ANALYSIS OF ALTERNATIVES

&

SOCIO-ECONOMIC ANALYSIS

Public version

Legal name of applicant(s):	EURENCO
Submitted by:	EURENCO
Substance:	1,2-Dichloroethane EC number: 203-458-1 CAS Number: 107-06-2
Use title:	Use-1 Industrial use of 1,2-Dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, an energetic oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.
Use number:	1

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LIST OF ABBREVIATIONS

AfA	Application for Authorisation
B	Billion (amount/quantity)
DGA	Direction Générale de l'Armement *French Armament Procurement Agency - French Ministry of Defence*
CMIC	Critical military industrial capabilities
DALY	Disability-Adjusted Life Years
EDC	1,2-Dichloroethane
FReD	Fonds pour la restructuration de la défense *Supporting funds for the restructuration of the defence industry*
GAP	Glycidyl Azide Polymer
INSEE	Institut national de la statistique et des études économiques *National Institute for Statistics and Economics Studies*
k	Thousands (amount/quantity)
M	Million (amount/quantity)
PECH	Polyepichlorohydrin
PPS	Permanent Posture of Security
SGA	Secrétariat Général pour l'Administration *General Secretariat for Administration - French Ministry of Defence*
SNPE	Société Nationale des Poudres et Explosifs *National Society for Powders and Explosives*
STANAG	Standardised Agreement
WTO	World Trade Organisation
YLD	Years lived with disability
YLL	Years of Life Lost due to premature mortality

1. SUMMARY

CONTEXT

EURENCO is a leading European company for military explosives, propellants and combustible items, as well as explosives for the civil sector (oil & gas perforation, mining) and additive for diesel fuel. EURENCO employs 900 employees and generated € 220M of revenues in 2014.

EURENCO uses 1,2-Dichloroethane (EDC) in the synthesis of Polyepichlorohydrin (PECH), a precursor subsequently used in the production of Glycidyl Azide Polymer (GAP).

GAP is an energetic oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives. GAP is used by several customers of EURENCO in two types of applications: rocket solid propellants and submarine rescue systems.

EURENCO is the sole producer of GAP in the European Union. Given its performances, notably in terms of specific energy and insensitivity, GAP constitutes a very strategic product, both for EURENCO and for its customers.

SUBSTANCE FUNCTION

Key functions of the substance include:

- solubilisation of raw materials of synthesis of polyepichlorohydrin (epichlorohydrin, 3-chloro 1,2-propanediol, trichloroacetic acid and tin tetrachloride),
- solubilisation of polyepichlorohydrin,
- chemical inertia toward reagents,
- controlled water content and acidity,
- non-miscibility with water,
- controlled boiling point.

IDENTIFICATION OF ALTERNATIVES

Through its extensive research works led in partnership with its customers, EURENCO identified three potential alternative solvents to EDC: [redacted](#1a) (*Alternative 1*), [redacted](#1b) (*Alternative 2*) and toluene (*Alternative 3*).

On the one hand, these potential alternatives appear promising in terms of functional properties and are expected to be developed, tested and industrially implemented in 2021.

Alternative 1, Alternative 2 and Alternative 3 are class 2 CMR substances and appear to either provide an adequate control or an overall reduction of risk as compared with EDC. As of today, and taking into account CMR properties of these substances, this substitution step however does not qualify as an acceptable long-term option. It is therefore considered as a temporary solution allowing pursuing the production of GAP and satisfying customer requirements during the period of time needed for the development of a sustainable alternative.

On the other hand, EURENCO is thus engaged in a research project aiming at a complete reengineering of the synthesis process of GAP with human health as a main criterion. Such a redesign constitutes a major innovation step and will be developed from scratch. This substitution strategy is considered as a promising solution for a low human health and environmental risk synthesis of GAP.

To achieve this goal, a long-term research program was validated, in partnership with DGA, the French Armament Procurement Agency, which will lead to several consecutive 3-year studies (doctoral or post-doctoral positions). Taking into account development, testing, validation and industrialisation steps, such synthesis process is expected to be industrially implemented in 2024.

"APPLIED FOR USE" AND "NON-USE" SCENARIO

In the "applied for use" scenario, EURENCO will pursue the use of EDC in the synthesis of PECH and will therefore be able to pursue the supply of GAP to customers.

In the "non-use" scenario, EURENCO will cease use of EDC as of 2017/11/22, therefore disrupting the supply of GAP for its customers between 2017 and 2021, subsequently followed by a substitution by Alternative 1, Alternative 2 or Alternative 3.

IMPACTS OF GRANTING AUTHORISATION

The main impacts of the "applied for use" scenario include costs related to the medical treatment, morbidity and mortality associated with the excess of risk of cancer arising from the exposure to EDC of workers over the review period.

The total monetised impacts of the "applied for use" scenario amount to € 4.1.

Main monetised impacts of the "non-use" scenario include the loss of profits and the loss of investments.

The total monetised impacts of the "non-use" scenario amount to € 659k.

Based upon the present assessment, the socio-economic benefits outweigh the risks arising from the use of the substance by a factor of approximately 160,000.

In addition to monetised impacts, the "non-use" scenario involves contractual penalties, indirect impact on employment, loss of investments for the French State, loss of revenues for EURENCO's defence industry customers and will have an impact on operational availability of defence applications systems for French, German and foreign armed forces.

CONCLUSION

Based on the argument put forward, and in order to develop, implement and qualify an alternative solution for Use-1, EURENCO applies for a four-year review period.

2. AIMS AND SCOPE OF THE ANALYSIS

EURENCO uses 1,2-Dichloroethane (EDC) in the synthesis of Polyepichlorohydrin (PECH), a precursor subsequently used in the production of Glycidyl Azide Polymer (GAP), an energetic oligomer with hydroxyl terminations used to increase the energetic performance of propellants, high explosives and powders.

The aim of the present document is to provide a detailed presentation of both the Analysis of Alternatives and Socio-Economic Analysis parts of EURENCO's Use-1 Application for Authorisation (AfA), i.e:

- to provide a comprehensive understanding of the context of the AfA,
- to describe EURENCO's research works for alternatives, potential alternatives and substitution strategy,
- to provide a comparative assessment of the monetised impacts of the pursued use of the substances ("applied for use" scenario) and the impacts of the denial of an authorisation ("non-use" scenario).

→ *Scope in a nutshell*

EURENCO is a leading European company for military explosives, propellants and combustible items, as well as explosives for the civil sector (oil & gas perforation, mining) and additive for diesel fuel.

Created in 2004, the history of EURENCO (formerly known as "SNPE", standing for "Société Nationale des Poudres et Explosifs", since 1971) began in the 14th century, in the form of the French State's monopoly on explosive powders.

Key figures of EURENCO's activity for 2014 include:

	EMPLOYEES	REVENUES
Global	900	€ 220M
Sites of Sorgues	276	≈ € 100M
Related to Use-1	6	≈ € 1.5M

Table 1. Main figures of EURENCO's activity in 2014

The company's implantations are the following:

Figure 1. Geographical location of EURENCO's sites
Headquarters (Paris), plants (Bergerac, Sorgues and Karlskoga), commercial office (Washington DC) and distribution company (Houston)

In the context of the present AfA, EURENCO uses 1,2-Dichloroethane (EDC) as a solvent in the synthesis of Polyepichlorohydrin (PECH), a precursor subsequently used in the production of Glycidyl Azide Polymer (GAP)[1]. GAP is an energetic oligomer with hydroxyl terminations used to increase the energetic performance of propellants, high explosives and powders used with firearms[2].

Main required chemical and functional properties of EDC as a solvent in the synthesis of PECH comprise:

- solubilisation of raw materials of synthesis of polyepichlorohydrin (epichlorohydrin, 3-chloro 1,2-propanediol, trichloroacetic acid and tin tetrachloride),
- solubilisation of polyepichlorohydrin,
- chemical inertia toward reagents,
- controlled water content and acidity,
- non-miscibility with water,
- controlled boiling point.

The batch synthesis of PECH is carried out by EURENCO:

- in a single facility at the site of Sorgues (Vaucluse, France),
- for a total duration of less than one month per year (22 days in 2015, 15 days in 2014),

[1] Also known as : "Glycidyl Polyazide" or "Poly(Glycidyl Azide)"

[2] Association Française de Pyrotechnie, Dictionnaire de pyrotechnie, 6ème édition, 2008

- by a total of six operators distributed over two to three 8hr-shifts.

EURENCO's use of EDC for the synthesis of PECH amounts respectively to 1.0 and 2.5 tons for the last two campaigns of 2014 and 2015.

Personal protection equipment is worn by operators all along the process. The synthesis is mostly conduced in closed systems, thus reducing the potential exposure of workers to a few manual operations over the overall synthesis duration. Exposures and emissions to water are monitored according to the French labour code as well as other regulations in force[3].

Sampling and laboratory testing demonstrate the absence of EDC in the PECH at the end of the reaction, therefore eliminating any risk of exposure during the synthesis of GAP or during the manipulation of PAG by EURENCO's customers for their applications.

Eurenco is the sole producer of GAP in the European Union, making the company a strategic supplier for its customer, notably in the context of defence, where sovereignty matters and security of supply play a major role in the design, development and manufacture of applications.

In addition, the type of GAP synthesised by EURENCO (GAP-diol) is very specific as compared with other manufacturers producing GAP-triol as the exact functional properties of EURENCO's GAP are the result of a long-term process of adaptation to the customers' exact expression of needs. Substituting by a potential alternative would therefore entail extensive research, development and modification works from both the producer and the customer in order to attempt to adapt GAP's final properties to the requirements related to its applications.

Given its performances notably in terms of specific energy and insensitivity, GAP is considered as a very promising product and is poised for a significant growth in a mid-term future. It therefore represents a very strategic application, both for EURENCO and for its customers since it is expected to occupy a central place in the company's portfolio.

[3] Articles R4412-1 to 31 of "Code du travail" (protection of workers against chemical risks), articles R4412-59 to 81 of "Code du travail" (protection of workers against CMR risks), article R4412-27 alinéa 1 for ACD et R4412-76 alinéa 1 for CMR) for substances with a regulatory and limit value for which a methodology is defined in the arrêté du 15 Décembre 2009 and Directive 2006/11/CE.

2.1. Supply chain

The global supply chain of EDC for the synthesis of PECH and GAP as well as its application by EURENCO's customers can be described as follows:

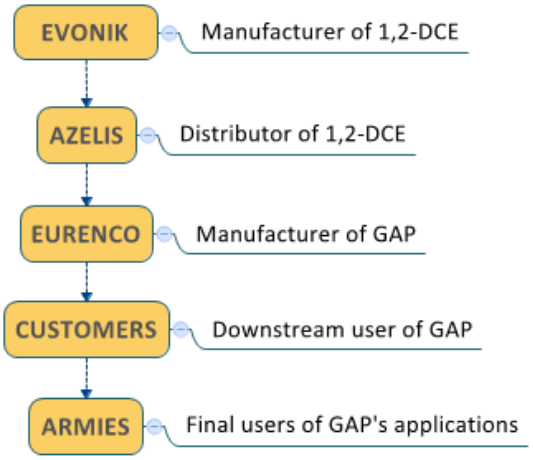

Figure 2. Supply chain of GAP in the context of the AfA

Downstream users of GAP are industrial companies of the defence sector, implementing GAP in their applications, be it in the production of missile propellants or submarine rescue systems.

2.2. Applications of GAP

2.2.1. Global context: need for more powerful yet insensitive explosives

The main challenge in the development of advanced solid propellants, gun propellants and explosives lies in the pursuit of two conflicting properties: **increased performance** (high specific impulse to meet operational requirements of the applications) in conjunction with **reduced vulnerability** (sufficient chemical stability to withstand mechanical shocks or fire and therefore offer a high level of safety during transportation and handling).

A general definition of Insensitive Munitions has been proposed by the US Chief of Naval Operations[4]: "Insensitive Munitions are those that reliably fulfil their performance, readiness, and operational requirements on demand, but are designed to minimize the violence of a reaction and subsequent collateral damage when subjected to unplanned heat, shock, fragment or bullet impact, electromagnetic pulse or other unplanned stimuli."

[4] CNO Executive Board (CEB) on Insensitive Munitions briefing book dated 29 March 1984

The UK Ordnance Board Proceeding 42657 summarized the potential benefits of Insensitive Munitions as follows[5]:

"In Wartime.

- Improved survivability of weapon systems and platforms as a result of reduced levels of damage caused by enemy strikes or credible accidents.
- Reduced casualty rates and mission losses.
- Reduced losses of ammunition as a result of enemy strikes on, or credible accidents in, magazines and storage areas.

In Peacetime.

- Reduced risks in storage leading to better utilization of and a probable reduction in both the number and size of storage areas.
- Reduced risks in handling and more economical use of transport.
- Reduced damage from accidents and hence, relaxation of restrictions applied to achieve an acceptable level of safety."

2.2.1.1. Illustration: the French policy toward insensitive munitions

The French policy on insensitive munitions[6], referred to as "MURAT" for "*Munitions à Risques Atténués*"[7], was approved in 1993 and identifies three labelling categories for insensitive munitions, according to the acceptable reaction level for each type of stimuli[8].

This policy was updated in 2011[9], acknowledging the Ministry of Defence's requirements in terms of munitions insensitivity. Key points of the French policy comprise that:

- STANAG 4439 "Policy for introduction and assessment of insensitive munitions (IM)" reference requirements are to be specified in all new acquisitions;
- Any waiver to the MURAT reference requirements must be justified using hazard and risk based analysis methods.

The French example illustrates the growing requirements in terms of insensitivity of munitions. This tendency is observed within all major armies.

[5] Beauregard, The history of Insensitive Munitions - www.insensitivemunitions.org

[6] DGA Décision # 101087 du 4 Août 1993; Objet: Sécurisation des munitions conventionnelles.

[7] "Low vulnerability ammunition"

[8] Instruction no 0260 DGA/IPE, "Doctrine Nationale Française en Matière de Munitions à Risques Atténuées", Édition de Juillet 1993. Via : www.insensitivemunitions.org.

[9] MoD's Instruction n°211893/DEF/DGA/INSP/IPE

2.2.2. Introduction on solid propellants

Solid propellants are the widest spread solution to the aforementioned requirements of performance and insensitivity. Thanks to their simple configuration, solid propellants offer a long shelf-life (to endure a long period of storage, typically decades) and a minimum of maintenance[10].

In order to achieve such insensitivity properties, cast-cured polymers have been developed, in which the explosive ingredient is suspended in a polymeric binder, cured in-situ as an elastomeric rubber which absorbs and dissipates the energy from hazardous stimuli. Binders are typically cross-linked polymers providing a matrix to bind the solids together with a plasticiser so as to improve the mechanical properties of the final composition[11].

Solid composite propergols are therefore composed of a binder in which an oxidiser load is dispersed, of a powerful reducing agent and different catalysts and/or additives such as ballistic or combustion catalysts, preservatives, plasticisers, curing catalysts, etc.

The binder has to deliver two main critical properties for the proper operation of solid propellants: provide sufficient **mechanical properties** for the overall applications' requirements in terms of mechanical resistance or insensitivity as well as contribute as an **energetic polymer** during combustion. The current state of the art for binder technology enables to achieve such properties with the reaction of a prepolymer and a curing agent[12].

GAP is an energetic binder. Energetic binders, as opposed to inert binders, contribute to the combustion mechanisms by an increase in overall enthalpy[13]. They are therefore being currently investigated for the development of innovative propellant solutions.

2.2.3. Specific properties of azido polymers

GAP is a highly energetic and low-molar-mass (≈ 2,000 g/mol) liquid prepolymer which was mainly developed during the last decade as an energetic binder for the preparation of highly energetic, high-burning-rate, chlorine-free smokeless solid rocket propellants. GAP offers an outstanding combination of thermal stability and insensitivity properties[14].

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[10] Hagen, Energetic Binders for Solid Rocket Propellants, Master Thesis 2014, Norwegian Univsesity of Life Sciences, Faculty of Veterinary Medicine and Biosciences Department of Chemistry, Biotechnology and Food Science, 2014

[11] Provatas, Energetic polymers and plasticisers for explosive formulations-A review of recent advances (No. DSTO-TR-0966). Defence Science and Technology Organisation Melbourne (Australia), 2000

[12] Ibid. 10

[13] Enthalpy is ususally chosen to express system energy changes in many chemical, biological, and physical measurements at constant pressure

[14] Frankel, Grant and Flanagan, Historical development of glycidyl azide polymer, Journal of Propulsion and Power, Vol. 8, No. 3 (1992), pp. 560-563. doi: 10.2514/3.23514, 1992

GAP-diol contains energetic pendant azidomethyl groups (-CH_2-N_3) on the polyether main chain and has a positive heat of formation (+957 kJ/kg). It therefore has the ability to self-decompose exothermically even at relatively low temperatures and produce fuel-rich gases. This high energy potential and relatively low detonation and sensitivity properties lead to a greater degree of safety in the handling and storing of these types of propellants.

GAP offers excellent physico-chemical properties: low glass transition temperature, low viscosity and high density compared to other prepolimers used in the rocket-propellant technology[15].

Mechanical properties of the final GAP-based propellant structure are nevertheless highly dependent on the number average molar mass between junction points. The specificity of the GAP produced by EURENCO is to be optimised in terms of two-function reactants in the network formulation. Such properties are specifically developed and adapted according to EURENCO's customers and therefore constitute a key sales parameter.

