in the supply chain (via purchase order cascade).
Supply chain	Network created by customer, prime contractor, subcontractors and sub-tier suppliers producing, handling, and/or distributing a specific product.
Type Certificate	Document issued by an Aviation Authority to define the design of an aircraft type and to certify that the design meets the appropriate airworthiness requirements.
Type model	Top level configuration designator for the end item and for civil aircraft having Approved Design Data approval by a regulatory authority.

DECLARATION

The Applicant is aware of the fact that evidence might be requested by ECHA to support information provided in this document.

Also, we request that the information blanked out in the "public version" of the Analysis of Alternatives and Socio-economic analysis is not disclosed. We hereby declare that, to the best of our knowledge as of today (1st July 2019) 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: ppa. Schönfeldt

Date, Place: 01/07/19 Frankfurt am Main

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1. SUMMARY

Introduction to Chemetall GmbH Application for Authorisation

This application for authorisation covers the use of nonylphenol ethoxylate (NPE) in the formulation and mixing of a range of specialty two-part polysulfide sealants manufactured by Chemetall GmbH (Chemetall) for use in the Aerospace industry sector.

This application is submitted by Chemetall as specialist formulator for the Aerospace industry. Chemetall customers, including Airbus Group companies (as OEM) and their suppliers and customers such as airlines (together representing the vast majority of sales), rely on these specific polysulfide sealants during production and maintenance, repair, and overhaul (MRO) of aerospace components and completed products, as civil and military aircraft (including helicopters).

The total tonnage of NPE covered by this application is low (much less than 1 tonne per annum). Despite the low volume of NPE covered by this application, the availability of the polysulfide sealant products containing NPE is of critical importance to the aerospace customers of Chemetall that rely on them. Without these polysulfide sealants (i.e. in case an authorisation is not granted), it will not be possible to manufacture, maintain, or repair aerospace components in the EEA. Chemetall's customers rely on polysulfide sealants containing very low volumes and concentrations of NPE to ensure reliable and safe performance of critical aerospace systems that are vital to the EEA economy. MRO organisations, including EEA airlines and military aircraft operations, also need access to the formulations to comply with OEM specifications for the maintenance and repair.

This application for authorisation has been prepared to address the specific circumstances relating to the use by aerospace companies of polysulfide sealants that are formulated by Chemetall. The scope and content of this application should not be considered relevant for other applications for authorisation, and vice versa.

Need for an Upstream Application

Authorisations held by downstream users would not be adequate to cover the necessary operations across the supply chain, as aerospace processes specified are carried out by indirect, as well as direct, suppliers, as well as customers (e.g. airlines) and their supply chains.

As a Downstream User authorisation only covers supply of that substance by an immediate upstream supplier to the Downstream User having its own authorisation, those entities who are not able to justify the time and cost of preparing and submitting an AfA would have to cease operations that involved use of the polysulfide sealants. This presents the very significant risk to the aerospace industry that critical suppliers/customers will no longer be able to conduct their operations beyond the sunset date. For this reason, an upstream application is necessary to secure the supply chain for these products that is not covered by other applications for authorisation.

Use of nonylphenol ethoxylate (NPE)

The application for authorisation covers two closely related uses.

The first use applied for is to use a surfactant containing NPE for formulation of the hardener component of the two-part polysulfide sealants, that are specified for use in the aerospace industry.

The hardener, containing very low concentrations of NPE (less than 0.6% w/w), is manufactured by the applicant at one location in Germany. The ability to manufacture in the EEA is necessary to allow uninterrupted supply of these sealants in the EEA. Chemetall manufactures several different types of hardener/sealant for use in aerospace products, each with different specific applications and performance characteristics (as described in detail in the AoA).

The second use applied for covers the mixing by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with the hardener containing NPE. The specific base and hardener are packaged together and distributed as a unit. The base and hardener are mixed together, usually at the point of use, typically in a ratio of 10 parts base to one part hardener, to form the polysulfide sealant. The hardener causes the sealant to polymerise and cure, with full strength typically attained after several days. Subsequent use of the polysulfide sealants is exempt from authorisation according to REACH Art. 56(6)(a), as the concentrations of NPE in the mixed polysulfide sealant is less than 0.1% w/w.

Polysulfide sealants are essential in the manufacture and assembly of aerospace components to deliver specific safety functions, including, but not limited to:

- Sealing structures/components to:
    - keep moisture or other fluids out (to prevent corrosion or attack of structures/components)
    - keep fluids in (e.g. fuel, hydraulic fluids, etc.)
    - prevent airflow to maintain cabin pressure
- Isolating components to separate dissimilar substrates/metals to prevent corrosion or provide thermal/electrical insulation
- Filling gaps to create an aerodynamic surface (aero smoothing) and eliminate moisture accumulation or traps
- Provide adhesion in engines and nacelles, when flexibility and compatibility with mating gap filler is required; bonding structures requiring flexibility; and bonding/sealing of wires
- Electrical potting in connectors, PC boards, circuit boards

These specialty polysulfide sealants are used in production and MRO applications on aerospace products. For example, they are used for fuel tanks (to prevent leakage), window sealing (ensuring air tightness and pressurization of passenger cabins), actuators, electronic controller connections, gyros, wiper blade systems, propeller blades, ball screws for actuators, flight control rudder pedals, joint sealing of general aircraft structures during assembly process, to assemble structures, etc.

The scope of this AfA relates to all components for which use of these specialist polysulfide sealants is specified to meet the requirements of airworthiness regulations or comparable performance requirements. In the context of this AfA, an "aerospace application" refers to a single component in a single system for a single OEM's specific hardware. Each OEM is responsible (i.e. according to airworthiness regulations or similar performance requirements) for its own product qualification, validation and certification. Within a single OEM, even ostensibly 'similar' components or hardware used in different systems/aircraft models have unique design parameters and performance requirements.

Functional Requirements of Nonylphenol ethoxylate

Polysulfide sealants are a specific type of sealant used extensively in, and relied upon by, the aerospace industry sector. They are critical for the production, repair and maintenance of aerospace systems in the EEA and the rest of the world. The unique properties of this class of sealants relevant to aerospace applications include, but are not limited to:

- Resistance to degradation by fuel and other chemicals
- Flexibility over a wide range of temperatures, most uniquely extreme cold
- Adhesion to a wide range of substrates
- Ability to stress-relax, thereby maintaining adhesion to expanding and contracting substrates

The base and hardener component of any one polysulfide sealant are formulated according to a precise recipe and paired together to ensure the final sealant meets all performance requirements. NPE is a minor but critical component (2.5-10%) of a surfactant[1] used to concentrate and disperse manganese dioxide (MnO_2) in the final hardener formulation.

The MnO_2 acts as an agent to permanently cure the sealant by oxidative crosslinking, thus playing a crucial role in the formulation, application and end property development of the polysulfide sealant. The concentration of MnO_2 in the hardener and, following mixing, in the uncured sealant mixture is essential in determining the key properties of the sealant and to meet the technical performance requirements of the end use application.

Without the right surfactant, it is not possible to deliver enough curing agent into the hardener component and subsequently into the final uncured sealant mix. This affects the ability of the sealant to cure. If the concentration of curing agent in the hardener is reduced, the proportion of hardener in the uncured sealant mix would need to be increased to compensate and keep the sealant cure time the same, but this would alter the sealant properties. For example, by increasing the hardener proportion to adjust for the curing agent, more plasticiser from the hardener component will be introduced to the uncured sealant mix, so the cured sealant is softer than specifications require. The sealant applied to aerospace parts must achieve a Shore A Hardness score of >30 to enable it to be moved or processed further, and the final full cure of the sealants should achieve a Shore A hardness score of 40-50. The curing agent content in the hardener and mixed sealant also has an impact on other key parameters, such as viscosity of the sealant pre-cure and pot life/working time. Therefore, ensuring adequate concentration and dispersion of the curing agent in the hardener is key to the functionality and use of the sealant. As such, the surfactant used to aid this process is an important component and replacement is not straightforward.

The key technical criteria for selection and usage of sealants to meet manufacturing and industrialisation requirements are numerous. Those properties required for proper

[1] The maximum concentration of the surfactant in the hardener is 6%, so the maximum concentration of the NPE in the hardener is 0.6%w/w.

application of sealants on aerospace hardware and performance of the in-service cured sealant include, but are not limited to:

- Viscosity
- Density
- Hardness
- Tensile/tear strength
- Bond shear strength
- Electrical insulation
- Galvanic isolation
- Adhesion of coatings
- Chemical and water resistance
- Corrosion resistance
- Thermal cycling resistance
- Compatibility with substrates/other coatings
- Erosion resistance and slump resistance
- Pot life/working life
- Cure time and temperature
- Tack-free time
- Shelf-life

Specific performance criteria are set for each of these properties, and must be demonstrated through rigorous, repeatable testing.

Controlled Use and Minimisation of Exposure (no potential for release to the Environment)

NPE is included on REACH Annex XIV due to concern for the aquatic environment as a result of endocrine disrupting properties of its degradation product[2].

An important aspect of this AfA is that use and handling of NPE, the hardener and the sealant are such that release to the environment is effectively precluded. Formulation, mixing and use are carried out only at industrial facilities. Workers are trained, and procedures and management systems are in place to ensure quality, health and safety, and environmental protection are delivered through aircraft production, maintenance and repair processes.

The manufacture, mixing and use of the polysulfide sealant hardener does not involve the use of water at any point. Water is not present in the area that the hardener is formulated, nor typically when it is mixed and applied. Cleaning and maintenance of equipment also excludes use of water. For example, cleaning is carried out by wiping with dry or solvent impregnated cloths, or collecting residual cured material with, for example, a vacuum unit and/or brush. Therefore, there is no possibility that NPE can come into contact with water or be released to wastewater. Risk Management Measures to preclude the hardener or mixed sealant coming into contact with water are set out in the Chemical Safety Report.

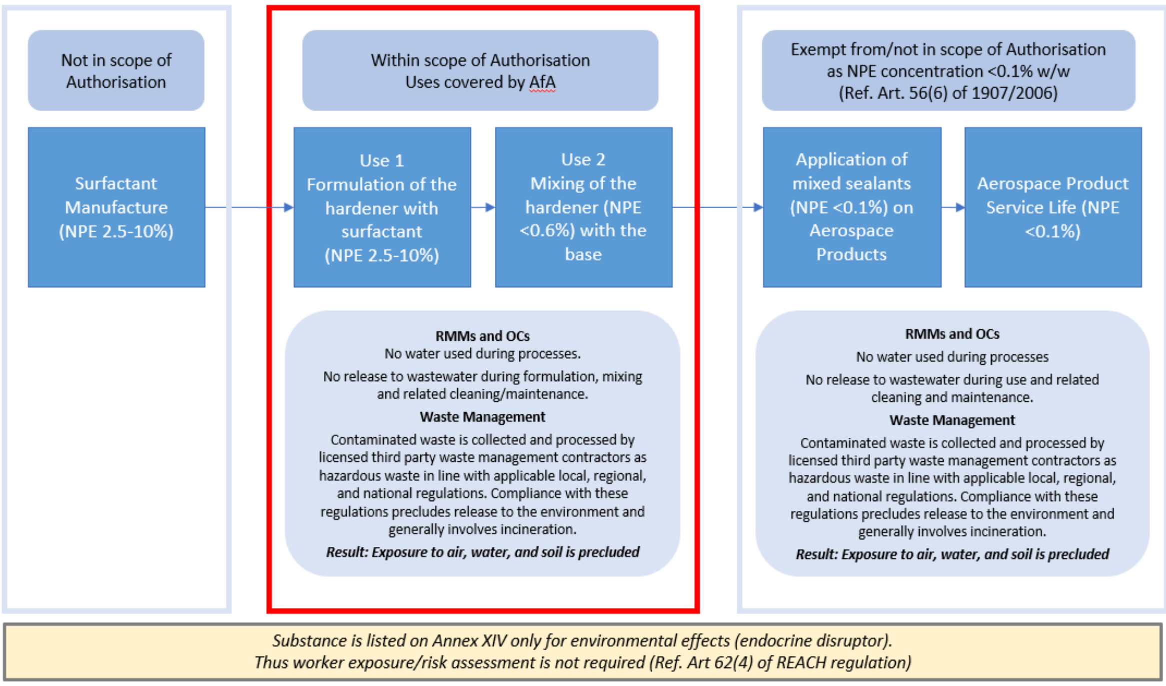
Risk Management Measures require NPE contaminated waste be managed as hazardous waste, as set out in the Chemical Safety Report. The collection of NPE contaminated waste

[2] As such, evaluation of any potential hazards to human health is not required in this application for authorisation.

(including disposable gloves and aprons, rags, disposable equipment, empty packaging, etc.) is managed by licensed third party waste management contractors in line with the applicable local, regional, and national regulations. Compliance to these regulations preclude release to the environment and generally involve incineration.

NPE is of limited volatility and will not be released to air during formulation or mixing of the hardener or use of the sealant.

The scope of the CSR and a summary of risk management measures and releases of NPE is provided in the figure below.



Regulatory Imperatives relating to substitution of Nonylphenol ethoxylate

Aerospace components are subjected to some of the most aggressive and corrosive environments around the world. They must operate successfully in extremes of altitude, temperature and precipitation, while having to fulfil the highest possible technical reliability and safety requirements. To ensure aircraft safety, comprehensive airworthiness regulations[3] have been in place in the European Union (as well as around the world) for decades. Parallel requirements[4] are in place to ensure airworthiness for military systems in Europe. These regulations require qualification of all materials and processes according to a systematic and rigorous process to meet stringent safety requirements that are ultimately subject to independent certification and approval.

[3] E.g. European Union (EU) Regulation No 216/2008 and the EASA CS-25 and EASA CS-E in the EU

[4] The European Aviation Requirements (EMARs) established by the European Defence Agency (EDA) Airworthiness Authorities (MAWA) Forum

Considering these requirements and the role of NPE in polysulfide sealants, the preferred substitution strategy for this specific case of the polysulfide sealants involves developing reformulated 'NPE-free' products that are completely interchangeable with the products they are intended to replace. To achieve this, the NPE-free sealants must perform in the same way and be applied following the same process instruction as the currently qualified sealant. When this is the case, no aircraft part design changes (e.g. no specification, drawing, part number, or name changes) are needed, and conformance to existing certification requirements can be maintained. When this is not the case, far more extensive effort is required to qualify/validate or certify the use of the reformulated product in each aerospace application. Polysulfide sealants containing NPE specified for use in aerospace systems can only be substituted when the reformulated product has been shown through rigorous and repeatable testing to meet all relevant process and performance requirements. Such interchangeability must be demonstrated for each product in each aerospace application before it can be industrialised for use by the OEM and its supply chain.

The formulators are responsible for developing and performing the preliminary assessment of a reformulated product/potential alternative's viability. However, only the OEM design owner can determine when a candidate alternative is fully qualified/validated and is therefore in line with airworthiness or comparable performance requirements for each of their aerospace applications.

The testing criteria are determined by the design authority and/or approval authority on a case-by-case basis, with due regard to the design and performance requirements of each component and system. In the case of the polysulfide sealants, testing for a range of parameters in a relevant environment over an appropriate timescale is necessary, and the results must prove the reformulated sealant meets the performance criteria and can so be used interchangeably with the current NPE-containing formulation. This requires an appropriate suite of testing on samples of the reformulated product, even when only very small volumes of the product are used. This qualification and validation process must be successfully completed for each of the polysulfide sealant products within the scope of this AfA.

Alternatives Analysis

The Applicant, as formulator, has undertaken significant research and development activities. During early reformulation activities, it was identified that surfactants that are not derived from NPE substances are not as efficient at bonding the curing agent into the rest of the liquid hardener mix. It was also determined that, contrary to initial expectations, it is not a straight-forward process to find a suitable alternative surfactant that works to the same standard but does not contain NPE. At this time, the Applicant considers this could be due to competition between surface active ingredients in the sealant. As adhesion is a key property of the sealants for Chemetall customers, the Applicant is also reformulating the adhesion promotor for these products separately.

There is a vast variety of surfactants in the market based on different chemistries. However, many of them develop their full potential only in aqueous environments or water-rich formulations. Surfactants for emulsions (oil in water/water in oil) or dispersions (solids in liquids) differ significantly in their impact on product performance and require specific designs.

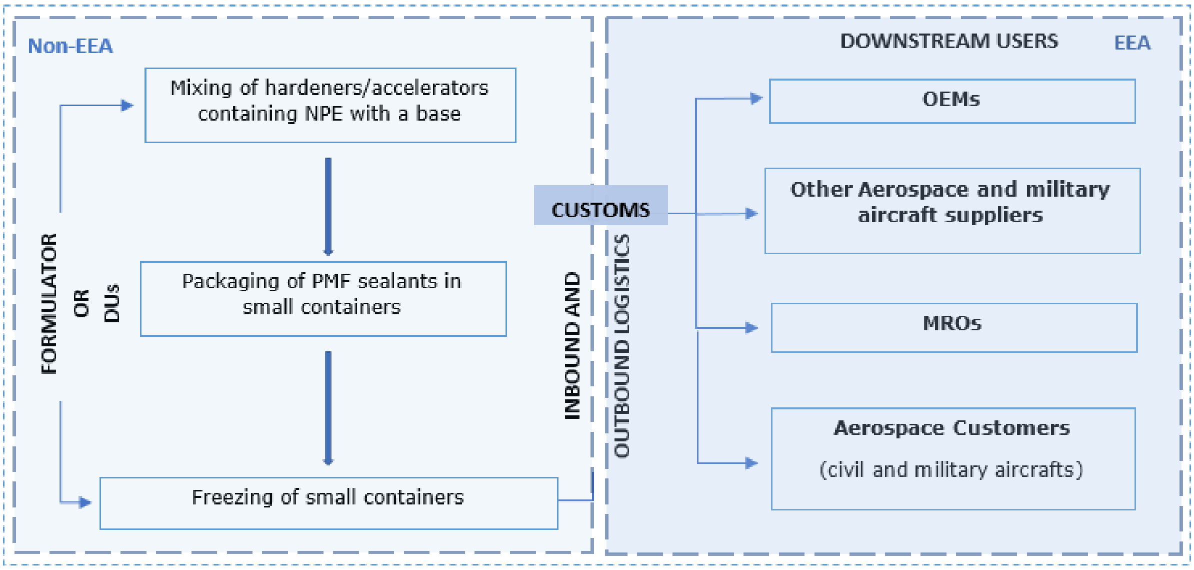
The Applicant has screened >100 different surfactants and has been investigating suitable alternatives for NPE surfactants in its polysulfide sealants. The Applicant had previously identified and developed a promising candidate alternative sealant formulation, but it did not pass technical qualification testing by the OEMs, due to unanticipated issues with the lack of adhesion of the sealant to different substrates during the final testing phase[5]. The remaining four potential alternatives are still being investigated and tested for suitability, and these are discussed in more detail in the AoA report. Chemetall is currently focusing efforts on four possible potential alternatives, carrying out intensive research and development to determine the best candidate alternative formulation (i.e. that retains all required properties (such as the required level of adhesion and viscosity) of the polysulfide sealant whilst removing NPE) to provide to the OEMs to commence qualification testing.

Non-Use Scenario

There are no immediate alternatives to polysulfide sealant formulations currently qualified for use in aerospace applications covered by the scope of this AfA. Flight safety, airworthiness or comparable performance requirements mean it is not an option to use another product or formulation that is not qualified. As discussed above, full qualification of any alternative cannot be completed before the sunset date.

In the event that an authorisation for formulation and mixing of hardener containing NPE is not obtained, the least disruptive non-use scenario (NUS) assumes logistics and processes for all aerospace operations in the EEA can be adapted to allow use of pre-mixed and frozen (PMF) polysulfide sealants. Polysulfide sealants with a pot life/working time > ½ hour can be pre-mixed, rapidly frozen and stored at -45°C for a maximum of 35 days for subsequent use. In this hypothetical NUS, the total volume of sealants needed within the EEA would be pre-mixed and frozen in a non-EEA country and imported to EEA via refrigerated airfreight for use at all Downstream User EEA sites. As the concentration of NPE in the mixed polysulfide sealant is less than 0.1%, the use of PMF sealant is not subject to authorisation. The NUS is depicted in the figure below.

[5] This demonstrates the importance of the qualification process to ensure the candidate alternative(s) fully meet performance requirements, as per specifications.



Very low temperatures have to be consistently maintained from the point of packaging immediately after mixing until use to maintain the quality standards and the short-term functionality of the PMF sealants by ensuring that they do not cure prematurely. The freezing process requires an ambient temperature of less than -70°C. Prior to and after distribution, the sealant should be preserved at an ambient temperature of -60°C ± 4°C and during transportation it must be preserved at an ambient temperature of -44°C ± 4°C.

Due to the need to rapidly and uniformly freeze the sealant, PMF sealants must be packaged, stored and transported in small units (i.e. cartridges). In practice, this means a large volume of PMF cartridges will be needed to deliver the large quantities of sealants that are used in aerospace equipment manufacturing and MRO, oftentimes replacing the larger containers currently used for the two-part systems. This will require investments in infrastructure by the applicant at one or more non-EEA sites to meet the demand for increased production and storage of PMF sealants. New low cold storage freezers, back-up generators and other relevant equipment will be needed, both by the applicant outside the EEA and all DUs in the EEA. Additional equipment will require upgrading of the existing facilities and/or acquisition of new land.

Due to the limited shelf life of PMF sealants compared to two-part sealants, the PMF sealant will need to be transported as air freight and stock will need to be carefully managed, resulting in more frequent deliveries, bearing in mind the various different products in the polysulfide sealant family held in stock and used by aerospace companies. Undue customs delays could result in increased wastage.

Considering these aspects, the NUS will, at a minimum, involve substantial additional costs relating to acquisition, installation and operation of new process and storage equipment and to transportation requirements. The energy requirements and increased CO_2 emissions associated with the NUS are also substantially greater than the current situation. As there is no potential for release of NPE to the environment under the authorised use, the NUS does not represent an improvement from an environmental perspective. Rather, considering the greater energy use required, the NUS has a far more substantial negative environmental impact than the authorised use.

In any case, there are substantial doubts about the technical feasibility of this NUS. For example, whether the formulator can establish a production facility outside the EEA capable of delivering the needed amounts of sealants as PMF product for Airbus and its EEA suppliers, as well as MRO operations, in the required timeframe is highly questionable. As the formulator would need time to transfer operations to and set up a PMF capability in a non-EEA location, this NUS would certainly entail a period of 1 to 2 years where no manufacturing or MRO of aircraft and aerospace equipment would be possible in the EEA due to unavailability of NPE-containing sealants. This period would be followed by a period with reduced production output, increased operational costs and MRO delays of 2 to 3 years, until an alternative is fully industrialised at all EEA aerospace operations.

If this non-EEA facility cannot be established in time, an alternative NUS where manufacturing and MRO of aerospace equipment would be stopped until a NPE-free alternative is fully industrialised at all aerospace companies in the EEA would result.

Additionally, it is important to recognise that use of PMF sealants may not be possible for applications where fast-cure sealants are specified. Fast-cure sealants have a working life of approximately 15 to 30 minutes and can therefore not be supplied as a PMF sealant (the sealant would cure during freezing and thawing, making it unusable). The possibility to switch from fast cure sealants to sealants with a longer cure time to support the use of PMF sealants will depend on each application on a case-by-case basis; the curing time may limit production rate and maintenance turnaround times. Moving to longer cure times will have a massive adverse effect on the process flow in the assembly and maintenance and repair operations, resulting, for example, in lower productivity and increased aircraft on ground times. It would be particularly disruptive for those last minute, unscheduled repairs performed at the gate or airport.

Socio-Economic Analysis

The Socio-Economic Analysis (SEA) submitted as part of this application evaluates the impact of a decision to authorise or not to authorise the continued use of NPE in the EEA. The Applicants employed a conservative approach to the economic assessment, based on the NUS, that assumes it is possible to source PMF from outside the EEA for supply and accounting for only those impacts within that NUS that can be reliably quantified with available hard data. Even so, the assessment demonstrates the NUS would involve socio-economic costs in the range of 5 145 - 10 130 million Euros, while the volume of NPE-containing sealants would not decrease at all. In addition, environmental impacts associated with the NUS would be greater than the baseline, due to substantial additional energy costs associated with the need to refrigerate the PMF sealant, and to transport by air.

The economic impacts to customers of the aerospace industry and those that rely on these industries will also be substantial. Interruptions in aerospace product and service (maintenance and repair) availability during the expected period where no aircraft production takes place while production is moved outside the EEA, will bring disruption to commercial and defence aerospace industries, with widespread implications. These include:

- cessation of production of aerospace products within the EEA

- adverse effects on the entire EEA industry and society caused by a decreasing operational readiness of the EEA aircraft fleet due to the inability to conduct MRO activities critical loss of support for military/security operations
- loss of efficacy of contingency response (military and humanitarian) to stabilise and control emerging threats
- threats to the safety of allied troops
- potential peril by reduced mission support capabilities
- inability to guarantee timely delivery of business-critical spare parts (e.g. to industry's production facilities with danger of further downtimes)
- reduced supply and increased costs of perishable consumer goods (e.g. flowers, fruits, fish)
- price increase of passenger flight tickets and air freight

Considering these downstream economic impacts during the quantitative assessment would greatly influence the ratio between economic benefits and safety and security impacts shown above, further distinguishing the benefits of authorisation.

An indicated above, there are substantial doubts about the technical feasibility of this NUS. For example, whether the formulator can establish a production facility outside the EEA capable of delivering the requisite amounts of sealants as PMF product for A&D companies and its EEA suppliers in the timeframe needed is questionable. In this case, production of A&D products and components (for instance, sealant is required for final assembly of aircraft) that require OPE-containing sealants in the EEA would stop. Aircraft could not be assembled in the EU and MRO activities that require these sealants would also stop. This realistic NUS would have extensive consequences for the aerospace industry and those that rely on it, as described in the SEA, with a significant portion (if not 100%) of the total turnover of 220.2 billion Euros (2016) delivered by the European aerospace industry impacted. The SEA shows, in case it is not possible to establish use of imported PMF in the medium term, the impact of stopping operations is estimated to be more than 5 673 – 20 116 million Euros.

Review Period

The substitution strategy for the specific case of the polysulfide sealants involves developing reformulated NPE-free products that are completely interchangeable with the product they are developed to replace. Such reformulated polysulfide sealants must be shown through the qualification process to meet the technical requirements documented in OEM product and/or process specifications and thus suitable and safe for use in accordance with the relevant airworthiness regulations or comparable performance requirements.

The process to develop and test new formulations that meet these specifications involves several stages. The Applicant is still carrying out intensive research and development to find a 'NPE-free' candidate alternative formulation that demonstrates all required properties. This development process by the Formulator can take a significant amount of time, as there are testing parameters that cannot be accelerated or amended. For example, a candidate alternative sealant could require several weeks to fully cure before it can be strength tested and undergo environmental exposure testing and the immersion in fuel tests requires 4,500 hours (half a year). Testing to date indicates the water penetration and fuel immersion tests appear most critical.

The Applicant currently believes that it will most likely be able to develop a NPE-free reformulated candidate alternative polysulfide sealant that can be provided to the OEMs ready to commence technical qualification by the end of Q2 2021. However, there is clearly uncertainty attached to this process, noting initial efforts were not successful.

Once the formulator has developed a candidate alternative that can reliably meet the standard specification for any product or formulation variant in the range of polysulfide sealants, it prepares samples for the OEM. The OEM then can start its own qualification testing against the often more technically challenging specifications relevant to its own applications of that particular product.

Qualification testing is extensive and multiple testing runs under different relevant conditions and for different substrates may be required for the same testing parameter (up to 100 tests on any single formulation variant may be required). As discussed above, ideally, the qualification testing will demonstrate the reformulated product and the current sealant are interchangeable, as this result will greatly simplify the substitution process. The OEMs expect that the minimum necessary time to complete qualification testing is 18 months from availability of the reformulated sealant, which under the current estimated timeline is by end of Q4 2022. However, successful sealant qualification at this stage is by no means assured and the timeline could be longer.

In case of failure, further iterations will be needed to refine the formulation until an interchangeable alternative is qualified. A reformulation that was not interchangeable would require a far more extensive effort associated with aerospace part design changes and approvals. Such changes would be cost prohibitive and significantly extend the timeline to replace the sealants in A&D products.

Once qualification is complete, the qualified alternative sealant formulation must be industrialised throughout the OEM manufacturing sites and throughout the wider supporting supply chain (over 200 suppliers). For a formulation change, significant investment, worker training and manufacturing documentation may be required to adapt the OEM aerospace manufacturing processes. A stepwise approach may be utilized, and formulation changes may not be implemented simultaneously across all sites and suppliers, but rather through a phased introduction to minimize technical risks and to benefit from lessons learned. It is currently estimated that industrialisation of an alternative sealant would take 18 months after OEM qualification activities had completed, which under the current estimated timeline is by Q2 2024.

Accordingly, a review period of 4 years is requested to allow sufficient time for the process to be completed to ensure compliance with the relevant regulations and safety of the final aerospace product.

Summary of Timelines to Substitution (Reasonable Case)																								
	2019				2020				2021				2022				2023				2024			
Activity	Q1-Q4				Q1-Q4				Q1-Q4				Q1-Q4				Q1-Q4				Q1-Q4			
R&D at Formulator	■	■	■	■	■	■	■	■	■	■														
Qualification by OEM											■	■	■	■	■	■								
Industrialisation by OEM																	■	■	■	■	■	■		
Requested Review Period (4 years)									■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Sunset Date (1st January 2021)
Anticipated extent of activity based on current assessment

The Applicant's supplier of the surfactant containing NPE has confirmed that the surfactant will no longer be available for sale in the EU after 1 January 2021. The Applicant has sufficient surfactant supplies to continue sealant manufacture until 2025 (end of requested Authorisation period). The Applicant will no longer be able to use this surfactant containing NPE to manufacture the affected sealants in the current formulation in the EU beyond this date. Therefore, it is imperative, and in the vested interest of the Applicant and customers, that viable alternatives are sourced and that the reformulated sealants are qualified and industrialised throughout the aerospace industry and supply chain by 2025 at the latest.

2. AIMS AND SCOPE OF THE ANALYSIS

2.1. Aims and Scope

This AfA covers the formulation and mixing of a range of specialty formulations referred to as polysulfide sealants manufactured by Chemetall GmbH for use in the Aerospace industry sector. These polysulfide sealants are comprised of a base component and a hardener component, which are mixed together in a typical ratio of 10 parts to 1 (by weight) respectively when mixed according to the Technical Data Sheet. The hardener component, which is used in far smaller volumes than the base, contains very low concentrations (0.6%) of NPE. The base component does not contain NPE. The concentration of NPE (after combining the two components) in the mixed sealant is less than 0.1% w/w.

The NPE present in low concentrations in the hardener component of the sealant is within the scope of Entry 43 of Annex XIV REACH and the subject of this analysis of alternatives (AoA) and socio-economic analysis (SEA).

#	Substance	Intrinsic property(ies)[6]	Latest application date[7]	Sunset date[8]
43	4-Nonylphenol, branched and linear, ethoxylated substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof	Endocrine disrupting properties (Article 57(f) - environment)	04/07/2019	04/01/2021

[6] Referred to in Article 57 of Regulation (EC) No. 1907/2006

[7] Date referred to in Article 58(1)(c)(ii) of Regulation (EC) No. 1907/2006

[8] Date referred to in Article 58(1)(c)(i) of Regulation (EC) No. 1907/2006

The specialty formulations covered by this application for authorisation (AfA) of NPE are proprietary products manufactured inside the EU by one Applicant company. These formulations are supplied across the EEA for use in the production, maintenance and repair of aerospace components and completed products (e.g. civil & military aircraft including helicopters etc.).

This AfA is submitted by the Applicant to support its customers, including Airbus Divisions and its suppliers/customers (together representing 89 – 99 ([redacted]) % of sales) for continued use of affected polysulfide sealants in aerospace applications until such time a fully qualified NPE-free alternative sealant is available. The scope of the application is limited to these companies and the use of these sealants in the aerospace industry.

An upstream application is necessary to allow the use of these sealants by the various manufacturing, airline and MRO facilities that rely on them, and facilitates a harmonised approach to supply, use and regulation of the products. Due to the complex and inter-dependent supply chain, inability to access these sealants to support the planned manufacturing, Airline and MRO activities at important points in the supply chain will have very clear and substantial consequences, as explained in both the description of the Non-Use Scenarios (***Section 4.2.3***) and ***Annex C*** (Aerospace Industry – Background Information) herein. Without an upstream application, multiple downstream user applications for authorisation utilising different approaches, assumptions and terminology as well as substance and product risk management measures and practices are unavoidable. Such differences would present challenges for implementation of authorisation within the supply chain. Additionally, managing multiple authorisations for the same substance uses within facilities would cause difficulties for enforcement authorities across the EEA.

Aerospace assemblies are complex and are required to meet stringent standards for performance, accounting for use in varied climates and considering the different types of services provided (civil and military). An aerospace product, for instance, is exposed to massive forces within a flight envelope, large variations in environmental conditions, and extremely high stress levels due to high velocities. Therefore, every part is designed, tested, and manufactured to strict performance and manufacturing specifications, and must undergo lengthy and rigorous testing programmes before being certified for use in production.

This combination of design complexity and extremely high-performance standards requires great controls in management of change in the Aerospace sector, which is described in ***Annex C.*** As described in ***Section 5.1.2.3***, the estimated timeframe (including risk margin) for provision of NPE-free sealant alternatives by the formulator is Q2 2021. This is followed by the OEM qualification testing, which is expected to complete by end Q4 2022, and industrialisation of the qualified alternative sealants could take until Q2 2024. Therefore, the Analysis of Alternatives (AoA) demonstrates that a review period of at least 4 years is warranted for the highly complex aerospace assemblies described and addressed in this Application for Authorisation (AfA) submission for NPE.

The Socio-Economic Assessment will demonstrate that the net benefit of a decision to allow continued use of these products until such time that they can be safely replaced is substantial. The accompanying CSR discusses the way in which these polysulfide sealants are used such that there is no potential for release of NPE to the environment during formulation or when using these sealants as a component of the aerospace components, sub-assemblies and assemblies.

2.2. Approach

The preparation of this AfA has been supported by Chemetall (the Applicant), OEMs, airlines and MROs in the supply chain of polysulfide sealants containing NPE under the auspices of the Ethoxylates in Aerospace Authorisation Consortium (EAAC).

An introduction to the aerospace industry, with an explanation of the regulatory requirements that must be complied with and an overview on the process of implementing new or replacement formulations on aircraft is provided in ***Annex C***.

As noted in ***Section 2.1***, the concentration of NPE in the mixed polysulfide sealant is below 0.1% w/w. Use of the mixed sealant itself is exempt from authorisation according to REACH Article 56, 6 (a)[9]. Nonetheless, information regarding the usage of the mixed sealant is vital to the rationale for the requested review period and the SEA and is discussed in this document and the accompanying CSR. The technical requirements placed on sealant components, mixed sealants (both cured and uncured), and usage conditions, must be validated for conformance before potential alternative products can be industrialised throughout the aerospace industry, and these are described in ***Section 4.3.4***.

This AfA is the result of the efforts to share data and prepare a comprehensive and reliable assessment of alternatives that is representative for the Downstream Users that will rely on it, supported by the EAAC. Airbus Divisions (whose supply chain represents 89 – 99 ([redacted]) % of Chemetall sales of these products) have reviewed and validated the findings in detail. As such, the Applicant consider the information presented in this AfA as reliable and representative of its customers' use of polysulfide sealants containing NPE.

3. CONSULTATIONS

Information was collected on the supply chain and the use of NPE in the aerospace sector through collaboration in different trade associations to undertake a preliminary situational assessment. Active engagement with supply chain members was achieved using informational webinars and extensive surveying activities. Initially this was conducted via online surveys and email responses and followed up with one-to-one engagement with impacted aerospace industry suppliers. These efforts were important in terms of mapping the uses of NPE in formulations for which alternative products were not readily available and already qualified or otherwise in use in aerospace manufacture and MRO activities. This work confirmed that there was no alternative for polysulfide sealants containing NPE and that an Application for Authorisation (AfA) for use of the polysulfide sealants containing NPE would therefore be required until such time an alternative was available.

[9] Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations: (a) for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0.1 % weight by weight (w/w)

This preliminary assessment provided the basis of the work and further supply chain information requests.

The Ethoxylates in Aerospace Authorisation Consortium (EAAC) was formed in mid-2018. The NPE Application for Authorisation sub-group was formed in October 2018 after the need for an Authorisation for polysulfide sealants containing NPE formulated by Chemetall was confirmed because the product substitution time was anticipated, due to qualification, and implementation procedure timelines, to exceed the Sunset Date for NPE (1 January 2021). Sub-group OEM members, as Airbus Divisions, and Chemetall, as formulator and applicant, then proceeded with preparation for the submission of an Application for Authorisation to allow for continued use of the sealants.

Information was provided by EAAC NPE sub group OEMs, their supply chain and the Formulator on their use of polysulfide sealants, specification criteria and parameters, minimum technical requirements and any previous experiences with identifying alternatives to polysulfide sealants containing NPE. This information was compiled to support the Analysis of Alternatives, the Socio-Economic Assessment and the Chemical Safety Report.

4. APPLIED FOR “USE” SCENARIO

4.1. Definition of the applied for use Scenarios

The European aerospace industry relies on approved and niche formulators for several ‘specialty’ formulations used during aircraft manufacture, maintenance and repair of aerospace products. These formulators have extensive expertise in the development and production of these formulations for the aerospace industry, their formulations have been developed over many years continuous testing and development and the formulations themselves are the intellectual property of those companies. The choice of formulations is very limited. In addition, the formulations are protected by patents and are the only products qualified to be used by OEM technical specifications and certified/approved for use on aerospace products.

Two separate uses are covered by this AfA.

4.1.1. Use 1 - Formulation

In the first use applied for, the applicant is applying for authorisation for the formulation of a hardener component containing NPE within aerospace two-part polysulfide sealants. Sealant manufacturing is carried out on one site in Germany. An AfA is necessary to allow uninterrupted supply of these sealants to the EEA aerospace supply chain.

Formulation of the hardener at the formulator´s site is covered by Use 1. The subsequent mixing of the two-part polysulfide sealants at the DU (downstream use) and Applicant’s site is covered by Use 2, as described in the following.

4.1.2. Use 2 - Downstream Use

In the second use applied for, the applicant is applying for authorisation for mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1% w/w of NPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a). There is a limited amount of time during which the mixed sealant can be applied to the hardware before the extent of curing changes the processing properties needed to properly apply the sealant to hardware (e.g. main frame and all parts attached to an airplane or helicopter). This requires that the end user (OEM, supplier, MRO facility, airline, etc.) mix the two components together just prior to applying it on the hardware. In limited cases, mixing is also performed by the formulator, when manufacturing pre-mixed frozen (PMF) products.

For further details on the areas of use and the functioning of the polysulfide sealants, please refer to ***Section 4.3.3.*** The aerospace regulatory setting and the process for developing, qualifying and implementing alternative formulations is summarised in ***Section 4.3.4*** and ***Annex C***.

4.2. Market and business trends including the use of the substance

The products affected under this AfA comprise of civil and military aircrafts (including helicopters). This section further provides an overview of market trends in the European civil aerospace as an example of downstream use of Naftoseal® polysulfide sealants in the aerospace industry, amongst others.

4.2.1. Overview of the European Civil Aerospace Industry

The European civil aerospace industry can be broken down into different sub-sectors - passenger transport and air freight. All these sub-sectors depend on one another to form a functional and profitable aerospace industry in Europe. The European aerospace industry is highly concentrated both geographically and regarding the involvement of a few large enterprises, where employment is particularly dense in EU countries like France, Germany, UK, Italy, Spain, Poland and Sweden. The EU aerospace products are exported all over the world (2).

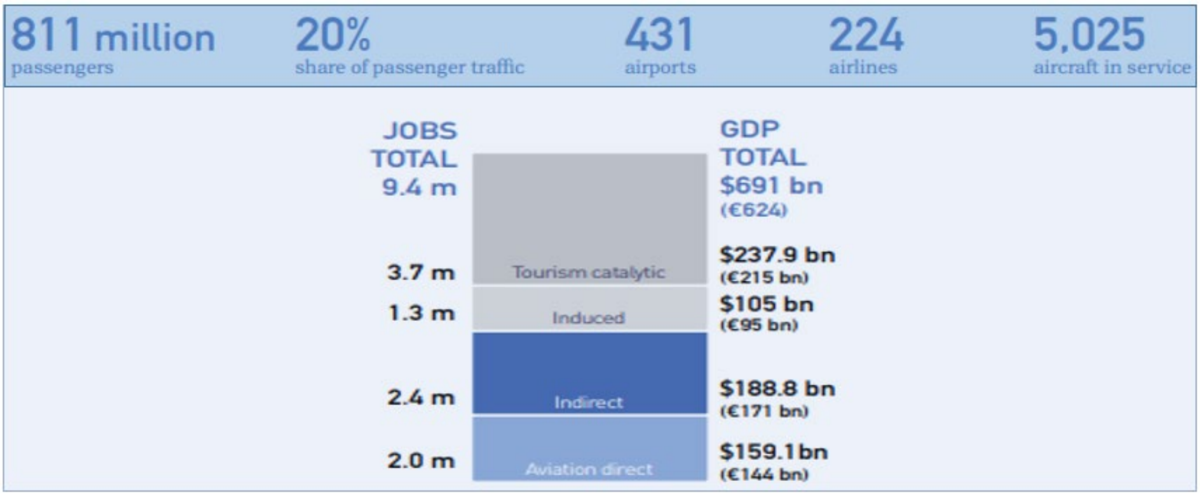


FIGURE 1: BREAKDOWN OF TOTAL EMPLOYMENT AND GDP FOR AIR TRANSPORT IN THE EU, 2016 (3)

Passenger transport and air freight

Passenger transport is one of the most competitive industries in Europe, bringing major socio-economic benefits to the entire European economy. In 2016, the EU aviation sector directly employed 2 million people, where, 18.8% were employed by airlines or handling agents (e.g., flight crew, check-in staff, maintenance crew or head office staff), 6.2% employed by airport operators (e.g., airport management, maintenance and security), 13.6% employed in the manufacture of civil aircrafts (e.g., assemblies, components, airframes and engines) and 2.2% employed by air navigation service providers (e.g., air traffic control and engineering). The rest accounts for on-site employment in retail outlets, restaurants and hotels. Furthermore, the European air transport system was connected by 431 airports, 224 airlines and 5 025 aircrafts in service with 811 million passengers, accounting for 20% of the total passenger traffic globally (3). Please refer to Case study 1 in ***ANNEX A*** for a breakdown of the total jobs and GDP supported by air transport in the EU28 economies. The industry directly and indirectly supported 9.4 million jobs, with its supply chain, wages and tourism contributing USD 691 billion (= EUR 614 billion as of 28 March 2019) in GDP to the total economic activity in the European Union (3). The EU is well positioned in the aerospace industry worldwide, producing 2 375 net commercial aircrafts in the region and a given share of 26% in the global civil MRO market in 2015 (4).

