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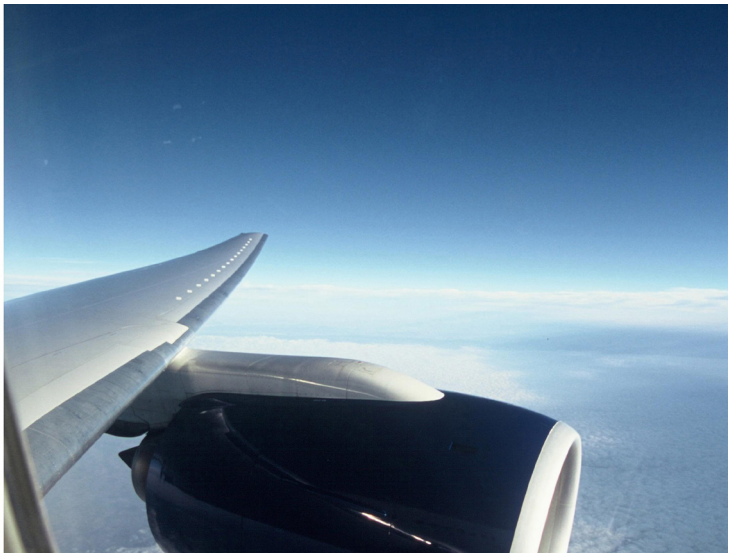
European Aviation Safety Agency

An elaboration of key aspects of the authorisation process in the context of aviation industry

April 2014



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Reference: ECHA-14-R-09-EN
Cat. number: ED-01-14-353-EN-N
ISBN: 978-92-9244-490-7
DOI: 10.2823/9437
Date: April 2014
Language: English

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Abbreviations

AEA	Association of European Airlines
ASD	AeroSpace and Defence Industries Association of Europe
Cefic	European Chemical Industry Council
DOA	Design Organisation Approval
EASA	European Aviation Safety Agency,
ECHA	European Chemicals Agency
EEA	European Economic Area
FECC	The European Association of Chemical Distributors
MRO	Maintenance Repair and Overhaul organisation
OEM	Original Equipment Manufacturer
QPL	Qualified Products List
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SEAC	Committee for Socio-economic Analysis
SME	Small and Medium-sized Enterprises
STC	Supplemental Type Certificate
SVHC	Substance of Very High Concern
UV	Ultraviolet

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Introduction

The aviation industry operates in environments which are highly challenging, due to the varied conditions in which aircraft are operated, such as extremes of temperature and humidity, and the stringent aviation safety requirements which must be met. To respond to these challenges, the aviation industry has used and will need to continue to use high-performance preparations, mixtures and formulations, some of which contain substances which have been placed in Annex XIV of the REACH Regulation 1907/2006 – implemented by the European Chemicals Agency (ECHA) – or which could be placed there in future.

Placing a substance in Annex XIV means that, if no suitable alternatives are available by the 'sunset date', the aviation industry will need to seek authorisation to continue to use it. To be suitable, alternatives must perform in such a way as to allow the aviation industry to continue to comply with the strict airworthiness standards established by Regulation 216/2008 and its associated Implementing Rules, and they can only be deemed available once they have passed through the extensive approval process by which compliance with this regulation is demonstrated.

The critical reliance of the aviation industry on Annex XIV substances, and the difficulty in finding and adopting suitable alternatives, mean there has been concern in the European Aviation Safety Agency (EASA) and the aviation industry generally to ensure that the REACH authorisation requirements do not lead to unnecessary disruption to normal operations in aviation. Accordingly, in October 2012, EASA approached ECHA to explore how the two Agencies could cooperate to ensure that the key requirements of the application for authorisation process can be implemented whilst still allowing airworthiness standards to be met.