2.2.4. GAP final applications by EURENCO's customers

EURENCO has been collaborating with its customers in order to specifically adapt the final properties of GAP to their very applications.

As of 2015, EURENCO's GAP is used for two main strategic applications: solid missile propellants and gas generators for submarine rescue systems.

2.2.4.1. Solid propellants for missiles

GAP is used by several defence industry companies in the development of next-generation solid propellants for missiles.

→ *Applications*

GAP was initially developed in France by the DGA (French Ministry of Defence) as an energetic binder in the formulation of propergols and explosives. Several GAP-based propergols formulations (Azorgol® family) have been developed by a customer of EURENCO for two tactical missiles applications: MMP and MRCM.

Missile Moyenne Portée (MMP), or Medium Range Missile, is a lightweight weapon system for land combat. With a range of 4,000m, MMP offers a high level of day-night and all-weather reconnaissance and identification capability, a confined space firing capability and a lethality against a wide range of targets. MMP is expected to be deployed within the French armed forces in 2025.

The overall development and production planning for MMP is the following:

- Missiles are currently in development and testing phase ;
- Qualification is planned for 2016;
- First supply to the armed forces is planned for 2017, using the current propulsion technology (SD propellant[16]);

[15] Ibid. 24

- Development of GAP-based Azorgol® propulsion systems by an European Defence industry company is currently on-going and its finalisation is expected for 2016;
- Development and testing of the implementation of Azorgol® propulsion systems within the missiles will begin in 2017;
- First supply to the armed forces of the Azorgol®-based missiles is planned for 2025.

The upgrade of MMP with Azorgol® propulsion systems is intended to provide a major improvement in terms of performances of the missiles in order to meet the needs of the French army for increased ballistic performances of tactical and strategic missiles. It therefore constitutes a key condition for (a) the French armed forces operational capabilities and (b) the competitiveness of MMP on the export market and therefore the activity of EURENCO's customer.

MultiRole Combat Missile (MRCM) is an antitank missile with a range of 8km and a firing capability exceeding direct line of view. MRCM is expected to be deployed within the French armed forces in 2023.

The overall development and production planning for MRCM is as follows:

- Development and testing of the implementation of GAP-based Azorgol® propulsion systems within the missiles will begin in 2019;
- Qualification is planned in 2021;
- First supply to the armed forces of the Azorgol®-based missiles is planned for 2023.

→ ***Research of alternatives***

GAP was selected for the Azorgol® missile propellant systems applications based on the technical improvements provided, as compared to current SD propellant technology:

- ***Better thrust ratio***, providing a gain of performances (acceleration, range) ;
- ***Better stability over time***, providing economic gains and logistics gains (lifespan and ownership cost) ;
- ***Improved discretion***, providing a tactical advantage, thanks to the absence of combustion smoke combined with a reduction in infrared signature.

Given the strategic applications of Azorgol® propulsion systems, and the fact that the only potential alternative supplier of GAP is located in the United States, supply of GAP outside France is subject to two very stringent limits:

[16] In French : "Sans dissolvant" – "Solvent free". From Dictionary of explosives related terms, Groupe de travail de la Pyrotechnie: "*Homogeneous propellant manufactured without the use of a solvent, since the shape is formed by hot extrusion in a vacuum of a thermoplastics mixture of nitrocellulose and nitroglycerine or another nitrated oil. The gelatinisation is achieved by rolling*".

- The use of US-produced GAP (Gap-triol) would imply both a complete redesign of the manufacture process as well as a requalification of the application;
- Using GAP manufactured outside the EU poses a strong risk in terms of security of supply, notably due to the US ITAR regulation.

The French origin of the EURENCO's GAP therefore allows securing the supply of the product for the French Ministry of Defence.

Focus: ITAR/EAR

ITAR (International Traffic in Arms Regulations) and EAR (Export Administration Regulations) are legislative tools of the United States government aiming at controlling defence-related products or services:

- A technical data or service is qualified as "ITAR-controlled" or "ITAR-free" depending on whether it includes a US-originated component requiring an export license under ITAR or not.
- Similarly, a technical data or service is qualified as "EAR-controlled" or "EAR-free" depending on whether it includes a US-originated component requiring an export licence that amounts to more than 25% of its overall value or not.

The fact that a product or service is may fall under ITAR/EAR U.S. export controls rules means that its security of supply cannot be guaranteed for European customers on a long-term basis.

→ *Market*

The global foreseen market for MMP and MRCM is detailed below:

- A total of 1,500 MMP units are planned for the French army and 5,000 units are planned for export markets. Production of MMP is planned to begin in 2025, at a production rate of 200 to 250 missiles per year.
- A total of 1,000 MRCM units are planned for the French army and 2,000 units are planned for export markets. The production of MRCM is planned to begin in 2023, at a production rate of 100 missiles per year.

2.2.4.2. Strategic missile propellant

A customer of EURENCO is involved on behalf of the French Ministry of Defence in the development of a GAP-based next-generation propellant for strategic missiles as well as for other ballistic applications.

Due to stringent confidentiality issues related to such applications, a more precise description cannot be provided. Impacts of the "non-use" scenario have, however, be outlined and notably include:

- The loss of past and future investments made by the company for the development of GAP-based applications;
- The loss of future revenues for the Company and the French State;
- The loss of operational capabilities for the French State.

2.2.4.3. Gas generator for submarine rescue systems

GAP is used by Bayern Chemie in the manufacture of Airbus Defense & Space's RESUS-Solid Gas Generator.

→ *Application*

RESUS (REscue system for SUbmarineS) is the standard rescue system installed aboard all German submarines as well as aboard submarines of other navies. It enables the rapid buoyancy and rescue of an entire submarine from any depth.

RESUS provides a powerful and responsive safeguard to all kinds of submarine emergency situations which are especially life-threatening, hazardous or potentially catastrophic when the craft is submerged. Typical scenarios for RESUS include:

- Hydroplanes jammed in a diving position due to an irreparable hydraulics systems failure or the effect of depth charges;
- Failure or unresponsive onboard manoeuvring system;
- Outbreak of fire;
- Compartment flooding due to ruptured pressure hull;
- Prevention of a submarine sinking to its crush depth;
- Submerged collision.

In these and other emergency situations, which make it necessary to surface a submarine as quickly as possible, RESUS is designed to blow the main ballast tanks of the submarine within a very short time: typically within 13-20 seconds.

The exact function sought-after with GAP-based RESUS-solid is to provide water-insoluble gases for surfacing a submarine in case of emergency, which requires the choice of a binder able to deliver nitrogen to a very high content. This binder forms together with the oxidizer a castable solid propellant which is also able to withstand mechanical loads coming from water bomb attacks on the submarine. The gases should be non-toxic. The system is able to surface the submarine from all diving depths it is designed for.

As of today, two versions of the RESUS system are put on the market: RESUS-solid and RESUS-liquid, which cannot be interchanged. Key properties of these solutions are synthesised in Table 2 below:

CHARACTERISTIC	RESUS-LIQUID	RESUS-SOLID
Propellant	Hydrazine	GAP + Strontium nitrate
Propellant mass	62 kg	157 kg
Gas compositions	H_2 (46%) N_2 (28%) NH_3 (20%) H_2O (6%)	N_2 (34%) CO_2 (36%) H_2O (30%)
Quantity required (*)	Ca. 10	Ca. 7

CHARACTERISTIC	RESUS-LIQUID	RESUS-SOLID
Views		

Table 2. Main properties of RESUS-liquid and RESUS-solid solutions[17]

(*) The number of gas generators required is based on 80 m³ MBT, 350 m depth and 100% blow out.

RESUS solid constitutes an improvement over RESUS liquid. Both systems are not interchangeable and bear specificities in terms of form factor, weight and quantity required per submarine.

→ *Research of alternatives*

As of today and despite the assessment and testing of many nitrogen-rich potential alternatives, hydrazine-based RESUS-liquid constitutes the only alternative to GAP-based RESUS solid solution.

All other potential alternatives suffered from poor mechanical properties since they required to be pressed in order to be shaped and did not appear to withstand water bomb attacks.

→ *Risks on human health and environment*

RESUS-solid as a final product is free of substances of very high concern.

On the other hand, RESUS-liquid uses hydrazine (CAS: 302-01-2; EC: 206-114-9), which poses significant risks for human health and the environment and is subject to the following classification:

[17] Airbus Defense & Space, RESUS - Rescue Systems for Submarines. http://cs.astrium.eads.net/sp/resus/index.html

HAZARD CLASS AND CATEGORY CODE(S)	HAZARD STATEMENT CODE(S)
Flam. Liq. 3	H226
Acute Tox. 3	H301
Acute Tox. 3	H311
Skin Corr. 1B	H314
Skin Sens. 1	H317
Acute Tox. 3	H331
Carc. 1B	H350
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Table 3. Classification of hydrazine[18]

Pictograms for hydrazine are the following:

Figure 3. Pictograms for hydrazine[19]

→ ***Qualification***

Substitution of GAP with any potential alternative for the manufacture of the RESUS rescue systems would entail a complete redesign and redevelopment of the application and therefore require:

- New development of the propellant and interfaces;
- New development of the complete hardware;
- FE-Analysis;
- Many tests on sample and full scale level;
- Surfacing tests with a submarine;
- Explosive material qualification;
- Qualification on system level.

[18] ECHA, Summary of Classification and Labelling

[19] Ibid. 18

This process would require approximately 5 years and would cost € 20M.

On the other hand, in case of sole modification of GAP's synthesis solvent or route, and as long as equivalent properties can be achieved, its final implementation on the RESUS solution would only require a short validation programme, during which GAP samples would undergo quality testing and suitability assessment. In case deviations in functional properties are experienced with this newly synthesised GAP, a new two-year qualification programme would be required, which would imply expenses in the order of magnitude of € 1M.

→ ***Market***

RESUS has been a standard equipment on board of all German submarines for over 25 years and has been installed on many export submarines classes 206, 209, 212A and 214. Despite the totally different geometry of the ballast tank it can also be retro-fitted to submarines 877EKM (Kilo Class).

Other navies relying on RESUS rescue system include: Greece, India, Israel, Italy, South Korea and Turkey. Different opportunities are foreseen for future submarines of other nations.

2.3. General methodology

On the basis of the carcinogenic properties of EDC for which it is not possible to determine a threshold, and since it cannot be demonstrated that the risk to human health or the environment from the use of the substance is adequately controlled, the "socio-economic route" applies for the present application. The socio-economic route applies where it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and there are no suitable alternative substances or techniques (Art. 60(4)).

As per ECHA's guidance, the assessment of the socioeconomic component of the present AfA will be based upon a Cost-Benefit Analysis approach. A comparative assessment will therefore be carried out, between the monetised impacts related to the "applied for use" and the "non-use" scenarios.

In order to best reflect the consequences of both these scenarios, an effort has been undertaken to place this AfA in the context of the realistic worst-case scenario. Whenever possible:

- Over-estimating hypothesis have been used to assess the impacts of the "applied for use" scenario and, conversely, under-estimating hypothesis have been used to assess the impacts of the "non-use" scenario;
- Representative examples have been provided and structuring hypothesis or assertions have been justified either based on literature or institutional sources.

Where appropriate, complementary elements of analysis will be provided, notably concerning:

- An alternative methodology of assessment of costs related to mortality and morbidity;

- An alternative assessment of the costs of the "applied for use" scenario, considering a 4% discount rate.

Furthermore, and so as to provide a comprehensive understanding of the limits of the proposed assessment, an uncertainty analysis was carried out for both the results of the "applied for use" and "non-use" scenarios. This analysis, carried out both quantitatively and qualitatively, is provided in section 5.6.

2.3.1. Scope of the AfA

Key elements of the scope of the AfA are provided in Table 4 below:

SCOPE	COMMENT
Temporal boundary	Four years post sunset date: 2017-2021. See Table 5 for a description of the triggering period for each impact.
Geographic boundaries	Impacts mainly concern France and Germany: - The use of the substance takes place in France; - EURENCO's customers, relying on GAP for their applications are located in France and Germany. Broader impacts concern foreign sovereign States, defence industry companies and armed forces, with a worldwide scope.
Economic boundaries	Monetised damage of the impacts on human health of the "applied for use" scenario includes: - Medical treatment, - Mortality and morbidity Main impacts of the "non-use" scenario include: - Economic impacts on EURENCO's activity include the loss of revenues and the loss of investments; - Distributional impacts include a loss of investments made by the French State over the last decade in the development of GAP-based applications, a loss of market share and revenues for defence industry companies which are involved in the development, implementation, industrialisation and commercialisation of GAP-based applications as well as severe availability issues for armed forces relying on GAP-based applications, thereby directly affecting both States' operational capabilities and sovereignty.
Tonnages	Quantities used: 2.6 tons in 2015 and 1.3 tons in 2014

Table 4. Scope of the AfA

Focus on the temporal boundaries and the impact period:

SCENARIO	IMPACT	IMPACT PERIOD	DISCOUNTING PERIOD
"Applied for use" scenario	Medical treatment	4 yrs: 2018-2021	6 yrs: 2016-2021
	Mortality and morbidity	4 yrs: 2018-2021	6 yrs: 2016-2021
"Non-use" scenario	Loss of profits	4 yrs: 2018-2021	6 yrs: 2016-2021
	Loss of investments	16 yrs: 2018-2033	18 yrs: 2016-2033

Table 5. Impact period of the AfA

Present value is set in 2015, at the date of drafting of this document. Considering that the sunset date for EDC takes place at the end of the year 2017, an assumption is made that impacts will take place in 2018. Similarly, the discounting period is set to begin in 2016.

In order to ensure consistency of analysis between impacts of both scenarios, and as recommended by ECHA's guidance, it was chosen to consider a common impact and discounting period for both the "applied for use" and "non-use" scenarios. In order to remain as close as possible to the temporal scope of the AfA, it was chosen to assume that the impact period and discounting period of both scenarios correspond to the review period of the AfA.

This assumption can be justified as follows:

- The period of time covered by the review period of the uses of the AfA comprises the period of time with the highest mortality rates after diagnosis, thereby encompassing the majority of the impacts;
- By assuming that the discount period is in line with the review period, and therefore assuming that the impacts will take place in a closer future than what is realistically foreseeable, it was deliberately chosen to discount the impacts of the "applied for use" scenario by a lower factor than if a more realistic period of time had been chosen, for example 20 or 30 years.

2.3.2. Actualisation

All final monetised results of this document are expressed in present value (PV). In this context, the following factors are used for the actualisation of past values (correction for inflation) or future values (discounting).

2.3.2.1. Inflation

Given the type of values considered (health expenditures, social benefits), it was chosen to rely on the Consumer Price Index to carry out actualisation according to inflation. The choice of this statistical estimate is in line with ILO/IMF/OECD/UNECE/Eurostat/The World Bank recommendations, stating[20]: "*CPIs are widely used for the index linking of social benefits such as pensions, unemployment benefits and other government payments, and also as escalators for adjusting prices in long-term contracts*."

[20] ILO/IMF/OECD/UNECE/Eurostat/The World Bank, Consumer price index manual: Theory and practice Geneva, International Labour Office, 2004

Given the low variation of CPI in France over the year 2015, it was chosen to rely on the average of the CPI value for the January to September 2015 period. This value is considered as representative of the year 2015, and therefore used for conversion of past financial amounts to present value.

The following values will be used in the present document:

PERIOD	INFLATION
2003-2015	18.3%
2008-2015	7.3%
2010-2015	5.6%

Table 6. Inflation values taken into account in this dossier[21]

2.3.2.2. Discounting

Comparing costs and benefits during different periods of time to present values requires the use of discounting technique to translate future costs and benefits into present-days values to account for the time value of money

The choice of discount rate is important since it can affect the cost-benefit results of the analysis. The higher the discount rate, the lower the future benefits and costs values will be, as compared to present values.

In our methodology, we deliberately chose to use two different discount rates depending on the type of future impacts evaluated.

Thus, future human health costs described in the "applied for use" scenario of this dossier will be evaluated using a lower discount rate that the one used to consider economic impacts in the "non-use" scenario. This difference is related to the different "nature" of these impacts and aims to reflect the society's rate of time preference with respect to health risks.

As per ECHA's guidelines, the calculation of discounted values is performed on an annualised basis, with the following formula:

$$PV = \sum_{n=1}^{n=t} F_n(1+r)^{-n} = \frac{F_1}{(1+r)} + \frac{F_2}{(1+r)^2} + \cdots + \frac{F_t}{(1+r)^t}$$

Where:

- PV = present value
- F_n = future costs at year n
- r = annual discount rate
- t = last annuity of the discount period

→ ***Discounting of health impacts***

[21] OECD, Main economic indicators, Consumer Price Index – data and methods

A 3% discount rate is used in this dossier for health impacts. This choice is in line with WHO[22], stating: "For many years, a discount rate of 5% per annum has been standard in many economic analyses of health and in other social policy analyses, but recently environmentalists and renewable energy analysts have argued for lower discount rates for social decisions. The World Bank Disease Control Priorities study and the GBD project both used a 3% discount rate, and the US Panel on Cost-Effectiveness in Health and Medicine recently recommended that economic analyses of health also use a 3% real discount rate to adjust both costs and health outcomes."