Overall, in 2018, passenger traffic across airports in Europe accounted for 2.34 billion passengers. When compared with the last five years, passenger traffic in Europe has increased by approximately 36%, accounting for more than 629 million additional passengers. With increasing growth, capacity and quality are major concerns for many airports in Europe, requiring increased investment and operational efficiency (5).

By 2040, a 53% increase in European flight movements is forecasted. This requires an associated increase in capacity. Approximately 1.5 million flights with a capacity of 160 million passengers will be unable to fly by 2040 if capacity is not increased (5).

The aerospace industry must operate in a long-term perspective of at least 20 to 30 years, which is the average lifetime of an individual aircraft, while any specific aircraft component may be manufactured for as many as 50 years. This demonstrates a healthy and growing industry for decades to come. Accordingly, the regulations that are established today and the respective allocated resources determine the perspectives and performance of the industry for decades to come (6).

Compared with passenger traffic, freight traffic decelerated in 2018 with a growth rate of 1.8% compared to a growth of 8.4% in 2017 (5). Reliable air freight is essential to the health of the EU's economy especially when exports play a leading role in the development of the economy. In 2016, the aerospace related exports amounted to EUR 106 billion, which includes one-third of the Intra-EU industrial flows (7). International Intra-EU-28 and extra-EU-28 transport (freight and mail) growth rates of 1.6% and 9.8% were observed respectively from 2016 to 2017 (8).

Air cargo is more vulnerable than passenger service. Air frames in aircrafts are dependent upon substances, parts and processes that were qualified decades ago. Disruptions in air service due to a non-authorisation of the use of compounds integral to the manufacture, maintenance, repair and overhaul of components and aircraft proven to keep flight air frames effective over many years of future service – compounds such as – NPE containing polysulfide sealants could profoundly impact EU economies.

4.2.2. Introduction of the applicant

Chemetall is one of the leading global suppliers of quality products and services with surface treatment and chemical treatment of metal surfaces being a core competence. The applicant focuses on worldwide surface treatment applications associated with the development and implementation of customized technology and system solutions. The products are developed for cleaning, corrosion protection, sealing, improving paint adhesion and facilitating the formation and treatment of metals (9).

The applicant is headquartered in Frankfurt am Main, Germany with 2 500 employees, 40 subsidiaries and 21 production sites globally. With sales offices, production facilities, service teams, laboratories and warehouses located worldwide, operations are performed in close proximity to its customers (10).

As a leading global supplier of choice for aerospace specialty chemicals, Chemetall provides Naftoseal® polysulfide aircraft sealants for all airframe, aerospace operation and aero-engine OEM and maintenance applications used by OEMs like Airbus (Group) and their supply chain, together representing 89 – 99 ([redacted]) % Chemetall sales share. The inter-relatedness of these customers is further elaborated in a general outline of the aerospace supply chain presented in ***Section 4.2.3***.

4.2.3. Supply Chain

The supply chain for the aerospace industry is highly complex, spanning many countries and regions, and having evolved over many years of successive investment, innovation and competition. The supply chain includes but is not limited to, chemical manufacturers, importers, distributors, formulators, processors, component manufacturers and OEMs as well as airlines and MRO companies as final customers (11). The complexity of the supply chain can provide a challenge to efficient communication and data gathering. It is difficult to characterise inter-dependency (i.e. the multitude of links/dependencies between companies) within the supply chain; however, the healthy functioning of the entire supply chain is clearly necessary for the health of the aerospace industry. Importantly, the complex structure of the supply chain also influences how quickly and efficiently change can be assuredly affected.

FIGURE 2: typical supply chain in the Aerospace Sector (11) shows, in highly simplified form, the various linkages between actors within the supply chain for the use of polysulfide sealants and shows how the supply chain often crosses borders to meet demands. The separations clarify that these companies are at different levels of production, however, not all the companies are limited to one single level or tier in the supply chain.

To provide a clearer view on the individual actors in the supply chain, a generalised definition of each 'tier' or group of companies involved has been elaborated by the European Aviation Safety Agency (EASA) (11) and is provided below.

The actors within the aerospace supply chain are:

- **Manufacturers** that produce the raw materials required by formulators. These formulators for various reasons might acquire the raw material from outside the EEA via **importers**.
- **Formulators**, in this AfA, Chemetall, purchase the raw materials from **manufacturers** or **importers** of surfactant containing NPE. They develop mixtures

(which are proprietary, such that formulation composition is highly confidential) to meet the requirements of their clients in each market and supply formulations containing NPE to meet performance specifications and industrial approvals. Their customers are generally component manufacturers, OEMs, and MRO operations.

- **Distributors** that purchase NPE or polysulfide sealant formulations from the manufacturer or formulator and deliver it to the customer (processors, component manufacturers, OEMs, operators, and maintenance repair and overhaul shops).
- **Processors** that are involved in the process of producing parts or final products to meet the requirements of other companies (OEMs or component manufacturers) they purchase polysulfide sealants to supply the required component parts.
- **Component manufacturers** (e.g. Airbus Qualified Suppliers) that 'build-to-print' (or Airbus design), produce and supply components. The components will be used by OEMs in the final stage of production. When producing parts, they purchase sealants themselves and mix *in situ*.
- **Original equipment manufacturers (OEMs)** (e.g. Airbus) that define the performance requirements of the components and the materials and processes they use in manufacturing and maintenance, or sub-contract to component manufacturers. OEMs are responsible for the integration and certification of the final product.
- **Maintenance repair and overhaul (MRO) shops** (e.g. Airlines and Airbus) that carry out aerospace product maintenance, repair and overhaul activities using polysulfide sealants during their daily activities.
- **Aircraft Operators (airlines)** and **military prime contractors** are the **customers** or end users of products containing or being treated with polysulfide sealants. For example, many airlines are using polysulfide sealants on a daily basis.

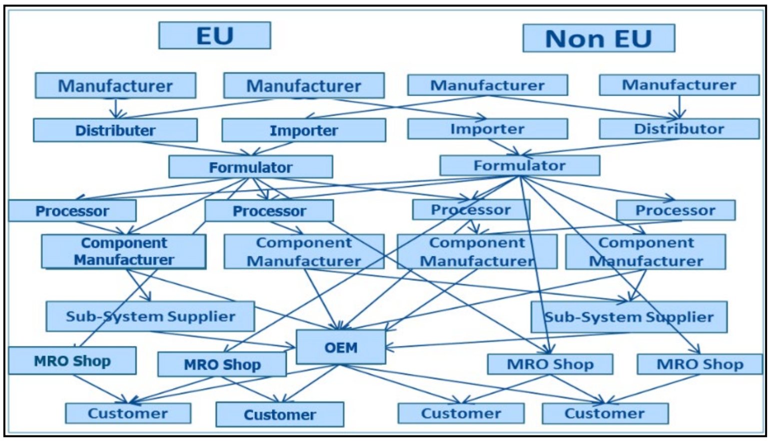


FIGURE 2: TYPICAL SUPPLY CHAIN IN THE AEROSPACE SECTOR (11)

FIGURE 2: typical supply chain in the Aerospace Sector (11) represents the supply chain where the use of sealants takes place.

4.3. Analysis of the substance function(s) and technical requirement(s) for the product (s)

4.3.1. Substance Specific Characteristics

Entry No. 43 to Annex XIV of the REACH Regulation does not list specific CAS or EC numbers and as such there are a range of substances that can be defined as a 'nonylphenol ethoxylate'. As described in ***Section 4.3.2***, the hardener component of the sealants included in consideration of this AfA contains low levels of NPE.

The physical and chemical characteristics typical of the NPE present in the affected sealant hardener formulations are summarised in Table 1.

TABLE 1 NPE PHYSICAL AND CHEMICAL PROPRTIES (CAS 68412-54-4) (12)

Parameter	Value
Appearance	Liquid
Water solubility	4.55 mg/L (slightly soluble in water)
Melting point/freezing point	-55°C
Boiling point	354°C
Flash point	193.5°C
Density	0.99 g/cm³
Partition coefficient	Log Pow 5.39
Surface tension	31.56 – 55.92 mN/m
Auto flammability/self-ignition temperature	410°C

4.3.2. Description of the technical function provided by the Annex XIV substance

The hardener component of polysulfide sealants manufactured by the Applicant includes a surfactant containing 'Nonylphenol, branched, ethoxylated, phosphated' (NPE-phosphate) (CAS 68412-53-3). The NPE-phosphate is not in scope of Annex XIV of the REACH Regulation, but contains the residual substance, Nonylphenol ethoxylate (NPE) (CAS 68412-54-4), which is within the scope of Entry 43 to Annex XIV. The surfactant is added to other constituents (e.g. manganese dioxide (MnO2), a plasticiser and other additives) and mixed together to form the hardener component. The hardener is then mixed with the base component to form the mixed uncured sealant.

- **NPE concentration in the surfactant is 2.5-10%**
- The surfactant is added up to 6% in the final hardener formulation
- **NPE concentration in the hardener formulation is up to 0.6%.**
- **The NPE concentration in the mixed sealant is <0.1% w/w** (base and hardener combined), when mixed according to the ratio requested in the technical data sheet.

Due to the ethoxylate functional groups, NPE (or similar substances) has a high surface activity and can act as a surface-active agent. This means that it lowers the surface tension of the medium in which it is dissolved, lowering the tension between substances of other phases, and is adsorbed at the liquid-vapour interface and other interfaces. Therefore, these substances are commonly used to fulfil a surfactant role to promote mixing between substances with differing surface tensions, such as between a solid particle and a liquid or between dissimilar liquids.

The choice of surfactant used in the formulation is linked to various factors, such as the type of plasticiser used. The concentrations of the surfactant must be optimised accordingly to avoid negative consequences (adhesion issues etc) of excess surfactant levels on the cured product. Fine tuning is required during product development and testing to obtain the optimum ratio between all key ingredients and ensure all performance requirements are met.

The hardener is manufactured as follows. The surfactant is manually added to the mixing vessel, along with the plasticizer and additional additives, and mixed as required. The solid MnO_2 powder is then weighed into the vessel and a homogenous paste is produced by stirring with the same mixer. Once fully mixed, the paste is automatically pumped directly into a mill. The mixture is then homogenised by mixing again. The whole process is run at ambient temperature and cooling is applied in all mixing and grinding steps, as these activities result in heat from mechanical friction (see CSR). The ratio between plasticizer and MnO_2 in the hardener is about 1:1 by weight and the additives (including the NPE-phosphate based surfactant) sum up to approximately 6% in the mixture. Once completed, an exactly fitting plate is attached to the top of the mill container and pressure is applied so the hardener is dispensed into a container for shipping or for transfer to the filling area where it is extruded out into the relevant compartments for the prefilled cartridge products. This ensures minimal residue of the hardener product remaining on the container.

4.3.2.1. Aerospace Industry Polysulfide Sealants– how they work

Aerospace polysulfide sealants come in two parts referred to as the base and the hardener. The base is composed primarily of a sulphide polymer with additives, such as resins, acetates and other batch chemicals, present at <10%. The hardener is composed of approximately 50% liquid polymer mix of the plasticiser and other additives and 50% solid manganese dioxide (MnO_2) particles. The MnO_2 is a significant component of the sealant.

MnO_2 functions as an agent to cure the polysulfide resins by oxidative crosslinking. It plays a crucial role in the formulation, application and end property development of the polysulfide sealant. The concentration of MnO_2 in the hardener and, following mixing, in the uncured sealant mixture, is important in determining the key properties of the sealant and to meet the specification requirements of the end use application.

Surfactants containing NPE-phosphate, with NPE present as a residual non-phosphated component of the surfactant, are added to the hardener formulation to promote bonding of the MnO_2 particles to the rest of the polymer mix and to ensure adequate dispersion of the MnO_2 particles in the hardener component. The surfactant is important because it is a determining factor for the concentration of the MnO_2 in the hardener. A surfactant that is too weak will not allow sufficient concentration of MnO_2 in the base. This has several important implications for the properties of the sealant. For example, if there is not enough MnO_2 present in the hardener, this affects the curing time of the mixed uncured sealant, as it will take longer to cure with less of the active MnO_2 component in the hardener. If there is too much MnO_2 in the hardener, it will be much thicker and more viscous than specified, so it cannot be pumped into packaging or efficiently processed further.

When the hardener and base components are mixed, the MnO_2 in the hardener and the base component mix together and start to chemically react to change the state of the sealant from a paste to a rubber-like solid over time. This is known as curing. This curing reaction can take place at room temperature and may also be accelerated by taking place under raised temperatures.

The requested mixing proportions as stated in the Technical Data Sheets range from 100 (Base): 9 (Hardener) to 100 (Base): 12 (Hardener).

Without the right surfactant, it is not possible to get enough MnO_2 into the hardener component and subsequently into the end uncured sealant mix. If there is less MnO_2 present in the hardener, then the ratio of hardener to base components would also need to change, as it must stay in proportion to achieve the same sealant properties. For example, if the concentration of MnO_2 in the hardener is reduced, the proportion of hardener in the uncured sealant mix would need to be increased to compensate and keep the sealant cure time the same. This would adjust the MnO_2 proportion, but there also will be more plasticiser from the hardener component introduced to the uncured sealant mix, so the cured sealant is softer and easier to peel off. The sealant applied to aerospace parts must achieve a Shore A Hardness (see ***Section 4.3.4.1.1***) score of >30 to enable it to be moved or processed further, and the final full cure of the sealants should achieve a Shore A hardness score of 40-50. The MnO_2 content in the hardener and mixed sealant also has an impact on other key parameters, such as viscosity of the sealant pre-cure and application time. Therefore, ensuring adequate concentration and dispersion of the MnO_2 in the hardener is key to the functionality and use of the sealant. As such, the surfactant used to aid this process is an important component and replacement may not be straightforward.

- Sealants are comprised of a base and a hardener which are typically mixed in a 10:1 ratio – the hardener contains 50% solid MnO_2 particles, which functions as the active curing agent for the sealant
- Surfactants are added to the hardener formulation to adequately disperse the MnO_2 particles through the liquid hardener mixture. NPE is present in the surfactant used for these polysulfide sealants
- Inadequate dispersion of the MnO_2, and therefore reduced concentration of the active component in both the hardener and mixed uncured sealant, can impact upon end mixed uncured sealant performance and cured sealant performance during aircraft operational life

4.3.3. Description of the product(s) resulting from the use of the Annex XIV substance

4.3.3.1. Sealants and the Aerospace Industry

Sealants are used to fill voids of various sizes, isolate dissimilar metals/substrates, bond two parts and provide a barrier to prevent the passage of liquids or gaseous media. These are just some of the examples of the applications that sealants are used for, as they have a wide range of key uses in the aerospace industry.

Polysulfide sealants are a specific type of sealant, originally developed over 70 years ago. Since then, they have been widely used in a variety of industries, including in aerospace. When used in aerospace applications, sealants add specific functionality to the hardware on which they are used. For example, they are used to protect against corrosion by e.g. preventing ingress of environmental moisture or water and providing an effective firewall in aircraft engines and exhaust assemblies by containing fluids, such as fuel and vapours. Polysulfide sealants are used extensively in, and relied upon by, the aerospace industry sector and are of vital importance for the aerospace sector.

The unique properties of this class of sealants that make it suitable for use in key aerospace applications include, but are not limited to:

- Resistance to degradation by fuel and other chemicals
- Flexibility over a wide range of temperatures, most uniquely extreme cold
- Adhesion to a wide range of substrates without the need for special surface preparation, and sometimes without requiring the use of additional adhesion promoters
- Ability to stress-relax, thereby maintaining adhesion to expanding and contracting substrates, limiting peeling of the sealant during aerospace product normal conditions of use

Due to this unique set of properties, and additionally their compatibility with a wide range of paint and primer systems, these sealants have been employed in innumerable sealing and adhesive uses in aerospace assemblies. These applications include anywhere that a fluid needs to be restricted from passage through, or presence in, some volume or space. Some examples are listed below, but this is by no means the entire list of key applications of these products in aerospace industry;

- Seal structures/components:
    - to keep moisture or other fluids out (e.g.to prevent corrosion or attack of structures/components)
    - to keep fluids in (e.g. fuel, hydraulic fluids, etc.)
    - to prevent airflow to maintain cabin pressure
- Component isolation:
    - to separate dissimilar substrates/metals to prevent corrosion
    - to provide thermal/electrical insulation
- Fill gaps:
    - to create an aerodynamic surface by a process referred to as aero smoothing
    - to eliminate moisture accumulation or traps
- Adhesive applications:
    - in engines and nacelles when flexibility and compatibility with mating gap filler is required
    - in bonding structures requiring flexibility
    - in bonding/sealing of wires
- Electrical potting in connectors, PC boards, circuit boards

Examples of the polysulfide sealants use in aerospace products include on structures, fuel tanks, actuators, electronic controller connections, gyros, wiper blade systems, propeller blades, ball screws for actuators, flight control rudder pedals and joint sealing of general aircraft structures during assembly process, wet installation of fasteners, etc. Other key uses include in flight controls, actuators, controllers, fuel tank (to ensure no leakage), window sealing for air tightness and pressurization of pressurized areas such as passenger cabins. They can also fulfil some adhesive and aircraft coating functions.

The ease of handling of sealants and their ability to adhere to a wide range of substrates, either as they are or with the additional use of an adhesion promotor, make them suitable for use in MRO operations. The ability to use the same formulations in MRO that are used in original manufacture is essential in aerospace assemblies for ensuring continuance of performance, safety of the component or assembly and compatibility between the two sectors.

There is significant overlap in the uses of polysulfide sealants in passenger, commercial and military aircraft assemblies.

The properties of polysulfide sealants have led to their usage beyond sealing. One such important use of sealants is as an adhesive. Polysulfide sealants are not used as structural adhesives, since these sealants are not as adhesively strong, compared to common structural adhesives, such as high strength epoxy-based adhesives where adhesion is the primary function. However, their ability to bond a wide range of substrates and to stress relax has led to their use for bonding where high strength is not a requirement, but reliable adhesion and flexibility at extreme temperatures, and/or reparability are required.

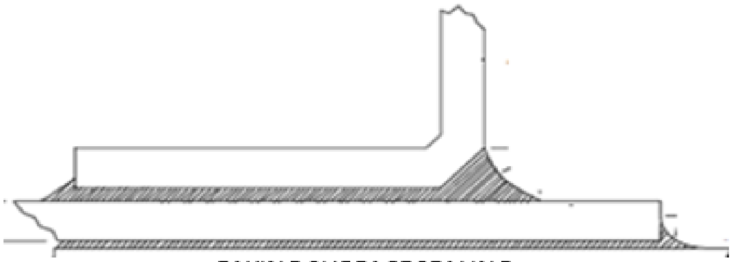
It is difficult to overstate the importance of uses of polysulfide sealants in aerospace assemblies. Virtually every aerospace system incorporates polysulfide sealants in multiple uses, see Figure 8 and Figure 9.

- Polysulfide sealants are widely used and provide specific functions on aerospace hardware on civil and military aircrafts, including helicopters
- Polysulfide sealants have varied and unique properties, as well as good adhesion to a variety of substrates, which makes them suitable for a variety of applications in the aerospace industry

4.3.3.2. Polysulfide Sealants – where they are used

Polysulfide sealants are applied in a variety of locations to fulfil key functions, such as;

Faying/Inter Fay Surface Sealant - A mixed sealant installed between two mating (overlapping) surfaces, e.g. between part of a hinge and the door of a cabinet to which it is installed. In aerospace, this includes on internal structural joints as well as exterior and interior surfaces. Faying surface sealants are used to prevent corrosion (e.g. for dissimilar substrates as corrosion resistant steel and aluminium), to protect against fretting and abrasion, and, in conjunction with fillet seals, to prevent a leak path from extending through a faying surface to another area. Additionally, the faying surface sealants prevent debris ingress. Faying surface sealant is used in dry areas as well as in wet fuel containing areas, as per Figure 3.



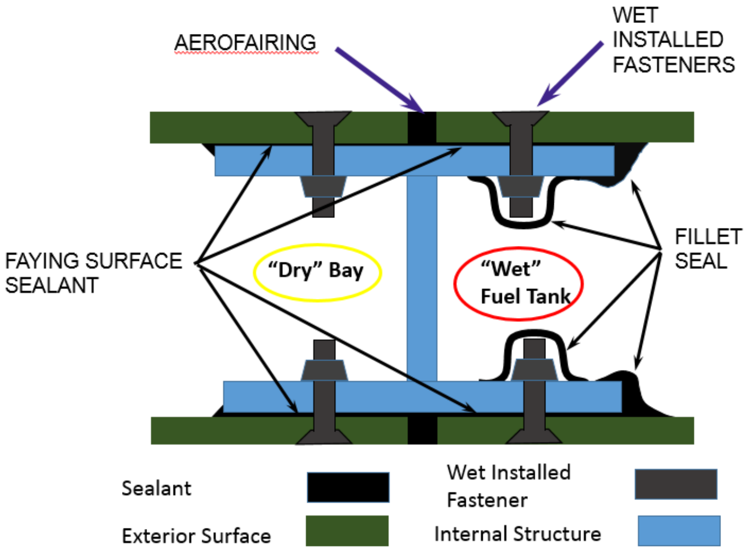


FIGURE 3 DIAGRAM OF FAYING SURFACE SEALANT LOCATION APPLICATIONS

Fillet Seal - A primary seal (post assembly) applied at the juncture of two perpendicular or angled adjoining components (a fillet joint), or surfaces, and along the edges of faying surfaces, as a continuous bead of sealant to create a continuous and smooth surface, see Figure 4. An everyday example of this would be between at the top interface between a wall and a bath. It can be applied over, along the edges of, and between installed components and fasteners. Fillet seals are predominantly used in fuel tanks but are also applied to dry areas that have contact with water, moisture and occasional exposure to other liquids to prevent corrosion.

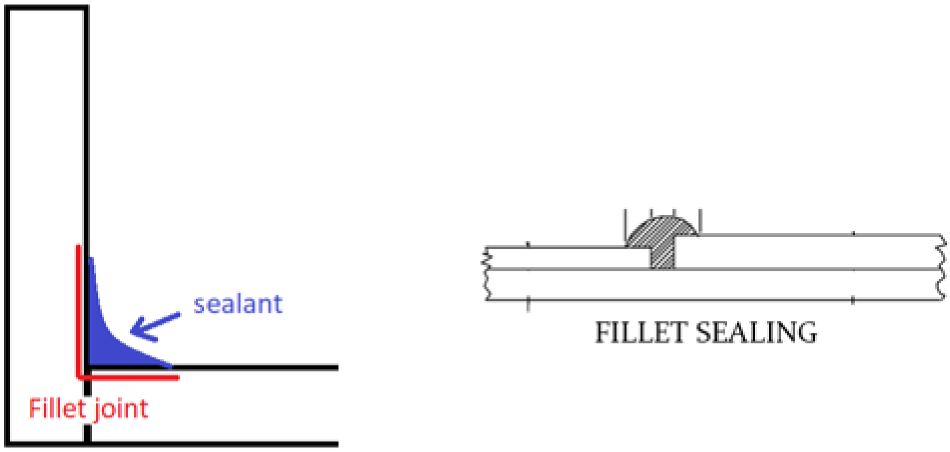


FIGURE 4 FILLET SEALING DIAGRAMS

Wet Installed Fastener - Fasteners that have sealant applied to their shank and under their head prior to installing to provide a corrosion barrier and secondary seal to ensure tightness against fuel and air.

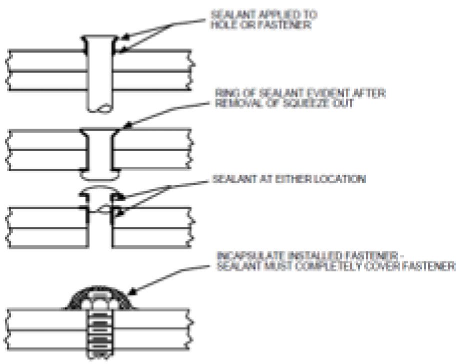


FIGURE 5 WET INSTALLED FASTNER DIAGRAM

Aerodynamic Sealant – Is formulated for filling and smoothing external depressions and seams. This provides smoother airflow across, for example, the fuselage and other external hardware, resulting in better fuel economy. It also enhances aerodynamic properties of the surface and prevents cavitation.

Corrosion Inhibiting Sealant – Is formulated to provide an effective barrier against corrosion on metals between dissimilar substrates.

Windshield Sealant – Specifically formulated to not attack or degrade polycarbonate or acrylic windshields.

Fuel Tank Sealant – Fuel tanks exist as a cavity in a wing or in the fuselage or both, and the sealant is an important part of ensuring fuel containment (see Figure 6).

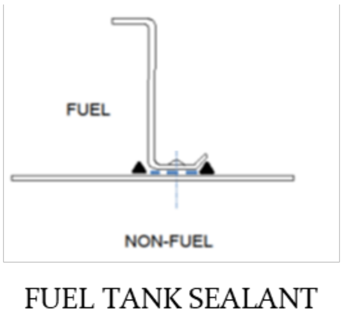


FIGURE 6 FUEL TANK SEALANT DIAGRAM

Firewall Sealant - The sealant is formulated to withstand high flash temperatures (e.g. 2000°F/1100°C) and seal structures against the passage of hot air and vapours.

Cabin Pressure Sealant - Creates an airtight seal on aircraft cabins to prevent pressure leakage and provide resistance to water and weathering.

Sealants can also be used to gap fill holes, act as a barrier to prevent abrasion, seal bonded structures, fill open cavities, in slot and injection sealing, firewall sealing, overlap sealing, etc., as per Figure 7 below. This is not an exhaustive list of uses for the sealants in the aerospace sector but demonstrates how widely they are used throughout the industry.

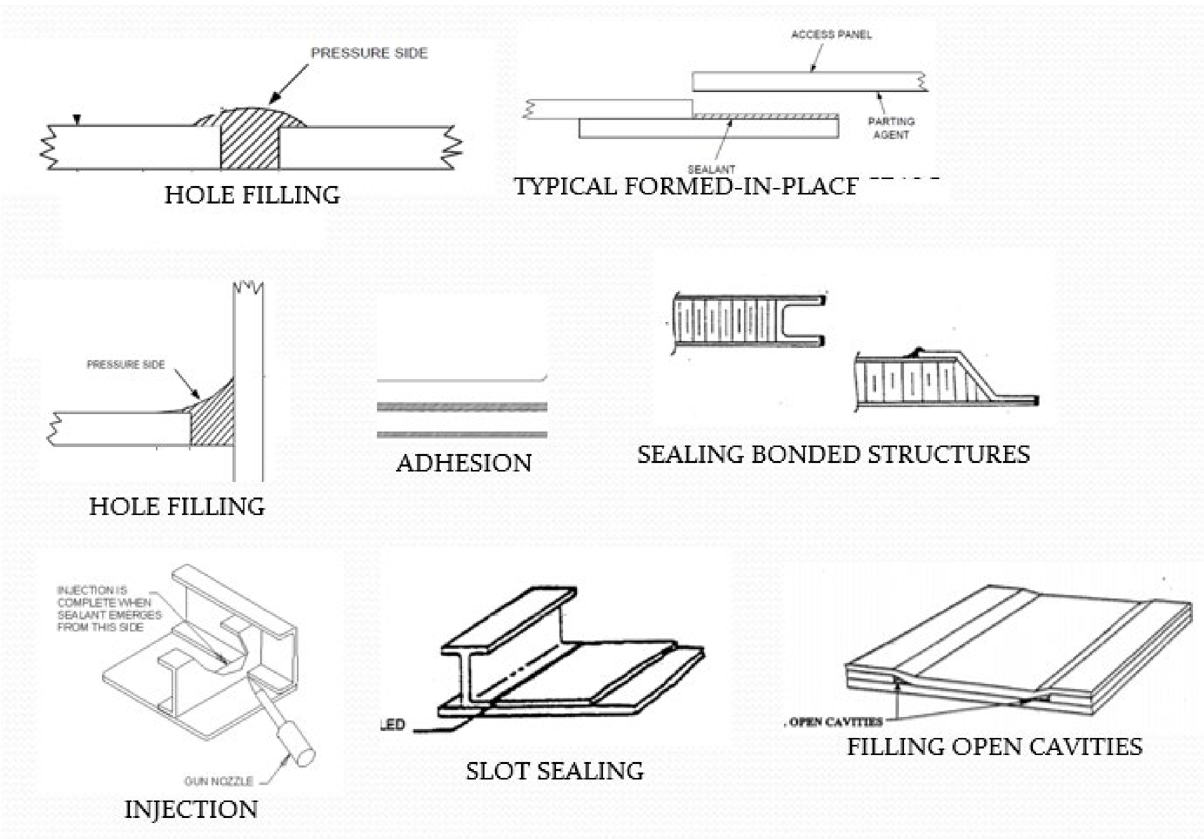


FIGURE 7 OTHER EXAMPLES OF SEALANT APPLICATIONS

Sealants are applied and bonded to aerospace components on the outside and inside of the aircraft, as they are typically applied between most mating joints and most fasteners during assembly of the structures, illustrated for aircraft (as per Figure 8) and military aircraft (as per Figure 9) below; although, it should be noted that corrosion inhibition is required all over the aircraft.

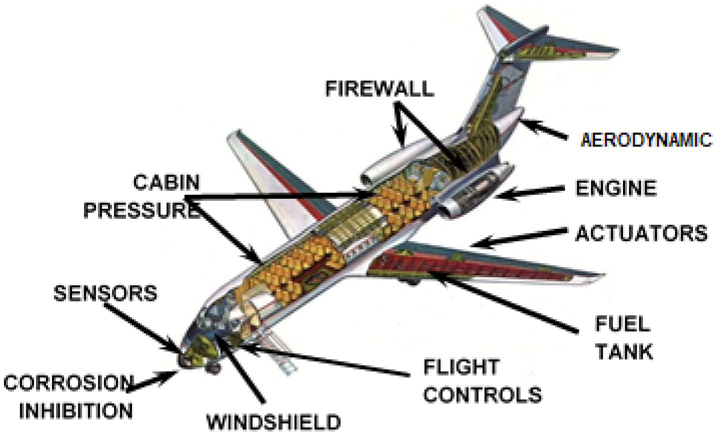


FIGURE 8 DIAGRAM OF TYPICAL SEALANT LOCATIONS ON AIRCRAFT

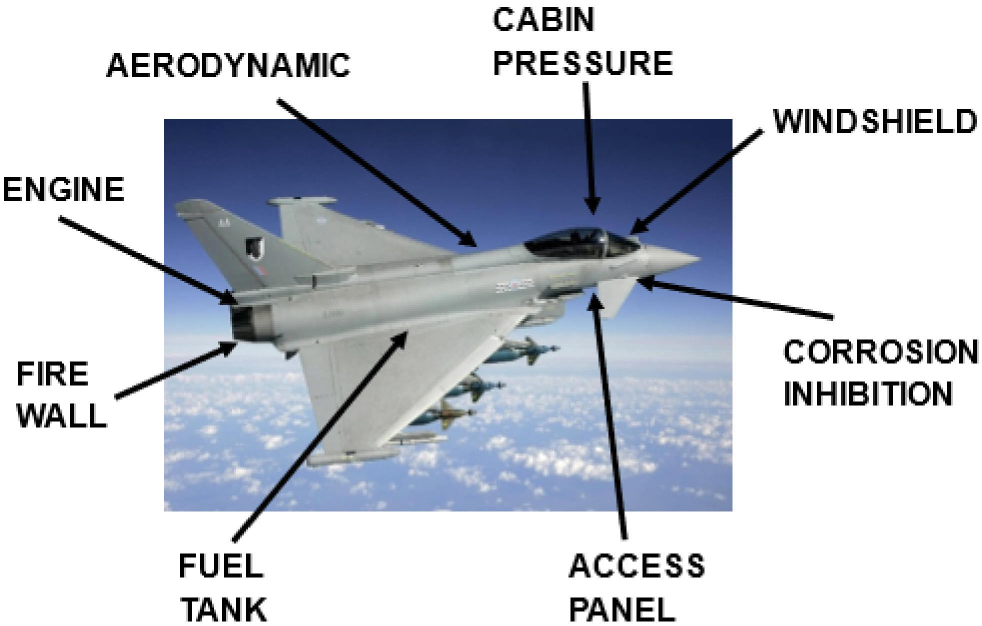


FIGURE 9 DIAGRAM OF TYPICAL SEALANT LOCATIONS ON MILITARY AIRCRAFT

4.3.3.3. Sealants – Packaging Methods

Sealants used by the aerospace industry are supplied in a variety of packages, but the most common are,

- two-part kit sets (which are available pre-packaged either in cans for smaller scale mixing or drums for bulk mixing),
- pre-metered two-part disposable cartridge-based systems (stores, mixes and applies multiple component adhesives/sealants)

- premixed and frozen (PMF) sealant

The different packaging methods have been developed over time, to not only optimise the product quality and performance to specification of the sealant, but to provide options to customers depending on their own requirements and manufacturing processes. Some OEMs may be using high volumes when manufacturing, so the two-part kit sets, which can be delivered in greatest volume, might be more appropriate than individual smaller volume cartridge systems.

For all the packaging methods, the hardener is required to be mixed into the base component prior to application. Product mixing is completed in a clean environment under room temperature conditions and in a controlled manner, to ensure thorough mixing in accordance with manufacturer's procedures.

The mixing activity is within the scope of Authorisation, due to the concentration of NPE in the hardener component (max. 0.6% w/w). Once the two components are mixed, the concentration of NPE in the mixture is <0.1%w/w and the application or further use of the uncured mixed sealant is outside the scope of Authorisation, see Figure 12.

Two-Part Kits

All sealants consist of a base and hardener, but for the two-part kits, it is delivered in two containers that are attached together and clearly labelled. Each container has the base and hardener components premeasured for the standard mixing ratio for that product (e.g. 10 Base:1 Hardener), ready to be mixed together. The volume in these kits can vary from smaller scale can kits to drums.

Each part is first mixed separately to uniformity, using a disposable spatula or tool for even consistency, as constituents of the hardener and base can occasionally settle. The hardener is added to the base and slowly, but thoroughly, mixed together, taking care to avoid leaving unmixed areas, particularly around the sides or bottom of the mixing container. This can be done manually or by machine for can kits or by machine for bulk mixing, as in Figure 10.

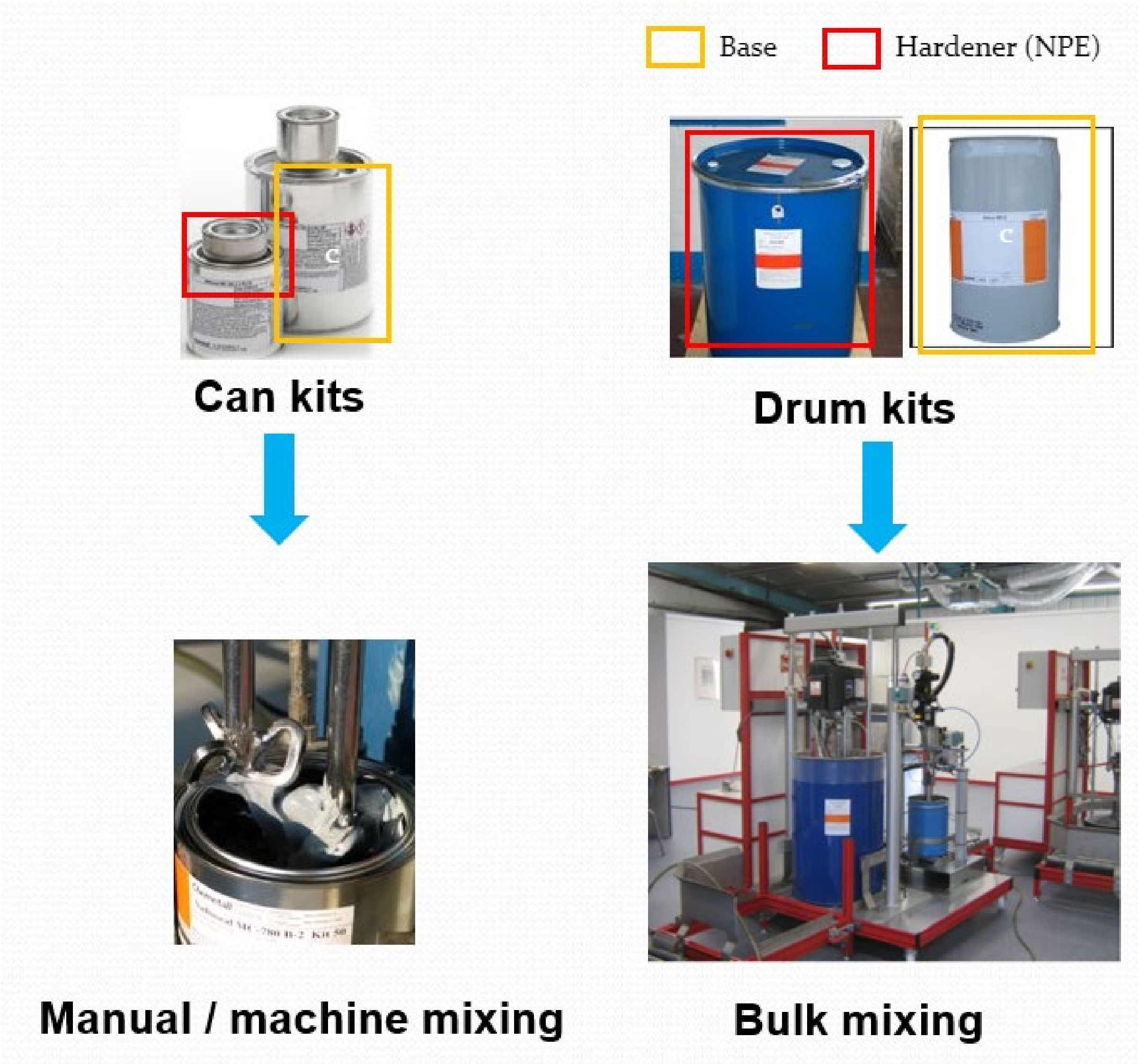


FIGURE 10 PICTORAL OVERVIEW OF TWO-PART SEALANT KIT MIXING

The mixed sealant is then applied to previously cleaned surfaces, for example at the interface between two pieces of structure, or adjacent to the joint, if a fillet seal is being applied, etc. It is applied within the pot life/working life time and per work instructions. In general, shorter working life is preferred due to the shorter time to produce full setting or cure of the sealant. Some sealants are self-levelling and suitable for brush application methods, and others are suitable for loading into an extrusion gun or onto a disposable spatula. Some designs require the use of bond primer or adhesion promotor to improve adhesion of the sealant to the surface.

Pre-metered Cartridges

In this case the sealant is stored, mixed and dispensed from a single cartridge where the base and hardener are pre-metered. When ready to be used, the internal mixing rod is pushed through the barrier separating the two parts and is repeatedly plunged the length of the syringe barrel, whilst being rotated to ensure an even mix of the sealant, see Figure 11. This can be done manually or by machine to ensure a uniform and repeatable standard of mix of the sealant. The mixed sealant is pushed from the kit via a plunger at the back and applied directly to the surface or gap through the cartridge nozzle or with a pneumatic gun.

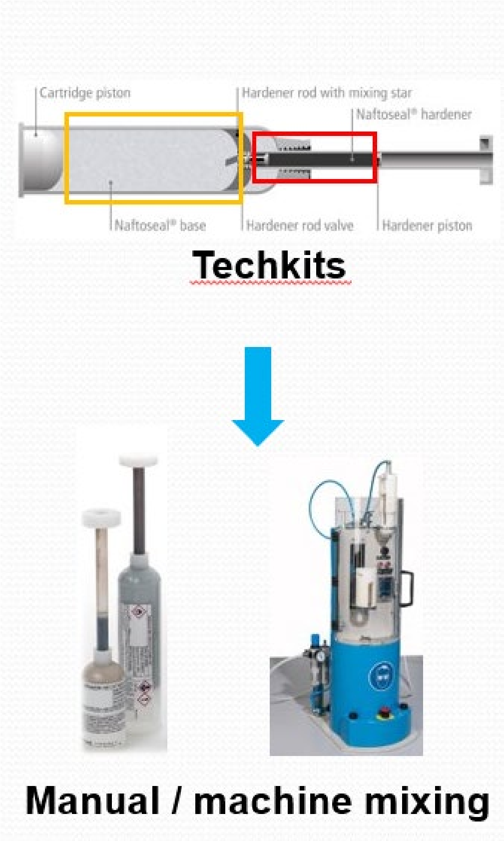


FIGURE 11 PRE-METERED CARTRIDGE MIXING METHODS

Premixed and Frozen (PMF)

PMF products have the mixing stages completed by the Formulator or downstream user and are placed into dispensing syringes and frozen before the sealant can cure. These must be stored at extremely low temperatures (typically below -70°C) and shipped in temperature-controlled (typically below -40°C) packaging and stored in speciality low temperature freezers to ensure the mixed sealant does not prematurely cure before it can be applied. These products have a maximum shelf life after deep freezing of 35 days and this option is limited to sealants with longer work life and longer cure time. Sealants with a short work life or fast cure products cannot be frozen due to the reduction of work life that freezing causes. Upon receipt, the Downstream User can then thaw the PMF dispensing syringes to room temperature and can then expel the mixed sealant directly to the surface or gap through the cartridge nozzle, in the same way as in the ready to mix cartridge systems. PMF is further discussed in ***Section 5.4.1*** (NUS Scenario 1).

PMF sealant can be provided in more specialist packaging methods, such as:

- Sealant strips: premixed sealant is shaped as required prior to being frozen. This can then be thawed by the Downstream User when needed, placed where required and left to cure
- Seal caps: the manufacturer creates moulded caps of cured sealant with a hollow inside, either filled with PMF uncured sealant or provided to the downstream user

unfilled. These are thawed for use and placed over bolts/fasteners to quickly and easily create a capping seal that can be left to cure

After applying the sealant, regardless of the method of application to the hardware, the surface is left undisturbed until the sealant is tack free, to allow the sealant to cure sufficiently before the part can be moved, and further assembly or maintenance activities can be undertaken. The other manufacturing or MRO activities can continue in the time between the sealant achieving a tack free surface and full sealant cure. Excess uncured sealant needs to be removed prior to cure to avoid fit issues.

Time taken to cure the sealant is dependent on the specific sealant and factors, such as temperature and relative humidity used. For example, 2 hrs might be possible for some sealants under oven conditions, whereas complete cure may require up to 90 days at room temperature. Over the course of the curing process, the sealant will have transformed from a liquid/paste consistency to a solid rubber. See Figure 12 for an overview of the process.