REACH Authorisation is a "mission-critical" process for the aerospace and defence industry in general, and the aviation industry in particular due to the following characteristics:

- The level of qualification and regulatory controls associated with introduction of alternative chemicals or other design change
- The industry's dependence on certain substances of very high concern to meet key functional requirements, in particular high standards of safety over long product lives
- The complexity of the supply chain (including but not limited to chemical manufacturers, importers, distributors, formulators, component manufacturers, OEMs, Airline operators, and aftermarket repair and overhaul activities).
- The relatively small volumes of chemicals used by the industry,

REACH Authorisation is a new process which introduces a number of issues, especially due to the need for interaction and cooperation between the many levels and competitors in the supply chain, in order to achieve both continued supply as well as the authorisation itself.

Thus far, the guidance documents published by ECHA have been fairly general. Therefore, ECHA and EASA agreed to work together with the ultimate aim of exploring and explaining how the current guidance can be interpreted in the context of the aviation sector, and to provide a better understanding of the implications for authorisation of some of the key characteristics of the aviation sector. In addition, it was hoped to provide better understanding to ECHA, its scientific committees as well as Member State Competent Authorities of the interplay between airworthiness requirements and the REACH regulation. Finally, given that other sectors might also have distinct characteristics (e.g. the space and defence industries), ECHA had the more general goal of understanding how the authorisation mechanisms can be effectively implemented in these general circumstances.

It soon became clear that EASA and ECHA would not be able to achieve these objectives alone, they joined forces with the aviation industry, the upstream chemical suppliers' associations in order to seek

solutions and answers to the major concerns of the Aviation industry. In April 2013 a Steering Committee was established, 'to support [EASA] in its discussion with [ECHA] and the European Commission towards the attempt to streamline the REACH mechanisms, in particular regarding the authorisation process for aviation.' The Steering Committee was to oversee two working groups, the first addressing how the 'use' of Annex XIV substances by the aviation industry could meaningfully be defined in authorisation applications, and the second how the analysis of alternatives and socio-economic analysis could be carried out in an effective and 'fit-for-purpose' way. The working parties consisted of representatives from ASD, AEA, Cefic, FECC, EASA and ECHA.

These working groups consisted of delegates from the industry associations representing aircraft and engine manufacturers, and maintenance and repair organisations, as well as staff from ECHA and EASA. The Steering Committee met five times both to oversee the work and to endorse the conclusions of the two groups, while the working groups convened several times in person and via teleconference, as well as working through correspondence.

This document, which comprises the output of the two working groups, is therefore the result of the collaborative efforts of the aviation industry, EASA and ECHA. The findings are interesting and instructive.

The objectives of this document are:

- To provide background information to interested stakeholders so that they might better understand the relevant characteristics of the aviation industry and the regulatory demands regarding airworthiness which are made upon it;
- To explore what these characteristics and demands might imply in the context of REACH, and specifically the possible requirement to gain authorisation to continue to use substances of very high concern (SVHCs);
- To highlight for future applicants potential points to consider in their authorisation applications, how they might think about interpreting the circumstances they face in authorisation 'language', and how this might support their case for authorisation.

The group working on the description of 'use' stressed the need to ensure effective engagement with their complex supply chains, especially upstream substance manufacturers, who might be unaware of the critical dependence of the industry on relatively low levels of consumption and, accordingly, of the need to seek authorisation. The group developed examples of good working practices to improve the supply chain communication, too.

The group working on the 'analysis of alternatives and socio-economic analysis' concluded that, given the critical function of Annex XIV substances in guaranteeing airworthiness, the implications of them not being available could be dramatic for the industry, with aircraft being grounded (in the short term) and manufacturing and maintenance facilities being relocated outside of the EU (in the longer term). Even when a suitable alternative has been found, it will generally take several years to pass through the approval process and be ready for adoption. Even then, the alternative is likely to be – to all intents and purposes – impossible to implement in 'legacy' and current production aircraft. These observations suggest a strong, prima facie, case for authorisation for the aviation industry, and relatively long review periods, although all applications will still need to be fully articulated and considered on a case-by-case basis by ECHA's scientific committees.

While the report is written in terms of the 'EU', it covers both the European Union and the European Economic Area, to which REACH applies. In this document 'aviation' refers to aircraft and helicopters including their engines. In addition, many elements of this guidance are not specific to aviation and can also apply to other industries.