Please note that, in order to ensure a complete consistency of the values with ECHA's requirements, a complementary assessment is provided for the "applied for use" scenario in section 3.5.5, considering a 4% discount rate.

→ ***General discounting***

Based on ECHA's recommendation[23], a 4% discounting rate is used to assess the future cost/benefits values for impacts not related to health matters.

2.3.3. Confidentiality

In order to preserve the confidentiality of strategic data of the present AfA, confidential business information has been blanked out in this public version of the AoA-SEA document.

In what follows, such figures will be indicated as follows: [€ 10-100M](#1a).

Please refer to section 8 for a justification of confidentiality claims.

2.4. General substitution strategy

Through extensive research works led in partnership with its customers, EURENCO only identified three potential alternative solvents to EDC: (#1d) (*Alternative 1*), (#1e) (*Alternative 2*) and toluene (*Alternative 3*).

These potential alternatives appear promising in terms of functional properties and are expected to be developed, tested and industrially implemented in 2021.

Alternative 1, Alternative 2 and Alternative 3 are class 2 CMR substances and appear to either provide an adequate control or an overall reduction of risk as compared with EDC. As of today, and taking into account the CMR properties of these substances, this substitution step however does not qualify as an acceptable long-term option. It is therefore considered as a temporary solution allowing pursuing the production of GAP and satisfying customer requirements during the period of time needed for the development of a sustainable alternative.

[22] World Health Organisation, Environmental Burden of Disease Series, No. 1 - Introduction and methods, Assessing the environmental burden of disease at national and local levels, 2003

[23] ECHA, Guidance on the preparation of socio-economic analysis as part of an application for Authorisation, 2011

In order to identify, develop and implement a sustainable route for the synthesis of GAP, EURENCO is engaged in a research project aiming at a complete reengineering of GAP's synthesis process with human health as main criteria. Such a redesign constitutes a major innovation step and will be developed from scratch. This substitution strategy is considered as promising for the synthesis of GAP using ingredients showing the lowest risks for human health and environment.

A long-term research program is therefore ongoing in partnership with DGA, the French Ministry of Defence's Armament Procurement Agency, which will lead to several consecutive 3-year studies (doctoral or post-doctoral positions). Taking into account necessary development, testing industrialisation and qualification steps, such a synthesis process is expected to be industrially implemented in 2024 within EURENCO's production chain. This long-term substitution step is covered in section 4.5.

2.5. Complementary elements of context

Several specificities of this AfA in the context of defence can be outlined:

- Very strong European countries' ***sovereignty matters*** are at play in this dossier : application of GAP in current or future defence systems are critical for the operational capabilities of several European countries;
- ***Performance requirements*** and ***development processes*** are very specific for defence industries as compared to "standard" private companies, due to the criticality of applications as well as to the involvement of the State as main customer;
- Stringent ***confidentiality*** issues strictly restricts communication of data;

These elements of context strongly define EURENCO's industrial capabilities as a company, and therefore the stakes of this dossier. These elements are further detailed in Appendix 9.1.

2.5.1. Synthesis: specificities of EURENCO's AfA in the context of defence

Applications of GAP by EURENCO's customers, such as tactical missiles or submarine safety equipments, are directly related to National Defence matters. This notably has direct consequences on the way "non-use" scenario impacts can be assessed. As a matter of fact, the ban of EDC would impact EURENCO but the vast majority of its impacts would affect the company's customers and the defence industries relying on GAP for their applications.

Sovereignty matters also represent a key component in the substitution strategy that can be undertaken by EURENCO. Due to the critical nature of GAP's applications for French or German defence capabilities, the sourcing of products and their ingredients has to be made in France or at the very least in Europe. EURENCO is the sole supplier of GAP in the European Union, meaning European defence industries and armed forces currently relying on GAP would have no alternative sourcing options, should the production of GAP by EURENCO cease.

Based on the argument put forward in the foregoing sections, three main characteristics place EURENCO's AfA in a particular context:

1	Applications of GAP are absolutely critical to the armament systems and military equipments in which they are integrated into. Without these components, and the level of performance provided by the GAP, these equipments are considered of no operational worthiness.
2	The level of performances required for GAP is defined by DGA for applications of the French armed forces, based on operational needs of the Ministry of Defence and specific engagement scenarios and by the German Ministry of Defence for the submarine rescue system application. Applications of GAP are therefore directly related to National Defence matters.
3	France's and European' sovereignty directly depend on the specific type of GAP produced by EURENCO, both to guarantee operational capabilities as well as to secure sales for domestic and export markets.

The context of EURENCO's AfA is therefore very specific, as compared to "standard", market-driven private companies: it has to be taken into consideration that sovereignty matters are at stake with this dossier even though they can hardly be monetised, due to the diversity of equipments concerned, the complexity of the downstream supply chains impacted (in terms of the specific financial and technical organisation of the armies) as well as stringent confidentiality matters.

2.6. Presentation of the "applied for use" and "non-use" scenarios

2.6.1. "Applied for use" scenario

Under the "applied for use" scenario, EURENCO will pursue the use of EDC for the synthesis of PECH and GAP for the period of time necessary to develop, qualify and implement an alternative process (4 years post-sunset date), thereby securing the supply of critical equipments and armament systems for the French and foreign armed forces.

Main impacts of the "applied for use" scenario concern operator's health and monetized damage includes costs associated with medical treatment, mortality and morbidity.

Risks and impacts of the "applied for use" scenario are detailed in section 3.5.

2.6.2. "Non-use" scenario

The most likely "non-use" scenario is the following: with the ban on the use of EDC and therefore the cease of synthesis of PECH, EURENCO will have to halt the synthesis of GAP for the period of time needed to develop and implement Alternative 1, Alternative 2 or Alternative 3.

This scenario entails direct economic impacts for EURENCO.

Given the facts that (a) applications of GAP are strategic for EURENCO's customers as well as for French and foreign armed forces, (b) in order to secure the supply for the main military applications of GAP, it is a compulsory requirement that GAP is produced in the European Union and (c) EURENCO is the sole European producer of GAP, this scenario also entails strong impacts for EURENCO's value chain. In the context of the present AfA, indirect impacts for EURENCO's value chain are foreseen to exceed direct impacts on the activity of EURENCO.

Impacts of the denial of an authorisation would mainly have economic, social and distributional dimensions:

- ***Economic impacts*** on EURENCO's activity include a loss of profits and a loss of investments;
- ***Social impacts*** include potential indirect job losses for EURENCO's customers;
- ***Distributional impacts*** include a loss of investments made by the French State over the last decade in the development of GAP-based applications, a loss of market share and revenues for defence industry companies which are involved in the development, implementation, industrialisation and commercialisation of GAP-based applications as well as severe availability issues for armed forces relying on GAP-based applications, thereby directly affecting both States' operational capabilities and sovereignty.

Impacts of the "non-use" scenario are detailed in section 5.

3. "APPLIED FOR USE" SCENARIO

The batch synthesis of PECH is carried out by EURENCO in a single facility at the site of Sorgues (Vaucluse, France) for a total duration of less than one month per year (22 days in 2015, 15 days in 2014). Each production operation requires two operators for a total duration of two to three 8hr-shifts. A total of six employees are currently involved in the production of PECH and are therefore potentially exposed to EDC.

The main chemical and functional properties of EDC as a solvent in the synthesis of PECH comprise: solubilisation of raw materials of synthesis of polyepichlorohydrin (epichlorohydrin, 3-chloro 1,2-propanediol, trichloroacetic acid and tin tetrachloride) and polyepichlorohydrin, chemical inertia toward reagents, controlled water content and acidity as well as non-miscibility with water and controlled boiling point.

3.1. Analysis of substance function

3.1.1. Synthesis reaction of GAP

As such, and although exposure to EDC is only encountered during the synthesis stage of PECH, EURENCO's use of EDC cannot be dissociated from the final sought-after product that is GAP. Functional properties of EDC as a solvent directly impact final properties of both PECH and consequently of GAP.

In order to provide a comprehensive understanding of the use of EDC and the general context within such use, the global chemical reaction is therefore discussed in what follows.

The global chemical reaction is a two-stage process, involving polymerisation of ECH to PECH followed by the conversion of PECH to GAP by nucleophilic displacement of chloride azide.

The global reaction is described below:

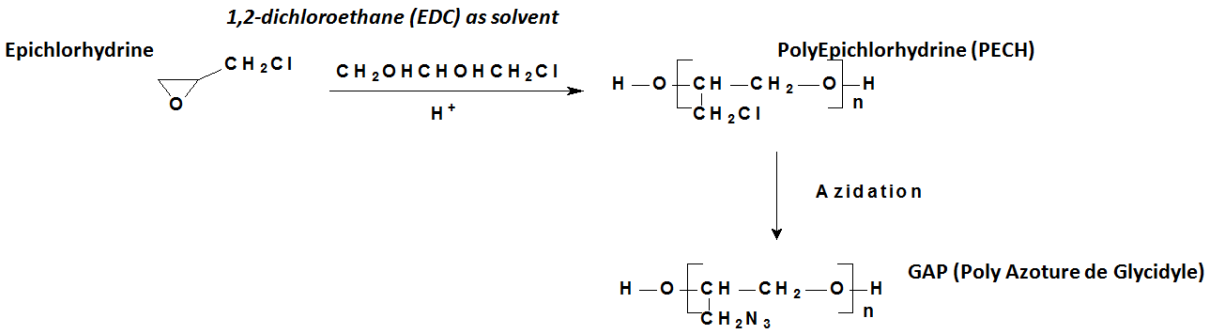

Figure 4. GAP-diol synthesis reaction

It should be emphasized that each synthesis batch of GAP is adapted to specific customer requirements, notably in terms of molecular weight and hydroxyl concentration, in order to comply with their applications' requirements. These specific requirements give rise to two general comments in the context of this AfA dossier:

- EURENCO is involved in strong partnerships with its customers which are directly involved (both in terms of theoretical knowledge, technical and financial support for testing operations) in the research for alternatives;
- EURENCO's process for the synthesis of GAP is the result of several years of research and development, testing and qualification, which have been necessary to achieve its customers' level of requirement.

3.1.1.1. Reaction step 1: Polymerisation of ECH to PECH

Polymerisation of ECH to PECH is carried out using EDC as a solvent in the presence of tin tetrachloride as a catalyst. In the context of the GAP synthesis, the reaction was specifically developed in order to obtain PECH-diol, i.e. a polymer having two –OH groups at the chain ends.

The key points of the reaction are:

- The polymerisation reaction is carried out between 17°C and 33°C;
- The polymerisation is followed by two consecutive washing steps: one with carbonated water and a second one with water;
- EDC in PECH is eliminated under vacuum at the end of the process.

Functional specifications for PECH include but are not limited to: molecular weight as well as hydroxyl, chloride or EDC content.

3.1.1.2. Reaction step 2: Azidation of PECH to GAP

GAP-diol possesses hydroxyl functional groups located at both ends of the chains and is synthesised via the nucleophilic reaction of its precursor, PECH, with sodium azide[24].

3.1.2. Functional properties of EDC

In the context of Use-1, the following properties are sought-after by EURENCO with EDC:

→ ***Solubilisation of raw materials***

In order to act as a solvent, any potential alternative to EDC has to solubilise all raw materials involved in the reaction of synthesis of PECH as well as to maintain the same solvent to reagents ratios:

[24] Eroglu, Network characterisation of energetic Poly(glycidyl azide), Tr. J. of Chemistry, 21 (1997), 256-261, 1997

REAGENT	EDC TO REAGENT WEIGHT RATIO
1,2-Dichlorethane (EDC)	-
Epichlorohydrin	0.6
3-chloro 1,2-propanediol	12.6
Trichloroacetic acid	21
Tin tetrachloride	53

Table 7. Main reagents and EDC to reagents weight ratio for the synthesis of PECH

→ ***Solubilisation of PECH***

As for EDC, any potential alternative has to solubilise polyepichlorohydrin.

→ ***Chemical inertia toward reagents***

In order not to interact with synthesis reagents during the reaction, any potential alternative has to be chemically inert toward reagents, which excludes both alcohols and ethers as potential alternatives.

→ ***Water content and acidity***

Water content and acidity constitute key parameters of the final properties of GAP. In order to obtain an acceptable product, the solvent of the reaction has to possess a water content that is lower than 100 ppm and an acidity (HCl) that is lower than 5 ppm.

→ ***Non-miscibility with water and boiling point***

In order to be compliant with the extraction process, non-miscibility with water constitutes a key parameter in the selection of a potential alternative to EDC, along with a boiling point that is lower than 86°C (and ideally comprised between 70 and 86°C).

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

3.2.1. Employees, revenues and profits

Key figures of the production of GAP for EURENCO are synthesised below:

	EMPLOYEES	REVENUES
Sites of Sorgues	276	≈ € 150M
Related to Use-1	7	≈ € 1.5M

Table 8. Key figures of GAP's production activity, 2014

3.2.1.1. Current EDC tonnages

Detail of the previous 2014 and 2015 PECH production campaigns are given below:

YEAR	PERIOD	NB OF OPERATIONS	EDC TONNAGE
2015	**20/01 to 18/02**	23	2.5 ton during syntheses + 0.1 ton for pre-campaign cleaning **=2.6 ton**
2014	**11/03 to 31/03**	10	1.0 ton during syntheses + 0.3 ton for pre-campaign cleaning **= 1.3 ton**

Table 9. Detail of the 2014 and 2015 PECH production campaigns.

The tonnage for 2015 (2.6 tons) is considered as representative of the use of EDC over the review period.

3.2.1.2. Production forecasts

On the basis of customer needs, GAP production forecasts are expected to remain stable for the period 2017-2021, i.e. at the levels of 2014 and 2015.

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

As described in the CSR, the "applied for use" scenario only presents a risk for operators dedicated to the synthesis of EDC, for one logistics worker as well as for one laboratory worker; risks for general population have been shown to be negligible and have therefore not been monetised.

In what follows, and according to the justification provided in the CSR, only the risk via inhalation exposure is considered in the present assessment of monetised impacts. An assessment taking into account the risk via dermal exposure is furthermore provided in 5.6.

3.4. Human health and environmental impacts of the "applied for use" scenario

3.4.1. Number of people exposed

A synthesis of the number of people exposed is given below and a comprehensive description is provided in the CSR.

3.4.1.1. Long-term exposures

Each production operation requires two operators for a total duration of two to three 8hr-shifts. A total of six workers are currently mobilised in the production of PECH and therefore potentially exposed to EDC. Production of PECH is only carried out during less than one month per year (22 days in 2015, 15 days in 2014).

As detailed in the Chemical Safety Report, the duration of the operations potentially involving an exposure of workers to EDC are limited to a maximum cumulated duration of 1.7 hour approximately for a whole batch and distributed over the two to three 8hr-shifts needed to synthesise a batch.

Exposures to EDC are identified and monitored, according to the French legislation.

3.4.1.2. Punctual potential exposures

In addition to the workers involved in the synthesis of PECH, two types of operators can potentially be exposed on a punctual basis to EDC at the site of Sorgues:

- Laboratory staff (1 operator), involved in the analysis of samples ;
- Logistics staff (1 operator), involved in the sampling of EDC.

3.5. Human health impacts and monetised damage of the "applied for use" scenario

Monetised damage of the impacts on human health of the "applied for use" scenario includes medical treatment, mortality and morbidity.

When relevant, and in order to offer a comprehensive understanding of the amounts at stake, it was chosen to supplement values taking into account the total excess risk of cancer with values based on the individual excess of risk of cancer.

In what follows:

- ***Individual*** values refer to values based on the individual excess risk of cancer, thereby related to ***one worker***;
- ***Total*** values refer to values based on the total excess risk of cancer, thereby related to ***all the workers concerned by the use***.

3.5.1. General considerations regarding hazards on human health associated with exposure to EDC

1,2-Dichlorothane (EDC) is listed as a Substance of Very High Concern according to Art. 57(a) due to its carcinogenic category 1B properties. It was included in the Annex XIV of REACh during ECHA's fourth recommendation. Sunset date for the use of EDC is 2017/11/22; latest application date was set to 2016/05/22.

Dose-response relationship for carcinogenicity of EDC was formalised by RAC[25], stating that: "The review of the carcinogenicity and genotoxicity data leads to the conclusion that there is a potential for a genotoxic mode of action with metabolic activation and that exposure to 1,2-dichloroethane can give rise to tumours in experimental animals, and can presume to have carcinogenic potential in humans".

[25] RAC, Application for Authorisation: establishing a reference dose response relationship for carcinogenicity of 1,2-dichloroethane - RAC/33/2015/09 Rev1, June 2015

The most recent long-term study (Nagano et al.[26]) gives three dose levels a linear response justifying the non-threshold approach for EDC. Under this study, a T25 for carcinogenicity in laboratory animals was derived from a two-year inhalation study in F344/DuCrj (SPF) rats using the combined frequency of mammary tumours: adenomas, fibroadenomas and adenocarcinomas.

However, as stated by RAC[27]: "The available epidemiological studies are insufficient to reach any conclusions on the carcinogenicity of 1,2-dichloroethane and do not provide any useful information on tissue sensitivity. Tumours in experimental animals often differ from humans in the site of carcinogenicity; for example, the human bladder appears a possible site for tumours caused by aniline-derived compounds but this target is rare in experimental animal studies with these compounds. Therefore, the choice of mammary tumours for this risk assessment is based rather on genotoxic potential and the best dose-response rather than its relevance to a specific human cancer."