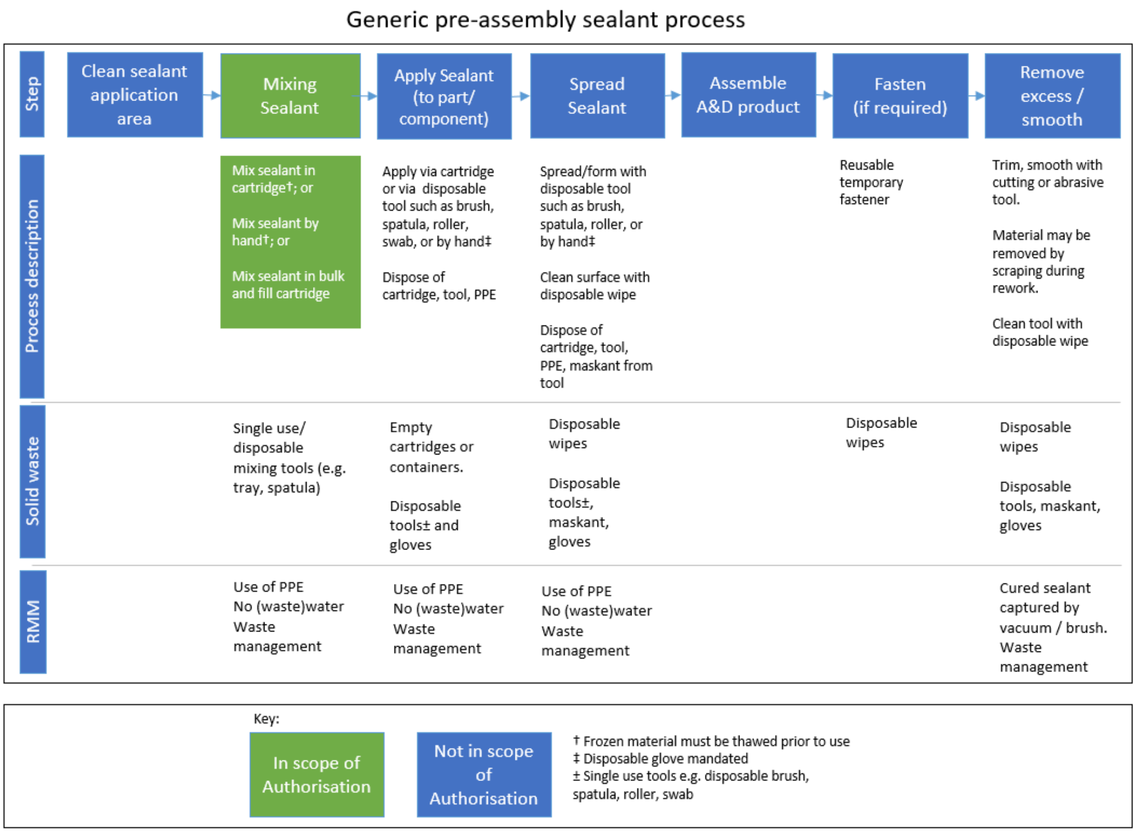


FIGURE 12 GENERIC PRE-ASSEMBLY PROCESSS OF SEALANT USE

The process for post-assembly sealant use is the same as in Figure 12 above, except cured sealant is first removed as part of the cleaning sealant application area activities. In the context of this application, and as highlighted in Figure 12, it is the mixing of the two parts of the sealant that is within the scope of the Authorisation.

4.3.4. Description of the technical requirements that must be achieved by the products(s) made with the substance

The European Aviation Safety Agency (EASA) established airworthiness regulations to ensure the highest common level of safety and environmental protection for EU citizens in civil aerospace. The European Military Aviation Requirements (EMARs) were created by the European Defence Agency (EDA) Military Airworthiness Authorities (MAWA) Forum to promote harmonisation of European military airworthiness regulations.

The regulatory requirements and responsibility placed upon OEM companies drives the need for creation, implementation and maintenance of agreed industry and internal specifications relating to all elements of the component or material. These specifications inform which component(s) or material(s) are suitable to be used in aircraft manufacture. The specifications detail the performance criteria the material must comply with to be considered as suitable for use and can include details on testing to verify if it meets the specified criteria (see ***Section 4.3.4.2***).

All changes to the materials, components, or manufacturing processes used in complex aerospace assemblies are subject to the highest level of scrutiny. No change is so minor that it does not require some degree of substantiation. Figure 13 provides a process overview, however, it must be noted that that this is an indicative illustration and not all companies use the same wording to describe each stage. For example, validation can be included in technical qualification in some cases. Any change to the components, materials, or manufacturing or maintenance processes must be qualified to prove it meets specifications performance requirement. Formal processes are in place to manage the change, and justifications/evidence provided for the qualification and certification of the change can take many forms. It is the responsibility of the OEMs, as design authority or Type Certificate Holder, to ensure that formulations used in key applications, or on aerospace parts or assemblies, are suitable and safe for use, in accordance with the airworthiness regulations (as detailed in ***Annex C***) and to agree the approach to certification (if needed) with relevant authorities.

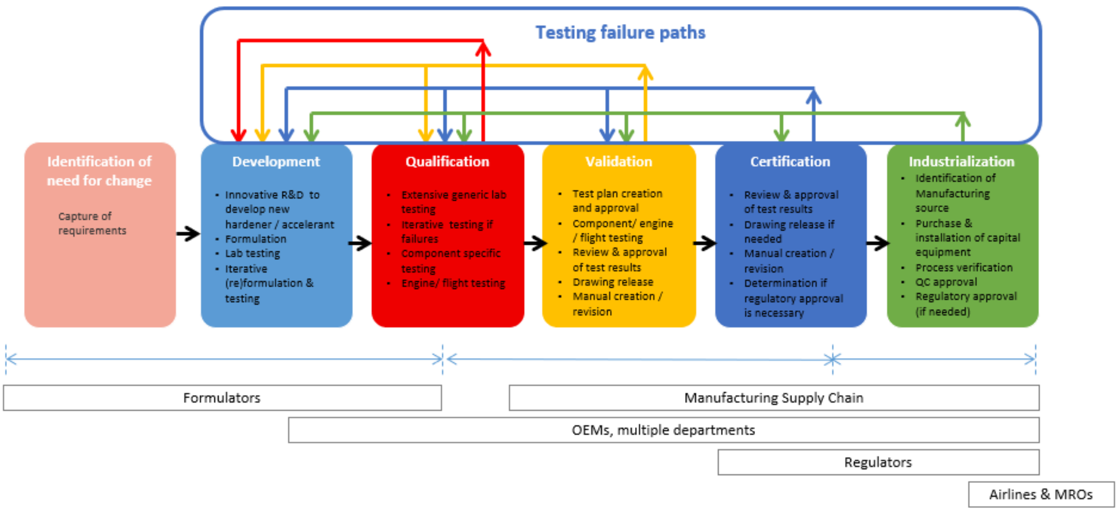


FIGURE 13 KEY PHASES OF INTRODUCING A CHEMICAL SUBSTANCE CHANGE INTO PRODUCTION HARDWARE MANUFACTURE

In the case of the replacement programme for polysulfide sealants containing NPE for each individual change, compliance with specifications, process instructions, and maintenance manuals provides the evidence that the alternative sealant is interchangeable and thus is airworthy. As a result, there is no need for an additional certification step or validation from EASA or relevant military certification authorities. This is crucial, since additional certification or validation from the relevant authority involves a much more extensive effort associated with aircraft part design changes (e.g. drawing, part number, and/or name changes). The reformulated alternative sealant will need to meet the same performance requirements as the existing sealants for each category.

New Formulation Development

The development of a formulation is complex, and several years are often necessary. Once a reformulation or substitution project is launched, technical specialists from engineering and manufacturing departments must align the numerous regulatory, performance and technical requirements that an alternative must fulfil.

In the development of new formulations, or changes to an existing formulation, it is important to note that many iterations are rejected in the Applicant's laboratory and do not reach sufficient maturity to proceed to OEM qualification testing.

Qualification through industrialisation is required to:

- Ensure that only reliably performing materials, components, and processes are approved for use to produce aerospace components.
- Ensure that the product, the process or method is compliant with both relevant Regulations and aerospace component manufacturer requirements to fulfil specified functions.
- Provide a very high level of confidence for both the use of the product and the resulting AD end components.
- Ensure consistent quality of materials being introduced.
- Ensure consistent use of the new or alternative product between different product or component suppliers, and to guarantee production and management system robustness, throughout the supply chain.
- Fulfil requirements of the Airworthiness Authorities (EASA) and applicable military requirements.

Technical qualification for the polysulfide sealants by Airbus Group is anticipated to require 1 to 2 years to complete, depending on the ease of meeting all the performance requirements that were established. This duration estimate assumes that the qualification process is successful, which may not always be the case. In the event of failure, product qualification will be stopped, and the development phase must start again from the beginning.

The newly qualified sealants must perform in the same way as current sealants and will be applied using the same process instruction. In this way, the alternative product can be considered a one to one replacement. When the alternative product is a one to one replacement, the interchangeability principle will be applicable.

Figure 14 highlights the progressive complexity of materials substitution from a change that is deemed interchangeable for any part (least complex) to a change where a unique alternative is required for all uses and no interchangeability is allowed (most complex)

(54).” [10] As no component design changes (e.g. no drawing, part number, or name changes), are expected in the case of the reformulated sealants, the changes at OEMs are anticipated to fall in Path 1. The newly qualified sealants are expected to perform in the same way as current sealants and to follow the existing process instructions. Interchangeability is achieved where the alternative product is proven to be a one to one replacement, and Path 1 is followed. (Re)Certification will not be required if no change to the specifications are necessary.

	Paths 1	Paths 2	Paths 3
Change context	Materials interchangeable for any part	Materials interchangeability limited to these parts	Loss of material interchangeability for these parts
Impact on **material spec**	Material interchangeability is managed at the spec level*	As many spec as materials	As many spec as materials
Impact on **drawing**	No change	Drawing of these parts shall call out the interchangeable materials	Drawing of these parts shall call out the relevant material (with potential consequential impacts on parts drawing)
Impact on **part number**	Not changed for any part	Not changed for these parts	Changed for these parts
Mean of traceability	On production documentation	On production documentation	On drawing

FIGURE 14 MATERIALS CHANGE PATH (13)

In the case of the polysulfide sealants in scope of this AfA, no change to the formulation name is anticipated, as the NPE-containing and NPE-free formulations are expected to be interchangeable.

For materials for which interchangeability between the existing and re-formulated product cannot be demonstrated, and the change cannot be considered as a one to one replacement, it may be necessary to undertake validation/certification activities, following Path 2 or 3 in Figure 14 above, prior to implementation.

Once the new formulation is qualified and ready for deployment in manufacturing plants, the industrialisation stage can commence.

Industrialisation may be scheduled to follow a stepwise approach to minimize the technical risks and to benefit from lessons learned. This means that changes may not be implemented universally or simultaneously across all sites and at all suppliers but rather via a phased introduction.

In the case of providing candidate alternative polysulfide sealants without NPE to OEMs to commence qualification testing, this development stage has been ongoing since 2017 and is expected to be concluded by Q2 2021. In line with best estimates about the degree of qualification testing that will be required, including a risk margin of safety, the qualification

[10] ASD19003 Issue 1: REACH Design changes best practices (17th April 2019), pg. 9

stage is expected to be able to conclude by Q4 2022 as discussed further in ***Section 5.1.2.3***.

Further details on the regulatory situation for aircraft and the required steps to implement a new or modified formulation in the aerospace industry is provided in ***Annex C***.

4.3.4.1. Sealants – Service Life

Sealants are required to perform as specified for the lifetime of the part for aerospace assembly equipment. Sometimes, due to the location or performance requirements of the part the sealant must maintain its properties (as described in ***Section 4.3.2***) for the lifetime of the system itself. Aerospace components containing polysulfide sealant perform over a wide range of service environments and face a variety of challenging operating conditions when cured, such as:

- extreme high and low temperature exposures
- vibration
- mechanical shock
- high and low ambient humidity
- exposure to fluids including jet fuel, hydraulic fluid, coolants, cleaning agents, de-icing fluid, lubricating oils, seawater, etc.
- exposure to sunlight, ozone and weathering

The long service life of aerospace assemblies drives MRO activities over their entire service lives, sometimes requiring the localized removal and replacement of the sealants where access to the equipment that requires repair may not be possible without removal of components (e.g. around access doors and panels, etc.). Upon repair, some of the old polysulfide sealant may remain, requiring the new sealant used at the time of repair to be compatible with previously cured sealants. This characteristic is commonly required across numerous aerospace assemblies.

4.3.4.1.1. Physicochemical/process/operational conditions for usage of sealants

The key technical criteria for selection and usage of sealants to meet manufacturing and industrialisation criteria, which affect the suitability of alternatives to using NPE in polysulfide sealants, as identified by EAAC sub-group member companies, are included below. This list in Table 2 is indicative and should not be considered exhaustive.

TABLE 2 KEY TECHNICAL CRITERIA – PHYSICOCHEMICAL/PROCESS/OPERATIONAL CONDITIONS

Key Technical Criteria	Description
Viscosity	Viscosity is defined as the magnitude of internal friction and the resistance to uniform flow of a fluid; the greater the resistance to flow in the fluid, the more viscous it is and the more the fluid behaves cohesively. The viscosity of a sealant is very important, as this can affect the method of physically applying the sealant and the suitability of the sealant to the area in question. For example, a sealant with very low viscosity could be uniformly applied to a level surface and not to any curved components, or the underside of a part. A sealant that is very viscous may not be suitable for extrusion using a cartridge and may have to be applied using a spatula or brush. Different sealants may fulfil a similar function but have different viscosities requirements, depending on the intended use and method of applying the sealant to the hardware (e.g. brush, extrusion, etc.).

Key Technical Criteria	Description
Density	Density is defined as the item's mass per its specific volume. For sealants, where usually the component it is being applied to defines the required amount in volume, the sealant density will play a role in the overall weight of the component. The sealant density therefore has a direct influence on the efficiency and fuel-consumption of an aircraft. On the other hand, lowering the density of a sealant, e.g. by including gas-filled balloons into the material matrix, might result in a decrease of mechanical properties, e.g. cohesive strength.
Pot Life / Working Life/ Application time	Pot life/working life/application time can be characterised as the period where reactive chemicals remain usable after mixing, until the viscosity of the mixed sealant is such that the sealant is no longer usable. This can be taken as the maximum length of time available to apply the sealant after the sealant is mixed or thawed, and remove any excess, which is determined by Standard Test Conditions. This can also give a rough indication of the curing time for the mixed sealant as those with a longer pot life/working life/application time take a longer time to cure. For different sealants, different working life times may be specified to ensure an optimal balance between consumption and throughput. This can be identified in the name of the sealant (e.g. MC-238 A-1/2; the numerical suffix (1/2 in this example) refers to the working life time in hours). If reformulated sealants have different working lives, it can adversely impact OEM manufacturing processes and usage efficiency.
Cure Time and Temperature	The cure temperature is a key criterion for sealants, as this is one of the main controls on the time the sealant takes to fully cure and can currently be completed at either ambient temperature or elevated temperatures using heat lamps or other heat sources. The time taken to cure is important for the OEM manufacturing facility, as this will affect the overall manufacturing process, if incorporating into a larger aerospace system, and impact upon delivery of final equipment pieces. It is also important for either civil or military aircraft repairs if the aircraft is not located near a repair facility. Any alternative sealants must not adversely impact the curing time and must be able to be cured under the same temperature conditions as the original formulation, otherwise the manufacturing and MRO processes will be impacted.
Tack Free Time	The tack free time is considered as the minimum length of time until the sealant can resist damage after some degree of contact to the surface (e.g. will not easily dent under gentle pressure) and can resist contamination with airborne particles or dirt. Therefore, the tack free time also is a measure of the minimum length of time the aerospace part in question must be left undisturbed before it can be moved or incorporated into a larger aerospace system in manufacture or repair. For example, a product may have a tack free time of 20 hrs, but a full cure time of 50 hrs, and a product with a tack free time of 10 hrs may have a full cure of 40 hrs or less. These examples illustrate that this is an important parameter for the planning and manufacturing/MRO process to assist avoiding unnecessary delays in continuing with the manufacturing and repair of the part.
Shelf Life	The shelf life of a product is the length of time that a product can be kept before it is no longer suitable for use. It is key that the sealant purchased retains its quality (e.g. has the same performance capabilities at the end of the shelf life as at the beginning) and is still in good condition to use when required. Settling or degradation of key ingredients over time would be unacceptable, as this can affect the end mixed sealant performance. Depending on the needs of the OEM manufacturing or MRO facility, it may be necessary to keep the sealant components or cartridges on site for several months, as there may be fluctuation for amount required during manufacture or repair of the aerospace components.

4.3.4.1.2. Sealant performance parameters for article lifecycle

The final cured sealant also must meet the following key technical criteria, to ensure adequate aerodynamic and bonded structure sealing of aerospace components which affect the suitability of alternatives. These are as identified by EAAC sub-group OEM member companies. As above, this list in Table 3 is indicative and should not be considered exhaustive of all requirements. These properties may not all simultaneously apply to one sealant, as some properties may be more relevant than others and this can vary between products.

TABLE 3 SEALANT PERFORMANCE PARAMETERS

Performance Parameters	Description
Hardness	The hardness of a sealant is defined as the resistance to permanent deformation (otherwise known as "plastic deformation"). It is measured by means of indentation, and for rubber-type compounds, this is typically measured against the Durometer Shore A hardness scale. The higher the score on the Shore A hardness scale, the harder the sealant and the greater its resistance to deformation. This is important when used in aerodynamic, faying sealant and overcoating uses to protect the system component and its integrity.
Tensile Strength / Tear strength	Tensile strength is the ability to withstand stress, measured (usually in force per unit of cross-sectional area) by the greatest load pulling in a single direction that a given item can stand without breaking). For example, the amount of force it takes to pull and break an elastic band. Tear strength is the related measure of how much tensile stress an item can withstand, when a tear is introduced. In the aerospace industry, components may have to withstand strong mechanical forces and, therefore, any sealants or coatings that are forming a resistance barrier or coating must not reduce the shear resistance of the component or aerospace system they are applied to, to ensure structural integrity is as specified and as expected. Any replacement products must also provide the necessary performance for this parameter and perform to current standards or better.
Bond Shear Strength	Shear strength is the strength against yielding or structural failure when unaligned forced push one part of a body in one specific direction, and another part of the body in the opposite direction. For example, cutting paper is performed by applying unaligned forces, resulting in the paper failing in shear. Aerospace components may have to withstand strong mechanical forces and, therefore, any sealants or coatings that are part of a component must not reduce the shear resistance of the component to which they are applied, to ensure that structural integrity of the overall component is as specified. Any replacement products must also provide the necessary performance for this parameter and perform to current standards or better.
Electrical Isolation	Electrical isolation is necessary to prevent corrosion in electrical systems, such as circuit boards, as conductors are prone to corrosion from stray current between dissimilar metals. In this case, sealant is sometimes used to keep electrical components in place, due to its adhesive properties, and it can act as an electrical barrier between components to reduce stray currents between the different metal components in the electrical assembly. Fully cured sealant is essentially an inert rubber-like compound, and so is not an electrical conductor. Tests to confirm electrical isolation are performed by running a current between the different sub circuits or different components and testing for the required level of electrical resistance or lack of current that is known to reduce the corrosion within the electrical assembly. Failure to meet these criteria could cause subsequent failure of vital electrical systems, if not sufficiently isolated where needed. Therefore, any replacement products must also provide the necessary performance for this parameter and perform to current standards or better.
Galvanic Isolation	Galvanic isolation is the principle of isolating different substrates/surfaces from each other to prevent electrical current flow between them. By isolating the substrates/surfaces in this way, it prevents unwanted electrical build up and galvanisation between dissimilar components. Sealant is utilised for this purpose as it is electrically inert and can act as an insulator.
Adhesion – subsequent coatings	Adhesion is the ability of different particles or surfaces to adhere to one another and is essential for long term performance. Many aerospace components are exposed to harsh environmental conditions, encounter other metallic components, and/or must withstand strong mechanical forces. The requirements for adhesion vary within the aerospace industry and depend on the required function, and location of the part. A variety of screening tests are used to evaluate

Performance Parameters	Description
	coating adhesion. Even where such a test is successfully completed, extensive further testing is required to substantiate and certify that the new formulation provides the necessary performance for the relevant design parameters.
Chemical Resistance & Water Resistance	Water resistance is defined as the ability of a solid to resist penetration or destruction by liquid and will instead repel the liquid. This is similar to chemical resistance, which is defined as the ability of solids to resist damage by chemical exposure. Aerospace components are often exposed to water and liquids, such as jet fuel, hot oil, de-icing fluids, hydraulic fluid, and other chemicals. Consequently, the candidate alternative sealant must be unaffected by prolonged exposure to these fluids during use. Water, fuel, hot oil and other fluid immersion tests called out in specifications are tools for screening suitability of proposed alternative compositions. Any suitable candidate alternative coating must provide the necessary performance for the relevant design parameters.
Corrosion Resistance	Corrosion describes the process of oxidation of a metal due to chemical reactions with its surroundings, or chemical reactions with environmental compounds (e.g. water or hydraulic fluid), and which can create corrosive electrolytes through the presence of other dissolved substances. In this context, corrosion resistance means the ability of a metal to withstand gradual destruction by chemical reaction with its environment. For aerospace, this parameter is one of the most important, since meeting its minimum requirements plays a key role in assuring the longest possible life cycle of aerospace assemblies and all the implicit components, the feasibility of repairing and maintenance activities and most importantly, continued safety and reliability of aerospace components during use. Ideally, the corrosion-inhibiting substances/systems are applicable in all surface treatment processes, compatible with subsequent layers and perform effectively on all major metal substrates. Furthermore, it must guarantee product stability (chemically and thermally) and must reinforce the useful sealant properties.
Thermal cycling resistance	This parameter describes the ability of a sealant to withstand repeated low and high temperature cycling. For the same reasons stated above, it is indispensable that components and sealants perform their functions optimally at all temperatures encountered during their service life. In general, different test methods are available within the aerospace industry, where aerospace components must meet test requirements to operate at both sub-zero and elevated temperatures. Thermal cycling requirements are tightly controlled by company and industry specifications.
Compatibility with substrates/ other coatings	Compatibility with a wide range of substrates and other formulations such as primers, topcoats, specialty coatings, adhesives and other sealants is a key performance characteristic for sealants used within the aerospace industry. To determine the compatibility between the sealant and other substrates/products, adhesion testing is carried out according to company and industry specification requirements.
Erosion Resistance	This parameter describes the ability to maintain adhesion to the substrate and cohesive integrity in the presence of impinging solid particles (such as sand or ice) or liquid droplets (such as rain). Erosion resistance is a key property for formulations and components that are exposed to high speed air streams. Erosion resistance requirements are tightly controlled by company and industry specifications.
Slump Resistance	The resistance of a sealant to slump is the measure by which after application, it retains its position and shape under its own weight and is linked to viscosity properties. This is necessary for application of sealant on vertical and overhead position, e.g. to overcoat fastener, and important for usage of sealant. A sealant with low slump resistance applied in vertical or overhead positions is unlikely to hold to the surface required and the sealant may drop, meaning that it would have to be re-applied.

4.3.4.2. Specifications of Polysulfide Sealants

A change in formulation needs to be qualified, validated and certified to ensure that the new formulation provides the necessary performance for the relevant design parameters and that the formulation performs as specified[11].

Whilst there are industry-wide specifications relating to sealants used in aerospace (e.g. Aerospace Materials Specifications, ISO standards, etc.), it is the OEM specifications that are most relevant for the sealants in question. The OEM specification documents detail the performance requirements and quality level which need to be met per sealant type, including test methods. They specify the physical, chemical and technical characteristics of formulations according to the type of sealant, e.g. general purpose, fuel tank, low adhesion, transparencies. In addition, OEM process specification documents can identify the engineering requirements in terms of performance requirements to be met as output of the sealant application process. This defines the key characteristics of the process and the formulation and defines mandatory series production inspections imposed by engineering. Further examples are provided below:

<u>OEM Materials Specifications</u>: defines the requirements for the approval of a formulations for a defined use for aerospace application e.g.:

- low, medium and high-density general-purpose sealants and adhesion promoters;
- low, medium and high-density fuel tank sealants and adhesion promoters;
- low adhesion sealants;
- aircraft external transparencies sealants;
- lightweight general-purpose sealants and adhesion promoters;
- lightweight high-performance fuel tank sealants;
- sealants containing a particulate foam filler that enables it to fill large cavities where conventional sealant would show unacceptable levels of slump; and
- two-part reaction polysulfide, curing at room temperature, non-structural bonding application.

<u>OEM Process Instructions:</u> defines the detailed work instructions for a defined process e.g. instructions on:

- installation of sealed nut caps as used during the assembly process for aircraft fuel tanks involved by the assembly drawings;
- sealing of aircraft structure defines procedures that enable effective joint sealing of general aircraft structure to prevent corrosion, moisture entrapment, leakage and ensure air and fuel tightness; and
- the application of sealants: faying, fillet, overcoat, aerodynamic fillet, overlap, cavity filling, high temperature and inactive firewall.

<u>OEM Process Specifications</u>: defines the engineering requirements for a defined process e.g. for:

- wet installation of fasteners;
- manufacture of form-in-place seals using sealant; and
- application of low adhesion sealants.

[11] When the candidate alternative can be demonstrated to be “interchangeable” with the one currently in use, it may not be necessary to seek external formal certification of the change in formulation, as described in Annex C.

Some of the example criteria to comply with these OEM specification requirements are detailed in Table 4 and Table 5 below. The parameters described in the tables below are examples only and are not the full list of specification requirements that a sealant may be required to perform to.

TABLE 4 EXAMPLE PROPERTIES OF CURED SEALANT PRIOR TO ENVIRONMENTAL EXPOSURE TO MEET THE OEM SPECIFICATION REQUIREMENTS

Property	Unit	Requirement
Density	g/cm3	Max 1.65
Lap shear strength	MPa	1.5 min. 100% cohesive failure
Lap shear strength with adhesion promoter		
Peel strength	N/25mm	120 min. 100% cohesive failure
Peel strength with adhesion promoter		
Tensile strength	MPa	1.5 min.
Tensile elongation	%	200 min.
Low temperature properties	NA	Pass 10% min.
Hardness	Shore A	40 min.

TABLE 5 EXAMPLE PROPERTIES OF CURED SEALANT AFTER ENVIRONMENTAL EXPOSURE TO MEET THE OEM SPECIFICATION REQUIREMENTS

Environmental Exposure	Property	Unit	Requirement
Fuel immersion, 4500 hours at (23±2) ºC	Peel strength	N/25mm	120 min.100% cohesive failure
	Peel strength with adhesion promoter		
	Hardness	Shore A	35 min.
	Tensile strength	MPa	1.5 min.
	Tensile elongation	%	200 min.
	Tensile strength after 1-day air dry at 60ºC	MPa	1.5 min.
	Tensile elongation after 1-day air dry at 60ºC	%	200 min.
	Peel strength after 1-day air dry at 60ºC	N/25mm	120 min.
Fuel immersion, 336 hours at 100ºC	Peel strength	N/25mm	120 min100% cohesive failure

Environmental Exposure	Property	Unit	Requirement
	Hardness	Shore A	30 min.
Water immersion, 1000 hours at 35ºC	Peel strength	N/25mm	120 min 100% cohesive failure
	Peel strength with adhesion promoter		
	Hardness	Shore A	30 min
	Tensile strength	MPa	1 min
	Tensile elongation	%	200 min
Corrosion prevention capability	N/A	N/A	Pass
Air exposure 2000 hours at 80ºC	Peel strength	N/25mm	65 min 100%cohesive failure
	Peel strength with adhesion promoter		
	Tensile strength	MPa	1 min
	Tensile elongation	%	125 min
De-icing fluid immersion, after 168 hours at 23ºC	Peel strength	N/25mm	120 min 100% cohesive failure
	Peel strength with adhesion promoter		
	Tensile strength	MPa	1 min
	Tensile elongation	%	150 min

There are a wide range of sealant formulations to meet the different, highly refined specification requirements of the OEMs reflecting the different sealant applications that are required in the aerospace industry. Each sealant has several variants (e.g. MC-216 A-2, MC-216 B-2, MC-238 A-1/2, MC-238 A-2 etc.), considering the processing and performance criteria the sealants are required to meet by the OEM customers, and depending on usage area of the sealant. As shown in Table 6, there can be different requirements that the products must demonstrably meet, even across the same product name and class range. The example below is for illustrative purposes only and other sealant variants could have different application/cure times.

TABLE 6 APPLICATION LIFE AND CURE TIME COMPAIRSON OF PRODUCT RANGE MC-238 CLASS A AT 23°C / 50% RELATIVE HUMIDITY

Product Type	Min. Application Time	Tack-Free Time	Time to Shore A Hardness 35
MC-238 A-1/2	0.5 hrs	≤ 10 hrs	≤ 30 hrs
MC-238 A-2	2 hrs	≤ 12 hrs	≤ 48 hrs
MC-238 A-4	4 hrs	≤ 18 hrs	≤ 48 hrs

This wide range of products with unique processing and performance requirements adds substantial complexity to the challenges faced when attempting to source and qualify new or replacement products.

The affected sealants containing the NPE-phosphate surfactant with NPE in the hardener component above the Authorisation threshold (≥0.1% w/w) that require reformulation and are manufactured and sold in the EU include, but may not be limited to, products identified in Table 7. The products listed in this table have been identified as within the scope of this application for authorisation, as they are currently known by the EAAC sub-group OEM members and Applicant and may be augmented if further formulations (e.g. formulations that are used very rarely) are identified as affected by the Authorisation listing for NPE prior to the Sunset Date. It should also be noted that the uses listed are examples only and are not the only applicable usages of the products in question, and do not include each variation based on application time, as in Table 6. For example, a fuel tank sealant may not only be used in fuel tanks, depending on the OEM or MRO company.

TABLE 7 NON-EXHAUSTIVE LIST OF AFFECTED SEALANT PRODUCTS MANUFACTURED BY THE APPLICANT

Formulation	Aerospace Use Examples
Naftoseal MC-238 Class A	Fuel tank and fuselage sealant
Naftoseal MC-238 Class B	Fuel tank and fuselage sealant
Naftoseal MC-780 Class A	Fuel tank and fuselage sealant
Naftoseal MC-780 Class B	Fuel tank and fuselage sealant
Naftoseal MC-780 Class C	Fuel tank and fuselage sealant
Naftoseal MC-216 Class A	Access door sealant
Naftoseal MC-216 Class B	Access door sealant
Naftoseal MC-630 Class A	Fuel tank and fuselage sealant
Naftoseal MC-630 Class C	Fuel tank and fuselage sealant
Naftoseal MC-650 Class B	Fuel tank and fuselage sealant
Naftoseal MC-340 Class B	Fuel tank sealant also used for aerodynamic smoothing and protection of landing gears
Naftoseal MC-770 B-2 Grey	Fuel tank and fuselage sealant

4.3.5. Annual tonnage

The average tonnage of NPE used in sealants for the European aerospace industry is 50-350 ([redacted]) kg per year.

4.4. Remaining risk of the "applied for use" scenario

A comprehensive analysis in the CSR points out specific risk management measures (RMMs) and operational controls (OCs) performed by the EAAC sub-group members and their associated supply chains at their respective sites. These measures have been split out by the two applied for uses and are summarized in the following section.

4.4.1. Implemented risk management measures and resulting emissions

4.4.1.1. Use 1 - Formulation

As mentioned in the CSR, during the formulation and filling process, including cleaning and maintenance, workers wear disposable PPE. This is disposed of as solid hazardous waste to the relevant marked bin after use. If contaminated, the PPE may be cleaned with a rag, which is also disposed as solid hazardous waste.

Workers receive training in the correct handling of waste materials, including surfactant containing NPE and waste materials, such as PPE or rags that may be contaminated with NPE. Training includes instructions to manage contaminated materials as solid hazardous waste, including disposal to designated, marked bins.

Workers are instructed to not dispose of, launder or wash any contaminated material in the workplace or home. Risk management measures are in place to avoid contamination of clothing. Overalls are cleaned regularly. The overalls are deposited in a closed laundry unit and collected by a specialist third party industrial laundering company. Chemetall advise the laundering company of potential contaminants by provision of the relevant SDS.

No water is provided to the production area. There is no wastewater from the production area.

All contaminated equipment is cleaned by wiping with a cloth or rag. All materials containing or contaminated with NPE surfactant, hardener, or sealant, including disposable PPE, contaminated rags, and plastic sheeting, is disposed to designated hazardous waste bins and managed as described in section 9.1.2 in the CSR.

For waste management, workers with appropriate training in waste management handle waste materials. When empty, the drums containing the surfactant are cleaned out with a solvent soaked rag. The rags are consigned as hazardous waste. The empty drums are collected for recycling and disposal by a specialist recycling company. The drums are clearly labelled with their contents. The drum recycling company is a specialist contractor, and any processes will consider the classification of the material as hazardous and insure that processing the material for recycling does not result in potential release of NPE to the environment. In the process of handling the drum for recycling and subsequent disposal, the waste is first homogenised by mechanical shredding. Container remains and impurities from this process are subsequently recovered for reuse, while any contaminated material is processed for hazardous waste.

After use, the measuring cylinder is cleaned using a disposable, solvent impregnated rag, which is subsequently disposed of as hazardous waste into the relevant marked bin. The disposable tool is also treated as hazardous waste. Contaminated PPE and plastic sheeting are also disposed of as hazardous waste. All solid hazardous waste is disposed of to the relevant marked bin on site.

Moreover, workers are trained to manage spillages. In the rare event of a release during formulation or filling, workers use disposable rags to contain and clean up the spill. After the bulk of the spill was dealt with, the area may be wiped down with solvent soaked rags. All the contaminated rags generated from such a process would be consigned as hazardous waste.

There is no potential for release to the environment of the NPE substance during formulation of the NPE-containing hardener component.

TABLE 8: LOCAL RELEASES TO THE ENVIRONMENT ASSOCIATED WITH FORMULATION

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing operator controls and risk management measures	**Initial release factor**: 0 % **Final release factor**: 0 % **Local release rate**: 0 kg/day **Explanation / Justification**: A range of operational controls and risk management measures are in place which effectively precludes any release of NPE to the environment during formulation and packaging. There is no release to waste water on site.

4.4.1.2. Use 2 - Downstream Use

The process of mixing the hardener through the base component can be carried out in three ways:

- Mixing within a two-compartment kit; or,
- Mixing in small scale batches by hand; or,
- Bulk mixing by machine.

Due to the contained nature of the cartridge, no exposure of the NPE containing hardener component to the environment is possible under typical operation of the cartridge. Whether mixed by hand or machine, the operators wear the relevant PPE. After mixing, any disposable PPE are disposed of as hazardous solid waste in a bin on site. These scenarios are each introduced in the CSR and described further in detail.

During mixing of the sealant, several RMMs and OCs are in place to ensure the hardener constituents, including NPE, are not released to the environment.

The polysulphide sealants contain multiple ingredients. A range of environmental hazards is associated with these materials. The RMMs and OCs in place at the facility therefore must adequately manage the range of hazards associated with all constituents. Consequently, the overall level of protection is high, and RMMs and OCs are in place so that the mixing processes do not result in potential release to the environment of NPE.

Risk management measures are in place to avoid contamination of clothing. Therefore, there is no significant residual contamination on overalls. Overalls are cleaned regularly in line with normal hygiene.

The RMMs below are observed during all activities involving handling and mixing the hardener component. When mixing sealant, workers wear gloves, protective overalls, and eye protection. A disposable apron may also be worn over the overalls.

During handling and mixing of the hardener, workers will wear a combination of disposable and reusable PPE. After use, disposable PPE is removed carefully by the worker and disposed of to the hazardous waste containers in the production area.

Reusable PPE would, if contaminated with either NPE or formulated hardener, be cleaned with a rag soaked in solvent. The rags are subsequently disposed of to the hazardous waste containers in the production area. Once clean, the reusable PPE is returned to storage for future use.

Waste that may be generated during mixing of the hardener include disposable PPE, waste two compartment kits, waste containers from the two container kits and rags with solvent that are used to clean equipment. The rags are handled and disposed as hazardous waste.

Hazardous waste bins are labelled with the waste description and waste code. Materials in the bins are consigned as hazardous and subsequently removed by licensed third party waste contractors in line with applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and generally involves incineration.

TABLE 9: LOCAL RELEASES TO THE ENVIRONMENT ASSOCIATED WITH DOWNSTREAM USE

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing operator controls and risk management measures	**Initial release factor**: 0 % **Final release factor**: 0 % **Local release rate**: 0 kg/day **Explanation / Justification**: There is no release to wastewater on site. RMMs and OCs in place on site to prevent any release to the environment of the NPE containing hardener or sealant.

For a more detailed assessment of the risk management measures pertaining both use groups and their contribution to zero emissions, please refer to the CSR.

4.5. Environmental impacts of the applied for use scenario

According to the Annex XV dossier on the identification of SVHC, the primary environmental compartment of interest for NPE is the aquatic environment. Degradation of NPE to the respective alkylphenol (NP) is expected to occur in wastewater treatment plants, surface water and soils, and more slowly in sediments. Thus, the qualitative assessment focused on use of water and/or discharge of wastewater and/or generation of waste materials (solid, liquid) in the formulation or mixing process or in ancillary processes, such as cleaning and maintenance. The qualitative exposure assessment concludes that there is no potential for releases or emissions to the environment from the uses covered by this application for authorisation. OCs and RMMs in place, as described in ***Section 4.4.1***, are effective in preventing release of NPE to the environment. The applicant's and downstream users' compliance with the requirements of the Exposure Scenarios described in the CSR and relevant OCs and RMMs included in the safety data sheet (SDS) supplied by the formulator, respectively, allows for a high level of certainty that there is no potential for emissions to the environment.

Given the above reasoning, there is no potential for releases to the environment of the NPE-containing hardener component of the two-part sealant during formulation or mixing within the two-compartment kit, in small scale batches by hand or bulk mixing by machine, in line with the above RMMs and OCs. Accordingly, there is no potential risk to the environment from the uses mentioned above.

4.6. Monetised damage of environmental impacts

According to the results of the CSR, a quantitative analysis of environmental media, including water, air, sediment, and soil, was considered, but not conducted. Since no emission/exposure is assumed, it is implied that the operational controls and risk management measures in place preclude the release to the environment.

The findings of the emissions assessment were such that the need for a detailed exposure assessment was deemed unnecessary and the exposure assessment can be carried out using qualitative approaches. Since exposure is not predicted, the risk assessment was carried out based on a simple comparison of the findings of the exposure assessment with the outcome of the hazard assessment (a detailed hazard assessment is performed in Section 7 of the CSR). Subsequently, no quantitative assessment of the environmental impacts of the applied for use scenarios are performed in the related sections of this AoA/SEA. For other technical reasons, please refer to the Section 9.0.2.1 of the CSR.

5. SELECTION OF THE “NON-USE” SCENARIO

5.1. Efforts made to identify alternatives

The preparation of this AfA has been supported by the Applicant and OEMs in the supply chain of polysulfide sealants under the auspices of the EAAC. The products are manufactured by an EEA Applicant and used on aerospace products in the EEA, as well as the rest of the world. The sealant formulations covered by this AfA are themselves proprietary and confidential.

5.1.1. Substitution of NPE in Aerospace industry products

As described in ***Section 3*** extensive research of products that are used in the aerospace supply chain was undertaken as part of the initial process of assessing the potential need for an Application for Authorisation for NPE, prior to the formation of EAAC. This assisted members in the identification of products for which alternative products were not readily available and already qualified, or otherwise in use in aerospace manufacture, MRO or supplier activities.

Here, the distinction between a change in a process chemical/formulation and a formulation that is part of a final delivered aerospace product is important. For process-only chemical formulations, alternatives must be evaluated to ensure they provide equivalent results (e.g., the replacement cleaner performs as well as its predecessor and meets cleanliness requirements). For a chemical formulation that forms part of a final delivered aerospace product (e.g., sealants), testing to confirm equivalent properties is just the first step, as additional evaluations are needed to verify long-term performance of the impacted aerospace component and related assemblies. Both formulation types are important to the aerospace industry and require extensive evaluation and qualification. However, evaluation of anything that forms part of the final delivered product has the additional burden of understanding its properties and performance over the entire life of the aerospace system, including inspect-ability and repair-ability. This additional burden significantly complicates the evaluation required.

OEM sub-group members worked on a one to one basis with Chemetall, as the formulator of identified NPE-containing polysulfide sealant formulations, to determine the status of NPE within the formulations. The hardeners required for certain polysulfide sealants manufactured by Chemetall were identified in the initial assessment as formulations that contain NPE, are incorporated onto end aerospace assemblies, and for which alternatives will not be available in time for full qualification prior to the Sunset Date, and thus are addressed in the Application for Authorisation, as discussed further below.

5.1.2. Research and Development

5.1.2.1. Research and Development Activities by Formulator

The Applicant, as formulator, has undertaken significant research and development activities.

There is a vast variety of surfactants in the market based on different chemistries. Unfortunately, many of them develop their full potential only in aqueous environments or water-rich formulations (e. g. dish detergents). Surfactants for emulsions (oil in water / water in oil) or dispersions (solids in liquids) differ significantly in their impact on product performance and require specific designs. During preliminary reformulation activities, it was identified that surfactants that are not derived from NPE substance are not as efficient at bonding the MnO_2 particles into the rest of the liquid hardener mix. It was also determined that, contrary to initial expectations, it is not a straight-forward process to find a suitable alternative surfactant that works to the same standard but does not contain NPE. At this time, the Applicant considers this could be due to competition between the surfactant constituent and the adhesion promotor constituent of the formulation, both of which are surface active. As adhesion is a key property of the sealants for Chemetall customers, the Applicant is also reformulating the adhesion promotor constituent of the formulation for these products separately.

The Applicant has screened >100 different surfactants and has been investigating suitable alternatives for NPE surfactants in its polysulfide sealants containing NPE. The Applicant had previously identified and developed a promising candidate alternative sealant formulation, but it did not pass technical qualification testing by the OEMs, due to unanticipated issues with the lack of adhesion of the sealant to different substrates during the final testing phase. This demonstrates the importance of undertaking the requalification activities, both for the Applicant and for OEMs, and that unanticipated failures can occur, resulting in the potential for several testing iterations to ensure the candidate alternative(s) fully meet OEM performance requirements, as per specifications.