It has also been written as a collaborative effort with colleagues from the US, and therefore offers more global interest. After all, aircraft and components produced outside the EU could become affected by the REACH Regulation if they are maintained in the EU. Thus, we hope that the report is also helpful to interested readers right across the global aviation sector.

Answers developed may be applied to other industries as well, though the analysis is based on the specific case of the aviation industry.

While the Steering Committee has endorsed this report, it does not necessarily represent the official view of the European Chemicals Agency, the European Aviation Safety Agency or the organisations which have participated in its preparation.

The aviation industry will continue to encourage its upstream suppliers to communicate their uses and intent for Annex XIV substances, and continue to monitor the responses to its communication to the chemical manufacturers and distributers sectors. The aviation industry will also be investigating in 2014 whether suppliers several tiers upstream understand the need to apply for authorisations where needed to cover end users, in particular where they are SMEs. ECHA and EASA hope to support this by disseminating this report on their websites.

Section 1: Who should apply for Authorisation in the context of REACH for the aviation industry and how should use be defined?

1. Who may need an Authorisation?

The example below shows a supply chain where surface treatment of metals takes place, those industries highlighted need to have their uses included in an authorisation application.

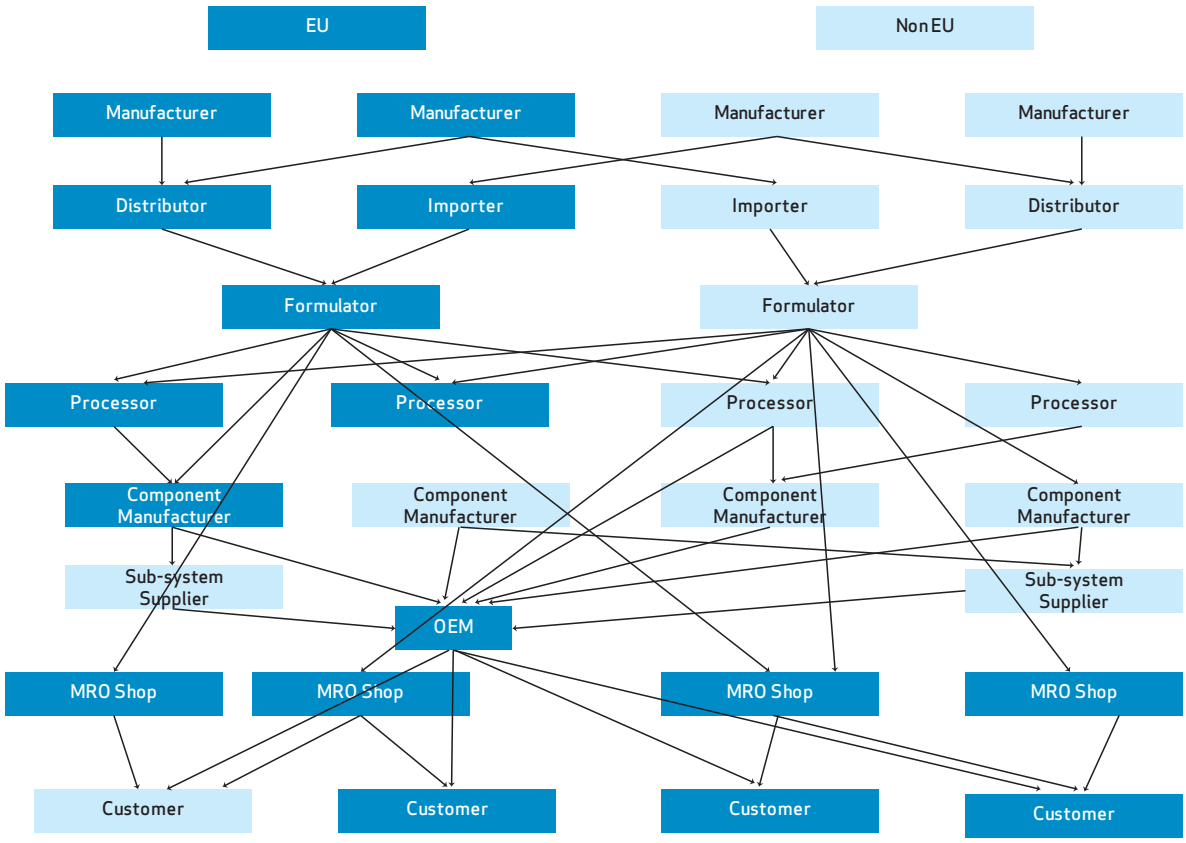

FIGURE 1: EXAMPLE OF AVIATION INDUSTRY SUPPLY CHAIN WHERE METAL SURFACE TREATMENT TAKES PLACE

2. Who should apply?

The requests for authorisation may be submitted by:

- the manufacturers or importers of the substances;
- the downstream users, which may include both formulators as well as end-users of the substance on its own or in a mixture.

- the Only Representative (OR) of a company outside the EEA
- any combination of these

An application for authorisation can be submitted:

- for one or several uses
- for one or a group of (similar) substances

An Authorisation application by a Manufacturer or Importer of a substance could cover the entire supply chain where all uses are already known.

An Authorisation application by a Formulator would cover the supply of chemicals from the Manufacturer or Importer (but if they had any uses such as packaging they would need their own authorisation if in the EEA) and the supply chain below them.

However, an Authorisation application from an OEM will only cover its own use and its immediate suppliers' right to supply the substance (on its own or in a mixture) but not the supplier's uses (if any).

Additionally, when a formulation is used, an article manufacturer or OEM cannot apply alone for an authorisation as they do not have the knowledge necessary to complete an application.

The problem, however, is that the companies who are "downstream" at the bottom of the supply chain do not in many cases have a direct relationship with the "upstream" companies at the top of the supply chain.

It is therefore imperative that Aviation companies engage with the suppliers at the top of the supply chain to encourage them to apply for authorisation and include all of the "uses" of the "downstream" users.