On the basis of these elements, and considering that (a) the human sites for carcinogenicity may differ from those observed in animals and (b) all EURENCO employees concerned by the AfA are males, it was chosen to use global cancer data to characterise the carcinogenic effects of EDC.

3.5.2. Medical cancer treatment

The average cost related to the medical treatment of cancer in France was derived from the State's health care annual expenditures related to cancer and the number of persons covered by a health care regime.

The total expenditures for the French health care system related to cancer in France amounted to € 11.5B in 2010[28].

Persons covered by a health care regime in France in 2010 for cancer are distributed as follows:

PATHOLOGY	NUMBER OF PERSONS
Breast cancer (active treatment)	183,035
Breast cancer (remission and surveillance)	386,849
Colorectal cancer (active treatment)	121,293
Colorectal cancer (remission and surveillance)	113,935
Lung cancer (active treatment)	75,914

[26] K., Umeda, Y., Senoh, H., Gotoh, K., Arito, H., Yamamoto, S. and Matsuhima, T. (2006). Carcinogenicity and Chronic Toxicity in Rats and Mice exposed by Inhalation to 1,2-Dichloroethane for Two Years. J. Occup. Health, 48, 242-436.

[27] ECHA, Application for Authorisation: establishing a reference dose response relationship for carcinogenicity of 1,2-dichloroethane - RAC/33/2015/09 Rev1, June 2015

[28] ONDAM 2010 hors MIGAC y compris IJ maternité et dépenses d'invalidité, source CNAMTS extrapolé tous régimes. In: rapport de l'Assurance Maladie sur les charges et produits pour l'annee 2013 - constats

Lung cancer (remission and surveillance)	31,088
Prostate cancer (active treatment)	134,137
Prostate cancer (remission and surveillance)	241,960
Other cancers (active treatment)	418,478
Other cancers (remission and surveillance)	486,268
TOTAL	**2,192,957**

Table 10. Number of persons covered by the French health care regime for cancer, 2010[29]

Considering (a) the average individual cost of cancer derived from the above data (€ 5,244 per year[30]), (b) that the average survival duration of persons suffering from cancer in France is 6 years post-diagnosis[31] and (c) a 3% discount rate, the individual cost of cancer amounts to:

YEARS AFTER DIAGNOSIS	COSTS
Individual cost of cancer	**€ 20,976**
Individual cost of cancer, discounted(*)	**€ 18,374**

Table 11. Individual cancer costs during the review period, not taking into account the excess of risk for workers

(*) Taking into account a 3% discount rate until the end of the review period

The following table synthesises the cancer costs per worker, taking into account the total excess of risk for Use-1 (**$4.6x10^{-6}$**):

YEARS AFTER DIAGNOSIS	COSTS
Total cost of cancer	**€ 0.10**
Total cost of cancer, discounted(*)	**€ 0.09**

Table 12. Total cancer costs during the review period, considering the total excess of risk for workers and the respiratory equipments

(*) Taking into account a 3% discount rate until the end of the review period

3.5.3. Mortality and morbidity

Several summary measures of population health have been devised, including the Quality-Adjusted Life Year (QALY), the Disability-Adjusted Life Expectancy and the Healthy Life Year[32,33,34,35]. The benefits and challenges of these measures have been examined in several publications[36,37,38,39,40].

[29] Rapport de l'Assurance Maladie sur les charges et produits pour l'annee 2013 - constats

[30] 2,192,957 / $11.5x10^9$

[31] Institut National du Cancer, Epidémiologie nationale des cancers - Données essentielles, 2015

[32] Weinstein, Stason, Foundations of cost effective analysis for health and medical practices. New England Journal of Medicine, 296:716-721, 1977

According to the WHO recommendations[41] and since it has been widely used, it was chosen to assess the impacts of both mortality and morbidity associated with an excess risk of cancer through one combined measure: the Disability-Adjusted Life Years or DALY.

The DALY method is recommended by ECHA for the assessment of mortality and morbidity impacts[42,43].

3.5.3.1. General methodology

The following methodology is based on the general WHO methodology for the calculation of DALYs[44].

DALY is a combined measure of the period of time lived with disability and the period of time lost due to premature mortality:

$$DALY = YLL + YLD$$

Where: YLL = years of life lost due to premature mortality and YLD = years lived with disability.

In such an approach, time is used as a common currency for non-fatal health states and years of life lost. Disability weights are thus used to formalize and quantify social preferences for different states of health, measured as number on a 0-1 scale, where: "0" is assigned to a state of ideal health and "1" to a state comparable to death.

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[33] Murray, Rethinking DALYs. In: Murray, Lopez, eds. The global burden of disease. Geneva, World Health Organization, Harvard School of Public Health, World Bank, 1996

[34] Hyder, Rotllant, Morrow, Measuring the burden of disease: healthy life years. American Journal of Public Health, 88:196-202, 1998

[35] Murray, Salomon, Mathers, A critical examination of summary measures of population health. Bulletin of the World Health Organization, 8(8):981-994, 2000

[36] Anand, Hanson, Disability-adjusted life years: a critical review. Journal of Health Economics, 16:695-702, 1997

[37] Williams, Calculating the global burden of disease: time for a strategic reappraisal? Health Economics, 8:1-8, 1999

[38] Murray, Lopez, Progress and directions in refining the global burden of disease approach. Geneva, World Health Organization (GPE Discussion Paper No 1), 1999

[39] Ibid. 35

[40] Murray, Salomon, Mathers, Lopez, Summary measures of population health: concepts, ethics, measurement and applications. Geneva, World Health Organization, 2002

[41] World Health Organisation, Environmental Burden of Disease Series, No. 1 - Introduction and methods, Assessing the environmental burden of disease at national and local levels, 2003

[42] ECHA, Guidance on Socio-Economic Analysis – Restrictions, May 2008

[43] ECHA, Applying socio-economic analysis as part of restriction proposals under REACH - Workshop proceedings, Helsinki, 21-22 October 2008

[44] Mathers, Stein, Fat et al, Global Burden of Disease 2000: Version 2 methods and results, Global Programme on Evidence for Health Policy Discussion Paper No. 50: World Health Organization, 2002

3.5.3.2. Years of Life Lost due to premature mortality

The basic formula for calculating the years of life lost (YLL) metric is the following:

$$YLL = N \times L$$

Where: N = number of deaths and L = standard life expectancy at the age of death (in years).

The number of deaths (N) is supposed to be the total excess risk of cancer. Life expectancy at age of death (L) is calculated by subtracting the standard life expectancy (82.4 years in France[45,46]) and the average age of death by cancer in France (72 years in France[47]).

A 3% discount rate was applied to YLL in order to take into account time preference and express the cost in current value.

YLL and intermediate data are detailed in Table 13 below.

PARAMETERS	VALUES
Standard life expectancy	82 years
Mean age of cancer death	72 years
Number of years lost	10 years
Total excess of risk of cancer	4.6×10^{-6}
Total YLL, discounted(*)	**4.2×10^{-5}**

Table 13. Years of Life Lost (YLL) for Use-1
(*): considering a 3% discount rate until the end of the review period

3.5.3.3. Years Lived with Disability

The calculation of the years of life with disability (YLD) is based on the following formula:

$$YLD = DW \times N \times L_D$$

Where: DW = disability weight, N = number of incident cases and L_D = average duration of disability.

In the case of cancer, the value of 0.75 was used for DW [48]. The number of incident cases (N) was estimated by multiplying the number of workers exposed and the excess of risk of cancer. The average duration of disability (L_D) was obtained by

[45] Eurostat, Mortality and life expectancy statistics, June 2015

[46] This value is furthermore in line with the WHO recommendations for calculation of DALYs and corresponds to the upper end of the life expectancy range to be considered.

[47] Institut National du Cancer, Epidémiologie nationale des cancers - Données essentielles, 2015

[48] WHO, global burden of disease 2004 update: disability weights for diseases and conditions, 2004

subtracting the mean age of death by cancer (72 years[49]) and the mean age of diagnosis (66 years[50]) of cancer.

A 3% discount rate was applied to YLD in order to take into account time preference and express the cost in current value.

YLD and intermediate data are detailed in Table 14 below.

PARAMETERS	VALUES
Mean age of cancer death	72 years
Mean age of cancer diagnosis	66 years
Number of years with disability	6years
Disability weight	0.75
Total excess of cancer risk	$4.6x10^{-6}$
Total YLD, discounted(*)	**$1.8x10^{-5}$**

Table 14. Years of Life lived with Disability (YLD) for Use-1
(*): considering a 3% discount rate until the end of the review period

3.5.3.4. Synthesis of the monetised damage related to mortality and morbidity

Monetised damage related to YLLs and YLDs was calculated using the central value of a statistical life-year recommended by ECHA[51] and based on the NewExt study[52]: € 55,800 (in 2003 price levels). This value is in line with Desaigues[53], which estimated the central value of life year to € 50k, based on a survey of French residents and with EurovaQ study[54], proposing a value per life year of € 45,064. Please note that an uncertainty analysis of the costs associated to mortality and morbidity using the lower and upper bounds of Value of a Statistical Life-Year is provided in section 5.6.

Correction for inflation was applied based on the change in consumer price index: 18.25% on average over the 2003-2015 period[55].

Final YLLs, YLDs and monetised damage are synthesised in the following table:

[49] Institut National du Cancer, Epidémiologie nationale des cancers - Données essentielles, 2015

[50] Institut National du Cancer, Epidémiologie nationale des cancers - Données essentielles, 2015

[51] ECHA, Guidance on Socio-Economic Analysis – Restrictions, May 2008

[52] NewExt, New Elements for the Assessment of External Costs from Energy Technologies, 2003

[53] Desaigues, Rabl, Ami, Boun My Kene, Masson, Salomon, Santoni, 2007a. Monetary Value of a Life Expectancy Gain due to Reduced Air Pollution: Lessons from a Contingent Valuation in France. Revue d'Economie Politique 117 (5), 675–698, 2007

[54] EurovaQ, European Value of a Quality Adjusted Life Year, Final Publishable Report, 2010

[55] Ibid. 21

PARAMETERS	VALUES
YLL	$4.2x10^{-5}$
YLD	$1.8x10^{-5}$
DALY = YLL + YLD	$6.0x10^{-5}$
Value of life year lost(*)	€ 65,985
Total cost for mortality and morbidity (PV)	**€ 4.0**

Table 15. Synthesis of YLLs, YLDs and monetised damage of mortality and morbidity related to the excess cancer risk associated with cancer, Use-1
(*): considering a 18.25% inflation rate over the 2003-2015 period

3.5.3.5. Complementary assessment

Since the costs associated with mortality and morbidity constitute the main monetised damage of the "applied for use" scenario, and in order to validate the previous calculation, another estimate methodology was used, based on the value of a statistical life and the willingness to pay to avoid a cancer case as provided in ECHA's SEA guidance:

	VALUE OF A STATISTICAL LIFE	WILLINGNESS TO PAY TO AVOID A CANCER CASE
Initial value	€ 1,052,000 (2003 price levels)	€ 400,000 per non-fatal case (supposed 2008 price levels)
Inflation	18.25% over the 2003-2015 period	7.32% over the 2008-2015 period
Present value	€ 1,244,022	€ 473,012

Table 16. Value of statistical life and willingness to pay to avoid cancer[56]

Please note that the value of € 400,000 per non-fatal case for the willingness to pay to avoid a cancer case is not referenced in ECHA's guidelines. It was nevertheless used in this complementary analysis since it is in line with the value of € 395,656 calculated by Alberini and Ščasný[57].

Mortality rate was derived from incidence and mortality data:

[56] ECHA, Guidance on the preparation of socio-economic analysis as part of an application for authorisation, Version 1, January 2011

[57] Alberini and Ščasný, Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union, FD7. Final Report - Part III: Carcinogens, Charles University in Prague (Environment Center), September 2014.

PARAMETERS	VALUES
Cancer incidence	194,552
Cancer mortality	90,111
Mortality rate	46.3%
Survival rate	53.7%

Table 17. Incidence and mortality associated with all cancers excluding non-melanoma skin cancer in France, for males, all ages[58]

Based on the parameters previously put forward, the overall impacts of cancer, as calculated with this methodology are synthesised below:

	PARAMETER	VALUE	COMMENT
Mortality	Number of fatal cancer cases over the review period	$2.1x10^{-6}$	Taking into account: the total excess risk of cancer and the average mortality rate cancer in France
	Subtotal: costs of mortality	***€ 2.3***	***Discounted until the end of the review period***
Morbidity	Number of non-fatal cancer cases over the review period	$2.5x10^{-6}$	Taking into account: the total excess risk of cancer and the average survival rate cancer in France
	Subtotal: costs of morbidity	***€ 1.0***	***Discounted until the end of the review period***
Total		**€ 3.4**	**Present value**

Table 18. Mortality and morbidity costs for Use-1, complementary assessment

The results of this complementary assessment (€ 3.4) validate the results obtained with the DALY approach (€ 4.0).

[58] GLOBOCAN 2012, IARC -20.1.2016

3.5.4. Synthesis of the monetised damage of the "applied for use" scenario

The overall monetised impacts of the "applied for use" scenario can be summarised as follows:

IMPACTS	COSTS
Medical treatment	**€ 0.1**
Mortality and morbidity	€ 4.0
Total	**€ 4.1**

Table 19. Overall impacts of the "applied for use" scenario, Use-1

3.5.5. Complementary elements of analysis: values taking into account a 4% discount rate

In order to ensure a complete consistency of the values with ECHA's requirements, monetised impacts of the "applied for use" scenario are also provided considering a 4% discount rate:

IMPACTS	COSTS
Medical treatment	€ 0.1
Mortality and morbidity	€ 3.8
Total	**€ 3.9**

Table 20. Overall impacts of the "applied for use" scenario, Use-1, complementary analysis taking into account a 4% discount rate

3.6. Environment and man-via-environment impacts and monetised damage of the "applied for use" scenario

3.6.1. Environment impacts and monetised damage

Environment impacts have been shown to be negligible and have therefore not been subject to a monetised quantification.

3.6.2. Man-via-environment impacts and monetised damage

Man-via-environment impacts have been shown to be negligible and have therefore not been subject to a monetised quantification.

4. SELECTION OF THE "NON-USE" SCENARIO

Through extensive research works led in partnership with its customers, EURENCO identified three potential alternative solvents to EDC: [redacted] (#1e-1) (Alternative 1), [redacted] (#1e-2) (Alternative 2) and toluene (*Alternative 3*).

On the one hand, these potential alternatives appear promising in terms of functional properties and are expected to be developed, tested and industrially implemented in 2021.

EURENCO is furthermore engaged in a long-term research project aiming at a complete reengineering of GAP's synthesis process with human health as main a criterion.

4.1. Efforts made to identify alternatives

Given the strategic importance of GAP for its customers' applications, EURENCO is involved in strong partnerships with its customers. EURENCO and its customers are therefore directly involved, both in terms of theoretical knowledge, technical and financial support for testing operations in the research for alternatives.

With regard to the AfA, and specifically the Analysis of Alternatives, properties of EDC in the context of the synthesis of PECH cannot be considered alone; the specific requirements related to its final application, GAP, have to be taken into account in the research for an alternative. A significant work of research for alternatives was therefore carried out by EURENCO, which is described in what follows.

4.1.1. Consultation of suppliers

The first step of research for alternatives was a consultation of suppliers on the basis of the functional requirements for Use-1. The following contacts have been taken:

SUPPLIER	RESULT OF THE CONSULTATION
[redacted] (#2a)	No potential alternative was identified in [redacted] (#2b)'s products portfolio
[redacted] *(#2c)*	Ethylal was proposed by [redacted] (#2d), but it was abandoned since it appeared to not be inert toward polymerisation reagents
[redacted] *(#2e)*	No potential alternative was identified by [redacted] *(#2f)*

Table 21. Consultation of customers

The consultation of suppliers did not lead to identify a potential alternative to EDC for the specific functional requirements of Use-1.

4.1.2. Literature review

A literature review was performed on the basis of the functional requirements and hazards for human health of Use-1, with the following criteria:

- **Chemical properties**: compliance with the functional requirements for the synthesis of PECH stated in section 3.1.2;
- **Toxicity**: impacts on human health or the environment;
- **Expert opinion**, mainly based on the risks for human health, on the basis of available bibliographic data.

Results of the literature review are synthesises in Table 22 below:

SOLVENT	CHEMICAL PROPERTIES(*)	TOXICITY	EXPERT OPINION(**)	CONCLUSION(***)
1-bromobutane	Boiling point 102°C Flash point 13°C Auto-ignition temperature 265°C	-	-	×
1-bromopropane	Boiling point 70/71°C	CMR		×
1-chlorobutane	-	Reprotoxic		×
Alpha-pinene	Presence of double bond			×
Beta-pinene	Presence of double bond			×
Ethyl tert-butyl ether	Ether function			×
Hexafluorobenzene	Potential reactivity with reagents of PECH Boiling point 82°C Flash point 10°C			×
Hexamethyldisiloxane	Ether function			×
Hexane	-	CMR		×
Heptafluoropropane	Gaseous			×
Hydrofluoroethers	Ether function			×
Limonene	Presence of double bond			×
Methyl tert-butyl ether	Ether function			×
2-Methyltetrahydrofuran	Ether function			×
Perfluorohexane		CMR		×
Tetramethylsilane	Boiling point 26.6°C			×

Trifluorobenzène	**Inertia toward PECH unknown**		×

Table 22. Potential alternatives to EDC

(*) In red: characteristics that are incompatible with the expected functional properties of the potential alternative to EDC

(**) = Hazardous; = positive judgement by experts; = non-hazardous

(***) × = rejected; ✓ = potentially compliant; TBD = under investigation

On the basis of the criteria synthesised in Table 22 above, none of the potential solvents identified is deemed appropriate for the substitution of EDC.