The remaining potential alternatives are still being investigated and tested for suitability, and the initial testing procedures can take a significant amount of time, as there are testing parameters that cannot be accelerated or amended and are dependent on each other to proceed. For example, a candidate alternative sealant could require several weeks to fully cure, which must occur as per the specification timeframe and with no other performance issues, before the cured candidate alternative sealant can then be strength tested and undergo environmental exposure testing as well.

The potential alternative formulation is initially assessed against environmental, health and safety (EHS) criteria to reduce the likelihood of new formulations containing substances that may be subject to later regulatory measures. Initial basic tests are conducted on the reformulation at laboratory phase, such as stability, and are duplicated to demonstrate that the results are repeatable.

If the reformulation passes the initial laboratory testing, the R&D testing process proceeds to the production phase, in which initial small (bench) scale testing is completed and then progresses on to full scale batch production testing, to identify issues in the manufacturing of the hardener component of the sealant that may result from the change in formulation. If the reformulation fails at the laboratory or production phase, then no further R&D activity or testing is carried out. However, if it passes these stages, the reformulated hardener and mixed sealant is tested to relevant sealant specifications, which can vary according to the OEM specifications. For example, some specifications require immersion testing in fuel for 2 weeks at higher temperatures, whereas other customers request 1000-hour (42-day) immersion testing in fuel at lower temperatures. The longest test runtime required for some customers is immersion in fuel for 4,500 hours (half a year). The Applicant has identified that the water penetration and fuel immersion tests are the most important and, therefore, if the alternative does not pass the adhesion/lamination criteria for those tests, then further research and development is not conducted on that option. Where possible, different specification testing is run in parallel to complete the process as quickly as possible. Even with testing completed in this way, it generally takes approximately 2.5 months to complete initial testing and, considering that tests must be run in duplicate to ensure repeatable and robust results, testing can generally take 5-6 months in total. Additionally, new composites used in aerospace parts have been recently introduced that also need to be tested to confirm compatibility with the reformulated sealants, and this also takes time. As per ***Section 4.3.4***, the product development process in not strictly linear, as some pre-qualification testing can be done by the OEM, before the alternative sealant proceeds to the Technical Qualification phase.

Overall, the Applicant believes that it will most likely be able to introduce an NPE-free reformulated candidate alternative polysulfide sealant to the OEMs ready to commence technical qualification by Q2 2021. However, such an outcome is by no means assured and it must be noted that previous efforts were not successful.

5.1.2.2. Research and Development Activities by OEM

Development of aerospace assemblies and end products is a complex process that must consider not only the design of the part, but also its use and maintenance history in varied climates and service environments.

Determining the extent of the testing required to qualify and implement a new or alternative formulation, product or technology is on a case-by-case basis, due to the many design parameters considered to quantify the risks of substitution for each specific use of the alternative in the aerospace system. These include but are not limited to:

1. Design of the part or assembly (e.g. substrate, inclusion or proximity to dissimilar substrates or mating surfaces, crevices that can entrap liquids, structural stress and strain environment, etc.)
2. Environmental conditions within the aerospace product (e.g. location, presence of condensation or liquids, entrapment of liquids, temperature range, microbial growth, etc.)
3. External environmental conditions (humidity, wind / rain erosion, impact from runways, exposure to fluids like de-icers and hydraulic fluids, etc.)
4. Probability of finish deterioration during use (e.g. chipping, scratches, abrasion, erosion, corrosion, etc.)
5. Historical performance in similar aerospace uses
6. Previous issues due to variation in maintenance practices
7. Ability to inspect during the lifetime of the product

Materials specialists, in conjunction with manufacturing engineering, develop extensive qualification test programmes performed in laboratories and in industrial conditions to cover material properties and requirements, as wells as process parameters, as per specifications, considering design and maintenance aspects.

Once the formulator's production samples of NPE-free sealants are available, the OEM will proceed with preliminary qualification testing to verify key properties and requirements. A first round of shop trials will also be launched to ensure the new formulations can be applied in the industrial environment in the same way, i.e. following the same process steps, parameters and equipment as with the existing formulations.

The first OEM test campaign includes tests on requirements prior and after environmental exposure, as previously illustrated in Table 4 and Table 5. Typically, the required level of performance for main properties, such as peel strength, tensile strength, hardness, etc. will be checked. Some immersion tests in fuel, water, de-icing fluid, as well as air exposure tests, will be also conducted in the OEM laboratories. Some tests, such as water immersion, have long lead times and require a minimum of 3 months to complete, including preparation, test duration and analysis. Overall, it is expected that a minimum of 50-100 laboratory tests will be needed per formulation variant, considering the need to demonstrate compatibility with different substrates.

In parallel, preliminary shop trials consisting of several checks for key process parameters, such as mixing ability, appearance, curing time, roller application in different positions, fillet application, covering of fastener, reparability, shrinkage, etc., will also be carried out.

Once all key requirements, properties and behaviours in a laboratory environment have been tested successfully, the formulations and key process parameters are fixed, and the official technical qualification testing programme can commence with formulators site-specific production batches (batches coming from a production line, not a lab environment). A comprehensive test program is then conducted in laboratories at OEMs and the formulator, and extensive industrial trials at OEM facilities are also repeated with these new production batch samples to confirm shop floor acceptance.

It is anticipated that over 15 new formulation variants will be tested in at least 3 or 4 OEM production sites as part of the qualification test programme supporting NPE sealant replacement.

The qualification compliance documentation will be issued only when the qualification test campaign has demonstrated that the reformulated alternative sealant is meeting the performance requirements, as per the relevant specifications, see Figure 15.

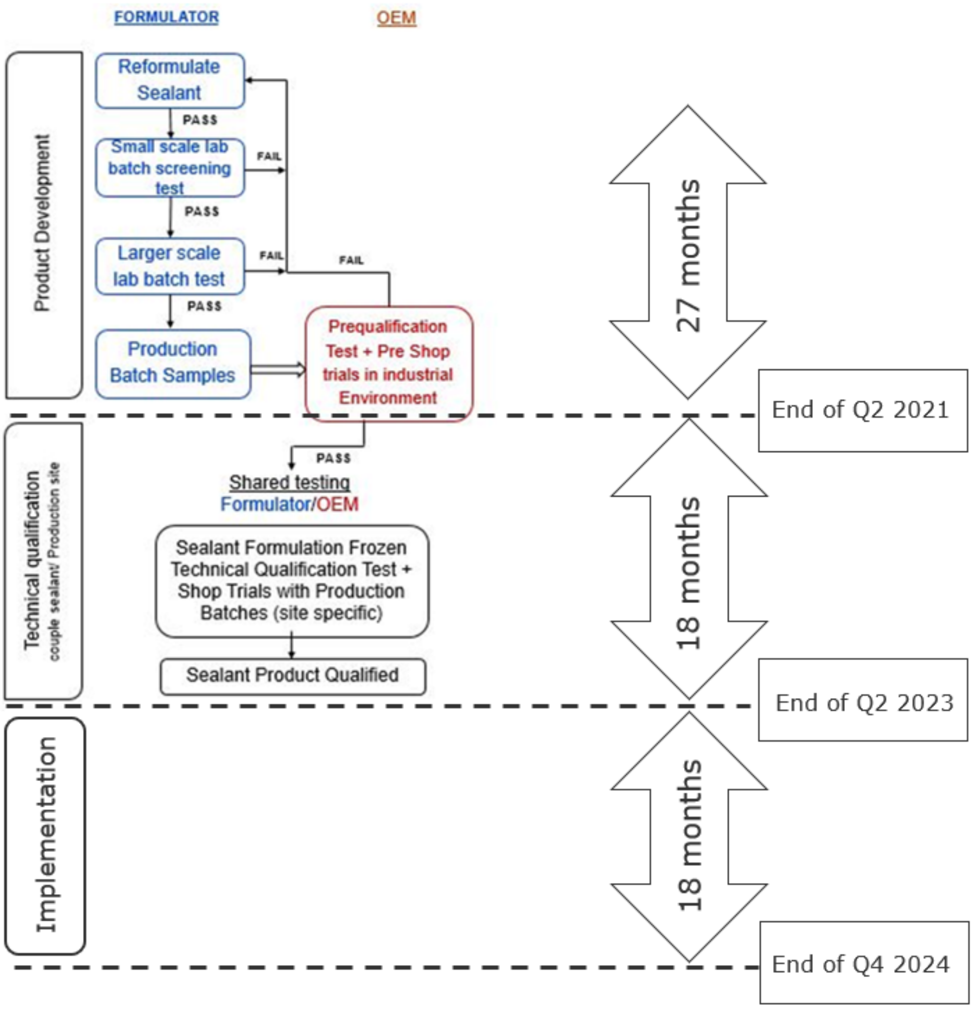


FIGURE 15 RELATIONSHIP BETWEEN FORMULATOR AND OEM TESTING WITH TIMELINE

5.1.2.3. Replacement Timeline of NPE in sealants

When the qualification test campaign has been completed and results clearly demonstrate that alternative sealant meets the performance requirements as per the relevant specifications, OEM companies issue internal confirmation of compliance with qualification documents, which marks the end of technical qualification. However, as illustrated in Figure 15, considerable time will be required to complete the OEM technical re-qualification testing, once the Applicant's product development phase of work has been completed successfully. Therefore, there is an urgent need for an Authorisation of NPE, to overcome the time gap between the sunset date and the date that an alternative product is fully qualified and industrialised within OEM supply chains and has fully replaced current sealants containing NPE.

As mentioned in ***Section 4.3.4***, newly qualified alternative sealants, modified or reformulated sealant, must perform in the same way as current sealants and must be applied following the same process instruction. The interchangeability principle will be applicable, as the alternative product must be a one-to-one replacement. As a result, no aircraft part design changes, e.g. no drawing, part number, or name changes, are expected once a candidate alternative sealant successfully completes the qualification process and there is no need for an additional certification step or validation from EASA or relevant military certification authorities.

The technical qualification is usually followed by an industrial qualification of the Applicant's production site to ensure compliance with quality standard EN9100 (e.g. check reproducibility criteria) via a first article inspection (first commercial batch). Once all compliance documentation is available, the deployment of the alternative reformulated sealant in OEM manufacturing plants and at suppliers can begin. The product can then be used on the aircraft or aerospace equipment and industrialized in production, following relevant internal procedures to trigger the change of product.

The deployment of the reformulated NPE-free versions of polysulfide sealants impacted by this AfA will concern dozens of OEM manufacturing sites, and around 200 suppliers' sites. A stepwise approach may be utilized, and formulation changes may not be implemented simultaneously across all sites and suppliers, but rather through a phased introduction to minimize technical risks and to benefit from lessons learned. It is currently estimated that the industrialisation step will require 18 months to complete. As such, the estimated timeline for qualifying and implementing a candidate alternative NPE-free sealant is as follows (also see Figure 16);

- Applicant R&D stage (including pre-tests); 27 months to complete from April 2019: estimated end Q2 2021
- OEM Qualification stage; 18 months, estimated end Q4 2022
- OEM Implementation of newly qualified alternative sealant in OEM plants and supply chain; 18 months, estimated end Q2 2024

Updated worker training and manufacturing documentation may be required to adapt the OEM aerospace manufacturing processes.

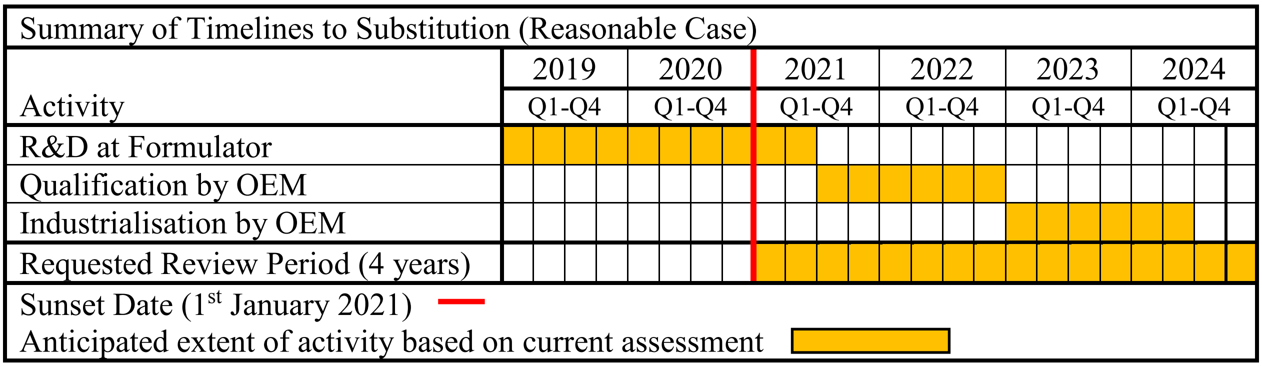


FIGURE 16 NPE REPLACEMENT TIMELINE

In addition, the Applicant has undertaken discussions with its supplier of the surfactant containing NPE, who have confirmed that the surfactant will no longer be available for sale in the EU after the sunset date for the NPE substance (1 January 2021). To continue manufacture of the current sealant formulations, as currently qualified and accepted by

OEM customers, the Applicant has stockpiled sufficient surfactant supplies to continue sealant manufacture until 2025 (expected end of requested Authorisation period). This provides a contingency plan to continue sealant manufacture, where a reformulated product is not available, qualified and industrialised by aerospace OEM customers prior to the Sunset Date, which is expected to be the case for polysulfide sealants, and the Authorisation to continue use of the substance is granted. However, after this stockpiled sealant is used, the Applicant will no longer be able to manufacture the affected sealants in the current formulation (containing NPE) in the EU.

Therefore, it is imperative, and in the vested interest of the Applicant and customers, that viable alternatives are sourced and that the reformulated sealants are qualified and industrialised throughout the aerospace industry and supply chain by Q2 2024 at the latest.

5.2. Identification of known alternatives

5.2.1. Alternative Substances

The following chapter provides a description of the most promising potential alternatives. Table 10 provides an overview and summary results. These alternative surfactants that are based on other substances have been, or are currently, the focus of the EAAC NPE sub-group members, through the continued development and testing of various confidential formulations. This list is evolving as R&D continues in this area.

TABLE 10 LIST OF POTENTIAL ALTERNATIVE SURFACTANTS FOR USE IN NPE-FREE SEALANT HARDENER FORMULATION

Candidate Alternative No.	Alternative Substance to NPE	Technical limitations	Further R&D?
1	Polyglycolether	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes
2	Polyetherphosphate	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes
3	Alkylammonium salt of a copolymer with acidic groups	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes
4	Anionic aliphatic ester	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes

Table 11 below details the alternative substances that were initially considered but have since been eliminated from further consideration during the R&D phase, due to test failures or issues encountered during testing, so will not be discussed further in this chapter.

TABLE 11 LIST OF POTENTIAL SURFACTANT REPLACEMENTS THAT ARE NO LONGER IN CONSIDERATION

Alternative Substance to NPE	Technical limitations	Economic considerations	Regulatory and Safety concerns	Further R&D?
Poly(oxy-1,2-ethandiyl) alpha-isotridecyl)-omega-hydroxy-phosphate	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	*none*	*GHS H411*	No, the influence on the mechanical properties was too big

Alternative Substance to NPE	Technical limitations	Economic considerations	Regulatory and Safety concerns	Further R&D?
Modified Polyester derivative	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Phosphoric acid salt of a copolymer	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	GHS H410	No, the influence on the mechanical properties was too big
Copolymer with pigment affine groups	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Highly crosslinked polyester	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Block-copolymer with pigment affine groups	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Solution of an unsaturated poly carbonic acid polymer	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, it was not compatible with other raw materials in the formulation
Modified natural oil	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big

5.2.2. Alternative Products

In addition to the potential alternatives being considered for use in reformulation of existing sealants containing NPE by the Applicant, analysis of another existing sealant manufactured by the Applicant that could be a potential alternative replacement product is listed in Table 12. However, in this case, the potential alternative sealant was determined to not be suitable for further consideration, due to issues with performance or safety requirements in accordance with the specifications, and so will not be discussed further in this chapter.

TABLE 12 POTENTIAL ALTERNATIVE REPLACEMENT PRODUCTS IDENTIFIED

Alternatives	Performance parameter fulfilled	Performance parameter not fulfilled	Consequences/ comments
MC216	Fuel immersion (peel strength) Water immersion Immersion NaCl Air exposure De-icing fluid immersion	Hardness (prior environmental exposure) Water immersion @ 1000h (Hardness)	*Not meeting safety / certification requirements*

5.2.3. Alternative Technologies

As part of the work by both the EAAC sub-group OEM and Applicant member companies when identifying potential alternative substances and products, no alternative technologies that could be implemented to compensate for the lack of NPE in the sealants were identified as successful potential alternatives.

5.3. Assessment of shortlisted alternatives

Due to the confidential nature of the formulations and OEM-specific uses, for the purposes of qualification, the potential alternatives are each treated as unique, despite similarities in chemical behaviour or composition. Therefore, each re-formulation option must be tested completely for the requirements of its specific design parameters. The potential alternatives assessed in this section have already undergone considerable R&D efforts within the aerospace industry and testing is still ongoing to determine the most suitable alternative to provide as a candidate alternative to OEMs for qualification testing.

The Applicant considers that substitution of the NPE-based surfactant with a surfactant based upon another substance is feasible, although such a substitution has not been successfully identified, based on research to date. Several of the potential surfactant replacements allow for the possibility to produce the hardeners in a similar manner, so equipment/process changes would be minimised. However, as a two-component sealant is a very complex system, with, in total, more than 20 ingredients, unpredicted reactions or interactions between raw materials are always possible. Therefore, comprehensive testing of an amended formulation is always mandatory. With flight safety at stake, the technical performance of any reformulated products, foremost, must demonstrate "equal or better" capabilities with respect to design parameters. As discussed in ***Section 4.3.2.1***, insufficient quantities of MnO_2 being mixed into the hardener component during formulation, and then also during mixing of the hardener and base sealant components, can cause performance issues. For example, this can affect the viscosity of the mixed uncured sealant (which in turn can affect delivery method) and the overall cure time of the sealant, which are both key technical parameters that a candidate alternative product must demonstrate adequate equivalent performance with to pass that test criteria.

At the current state of knowledge, it is not clear which potential alternative(s), will be successful and possibly implemented for aerospace applications within the scope of the AfA and, at what point in time this may be the case. During initial testing, the Applicant has observed the influence of the surfactants used in the hardener component on different sealant properties, such as adhesion, viscosity, aging behaviour, tensile strength and others, and has selected alternative surfactants for the sealant reformulation test programme. That does not necessarily mean that these cannot successfully be used as alternatives to the NPE-containing surfactant, but that at the very least, the amended formulations need to be further adjusted according to the different behaviour of the alternative surfactant in the reformulation. However, it may be the case that even after such adjustments, the reformulated product will not meet performance specifications. This reformulation and testing process can take a significant amount of time, as sealants are complex and sensitive systems. For example, in the experience of the Applicant when assessing replacement surfactants, it may be that the alternative NPE-free surfactant is used and there are no issues with manufacture of the hardener, but when the base and hardener components are mixed and samples prepared for initial testing, it is likely that there will be a failure in a key performance parameter (such as adhesion, application time, etc.). Therefore, further adjustments are required, such as increasing the active hardener component or modifying the adhesion promotors in the hardener, so that when the test is re-run with the adjusted hardener formulation, the mixed sealant meets the required specifications. It can also be the case that in making these adjustments, the mixed sealant then fails on other criteria, such as the viscosity is now too high, and the elongation parameter (degree of strain a sealant can undergo before tensile failure) is affected. This illustrates that the process of creating a candidate reformulated sealant hardener that meets all required specifications can be very iterative and responsive, depending on the initial testing outcomes, and that this can take a significant period.

5.3.1. Alternative 1 – Polyglycol ethers

5.3.1.1. Substance ID, properties

Polyglycol ethers are polymers composed of glycol ethers. They represent a group of solvents based on alkyl ethers of ethylene glycol or propylene glycol and contain both an ether and alcohol functional group in the same molecule. These functional groups allow for additional sites for hydrogen bonding and compatibility with other substances and, therefore, these substances have good solubility properties and chemical stability. These properties are why these substances are considered as such useful organic solvents, and why they can be used as chemical manufacturing intermediates. Depending on whether they are manufactured from ethylene oxide or propylene oxide, they are categorised into either 'e-series' or 'p-series' glycol ethers, respectively. P-series glycol ethers are more commonly used in surfactant formulations, such as degreasers or cleaning agents. Most glycol ethers are water-soluble, biodegradable and generally have no or low hazard classifications. The surfactant containing polyglycol ether currently being assessed by the Applicant has a flash point >100 °C and it creates a relatively pH neutral solution (pH 5-7) when mixed with water.

5.3.1.2. Technical feasibility of Alternative 1 – Polyglycol ethers

Alternative 1, through initial tests, has demonstrated that it fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previous formulation containing NPE. However, use of Alternative 1 results in significant impacts on the mixed sealant mechanical properties, viscosity and adhesion properties to some substrates and is not currently considered as satisfactorily meeting the performance criteria on all tested substrates. It has been observed to increase or otherwise affect the viscosity of the hardener component, which in turn affects the performance and stability of the hardener over time, as well as impacting shelf life of this sealant component. Through these R&D activities, it has been determined that Alternative 1 is not suitable for use in all sealant hardener formulations.

Therefore, further reformulation work is required before Alternative 1 can be considered as a technically viable alternative, as any sealants containing reformulated hardener components must comply with the appropriate specifications and product performance parameters to be considered as a viable, interchangeable alternative product. At this stage, whilst the Applicant's R&D team is positive that these technical challenges could be overcome in time through further formulation adjustment, it is unclear if this potential alternative will be carried forward for further R&D activities, depending on the testing outcomes of the other potential alternatives.

5.3.1.3. Economic feasibility and economic impacts of Alternative 1 – Polyglycol ethers

The economic impact due to changes in raw material prices is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost profile. It is also not expected that there will be any manufacturing equipment changes due to changes in surfactant. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 per month. Once a candidate alternative has been identified as the most feasible option, it is expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate alternative, but even so, the cost of conducting laboratory and production phase testing is significant.

For the OEM customers, it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, sub-assemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants, to ensure that the replacement product meets the OEM specifications and performs as expected. Overall, the replacement costs for the entire operation are estimated by some OEM companies to be > €3 million. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant, to replace the NPE in the hardener component of the sealant.

5.3.1.4. Availability of Alternative 1 – Polyglycol ethers

The surfactant product based on polyglycol ether is commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener components utilising this surfactant option, this is controlled primarily by the outcome of the Applicant's technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with the OEM customers.

5.3.1.5. Reduction of overall risk due to transition to Alternative 1 – Polyglycol ethers

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure the replacement surfactants do not contain any other substances that may be subject to EU regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 1, instead of the current surfactant containing

NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

Further risk for Alternative 1 is the chance that the reformulated hardener may not be successfully approved by OEM customers, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by the OEM customers. If this situation occurs, this would negatively impact upon the timeline and delay the replacement of the current sealants with NPE free versions.

5.3.1.6. Conclusions on Alternative 1 – Polyglycol ethers

There are no concerns on availability of Alternative 1 or any further EU regulatory controls expected for components of this surfactant blend, as currently known. There is no significant economic impact on the Applicant for switching to use of Alternative 1 and this is not expected to impact upon the final pricing of the sealants. The primary economic impact of Alternative 1 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 per month for the Applicant. Once there is a reformulated product using the most successful candidate alternative, there will also be a cost to the OEM customer companies to conduct the qualification of the reformulated sealant. These economic impacts are not specific to Alternative 1 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing polyglycol ethers instead of NPE has been shown in initial laboratory testing to suitably disperse MnO_2 particles in the hardener formulation but has been shown to cause significant impacts on the mechanical, adhesion, curing and viscosity properties of the mixed sealant, as well as causing issues with the stability and viscosity of the hardener over time. Despite this Alternative not currently meeting the definition of a technically feasible alternative, the Applicant is still conducting some reformulation work and laboratory testing is still ongoing. It is anticipated that the issues with adhesion, curing and performance over time can be addressed, but further progression of Alternative 1 is also dependant on the outcomes of laboratory testing for the other potential alternatives. The Formulator believes that NPE will be able to be successfully replaced, either with Alternative 1 or another potential alternative, in the sealants and provided to OEMs to commence qualification testing by Q2 2021.

The timeline for qualification and industrialisation of the reformulated products, even if ultimately successful, cannot be assuredly achieved before the Sunset Date, as the reformulated product is forecasted to be available to start this testing Q2 2021. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3 years (18 months for qualification following sealant formulation development and 18 months for industrialisation). However, the possibility that the reformulated products may not be successfully approved due to a product, or several products, not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline until full requalification and replacement of the current sealants is complete. The intent of this AfA is to allow enough time to successfully complete qualification, industrialization and supply chain implementation of the NPE-free sealant versions.

5.3.2. Alternative 2 – Polyether phosphate

5.3.2.1. Substance ID, properties

Polyether phosphate esters are esters of phosphoric acid with polyalkylene glycol ether(s), with a generic formula of R-(AO)n-P(O)(OH)3-n, where n is an integer from 1 to 3. They can be prepared by reacting a polyalkylene glycol ether with a phosphating agent. These phosphate esters, and salts thereof, are useful as extreme pressure/anti-wear additives. The flash point of the substance is above 100 °C and it has an acidic pH when mixed with water (1.5-2.5 pH).

5.3.2.2. Technical feasibility of Alternative 2 - Polyether phosphate

Through initial tests, it has been demonstrated that Alternative 2 fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previously used NPE-phosphate based surfactant. Use of this Alternative in the hardener formulation has been demonstrated in laboratory testing to have improved the viscosity and stability of the hardener, compared to the NPE-phosphate based surfactant. This Alternative has been shown to be suitable for use in all hardener formulations and has equivalent performance with the NPE-phosphate surfactant in relation to the viscosity, curing, adhesion and mechanical properties of the mixed sealant, when used in the hardener formulation.

This is currently the most technically feasible alternative out of the different potential alternatives listed, and only final adjustments are thought to be required for use of this Alternative in hardener formulations going forward.

5.3.2.3. Economic feasibility and economic impacts of Alternative 2 - Polyether phosphate

Similarly, to Alternative 1, the economic impact due to changes in raw material prices for Alternative 2 is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost. It is also not expected that there will be any manufacturing equipment changes due to changes in surfactant. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 per month. Once a candidate alternative has been identified as the most feasible option, it is expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate, but even so, the cost of conducting laboratory and production phase testing is significant.

For the OEM customers, it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or to the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, subs-assemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants to ensure that the replacement formulation meets the OEM specifications and performs as expected. Overall, the replacement costs for the entire operation is estimated by some OEM companies to be > €3 million. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant to replace the NPE in the hardener component of the sealant.

5.3.2.4. Availability of Alternative 2 - Polyether phosphate

The surfactant product based on polyether phosphate is readily and commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener components utilising this surfactant option, this is controlled primarily by the outcome of the Applicant's technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with the OEM customers.

5.3.2.5. Reduction of overall risk due to transition to Alternative 2 - Polyether phosphate

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure the replacement surfactants do not contain any other substances that may be subject to EU regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 2, instead of the current surfactant containing NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

Further risk for Alternative 2 is the chance that the reformulated hardener may not be successfully approved by OEM customers, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by the OEM customers. If this situation occurs, this would negatively impact upon the timeline and delay the replacement of the current sealants with NPE free versions.

5.3.2.6. Conclusions on Alternative 2 - Polyether phosphate

There are no concerns on availability of Alternative 2 or any further EU regulatory controls expected for components of this surfactant blend, as currently known. There is no significant economic impact on the Applicant for switching to use of Alternative 2, and this is not expected to impact upon the final pricing of the sealants. The primary economic impact of Alternative 2 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 per month for the Applicant. Once there is a reformulated product using the most successful alternative, there will also be a cost to the OEM customer companies to conduct the qualification testing for the reformulated sealant. These economic impacts are not specific to Alternative 2 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing polyether phosphate, instead of NPE, has been shown in initial laboratory testing to suitably disperse MnO_2 particles in the hardener formulation, not to cause any issues during manufacture, and to not adversely affect the viscosity and sealant of the hardener. Equivalent performance of mixed sealant using hardeners containing Alternative 2 has also been demonstrated for the mechanical, adhesion, curing and viscosity properties of the mixed sealant. Alternative 2 is currently considered as the most promising potential alternative, as it works in all sealant hardeners and most results are within specification, but final formulation adjustments are needed. The Applicant believes that NPE will be able to be successfully replaced, and this is currently thought to be most likely with Alternative 2, in the sealants and provided to OEMs to commence qualification testing by Q2 2021.

The timeline for qualification and industrialisation of the reformulated products, even if ultimately successful, cannot be assuredly achieved before the Sunset Date, as the reformulated product is forecast to be available to start this testing Q2 2021. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3 years (18 months for qualification following sealant formulation development and 18 months for industrialisation). However, the possibility that the reformulated products may not be successfully approved due to a product or several products not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline, until full requalification and replacement of the current products is complete. The intent of this AfA is to allow enough time to successfully complete product qualification for the NPE-free product versions and implementation of this alternative.

5.3.3. Alternative 3 - Alkylammonium salt of a copolymer with acidic groups

5.3.3.1. Substance ID, properties

“Alkylammonium salt of a copolymer with acidic groups” is a type of quaternary ammonium salt (QAS), which are commonly used in anti-microbial disinfectants and surfactants, due to the high solubility of these compounds in water. These are typically formed of alkyl groups in a long hydrocarbon chain, with different functionalities, e.g. methacrylic acid copolymer containing pendant carboxylic acid groups.

5.3.3.2. Technical feasibility of Alternative 3 - Alkylammonium salt of a copolymer with acidic groups

Alternative 3, through initial tests, has demonstrated that it fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previously used NPE-phosphate surfactant. Alternative 3 is considered suitable for use in all hardeners and no issues with the viscosity of the hardener have been encountered. However, use of Alternative 3 has a slight impact upon the stability of the hardener, and further work is required to match the efficiency of the NPE phosphate surfactant in this respect. Use of Alternative 3 has been demonstrated to have slight negative impacts upon the curing, adhesion and viscosity of the mixed sealant, and significant impacts on the other mechanical properties of the sealant.

However, despite these issues, Alternative 3 is considered one of the more technically feasible alternatives after Alternative 2. Further reformulation work is required before Alternative 3 can be considered as a technically viable alternative, as any sealants containing reformulated hardener components must comply with the appropriate specifications and product performance parameters to be considered as a viable, interchangeable alternative product. At this stage, whilst the Applicant's R&D team is positive that these technical challenges could be overcome in time through further formulation adjustment, it is unclear if this potential alternative will be carried forward for further R&D activities, depending on the testing outcomes of the other potential alternatives.

5.3.3.3. Economic feasibility and economic impacts of Alternative 3 - Alkylammonium salt of a copolymer with acidic groups

Similarly, to Alternatives 1 and 2, the economic impact due to changes in raw material prices for Alternative 3 is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost profile. It is also not expected that there will be any manufacturing equipment changes due to changes in surfactant. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 per month. Once a candidate alternative has been identified as the most feasible option, it is expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate, but even so, the cost of conducting laboratory and production phase testing is significant.

For the OEM customers, it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, subassemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants, to ensure that the replacement formulation meets the OEM specifications and performs as expected. Overall, the replacement costs for the entire operation is estimated by some OEM companies to be > €3 million. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant, to replace the NPE in the hardener component of the sealant.

5.3.3.4. Availability of Alternative 3 - Alkylammonium salt of a copolymer with acidic groups

The surfactant product based on alkylammonium salt of a copolymer with acidic groups is readily and commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener components utilising this surfactant option, this is controlled primarily by the outcome of the Applicant's technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with the OEM customers.

5.3.3.5. Reduction of overall risk due to transition to Alternative 3 - Alkylammonium salt of a copolymer with acidic groups

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure that the replacement surfactants do not contain any other substances that may be subject to EU regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 3, instead of the current surfactant containing NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

Further risk for Alternative 3 is the chance that the reformulated hardener may not be successfully approved by OEM customers after the Applicant testing has completed, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by the OEM customers. If this situation occurs, this would negatively impact upon the timeline and delay the replacement of the current sealants with NPE-free versions.

5.3.3.6. Conclusions on Alternative 3

There are no concerns on availability of Alternative 3 or any further EU regulatory controls expected for components of this surfactant blend, as currently known. There is no significant economic impact on the Applicant for switching to use of Alternative 3, and this is not expected to impact upon the final pricing of the sealants. The primary economic impact of Alternative 3 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 per month for the Applicant. Once there is a reformulated product using the most successful alternative, there will also be a cost to the OEM customer companies to conduct the qualification testing of the reformulated sealant. These economic impacts are not specific to Alternative 3 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing an alkylammonium salt of a copolymer with acidic groups has been shown in initial laboratory testing to disperse MnO_2 particles equivalently to the previously used NPE-phosphate surfactant, no issues with the viscosity of the hardener have been encountered and is considered as suitable for use in all hardener formulations.

However, use of Alternative 3 has a slight impact upon the stability of the hardener, and use of Alternative 3 has been demonstrated to have slight negative impacts upon the curing, adhesion and viscosity of the mixed sealant, and significant impacts on the other mechanical properties of the sealant. Alternative 3 is currently considered as the second most promising potential alternative, as it works in all sealant hardeners and most results are within specification, but further reformulation work and testing is required to address the current gaps in performance. The Applicant believes that NPE will be able to be successfully replaced, and this is currently thought to be most likely with Alternative 2, in the sealants and provided to OEMs to commence qualification testing by Q2 2021.

Whilst Alternative 3 is not yet as close to being ready to be issued to OEM customers for qualification testing, compared to Alternative 2, the same concerns around timeline and availability of the reformulated sealants are relevant for Alternative 3. The timeline for qualification and industrialisation of the reformulated products, even if ultimately successful, cannot be assuredly achieved before the Sunset Date, as the reformulated product is forecast to be available to start this testing Q2 2021. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3 years (18 months for qualification following sealant formulation development and 18 months for industrialisation). However, the chance that the reformulated products may not be successfully approved due to a product or several products not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline until full requalification and replacement of the current products is complete. The intent of this AfA is to allow enough time to successfully complete product qualification for the NPE-free product versions and implementation of this alternative.

5.3.4. Alternative 4 - Anionic aliphatic ester

5.3.4.1. Substance ID, properties

An anionic aliphatic ester is an open hydrocarbon chain with alkyl functional groups and an overall negative charge. These substances are derived from an alcohol that is reacted with an acid (organic or inorganic) resulting in at least one –OH (hydroxyl) group being replaced by an –O–alkyl (alkoxy) group. These additional alkyl functional groups allow for additional sites for hydrogen bonding and promote compatibility and solubility with other substances, which is why they are included in surfactant blends. The surfactant currently being assessed by the Applicant contains Dioleyl maleate (CAS 105-73-7), which has a flash point > 275 °C and is not classified as hazardous.

5.3.4.2. Technical feasibility of Alternative 4 - Anionic aliphatic ester

Alternative 4, through initial tests, has demonstrated that it fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previously used NPE-phosphate surfactant. However, use of Alternative 4 results in significant impacts on the mixed sealant mechanical properties, viscosity and adhesion properties to some substrates and is not currently considered as satisfactorily meeting the performance criteria on all tested substrates. It has been observed to increase or otherwise affect the viscosity of the hardener component, which in turn affects the performance and stability of the hardener over time, as well as impacting shelf life of this sealant component. Through these R&D activities, it has been determined that Alternative 4 is not suitable for use in all sealant hardener formulations.

Therefore, further reformulation work is required before Alternative 4 can be considered as a technically viable alternative, as any sealants containing reformulated hardener components must comply with the appropriate specifications and product performance parameters to be considered as a viable, interchangeable alternative product. At this stage, whilst the Applicant's R&D team is positive that these technical challenges could be overcome in time through further formulation adjustment, it is unclear if this potential alternative will be carried forward for further R&D activities, depending on the testing outcomes of the other potential alternatives.

5.3.4.3. Economic feasibility and economic impacts of Alternative 4 - Anionic aliphatic ester

The economic impact due to changes in raw material prices is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost profile. Due to the differences in mechanical properties of the hardener manufactured with this potential alternative surfactant, it is possible that use of Alternative 4 may require manufacturing process or equipment changes, which will inherently incur additional cost. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 per month. Once a candidate alternative has been identified as the most feasible option, it expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate, but even so, the cost of conducting laboratory and production phase testing is significant.

For the OEM customers, it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, sub-assemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants, to ensure that the replacement formulation meets the OEM specifications and performs as expected. Overall, the replacement costs for the entire operation is estimated by some OEM companies to be > €3 million. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant to replace the NPE in the hardener component of the sealant.

5.3.4.4. Availability of Alternative 4 - Anionic aliphatic ester

The surfactant product based on anionic aliphatic ester is readily and commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener component utilising this surfactant option, this is controlled primarily by the outcome of the Applicant's technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with the OEM customers.

5.3.4.5. Reduction of overall risk due to transition to Alternative 4 - Anionic aliphatic ester

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure that the replacement surfactants do not contain any other substances that may be subject to EU regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 4, instead of the current surfactant containing NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

Further risk for Alternative 4 is the chance that the reformulated hardener may not be successfully approved by OEM customers after the Applicant testing has completed, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by the OEM customers. If this situation occurs, this would negatively impact upon the timeline and delay the replacement of the current sealants with NPE-free versions.

5.3.4.6. Conclusions on Alternative 4

There are no concerns on availability of Alternative 4 or any further EU regulatory controls expected for components of this surfactant blend, as currently known. There may be impacts on the manufacture process or equipment resulting from switching to use of Alternative 4, which would incur additional cost on the Applicant. However, the primary economic impact of Alternative 4 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 per month for the Applicant. Once there is a reformulated product using the most successful alternative, there will also be a cost to the OEM customer companies to conduct the qualification testing of the reformulated sealant. These economic impacts are not specific to Alternative 4 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing anionic aliphatic ester instead of NPE has been shown in initial laboratory testing to suitably disperse MnO_2 particles in the hardener formulation but has been shown to cause significant impacts on the mechanical, adhesion, curing and viscosity properties of the mixed sealant, as well as causing issues with the stability and viscosity of the hardener over time. Despite this Alternative not currently meeting the definition of a technically feasible alternative, the Applicant is still conducting some reformulation work and laboratory testing is still ongoing. It is anticipated that the issues with adhesion, curing and performance over time can be addressed, but further progression of Alternative 4 is also dependant on the outcomes of laboratory testing for the other potential alternatives. The Applicant believes that NPE will be able to be successfully replaced, either with Alternative 4 or another potential alternative, in the sealants and provided to OEMs to commence qualification testing by Q2 2021.

Whilst Alternative 4 is not yet as close to being ready to be issued to OEM customers for qualification testing, compared to Alternative 2 or 3, the same concerns around timeline and availability of the reformulated sealants are relevant for Alternative 4. The timeline for qualification and industrialisation of the reformulated products, even if ultimately successful, cannot be assuredly achieved before the Sunset Date, as the reformulated product is forecast to be available to start this testing Q2 2021. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3 years (18 months for qualification following sealant formulation development and 18 months for industrialisation). However, the chance that the reformulated products may not be successfully due to a product or several products not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline until full requalification and replacement of the current products is complete. The intent of this AfA is to allow enough time to successfully complete product qualification for the NPE-free product versions and implementation of this alternative.

5.3.5. Summary of Alternatives Assessment

The assessment of the potential alternatives as replacements for the NPE-phosphate based surfactant is summarised in Table 13. The maturity levels of the candidate alternatives are categorised as follows;

- 1 = most promising potential alternative, works in all sealant hardeners, most results are within specification, final adjustments needed
- 2 = promising potential alternative, higher amount is needed, which means higher cost and bigger influence on the whole system, adjustments of the formulation ongoing to compensate
- 3 & 4 = potential alternatives which require further and deeper re-formulation work, however R&D is positive about the feasibility to use the alternatives in the end

TABLE 13 ASSESSMENT OF POTENTIAL ALTERNATIVE OPTIONS

Key Parameter	Potential Alt 1 - Polyglycol ethers	Potential Alt 2 - Polyether phosphate	Potential Alt 3 - Alkylammonium salt of a copolymer with acidic groups	Potential Alt 4 - Anionic aliphatic ester
MnO_2 dispersion properties / Ease of manufacture of hardener	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant

Key Parameter	Potential Alt 1 - Polyglycol ethers	Potential Alt 2 - Polyether phosphate	Potential Alt 3 - Alkylammonium salt of a copolymer with acidic groups	Potential Alt 4 - Anionic aliphatic ester
Viscosity of the hardener	ok, but twice the amount is needed to reach the efficiency of the NPE phosphate surfactant	Improved in comparison to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant
Stability of the hardener	poor - viscosity increase over time	Improved in comparison to NPE phosphate surfactant	ok, but a little bit more is needed to reach the efficiency of the NPE phosphate surfactant	poor - viscosity increase over time
Suitable for all sealant hardeners?	no	yes	yes	no
Impacts on mechanical properties of the mixed sealant	significant impact	significant impact	significant impact	significant impact
Impacts on mechanical properties of the mixed sealant after adjustment of the base/hardener formulation	slight impact	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	slight impact
Impacts on the curing behaviour of the mixed sealant	slight impact	equivalent to NPE phosphate surfactant	slight impact	slight impact
Impacts on the viscosity of the mixed sealant	significant impact	equivalent to NPE phosphate surfactant	slight impact	significant impact
Impacts on the adhesion of the mixed sealant	significant impact	significant impact	significant impact	significant impact
Impacts on the adhesion of the mixed sealant after adjustment of the base/hardener formulation	significant impact	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	significant impact

Key Parameter	Potential Alt 1 - Polyglycol ethers	Potential Alt 2 - Polyether phosphate	Potential Alt 3 - Alkylammonium salt of a copolymer with acidic groups	Potential Alt 4 - Anionic aliphatic ester
Maturity Level	**3**	**1**	**2**	**4**

Overall, the Applicant believes that it will most likely be able to introduce a fully working NPE-free reformulated alternative sealant product to the OEMs, ready to commence technical qualification, by Q2 2021. As summarised above potential Alternative 2 (Polyether phosphate) is currently considered as the most mature candidate and will be focussed on as a priority. This alternative is the most likely to successfully complete the development testing phase, before reformulated sealant samples are made available to OEMs for testing. However, the other potential alternatives are undergoing similar development tests, and in the case of multiple viable potential alternatives, the Formulator may use multiple surfactants in sealant formulations going forward to avoid dependence on a single surfactant source. The R&D work with the formulator is still ongoing and is expected to end Q2 2021.