EXAMPLE 1

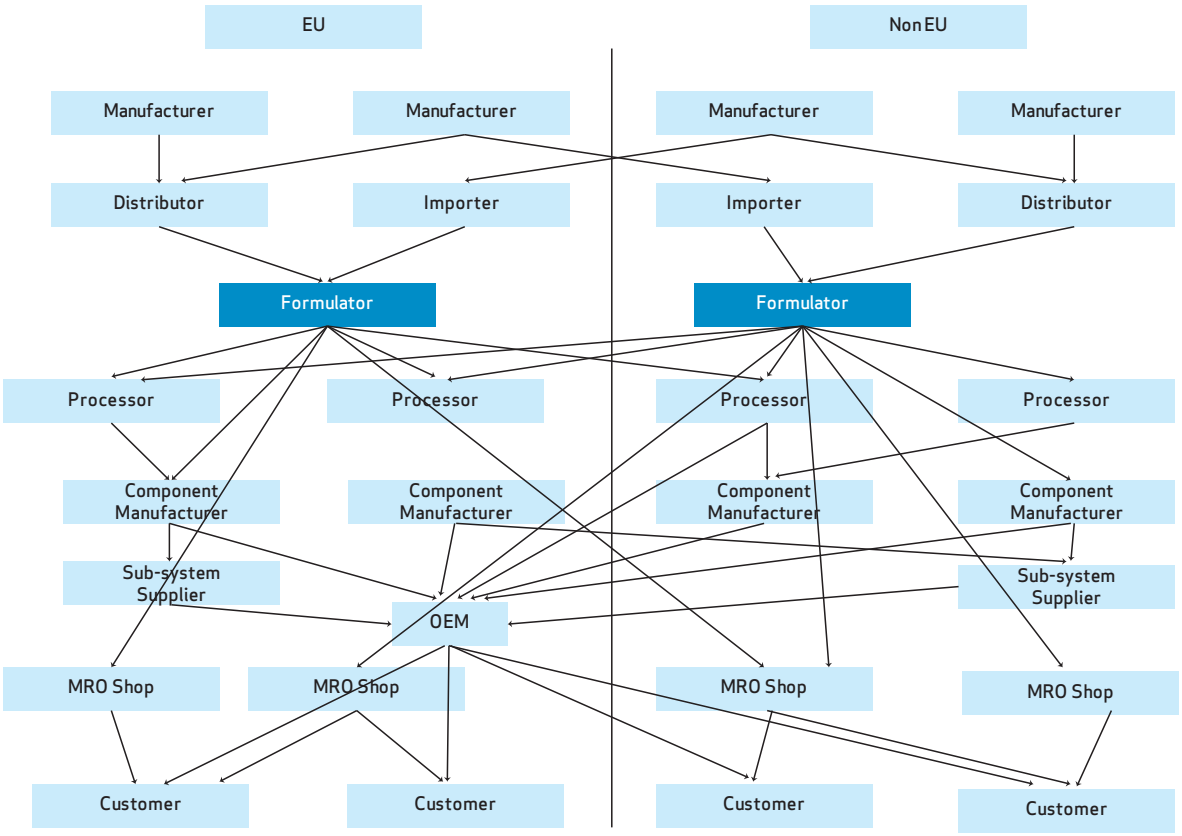

FIGURE 2: SUPPLY CHAIN: APPLICATION FOR AUTHORISATION BY A FORMULATOR.

In this example of an actual aviation supply chain, the ideal applicants are the formulators as they get their chemicals from a number of different substance manufacturers or importers (the EU manufacturers or importers may need authorisation for their own uses):

- Authorisation held by formulators can cover the downstream supply chain