4.1.3. Experience-based research for alternatives

Within the current knowledge, the only category of solvents that theoretically comply with the functional properties of EDC in the context of the synthesis of PECH is [redacted](#1f-1).

Preliminary laboratory-scale trials of synthesis of PECH permitted to identify two potential solvents to Use-1: Alternative 1 and Alternative 2.

4.2. Other publicly available potential alternatives

4.2.1. Potential alternative solvents in the synthesis of PECH

In a publication in the Journal of Macromolecular Science, Gaur[59] proposes two alternative solvents categories to EDC in the synthesis of PECH: ethers (dioxane, diethyl ether) and hydrocarbons (toluene).

Ethers appear to be reactive in the conditions of polymerisation and therefore show very low yields (respectively 5% and 11% for ethyl ether and dioxane, as compared to 98% for EDC)[60]. It has to be reminded that such yields have been obtained on a laboratory scale, and scaling up to the industrial scale will result in an even lower yield. Ethers have therefore not been considered in what follows as potential alternatives to EDC.

The use of toluene as an alternative solvent to EDC in the synthesis of PECH is being studied by an industrial partner of EURENCO. These works are confidential; EURENCO possesses and can only disclose a low level of information regarding its advancement. Toluene is considered as a potential alternative and further described in section 4.4.3.

[59] Gaur, Lochab, Choudhary & Varma, Azido Polymers—Energetic Binders for Solid Rocket Propellants, Journal of Macromolecular Science, Part C: Polymer Reviews, 43:4, 505-545, DOI: 10.1081/ MC-120025976, 2003

[60] Ibid. 59

4.2.2. Direct potential alternatives to EURENCO's GAP

EURENCO is the sole GAP manufacturer in the European Union. The only potential alternative supplier is based in the United States. There are nevertheless extremely strong impediments to the purchase of GAP outside EURENCO:

- quality issues and insufficient mechanical properties,
- US GAP cannot be transported in its neat form but with solvent,
- high transportation costs,
- no transport license from DoT,
- GAP is ITAR controlled.

As a consequence, no potential outsourcing of GAP outside EURENCO can be envisaged for current applications of EURENCO's customers.

4.3. Identification of known alternatives

Through its extensive research works led in partnership with its customers, EURENCO only identified three potential alternative solvents to EDC: [redacted](#1g (*Alternative 1*), [redacted](#1h) (*Alternative 2*) and toluene (*Alternative 3*). Alternative 1, Alternative 2 and Alternative 3 are covered in section 4.4.

These potential alternatives appear promising in terms of functional properties and are expected to be developed, tested and industrially implemented in 2021.

As of today, and taking into account the intrinsic carcinogenic properties of these substances, this substitution step does not qualify as an acceptable long-term option. It is therefore considered as a temporary solution allowing pursuing the production of GAP and satisfying the customer requirements during the period of time needed for the development of a sustainable alternative.

In order to identify, develop and implement a sustainable synthesis route, EURENCO is engaged in a research project aiming at a complete reengineering of GAP's synthesis process with human health as main criterion. Such a redesign constitutes a major innovation step and will be developed from scratch. This substitution strategy is considered as promising for the synthesis of GAP using ingredients showing the lowest risks for human health and environment.

A long-term research program was therefore validated in partnership with DGA, the French Armament Procurement Agency, which will lead to several consecutive 3-year studies (doctoral or post-doctoral positions). Taking into account development, testing, validation and industrialisation steps, such synthesis process is expected to be industrially implemented in 2024. This long-term substitution step is covered in section 4.5.

4.4. Assessment of shortlisted alternatives

4.4.1. Alternative 1: [redacted] (#1i)

4.4.1.1. Substance ID, properties, and availability

[redacted] [Organic compound](#1j)

4.4.1.2. Technical feasibility of Alternative 1

Preliminary laboratory-scale trials of Alternative 1 demonstrated the potential technical feasibility of Alternative 1 for the synthesis of PECH.

Substitution timeline of Alternative 1, Alternative 2 and Alternative 3 is presented in section 4.4.4.

4.4.1.3. Economic feasibility and economic impacts of Alternative 1

Alternative 1 is at a too early stage of development to assess economic impacts of its implementation in the process of synthesis of PECH.

4.4.1.4. Availability of Alternative 1

The definition of the exact requirements for its specifications (purity, water context, etc.) is still in progress and so is the assessment of availability of Alternative 1.

4.4.1.5. Hazard and risk of Alternative 1

Human health and environment hazard properties of Alternative 1 are synthesised in Table 23 below:

CHARACTERISTICS	[redacted] (#1k)
CAS number	[redacted] (#1l)
EC number	[redacted] (#1m)
Hazard Class and Category Code(s) **Hazard Statement Code(s)**	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Acute Tox. 3 H331 Carc. 2 H351 Repr. 2 H361d STOT RE 1 H372
Pictograms	

Table 23. Human health and environment hazard characteristics of Alternative 1[61]

It has to be mentioned that the risk characterisation for carcinogenic effects of Alternative 1 can be potentially conducted on a threshold basis[62]. Consequently, the risk due to the use of Alternative 1 can be adequately controlled as the exposure levels may be demonstrated below the appropriate DNEL.

4.4.1.6. Conclusions on Alternative 1

In terms of both functional properties and CMR properties, Alternative 1 constitutes the most promising potential alternative to EDC for the synthesis of PECH.

4.4.2. Alternative 2: [redacted] (#1m-1)

4.4.2.1. Substance ID, properties, and availability

[redacted] [Organic compound](#1n)

4.4.2.2. Technical feasibility of Alternative 2

Preliminary laboratory-scale trials of Alternative 2 demonstrated the potential technical feasibility of Alternative 2 for the synthesis of PECH.

Given the difference in boiling points between EDC and Alternative 2, its implementation in the synthesis of PECH is expected to require an improved cooling capacity of the synthesis facility.

Substitution timeline of Alternative 1 and Alternative 2 is presented in section 4.4.4.

4.4.2.3. Economic feasibility and economic impacts of Alternative 2

Alternative 2 is at a too early stage of development to assess economic impacts of its implementation in the process of synthesis of PECH.

4.4.2.4. Availability of Alternative 2

The definition of the exact requirements for its specifications (purity, water context, etc.) is still in progress and so is the assessment of availability of Alternative 2.

4.4.2.5. Hazard and risk of Alternative 2

Human health and environment hazard properties of Alternative 2 are synthesised in Table 23 below:

[61] ECHA, Summary of Classification and Labelling

[62] [redacted] *(#1n-1)*

CHARACTERISTICS	[redacted] (#1o)
CAS number	[redacted] (#1p)
EC number	[redacted] (#1q)
Hazard Class and Category Code **Hazard Statement Code**	Carc. 2 H351
Pictogram	

Table 24. Human health and environment hazard characteristics of Alternative 2[63].

Within the current knowledge, the risk characterisation for carcinogenicity of Alternative 2 is presumed to be conducted on a non-threshold basis[64,65].

4.4.2.6. Conclusions on Alternative 2

Alternative 2 is considered as a potential alternative to EDC for the synthesis of PECH in the context of Use-1.

4.4.3. Alternative 3: toluene

4.4.3.1. Substance ID, properties, and availability

Toluene (CAS: 108-88-3) is an aromatic hydrocarbon also known as methylbenzene.

4.4.3.2. Technical feasibility of Alternative 3

The use of toluene as a substitute to EDC in the synthesis of PECH is currently studied by an external research centre under stringent confidentiality agreements. Results of these works will be communicated to EURENCO in the first semester of the year 2017.

Alternative 3 will therefore follow the general timeline as described in section 4.4.4.

4.4.3.3. Economic feasibility and economic impacts of Alternative 3

Economic feasibility of Alternative 3 will be known in the first semester of 2017.

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[63] ECHA, Summary of Classification and Labelling

[64] [redacted] *(#1o-1)*

[65] [redacted] *(#1p-1)*

4.4.3.4. Availability of Alternative 3

The definition of the exact requirements for its specifications (purity, water context, etc.) is still in progress and so is the assessment of availability of Alternative 3.

4.4.3.5. Hazard and risk of Alternative 3

Human health and environment hazard properties of toluene are synthesised in Table 25 below:

CHARACTERISTICS	TOLUENE
CAS number	108-88-3
EC number	203-625-9
Hazard Class and Category Code(s) **Hazard Statement Code(s)**	Asp. Tox. 1 H304 Flam. Liq. 2 H225 Skin Irrit. 2 H315 Repr. 2 H361d STOT RE 2 H373 STOT SE 3 H336
Pictograms	

Table 26. Human health and environment hazard characteristics of Alternative 3[66]

It has to be mentioned that the risk characterisation for reproductive toxicity of Alternative 3 can be potentially conducted on a threshold basis[67], with a threshold value of 20ppm. As this threshold value corresponds to the French regulatory threshold limit value, it constitutes a legal requirement and therefore has to be monitored. Consequently, the risk due to the use of toluene can be adequately controlled as the exposure levels will have to be demonstrated below the appropriate DNEL.

4.4.3.6. Conclusions on Alternative 3

Alternative 3 constitutes a potential alternative to EDC. Its feasibility, however, is studied by an external research centre and will only be known in the first semester of the year 2017.

[66] ECHA, Summary of Classification and Labelling

[67] Finnish Safety and Chemicals Agency – Tukes, substance evaluation conclusion document as required by REACH Article 48 for Toluene, 12 November 2013

4.4.4. Common considerations for Alternative 1, Alternative 2 and Alternative 3

Both Alternative 1, Alternative 2 and Alternative 3 are at the same levels in terms of technical readiness in the context of Use-1.

The general timeline for their development, industrialisation and implementation is the following:

	2016		2017		2018		2019		2020		2021	
	S1	S2	S1	S2	S1	S2	S1	S2	S1	S2	S1	S2
Laboratory-scale works												
Technical-economical study												
Choice of an alternative			✓									
Industrial scale transfer												
Formulation validation												
Green light for production									✓			
Qualification of PAG												

Table 27. Timeline of development and implementation of Alternative 1 or Alternative 2
S1/S2 = 1st / 2nd semester

On the basis of the timeline presented above, and considering both uncertainties on the technical steps and research results, as well as the period of time needed to submit a new dossier should the need arise, the future alternative to EDC is expected to be fully developed, implemented and qualified in 2021.

4.5. Development of a sustainable synthesis route of GAP

In parallel with research works for the direct substitution of EDC as a solvent in the synthesis of GAP, EURENCO is engaged in a research project aiming at a complete reengineering of GAP's synthesis process with human health as main criterion.

Such a redesign constitutes a major innovation step and will be developed from scratch. This substitution strategy is considered as promising for the synthesis of GAP using ingredients showing the lowest risks for human health and environment.

A long-term research program is therefore ongoing in partnership with DGA, the French Ministry of Defence's Armament Procurement Agency, which will lead to several consecutive 3-year studies (doctoral or post-doctoral positions). Research works will be carried out in one or two university laboratories specialised in polymers chemistry and will be followed-up by EURENCO.

The general planning of the research project, as validated by EURENCO and the DGA, is the following:

	2016		2017		2018		2019		2020		2021		2022		2023		2024	
	S1	S2	S1	S2	S1	S1	S1	S1	S1	S2	S2	S2	S2	S2	S1	S2	S1	S2
Preliminary works of identification of synthesis routes																		
Research works at laboratory scale																		
Knowledge transfer to EURENCO of synthesis conditions																		
PECH / PAG sample production																		
Industrial scale transfer																		
Formulation validation																		
Green light for production																✓		
Qualification of PAG for customers applications																		

Table 28. Timeline of development and implementation of the future sustainable alternative synthesis route of GAP
S1/S2 = 1st / 2nd semester

The initial research market, of an overall duration of 54 months, was notified by DGA on October 30th, 2015. The research project is divided as follows:

- a confirmed phase of 18 months,
- a conditional phase of 36 months.

At the end of this period, this market is expected to be extended

The outcome of this research market is expected to be a new synthesis route for PECH or PAG, specifically developed to not involve the use of human health and environment hazardous substances.

Although the exact timeline of development is subject to the inherent uncertainties of research projects, it is expected that the final GAP' sustainable synthesis route will be implemented within EURENCO's production facility and qualified for customers applications in 2024.

4.6. The most likely "non-use" scenario

The most likely "non-use" scenario is the following: with the ban on the use of EDC and therefore the cease of synthesis of PECH, EURENCO will have to halt the synthesis of GAP for the period of time needed to develop and implement Alternative 1, Alternative 2 or Alternative 3, i.e. during four years after the sunset date of EDC.

This scenario entails direct economic impacts for EURENCO.

Given the facts that (a) applications of GAP are strategic for EURENCO's customers as well as for French and foreign armed forces, (b) in order to secure the supply for the main military applications of GAP, it is a compulsory requirement that GAP is produced in the European Union and (c) EURENCO is the sole European producer of GAP, this scenario also entails strong impacts for EURENCO's value chain.

Impacts of the denial of an authorisation would mainly have economic, social and distributional dimensions:

- ***Economic impacts*** on EURENCO's activity include a loss of profits and a loss of investments;
- ***Social impacts*** include potential indirect job loss for EURENCO's customers;
- ***Distributional impacts*** include a loss of investments made by the French State over the last decade in the development of GAP-based applications, a loss of market share and revenues for defence industry companies which are involved in the development, implementation, industrialisation and commercialisation of GAP-based applications as well as severe availability issues for armed forces relying on GAP-based applications, thereby directly affecting both States' operational capabilities and sovereignty.

Impacts of the "non-use" scenario are detailed in section 5.

5. IMPACTS OF GRANTING AN AUTHORISATION

The "non-use" scenario of the present AfA entails economic impacts on EURENCO (loss of profits and loss of investments), as well as economic impacts on EURENCO's customers relying on GAP for their applications and impacts on the availability of armament systems for armed forces.

Direct economic impacts of the "non-use" scenario for EURENCO include a loss of revenues and a loss of investments.

One of the specificities of the present AfA, however, lies in the diversity of actors concerned by the production of GAP within EURENCO's chain of value. The "non-use" scenario will therefore generate indirect impacts that can be expected to significantly exceed the direct impacts for EURENCO. Assessment and monetisation of such indirect impacts appeared to be too complex to be carried out but a qualitative description is provided in what follows regarding the impacts for the French State, industrial defence companies as well as several armed forces and armies relying on GAP for their applications.

5.1. Economic impacts

5.1.1. Loss of profits

The assessment of the loss of profits foreseen during the review period in the context of the "non-use" scenario is based on internal financial and accounting information regarding cost price and selling price.

Profits forecasts for PAG over the 2017-2021 period are provided in Figure 5 below:

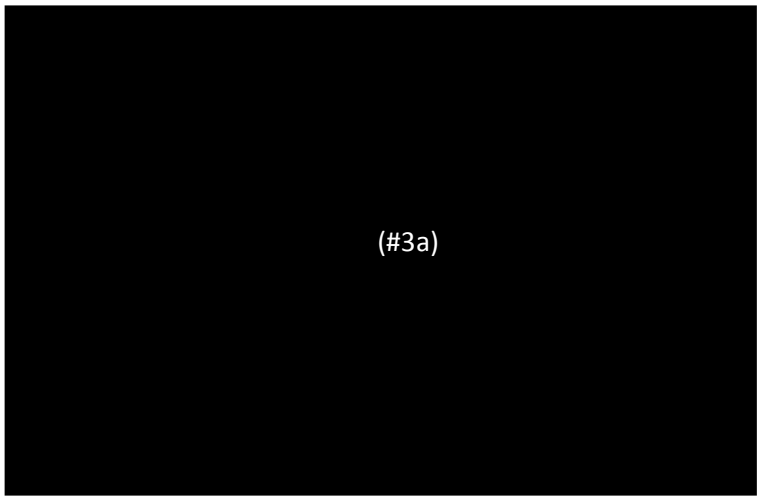


Figure 5. PAG profits forecasts over the 2017-2021 period
(*) = Based on actual contractual agreements; (**) = Preliminary forecasts

In the context of the "non-use" scenario, it is estimated that profits for the 2018-2021 period would be lost.

Taking this assumption into account, as well as a 4% discount rate, the total loss of profits generated by the "non-use" scenario over the 2018-2021 period amounts to € 390k.

5.1.2. Lost investments

The inventory of all the investments made in favour of the production of PAG has been carried out by EURENCO's accounting department.

The assessment of the lost investments foreseen in the context of the "non-use" scenario is based:

- On the identification of the investments still due for amortisation after the year 2018, as well as the precise number of amortising years remaining;
- On the annualised costs method;
- On a 4% discount rate.