5.4. The most likely non-use scenario

The NUS were developed with input from multiple sources. First, aerospace industry members of EAAC prepared a description of the NUS. These were then developed and validated through a series of bilateral discussions and meetings, conducted by independent consultants experienced in the process of developing such scenarios for EU regulatory purposes, to test the robustness of, validate, and elaborate the scenarios. Companies from across the aerospace industry sector were involved in the scenario development process. Consolidated NUS were developed based on these responses and are representative of the industry.

FIGURE 17 shows the causal chain for the most likely NUS. As shown in the AoA, there is no alternative readily available for use at all EEA aerospace sites. Naturally, the use of a worse performing alternative is not an option, due to flight safety and airworthiness requirements. Therefore, as will be outlined in the following sections, two different non-use scenarios have been found to be most likely, should an authorisation not be granted. As outlined in the following, NUS 1 represents the lower bound and NUS 2 represents the upper bound in terms of negative socio-economic impacts that need to be considered in the case of non-authorisation.

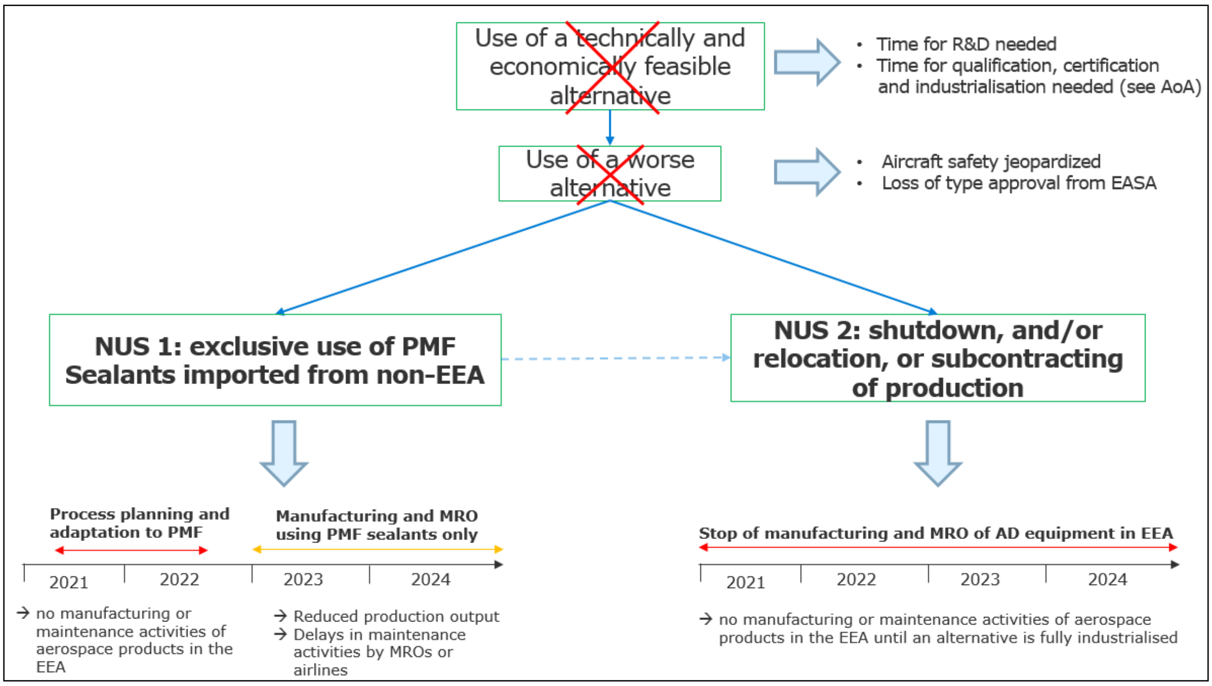


FIGURE 17: CAUSAL CHAIN FOR NUS

NUS 1, as described in detail in Section 5.4.1, refers to a situation where all processes of all aerospace operations in the EEA would be changed to the exclusive use of PMF sealants, with all technical and procedural drawbacks. In this scenario, the total volume of sealants needed within the EEA would be pre-mixed and frozen in a non-EEA country and imported to the EEA via refrigerated airfreight. This NUS would entail a period of 1 to 2 years where no manufacturing or MRO of aerospace equipment would be possible in the EEA, due to unavailability of NPE-containing sealants. This period would be followed by a period of 2 to 3 years with reduced production output, increased operational costs and drastically decreased operability of aerospace products, due to MRO delays, until an alternative is fully industrialised at all EEA aerospace operations. Although two-part sealants can theoretically be replaced by PMF sealants, the applicability of this NUS is highly questionable for different reasons (see ***Section 5.4.1.3***). It is important to note that there are substantial doubts about the technical feasibility of this NUS. For example, it remains questionable if the formulator can manage to establish a production facility outside the EEA capable of delivering the needed amounts of sealants as PMF product for Airbus and its EEA suppliers as soon as needed. Therefore, a situation as described in the following **NUS 2** could materialise.

However, for the sake of providing an alternative, more conservative NUS compared to **NUS 2**, it is assumed that necessary amounts of PMF sealant can be readily delivered as soon as all processes at Airbus and its suppliers, as well as MRO operations, have been adapted to the use of PMF sealants only.

NUS 2, as described in Section 5.4.2, refers to a situation where manufacturing and MRO of aerospace equipment would need to be stopped until an NPE-free alternative is fully industrialised at all aerospace companies in the EEA.

As shown in the following, the impacts attributed to the NUS described by the aerospace companies are significant. This can be regarded as a reflection of the essential function that polysulfide sealants play in aerospace product manufacturing, operations and maintenance, and the technical and logistical challenges associated with replacing them in the foreseeable future.

Thus, the sections below present an overview of NUS 1 and NUS 2; the following sub-sections describe the scenario separately for the formulators and the DUs. The impacts associated with NUS 1 and NUS 2, mentioned briefly in this section, have been elaborated in Section 6.2 and Section 6.3, separately for the formulators and the DUs.

5.4.1. NUS 1 – Exclusive Use of PMF Sealants

As an alternative to the preparation of the polysulfide sealants directly before use, sealants with application time > 0.5 hours can theoretically be pre-mixed, frozen and stored at -45°C for a maximum of 35 days for later use. Pre-mixing can take place either directly at the DU site or at the formulator site. Pre-Mixed and Frozen (PMF) sealants are therefore an alternative method of delivering polysulfide sealants to the point of use inside a DU facility.

The NUS presented here considers a hypothetical situation where the total sealant volume is mixed outside of the EEA by the applicant and/or the DU themselves or via subcontractors at non-EEA sites. The PMF sealant is then imported into the EEA and used at the DU sites. DU sites covered by this AfA comprise all EEA sites of Airbus Group companies, as well as their suppliers and customers, including MROs and airlines.

Production of PMF sealants will take place outside the EEA until an NPE-free alternative is developed, qualified and industrialized by the aforementioned aerospace companies. Since PMF sealants can only be transported and stored in small packaging (cartridges), a large volume of PMF cartridges will need to be produced to substitute the large quantities of sealants that are used in aerospace equipment manufacturing and MRO. This will require investments in infrastructure by the applicant at one or more non-EEA sites to meet the demand for increased production and storage of PMF sealants. Installation of additional cold storage freezers, back-up generators and other relevant equipment will be required both by the applicant outside the EEA and all DUs in the EEA. The installation of this equipment and the need to immediately store PMF sealants at the requisite temperature after production will create the need for additional cold storage freezers at the site of formulation and downstream use. The provision of these extended cold storage freezers will require additional infrastructure by either upgrading the existing facility or acquisition of new land.

As a result of this relocation to a non-EEA country, job losses can be expected at the EEA site of the applicant.

To maintain the quality standards and the short-term functionality of the PMF sealants, it is crucial to maintain low temperatures during the entire process from mixing until end use. Different steps during the supply chain will require different temperature specifications to preserve the PMF sealants. For instance, the freezing process will require an ambient temperature of less than -70°C. Prior to distribution, it should be preserved at an ambient temperature of -60°C ± 4°C and during transportation, it must be preserved at an ambient temperature of -44°C ± 4°C. It will require the PMF sealants to be packaged using dry ice in small containers and further transported via refrigerated air freight to the site of end use in the EEA at a constant temperature matching the specifications. Transport via air freight is mandatory due to the requirement to maintain very low temperature as well as due to the limited shelf life of PMF sealants. Consequently, additional logistical costs of transporting the PMF sealants from a non-EEA site to an EEA facility of use will be incurred by the applicant and the downstream users.

Figure 18 shows the stages involved in this scenario. As it can be seen in this non-use scenario, the sealant is manufactured in a non-EEA country by mixing of hardener and base and subsequent freezing and packaging. This can be done by a formulator or by a non-EEA site of an aerospace company. The PMF sealant is then transported via refrigerated air freight to the point of use in the EEA.

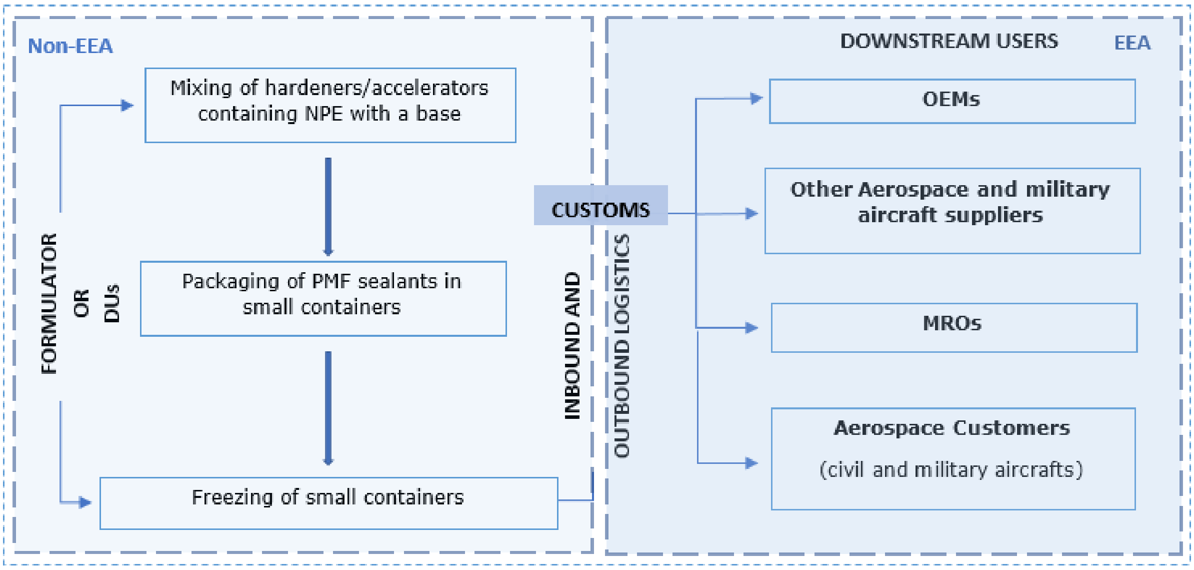


FIGURE 18: DIAGRAMMATIC REPRESENTATION OF THE NON-USE SCENARIO

5.4.1.1. Use 1 - Formulation

The affected sealants are currently only produced at one site in Germany. As a result of non-authorisation, the production will need to be relocated outside the EEA and adapted to the production of PMF sealants. The applicant reports that such a process could take approx. 3 years.

Therefore, it is considered highly unlikely that relocation, adaptation to exclusive production of PMF sealants for the European market and requalification of the production can be finished before all processes at Airbus/its suppliers/MROs have been adapted and can commence with PMF sealants.

However, even if it is seen as unrealistic, for the purposes of evaluation of this NUS in the SEA, it is assumed that the necessary amounts of PMF sealants could be delivered as soon as Airbus and its suppliers have finished the adaptation of their production processes to the exclusive use of PMF sealants.

Thus, the main socio-economic impacts entailed by the formulator and assessed in this SEA due to relocation of the affected production and adaptation to exclusively PMF production include:

- Costs associated with relocation
- Foregone profits due to supply interruption
- Social impacts

5.4.1.2. Use 2 - Downstream Use

Following the relocation of formulation outside the EEA, the downstream users would start importing the PMF sealants after the following steps have been completed:

- Qualification of formulator sites outside the EEA by the OEMs
- Requalification of longer cure sealants containing NPE to be used to replace fast cure PMF sealants

The time required for the completion of these two regulatory requirements would be approximately 1 to 2 years, leading to a production stop. As a result of this interruption, delays in the manufacture, maintenance and repair of aerospace products would be experienced, due to unavailability of sealants. However, these processes are assumed to commence after the regulatory requirements have been fulfilled.

Most importantly, costs for process adaptations and related production stops, as well as supply disruptions and potentially significant process delays and output reductions at Airbus, must be considered in this NUS.

For MRO activities, such a scenario would be difficult to implement, especially for the line maintenance activities or unscheduled repairs, where the amount of sealant required cannot be forecasted. Field repairs (e.g. on-wing or fuselage repairs) usually require the use of fast cure sealants with a short working life. An on-site repair requires the immediate use of these sealants wherever an aircraft lands, in case of a defect. While non-MRO operations could theoretically cope with longer cure times of PMF sealants (provided process adaptations are successful), such a scenario is deemed infeasible, especially for unscheduled MRO operations, where a short cure time for sealants is essential to avoid prolonged aircraft on ground (AOG) times and related costs and impacts. (see ***Section 6.2.2.4*** and Case Study 1 in ***Annex A***).

5.4.1.3. Conclusion

It is important to re-iterate that there are substantial doubts about the technical feasibility of this NUS. For example, it remains questionable if the formulator can manage to establish a production facility outside the EEA capable of delivering the needed amounts of sealants as PMF product for Airbus and its EEA suppliers as soon as needed.

As mentioned in the introduction to NUS 1, this scenario was developed to provide an alternative, less costly scenario, compared to the "total shutdown of all A&D operations in the EEA-scenario" with all its tremendous consequences for the European Economy and Society.

In addition to that, the following must be considered when evaluating this NUS.

- The entire process of producing pre-mixed and frozen sealants has several limitations, which are discussed in greater detail in the subsequent sections. Being able to only use PMF sealants in this scenario will be especially problematic for applications where currently fast-cure sealants are used. Fast-cure sealants have an application time of only several minutes or less and can therefore not be supplied as a PMF sealant (the freezing and unfreezing steps reduce the application time even further, inhibiting later use of the sealant, i.e., the sealant cures during freezing and thawing, making it unusable). For this reason, the processes requiring fast cure sealants will have to be adapted. The possibility to switch from fast cure sealants to sealants with a longer cure time, allowing the use of pre-mixed and frozen sealants, will depend on each application on a case-by-case basis and may jeopardize the complete process flow in the assemblies. The time required for switching from fast cure sealants to PMF sealants with a relatively longer cure time is individual to each DU.
- Theoretically these fast cure sealants can be replaced by products that can be imported as PMF; however, this will slow down the processes at the DUs (see FIGURE 22). For MROs and airlines, this can result in increased AOG times with all related consequences, as laid out in the Case Study 1 in ***Annex A***. Curing might also be subject to weather, such that it depends on outside temperature and humidity. The colder and more humid the weather, the longer it takes for the sealant to cure. Therefore, fast-cure sealants are often used in cold climates and in winter, when using normal products in such a climate, curing/hardening would require a much longer time.
- This scenario would not only imply investment costs, but also high transport (see TABLE 23) and energy costs (see TABLE 20), to maintain the cold storage freezers at a specific temperature at all times.
- Besides that, there is a constant need to maintain the sealants at -45°C to protect its functionality and applicability. To maintain such low temperatures while transporting PMF sealants in small containers, transportation would be carried out using dry ice at -70°C (large containers cannot be deployed for such packaging, noting the non-uniform freezing of large quantities of PMF sealants resulting in poor quality and increased freezing time versus freezing of small quantities of PMF sealants). A complete cooling to about -45°C must be ensured from production to end customer. Subsequent external environmental costs associated with increased CO_2 emissions (shown in TABLE 25) and generation of plastic packaging waste are expected, which will be borne by society.
- As shown in Figure 18, importing the pre-mixed sealants in a frozen form from a non-EEA country would imply customs clearance. Holding the package at customs could intensify the difficulty of maintaining low temperatures for the pre-mixed and frozen sealants containing NPE. An inability to do so could result in the possibility of air entering the material, consequently leading to loss of adhesion properties, rendering the sealants unfit for use on an aircraft.

A comparison of this scenario with the applied for use scenario highlights the **tremendous economic and procedural downsides** of importing and using PMF sealants, providing no environmental benefit. Indeed, there is no potential to reduce **NPE emissions, which are already, at worst, precluded** throughout the life cycle of an aircraft. Additionally, high external environmental costs related to packaging waste and **increased CO_2 emissions from transport** would be incurred in this non-use scenario.

In conclusion, this scenario would involve socio-economic costs in the range of 5 - 10 billion Euros while the volume of NPE containing sealants would increase, due to higher storage volumes and subsequent scrapping of unused sealants at the end of their shelf life.

For the reasons outlined above, which might render this NUS unfeasible, an additional NUS (**NUS 2**) is presented in the following to provide an upper bound of socio-economic impacts that can be expected, should an authorisation not be granted.

5.4.2. NUS 2 – Shutdown/Relocation/Subcontracting to non-EEA

As outlined, this scenario is relevant when more detailed analyses conclude that a temporary change to PMF sealants would take equally long or technical/procedural limitations of change to PMF sealants could not be overcome.

5.4.2.1. Use 1 - Formulation

In NUS 2, it is assumed that the formulator would stop production of NPE-containing sealants in the EEA because timeframes needed for development of NPE-free sealants and relocation and adaptation of production would be similar, making it overall more cost-efficient for the formulator to temporarily shut down production until it can commence without NPE in 2025.

In parallel, the formulator would invest in R&D and prepare for the qualification and industrialisation of the NPE-free alternative.

In this case, the following minimum impacts would have to be considered:

- Foregone profits due to production interruption
- Social impacts due to the temporary dismissal of 40-100 ([redacted]) employees

Please refer to Section 6.2.1 for the impact assessment of this NUS.

5.4.2.2. Use 2 - Downstream Use

OEMs unanimously advise that they would be forced to stop production of aerospace products and components (including civil and military aircraft) that require NPE containing sealants in the production process in the EEA.

The NUS for MRO activities needs to be distinguished between scheduled activities (so called 'letter' checks (A-, B-, C-, D-)) and unscheduled activities which may be required at any time and at any place. Unscheduled activities are either executed *in situ* for parts that cannot be disassembled (e.g. on the fuselage) or activities that do not necessarily require moving the aircraft to a hangar (e.g. can be performed at the gate and therefore allow minimised interruptions of the flight plan), or *ex situ,* which describes all activities for which parts need to be taken off the aircraft.

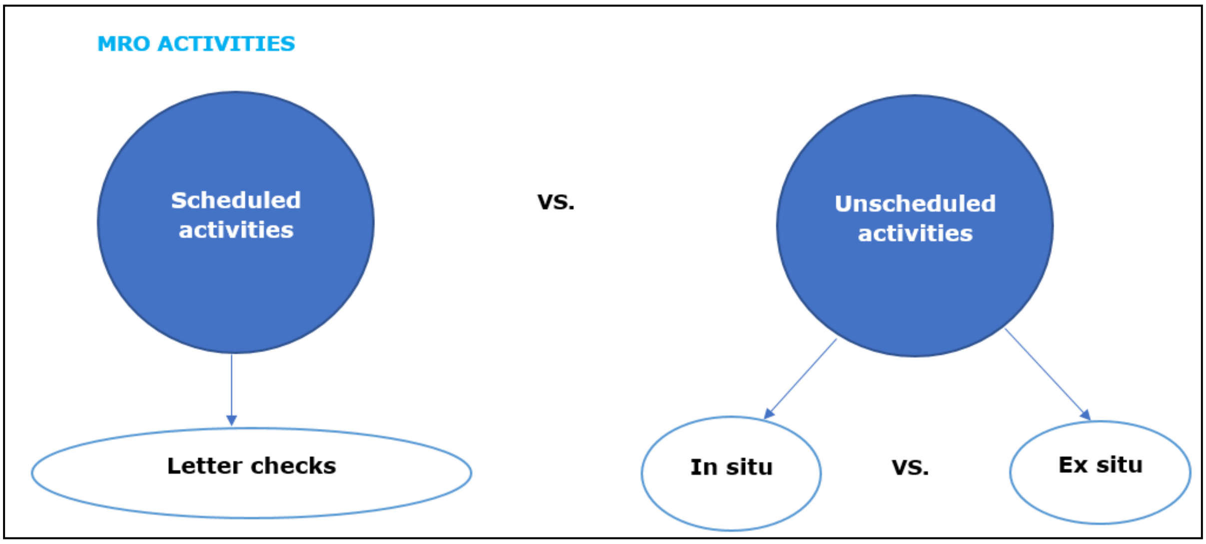


FIGURE 19: SCHEDFULED AND UNSCHEDULED MRO ACTIVITIES

Scheduled MRO activities

The Letter checks need to be executed on a regular basis. The following numbers provide typical intervals of these checks and required working efforts to perform the MRO activities:

A-check:

- every 400-600 flight hours or 200–300 cycles
- MRO activities take 50-70 man-hours

B-check:

- every 6-8 months
- MRO activities take 160-180 man-hours

C-check:

- every 20–24 months
- MRO activities take up to 6,000-man hours and the time needed is at least 1–2 weeks

D-check:

- every 6-10 years
- MRO activities take up to 50,000 man-hours and 2 months to complete

Like production activities, a partial shutdown of MRO activities would be necessary, relocating repair and maintenance of aerospace products requiring the use of NPE containing polysulfide sealants to non-EEA countries, again assuming that capacity would be available, at least in the short term. If capacity was not immediately available, then delays in the maintenance and repair of aerospace products could be expected. MROs could still perform maintenance and repair activities but would lose the ability to use these sealants. However, no maintenance of airframes and other components would be possible, causing all such maintenance to be moved outside of the EEA.

Clearly, with only component replacement and non-usage of NPE in polysulfide sealants for maintenance of components and aircraft and other aerospace products being possible in the EEA, the economic viability of EEA-based maintenance and repair operations would be significantly affected. The most likely scenario for MROs is that the maintenance facilities in the EEA would be closed (at least eventually) and relocated to non-EEA countries, where possible.

While this scenario might be theoretically feasible, with all the related negative impacts, it is completely unfeasible for some small aircrafts. Smaller aircrafts (e.g. jets, turboprops) used by airline operations (and freight companies) for regional and national flights are only certified to fly a limited distance from an airport, due to their limited fuel supply. Considering this scenario, these planes would need to ‘hop’ overland by a series of shorter flights to non-EEA countries (e.g. Turkey, Egypt) for scheduled maintenance and then fly back, already shortening the time between the next letter check due to additional flight cycles. In practice, this would be practically, financially and environmentally unfeasible for such aircrafts.

<u>Unscheduled MRO activities</u>

Unscheduled activities are either executed *in situ* for parts that cannot be disassembled (e.g. on the fuselage) or activities that do not necessarily require moving the aircraft to a hangar (e.g. can be performed at the gate and therefore allow minimised interruptions of the flight plan) or can be performed *ex situ.*

The following non-exhaustive incidents may result in unscheduled MRO activities:

- Damage from foreign objects like
    - Ramps
    - Bridges
    - Fuel trucks
    - Baggage loaders
    - Bird strike
    - Hail
- Hard landing

Unscheduled MRO activities (in situ)

In situ or 'on-wing' repairs are necessary where the part cannot or does not need to be disassembled. For time-essential repairs, as much work is completed 'on-wing' as possible to minimise turnaround time for the airline.

The non-use scenario would require grounding of the aircraft (as permission to flight is lost) and shipping it to a non-EEA country for repair and then flying it back to the EEA. As an assembled aircraft cannot just be loaded onto a truck and be transferred somewhere else, this is, if at all, a very costly scenario. Airlines would need to massively increase their fleet with mostly unused aircraft to continue their services at any time. This contrasts with current repair cases, which allow putting the aircraft into service again after a short time.

Unscheduled MRO activities (ex situ)

Ex situ or 'off-wing' repairs apply to the repair of parts that need to be taken off the aircraft. Parts that are typically removed for unscheduled repair include engine parts that require bond repairs and autoclave or oven cure, etc. Parts that are not typically removed for unscheduled repair but could conceivably be removed through a complex process of disassembly, if so needed, include landing gear, gearbox, fan case, air seals, bleed valve, etc.

For unexpected/unscheduled maintenance, the aircraft would have to be grounded (as permission to flight is lost) and physically shipped to a non-EEA country for repair and then flown back to the EEA, thereby extremely extending the AOG time, or flown with a special permit (permit to fly) issued by the state of registration for the aircraft to a non-EEA country for maintenance. This would require airlines to massively increase their fleet with mostly unused aircraft to continue their services at any time.

Further, although moving *ex situ* repairs or 'base maintenance activities' (letter checks) to a location outside the EEA is a comparatively easy step to make, as repair facilities exist in numerous other regions, this could never be justified in the case of 'line maintenance activities' or *in situ* repairs (i.e. day-to-day activities, including defect rectification). This is because being unable to undertake these activities where an aircraft lands would basically imply suspending the operation of the aircraft every time there is a defect, disassembling the aircraft, shipping it to non-EEA for repair, and flying it back to EEA again. This would decrease both performance/compliance/availability of the products, as well as significantly increase cost. Normal operation of revenue aircraft would be impossible under these circumstances, with consequent drastic implications for the entire commercial aviation industry, and in the end, on the European Economy and Society (11).

Manufacturers of components used in aerospace products would need to stop the production of parts treated with NPE-containing sealants in the EEA as a NUS. Companies that have the capability of relocating the production facilities to a non-EEA country might do so, at considerable expense. Highly specialised component manufacturer SMEs that do not have the financial capabilities will cease production and be forced from the market.

5.4.2.3. Conclusion

This NUS will have important implications for aerospace product life, quality, cost, schedule and security of supply. The loss of spare production capability may decrease the life of more complex sub-assemblies and/or durable articles, thus increasing the likelihood that the article will be disposed of. Some companies note that considering the negative impacts in the NUS, they might not be able to stay competitive. In these cases, the NUS will result in a temporary complete shutdown of all activities and result in the loss of production and supply. Losses in industrial capacity, jobs, market revenue and cancelations of contracts are a distinct possibility.

The reactions of the different actors in the aerospace industry supply chain as a result of not gaining authorisation point to considerable losses for the EEA and jeopardising European competitiveness and workplaces. Furthermore, environmental emissions will not be reduced. In fact, they are likely to increase, due to less stringent regulations in many non-EEA countries that may be the recipients of relocated production or maintenance and repair activities. This is true for all industry sectors.

As a conclusion, the NUS can be summarised as follows:

- Stop of production processes related to NPE containing sealants in the EEA.
- Where feasible, relocation of all affected processes to non-EEA countries to maintain production and/ or maintenance and repair activities.

This NUS will have the following consequences:

- Temporary loss of 'value added', not only from sealant activities, but also from further and final steps in the value chain (parts manufacturing and final assembly).
- Absence of one single part can severely disrupt, or even prevent, the delivery of many aerospace products (including aircraft). Hundreds of suppliers deliver parts from around the world which are ultimately connected in assembly lines. For example, the fuselage consists of several single sections (e.g. forward and centre fuselage, centre wing box, tail cone, etc.) which need to be joined. Assembling is a mechanical process and tolerances of the parts need to be corrected by machining. During this process, e.g. docking of wings or engines, the surface can suffer damage. Therefore, loss of even a limited number of parts treated with NPE containing sealants will have substantial effects. Using these sealants is mandatory and is essential to the safety of the aircraft. When these processes are no longer available, the entire process must stop or be relocated. From an operational perspective, these sealants are a small element of the overall process flow in most mixed facilities, with the combination of machining, finishing, assembling, testing and inspection dominating. However, as noted above, they cannot be separated from one another. The impacted operations, and therefore socio-economic impacts to industry in the non-use scenario, go far beyond the specific processes directly using these sealants and have substantial implications for processes that are indirectly affected to be performed one after the other. Hence, individual parts of this process cannot be moved – only the whole process.

Moreover, this situation is the same even if – hypothetically again – an NPE-free alternative was successfully qualified for one or two components. This would not change the overall impacts, since, as stated at many points in this report, the whole supply chain must be available to produce an aircraft – an aircraft cannot operate with even one missing component. If only one part requiring these sealants is not available/usable, production or repair/maintenance of the affected component would simply stop, with knock-on consequences down the supply chain, ultimately impacting operational activities. The following illustrations demonstrate the interdependency of every single part used, and the effect of only one part missing, for the overall assembly process of the aircraft. It should be noted that this represents only a highly simplified supply chain of parts needed for the final assembly of an aircraft. If only one part cannot be produced according to type certification, the manufacture of the entire aircraft is jeopardised (see FIGURE 20).

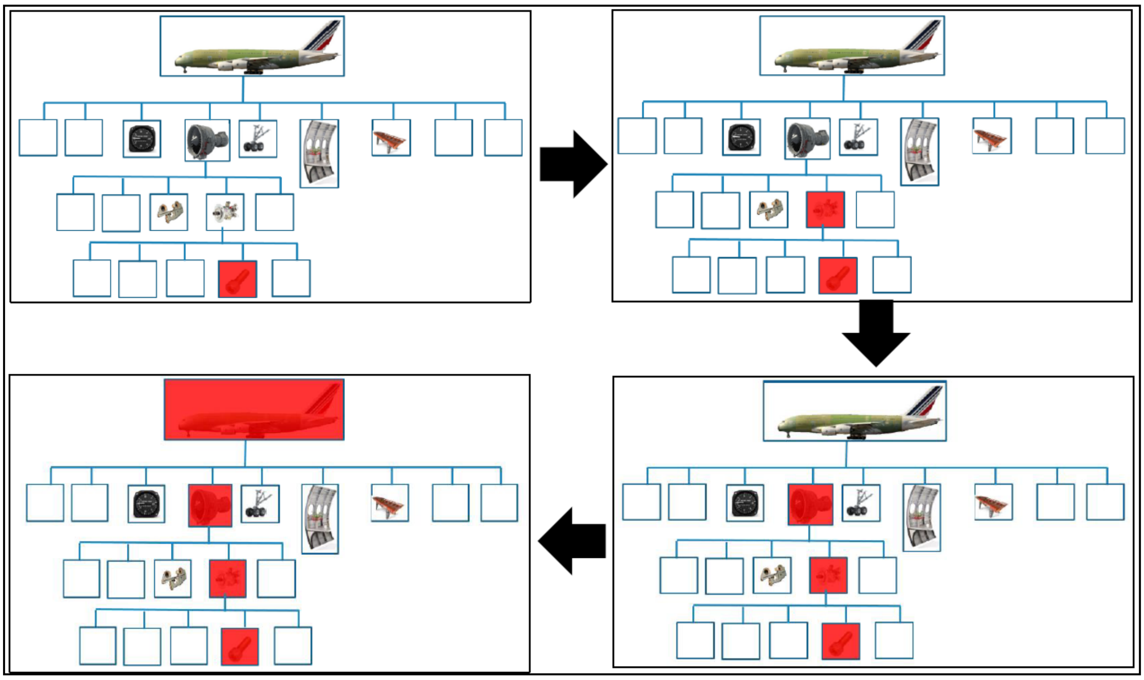


FIGURE 20: DEMONSTRATION OF INDIVIDUAL COMPONENT INTERDEPENDENCY

In conclusion, it is not possible to relocate single NPE based sealant activities. These processes mostly are an integral part in the production chain and cannot be separated from previous or following process steps. As a further illustration, consider sealing during the assembly process of the fuselage. In this case, it is simply impossible to ship the entire fuselage to a non-EEA country, ship it back into the EEA for continued assembly, and so on. Therefore, delivery of the final product in the aerospace value chain – Aircraft and other aerospace products - is not possible anymore!

There are several other cases to consider:

- ***Small Parts***: Currently, some small parts may be able to be removed and then repaired on-site or replaced with a new part from stock (from inside or outside Europe). In the case of a denied authorisation, no on-site repair would be possible. The part would either must be sent outside of Europe for repair, or a new part from stock would ultimately have to originate from outside Europe. However, since NPE-containing sealants are needed in many final assembly processes, even if those parts could be repaired in non-EEA, they could not be re-assembled to the aircraft, rendering such maintenance in the EEA unfeasible.

- ***Assemblies***: Sometimes a small part can be removed from a larger assembly, or from the airframe itself, but cannot be treated as above for small parts because a sealant-based treatment is required to be applied at the assembly level (e.g. to bridge across joints of different parts in the assembly to prevent corrosion). Outsourcing of this process would require the entire assembly/airframe to be repaired outside the EEA.
- ***Large Parts***: Some large parts, like wing or fuselage skins, are rarely or never removed, so processing *in situ* is the primary method for repairs. Without moving the entire aircraft outside the EEA, the repair is not possible.

In the base case, the repairs that require *in situ* use of NPE-containing sealants can be planned to be performed outside Europe. This may entail the added cost of longer, non-revenue flights to the non-EEA repair centre. In the worst case, unplanned damage needs to be repaired before the aircraft can be moved. If this is in Europe, this creates an unworkable situation. From these examples, it is therefore crystal clear that relocation of single activities is in most cases not an option. Consequently, in the non-use scenarios of the companies affected by authorisation, more and more parts of the supply chain, and alongside jobs, know-how and R&D investments, will move out of Europe. For the majority of the parts that require NPE containing sealants, the substance is applied at key stages in the production and assembly process, and timing of the application is essential. Related processing steps are typically done at a single location.

Consequently, a significant portion (if not 100%) of the total turnover of €220.2 billion (2016) delivered by the European aerospace industry will be impacted (7).

For the avoidance of doubt, this does not account for the impact on airlines and other users of aerospace products that do not receive them and cannot maintain operations because of missing spare-parts and maintenance operations that rely on NPE containing sealants.

- Furthermore, industry expects adverse impacts on contract commitments, damage to business relationships, loss of future contracts, impacts on future competitiveness, etc.
- Because exact monetary values connected to the impacts stated above are very hard to quantify, the aim is to assess the minimum socio-economic impacts connected to a non-authorisation.

However, it must be clear that the impacts assessed in ***Section 6*** represent a massive underestimation of the real impacts to be expected. The overall scale of the known impacts to the aerospace industry alone are expected to be of the order of several billion Euros. The scale of the impact to industries that rely on the smooth operation of the aerospace industry (e.g. air travel, cargo, commerce, tourism, telecommunication, navigation, weather forecasts, etc.) will be many-fold higher. Further non-quantifiable impacts on national defence, military, humanitarian relief missions, safety of armed forces and rescue operations must be considered.

For a case by case analysis of impacts on the industries mentioned above, please refer to the case studies provided in ***Annex A***.

Summary of Conclusion

- The substitution of NPE in polysulfide sealants is currently in the R&D phase of development with the formulator. Several potential alternatives have been identified and are still being investigated and tested for suitability prior to providing reformulated sealants without NPE to the OEM for qualification testing. Under current best estimates, it is expected that the reformulated sealants will be able to be successfully qualified and implemented by the end of 2024 (see section 5.1.2 in the AoA)
- The use of a substitute that does not meet all the performance or quality criteria is not an option since, amongst other reasons, aerospace has strict regulatory obligations which require it to adhere to safety and quality standards, procedures and requirements.
- Even when new substances or processes would be introduced in the market and claimed as 'alternatives' to NPE-containing sealants, the extensive testing, qualification, certification and industrialisation processes of such candidate alternatives are very time consuming (see AoA).
- The conversion of whole supply chains to one or more alternatives which might become available in the future is highly complex and needs time.

6. IMPACTS OF GRANTING AUTHORISATION

The impacts of granting an authorisation in this SEA are assessed as environmental impacts and socio-economic impacts of not granting an authorisation for continued use of the Annex XIV substance by comparing the "applied for use" and the "non-use" scenarios. The socio-economic impacts are evaluated based on NUS 1 and NUS 2, relating to a lower and upper bound of impacts, respectively.

6.1. Environmental Impacts

Given the risk management measures and operator controls in place, there is no potential for releases to the environment of the NPE containing hardener component of the two-part sealant during formulation or when mixing within the two-compartment kit, in small scale batches by hand or bulk mixing by machine. Accordingly, there is no risk to the environment from the uses targeted in this AfA. As such, a more detailed quantitative assessment of exposure to the environment is not meaningful. No qualitative or quantitative assessment of the environmental impacts of the applied for use scenario are performed in the related sections of this SEA. Nevertheless, the uncertainty analysis in ***Section 6.6*** of this report examines a scenario that considers absolute worst-case emissions throughout the life-cycle of an aerospace product (see CSR for details).

6.2. NUS 1 – Exclusive use of PMF sealants

This NUS would yield the following direct costs/consequences for the formulators and/or aerospace companies, some of which are detailed and quantified in the following sections:

- Relocation costs
    - Cost of transferring existing equipment and installation to non-EEA
    - Extension of production capacity in non-EEA
    - Adaptation of production processes and logistics to PMF sealants

- Social impacts
    - Costs of unemployment due to relocation of formulator activities related to production of PMF sealants for the European market.

- Costs associated with Process Planning and Adaptation
    - Costs associated with production interruption
    - Technical and procedural adaptations
    - Requalification costs
    - Reduction in output efficiency
    - Costs of unmet contractual obligations

- Costs associated with Installation of additional Equipment
    - Cost of freezing equipment
    - Cost of cold storage capacity
    - Cost of back-up generators
    - Cost of de-frost equipment

- Additional operating costs
    - Electricity costs associated with increased energy consumption
    - Increased storage costs
    - Increased costs for quality control
    - Increased scrapping costs for products at the end of shelf life
    - Increased sealant costs (PMF Cartridges vs. Bulk Sealants)

- Costs associated with Logistics

- Environmental Costs
    - Costs associated with increased CO_2 emissions from transportation
    - Costs associated with increased packaging-related waste generation
    - Costs associated with scrapping of PMF sealants due to their short shelf life

- Impacts on MROs, Airlines and Military Operations
    - Process delays and additional AOG times

6.2.1. Impact Assessment for Use 1 - Formulation

The main socio-economic impacts entailed by the formulator and assessed in this SEA due to relocation of the affected production and adaptation to exclusively PMF production include:

- Costs associated with relocation
- Foregone profits due to supply interruption
- Social impacts

6.2.1.1. Economic impacts

The following impact assessment considers a review period of 4 years, a discount rate of 4% and the base year 2020, assuming that the impacts will be incurred starting from January 2021, in case an authorization is not granted.

6.2.1.1.1. Relocation Costs

To supply only PMF sealants for all relevant DU applications in the EEA, the formulators will have to adapt the production process based on OEM specific updated material and process specifications and relocate it outside the EEA.

TABLE 14 summarises the costs that would be incurred by the formulator when relocating the sealant mixing activities outside the EEA and adapting the processes to PMF sealants only.

TABLE 14: INVESTMENT COSTS FOR RELOCATION

Investment costs for relocation of production	
Cost item	EUR million
Cost of transferring existing equipment and installation to non-EEA in 2021	1-9 ([redacted])
Extension of production capacity in non-EEA distributed equally across 2021-2022	5-15 ([redacted])
TOTAL (NPV in 2020)	**6-24 ([redacted])**

Relocation to a non-EEA country will also increase the lead-time and shipping costs, given that the supply would require longer time to be transported, when compared with the baseline scenario.

6.2.1.1.2. Costs associated with Production Interruption

For the period of supply interruption due to relocation and adaptation of processes, in case of a non-granted authorisation, impacts in the form of foregone profits with a lower bound of one year (i.e., 2021) and an upper bound of two years (i.e., 2021-2022) must be expected.

The applicant cannot disclose these profits for confidentiality reasons.

6.2.1.2. Social impacts

It is estimated that 40-100 ([redacted]) employees will have to be dismissed in the beginning of 2021, if no authorisation title is granted.

Following the methodology presented in a report commissioned by ECHA (14), the social costs related to expected job losses in the most realistic NUS are valued under consideration of the following components:

- The value of lost output/wages during the period of unemployment
- The cost of acquiring a new job
- Recruitment costs
- The "scarring costs" (i.e. the impact of being made unemployed on future earnings and employment possibilities)
- The value of leisure time during the period of unemployment

The latter component is defined as a negative cost (i.e. a benefit) of unemployment. As such, it is subtracted from the total cost resulting from the first four components.

The figures from the aforementioned paper have been updated with most recent data reported in 2018, using information on wages presented by Rogers and Philippe in 2018 (15) and using most recent data on the duration of unemployment in 2017, as reported by Eurostat (16). Moreover, the figures for average wages were projected to 2019 by considering data presented by Eurostat on the labour cost index (17).

TABLE 15: SOCIAL IMPACTS

Monetised Social Impact of Workforce Dismissals (NPV 2020)		
	Lower bound	Upper bound
Number of dismissals	40	100
Cost of 1 lost job (EU28 average)	EUR 97 692	EUR 97 692
Total cost of all lost jobs	**EUR 3 907 680**	**EUR 9 769 200**

As described in TABLE 15, social costs of unemployment can be valued at approximately **EUR 4 - 10 million ([redacted])**. This value is based on the use of the latest available average gross salary in EU-28 as an input to the standard calculation of social costs.

6.2.1.3. Total Socio-Economic Impacts at the Formulator

The total socio-economic impacts incurred at the formulator over the entire review period is summed in TABLE 16.

TABLE 16: TOTAL COSTS FOR THE FORMULATOR

Cost item	**EUR million (approx.)**
Investment costs associated with relocation	6 – 24 ([redacted])
Foregone profits	Cannot be disclosed
Social costs	4 – 10 ([redacted])
TOTAL	**10 – 34 ([redacted])**

6.2.2. Impact Assessment for Use 2 - Downstream Use

The following impact assessment focuses on impacts on Airbus only. An exception exists for the assessment of logistics costs and external environmental costs, where the costs have been calculated based on the total tonnage of NPE containing sealant used in EEA.

The impact assessment rests upon some general assumptions:

- Transport costs are estimated to be EUR 2 050 for 1 000 kg of deep-frozen goods transported via air freight from a non-EEA site to an exemplary site of downstream use in France.
- Investment and operating costs for freezing equipment are estimated based on a cold storage freezer with a capacity of 200 liters, power input of 0.685 kW and a temperature -85°C.

The following sections aim to quantify the impacts related to process planning and adaptation (***Section 0***) and the costs associated with installation and operation of cold storage freezers at all Airbus sites (***Section 6.2.2.1.2***).

Impacts are monetized based on a review period of 4 years, discounted to the base year in 2020 at a rate of 4%, assuming that the impacts will be incurred starting from January 2021, in case an authorization is not granted. Given the nature of these impacts, different impacts will occur at a different time in the future and have been discounted accordingly. A representation of the different timings of impacts for Airbus can been seen in FIGURE 21.

It is important to highlight that the following impact assessment focuses on impact on Airbus only. That means that impacts upstream or downstream of the supply chain have not been quantified.