    - For non-EU formulators through EU Only Representatives
- Best option to protect Formulator CBI
- Other options introduce new supply chain constrains

EXAMPLE 2

In this simpler example Airline repair shops buy directly from formulators, who ideally need authorisation to cover their use and that of the maintenance, repair & overhaul shops (MRO):

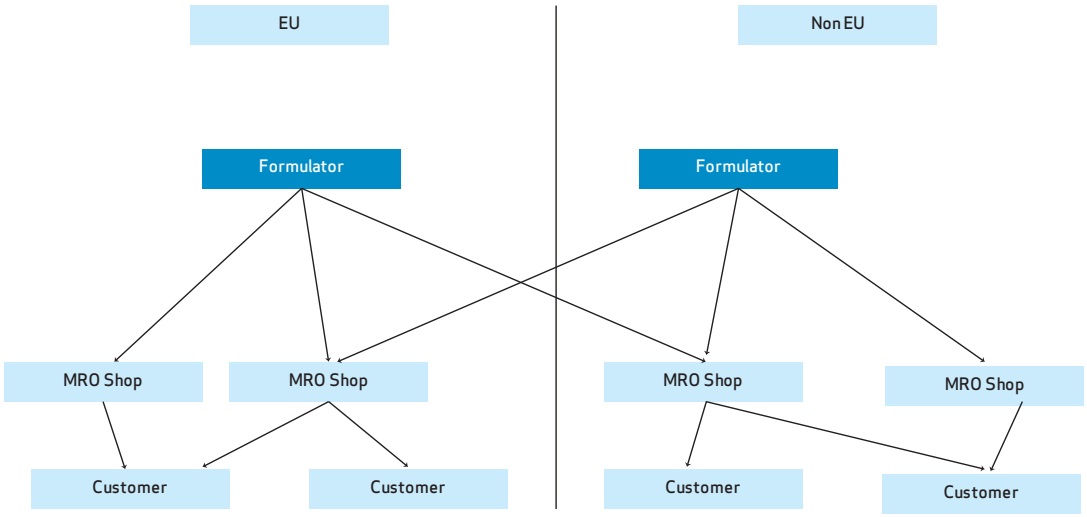

FIGURE 3: SUPPLY CHAIN: APPLICATION FOR AUTHORISATION BY A FORMULATOR (SIMPLIFIED VIEW)