A synthesis of the investments amounts concerned by the assessment is provided below:

LAST ANNUITY	TOTAL AMOUNT IN AMORTISATION
2019	€ 13,359
2020	€ 11,438
2021	€ 6,226
2022	€ 1,902
2023	€ 69,655
2024	€ 78,695
2025	€ 39,320
2026	€ 44,919
2033	€ 2,378
TOTAL	**€ 267,892**

Table 29. Detail of investments in amortisation, by year of last annuity

The total lost investments foreseen in the context of the "non-use" scenario amounts to € 268k.

5.1.3. Contractual penalties

GAP concerns long-term defence applications, for which contractual agreements stipulate commitments in terms of supply. Contractual penalties are foreseen in the context of the "non-use" scenario, either directly for EURENCO or for EURENCO's customers.

Contractual agreements being confidential, the amounts of such penalties cannot be disclosed in the present dossier.

5.2. Human health or Environmental impact

The "non-use" scenario will generate a four-year cease of production of GAP and therefore of consumption of EDC; no human health or environmental impacts are therefore foreseen.

5.3. Social impact

5.3.1. Direct impact on employment

In the current context, the production of PAG does not constitute the main activity of the synthesis facility. Reassignment of workers concerned by the present AfA is therefore foreseen by EURENCO as possible.

No direct impact on employment is foreseen in the context of the "non-use" scenario.

5.3.2. Indirect impact on employment

The present AfA indirectly concerns EURENCO's customer applications relying on GAP for their development and/or their commercialisation.

The 4-year disruption of supply of GAP will thus impact such applications and interrupt the activity of EURENCO's customers, thereby generating either forced reassignment or layoff of workers.

Even though the knock-off effect of the AfA on employment for EURENCO's customers cannot be estimated, the "non-use" scenario will have an indirect impact on employment for EURENCO's customers.

5.4. Wider economic impact

No wider economic impacts (international trade, competition and economic development) are considered in this AfA.

5.5. Distributional impact

5.5.1. Loss of investments for the French State

As stated in section 2.2.4.1, a strong investment was made by the French Ministry of Defence for the development of a new generation of GAP-based tactical missiles. It is reminded that MMP and MRCM are expected to constitute a key asset within equipment of the French armed forces in 2023 and 2025.

The development of these applications is the result of a decade of research works and investments made by the French Ministry of Defence.

A four-year disruption of supply of GAP will generate a significant technological backwardness as compared to competing companies, that will strongly jeopardise export potential for both MMP and MRCM.

As the "non-use" scenario, and therefore the cease of supply of GAP by EURENCO, would strongly jeopardise the development of both MMP and MRCM tactical missiles, such investments would be considered as lost in this case.

The amount of research and development works related to the development of new generation propergols was estimated by the French Ministry of Defence's DGA to around € 1M per year over the last two decades.

Approximately € 20M of investments has been made by the French State in favour of the development of GAP-based propellant systems. In the context of the "non-use" scenario, a significant delay will be introduced in the development process of the applications.

Since defence companies are already putting competing solutions on the market, this delay may jeopardise the very commercialisation of these applications on the export market. In such a case, the investments made by the French Ministry of Defence would be considered as lost, as the financial sustainability of the programme could not be ensured.

5.5.2. Impact on the activity of EURENCO's defence industry customers

As already stated in section 2.2.4, several defence industry companies are directly or indirectly involved in the development, the production and the commercialisation of GAP-based applications.

5.5.2.1. MMP and MRCM tactical missiles

As stated in section 2.2.4.1, MMP and MRCM tactical missiles represent a strong export potential: at the time of drafting of this document, export sales of around 5,000 units of MMP and 2,000 units of MRCM are expected and sales of around 1,500 MMP and 2,000 MRCM are expected for French armed forces. In the context of the "non-use" scenario, it is expected that:

- The development and operational deployment of MMP and MRCM intended for the French armed forces will be significantly delayed;
- The technological backwardness generated by the 4-year cease of supply of GAP is considered as critical as compared to competing offers on the market. A significant share of export sales of MMP and MRCM will therefore be lost.

For commercial reasons, the exact unit costs of MMP and MRCM have not been disclosed and the total impact of the 4-year disruption of supply of GAP cannot be estimated. It has however to be noted that the manufacturer of the MMP missile,

estimates that a total of 9,000 export sales is necessary to ensure profitability of the MMP development programme[68].

The "non-use" scenario will directly impact the availability of strategic defence equipment for the French armed forces, as well as generate a significant loss of revenues for companies involved in the development and commercialisation of MMP and MRCM.

The loss of export sales foreseen in the context of the "non-use" scenario will potentially jeopardise the overall profitability of the MMP and MRCM programmes and therefore endanger their very sustainability.

5.5.2.2. RESUS submarine rescue system

The 4-year disruption of supply of GAP foreseen in the context of the "non-use" scenario will significantly impact the production and commercialisation of Bayern Chemie's RESUS solid submarine rescue system, with two main consequences:

- A loss of revenues related to the cease of commercialisation of RESUS solid to navies and,
- A cease of supply of RESUS solid to the navies and therefore the potential operational unavailability of submarine forces.

Gap-based RESUS solid accounts for around 5% of the revenues of Bayern Chemie. The exact quantitative assessment of the loss of revenues for the company, however, cannot be precisely estimated.

The "non-use" scenario will generate a significant loss of revenues for Bayern Chemie and will impact submarine forces over the world.

5.5.3. Impact on operational unavailability of armament systems for armed forces

Given its specific applications, the cease of supply of GAP by EURENCO will have strong consequences for the end-users of GAP-based applications: armed forces.

5.5.3.1. French armed forces

Thanks to the increased performances of Azorgol-based MMP and MRCM as compared to current-generation missiles, MMP and MRCM are foreseen to constitute key assets for the French armed forces.

Such increases in performances include: increase in thrust (acceleration, range), stability over time (economic and logistics gains) and stealth properties (lack of smoke and reduced infrared signature).

[68] François Julian, La DGA lance le développement du Missile Moyenne Portée (www.air-cosmos.com), December 5th, 2013

In the context of future military engagements, such properties are foreseen to be of major interest for armed forces. The unavailability of such GAP-based missiles within the expected timeframe will incur a strong stepback both in terms of technological advancement and operational capabilities.

5.5.3.2. German and foreign navies

GAP-based RESUS is the main rescue system of all German submarines and is installed in many foreign navies, notably: Greece, India, Israel, Italy, South Korea and Turkey.

The lifespan of the RESUS system is 10 years, meaning that RESUS systems have to be regularly replaced. The unavailability of GAP in the context of the "non-use" scenario will see the need for a replacement with the hydrazine-based RESUS liquid or the rescue system of a competing company. Although subject to compatibility issues, both options involve adaptation costs and delays.

5.6. Uncertainty analysis for both the "applied for use" and the "non-use" scenario

5.6.1. "Applied for use" scenario

5.6.1.1. Preliminary observation: uncertainty of exposure and risk values

The assessment of exposure to EDC is mainly based upon ART modelling. In order to reduce the uncertainty on these values, it was chosen to rely on values for the 90th percentile of exposures.

The exposure data and therefore the excess of risk of cancer used all along this AfA for the monetisation of impacts are considered to reflect the actual exposures of workers; no further uncertainty analysis was carried out concerning these parameters.

5.6.1.2. Uncertainty analysis of the Value of a Statistical Life-Year

Uncertainty analysis of the costs associated to mortality and morbidity was carried out using the lower and upper bounds of Value of a Statistical Life-Year defined by NewExt[69]: respectively € 27,240 and € 225,000. Please note that these two values are considered as less robust than the central value used for the assessment because they are based upon survey results derived from smaller sample sizes.

Taking into account the correction for inflation over the 2003-2015 period, the total costs associated to mortality and morbidity for these two values amount to:

[69] NewExt, New Elements for the Assessment of External Costs from Energy Technologies, 2003

	COSTS ASSOCIATED TO MORTALITY AND MORBIDITY
Considering the upper bound of Value of a Statistical Life-Year (€ 225,000)	€ 16.1
Considering the lower bound of Value of a Statistical Life-Year (€ 27,240)	€ 1.9

Table 30. Uncertainty analysis for mortality and morbidity, Use-1

5.6.1.3. Dermal exposure

As stated in section 3.5, only exposure via inhalation was considered in the assessment of the monetised impacts of the "applied for use" scenario. In order to provide as a comprehensive picture as possible of the impacts related to the exposure to EDC, an assessment taking into consideration dermal exposure was also carried out.

On the basis of the same methodology than described in section 3.5.2 and section 3.5.3, the costs associated with dermal exposure amount to:

	COSTS ASSOCIATED WITH DERMAL EXPOSURE
Medical treatment	€ 3.8
Mortality and morbidity	€ 177.1
Total	**€ 180.8**

Table 31. Costs of the "applied for use" scenario associated with dermal exposure

Considering both costs associated with inhalation and dermal exposure, the cost-benefits ratio of the present AfA amounts to approximately 3,500.

5.6.1.4. Other parameters: qualitative uncertainty analysis

A qualitative uncertainty analysis of the main hypothesis, assumptions and parameters used for the assessment of the "applied for use" scenario is provided below:

APPLICATION	PARAMETER	UNCERTAINTY ANALYSIS
Mortality and morbidity	- Standard life expectancy - Mean age of cancer death - Mean age of cancer diagnosis	*Low uncertainty*: although data used are average and are not directly representative of the population of workers concerned by the AfA, uncertainty is reduced by the use of specific data for the French population.
	- Disability weight	*Low uncertainty*, since the value used is specific for cancer
Medical treatment	- Costs of medical treatment	*Low uncertainty*, since the value used is specific for cancer in France
	- Survival rate	*Low uncertainty*, since the values used are specific for cancer in France

Table 32. Qualitative uncertainty analysis of the main parameters of the "applied for use" scenario

5.6.2. "Non-use" scenario

5.6.2.1. Qualitative uncertainty analysis

A qualitative uncertainty analysis of the main hypothesis, assumptions and parameters used for the assessment of the "non-use" scenario is provided below:

APPLICATION	PARAMETER	UNCERTAINTY ANALYSIS
Loss of revenues, profits and orders	- Profits impacted by the AfA	*Low uncertainty*: the values used to estimate the loss of profits are based on accounting data and specifically concern the production of GAP.
Loss of investments	- Investments related to the development and production of GAP	*Low uncertainty*: the values used to estimate the loss of investments are based on accounting data and specifically concern the production of GAP.

Table 33. Qualitative uncertainty analysis of the main parameters of the "applied for use" scenario

5.6.3. Conclusion

The results of both the quantitative and qualitative uncertainty analyses presented above do not seem to invalidate the overall results of the AfA: the variability for the parameters assessed does not call into question the fact that the risk-benefits ratio is favourable to AfA.

5.7. General conclusion on the impacts of granting an authorisation

A synthesis of the monetised impacts of the "non-use" scenario is provided below:

		MONETISED IMPACTS
Economic impacts	Loss of profits	€ 390,661
	Lost investments	€ 267,892
Total monetised impacts of the "non-use" scenario		**€ 658,554**

Table 34. Synthesis of the monetised impacts of the "non-use" scenario

As a complement, other impacts of the "non-use" scenario are synthesised in the table below:

		IMPACTS	ORDER OF MAGNITUDE
Economic impacts	Contractual penalties	Since security of supply constitutes a strategic element, contractual agreements regulate markets related to defence applications. Such contracts may require contractual penalties in case of a disruption of supply such as foreseen in the context of the "non-use" scenario	Not assessed
Social impacts	Indirect employment	Several EURENCO's customers rely on GAP for the development and commercialisation of defence applications. The disruption of supply of GAP will generate either forced reassignment or layoff of workers.	Not assessed
Distributional impacts	Loss of investments for the French State	GAP-based versions of MMP and MRCM are the result of around 20 years of research and development works. A significant share of those investments will therefore be considered as lost in case such applications are delayed or abandoned.	Tens of millions of Euros
	Impact on the activity of EURENCO's defence industry customers	The "non-use" scenario will have significant impacts on revenues of the defence companies involved in the development and the commercialisation of GAP applications.	Not assessed
	Impact on operational unavailability of armament systems for armed forces	The "non-use" scenario will impact the operational availability of defence applications for armed forces and therefore impact the sovereignty of several States in the world and notably France and Germany.	Not assessed

Table 35. Other impacts of the "non-use" scenario

6. CONCLUSIONS

6.1. Comparison of the benefits and risks

On the basis of the foregoing assessment, the socio-economic benefits outweigh the risks arising from the use of the substance by a factor of approximately 160,000.

6.2. AoA-SEA in a nutshell

AoA – SEA IN A NUTSHELL

APPLICATION FOR AUTHORISATION

APPLICANT: EURENCO

SUBSTANCE: 1,2-Dichloroethane

USE: Industrial use of 1,2-Dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, an energetic oligomer with hydroxyl terminations used to increase the energetic performance of propellants, high explosives and powders used with firearms.

ANALYSIS OF ALTERNATIVES

The main sought-after functional properties 1,2-Dichloroethane under Use-1 notably include:

- Solubilisation of raw materials of synthesis of polyepichlorohydrin
- Solubilisation of polyepichlorohydrin,
- chemical inertia toward reagents,
- controlled water content and acidity
- non-miscibility with water
- controlled boiling point

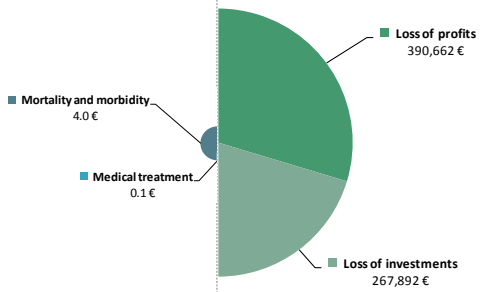
A significant work of research carried out by EURENCO in collaboration with its customers led to identify three potential alternatives for the functional requirements of Use-1: (#1w) and toluene

As a consequence, no potential alternative will be available before the sunset date of 1,2-Dichloroethane and a **four-year review period** is needed to achieve substitution.

SOCIO-ECONOMIC ANALYSIS

As per Art. 60(4) concerning the Socio-economic assessment route, evidence was provided that the socio-economic benefits outweigh the risks arising from the use of the substance by a **factor of approximately 160,000.**

Complementary impacts of the "non use" scenario involve contractual penalties, indirect impact on employment, loss of investments for the French State, loss of revenues for EURENCO's defence industry customers, as well as impacts on operational availability of defence applications systems for French, German and foreign armed forces.



Monetised impacts of the "applied for use" scenario: € 4.1

Monetised impacts of the "non use" scenario: € 658,554

6.3. Information for the length of the review period

On the basis of the arguments put forward, EURENCO applies for a four-year review period.

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

If an authorisation is granted, EURENCO will pursue the substitution process described in section 4.4.4.

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8. ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

In order to preserve the confidentiality of strategic data of the present AfA, confidential business information was blanked out.

The following table provides a justification for confidentiality of the blanked out data of this document.

BLANKED OUT ITEM REFERENCE	PAGE NUMBER	JUSTIFICATION FOR CONFIDENTIALITY
#1	7, 25, 42, 44, 45, 46, 47, 48, 65	**Strategic data**: the blanked data concern non-public results of research works; their disclosure would provide a potential competitive advantage to competitors. These data are furthermore subject to confidential research works with the French Ministry of Defence.
#2	42	**Strategic data**: the blanked data concern research works of EURENCO; their disclosure would provide a potential competitive advantage to competitors.
#3	54	**Strategic data**: the blanked data concern non-public financial figures characterising the activity of EURENCO.

Table 36. Justification for confidentiality claims

Please note that, wherever possible, and in order to not affect the understanding of the application, an effort was made to provide range of values for key confidential data. These data ranges are presented in square brackets, e.g. [10-100].

9. APPENDIXES

9.1. Complementary elements of context: the defence sector

With around 400,000 direct and up to 960,000 indirect jobs as well as revenues estimated to € 96B for 2012, the defence sector is a key component of the European industrial capabilities and competitiveness[70]. As stated by the report of the EU Parliament of 30 October 2013, this industry is also necessary to achieve an operational Common Security and Defence Policy[71].

As a major European defence actor, France boasts the second largest defence industry, right behind the United Kingdom. Key figures of the French defence industry comprise[72]:

- € 17,5B of revenues for 2011, of which 35% from export;
- A positive balance of trade of € 2.7B where the national deficit is € 70.1B;
- A total of 165,000 of mainly highly qualified jobs;
- A dozen of world-class players (Airbus, Thales, DCNS, Dassault, Safran, Nexter, MBDA…) and more than 4,000 small, medium and intermediate-sized companies.

Altogether, France's armament industry amounts to 7% of worldwide global armament exports[73] and to 32% of the European armament exports[74].

It should be stressed that, unlike other traditional industrial sectors, matters of sovereignty profoundly impact the defence industry's organisation and choices, especially in France. EURENCO, as a supplier of critical technologies, is therefore subject to significant specificities and constraints in its relation with the French administration. These specificities are key to understanding this AoA and SEA and also explain why a major focus is made on the French system.

Below considerations are therefore meant to provide the reader with first elements of context necessary for the building of the "applied for use" and the "non-use" scenarii. It will be shown that France created an idiosyncratic model of defence industry, fuelled by the concept of sovereignty *(9.1.1)*. A centralized system stemmed from this model and contributed to impact the autonomy of Defence companies *(9.1.2)*. European law also impacts the companies' international strategies by framing the import/export of weapons (*9.1.3)*.