Additionally, only a fraction of real impacts at Airbus was monetized in the following. Examples for impacts that have not been quantified include:

- Reduced output at Airbus due to inability to use fast-cure sealant products
- Costs of unmet contractual obligations
- Impacts on MRO operations and related impacts on air transport, air travel and Military operations.
- Impacts on Airbus suppliers

These impacts have not been quantified due to the lack of information and the related uncertainties. However, as it is shown in the following sections, the fraction of impacts that was quantified for Airbus only gives an impression of the order of magnitude of impacts in this scenario.

For NUS 1, FIGURE 21 visualises the real impacts that would occur at Airbus (Panel A) versus the impacts that have been monetised in this impact assessment (Panel B). Panel A exemplifies the real impacts that would most likely occur over different timelines specific to each impact, across the entire review period. The blue bars ( ) are intended to show the different timelines for which the impacts have been discounted.

The overall aim of this visual is to represent the underestimation in monetisation of impacts compared with the real impacts, which were not quantifiable due to lack of information based on current practices for NUS 1. Irrespectively, a small part of the quantifiable impacts is overestimated. For example, in the case of investment or asset acquisition costs, the figure shows an overestimation of costs when monetised in this SEA; however, when depreciated across three years of use ( ), the present value of these costs would be lower, as compared to the present value of acquiring assets in 2022 calculated without depreciation ( ). This, however, has a negligible effect on the total estimated impact when compared with a much higher magnitude of financial losses (as will be seen in the subsequent sections). Thus, when comparing the order of magnitude of impacts in this scenario between Panel A and B, it is quite evident that the real impacts (Panel A) are much higher than the impacts quantified in this SEA (Panel B). The basis of monetisation of the impacts in Panel B is elaborated further in sections below.

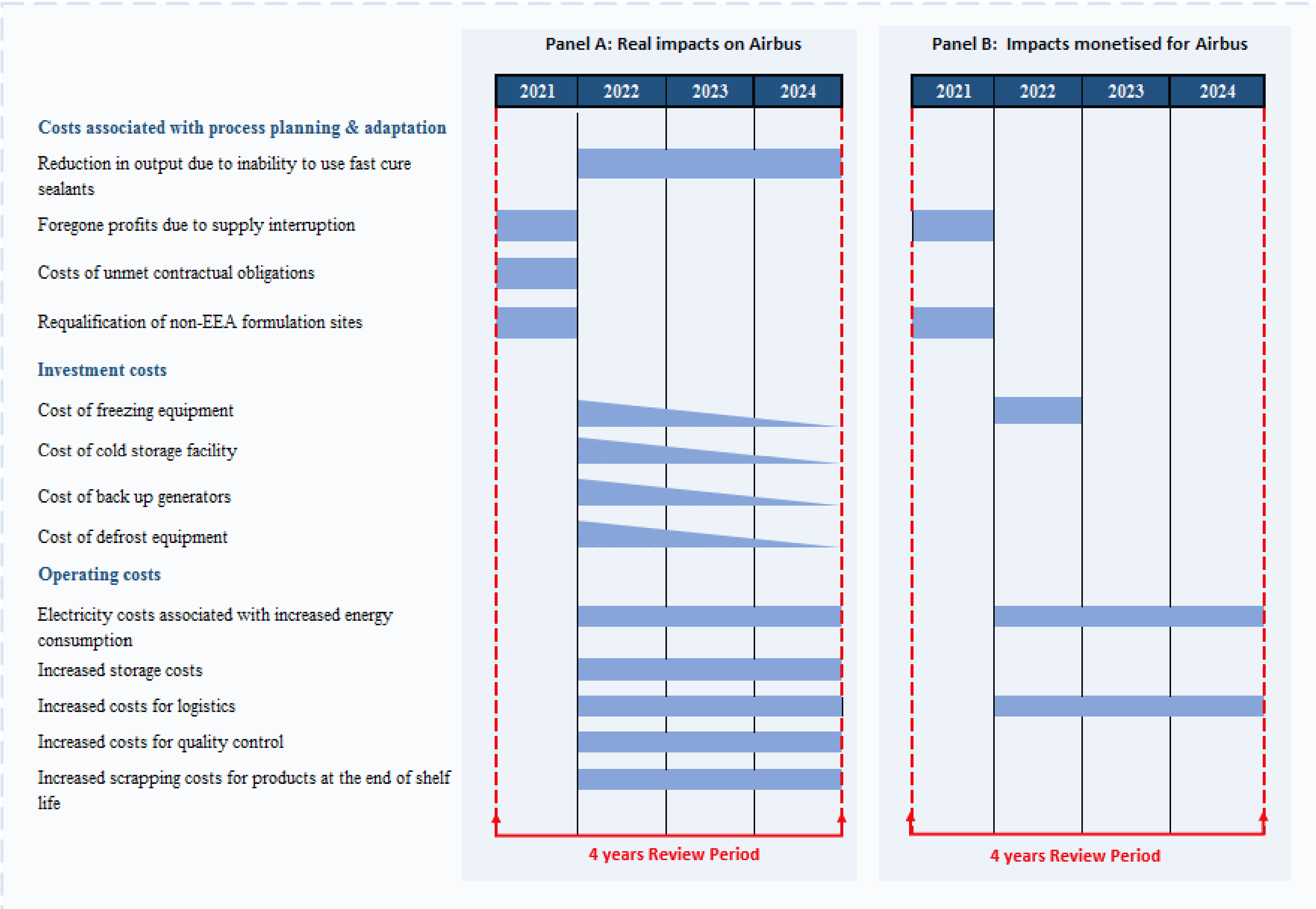


FIGURE 21: REAL IMPACTS VS. MONETISED IMPACTS ON AIRBUS

6.2.2.1. Economic Impacts

The impact assessment considers a review period of 4 years, a discount rate of 4% and the base year 2020, assuming that the impacts will be incurred starting from January 2021, in case an authorization is not granted.

6.2.2.1.1 Costs associated with Process Planning and Adaptation

6.2.2.1.1.1. Requalification Costs

To use only PMF sealants, all DU sites will have to update their material and process specifications. This implies that these sites cannot use PMF sealants until all the process specifications have been updated to adapt the use of PMF sealants for all former sealant applications. Simultaneously, the non-EEA formulation site will need to be requalified by Airbus.

TABLE 17 estimates the cost of requalification of non-EEA formulation sites by the OEMs. Assuming that the costs of requalification are equally distributed during the period of process planning and adaptation, it is discounted as follows:

TABLE 17: COSTS ASSOCIATED WITH REQUALIFICATION OF NON-EEA FORMULATION SITES INCURRED BY THE OEMS

Cost Item	EUR million
Requalification cost in 2021	1-9 ([redacted])
NPV in 2020	**1-9 ([redacted])**

6.2.2.1.1.2. Production interruption

As a result of process adaptations, all Airbus activities will incur a production interruption of 1 to 2 years, leading to profit losses and additional costs or penalties related to delayed or no product delivery during this time.

The following steps are necessary before production could commence:

- Re-qualification of all Chemetall sealants after technical qualification: 18 months
- Qualification of the non-EEA formulator site (industrial qualification + validation): 3 to 6 months

In addition to that, Airbus internal manufacturing processes would need to be adapted, e.g.:

- New line balancing: e.g. if current processes are not feasible with longer cure sealants, a completely new assembly concept/line would be needed. This could involve purchasing of new equipment and reworking the assembly layout with the new equipment
- Validation of new equipment

One example for an Airbus internal process adaptation that would be needed in case only PMF sealants could be used is the following.

[redacted]

[redacted]

Adaptations of such processes potentially requires significant resources, that have not been accounted for in this SEA.

For the period of supply interruption, in case of a non-granted authorisation, impacts are only estimated in the form of foregone profits with a lower bound of one year (i.e., 2021) and an upper bound of two years (i.e., 2021-2022). This has been estimated based on the

EBIT figures segmented by business units for the year ended 31 December 2018, obtained from the Airbus SE financial statements 2018 (18).

TABLE 18: FOREGONE PROFITS FOR AIRBUS DUE TO PROCESS PLANNING AND ADAPTATION

Foregone profits: Lower bound (in EUR million)	
2021	5 337
NPV in 2020	**5 132**
Foregone profits: Upper bound (in EUR million)	
2021	5 337
2022	5 337
NPV in 2020	**10 066**

For the sake of the impact assessment from here on, a conservative approach has been taken assuming a supply interruption of only one year and resuming of all former processes with PMF sealants thereafter from 2022-2024, as shown in FIGURE 21. However, for the remaining years of the review period (i.e., 2022-2024) after the processes have been adapted and implemented with the use of PMF sealants, a reduction in output efficiency is anticipated due to the inability to use fast cure sealants, as fast cure sealants cannot be frozen.

6.2.2.1.1.3. Reduction in output efficiency

The inability to use fast cure sealants will reduce the output efficiency (as shown in FIGURE 22), i.e. increase the lead time of the processes that are achieved at specific efficiency rates and cannot be ensured anymore.

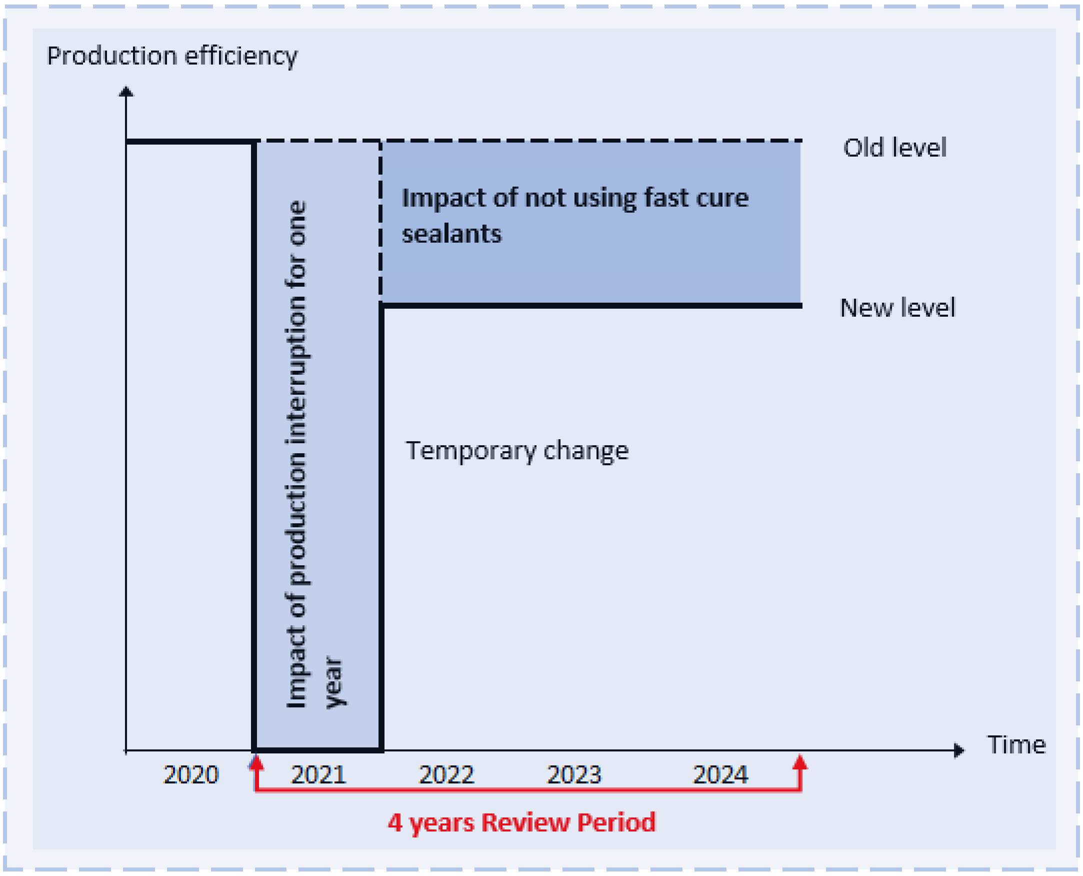


FIGURE 22: IMPACT OF PROCESS ADAPTATION ON LEADTIME

[redacted]
However, this impact could not be monetised at the time of finalisation of this AfA.

Further, material and process specifications would need to be updated but the costs of such cannot be estimated at present.

6.2.2.1.2. Costs associated with Installation of Additional Equipment

As mentioned, in case an authorization is not granted, the base/hardener mixing will need to be performed outside the EEA. Consequently, PMF sealants will be imported and used at EEA sites of aerospace companies (NPE concentration <0.1%).

The costs incurred by the DUs in this scenario are highly dependent on the existing infrastructure of every site in the EEA. It is anticipated that all sites will have to procure equipment, such as cold storage freezers. The number of cold storage freezers has been provided by Airbus, based on freezer capacity and the amount of sealant consumed at each industrial site in the EEA, segmented by business units. Assuming that the equipment is bought in 2022 after the process planning and adaptation is finished, the investment costs are discounted as follows.

TABLE 19: INVESTMENT COSTS IN EQUIPMENT AT AIRBUS

Costs associated with the installation of additional equipment	
Cost of acquiring a low temperature freezer in 2022 (in EUR million)	0.01 - 0.09 ([redacted])
Number of low temperature freezers required for all operations	300 - 400 ([redacted])
Cost of acquiring all low temperature freezers in 2022 (in EUR million)	1 - 9 ([redacted])
NPV in 2020 (in EUR million)	**1 - 9 ([redacted])**

Additional investment in cold storage freezers, de-frost equipment (where applicable), back-up generators and temperature recorders during transportation have not been considered due to lack of information.

6.2.2.1.3. Additional Energy Costs

This section estimates the cost of running all cold storage freezers to store PMF sealants that will be imported to the EEA to preserve quality standards. The electricity costs proportional to the energy consumption have been estimated, based on the Eurostat EU non-household electricity price of EUR 0.20 per kWh (19). Assuming that these costs only occur from 2022-2024, after process planning and adaptation of PMF sealants for all applications, the costs are discounted as follows.

TABLE 20: ADDITIONAL OPERATING COSTS

Costs associated with electricity consumption	
Power input of one low temperature freezer [kW]	0.1 - 0.9 ([redacted])
Electricity consumption per year [kWh]	5 500 - 6 500 ([redacted])
Number of freezers needed	300-400 ([redacted])
Electricity cost in 2022 (in EUR million)	0.1 - 0.9 ([redacted])
Electricity cost in 2023 (in EUR million)	0.1 - 0.9 ([redacted])
Electricity cost in 2024 (in EUR million)	0.1 - 0.9 ([redacted])
NPV in 2020 (in EUR million)	**0.3-3 ([redacted])**

In addition to the costs associated with electricity consumption, increased costs associated with maintenance of the storage facility and quality control are also anticipated but not included in the assessment due to lack of estimates around such costs. Another important cost element anticipated alongside the use of PMF sealants from 2022-2024, is the increased cost associated with scrapping of sealants due to shelf-life limitations. Assuming that a safe quantity of PMF sealants is ordered as compared to actual working units required per year, scrapping of unused PMF sealant due to expiry of use is foreseeable but difficult to quantify based on current practices.

6.2.2.1.4. Costs associated with Logistics

The following exemplary impact monetisation is based on the difference in transportation cost of the baseline scenario and NUS 1. The logistics cost for the baseline scenario is based on the transportation of 1 000 kg of PMF sealants from Germany to a DU site in France and has been calculated based on an average cost of 0.89 EUR/km for 20 tonnes of cargo transportation in Europe (20).

TABLE 21: A. LOGISTICS COSTS FOR 1 TONNE OF GOODS

Costs associated with logistics [EUR]	
Average road transport costs for 20 tonnes of goods in EU	0.89 EUR/km
Average road transport costs for 1 tonne of goods in EU	0.044 EUR/km
Distance between Langelsheim, Germany and Toulouse, France (in km)	1 519.2
Average road transport costs for 1 tonne of goods from Langelsheim, Germany and Toulouse, France	67.60
TOTAL	**68**

The logistics cost for NUS 1 is based on the transportation of 1 tonne of PMF sealants as deep-frozen goods from Africa to a DU site in France and has been calculated based on an air freight calculator deployed by DHL (21).

TABLE 22: B. LOGISTICS COSTS FOR 1 TONNE OF DEEP-FROZEN GOODS

Costs associated with logistics [EUR]	
Air transport costs for 1 tonne of deep-frozen goods	2 000
Export customs clearance	20
Import customs clearance	30
TOTAL	**2 050**

Note: The estimation of the costs associated with logistics is calculated based on the total tonnage of sealants containing NPE in the EU. Assuming that the import of PMF sealants occurs after the process adaptation by Airbus from 2022-2024, the costs are discounted to 2020 as follows:

TABLE 23: TOTAL COST OF LOGISTICS BASED ON TOTAL TONNAGE FOR THE DOWNSTREAM USERS

Costs associated with logistics	
Air transport cost for 1 tonne of deep-frozen goods per annum (in EUR)	2 050
Road transport cost for 1 tonne of deep-frozen goods per annum (in EUR)	68
Impact on Air transport costs for 1 tonne of deep-frozen goods (in EUR)	1 982

Cost item	Lower bound	Upper bound
Volume of PMF sealant required per annum (in tonnes)	250	1 750
Impact on Air transport costs for total volume of PMF sealants in 2022 (in EUR million)	0.49	3.46
Impact on Air transport costs for total volume of PMF sealants in 2023 (in EUR million)	0.49	3.46
Impact on Air transport costs for total volume of PMF sealants in 2024 (in EUR million)	0.49	3.46
NPV in 2020 (in EUR million)	**1.32**	**9.26**

Thus, the total cost of logistics based on the total tonnage of 250 – 1 750 ([redacted]) tonnes for the downstream users will be EUR 1.32 – 9.26 ([redacted]) million.

6.2.2.2. Total Economic Impacts on Airbus

The total economic impact incurred at Airbus over the entire review period is presented in TABLE 24.

TABLE 24: TOTAL COSTS

Cost item	EUR million
Process planning and adaptation	5 133 – 10 075 ([redacted])
Investment costs	1-9 ([redacted])
Operating costs (energy + logistics costs)	2 - 12 ([redacted])
TOTAL	**5 136 – 10 096 ([redacted])**

Note: The economic impacts presented above represent a clear underestimation of the real impacts that would occur in this scenario. NPE-containing sealants are important for production and operational readiness of aircraft. A (temporary) discontinuation of the NPE hardener production would not only result in a (temporary) stop of production of aircraft, but also a stop of the maintenance activities for existing aircraft in the EEA.

6.2.2.3. External Environmental Costs

The following cost estimation is based on transportation of 1 000 kg of PMF sealants from an exemplary site of formulation in Africa to an exemplary DU site in France. The values of CO_2 emission during this transportation is estimated via DHL's Carbon calculator in $kgCO_2e$, i.e., the amount of CO_2 emitted (in kg) (22). The monetised value of these emissions is calculated on the basis of the price for a European Emission Allowance (20 EUR/tCO_2) in 2019 (23). These costs are not representative of the costs borne by either of the parties but the society as a whole (presuming the EU Emission Trading Scheme is working) and can, however, be seen as a result of pursuing this non-use scenario.

TABLE 25: EXTERNAL COSTS RELATED TO ENVIRONMENTAL EMISSIONS

Costs associated with the environmental emissions during logistics	
CO_2 emissions during transportation of 1 000 kg PMF sealant (in $kgCO_2e$) (26)	1 707
Monetised value of 1 000 $kgCO_2$ (in EUR)	20

Total external environmental cost per 1 000 kg of PMF sealant (in EUR)	**34**

The total external costs related to environmental emissions have been calculated in TABLE 26 using the base values in TABLE 25 and discounted as follows.

TABLE 26: TOTAL EXTERNAL COSTS RELATED TO ENVIRONMENTAL EMISSIONS

Costs associated with the environmental emissions during logistics		
Total external environmental cost per tonne of PMF sealant (in EUR)	34	
Cost item	Lower bound	Upper bound
Total tonnage of PMF sealant (in tonnes)	250	1 750
Total external environmental cost for the total tonnage of imported PMF sealant in 2022 (in EUR million)	0.01	0.06
Total external environmental cost for the total tonnage of imported PMF sealant in 2023 (in EUR million)	0.01	0.06
Total external environmental cost for the total tonnage of imported PMF sealant in 2024 (in EUR million)	0.01	0.06
NPV in 2020	**0.02**	**0.16**

Thus, total external costs related to environmental emissions for 250 – 1 750 ([redacted]) tonnes of sealant are EUR 0.02 – 0.16 ([redacted]) million.

Additional environmental costs would include high volumes of plastic packaging waste generated due to high quantity of cartridges being produced and transported. Further costs associated with scrapped sealants will also be incurred.

Again, it is important to highlight that only the environmental costs related to CO_2 emissions from transport have been considered here. Costs arising from CO_2 emissions stemming from electricity production needed to run the freezing equipment have not been considered here.

6.2.2.4. Impacts on MROs (civil and military), Airlines Operations

The application of sealants for MROs is similar to its applications in the commercial production of aircraft. Sealants are especially used in structural repairs for sealing and delaying corrosion by MROs and airlines. Some MROs activities need to be carried out overnight.

For MRO activities, such a scenario would be difficult to implement, especially for the line maintenance activities or unscheduled repairs, where the amount of sealant required cannot be forecasted. Field repairs (e.g. on-wing or fuselage repairs) usually require the use of fast cure sealants with a short working life. An on-site repair requires the immediate use of these sealants wherever an aircraft lands, in case of a defect. While non-MRO operations could theoretically cope with longer cure times of PMF sealants (provided process adaptations are successful), such a scenario is deemed infeasible, especially for unscheduled MRO operations where a short cure time for sealants is essential to avoid prolonged AOG times and related costs and impacts.

Please consider the case studies presented in ***Annex A*** for further details.

It is commonly accepted in the commercial aircraft industry that a majority of sealants used on the aircraft are in fuselage, electrical and electronic common installation, wings, doors and air conditioning and pressurization systems. Loss in the functionality and applicability of these sealants at any MRO site would result in delays or flight cancellations and the aircraft would have to be grounded. The PMF sealants have a short shelf life of 4-6 weeks. Storing large amounts of it, without knowing its forecasted need in the future, would only lead to an equivalent amount of NPE-containing sealant waste at these sites.

The exact dimensions of impacts on MRO operations remain difficult to estimate but can be reasonably expected to be in the same order of magnitude as the quantified impacts presented above, especially if cascading impacts on the "end-use applications" of aircraft, such as air transport, air travel, armed forces, are included in the assessment.

6.2.3. Total Socio-Economic Impacts in NUS 1

The total economic impact of this non-use scenario is calculated as follows.

TABLE 27. TOTAL SOCIO-ECONOMIC COST OF THE NUS

Cost Item	Impact [EUR million]
Total costs incurred by Formulators	**6 – 24 ([redacted])**
Relocation Costs	6 – 24 ([redacted])
Costs associated with production interruption	Cannot be disclosed
Total costs incurred by DUs	**5 135 – 10 096 ([redacted])**
Requalification Costs	1-9 ([redacted])
Costs associated with Production Interruption	5 132 – 10 066
Costs Associated with Installation of additional Equipment	1-9 ([redacted])
Additional Energy Costs	0.3-3 ([redacted])
Costs associated with Logistics	1 – 9 ([redacted])
External Environmental Costs	**0.02 – 0.2 ([redacted])**
Social Impacts	**4 – 10 ([redacted])**
Total costs across the review period (NPV 2020)	**5 145-10 130 ([redacted])**

Thus, the total economic impact of this non-use scenario is far higher than **EUR 5 145-10 130 ([redacted]) million**. This figure represents the **lower limit** of the monetised **economic impact of a not granting an authorisation for the continued use of the substance.**

6.3. NUS 2 – Shutdown/Relocation/Subcontracting to non-EEA Country

The following impact assessment focuses on impacts on Airbus only.

6.3.1. Impact Assessment for Use 1 – Formulation

If the formulator stops all production activities until an alternative is industrialised, the following minimum impacts will be incurred.

6.3.1.1. Economic impacts

For the period of supply interruption due to shut down, in case of a non-granted authorisation, impacts in the form of foregone profits, with a lower bound of one year (i.e., 2021) and an upper bound of 4 years, must be expected.

The applicant cannot disclose these figures for confidentiality reasons.

6.3.1.2. Social impacts

It is estimated that 40 – 100 ([redacted]) employees will have to be temporarily dismissed in the beginning of 2021, if no authorisation title is granted.

Following the methodology presented in a report commissioned by ECHA (14), the social costs related to expected job losses in the most realistic NUS are valued under consideration of the following components:

- The value of lost output/wages during the period of unemployment
- The cost of acquiring a new job
- Recruitment costs
- The "scarring costs" (i.e. the impact of being made unemployed on future earnings and employment possibilities)
- The value of leisure time during the period of unemployment

The latter component is defined as a negative cost (i.e. a benefit) of unemployment. As such, it is subtracted from the total cost resulting from the first four components.

The figures from the aforementioned paper have been updated with most recent data reported in 2018, using information on wages presented by Rogers and Philippe in 2018 (15) and using most recent data on the duration of unemployment in 2017, as reported by Eurostat (16). Moreover, the figures for average wages were projected to 2019 by considering data presented by Eurostat on the labour cost index (17).

TABLE 28: SOCIAL IMPACTS

Monetised Social Impact of Workforce Dismissals (NPV 2020)		
	Lower bound	Upper bound
Number of dismissals	40	100
Cost of 1 lost job (EU28 average)	EUR 97 692	EUR 97 692
Total cost of all lost jobs	**EUR 3 907 680**	**EUR 9 769 200**

As described in Table 28, social costs of unemployment can be valued at approximately **EUR 4 – 10 ([redacted]) million**. This value is based on the use of the latest available average gross salary in EU-28 as an input to the standard calculation of social costs.

6.3.2. Impact assessment for Use 2 – Downstream Use

The following impact assessment focuses on impacts on Airbus only.

For the evaluation of this scenario, it is assumed that polysulfide sealants are not available until an alternative has been fully industrialised by Q2 2024. This means that no aerospace equipment can be produced in this timeframe.

6.3.2.1. Economic impacts

For this period of supply interruption, in case of a non-granted authorisation, impacts are estimated in the form of foregone profits, with a lower bound of one year (i.e., 2021) and an upper bound of 4 years. This has been estimated based on the EBIT figures, segmented by business units for the year ended 31 December 2018, obtained from the Airbus SE financial statements 2018 (18).

TABLE 29: FOREGONE PROFITS FOR AIRBUS DUE TO PROCESS PLANNING AND ADAPTATION

Foregone profits: Lower bound	
2021	5 337
NPV in 2020	**5 132**
Foregone profits: Upper bound	
Cost item	EUR million
2021	5 337
2022	5 337
2023	5 337
2024	5 337
NPV in 2020	**19 373**

6.3.2.2. Social impacts

It is estimated that a minimum of 5 500 - 7 500 ([redacted]) employees will have to be temporarily dismissed in the beginning of 2021, if no authorisation is granted.

Following the methodology presented in a report commissioned by ECHA (14), the social costs related to expected job losses in the most realistic NUS are valued under consideration of the following components:

- The value of lost output/wages during the period of unemployment
- The cost of acquiring a new job
- Recruitment costs
- The “scarring costs” (i.e. the impact of being made unemployed on future earnings and employment possibilities)
- The value of leisure time during the period of unemployment

The latter component is defined as a negative cost (i.e. a benefit) of unemployment. As such, it is subtracted from the total cost resulting from the first four components.

The figures from the aforementioned paper have been updated with most recent data reported in 2018, using information on wages presented by Rogers and Philippe in 2018 (15) and using most recent data on the duration of unemployment in 2017, as reported by Eurostat (16). Moreover, the figures for average wages were projected to 2019 by considering data presented by Eurostat on the labour cost index (17).

TABLE 30: SOCIAL IMPACTS ON AIRBUS

Monetised Social Impact of Workforce Dismissals (NPV 2020)	
Number of dismissals	5 500-7 500 ([redacted])
Cost of 1 lost job (EU28 average)	EUR 97 692
Total cost of all lost jobs	**EUR 537– 733 ([redacted]) million**

As described in Table 30**,** social costs of unemployment can be valued at approximately EUR 537 - 733 ([redacted]) million. This value is based on the use of the latest available average gross salary in EU-28 as an input to the standard calculation of social costs.

6.3.3. Total Socio-Economic Impacts in NUS 2

The total economic impact of this non-use scenario is calculated as follows.

TABLE 31. TOTAL COST OF NUS 2

Cost Item	**Impact** **[EUR million]**
Total costs incurred by Formulators	Cannot be disclosed
Total costs incurred by DUs	5 132 - 19 373
Social Impacts	541 – 743 ([redacted])
Total costs across the review period	**5 673 – 20 116 ([redacted])**

Thus, the total economic impact of this non-use scenario is **EUR 5 673 – 20 116 ([redacted]) million**. This figure represents the **upper limit** of the monetised **economic impact of a not granting an authorisation for the continued use of the substance.**

6.4. Wider economic impacts

The relationship between a country's connectivity via the global air transport (w.r.t passengers or cargo) and its productivity and economic growth is directly proportional. The case studies in ***Annex A*** provide a glimpse of the wider economic impacts, due to a bottleneck in the production, maintenance and repair of aerospace products, because of a non-granted authorisation. This covers the impacts on airlines and passengers (in and outside the EU), due to delays in or inoperable aerospace products, targeting direct, indirect and induced impacts on air freight (cargo), tourism and other aviation-linked industries (for instance, aircraft interior and design, airline technology, on-board services and maintenance), accompanied by subsequent job losses. A decrease in these commercial activities would bring a proportional effect in the producer and consumer surplus, in general reducing the welfare of the society in the EEA. A temporary disruption in the production of aerospace products shall culminate in prolonged impacts beyond the review period applied for. Moreover, considerable losses for the EEA will jeopardise European competitiveness in the aerospace industry.

Limited aviation connectivity would cease existing trade within and outside the EU and may induce an impact on its foreign trade relations. This will entail economic restructuring, in part, because of increased prices and decreased accessibility due to limited aviation transport services causing paradigm shifts in marginal costs of OEMs and demand for related goods and services, rippling through market mechanisms, affecting employment, output and income in the short run. Over time, dynamic development effects originating from the market mechanisms set in motion in pursuance of the non-use scenarios will activate a plethora of interconnected economy-wide processes and yield a range of sectoral, spatial and regional effects, plummeting overall productivity and GDP growth in the EEA, as the increased price of overseas travelling would be passed on to the end user of the aerospace products. This could materialise as increased air fare for passengers and increased import tariffs on foreign trade, for example, hindering unfettered trading arrangements, increasing the economic burden for EU.

These impacts can only be theoretically anticipated but remain extremely difficult to monetise with accuracy. From the above-mentioned impacts and the provided case studies (***Annex A***), it can be reasonably argued that the wider economic impacts that would occur in the non-use scenario are much higher when compared with the applied for use scenario, where the economy is vested in maintaining the status quo with no environmental risks, given the zero-emissions strategy pursued by the applicant and the downstream users in the supply chain.

Finally, the socio-economic benefits of continued use are summarised in the following Table 32 below.

TABLE 32: SOCIO-ECONOMIC BENEFITS OF CONTINUED USE

Description of major impacts	**Quantification of impacts [annualised values in EUR million]**	
	NUS 1	**NUS 2**
1. Benefits to the applicant		
Avoided profit loss due to ceasing the use applied for	Cannot be disclosed	Cannot be disclosed
Avoided relocation	2 – 7 ([redacted])	n/a
Avoided net job loss	1 – 3 ([redacted])	1 – 3 ([redacted])
Sum of benefits to the applicant	**3 – 10 ([redacted])**	**1 – 3 ([redacted])**
2. Quantified impacts of the continuation of the SVHC use applied for Airbus		
Avoided profit loss due production costs related to the adoption of an alternative	1 414 – 2 773	1 414 – 5 337
Avoided additional cost for quality testing	0.3 - 2 ([redacted])	n/a
Avoided additional asset acquisition cost	0.3 - 2 ([redacted])	n/a
Avoided additional energy costs	0.1 - 1 ([redacted])	n/a
Avoided additional logistics costs	0 - 2 ([redacted])	n/a

Avoided net job loss	n/a	148 - 202 ([redacted])
Avoided other societal impacts (e.g. avoided CO_2 emissions)	0.01 – 0.1 ([redacted])	n/a
Sum of impacts of continuation of the use applied for	**1 415 – 2 780 ([redacted])**	**1 562 – 5 539 ([redacted])**
Aggregated socio-economic benefits (1+2)	**1 418 – 2 790 ([redacted])**	**1 563 – 5 542 ([redacted])**

6.5. Combined assessment of impacts

6.5.1. Comparison of impacts

The non-use scenarios imply a lower and upper bound to the duration (and impacts) of a temporary supply disruption in the provision of sealants, typically used to manufacture, maintain and repair aerospace products. Given the complexity of the Aerospace supply chain and the multitude of affected processes and applications, as well as the nature of impacts that would occur due to the non-use scenario, it was not possible to carry out a detailed impact assessment, quantifying all impacts at all actors in the supply chain. This however, does not change the overall conclusion of the SEA, as the consequent risks of the applied for use scenario are precluded. The NPE concentration is >0.1% only prior to mixing of the base and the hardener components. For Use 1 and Use 2, release is controlled by following proper risk management measures and operational controls. NPE releases are precluded throughout the sealant lifecycle of an aerospace product.

Based on these results from the CSR, the monetised environmental risk arising from the applied for use scenario is near zero (zero-emissions strategy). Thus, even if the socio-economic aspects of the impact assessment are substantially under-estimated, it is still clear that the benefits of continued use outweigh the monetised risks associated with continued use of the substance for authorisation.

In other words, there are no environmental benefits associated with either non-use scenario, since there is no potential for NPE release into the environment (i.e. no potential to reduce emissions). However, NUS 1 entails additional CO_2 emissions, due to import of sealants from outside the EU, and NUS 2 carries heavy socio-economic impacts. The applied for use scenario carries a smooth transition of production processes in aerospace companies from sealants containing NPE to NPE free sealants in 4 years. However, NUS 1 and NUS 2 (being the lower and upper bound of impacts respectively), entail financial losses for aerospace companies and its downstream users (airlines and MROs) in the EEA.

Economic impacts would be seen in terms of profit losses for these companies, along with cascading effects on the EEA economy and the society, leading to dismissal of 40-100 ([redacted]) workers and 5 540-7 600 ([redacted]) workers in NUS 1 and NUS 2, respectively. Even so, these job dismissals represent a minimum estimate at the applicant and Airbus only. No dismissals at companies upstream or downstream the supply chain have been considered here.

A quantitative comparison of the socio-economic benefits and risks of continued use can be seen in Table 33 below. It should be highlighted again that the impacts described as the difference between the "applied for use" and the "non-use" scenarios represent the absolute minimum impact at Airbus. Real impacts are, by far, much higher than the impacts anticipated in this SEA.

TABLE 33: COMPARISON OF SOCIO-ECONOMIC BENEFITS AND RISKS OF CONTINUED USE

Socio-economic benefits of continued use		**Monetised excess risks associated with continued use**	
Benefits to the applicant and Airbus [annualised to EUR million per year]	1 418 – 5 542 ([redacted])	Monetised excess risks associated with continued use [annualised to EUR million per year]	n/a
Additional qualitatively assessed impacts	-	Additional qualitatively assessed risks	-
Aggregated socio-economic benefits [annualised to EUR million per year]	1 418 – 5 542 ([redacted])	Aggregated monetised excess risk [annualised to EUR million per year]	n/a

To conclude, the net benefit of a granted authorisation will be much higher than EUR 5 - 20 billion. Given that only a small fraction of real socio-economic impacts has been quantified for the purposes of this SEA, this outcome must be considered robust.

TABLE 34: BENEFIT / RISK SUMMARY

Net benefits (in EUR million)	5 145 – 20 116 ([redacted])

Table 34 above shows the net benefits of authorisation or continued use of the substance in the EEA. As the applicant and the downstream user, Airbus, carry a zero-emissions strategy, potentially, no or near zero emissions can be assumed and thus estimation of a benefit/monetised risk and a cost effectiveness ratio is not applicable here.

Since NPE emissions are foreseen to be zero, or only in the range of several kgs over the entire review period if unrealistic worst-case assumptions are applied, there is no imaginable case where the net benefit of a granted authorisation could become negative.

6.5.2. Distributional impacts

The previous sections have focused on the impacts of granting an authorisation in terms of costs avoided by the formulator and the downstream user, which in this SEA, only includes the OEM, Airbus.

The impacts on other members of the supply chain, such as chemical manufacturers, importers, distributors, processors, component manufacturers, as well as airlines and MRO companies as final customers or end users, have not been assessed in this SEA due to limitations in availing the information.

However, these individual groups will be directly or indirectly impacted (see FIGURE 2: typical supply chain in the Aerospace Sector (11)) because of non-authorisation leading to a temporary unavailability of sealants to produce aerospace products. The relevant impacts would be related to lower or no utilisation of the production factors previously used to produce the substance or the formulations where the substance was a key component in the EEA.

A quantitative assessment of such a distributional impact was not possible. However, a qualitative assessment of distributional impacts has been provided. The severity of impacts is estimated using scale high (+++ or ---), medium (++ or --), low (+ or -) or not applicable (n/a). Table 35 presents the distributional impacts of continued use broken-down along the supply chain and socio-economic groups.

In the non-use scenarios, as compared to the applied for use scenario, the applicant and the supply chain (customer groups 1, 2 and 3) in the EEA will experience negative socio-economic impacts along with wider sub group of uses that aerospace products are used for, in and outside the EEA (affected passengers and trade). These socio-economic impacts are listed in Table 35 below, separately, for the applicant and the downstream user, Airbus Group companies. Since, no NPE emissions are seen throughout the sealant life cycle of the aerospace products, no environmental impact during continued use of the substance for authorisation is estimated throughout the supply chain.

Since a technically and economically feasible alternative to the use of NPE has not been identified in the AoA, impacts on the suppliers of alternatives in and outside the EU are not applicable here. In addition, NPE-free polysulfide sealants in the EU market at present have not been qualified, validated, or industrialised for the applications in the scope of this AfA and hence cannot replace the NPE containing sealants currently in use.

The public at large will be affected majorly due to aircraft delays and other wider economic impacts due to non-authorisation, discussed in ***Section 6.4***.

As for the geographical span, the entire EEA will be affected as a result of decreased GDP and lost jobs due to a non-authorisation, leading to incompliance of services related to the aerospace industry affected due to non-authorisation. The environmental benefits, seen as a result of the non-use scenario, are not significant, when compared to negligible NPE related environmental risks in the applied for use scenario, as per the results of the CSR.

Within the applicant's business, employee dismissals (permanent and temporary dismissals in NUS 1 and NUS 2 respectively) would be seen, negatively impacting the revenue gained by the employer.

Thus, as a result of non-authorisation, all the actors in the supply chain in the EEA as well as the public at large would be economically worse off as compared to the applied for use scenario. The environmental impacts remain near zero, with or without authorisation. However, external environmental impacts, due to increased CO_2 emissions because of increased logistics required to import sealants from outside the EEA (NUS 1), would be experienced, theoretically making the non-use scenario worse-off than the applied for use scenario in terms of environmental benefits obtained.

TABLE 35: DISTRIBUTIONAL IMPACTS

Affected group	**Economic impact**	**Environmental impact**
Economic operator		
Applicant	--	0
Suppliers of alternatives in the EU	n/a	n/a

Suppliers of alternatives outside the EU	n/a	n/a
Competitors in the EU	n/a	n/a
Competitors outside the EU	+	-
Customer group 1 (OEM: Airbus)	---	0
Customer group 2 (chemical manufacturers, importers, distributors, processors, component manufacturers)	---	0
Customer group 2 (End customers: airlines, MROs)	---	0
Public at large in the EU	---	0
Geographical scope		
Region (EU)	---	n/a
Within the applicant's business		
Employers/Owners	--	0

6.6. Uncertainty analysis

The ECHA Guidance on SEA (24) proposes an approach for conducting the uncertainty analysis. This approach provides three levels of assessment that should be applied if it corresponds:

- qualitative assessment of uncertainties;
- deterministic assessment of uncertainties;
- probabilistic assessment of uncertainties.

The ECHA Guidance further states: the level of detail and dedicated resources to the assessment of uncertainties should be in fair proportion to the scope of the SEA. Further assessment of uncertainties is only needed if the assessment of uncertainties is of crucial importance to the overall outcome of the SEA.

Hence, a deterministic assessment of uncertainties has been carried out. To monetise the environmental impacts related to these emissions, the methodology as outlined in ***ANNEX B***: Environmental impacts in the applied for use scenario has been used.

Since a probabilistic assessment of uncertainties would not be of significant importance for the overall outcome of the SEA, this assessment has not been carried out in this SEA.

6.6.1. Qualitative assessment of uncertainties

TABLE 36 illustrates the systematic identification of uncertainties related to environmental and socio-economic impacts.

TABLE 36: UNCERTAINTIES CONCERNING SOCIO-ECONOMIC IMPACTS

Identification of uncertainty (assumption)	Classification	Evaluation	Criteria and scaling (contribution to total uncertainty)
NPE emissions to the environment	Parameter uncertainty	Over/underestimation	Low

Identification of uncertainty (assumption)	Classification	Evaluation	Criteria and scaling (contribution to total uncertainty)
Foregone profits for aerospace companies	Parameter uncertainty	Underestimation	High
Estimation of investment costs	Parameter uncertainty	Based on past experiences and conservative estimation	Low
Estimation of electricity cost	Parameter uncertainty	Based on publicly available data and conservative estimation	Low
Estimation of logistics cost	Parameter uncertainty	Based on market data and conservative estimation	Low

6.6.2. Deterministic assessment of uncertainties

A conservative mass-balance approach in the CSR aims to evaluate absolute worst-case releases of NPE to the environment from the sealant life cycle, under highly unrealistic conditions. This deterministic assessment of uncertainties is based on the outcomes of this analysis and aims to provide an absolute worst-case estimate of environmental costs, considering these overestimated emissions over the sealant life cycle of aerospace product.

For this purpose, it is assumed that, **1.75 kg of NPE** are emitted to the environment per annum. Assuming a constant release per annum across the entire review period of 4 years, these costs have been monetised based on the methodology described in ***ANNEX B***: Environmental impacts in the applied for use scenario and discounted to the base year in 2020 at a discount rate of 4%.

Thus, in case of a granted authorisation, the present value of monetised emissions to the environment of the NPE-containing hardener component of the two-part sealant when mixing within the two-compartment kit, in small scale batches by hand or bulk mixing by machine would be **EUR 6 352 – EUR 317 616** across 2021-2024. To assess the benefit/monetised risk ratio (see TABLE 37), the upper bound of the monetised risk i.e. EUR 0.32 million has been used.