EXAMPLE 3

In this example there is no formulation and the raw chemical imported or manufactured by the same company in the EU, the ideal applicant would be the manufacturer:

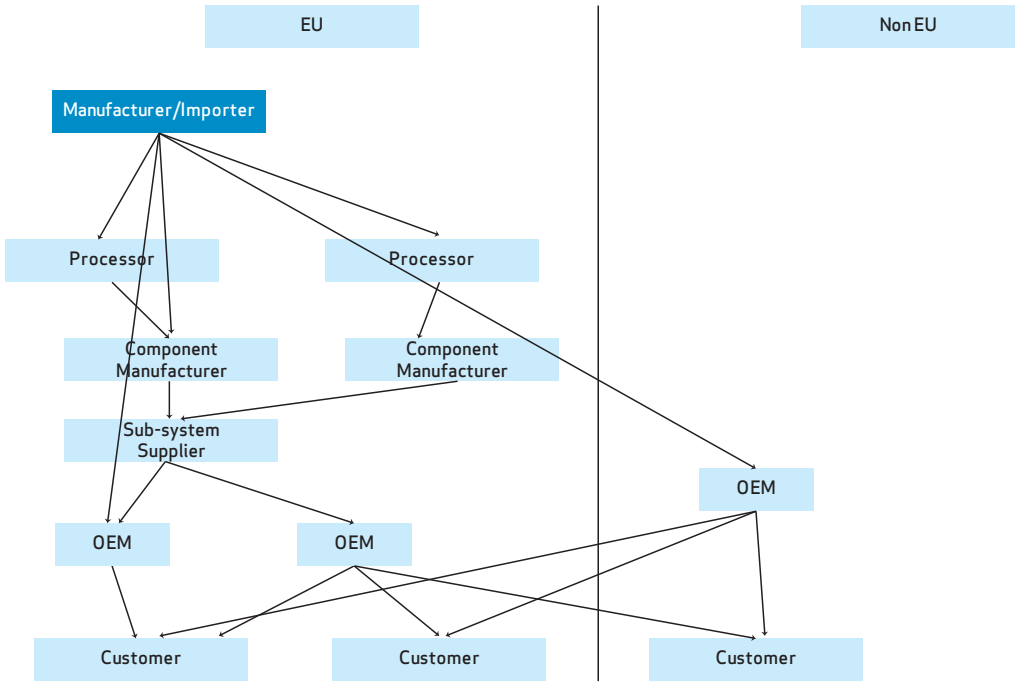

FIGURE 4: SUPPLY CHAIN: APPLICATION FOR AUTHORISATION BY A MANUFACTURER/IMPORTER

As a result of the above the aviation industry contacted the chemical manufacturers, formulators and distributers to try to ensure that they will be applying for authorisations and that those authorisations will include the uses of the aviation products manufacturers and suppliers. This was done with the help of Cefic the European chemical producers trade association and FECC the European distributors trade association, who kindly distributed a letter from the aviation industry to their members who may be selling products containing Annex XIV substances (See Appendix 1). The letter included a dedicated mail box for those companies to email their responses. **Results so far have been limited to only a few responses. The Aviation Industry needs and strongly encourages manufacturers, importers, formulators and distributors to respond and work closely with the industry in 2014 to mitigate the risk of disruption.**

3. How should use be defined?

The definition of use can be obtained using the guides already developed by ECHA. The difficulty in the Aviation industry is to understand the many layers of the supply chain, where "their" uses may need authorisation. Aviation companies also need to ensure that wherever there is a use or an application within the supply chain, it clearly includes a description of the specific aviation uses so that the peculiarities of aircraft and engine certification can be taken into account in both the analysis of alternatives and the socio economic analysis.

Following discussion with ECHA's experts it was concluded that new "use codes" specific to aviation could not be created, but use code "SU0" could be used to clarify the industry use of the substance with specific wording covering aviation hence the following was created for the definition of aviation products:

> **Substances used in the manufacture, operation, maintenance, repair and overhaul of Aviation Products that meets the airworthiness certification requirements**

The significance of "airworthiness certification" is explained below in Section 2. It should be emphasised that they are key to any application as they govern the success and timescales of any analysis of alternative substances or manufacturing techniques and the resulting socioeconomic analysis.