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[70] European Commission, On defence - Towards a more competitive and efficient defence and security sector - Commission staff working document, 2013

[71] Report of the EU Parliament on the European Defence Technological and Industrial Base (2013/2125(INI)) of 30 October 2013: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2013-0358+0+DOC+PDF+V0//EN

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9.1.1. The rationale behind the French industry of Defence: a concept embedded in the notion of sovereignty

9.1.1.1. From sovereignty to a fit for purpose French defence technological and industrial base (DTIB)

→ *Sovereignty à la française: a multifaceted concept*

The defence industry is not at all times and under all circumstances a market only. On a broader level, this industry is a system[75] established between a State and an industry, fuelled by History and idiosyncratic defence principles. By definition, this relationship and its consequences will vary from one country to another, as it forms an integral part of the country's diplomacy and military power. It is also a part of the notion of sovereignty.

Sovereignty is first and foremost a legal concept of international law that was formalised by Jean Bodin in 1576 in the sixth volume of the "Livres de la République" (books of the Republic). The currently accepted legal definition was stated by Louis le Fur at the end of the 19th century: "*Sovereignty is the right of the State to be obliged or directed only by its own will within the limits of law, and according to the purposes it is supposed to achieve*".

It is therefore different from the notion of independence, which is a *de facto* concept that is variable (e.g. energetic or technological independence) and contingent (i.e. which may possess several states from dependency to independency). Based on its very own purposes, a State is therefore either sovereign or it is not. This clear dichotomy is the result of the sensitivity of matters impacting sovereignty (like major technological changes undergone by defence programs), any change being likely to tilt the balance one way or the other.

As regards France, a definition of sovereignty was given by the "Livre blanc de la défense et de la Sécurité" (French White Paper on defence and national security) of 2013. The following excerpts illustrate both the definition and the commitment of the French State towards its sovereignty[76]:

- "The defence industry is a key component of France's strategic autonomy. It also contributes to coherent political, diplomatic and economic ambitions. It alone can guarantee the secure supplying of equipment supporting our sovereignty and of critical weapons systems and ensure that it matches operational needs as defined by the Ministry of Defence".
- "The President of the Republic has chosen to preserve all the critical industrial sectors that make our industrial and technological base an instrument for preserving France's strategic autonomy and its sovereignty".
- "France considers that the greater its autonomous capacity for initiative and action, the greater will be its contribution to a collective response and its ability to mobilise allies and partners. France therefore considers the

[75] AACHEAR (2014) Quelle évolution pour l'industrie française de l'armement terrestre? In Géostratégie et armement au XXIème siècle - Collection Armement et Sécurité

[76] Ministère de la Défense, French White Paper – Defence and national security, 2013

principle of strategic autonomy as the main pillar of its external intervention strategy".

- "The French defence budget will continue to be the second largest military budget in the European Union. It represents the price to be paid to maintain France's ambitions and preserve its strategic autonomy".

The French national defence industry is a pillar of the country's sovereignty.

→ ***The consequences of this concept in terms of acquisition of equipments***

France's defence initiative is based on two pillars: a strategic analysis and an active defence policy. Main components of these two pillars are detailed below.

STRATEGIC ANALYSIS (REFLEXION)	DEFENCE POLICY (ACTION)
Operational prospective Military characterization of risks and threats Operational scenarios	**Upstream technical studies**
Geopolitics and geostrategic prospective Identification of potential threats	**Procurement strategy and industrial strategy**
Defence prospective Impacts of technologies on threats and risks	**Definition of armed forces** Operational contracts
Defence ambitions Doctrine	**Alliance strategies** Defence agreements
Budgetary parameters	

Table 37. Global elements of France's defence long-term strategy[77]

Acts of sovereignty like national purchase of defence equipments (as highlighted in the above table) are driven by many factors, such as the necessity not to depend on foreign supply. Even though transfers of defence-related products within the Community have been greatly simplified thanks to the introduction of Directive 2009/43 of May, 6 2009, Member States still benefit from a safeguard provision under article 15 of the Directive so as to suspend the effect of a transfer licence.

An example of such a risk, though anterior to this Directive, is given by the United Kingdom and Belgium during the Gulf War. United Kingdom had chosen to rely on Belgium for its ammunitions supply. During the Gulf War, Belgium did not join the coalition and therefore refused to supply medium calibre ammunitions for its infantry combat vehicles. The supply of such ammunitions was only obtained after

[77] Projet de loi de finances pour 2013: Défense: environnement et prospective de la politique de défense, 2013

the United States used its diplomatic clout on a Swiss manufacturer that had also initially refused to supply the UK[78].

On a more global perspective (outside the scope of the EU), a recent example of the stakes of sovereignty and procurement autonomy can be found in France's refusal to deliver a Mistral-class amphibious assault ship to the Russian Navy because of the crisis in eastern Ukraine.

The constraints of sovereign military power therefore put pressure on States, who need to decide between two strategies[79]:

- **The acquisition strategy**, based on the actual needs of the army. It aims at a greater efficiency, achieving the best value for money and ensuring the highest possible level of interoperability between allies;
- The national industry defence strategy, whose aim is twofold:
- From the point of view of keeping a broad and well-functioning **industry of defence**, its objective is to preserve jobs, foster R&D, acquire competitive advantages, etc.
- From the point of view of **military effects**, its objective is to secure supply, develop better equipments than other armies and obtain a greater support from industry in case of massive field operations.

These two strategies are very often conflicting. In the UK, priority is for instance given to operational needs over industrial considerations in order to achieve the best value for money[80]. **In France, conversely, industrial manufacturing within the country was often prioritised[81]. Procurement strategy and industrial capacities are therefore intertwined.**

→ ***The necessary construction of a national DTIB to support this model***

To support this model, France built a Defence Technological and Industrial Base (DTIB) to help it prepare, acquire and implement armaments needed by its armed forces and answer the priorities of its Government.

The DTIB is constituted of all the SMEs and large companies involved in the defence industry. EURENCO is one of its prominent actors. The DTIB is absolutely necessary to ensure the availability, safe access, performance, evolution, supply of consumables and maintenance of the equipments during the whole life of an armament program[82].

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[78] AACHEAR (2014) Technologies et industries de défense et de sécurité. In *Géostratégie et armement au XXIème siècle* - Collection Armement et Sécurité

[79] Sénat (4 juillet 2012) Rapport d'information: Les capacités industrielles militaires critiques, p. 28

[80] MoD (February 2010) The defence strategy for Acquisition reform AND (February 2012) National Security through technology

[81] Sénat, Rapport d'information - Les capacités militaires industrielles critiques

[82] http://www.defense.gouv.fr/dga/industrie2/industrie-de-defense/maintenir-et-developper-la-base-industrielle-et-technologique-de-defense-francaise-et-europeenne"

The French institution for statistics (INSEE) is responsible for analysing the economics and structure of the French industry of Defence via the statistical register SANDIE[83]. This work helps fleshing out the very existence and nature of the DTIB and making sure that all resources are present on the territory to guarantee a supply in line with the interest of sovereignty.

From the very point of view of the territory, the DTIB also plays a major role in terms of employment. The Ministry of Defence is indeed France's second public employer and its first recruiter. From a local perspective, a strong historical context has dictated the implementation of the defence industry companies in very specific areas of France's territory (usually far from the eastern border), as shown below:

REGION	SHARE OF THE TOTAL EMPLOYEES OF THE DEFENCE INDUSTRY	SHARE OF THE INDUSTRIAL EMPLOYEES OF THE REGION
Île-de-France	28 %	12 %
Provence-Alpes-Côte d'Azur	15 %	20 %
Bretagne	9 %	10 %
Centre	9 %	10 %
Aquitaine	8 %	11 %
Pays de Loire	6 %	4 %
Midi-Pyrénées	6 %	7 %
Basse-Normandie	4 %	9 %

Table 38. Share of the total employees of the defence industry in France and share of the industrial employees by region, in 2012. Source: Conseil économique de défense[84]

As an example, the defence industry amounts to 9% of the overall defence industry employment and 10% of the regional industrial employment in the region Centre. In this region, one third of the companies generate more than 25% of their revenues in relationship with the defence industry[85], demonstrating the sensitivity of the territory to employment changes in the defence industry sector.

On an intra-regional level, the defence industry sector represents the largest industrial employer in cities such as: Bourges, Brest, Cholet, Fougères, Lorient,

[83] http://www.insee.fr/fr/insee-statistique-publique/default.asp?page=statistique-publique/defense.htm

[84] Mentioned in: Rapport d'information déposé en application de l'article 145 du Règlement par la Commission de la défense nationale et des forces armées en conclusion des travaux d'une mission d'information relatifs à une vue capacitaire des armées et présenté par MM. Yves Fromion et Gwendal Rouillard, Assemblée Nationale, n°1233, 10 juillet 2013, p41.

[85] Serfati,L'industrie française de la défense, La documentation Française, 2014

Roanne and Vendôme. Those areas are, therefore, extremely sensitive to any modification in the defence industry activities[86].

As a global consequence of its strategic defence choices and implantations, France is one of the only four countries in the world with the ability to design and manufacture nearly all the armament systems necessary for its defence and security, from rifles to missiles[87].

9.1.1.2. A DTIB to guarantee Critical Industrial Military Capabilities (CIMP)

→ *The different levels of equipments: from core equipments to off-the-shelf equipments*

The DTIB therefore produces industrial capacities, which are critical for the conception, operation and support of "sovereign armament systems", i.e. armament systems that directly participate to France's sovereignty.

Of course, not all the equipments supplied by the industry of defence are absolutely strategic or vital for the preservation of France sovereignty. It is therefore proposed to use the "three circles" model, as identified by the French National Assembly in its reports, so as to define the status of defence technologies:

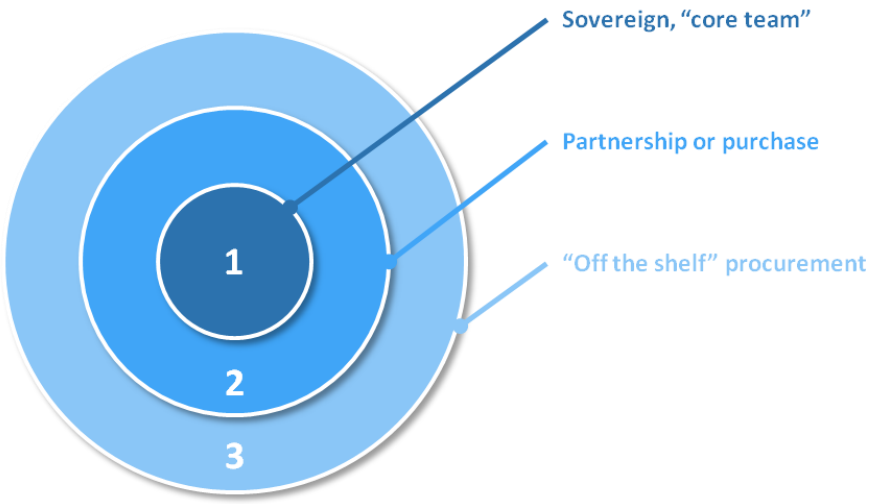

Figure 6. "Three circles" model of the statuses of defence technologies and competences[88].

[86] Cidef - L'industrie de la défense en 2012

[87] Besson, L'industrie de l'armement, un atout majeur pour la France, Le Figaro, 19/02/2008

[88] Saulnier, Les oscillations de l'industrie française de défense: entre continuité régalienne et transformations organisationnelles, 2010. In La Souveraineté, Prospective et stratégie, Association pour la Prospective et la Stratégie, 2010

The three concentric circles represent:

- ***Sovereign, "core team"***: technologies or competences that are compulsory to possess;
- ***Partnership or purchase***: technologies or competences that are essential, but that could be outsourced or obtained via specific partners;
- ***"Off the shelf" procurement***: technologies or competences that are neither sensitive nor necessary to possess internally.

The combination formed by sovereign armament systems and the industry producing them is called CMICs, which stands for "Critical Military Industrial Capabilities".

→ ***Definition of CMIC and application to the case of EURENCO***

"Critical military industrial capabilities"[89] (CMICs) regroup critical industrial capacities, technologies that are part of the "core team" as well as materials and human resources needed to allow the State's strategic autonomy. The French Ministry of Defence, as a tool to support the State's sovereignty, carries out the determination of CMICs.

It should be noted that the determination of CMICs differs from one country to another. For example, if nuclear capabilities are clearly critical military industrial capabilities for the French defence strategy, it is not the case for Germany, which did not rely on nuclear deterrence for its sovereignty. As explained by Scheel[90], such strategic choices in the context of national sovereignty are no mere choices: they are the expression of the State command.

Uses covered by this AfA impact both sovereign armament systems and a critical defence industry. The Authorisation requested by the Applicant should therefore be understood in the global technical, economic and strategic context attached to CMICs.

Finally, the attention of the reader is drawn to the fact that, in an even more stringent way than for other private sectors, confidentiality matters are **at the core of the defence industry's development and production strategies.**

Even though data concerning the global figures of defence, its equipments and staff are available, detailed data about specific performance levels of the equipments or on-board technologies remain strictly confidential.

In this context, an effort was made by the Applicant to disclose as many details as possible concerning the processes implemented, the reflection on potential alternatives and the stakes & requirements of the armed forces regarding the applications. Limits of this initiative were nevertheless attained when addressing three topics: the specific level of performance of the applications, the detailed implementation and use by the armed forces as well as the specific impacts for the army and the Ministry of Defence.

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[89] In french: "Capacités industrielles militaires critiques"

[90] Scheel, L'externalisation des fonctions opérationnelles et de soutien: une boîte de Pandore ? La tribune, n°28, p29-33, 2002

Weapon systems that are part of the CMICs cannot be compared to other types of articles, since they directly participate to the sovereignty of a country. It is the case for articles contemplated under this AfA and whose production will be jeopardized should an authorisation not be granted. Because these equipments are central to the achievement of the State's policy in terms of defence and assertion of sovereignty, moreover supporting a grassrooted industry, a particular organisation was put in place.

As a complement, stringent confidentiality matters and an overall territorial sensitivity to defence industry constitute key elements of this AfA.

9.1.2. The consequences of this model: the French State still has a central role to play in the industry of defence

The constraints applicable to the technological and economic strategies of French defence companies cannot be understood without explaining the various roles of the State in this matter. These roles can be described as follows[91]:

- The State is the main ***single customer*** of the French defence industry;
- The State, by defining the strategic defence policy, influences the development of armament programs and can therefore be seen as an ***architect*** of these programs;
- The State ***regulates*** the defence sector;
- The State, as part of its diplomacy and in order to support the industry, ***promotes*** the export of its industry;
- The State is a ***major shareholder*** of the French defence industry companies.

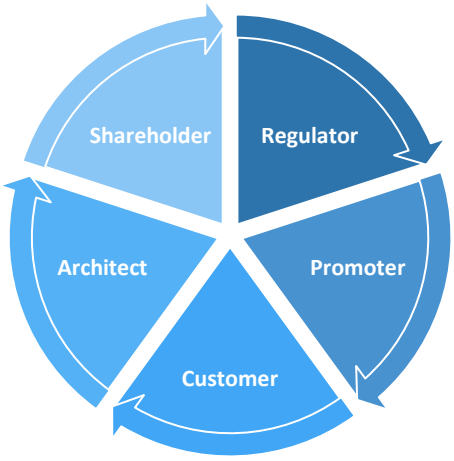


Figure 7. The five roles of the French State as regards the defence industry

In the following paragraphs, it is therefore proposed to further explain the implications of these roles.

[91] Assemblée Nationale, Journal official de la République Française, Session ordinaire du 2014-2015, Séances du jeudi 15 janvier 2015, Compte rendu integral, 2015

9.1.2.1. The multipurpose State: Architect, Prime contractor and Promoter

→ ***The State as an architect of high performance armament programs: from design to MOC (Maintenance in Operational Conditions)***

The strong involvement of the State in the definition, development and implementation of Defence programs and the resulting specific requirements for the defence industry - as opposed to "standard" private industries - can be illustrated by **France's general instruction 25/EMA-1516/DGA of March 26, 2010 for the conduct of armament operations**.

The French acquisition procedure can be presented as follows: the definition of France's policy toward armament is the responsibility of the President of the Republic, as the supreme commander of the armed forces, within the Defence & Security Council. The Ministry of defence, organized in investment committees, then carries out the management. The Ministry of defence comprises military (Etat-Major), administrative (Secrétariat Général pour l'Administration - SGA) and technical-commercial (Direction Générale de l'Armement - DGA) government agencies[92].

Expression of needs is defined by the Etat-Major, notably based on geopolitics and geostrategic works provided by the Delegation for Foreign Affairs[93].

DGA, in its role of prime contractor, then ensures the implementation of such expressed needs, based on the capabilities of the DTIB, the general "industrial strategy" for defence and its own budgetary constraints. DGA's annual expenditures budget amounts to around € 16B.