TABLE 37: UNCERTAINTY ANALYSIS FOR ENVIRONMENTAL IMPACT

Uncertainty analysis for environmental impact		
	NUS 1	NUS 2
Assumed worst-case emissions (kg NPE)	7	7
Willingness-to-Pay for avoided emissions (EUR million)	0.32	0.32
Socio-economic impacts (EUR million)	5 146 – 10 130 ([redacted])	5 673 – 20 116 ([redacted])
Total costs across the review period (EUR million)	5 146 – 10 130 ([redacted])	5 673 – 20 116 ([redacted])
Cost-benefit ratio	16 080 – 31 657 ([redacted])	17 728 – 62 863 ([redacted])
Cost-effectiveness ratio (Cost per kg of avoided NPE emissions) [EUR million / kg]	735 – 1 447 ([redacted])	810 – 2 874 ([redacted])

This assessment has been provided to preclude any uncertainty regarding the releases from the NPE-containing hardener component of the sealant. As concluded in the CSR, there are no releases to the environment and the net cost of not granting an authorisation would be far more than EUR 5 146 – 10 130 ([redacted]) million for NUS 1 and far more than EUR 5 673 – 20 116 ([redacted]) million for NUS 2.

In the conservative assessment provided in TABLE 37, assuming 1.75 kg of NPE emissions per annum it can be concluded that the net cost of not granting an authorisation would still be far more than the costs mentioned above for NUS 1 and NUS 2 respectively, considering the monetised risk of EUR 0.32 million. Overall, this assessment shows that even an unrealistic worst-case scenario does not change the outcome of this SEA. (see ***Section 6.5***).

6.7. Information for the length of the review period

The polysulfide sealants containing NPE in use by the aerospace OEM customers and supply chain of the Applicant currently comply with all relevant specifications, and regulations as required.

Therefore, as a formulation change of the polysulfide sealants and implementation of an NPE-free alternative is required to comply with REACH Annex XIV, OEMs must show compliance of an alternative sealant formulation with the Airworthiness regulations, and for each subsequent use of the formulation or process specification, through collaboration with the formulator and undertaking qualification testing as required, as detailed in Section 4.3.4 and ***Annex C***. In the case of polysulfide sealants, compliance with relevant materials and process specifications and maintenance manuals provides the evidence that the alternative sealant is interchangeable and thus is airworthy.

The development of a formulation is complex and several years are often necessary. As described in ***Section 5.1.2*** R&D activities are still underway to determine the best potential alternative formulation that allows the polysulfide sealant to keep all required properties (such as the required level of adhesion and viscosity), whilst removing NPE from the formulation. The Applicant estimates that this phase of work will be completed by Q2 2021. Although some small-scale testing can be done by the Formulator and OEM collaboratively, the reformulated sealants at industrial batch scale will not be available to OEMs to start qualification testing prior to the Sunset Date of NPE.

Once the reformulated sealant is available to the OEM, technical qualification at industrial batch scale can commence. Qualification testing is extensive and multiple testing runs under different relevant conditions may be required for the same testing parameter; more than 100 iterations on any single test may be required. Where the formulation passes some key initial tests, additional mandatory tests, which are performed in a second step, may fail. Successful sealant qualification is by no means assured. The OEMs supported by this AfA estimate that the necessary time to complete qualification testing (if successful) is 18 months from availability of the reformulated sealant, which under the current estimated timeline is by Q4 2022.

Once qualification activities have completed, the qualified alternative sealant must then be industrialised throughout the OEM manufacturing sites and throughout the wider supporting supply chain. For a formulation change, significant investment, worker training and manufacturing documentation may be required to adapt the OEM aerospace manufacturing processes. A stepwise approach may be utilized, and formulation changes may not be implemented simultaneously across all sites and suppliers but rather through a phased introduction to minimize technical risks and to benefit from lessons learned. It is currently estimated that industrialisation of an alternative sealant would take 18 months after OEM qualification activities had completed, which under the current estimated timeline is by end of Q2 2024.

Whilst the estimated timeline includes a small margin of safety, it must be noted that this does not include provision for significant development or qualification failures, which remains a possibility throughout the process until completed. Therefore, the timeline for a fully industrialised reformulated sealant, that no longer contains NPE, is not expected to be completed in the aerospace industry until mid-2024 (barring significant testing failures).

As such, the Applicant is requesting a review period of 4 years to allow sufficient time for the process to be completed to ensure compliance with the relevant airworthiness regulations and safety of the final aerospace product.

6.8. Substitution effort taken by the applicant if an authorisation is granted

The Applicant is committed to providing the highest quality of polysulfide sealants in compliance with REACH and EHS requirements for use in the aerospace industry. It intensively works on ensuring the compliance and implementation of the requirements resulting from the REACH and CLP regulations, relevant to its business (25). Significant R&D time, cost and effort has been invested in undertaking the assessment which has been underway since 2017. At this stage, failure to develop a suitable alternative sealant formulation which can be industrialised by OEM customers in the requested review period would have significant economic impacts upon the Applicant, if not able to recoup the costs of the R&D conducted.

As highlighted in this document, the reformulation of a formulation that has strict customer specification requirements and is a key formulation in use by the aerospace industry is only undertaken when necessary, due to the effort required from all parties to complete. The OEM customers of the Applicant are in turn committed and fully support the removal of harmful substance from use in the EU/EEA and are keen to qualify and implement an alternative sealant as soon as possible, within the boundaries of the required time to complete these activities.

In addition to the reasoning given in ***Section 4.3.4*** and ***Annex C*** the Applicant has undertaken discussions with its supplier of the surfactant containing NPE, who have confirmed that the surfactant will no longer be available for sale in the EU after the sunset date for the NPE substance (1 January 2021). To continue manufacture of the current sealant formulations, as currently qualified and accepted by OEM customers, the Applicant has stockpiled sufficient surfactant supplies to continue sealant manufacture until 2025 (expected end of requested Authorisation period). This provides a contingency plan to continue sealant manufacture, where a reformulated product is not available, qualified and industrialised by aerospace OEM customers prior to the Sunset Date, which is expected to be the case for polysulfide sealants, and the Authorisation to continue use of the substance is granted. However, after this stockpiled sealant is used, the Applicant will no longer be able to manufacture the affected sealants in the current formulation (containing NPE) in the EU and the NUS may have to be enacted, if the development, qualification and industrialisation activities have not been completed by the end of the granted Authorisation period. As described in ***Section 5.4***, the NUS have significant economic and social impacts upon not only the Applicant, its OEM customers and the aerospace industry but wider society as well. Therefore, it is imperative, and in the vested interest of the Applicant and customers, that viable alternatives are sourced and that the reformulated sealants are qualified and industrialised throughout the aerospace industry and supply chain by 2025 at the latest.

7. CONCLUSIONS

Please refer to Section 1. Summary.

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ANNEX A: Case Studies

Case study 1: Examples for affected daily operations due to a non-granted authorisation

Impacts on airlines

In the case of non-granted authorisation, aircraft on ground (AOG) situations will become increasingly common. These AOG scenarios are highly expensive and disruptive for airlines. AOG occur, for example, when planes are not allowed and/or able to fly due to technical defects or any other issues which require repair activities. There are thousands of maintenance and repair tasks (e.g., [redacted]) that require polysulfide sealants.

An inability to access sealants containing NPE makes MRO activities unfeasible and replacement of components[12] (if possible in the integrated design and structure of an aircraft) mandatory. For replaceable components, aircraft operators have only one possibility to keep their aircraft flying – stocking parts at flight destinations to avoid running out of parts. Because it is not always predictable which part will need replacement/service, this stocking of parts is associated with tremendous costs. Adding to that, the proper disposal of parts that may have suffered only minor damage (as opposed to the repair of such a part), the increase in costs and waste would be huge. Already today, where the possibility to use sealants containing NPE exists, the costs of maintaining such replacement stocks (> € 100 million per airline) as well as managing AOG scenarios are substantial; e.g. one source estimates that each cancelled transatlantic flight results in costs of approximately US$ 200,000. This can be further explained by the obligation to provide accommodation, meals and transport for passengers, to reschedule crew planning, cascade effects on the same day and the next day concerning the return flight as well as overtimes of mechanics to handle AOG (26).

Even so, AOG costs can be much higher. For example, DHL states a high cost scenario for an Airbus A380 on ground of € 925,000 per day (27). It should be clear that given 100 000 flights a day worldwide (28), such AOG scenarios due to non-granted authorisation quickly make aircraft use economically and operationally unfeasible. In the case of a non-granted authorisation, the frequency of AOG scenarios would increase and the costs needed to counter such scenarios would rocket.

A study about the disruption of 80 % of Europe's air traffic in 2010 due to the volcanic ash plume of Eyjafjallajokull demonstrates what happens 'when the system stops working' (29). In the EU, usually 25,000 flights per day take place in Europe. In one week 10 million passengers were affected and US$ 5 billion in the global economy was lost. The EU suffered a GDP impact of US$ 2.6 billion, and US$ 867 million lost in sales.

A non-granted authorisation would heavily affect today's business as well as future growth. IATA recently published a study (30) which demonstrates the current and predicted future economic activity supported by the aviation sector in the EU-28 (see summary in Table A-

[12] Components must be replaced with identical parts manufactured outside the EU

1). The study foresees substantial growth in revenue and employment over the next 20 years under normal circumstances.

TABLE A-1: ECONOMIC ACTIVITY SUPPORT BY THE AVIATION SECTOR IN EU-28

	2012		2035	
	Jobs, '000	GDP, € bn	Jobs, '000	GDP, € bn
Direct	2,031	121	2,727	170
Indirect and Induced	3,499	213	4,977	318
Tourism	3,749	178	4,856	235
Total	**9,279**	**512**	**12,561**	**722**

Furthermore, this study provides an analysis of delayed flights (about 18% of all flights were delayed in 2018) according to the United States Department of Transportation (31) which are broken down as follows:

- delays of air carriers (5.29 %);
- national aviation system delays (5.92 %);
- cancelled flights (1.14 %)
- diverted flights (0.23 %);
- extreme weather (0.5 %);
- security delays (0.05 %);
- on-time (80.33 %).

The value of time lost to EU passengers in 2012 for an average delay of 8.75 minutes per flight with a total of 84 million hours is quantified to be € 4 billion (31). Overall; the total costs of passenger delay borne by the airline, by delay duration and type of aircraft has increased by 20% from 2010-2014, mostly driven by increased passenger densities on European flights (3). If now due to a non-granted authorisation further AOG scenarios are unavoidable this value will dramatically increase.

Losing connection to global destinations will hamper Europe's productivity and economic growth. Statistical relationship between air connectivity and labour productivity yields an estimate that a 10 % rise in connectivity, relative to a country's GDP, will boost labour productivity levels by 0.07 % (30).

Cargo

Impacts due to a non-granted authorisation for air freight shall also be expected to be significant. In 2014, airlines transported globally 51.3 million metric tonnes of goods, representing more than 35 % of global trade by value but less than 1 % of world trade by volume. That is equivalent to US$ 6.8 trillion worth of goods annually, or US$ 18.6 billion worth of goods every day. An increase in the value of goods carried by air was estimated to be US$ 6.2 trillion in 2018. On average, cargo business generates 9 % of airline revenues, representing more than twice the revenues from the first-class passenger segment (26). Concerning cargo carriers, all earnings might be lost in the case of delayed deliveries due to heavy penalties; such penalties must be avoided by providing significant numbers of spare aircraft and spare parts resulting in considerable additional costs compared to passenger airline (26).

Air transport is especially essential for perishable goods and high-value components (electrical and machine parts and equipment). The following examples for perishable goods transported by air in 2009 are provided (32): US$ 300 million worth of flowers from South America; three-quarters of fresh cut flowers exported to the EU came by air, with a total monthly value of US$ 81 million in April. Also, in April, US$ 24 million worth of green beans were imported by air into the European market, over 90 % came from Africa during that month, while Kenya alone accounted for 54 % of the total. Additional examples show that industry production is strongly linked to a healthy and reliable air freight transport. Iceland's volcano interrupted the air freight supply in 2010 for only one week with massive impacts for the German car maker BMW which shut down three of its factories as high-value components from BMW suppliers were unable to reach their destinations. Impacts even affected Asian production sites, Nissan shut two factories as its supply of pressure sensors from an Irish supplier were grounded (32).

Tourism

The tourism industry will be negatively affected in the case of a non-granted authorisation of NPE. The connection of aviation and the tourism industry is strong, this is well understood by tourism management, and it is easy to find public strategy documents showing their vested interested in attracting and maintaining airline routes to their areas to promote tourism (33). Travelling by airplane is convenient and popular, contributing both to individual mobility and employment in the tourism sector. In fact, over 57 % of international tourists travel by air (3). The tourism industry relies heavily on the aerospace industry, for example a report by ATAG shows that in Africa '…an estimated 4.9 million people directly employed in tourism are supported by overseas visitors arriving by air, contributing US$ 36 billion to GDP in African economies in 2016 (3). Some economies significantly rely on tourism which in turn is heavily dependent on-air travel. According to the World Travel and Tourism Council (34), Travel and Tourism in Malta directly contributed € 2,425,5 million to the GDP (26.7 % of Malta's total GDP) in 2017 and 27,500 direct employments (15.5 % of Malta's total employment) were correlated to Travel and Tourism in 2016.

Important global figures for the dependence of tourism on air transport taken directly from the ATAG website are as follows:

- direct: 15.6 million direct jobs in tourism globally are estimated to be supported by the spending of foreign visitors arriving by air. This includes jobs in industries such as hotels, restaurants, visitor attractions, local transport and car rental, but it excludes air transport industry jobs.
- indirect: A further 14.1 million indirect jobs in industries supplying the tourism industry are supported by visitors arriving by air.
- induced: These direct and indirect tourism jobs supported by air transport generate a further 36.7 million jobs in other parts of the economy, through employees spending their earnings on other goods and services (3).

Thus, negative effects on the aviation industry due to non-granted authorisation will lead to consequences in the entire tourism industry, and even entire economies that are dependent on tourism and their related industries, creating a 'ripple effect' throughout these economies causing far reaching negative socio-economic impacts. The direct, indirect and induced effects included, air transport globally supported 292 million jobs within tourism, contributing to over US$ 7.6 trillion a year in 2016 (3).

Impacts on aviation-linked industries
Several examples of linked industries are provided below. Regarding the linked industries, it is important to note:

- In general, a healthy aviation industry can have positive effects on a country´s economy, since the attractiveness as business location is increased as integration in worldwide activities is enabled.
- The aviation industry significantly contributes to the development and maintenance of foreign trade relationships (import and export) of high-tech products, machine and vehicle parts, sensitive goods etc., through the ability to provide quick, safe and reliable transport over long distances.

Each of these linked industries represents large industries in themselves, and most are reliant on the aviation industry to even exist. The non-authorisation of NPE and the subsequent closure (even temporarily or partially) would result in massive negative socio-economic impacts not only for the aviation industry, but for the many linked industries, and for other industries supporting these linked industries. Furthermore, a plurality of other economic sectors, and thus workplaces of different educational levels, strictly depend on aviation (35). The following list gives an insight of possibly affected branches of aviation industry in case of non-authorisation (36):

- **Aircraft interior and design**
    - airline branding solutions (placards, aircraft paintings, technical stickers for aircraft interiors and exteriors etc.);
    - cabin interior designs (aircraft seats, LED reading lights, aircraft stowage, heat shielding and sound damping solutions etc.);
    - leather manufacturers for aircraft interior;
    - manufacturers of carpet and upholstery solutions (interior seats, aircraft flooring);
    - aircraft life-saving and emergency equipment (safety relevant seat components, life jackets etc.);
    - airline consultancy and planning (design, fleet and financing solutions, aviation IT-specialists, technical services etc.);
    - manufacturers of airline clothing, uniforms and cabin footwear.

- **Airline Technology**
    - airline communication solutions (voice communication systems for airlines and airports, tracking and tracing systems etc.);
    - airline check-in equipment (production of boarding passes, baggage tags, air waybills etc.);
    - passengers with reduced mobility (PRM) solutions (medical lifts, board transit chairs etc.);
    - inflight entertainment.

- **On-board services**

- airline food and beverages (sweet and savoury snacks, hot snacks and sandwiches, ready snacks, on-board bottled wines, boxed cakes and desserts etc.);
- aircraft cleaning and sanitation solutions (lavatory and water systems, dishwashing systems for aircraft kitchens, on-board waste-management, disposable tray sets etc.);
- manufacturers of airline passenger service products (hot and cold towels, pillows, napkins catering service carts etc.);
- the global market for in-flight catering services is projected to reach US$ 17.6 billion by 2020' (37), as seen above, EU flights account for approximately one quarter of worldwide flights, meaning the negative impact in the EU would be approximately US$ 4.4 billion.

- **Maintenance**
  - aircraft maintenance, repair, overhaul (MRO);
  - manufacturers of docking systems for aircraft movements;
  - manufacturers of airline cargo equipment (passenger ramps, luggage tow tractors, cargo high-loaders etc.);
  - aircraft de-icing equipment and chemicals.

Further impacts

In the absence of any alternative to maintain, repair or overhaul aircraft, the ground readiness for all types of aircraft will be impaired, with expected essential consequences. For example, helicopters are especially vulnerable to being affected by the lack of MRO services (38). In this context, air rescue must be mentioned as an important field of application in difficult to access terrain, such as mountains or on sea. Control and maintenance of pipelines (oil, gas, water) and high-voltage systems is another sector where helicopters are essential and frequently applied. Moreover, helicopters help to build up and supply oil plants and offshore wind farms, support agriculture by crop spraying, report news and sport events from the air and operate photo and film flights for terrain exploration and cartography. Finally, people can be easily transported in difficult landscapes or less developed regions without airports or simply for touristic purposes. The highest technical demands and safety standards must be ensured in all these situations, remembering that these aircraft operate in harsh environments and often at the limit of their specifications.

Conclusions

Impacts relating to a change in air transportation availability will significantly impact direct, indirect and induced employment, but have a much wider impact on the employment and income of services as economic activities that rely on the availability of air transportation services, such as tourism, trade, local investment and productivity improvement, are affected. Aggregate trend analysis shows that there is a correlation between air travel and GDP and that the cost of delays has an adverse effect on economic activity especially at the regional level as an air transportation system becomes saturated (39).

Case study 2: Military Aircraft– potential downstream user impacts of a non-authorisation

Military strength and readiness is key to maintain peace and prosperity in the EEA. Military aircraft would be impacted by a decision to not grant authorisation for the continued use of NPE. Some military aircraft in operation rely heavily upon well-known and time-tested processes that utilise NPE-containing sealants.

In the case of non-authorisation of NPE for use in military aircraft, availability and performance would be negatively affected. This would also have an adverse impact on European and allied military activities, especially in current and future conflict situations.

Interruption to the manufacture, repair and overhaul of these components due to the non-availability of NPE would jeopardise the availability and combat readiness of military aircraft and therefore the safety of armed forces in case of a military emergency.

Practical examples of how a decision not to authorise the continued use of NPE in polysulfide sealants could impact military aircraft include:

- Availability of mission critical aircraft could be impaired due to drastically shortened maintenance and service intervals or failure of aerospace components.
- Turnaround times for maintenance and repair of equipment might also be longer due to additional transport times where MRO activities cannot be performed in the EEA anymore. Furthermore, it might not be possible to export components for MRO to other countries due to national security regulations.
- Production, maintenance and/or repair costs for, or associated with military aircraft will increase for the industry and its customers.
- Any of the examples described above could affect the ability to successfully accomplish a mission, which could potentially have dire consequences.

It can be concluded that despite the limited quantities of these sealants used for military aircraft, the availability of this substance is essential to the European armed forces.

Case study 3: Production of aerospace products in the EEA – potential impacts due to a non-granted authorisation

Since there are no alternative substances or production processes available for the aerospace sector, the unavailability of NPE containing sealants due to a non-granted authorisation would result in cessation of production stop for certain aerospace components. It would force the relocation of these production processes to non-EEA countries. In best cases, existing production sites outside the EEA can be used, assuming adequate capacity available or can be created. However, many of the small and much specialised companies that are suppliers to OEMs do not have the resources, facility or know-how to relocate their production; they would be forced to simply cease their business activities.

Consequently, in this scenario, OEMs would, in theory, need urgently to identify and qualify non-EEA suppliers to continue their production, subject to the condition that the aerospace components will be identical to those currently produced. In practice, the OEMs advise it will be impossible to find and qualify new suppliers, re-certify and start production without business interruption.

Assuming only half a year of interruption (although two to three years interruption is considered more realistic, noting that relocating final assembly lines will take up to nine years), the direct socio-economic impacts will be potentially devastating. Table A-2 sets out the estimated turnover and employment of the European aerospace industry.

TABLE A-2: ECONOMIC DATA OF THE EUROPEAN AEROSPACE INDUSTRY (7)

	Turnover billion € [2016]	Employment ('000) [2016]
Aeronautics (civil + military)	162	543

As discussed within the SEA in detail, relocation of production is expected to ultimately result in a shift of production activity and logistics around component manufacture, since it makes economic and technical sense to carry out many production activities (e.g. machining, treatment, sub-assembly) in close proximity. Over time, it is expected there would be a loss in technical know-how, design and research and development as well as associated infrastructure in the EU as the centres of technical activity associated with the aerospace industry move elsewhere.

The aerospace sector in the EU continues to invest significant resources into the aerospace industry, including for environmentally friendly aircraft. One example of this is the Clean Sky initiative which is a public-private partnership worth € 1.6 billion. To maintain competitiveness, the aerospace industry needs to make huge investments which can take years to become profitable. Aerospace leaders in the EU such as France and the UK have '… taken an initiative to make improvement in policies that adapts to the concern of investors.' (40). France aerospace industry, one of the dominant in the EU is estimated to be worth US$ 15 billion, being involved in the production of essentially all major aerospace products and services. The turnover of the EU aeronautic industry, at well over € 140 billion will be impacted negatively on a huge scale; more specific analysis of socio-economic impacts can be found in Section 6.5.

Moreover, it must be noted that such a scenario results in distortion of an entire industry with severe distortion of global competition. Market forecasts state that 37,400 new passenger and freight aircraft will be required by 2037, approximately 19% of which will be required in Europe. This shows the steady growth of the industry and its contribution to healthy growth of other sectors (e.g. airlines and tourism, see case study 2). A decision not to grant an authorisation would therefore have dramatic impacts even on the global economy.

ANNEX B: Environmental impacts in the applied for use scenario

Due to the uncertainties regarding the effects of NPE (and endocrine disruptors in general), the assessment of environmental impacts derived from NPE emissions remains challenging. Therefore, and because of a lack of an agreed methodology for assessing the environmental impacts of endocrine disrupting substances, the assessment of potential environmental impacts related to the use of NPE requires the use of qualitative information combined with alternative quantification methods.

1. Suggested approaches to perform the assessment

For OPE and NPE, ECHA published the article *"SEA-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO"* (SEAC/37/2017/03) which provides suggestions for possible approaches to be followed in the assessments conducted in the SEAs (41).

According to what ECHA describes in the above-mentioned paper, it is important to recognise that the full quantification of both benefits and risks is not mandatory under REACH and that a mixed qualitative and quantitative socio-economic analysis can be conducted to demonstrate that the continued use of a substance outweighs the risks (41). Indeed, ECHA explains that in some cases a qualitative assessment may be sufficient when the benefits to society from continued use are considerable and the environmental emissions are properly controlled. Costs for additional risk management measures (that could be implemented or are currently in place) are not relevant for the assessment; however, ECHA states that such costs can be provided to justify releases and demonstrate that releases are minimised as much as possible, both technically and practically (41).

The main suggestion provided by ECHA on how to conduct a SEA in the case of endocrine disrupting substances (specifically OPE and NPE) is that *"…monetised benefits of continued use and quantified release estimates, complemented with qualitative information, form the basis of a semi-quantitative approach to justifying that the benefits of continued use outweigh the risks."* ((41), page 2).

In ECHA's opinion, the information listed above should be sufficient to qualitatively conclude whether the benefits of a use outweigh the risks. However, still according to ECHA, further contextual information on the likelihood and significance of potential impacts can be provided to support the case - *"e.g. the margin of safety between predicted or measured environmental concentrations and relevant thresholds of exposure/adverse effect in biota or quality standards from other legislation" (* (41), page 2). A qualitative comparison of benefits and risks explaining why, from a societal perspective, it is better to continue the use of the substance should be performed by the applicant.

ECHA has declared that *"any benchmarks (e.g. € of reducing kg of release) above which an authorisation would always be granted cannot be set"* ((41), page 3). A magnitude of such a benchmark has been reported in the form of a range for PBT/vPvB substances in the SEAC PBT approach, however, ECHA notes that such benchmark cannot be directly transferred for use in the case of endocrine disrupting substances (41).

Despite the fact that ECHA states that such ranges cannot be directly applicable to the case of endocrine disruptors, since the use of only qualitative information is always open to subjective interpretations, the benchmark ranges derived in a paper about PBTs/vPvBs will be used in this SEA at least as an auxiliary measure for the assessment (41).

2. Efforts to monetise environmental impacts of endocrine disrupting substances: taking advantage of the PBT and vPvB case to derive an auxiliary monetised value of impacts

Due to the issues surrounding the assessment of endocrine disruptors and NPE specifically, alternative methods for evaluating the environmental impacts need to be considered. A PBT/vPvB benchmark study by the Vrije Universiteit Amsterdam (VU) is used here as an initial basis for the analysis (41). This assessment was conducted by VU with the aim to develop a benchmark for regulatory decision making under REACH restriction and authorisation processes of PBT and vPvB substances under the premise that to decide whether a regulatory action is justified, it is useful to have a comparator or benchmark which reflects the amount of costs that are worth taking for the reduction of PBT and vPvB. The VU assessment project collected information on costs to reduce the stocks and flows of emissions to the environment of eight groups of PBT substances and, where possible, related this information to the final decision making (whether the reduction measure had been implemented or rejected due to excessive costs). The cost levels of rejected measures can provide an indication of the maximum willingness to pay for the reduction of PBTs. This can be considered in the context of NPE due to some similarities in the properties of such substance groups, as well as the conclusion from the VU study which states *that "once control is included for other influencing factors […] the average unit costs per kg seem transferable across substances"* (41).

The report by VU examines 36 studies from 10 countries spanning 25 years, with approximately 80% of these being from the EU. Most of these studies were carried out after 2009. In this report, VU considers three main cost categories for environmental improvements (42):

- Substitution costs – which is either the replacement of the substance with another, or the elimination the substance with a new process.
- Emission reduction costs – cases where the use of the substance changed, such as a new process with closed applications that ensures drastically reduced (near zero) emissions and exposure.
- Clean-up costs – also known as remediation costs; VU includes many forms of clean up from the studies ranging from the removal of the substance from the environment to removal of the substance from man-made structures and equipment.
- Other costs – VU notes that each of the examined studies varies in which costs are included or excluded, and that some of the outliers failed to include the "real cost" due to various factors such as secondary benefits, for this reason among others, the outliers are excluded from the final conclusion.

In the studies reviewed by VU, the range of costs was found to be highly sensitive to outliers due to many factors, primarily a different in methodology between the studies, such as the exclusion/inclusion of secondary benefits and certain extreme scenarios e.g. the economic impacts of temporarily closing a high traffic tunnel down as part of clean-up costs. In addition, a pattern of increasing costs with decreasing concentrations of a substance is observed. The below Figure B-1 is adapted from the VU report, it demonstrates the median costs per kg for the three different cost types, with remediation having nearly double that of emission control.

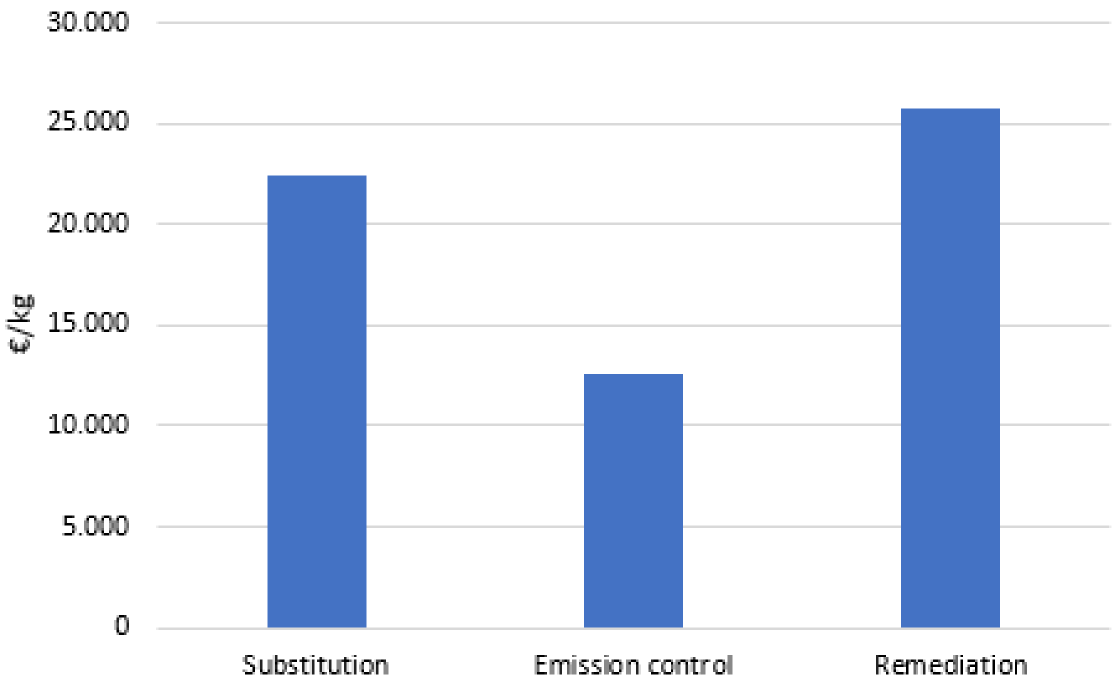

FIGURE B-1: MEDIAN UNIT COSTS OF DIFFERENT COST TYPES, EXCLUDING OUTLIERS (ADAPTED FROM (43))

While the previous figure represents the median cost per kg, the upper bound of acceptable cost-effectiveness is of interest for a conservative estimation. VU concludes that the viable range depends on the specific substance and situation, though with a broad "grey zone" in which the cost per kg is no longer considered acceptable, while there are some outliers, VU suggests that EUR 1 000 – EUR 50 000 per kg demonstrates a probable "grey zone", though VU notes that the range is not based on specific cases, but is their general conclusion and that accuracy of this range could be improved with additional data in future studies. This range of acceptable cost-effectiveness is demonstrated below in Figure B-2.

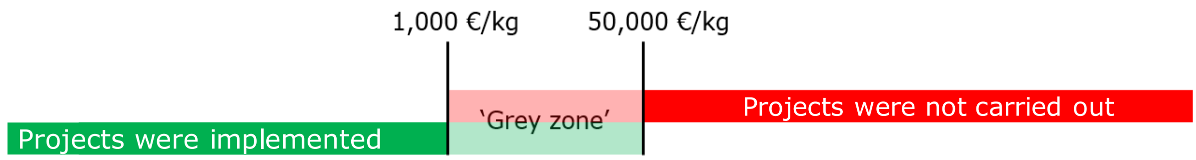

FIGURE B-2: VISUAL REPRESENTATION OF VU'S COST-EFFECTIVENESS "GREY ZONE" (ADAPTED FROM (43))

Despite the fact that no benchmark could be defined by the VU project, VU concludes that the range of the so-called "grey zone" is the range in which the measures to reduce the use, presence or emission of PBTs may be prohibitive from a cost-effectiveness standpoint, depending on the specific case. As the sample is limited and there are significant outliers, VU emphasizes that the use of this "grey zone" cannot be used as a pass-fail criterion in decision making. However, VU suggestions such a grey zone could be used in the benchmarking process as an initial screening for which further situation-specific assessments would be required on a case-by-case basis. While this grey zone is provided with caution and is based on limited data, it is currently the best estimate for the costs-effectiveness ratio that is still considered acceptable. VU's linear regression analysis finds *"[…] that the type of substance does not have a significant effect on the mean unit costs […]"* which further supports the case for the relevance of these figures with the endocrine disruptor NPE (41).

With this data and range for acceptable cost-effectiveness, it is important to note that this estimate is provided as a general measure only and should only be used to form an opinion when also considering the qualitative aspects described in this report.

Under these considerations, an auxiliary limit for acceptable costs of emission reduction is EUR 50 000 per kg of NPE emissions.

ANNEX C: Aerospace Industry – Background Information

1. Unique Challenges Inherent to the Aerospace Industry

The aerospace industry has several unique aspects that influence the way it operates and manages change, including but not limited to:

- Rigorous performance, operational and safety requirements across a wide range of environmental conditions, which have been developed over the past 50- 60+ years
- Design complexity
- Long in-service time (e.g. multiple landing-take-off cycles for aerospace assemblies; high utilization and expected reliability), including need for maintenance, repair and overhaul of aerospace parts entered into service
- Long investment cycles

These are further discussed in the sub-sections below.

In addition to these aspects, the aerospace industry has an extremely complex supply chain, covering production, maintenance, repair and overhaul (MRO) of aerospace hardware. The supply chain in turn, requires qualification of formulations, processes and of suppliers (e.g. validated that they can perform the process), which further complicates the process for management of change. This issue was briefly introduced in terms of the need for an upstream application in ***Section 2*** and is referenced below. A more extensive discussion on supply chain is set out at ***Section 4.2.3***.

1.1. Regulatory and Standardised Requirements

1.1.1. Background

Aerospace assemblies typically operate in environments that are highly challenging due to the extreme and varied conditions encountered (e.g. temperature, humidity, salt, sand, dust etc.). The consequences of aircraft component failure can be severe –accidents and related loss of life, injuries and property damage. The failure of military aerospace assemblies threatens the lives of service personnel and the citizenry they serve. To guard against this and building on the learnings from in-service performance since the 1950s, the development of aerospace assemblies is highly regulated, with numerous and stringent requirements on the testing and use of formulations, components, equipment and the finished hardware to ensure extremely high levels of safety and performance. These constraints often result in specification of unique formulations, components and processes and are one of the reasons implementations of alternatives can be a long process, requiring qualification, validation and certification.

Airworthiness is defined as the status of an aircraft when it conforms to its approved type design and is in a condition for safe operation. Since 2002, Airworthiness is legislated at an EU level to ensure safe flight (Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/E repealed by Regulation EC 216/2008). Additionally, since the aerospace products manufactured will be used outside as well as within the EU, they must meet airworthiness requirements across all global markets that EU aerospace manufacturers service as well. These regulations cover every aspect of design, maintenance, repair, overhaul and safe operation of aircraft.

1.1.2. Airworthiness Requirements According to EU Regulation No 216/2008

Notably, the aerospace industry must comply with the airworthiness requirements derived from EU Regulation No 216/2008 in Europe, and others as summarised in Table 38. According to the regulation, all components incorporated in an aircraft fulfil specific functions and must be *qualified, certified,* and *industrialised* before serial production can commence. Similarly, if, in this case a polysulfide sealant used in a process, component, or aerospace hardware is changed, it must be proven that the change does not adversely affect performance or safety in order to ensure continued compliance with the airworthiness requirements according to EU Regulation No 216/2008 before the change can be incorporated into the design (44).

The European Aviation Safety Agency (EASA) established these Airworthiness regulations to ensure the highest common level of safety and environmental protection for EU citizens. The industry must also cooperate with numerous global regulator bodies and international actors to achieve the highest safety level for EU citizens globally.

Key points to understand regarding adherence to the airworthiness requirements when any change to a substance used for production of aerospace equipment is made include:

- If a polysulfide sealant used anywhere in the manufacture or maintenance of aerospace hardware needs to be changed, the status of the alternative relative to the original substance must be established and it can be determined if undertaking the entire extensive process [of development, qualification, validation, certification and industrialization] is required to demonstrate that the change has no adverse effect upon performance in meeting the airworthiness requirements or if it is sufficient to demonstrate equivalence between the original formulation and the alternative.
- For trivial changes, where equivalence with the required standards can be demonstrated, requalification may be obtained without the need to resort to further testing
- For a change in polysulfide sealant, as mentioned above, several options are possible for OEMs: use of an existing alternative equivalent sealant already qualified for the aerospace industry, engage with formulators on reformulated sealant development, or investigate viability of new sealant technologies (e.g. not polysulfides, see ***Section 5.2***)
- Airworthiness regulations (and associated requirements for the design, manufacturing and certification of an aerospace product) set performance specifications/requirements that must be met which will limit the options regarding which formulations can be used either directly in the aircraft or during the manufacturing and maintenance activities.
- Depending upon the difficulty of meeting the applicable performance specification(s), where, qualification is required prior to the introduction of an alternative substance or formulation, the qualification and implementation of the change can take several years, as discussed further in ***Annex C-1.6***.

The airworthiness and approvals process in the aerospace industry is fully discussed in the report "An elaboration of key aspects of the authorisation process in the context of aviation industry" published in April 2014 by ECHA and European Aviation Safety Agency (EASA). (11).

TABLE C-1 SUMMARY OF EU AIRWORTHINESS REGULATIONS (45)

Regulation	Title
Implementing Regulation (EU) 2019/133	…amending Regulation (EU) 2015/640 as regards the introduction of new additional airworthiness specifications
Regulation (EU) 2018/1142	…amending Regulation (EU) No 1321/2014 as regards the introduction of certain categories of aircraft maintenance licences, the modification of the acceptance procedure of components from external suppliers and the modification of the maintenance training organisations' privileges
Regulation (EU) 2018/1139	…on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91
Regulation (EU) 2016/5	…amending Regulation (EU) No 748/2012 as regards the implementation of essential requirements for environmental protection
Regulation (EU) 2015/1536	…as regards alignment of rules for continuing airworthiness with Regulation (EC) No 216/2008, critical maintenance tasks and aircraft continuing airworthiness monitoring
Regulation (EU) 2015/1088	…amending Regulation (EU) No 1321/2014 as regards alleviations for maintenance procedures for general aviation aircraft
Regulation (EU) 2015/1039	…amending Regulation (EU) No 748/2012 as regards flight testing
Regulation (EU) 2015/640 (Additional airworthiness specifications for operations (Part-26))	…on additional airworthiness specifications for a given type of operations and amending Regulation (EU) No 965/2012, OJ L 106, 24.04.2015, p. 18.
Regulation (EU) No 1321/2014	…on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks
Regulation (EU) No 69/2014	…amending Regulation (EU) No 748/2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations
Regulation (EU) No 7/2013	…amending Regulation (EU) No 748/2012 laying down Implementing Rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations
Regulation (EU) No 748/2012	…laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations
Implementing Regulation (EU) 2019/133	…amending Regulation (EU) 2015/640 as regards the introduction of new additional airworthiness specifications

1.1.3. European Military Airworthiness Requirements

The European Military Aviation Requirements (EMARs) were created by the European Defence Agency (EDA) Military Airworthiness Authorities (MAWA) Forum to promote harmonisation of European military airworthiness regulations. The EMARs already published are summarised in Table 39.

TABLE C-2 SUMMARY OF EMAR REQUIREMENTS

	Title	Requirements
EMAR 21	Certification of Military Aircraft	Regulates the certification of military aircraft and related

	and Related Products, Parts and Appliances, and Design and Production Organisations	products, components and appliances and design and production organisations. E.g.: Sets requirements for Flammability Reduction Means (FRM) reliability Determination and action on any unsafe conditions Reporting time and guidance to the authorities
EMAR 145	Requirements for Maintenance Organisations	Outlines the requirements for maintenance organisations. E.g. “Dust and any other airborne contamination to be kept to a minimum in the work area…” “Lighting shall be such as to ensure each inspection and maintenance task can be carried out in an effective manner…” “The maintenance organisation shall establish and control the competence of personnel involved in any maintenance, management and/or quality audits in accordance with a procedure and to a standard defined through the MOE…”
EMAR 147	Aircraft Maintenance Training Organisations	Regulates the Maintenance Training Organisations, including requirements relating to the organisation, the instructors, records kept, content of basic and advanced training courses etc.
EMAR 66	Military Aircraft Maintenance Licencing	Defines the Military Aircraft Maintenance Licence and includes the requirements for application, issue and continuation of licence validity.
EMAR M	Continuing Airworthiness Requirements	Regulates the establishment and functions of Continuing Airworthiness Management Organisations (CAMOs) and establishes the measures to be taken to ensure that airworthiness is maintained.

The MAWA Forum does not have the authority to mandate airworthiness regulations on individual nations. Participation in the MAWA Forum is voluntary but participating Member States are encouraged to transpose the EMARs across into national military airworthiness regulations. The responsibility and timescale in which these harmonised approaches through the EMARs are implemented into national military airworthiness regulations is a decision for each participating Member State.

The following Member States are participating parties in the MAWA Forum (46):

Belgium	Bulgaria	Czechia	Germany
Estonia	Ireland	Greece	Spain
France	Croatia	Italy	Cyprus
Latvia	Lithuania	Luxembourg	Hungary
Malta	Netherlands	Austria	Poland
Portugal	Romania	Slovenia	Slovakia
Finland	Sweden	United Kingdom	

Military hardware products and assemblies also are subject to rigorous qualification requirements (see Figure C-1).

FIGURE C-1 MILITARY INTERNATIONAL AIRWORTHINESS FLEET RELEASE PROCESS

Once a configuration has been qualified to the requirements of the controlling state ministry or department with responsibility for military, changes cannot be made to the design or the manufacturing processes without requalification. As with commercial and passenger aircraft, for trivial changes where equivalence with the required standards can be demonstrated, requalification may be obtained without the need to resort to further testing. However, more significant changes that would affect the performance of a formulation or aerospace component used on the system typically would require testing and analysis to provide requalification.

Qualification and requalification of military aerospace assemblies can involve verification of performance to unique design parameters such as resistance to chemical agent decontamination fluids. Therefore, qualification and certification of a specific piece of hardware for passenger or commercial aerospace requirements do not necessarily guarantee qualification for a specific military use. Because of the stringent and unique requirements for qualification and certification, a formal process for technology readiness and manufacturing readiness is followed.

1.2 Design Complexity

Components in an aerospace system are designed and chosen to fulfil the specific functions required and therefore changes to these sub-assemblies or assemblies need to be done methodically on the design level as well as on the manufacturing level, so as not to negatively impact the overall assembly or end aerospace product. An improvement in one component is not necessarily beneficial for the whole system or component. The complex interplay of the complementary components needs to be re-evaluated, potentially entailing long approval periods. As with the polysulfide sealants, where a small change is feasible in principle, the implications can be significant and highly complex due to unforeseen consequences of the change. Time consuming and systematic implementation is required to minimise the possibility of failures and the serious repercussions they might cause.

Consequently, there is a connection between formulations used, processes, and hardware to ensure complete compatibilities of each element of a complex system and the performance of the sealant at all required levels must be considered. When assessing a reformulated sealant, the whole system must be considered, including all related manufacturing and maintenance processing steps.