4. What are the actual uses applied for?

Preparations of Applications for Authorisation for key substances used in the aviation industry are already in progress and these have already highlighted a number of different uses. In order to understand the complexity of an authorisation for aviation the group "mapped" a typical production supply chains and ongoing maintenance/repair uses using the guidance supplied by ECHA. The detailed output can be seen in Appendix 2 (which was created based upon a chromates example), but in summary the substance has a functional use as a corrosion inhibitor and it may be applied by brushing, spraying, rolling, immersion or a high temperature application. Whilst eleven different processes were identified throughout the supply chain, it was assessed that there may only be four or five different exposure scenarios that would need to be considered for authorisation purposes as some activities would result in the same type and length of exposure. The group expects further refinement of this activity as a result of ongoing Applications for Authorisation and will revisit this appendix as further information becomes available.

Section 2: The analysis of alternatives and socio-economic analysis in the context of REACH authorisation for the aviation industry

1. Airworthiness and the approvals process in the aviation industry

Flying is one of the safest means of transportation. This is the result of decades of experience and research, including after incidents, which have resulted in changes to the designs, manufacturing or maintenance processes employed in the industry. All companies in the aviation industry are highly controlled and regulated by authorities and have to comply with many standardised design requirements, manufacturing and maintenance procedures which contain a high level of stringency.

An aircraft must be able to perform safely, with a high level of utilization (-around 16 hours per day), in a severe operational environment, such as:

- sub-zero temperatures at cruise altitude to ground temperatures exceeding 60oC,
- humidity,
- pressure,
- altitude,
- flight loads (including turbulent conditions),
- the possibility of being struck by lightning.

Airworthiness requirements are set as the measure of an aircraft's suitability for safe flight under these conditions.

The aviation industry must comply with the airworthiness requirements derived from EU Regulation No 216/2008 in Europe, and with similar airworthiness requirements in all countries where aeronautical products are sold. All components, from seats and galleys to bolts, equipment, materials and processes incorporated in an aircraft fulfil specific functions and must be, certified, qualified and industrialised. If a substance used in a material, process, component, or equipment, needs to be changed, this extensive process has to be followed in order to be compliant with the airworthiness requirements,

This process requires the cooperation of multiple stakeholders with each having their own responsibilities:

- The airworthiness authority (in the EU: European Aviation Safety Agency - EASA) is responsible for all the issues related to design, in particular, issuing the airworthiness requirements and approving products, parts and appliances under these requirements (such as deliverance of Type Certificates, approval of major aircraft changes and approval of design organisations);
- The Original Equipment Manufacturer (OEM) must comply with aircraft certification requirements and is responsible for issuing instructions for continued airworthiness to be used by maintenance organisations. The OEM is the Type Certificate Applicant or Holder (depending on the certification status);
- The Airline operators must operate and maintain the aircraft per the OEM instructions. They may choose to utilize a Maintenance Repair and Overhaul organisations (MRO) to provide maintenance of aircraft in accordance with approved programs, procedures and processes;
- The suppliers of parts or equipment have to provide OEMs, Airlines and MROs with instructions in conformity with their specifications. These specifications must allow the user to show compliance with the airworthiness requirements.

In order to understand the implications of the airworthiness requirements, the, certification, qualification and industrialisation processes are described below.

1.1 CERTIFICATION

Certification is the process under which it is determined that an aircraft, engine, propeller or any other aircraft part or equipment comply with the safety, performance environmental (noise & emissions) and any other requirements contained in the applicable airworthiness regulations, like flammability, corrosion resistance etc.