The general steps defining the lifecycle of armament programs are the following[94]:

[92] AACHEAR, Le management de l'Armement. In: Géostratégie et armement au XXIème siècle, Collection Armement et Sécurité, 2014

[93] "Délégations aux Affaires Etrangères" - DAT

[94] Ministère de la Défense, Le déroulement et la conduite des opérations d'armement (Instruction générale 125/EMA-1516/DGA du 26 mars 2010), 2011

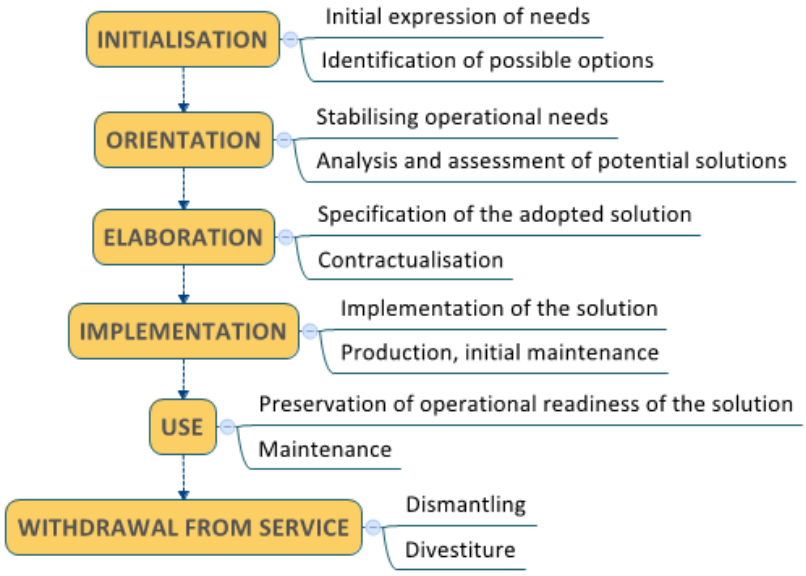


Figure 8. Lifecycle steps of French armament programs.

Given their applications, the level of performance of defence applications is subject to stringent requirements and assessment processes. Three formal assessment steps conducted by the State therefore ensure the initially defined level of performance is attained, during the whole lifecycle of the programs[95]:

- Technical tests, for the qualification of the equipments, to allow a transfer of responsibility from the supplier to the State (DGA);
- Evaluation, for adoption of the solution, to allow a transfer of responsibility from DGA to the armed forces;
- Experimentations, for entry into operational service, to finally validate combat readiness of the equipments.

[95] Ibid. 94

Validation steps are synthesized in the following table:

ACTOR	DECISION	ASSESSMENT OF COMPLIANCE…	AUTHORISATION…
DGA	**Qualification**	… with technical requirements	… of production and support
	Acceptance	… with contractual terms	… of property transfer of the equipments
Armed forces	**Adoption**	… with military characteristics	… of implementation
	Entry into operational service	… with conditions of use	… of operational use

Table 39. Verification & validation approach[96]

Performance targets are specified in the contracts between DGA and the manufacturers. Such targets may, for example, concern speed, autonomy, shooting range or shooting rate, resistance to shocks or resistance to corrosion, precision of armaments, etc. Penalties and compensations are usually stipulated in case of non-attainment of such performance levels. General terms in contractual documents are the following[97,98]:

"The holder has the responsibility to deliver a product in compliance with the market's requirements. The holder has to obtain the requested results with the means it chooses and to provide a satisfactory visibility on the processes it implements. The holder has the responsibility to implement an organisation, methods or any means allowing the attainment of quality requirements for the supplied products as well as their compliance with the requirements of the present market and to produce evidence for it."

Along with high performance requirements, the development of defence applications is characterised by stringent testing and qualification requirements. Delays between the manufacture of the initial pre-production sample and the start of industrial production are therefore much longer than those encountered in other industries.

As an illustration, the period of time needed from the laboratory scale sample to a qualified industrial process was of 3 years for the CT40 cannon barrel surface treatment. Two more years were then needed for the qualification of the gun itself.

[96] Ibid. 94

[97] JM Oudot, Renégociations des contrats de défense: le rôle des aspects informels. In: Fondements économiques et industriels de la Défense, Innovations, Cahiers d'économie et de management de l'innovation. Numéro 42. 2013

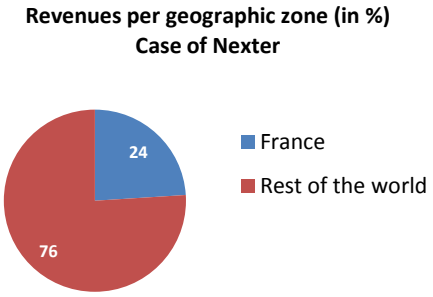
[98] Free translation

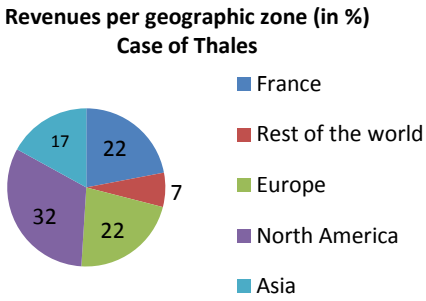
As a consequence, both from a budgetary and a staff point of view, the costs and conditions of the MOC need to be controlled and can only be subject to minor changes.

The contribution of the State to armament programs is therefore very strong, both in terms of priorities (based on its own geopolitical needs) and definition of the technological solution, at the start of the project and during its whole life (because of the MOC constraints). This process is deemed moreover representative for a majority of situations since the State is one of the prime contractors for its industry of defence.

→ ***The State as one of the prime contractors of its industry of defence***

France still represents the single biggest buyer for its industry of defence, even though the share of export inside and outside the EU increases dramatically. From this point of view, it should be noted that the proactivity of France as regards its exports is fully part of its sovereignty politics: by ensuring export outlets, France guarantees the sustainability of its model (i.e. one able to keep a strong DITB that safeguards CIMCs) in a context of budgetary restraint[99]. Below are presented the share of France in the revenues of 4 of its main defence companies[100]:





[99] Rapport au Parlement 2015 sur les exportations d'armement de la France, p. 16

[100] Calepin des entreprises internationales de défense, Edition 2014, DGA. Except for Nexter, only part of the revenues presented are dedicated to defence activities. In most cases, figures should therefore be much higher for the part dedicated to France. For instance, it was only recently that Dassault started to sell its Rafale aircraft abroad. Relative shares for the defence activities are the following: Dassault (31%); Thales (49%); Safran (9%).

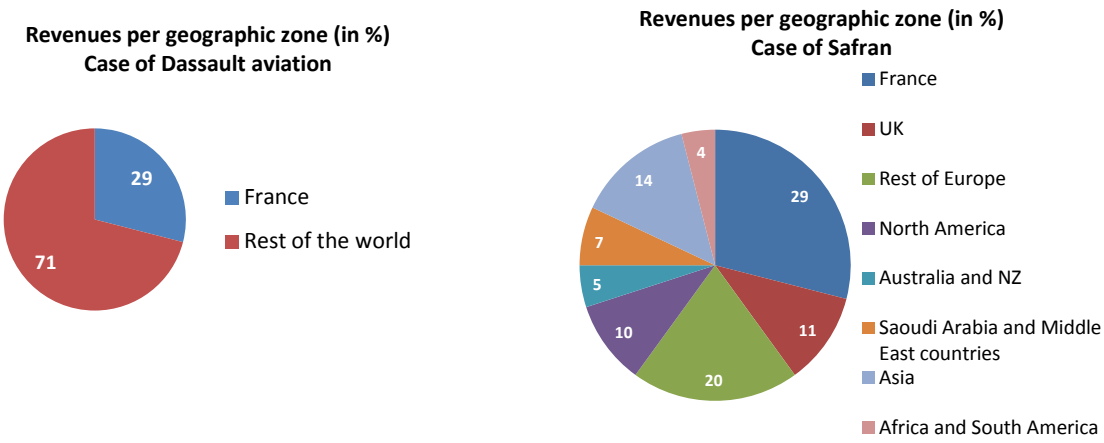


Figure 9. Share of revenues per geographic zone, for Nexter, Thales, Dassault Aviation & Safran

It should be further noted that the preference given by a country to its national industry, as it is the case for France with EURENCO, is admitted to a certain extent under European and French law. Indeed, and as provided by article 346 of the Treaty on the Functioning of the European Union:

"1. The provisions of the Treaties shall not preclude the application of the following rules:

(a) […];

(b) any Member State may take such measures as it considers necessary for the protection of the essential interests of its security which are connected with the production of or trade in arms, munitions and war material; such measures shall not adversely affect the conditions of competition in the internal market regarding products which are not intended for specifically military purposes".

This possibility was extensively used but is now framed and limited by Directive 2009/81/EC on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security. It was implemented in France by a Law of June 22 2011. Section 3 of the Directive, titled "Excluded contracts", limits this exclusion to contracts listed under articles 12 and 13 whereby (art.13):

"This Directive shall not apply to the following:

(a) contracts for which the application of the rules of this Directive would oblige a Member State to supply information the disclosure of which it considers contrary to the essential interests of its security";

Directive 2009/81/EC therefore does not preclude support given to national champions.

In this context, and in spite of the numerous calls for a more integrated European defence industry, Member States still have the possibility to favour their national supply over foreign procurement when they deem it necessary. This

situation therefore creates a strong technical and commercial link with the State, on top of the financial aspects already described.

Finally, the role of the State can clearly be seen in the action of the Ministry of Defence to sell abroad weapons and vehicles.

→ ***The State as one of the promoters of its defence industry***

Selling weapons or equipments is no usual business. The responsibility attached to it means that such sales cannot stem from occasional business but rather from a durable relationship. For a State, it even has a diplomatic dimension

This is the reason why the COMED (Comité ministériel des exportations de défense - Ministerial Committee for Defence Exports) that was set up in 2013 within the Ministry of Defence, is in charge of coordinating the efforts of the Ministry, the diplomatic posts and the Industry so as to foster exports of the defence industry.

The DGA and in particular its international bureau (DGA/DI) also intervenes upstream to facilitate the participation of the French industry to international showcases, as well as downstream, through its export directors (DOE) who sees the execution of the contracts.

Finally, the EMA (Etat-Major des Armées – military staff) is also a key actor of the export process: the fact that the French army uses the equipments gives a guarantee of reliability (the so-called "Armée française" label), while its staff participates to international showcase, perform demonstration, train foreign armies (especially through DCI – Défense Conseil International) etc.

The presence of the State and its powers directly impact the French defence companies, notably in terms of joint venture, partnership, change in the products or export.

European law and the rules applicable to export also regulate these possibilities.

9.1.3. Defence companies are furthermore entrenched in a constrained European legal environment

Rules applicable to the import and export of defence-related products play a major role in the production and commercial strategies of defence companies. The ban of a substance placed in the Annex XIV of REACh will therefore trigger industrial reflections taking into account these aspects.

9.1.3.1. Presentation of the EU and French frameworks

Several acts or regulations are applicable to the control of import and export of weapons.

Firstly, the Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment list 8 criteria to evaluate the request for licenses. It also defines best practices and creates a consultation and notification mechanism between Member

States to inform each other of the refusal to grant licenses. In 2014, France notified 13 such refusals.

Secondly, Directive 2009/43/EC of the European Parliament and of the Council of the European Union of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community is the basic regulation for the regime applicable to the import and export of weapons in the EU.

This system is here detailed for France but similar systems were implemented in the EU Member States, based on the aforementioned directive.

In France, the directive was indeed implemented and complemented by various texts destined to precise the procedure and follow up the compliance with the applicable rules. An overview of this legal framework is given in Table 41.

9.1.3.2. Rules applicable to the export of defence-related products in France

An authorisation called license is required for export operations. From this point of view, one needs to differentiate between two licenses, depending on whether the equipments are transferred to EU or non-EU countries:

- **Transfer Licenses** are meant to accompany the transfer of a defence-related product to a Member State of the EU;
- **Export Licenses** are meant to accompany the transfer to a non EU country;

These licenses can be accompanied by technical and / or legal conditions that are notified by the Ministry of Defence to the company. Customs officers check compliance with these conditions.

Moreover, 3 types of transfer and export licenses exist:

- **Individual licenses**: authorise the shipment of goods to one customer in one or several instalments;
- **Global licences**: authorise the shipment of goods to one or several customers, for a limited duration but without any limitations in terms of quantities or amount;
- **General licences**: authorise export or transfer operations comprised in its scope without having to ask an individual license for each operation. This scope is however restrictively defined by a decree.

Finally and depending on the license needed, different procedures apply in France:

- Individual and global licenses, both for transfer or export, are submitted to DGA and are evaluated by the CIEEMG (Commission Interministérielle pour l'Exportation de Matériels de Guerre – Inter-ministerial Commission missions for the study of exports of war material) once a month. Authorisations are granted by the Prime Minister after consultation of the CIEEMG and are then notified to the Minister responsible for customs.
- The use of General licenses, both for transfer or export, are not subject to the scrutiny of the CIEEMG since their scope has already been established. A declaration must however be submitted by the French industrial operator to the DGA who grant him a registration number.

Types of licenses are summarised below:

CRITERIA		PROCEDURE
Geographic criteria	Transfer license: Towards EU countries Export license: Towards non-EU countries	
Operational criteria	Individual licenses 1 customer	DGA ↓ CIEEMG ↓ Prime Minister and Minister responsible for customs
	Global licenses 1 or several customers for a limited duration	
	General licenses All operations in the restrictive scope of the license	DGA who deliver once a registration number

Table 40. French types of licenses for export operations in the context of defence

French companies must record all their operations and transmit twice a year (1st March and 1st September of each year) a complete report to the Ministry of Defence. These reports are subject to out-of-site supervision as well as on-site supervision for the cases of global and general licenses.

These procedures are both costly and time consuming. They greatly influence companies' strategies as regards their production locations since any new site or any new subcontractor outside the final equipment country of origin would subject the weapon or the armament system to new licences request.

On top of these stringent export rules, importers are also subject to burdensome procedures.

9.1.3.3. Rules applicable to the import in France of defence-related products

The import of defence-related products in the French territory requires an Authorisation also called AIMG (Autorisation d'Importation de Matériels de Guerre – import authorisation of defence-related products). The Ministry responsible for customs grants it after consultation of other Ministers (Defence, Domestic or International Affairs). This decision is essentially based on public safety and international geopolitics considerations.

One recent example is given by Decision n° 2014/512/PESC of 31 July 2014 and Regulation n° 833/2014 of 31 July 2014 imposing restrictions against Russia because of the turmoil in eastern Ukraine. Based on this, the French customs have put on hold more than 700 declarations and have conducted out-of-site and on-site supervisions to ensure that the terms of the restrictions were applied, both for import and export of defence-related products from and toward Russia.

These rules are of primary importance in deciding where production will take place. For instance, subcontracting in or outside the EU, as it could be the case on a

long term or temporary basis to overcome substitution difficulties created by the Annex XIV of REACh, is far from being an easy solution. It would indeed require for both companies to be granted licenses or authorisations for either import or export, with possible risks of disruption depending on where subcontracting is made.

9.1. Overview of France's legal framework

	TEXT	SCOPE
Military and assimilated material	- Act No. 2011-702 of 22 June 2011 - Decree No 2012-901 of 20 July 2012	Export and import of military equipment and related materials and intra-Community transfers of defence-related products
	Act No. 2012-304 of 6 March 2012 - Decree No 2013-700 of 30 July 2013	Plan of military materials, weapons and ammunition (classification of materials, organization and operation of AFCI, rules on the acquisition, holding, port, transport and transfer of arms)
	Decree No. 2012-1176 of 23 October 2012 amending Decree No. 55-965 of 16 July 1955	Update of the Inter-ministerial Commission missions for the study of exports of war material (CIEEMG)
	Decree of 27 June 2012 amended	List of war materials and assimilated subject to authorisation prior to export and products related to the defence subject to authorization prior to transfer
	Decree of 30 November 2011 as amended relating to the corporate certification procedure wishing to be recipient of defence related products	Corporate certification procedure
	Decree of 30 November 2011 amended establishing the organization of control out-of-site and on-site conducted by the Ministry of Defence under Article L2339-1 of the Defence Code	Obligations of exporters reporting transactions carried out; provisions of control in place; operation of the ministerial committee of the subsequent verification
	Decree of 16 July 2012 concerning the accounts of imports carried out and transfers of war weapons and ammunition from Member States of the European Union materials	Obligations on account of the import / transfers from EU Member States
	Decree of 14 April 2014 concerning the manner of request of individual licences and global export of war and assimilated equipment and manner of request of individual and global licenses of transfer of defence related products	Manner of declaration in respect of export restrictions

	- Decrees of general transfer license of 6 January 2012 - Decree of general transfer license of 3 June 2013 - Decree of general export and transfer of 6 June 2013	General transfer/ export licenses
Specific restrictions applying to the export, import and transfer of certain goods.	Decree No. 2014-62 of 28 January 2014	Export of firearms, ammunitions and its components
	Decree No. 2011-978 of 16 August 2011	Export and import of certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment.
	- Decree 2009-1140 of 23 November 2009 - Decree of 4 October 2007	Export, import and transfer of explosive substances and products (with the exception of explosives on the list of war and assimilated equipment)

Table 41. Overview of France's legal framework[101]

[101] Rapport au Parlement 2015 sur les exportations d'armement de la France – 2015 Report to the Parliament for the export of French defence related products, Annexes 1, 2 and 3