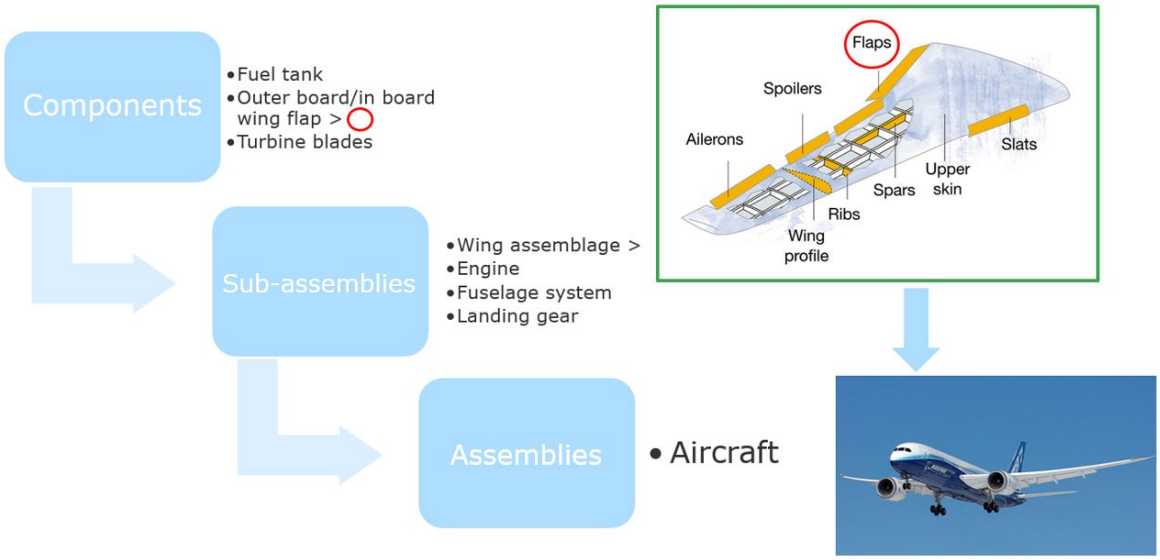

FIGURE C-2 ILLUSTRATION OF COMPONENTS, SUB-ASSEMBLIESS AND OVERALL ASSEMBLY

Reliable and safe operation of complex aerospace assemblies depends upon the proper functioning of a multitude of components and formulations, as shown in Figure C-2. Failure of even a single small component can lead to undesirable events. For example, in June 1999 an emergency landing of a Boeing 767-232 air carrier was initiated due to faults with the landing gear. It was found that total failure of the main landing gear retract actuator had occurred due to stress corrosion caused by sealant failure that allowed moisture to enter the joint. A factor was the use of an improper fillet seal (47). For this reason, all changes to the formulations, components, or manufacturing processes used in complex aerospace assemblies are subject to the highest level of scrutiny. No change is so minor that it does not require some degree of substantiation. Qualification (and certification, where required) of assemblies are applicable to a single specific configuration of components and formulations, assembled (or maintained) by a single set of manufacturing processes.

Formal processes are in place to manage the change and justifications/substantiations provided for the qualification and certification of the change evidence can take many forms.

1.3. Specifications in Aerospace Industry

Specifications in the aerospace industry are the primary mechanism of documenting the requirements formulations must meet or exceed to be used on aerospace hardware. The regulatory requirements and responsibility placed upon OEM companies drives the need for creation, implementation and maintenance of agreed industry and internal specifications relating to all elements of the component or formulations, which controls what is considered as acceptable to allow it to be used in aircraft manufacture.

Specifications set out explicit technical performance requirements, test methods, acceptance testing, and other characteristics that are based upon the results of research & development, and prior industry experience. They can also provide guidelines and criteria for formulation usage or method of applying the sealant to hardware and can include specific guidelines on formulation categories as well as more general specifications on raw materials for aerospace part manufacture (e.g. on steel welding, piping, aluminium sheeting etc. as well as for chemical products). The testing by the OEM that is required to be undertaken to show that formulations used meet the required specification criteria is termed, in the aerospace industry, as product qualification and certification and is described in ***Annex C- 1.6*** onwards.

Specifications can be OEM specific (e.g. if the OEM has different or more stringent requirements). Where industry consensus on requirements can be reached, this can form the basis of an industry standard for a formulation or component. One of the most widely used aerospace industry standards are the Society of Automotive Engineers (SAE) International Aerospace Materials Specifications (AMS), which are authored and maintained by different Aerospace Quality Committees of SAE International.

The US Military Defence Standards, shortened to MIL standards, are widely used in the military aerospace industry for formulation, component and process specifications, criteria, and technical requirements applicable when manufacturing products required for military contracts. However, these are not applicable when discussing polysulfide sealants containing NPE in the context of the AfA, so are not discussed further in this document.

Further details on specifications applicable to polysulfide sealants is in ***Section 4.3.4.2***.

1.4. Long in-service time / Life Cycle Stages of Aerospace Products

Service time of passenger or commercial aerospace assemblies is typically a minimum of 20-30 years and for military assemblies is typically a minimum of 40 years, during which these products must meet the highest possible safety standards for their entire working lives. The production of one type of aircraft may span more than 50 years. The longevity of aerospace products constrains the industry's ability to adopt changes in the short, medium, or even longer terms – especially for products that are already certified and are in operation.

A representative life cycle of a typical aerospace product – air transport (passenger) aircraft - is illustrated in Figure C-3. Such life cycles can be significantly longer than 50 years.

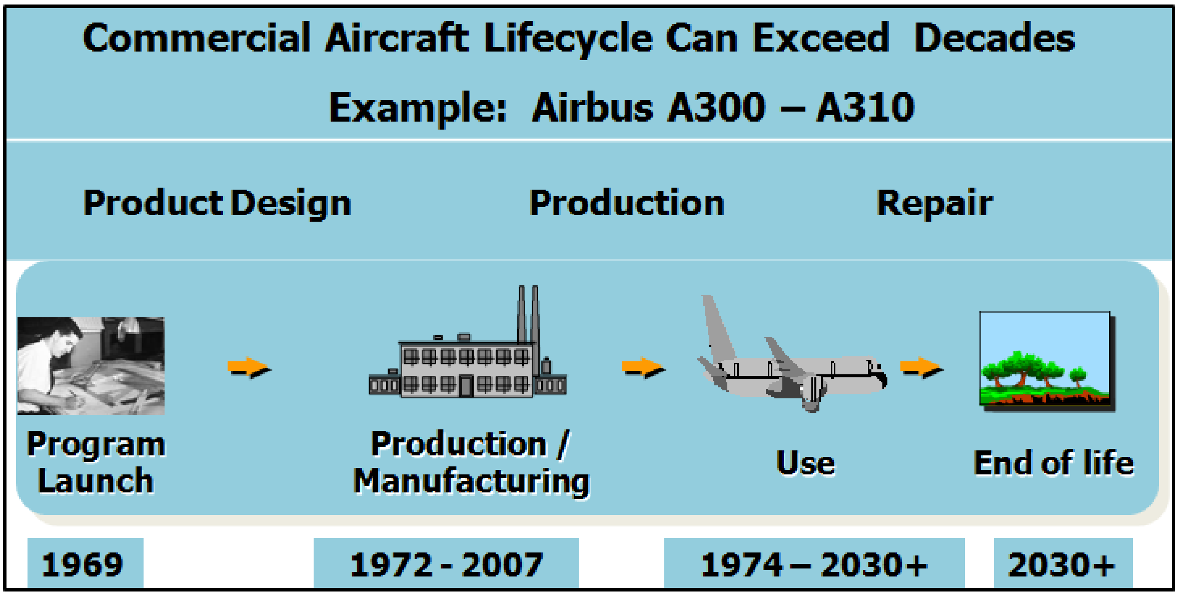

FIGURE C-3 COMMERCIAL AIRCRAFT LIFECYCLE (11)

Some key figures to be considered are the following:

- The development of a new aircraft can take up to 15 years.
- The lifespan of an aircraft is minimum 20-30 years and may span more than 50 years.
- New aircraft are not developed every year, but developed in accordance with lifespan of parts entered into service (approx. every 20 years)

Therefore, aircraft may be considered according to the following general categories:

- Operating aircraft
- Future aircraft for which airworthiness certification has not yet been achieved (11).

For aerospace assemblies, MRO activities in the industry is required at defined intervals, like the regular engine check requirements for road vehicles. This includes scheduled maintenance where an extensive overhaul of the entire aircraft is performed. Aerospace components are designed as parts of major assemblies (fuselage; wings; engines, etc.) and therefore must meet similar performance expectations of all components in that assemblies between overhauls. For example, a system designed to achieve 25,000 cycles (the number of take-offs and landings) between overhauls, in which a new component is installed rated for 5,000 cycles (because it is less durable or because its durability is not sufficiently evidenced), by default is de-rated to 5,000 cycles. This adds inherent inspection, maintenance, and repair costs to the operators/end use customers. Aerospace assemblies can also be subject to unscheduled repair activities, including on flight line, to continue functioning safely. This can, in turn, incur inspection and repair costs to operators/end use customers as well.

1.5. Long investment cycles

Technologies which are put on the market today are the result of extensive research, including those funded by grants from both private organizations and government, and conducted during the last 25+ years. Research and development (R&D) by its very nature, has a high risk of failure and the expected returns on investment are uncertain with long payback periods. In 2016, the European ASD industries spent in total €20 billion in Research & Development, one third financed by public funding and two third from its own funds (48).

1.6 Practical Implementation of Regulatory Requirements

In ***Annex C-1.1***, the regulatory requirements with which aerospace companies are required to comply were described, highlighting the responsibility that is placed on the aerospace OEMs to ensure that all elements that go into production of an aerospace product are suitable for purpose, safe for use and will continue to function as designed for the expected life of the product. In practical terms, this is implemented through stringent standards, testing, analysis, maintenance and inspection for all elements involved; from equipment such as engines and structural elements to, in this case, sealant formulations used to fulfil a specific function on the aerospace product. The regulatory requirements and responsibility placed upon OEM companies drives the need for creation, implementation and maintenance of agreed industry and internal specifications relating to all elements of the component or formulation. These specifications define what is required for component or formulation to be used in aerospace product manufacture. The specifications detail the criteria the formulation must comply with to be considered as suitable for use and can include details on testing that is conducted to verify if it meets the specified criteria. In the case of the aerospace industry, this is termed as qualification and is described fully in ***Annex C-1.7.3*** onwards.

1.6.1. Challenges of Managing Annex XIV substances in Aerospace products

The Applicant monitors REACH SVHC listings and other regulatory updates such as CoRAP etc. and reviews the substances in the raw materials used and the substances present in finished products. If a substance that is in a product or raw material has greater regulatory control imposed, the Applicant reviews whether the product can be substituted or withdrawn, whether the raw material will be modified by its supplier, whether reformulation of the product to replace or remove the substance is possible or as a last resort, seek REACH Authorisation for continuation of use until the substance can be removed from product formulations. New product development includes review of proposed new raw materials and whether they contain any known or proposed Substances of Concern.

The identification of a need for a design change may be triggered for many reasons. In the case of substances that are currently used in the production of aerospace products or used by airlines and MRO facilities of aerospace components, the trigger for a design change occurs when such substances are targeted for substitution by the formulator, which is often the result of a regulatory program (i.e. REACH Annex XIV), but also occurs through planned product development activities driven by other factors. Where possible the industry takes a proactive substitution stance, but this can create a large burden on members of aerospace industry where, alongside responding to REACH Annex XIV, it is no longer practical to continue with proactive substitution activities. Effectively, in some cases, REACH Authorisation can eclipse the aerospace industry's own substitution plans and priorities. Completely substituting or removing one substance from a product formulation may impact various components and assemblies and may involve many different performance requirements. Any health or environmental benefit of replacing the substance may be overshadowed by an increased safety risk if the performance of the replacement is not at least equivalent to the regulated substance. As such, product substitution or removal is not a trivial process and is only done methodically and following comprehensive testing.

When a substance is included on Annex XIV REACH, OEMs must assess the dependence upon the substance across the life cycle of aerospace products, including identification and assessment of significance of all the components containing or relying on that substance. Aerospace companies rely upon the composition information provided by the formulation manufacturer in the safety data sheet (SDS). This itself presents a massive challenge, considering the extensive number of formulators and formulations in use by OEMs, suppliers and MRO companies, and requires extensive qualification testing. This is even more difficult when multiple substance identifiers are in use, as in the case of NPE. Clear and open communication with formulators is needed to confirm which formulations are affected and currently in use. Formulators themselves rely on full disclosure from their raw material suppliers and so may need confirmation from several other parties to fulfil the information request from the OEM. There may also be instances where OEM companies will use formulations that are "commercial off the shelf (COTS)" or bought through distributors. Such products may be qualified for specialist applications in-house without the direct knowledge of the formulator.

Formulators with an Annex XIV SVHC in a formulation may plan to reformulate without visibility of all their downstream dependencies or uses of the formulation important to different customer sectors when it does not deal directly with all end customers. Generally, formulators have standard procedures for notifying customers whenever there is any change to the formulation or manufacturing process for formulations they deliver, and change can be due to a variety of circumstances (e.g. disruption in their supply chain, relocation of a manufacturing facility, etc.). Such notification is a requirement imposed by the standards organizations, and by the OEM customers. This is usually done by providing a brief statement on the change and would not typically include evaluating the potential impact of this change on all known end customers. In the case of polysulfide sealants, communication efforts are further hampered by aerospace industry typically having low volume usage of formulations, such as sealants and adhesives, compared to other industries. Therefore, the burden is on the aerospace OEMs, when a substance goes onto Annex XIV, to check how they are impacted and contact the manufacturers of the formulations before these are inadvertently reformulated or withdrawn from the market without knowledge of the industry. However, where it is possible and where the significance of the product in an industry is known, the formulator does engage with key OEM or specification holder customers in more detail regarding the change.

After identifying the affected formulations and processes, these are mapped against specifications and other design references to identify affected hardware and related assemblies to evaluate the impact upon current manufacturing or MRO processes. For OEM companies, this involves investigating which aerospace hardware/processes that the formulation containing the SVHC has been specified for use within, and which suppliers may also be using them (this may also include repair schemes that are carried out by third parties). This can be further complicated if a specification provides for more than one option e.g. if the SVHC is in a formulation and the specification details that it can be used on some substrates and not others, or for some applications only and not others. This evaluation requires contributions from numerous personnel across various departments of an aerospace company, including Materials & Processes, Research & Development, Engineering, Customer Service, Procurement, Manufacturing, Certification, as well as affiliates in other countries. As part of the impact assessment, some uses of the formulation(s) containing the Annex XIV substance may be found for which alternatives are readily available and would be suitable for use in all relevant applications (e.g. if there were an alternative product that would be suitable for use on all current substrates and applications). Where possible, this is the route that OEMs take, and they may only need to proceed with "fast track" qualification testing before implementation of the alternative formulation. An Aerospace AfA is only submitted when there are substances that cannot be eradicated from the OEM manufacturing processes and aerospace supply chain before the Sunset Date.

Current production aerospace components may have been designed 20 - 30 years ago (or more) using design methods and tools that are not easily revisited (e.g. these may no longer be in wide circulation, or commonly used), nor are they standardized between OEMs, so each company must undertake this assessment to evaluate the impact of the Annex XIV substance listing.

This highlights the challenges of managing Annex XIV substances in the aerospace industry and the different situational aspects that must be considered, prior to commencing qualification, validation and certification of an alternative product.

1.7 Formulation Development to Implementation in the Aerospace Industry

In this section, the general process for development of new/ reformulated sealants through qualification, validation, certification (where required), and industrialisation within the aerospace industry phases are described. There is a significant level of R&D by the formulator prior to putting the new/reformulated sealant through the above mentioned steps, which itself is an extensive internal approval process with many different steps from basic technology research up to technology demonstration in a lab environment, which if successful culminates in manufacture of the new/amended formulation and implementation by OEM customers (11).

The formulator develops products to meet the minimum requirements of its customers and tests to the required specifications. These specifications effectively represent the first 'gate' in the R&D process. New potential alternative sealants must be reformulated to pass the criteria of each testing phase before it can proceed to the next. If it does not pass the criteria, then further development of that potential alternative is not continued unless changes to the technology (e.g. sealant reformulation or process adaptation) are made to address the failures. Even if the formulation passes some key initial tests, additional mandatory tests which are performed in a second step may fail. Several loops are usually needed between early product development stages to adjust the formulation to answer successfully to a complete aerospace industry qualification programme.

It is the responsibility of the OEMs, as design authority or Type Certificate Holder, to ensure that formulations used in key applications, or on aerospace parts or assemblies, are suitable and safe for use, in accordance with the Airworthiness regulations as detailed in ***Annex C – 1.1*** and to agree the approach to certification (if needed) with certification authorities. For each individual change, OEMs must show compliance of the new formulation or process specification with the Airworthiness regulations, and for each subsequent use of the formulation or process specification, OEMs will manage the change under their own delegated privilege.

Each of these process phases can be closely aligned with the specific Technology Readiness Levels/ Manufacturing Readiness Levels originally developed by the US National Aeronautics and Space Administration (NASA). OEMs usually adapt this Technical/Mechanical Readiness Level approach resulting in individual versions, which are considered confidential and cannot be presented here. Technical Readiness Level phases answer the questions, "Can it be designed?" and Manufacturing Readiness Level phases answer the question, "Can it be manufactured?". A general overview is provided in Figure C-4. Technology and Manufacturing Readiness Levels are a standard framework for evaluating and communicating material, process, component or technology maturity during the discovery, development, qualification, validation, certification, and industrialisation phases. Technology Readiness Levels are based on a scale from 0 to 9 with 9 being the most mature technology. Manufacturing Readiness Level-related activities are more intensive in the later phases of the process after promising candidates have been identified (typically after TRL 3).

LEVEL	TRL Definition	MRL Definition
1	Basic principles observed and reported.	Basic manufacturing implications identified.
2	Technology concept and/or application formulated.	Manufacturing concepts identified.
3	Analytical and experimental critical function and/or characteristic proof of concept.	Manufacturing proof-of-concept developed.
4	Component and/or breadboard validation in laboratory environment.	Capability to produce the technology in a laboratory environment.
5	Component and/or breadboard validation in relevant environment.	Capability to produce prototype components in a production relevant environment.
6	System/subsystem model demonstration in relevant environment.	Capability to produce a prototype system or subsystem in a production relevant environment.
7	System prototype demonstration in relevant environment.	Capability to produce systems, subsystems, or components in a production representative environment (MRL 7). Pilot line capability demonstrated; ready to begin low-rate, initial production (MRL 8).
8	Actual system completed and qualified through test and demonstration.	Low-rate production demonstrated; capability in place to begin full-rate production (MRL 9).
9	Actual system proven through successful mission operations.	Full-rate production demonstrated and lean production practices in place (MRL 10).

FIGURE C-4 OVERVIEW OF TECHNICAL AND MANUFACTURING READINESS LEVELS STEPS IN PRODUCT DEVELOPMENT AND APPROVAL (FOR LEVELS 1-9) (49) (50) (51)

The Technical Readiness Level assessments guide engineers and management in deciding when a candidate alternative (a formulation or process) is ready to advance to the next level. The Technical Readiness Level approach addresses all dimensions of maturity and risks associated to:

- Performance & Integration
- Engineering
- Manufacturing (including industrialization)
- Operations (in-service)
- Value & Risks: identification of risks and opportunities, technical/industrial risks, impact on planning, applicable rules and regulations including Environment Health and Safety (EHS)

The starting point when launching an alternative qualification programme is the definition of requirements. Many requirements, in particularly technical requirements, are recorded in the specification documents (specifications, process specifications, process instructions, maintenance manuals). In the case of NPE replacement programmes, the performance requirements remain as documented in the relevant specifications. The alternatives will need to meet the same performance requirements as the existing sealants for each category (i.e., be interchangeable). Early in the process, technical experts establish basic success test criteria, and deliverables, in line with internal and customer specification documents, required to proceed from one level to the next. Similarly, the maturity of manufacturing processes is formally tracked using the Manufacturing Readiness Level process. Many companies combine the aspects of Technical and Manufacturing Readiness Levels in their maturity assessment criteria, as issues in either the technology or manufacturing development will determine production readiness and implementation of any new technology. It is important to note that, whilst these procedures are often aligned, they are separate and it is possible for a candidate alternative to pass a Technical Readiness Level requirement but not an Manufacturing Readiness Level requirement e.g. the candidate alternative may not spray as easily as the original product, so changes to spray equipment/processes may be needed before it can proceed to both the new Technical and Manufacturing Readiness Levels for further validation.

As the candidate alternative matures and it passes through the different Technical and Manufacturing Readiness Level stages, additional stakeholders become involved and the criteria are refined, or specific criteria are added, based on the relevant design and manufacturing requirements. In addition to the primary technical requirements, other requirements must be considered including, for example; design requirement (e.g. electrical conduction / insulation properties of the replacement coating.), industrial requirements (application means and conditions, compatible with pre/post processes, avoid single source, equivalent part cost, equivalent manufacturing lead time), EHS requirements etc.

Developing solutions usually necessitates several "reformulation & testing" loops before meeting the numerous requirements. There is no guarantee that the initial process to identify an alternative for a substance will be successful, and failure is possible at every stage of the process. The impact of failure can be significant in terms of time and resource, due to the iterative nature of the process.

In the case of chemical products such as polysulfide sealants, in the early development process, much of the initial research effort is conducted by the formulator, who carries out initial feasibility studies to assess the viability of potential alternatives before advising the OEMs of candidate alternatives that might be considered for more extensive assessment.

Once a new or reformulated sealant is provided to the OEM, each candidate formulation goes through an assessment process, typically based on Technical Readiness Level methodology as described previously. The goal for initial screening tests is to assess relevant physical properties and performance against a broad range of requirements (e.g., viscosity, hardness, adhesion strength, corrosion resistance etc.). The existing formulation in use also undergoes the same testing as a reference. If failures occur (e.g., unacceptable adhesion), a risk analysis is performed, and a decision is made to continue or end testing with that formulation. This decision process is repeated in further development testing with additional formulations provided by the formulator, until a suitable candidate alternative passes all the required Technical or Manufacturing Readiness Level testing.

For chemical formulations such as sealants, paints, primers etc. where variations may exist between production batches, it is standard practice for aerospace OEMs to repeat a series of physical property and performance testing on a minimum of 3 production batches. This is typically done in Technical Readiness Level 4 and 5. Separately from the production batch testing, chemical formulations are also tested for consistent performance over their stated shelf life and, if relevant, for reparability.

The Manufacturing Readiness Level process tests the manufacturability of hardware using the reformulation or new product. In case of chemical formulations this involves definition of use parameters/process steps in the manufacturing environment and in some cases, performance of hardware after the product is applied at a manufacturing facility. Manufacturing and procurement departments of aerospace OEMs develop the supply chain for the new/reformulated product in the later Manufacturing Readiness Level stages.

Figure C-5 provides an overview of these key phases of introducing a chemical substance change into production hardware manufacture. However, it must be noted that that this is an indicative illustration and not all companies use the same wording to describe each stage. For example, validation can be included in technical qualification in some cases.

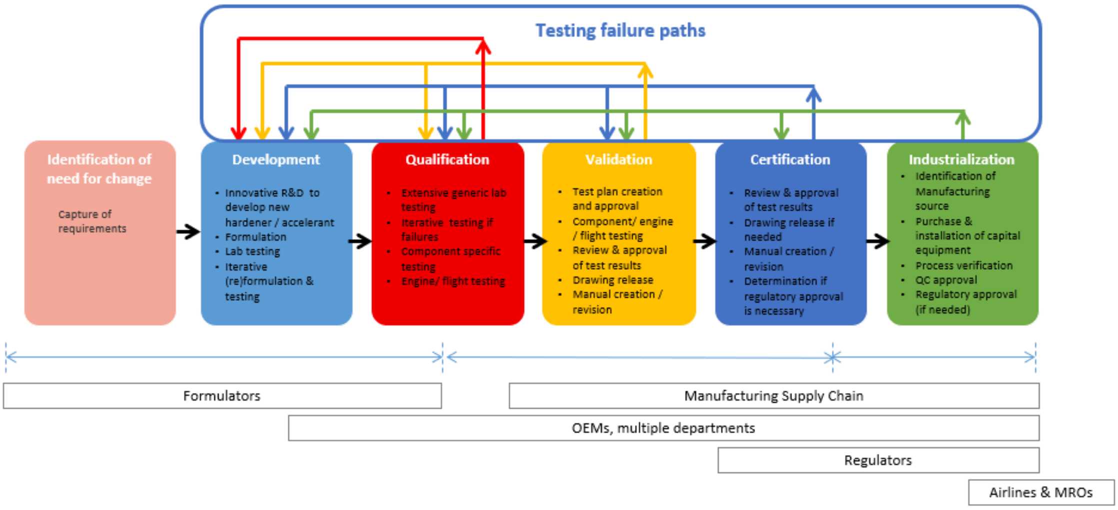

FIGURE C-5 KEY PHASES OF INTRODUCING A CHEMICAL SUBSTANCE CHANGE INTO PRODUCTION HARDWARE MANUFACTURE

In the case of the sealants containing NPE, compliance with specifications (see ***Section 4.3.4.2***), process specifications, process instructions, and maintenance manuals provides the evidence that the alternative sealant is interchangeable and thus is airworthy. As a result, there is no need for an additional certification step or validation from EASA or relevant military certification authorities. This is crucial, since additional certification or validation from the relevant authority involves a much more extensive effort associated with aircraft part design changes (e.g. drawing, part number, and/or name changes). The cost of such changes may be prohibitive.

Qualification through industrialisation is required to:

- Fulfil requirements of the Airworthiness Authorities (EASA).
- Ensure that only reliably performing formulations, components, and processes are approved for use to produce aerospace components.
- Ensure that the product, the process or method is compliant with both Industry Regulations and aerospace component manufacturer requirements to fulfil specified functions.
- Provide a very high level of confidence for both the use of the formulation or component and the resulting aerospace end components.
- Ensure consistent quality of formulations being introduced.
- Ensure consistent use of the new or alternative formulation, and to guarantee production and management system robustness, throughout the supply chain.

The qualification compliance documentation will be issued only when the qualification test campaign has demonstrated that the candidate alternative sealant meets the performance requirements as per the relevant specifications. Once the qualification compliance documentation is available, the implementation phase at manufacturing plants and at suppliers can begin. The sealant can then be used on the aircraft and industrialized in production following relevant internal procedures to trigger the change of product.

For example, some OEM companies issue internal confirmation of compliance with qualification documents when the qualification tests have been completed and results clearly demonstrate that alternative sealant meets the performance requirements as per the relevant specifications, process specifications, process instructions, and maintenance manuals. The technical qualification is usually followed by an industrial qualification of the Applicants production site to ensure compliance with quality standard EN9100 (e.g. check reproducibility criteria) via a first article inspection (first commercial batch). Once all compliance documentation is available, the deployment of the alternative reformulated sealant in OEM manufacturing plants and at suppliers can begin. The product can then be used on the aircraft or aerospace equipment and industrialized in production following relevant internal procedures to trigger the change of product.

The following sections describe the key steps of the entire process from the requirements capture that takes place before technology development begins through to implementation.

It is important to note that the industrialisation step refers to the whole supply chain. This includes external as well as internal industrialisation and poses its own challenges, which is discussed further in ***Annex C – 1.7.5***.

1.7.1. Development of New/Alternative Formulations

The development of a formulation is complex, and several years are often necessary. Once a reformulation or substitution project is launched, technical specialists, from engineering and manufacturing departments, must align the numerous regulatory, performance and technical requirements that an alternative must fulfil.

In many cases, requirements are identified that introduce competing technical constraints and lead to complex test programmes which can limit the evaluation of alternatives. Some formulations may have different performance specification requirements depending on the end usage (e.g. sealant used as adhesive and electrical potting compound may have different key requirements) and these may vary widely.

Requirements that need to be considered (but may not be limited to) include:

- Process requirements (e.g. viscosity, cure time)
- Design requirements (e.g. size, shape, weight, time to overhaul etc.)
- Performance requirements (e.g. corrosion resistance, adhesion strength)
- Industrial requirements (e.g. robustness and repeatability)
- Environment, Health & Safety (EHS) requirements

The defining of requirements is a complex activity to undertake and require a significant timeframe. The complexity can be due to:

- Wide range of uses of the product and therefore different technical requirements that must be met
- A potential alternative having unexpected differences in performance compared to the original formulation, e.g. viscosity is within the specified acceptance criteria, but an unacceptable difference in electrical conductivity is observed. This will lead to different testing requirements being defined.

- Reproducible testing and feedback to understand technically the differences between the alternative and the original at the laboratory scale is necessary to be able to define the acceptance criteria for the alternative.
- Requirements from raw material suppliers that may have an impact on the final formulations.
- Requirements from OEM that may have an impact on the final formulation
- Evolution of chemical regulations.

Technical requirements that the NPE polysulfide sealants must meet or exceed are defined in the relevant specifications and form the requirements baseline for the replacement programme which reformulated NPE-free polysulfide sealants must at least meet to demonstrate equivalent sealant performance.

Once initial technical requirements are defined, potential solutions can then be identified and tested. Note that requirements may be added and continue to be refined during the different levels of development and alternative maturity. In the case of NPE sealants, these requirements were initially defined during qualification of the current formulation and further refined through decades of subsequent in-service performance.

In the development of new formulations, or changes to an existing formulation, it is important to note that many iterations are rejected in the formulator's laboratory and do not proceed to OEM evaluation. It can typically take 1-3 years (and can be up to 5 years) of testing new formulations or amended formulations before a potential alternative is considered mature enough to provide samples to OEMs as the main candidate alternative to commence qualification testing. Some initial testing of different product iterations can be done collaboratively between the Applicant and OEM or tests can be conducted in series, as described in Figure C-6. In the case of providing candidate alternative polysulfide sealants without NPE to OEMs to commence qualification testing, this development stage has been ongoing since 2017 is expected to be concluded by Q2 2021, as discussed further in ***Section 5.1.2.3***.

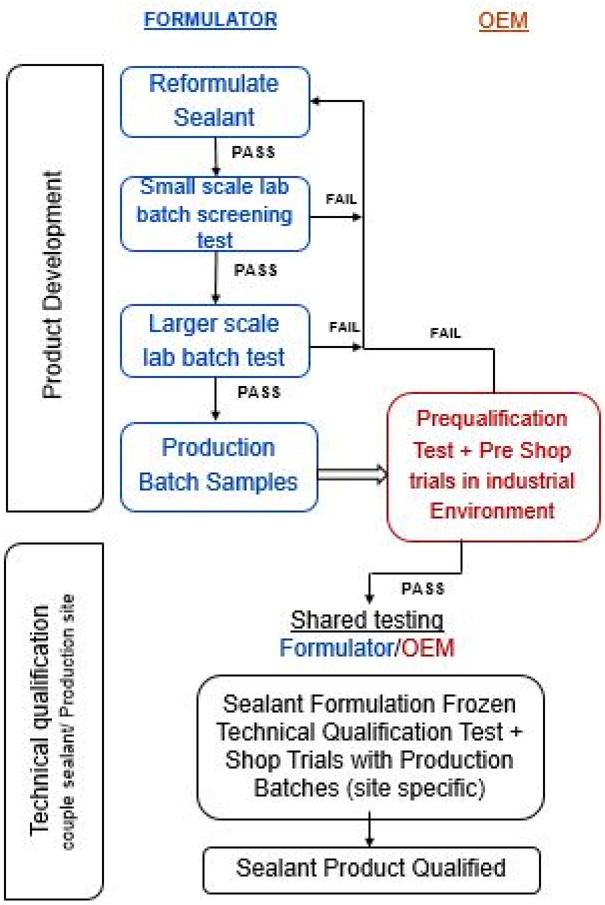

FIGURE C-6 TESTING PROCEDURE BETWEEN FORMULATOR AND OEM

Further detail on this process is provided in the "elaboration" document (11).

1.7.2. Qualification

Qualification is the process under which it is established whether a formulation, process, component or equipment has met or exceeded specific performance requirements, as documented in the technical standard or specification relevant to that formulation, process or component.

Qualification testing may include more general requirements (e.g. standard adhesion and temperature resistance testing). Validation testing becomes more specific to the design and operational parameters, (physical and environmental conditions that are relevant for an aerospace component while in-service) and begins after successful completion of initial qualification testing. The operational condition parameters include, but are not limited to; fluid exposures; external environment including temperature extremes, humidity, wind/rain erosion, etc.; functional characteristics; service life requirements; etc. These parameters are specific to each individual component and each individual use of a component. They can therefore vary between company and application.

Qualification and validation testing ranges from laboratory testing to testing using methods to simulate performance in a 'relevant environment' that is designed to emulate lifetime performance, for example, exposure to humidity and thermal cycling and unaffected by fluids likely to be present in the part location.

Extensive industrial trials in a production environment will also be needed to confirm shop floor acceptance of the reformulated sealants and ensure minimum disruption during deployment in manufacturing plants. These usually consist of several checks for key process parameters such as mixing ability, appearance, curing time, roller or brush application in different positions, fillet application, covering of fastener, reparability, shrinkage etc.

Qualification typically involves many individual testing runs, under different relevant conditions. For example, sealant peel strength testing can be conducted dry or under different fluid immersion conditions (e.g. water, jet fuel etc.) or durations (see ***Section 4.3.4.1*** for testing parameter descriptions). The exact detail and nature of the qualification testing procedures required is dependent on the individual OEM and the formulation undergoing qualification. After initial laboratory testing, each specific use must be reviewed (e.g. use as aerodynamic coating, use as a fuselage sealant, use as an adhesive etc.). Depending on the complexity of the changes, the qualification process may require more than 100 iterations on any test (e.g. under different conditions).

Appropriate due diligence must be exercised, and risks understood before replacing a formulation that has proven field experience, especially as some inaccessible locations cannot be inspected for the entire life of an aircraft (11).

Specifications, as a practical means of enabling manufacturing process quality control and acceptance testing of production batches, typically require a short duration test that can identify common defects in processing but are not suitable for initial alternative validation acceptance criteria. To reach consensus, the requirements may be less stringent than those required by individual companies. In such cases, an individual company will modify an industry standard, creating company-confidential specifications with more stringent and specific requirements to meet their product needs and regulatory requirements. These company specifications, and testing required, are confidential. In very few cases, are the industry standards sufficient to meet all OEM requirements, thus the reliance upon company specifications. For example, there are over 22,000 Aerospace Standards (AS) and Aerospace Materials Specifications (AMS) held and maintained by SAE International, but even so OEM companies have their own specifications as well, including members of EAAC.

For these reasons, qualification typically requires 1- 2 years to complete, depending on the ease of meeting all the performance requirements that were established. This duration estimate assumes that the qualification process is successful, which may not always be the case.

As mentioned in the previous section, qualification testing by the OEM is expected to be able to commence once candidate alternative NPE-free polysulfide sealants are available from the Applicant in Q2 2021. In line with best estimates about the degree of testing that will be required, including a risk margin of safety, the qualification stage is expected to be able to conclude by Q4 2022 as discussed further in ***Section 5.1.2.3***.

1.7.3. Certification

Certification is the process under which it is determined that all components of an aircraft comply with the safety, performance and environmental requirements in accordance with the Type Design of the aerospace product as approved by the relevant Authority. This ensures compliance of the aerospace product with the applicable airworthiness and military regulations.

Product improvements, improved manufacturing processes, new regulations (including those such as new authorisation requirements under REACH), customer options, or the need to perform certain repairs may drive changes to the approved type design. Any changes to the approved design must be shown to be compliant with the applicable airworthiness or military requirements. This means that when new formulations or design changes are introduced, a review of the new aspects of the changed formulation or design that could affect the certification of the aerospace product and must be compared to the original data used to demonstrate compliance for applicability and validity by the certification holder and relevant Authority. If the changes are determined to be equivalent or better, the design change is certified, and the change can be implemented.

However, as mentioned in ***Section 4.3.4***, the certification process may not be required if it is acceptable to demonstrate technical equivalence between the previously qualified and certified sealant and the alternative sealant.

The approval step by certification authorities may not be required if it is possible to demonstrate technical equivalence/interchangeability between the previously qualified sealant and the alternative reformulated sealant via laboratory testing and no changes to the drawing are required. Per the Aerospace and Defence Industries Association of Europe's (ASD) *REACH Design Changes Best Practices* guidance document, "Interchangeability can be understood, for example, as absence of impact on Form, Fit, Function." "This demonstration should be performed on a back to back basis with the existing material solution, to demonstrate that there is no regression of the new material performances. When non-regression of the new material is demonstrated by the back to back tests with the existing material, then the substitution solution can be added as an alternative in the existing material specification (= universal interchangeability)."

For polysulfide sealants containing NPE, the reformulation without NPE is not expected to result in any changes to the properties of the sealant. Based upon this and the testing data provided by the formulator, it is expected that it will be possible for OEMs to demonstrate interchangeability between the original and reformulated sealants. Assuming success, OEMs will only need to conduct testing to confirm that the reformulated sealant has the same properties as the current sealant containing NPE. Compliance of reformulated sealants to the relevant OEMs' proprietary specifications will provide assurance that the sealant will perform in the same way as the currently used sealants. In this event, there will be no need for an additional certification step from EASA and the alternative can be considered as a one to one replacement.

	Paths: 1	2	3
Change context	Materials interchangeable for any part	Materials interchangeability limited to these parts	Loss of material interchangeability for these parts
Impact on **material spec**	Material interchangeability is managed at the spec level*	As many spec as materials	As many spec as materials
Impact on **drawing**	No change	Drawing of these parts shall call out the interchangeable materials	Drawing of these parts shall call out the relevant material (with potential consequential impacts on parts drawing)
Impact on **part number**	Not changed for any part	Not changed for these parts	Changed for these parts
Mean of traceability	On production documentation	On production documentation	On drawing

FIGURE C-7 MATERIALS CHANGE PATH (13)

Figure C-7 highlights the progressive complexity of materials substitution from a change that is deemed interchangeable for any part (least complex) to a change where a unique alternative is required for all uses and no interchangeability is allowed (most complex)." (13). As no component design changes (e.g. no drawing, part number, or name changes), are expected in the case of the reformulated sealants, the changes at OEMs are anticipated to fall in Path 1, as in Figure C-7 above. The newly qualified sealants are expected to perform in the same way as current sealants and to follow the existing process instructions. Interchangeability is achieved where the alternative product is proven to be a one to one replacement, and Path 1 is followed. (Re)Certification will not be required if no change to the specifications are necessary.

If any OEM determines that a formulation does not meet technical equivalence/interchangeability, the change cannot be considered a one to one replacement, and it may be necessary for the OEM to undertake the full certification process, following Path 2 or 3 in Figure C-7 above, prior to industrialisation and implementation on the aerospace component.

1.7.4. Industrialisation

Aerospace products consist of thousands to several million components provided by thousands of suppliers or manufactured internally by OEMs, and communication between OEM companies to the supply chain on what is permissible for use on aerospace products is key. In addition to formulations and processes, suppliers must also be vetted and go through a supplier qualification process prior to being utilized. Supplier qualification typically involves internal approval, contract negotiation and undertaking an audit on potential risks of working with a supplier. A condition of working with a supplier can be requesting that the supplier signs up to a manual or code of conduct for that OEM, to ensure expectations for work and awareness of standards compliance is achieved. Once the supplier is qualified, this is documented and periodically audited to ensure continued compliance with specifications and standards.

For a formulation change, significant investment, worker training, and manufacturing documentation may be required to adapt the manufacturing processes, which sometimes require changes in existing facilities or the construction of new facilities or switching to a different facility (including a different supplier's facility).

Industrialisation may be scheduled to follow a stepwise approach to minimize the technical risks and to benefit from lessons learned, and therefore changes may not be implemented simultaneously across all sites and at all suppliers but rather via a phased introduction. Each OEM may operate dozens of manufacturing sites / final assembly lines worldwide.

For existing production, long-term agreements are often in place with suppliers. When a change is made to a product design to incorporate a new alternative, the contract with the supplier may need to be renegotiated. Additional costs and time delays may be incurred by the supplier when modifying a production process and/or introducing a new process. These may include purchase and installation of new equipment, training of staff, internal qualification of the new process, OEM qualification of the supplier, manufacturing certification of the supplier, etc.

As an aircraft is comprised of many different components and assemblies, there is the strong possibility that these different components are provided by different suppliers, e.g. the manufacturers of the engine vs. the manufacturers of the wing components may not be the same company, and each of these likely use many suppliers to provide sub-assemblies to them as well. Therefore, the replacement of a formulation in the industrialisation stage is complex and can involve many tiers of the supply chain that provide components that go into the aerospace product. As such, the entire supply chain may be impacted by the change to the alternative formulation, which must be implemented in accordance with the stringent safety procedures in place. In the case of alternative products to the NPE sealants currently in use, there may be no clear single alternative to replace all the current sealant usage throughout all components of the aircraft, which could result in increased complexity of manufacturing and repair solutions. The NUS for polysulfide sealants are discussed further in ***Section 5.4***.

The timeframe for industrialisation for the qualified alternative sealant is estimated to take up to 18 months, so is estimated to complete by Q2 2024 at the latest. Although the Formulator Applicant and supporting OEMs are believe that the alternatives for sealant formulations covered by this Application for Authorisation will be straight forward to industrialise, surety of success cannot be guaranteed until all the testing, evaluations, and implementations has been completed, which may take longer than estimated.

1.7.5. Implementation at customers and maintenance, repair and overhaul facilities (MROs)

Implementation of alternatives necessary for repair schemes used by customers (e.g., airlines, Ministry of Defence, etc.) and Maintenance, Repair and Overhaul facilities (MROs) further requires that such alternatives be approved and certified and documented in the maintenance and repair documents or notice that a document change is not required and confirmation that use of a one-to-one replacement is acceptable. Alternatives must be suitable for both scheduled and unscheduled maintenance and repair activities. Maintenance and repair activities on in-service hardware are more complex, due to restricted access to hardware as compared to access during manufacture and assembly.

During initial manufacture all the components of the system are in a pristine and relatively clean condition, whereas during repair and maintenance the components are likely to be contaminated and suffering from some degree of degradation. Furthermore, certain cleaning and surface preparation techniques that are readily available during initial manufacture may not be available or practical during repair and maintenance. These factors are important with respect to sealants and coatings, as their performance is strongly dependent upon the condition of the surfaces to which they are applied. For example, gaining access to the inner fuel tank where the sealant is present is more difficult during MRO activities compared to during manufacture, when the components are in components not yet set into the final assembly of the aircraft. As such, all these conditions must be addressed in the implementation of alternative formulations in the MRO process.