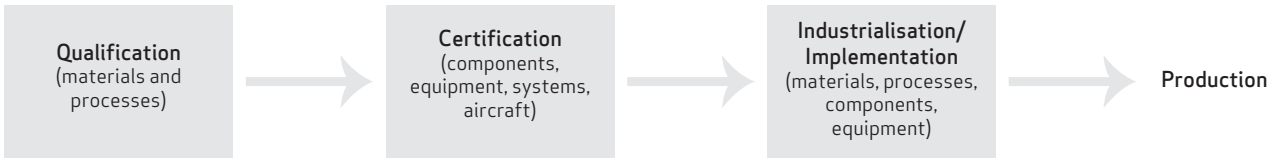

FIGURE 5: QUALIFICATION, CERTIFICATION AND INDUSTRIALISATION PROCESSES

Although the airworthiness regulations (and associated Certification Specifications) do not specify materials or substances to be used, they set performance specifications to be met (e.g. fire testing protocols, loads to be sustained, damage tolerance, corrosion control, etc.). These performance specifications will drive the choice of substances to be used either directly in the aircraft or during the manufacturing and maintenance activities. Some examples of performance requirements are the following:

- Resistance to deterioration (e.g. corrosion)
    - Environmental damage (corrosion for metal, delamination for composites) and accidental damage during operation or maintenance.
    - Corrosive fluids - Hydraulic fluids; Blue water systems (toilet systems and areas); leakage of corrosive fluids/substances from cargo.
    - Microbiological growth in aircraft fuel tanks due to moisture/contamination in fuel cause severe corrosion. Such corrosion debris has the potential to dislodge from the fuel tanks, migrate through the fuel system, and lead to an in-flight engine shutdown.

- Resistance to fire – Flammability Requirements
    - Fire-proof and fire-resistance. Aircraft elements are expected to withstand fire for a specified time without producing toxic fumes; this leads to using products like flame retardants, insulation blankets, heat protection elements in hot areas (e.g. around engines).

The primary certification of the aircraft (or engine and propeller) is granted to the manufacturer by the Competent Aviation Authority of the "State of Design" which is typically the authority of the state where the manufacturer of the aircraft (or engine or propeller) is officially located (EASA in the case of aircraft designed and manufactured in the EU and European Free Trade Association countries). Aircraft that are exported to other countries will have to be certified (validated) also by the authority of the "State of Registry".

Manufacturers work with the certification authorities to develop a comprehensive plan to demonstrate that the aircraft meets the airworthiness requirements. This activity begins during the initial design phase and addresses the aircraft structure and all systems in normal and specific failure conditions (e.g. tire

failure, failure of structural components, hydraulics, electrical or engines). The tests needed to demonstrate compliance, range from thousands of coupon tests of materials, parts and components of the airplane, up to tests that include the complete aircraft or represents the complete aircraft (system). The performance and durability of the various materials have to be confirmed while the behaviour of the parts, components and the complete airplane will have to be tested in the applicable environmental and flight conditions including various potential damage or failure conditions. For a new Type Certificate this overall compliance demonstration covers several thousands of individual test plans of which some will require several years to complete. Often, after the initial issuance of the Type Certificate, the tests that have the objective to demonstrate durability of the aircraft during its service life, will continue.

All the different aspects covered by the Type Certificate together define the "approved type design" which includes, among other aspects, all the materials and processes used during manufacturing and maintenance activities. Each individual aircraft has to be produced and maintained in conformity with this approved type design.

Changes to the approved type design may be driven by product improvements, improved manufacturing processes, new regulations (including those such as new authorisation requirements under REACH), customer options or the need to perform certain repairs. When new materials or design changes are introduced, the original compliance demonstration will have to be reviewed for applicability and validity, in addition to a review of potential new aspects of the new material or design change that could affect the airworthiness of the aircraft. Depending on the change, this review could be restricted to coupon or component tests, but for other changes this could involve rather extensive testing. E.g. changes in protective coatings could affect not only the corrosion resistance but could also affect the friction characteristics of moving components in actuators in the different environmental conditions, changing the dynamic behaviour of the system, which in the end affects the dynamic response of the airplane.

Before the new material or design change can be introduced on the aircraft, all test and compliance demonstrations have to be successfully completed and approved by the Competent Authority. This approval results in the issuance of a Supplemental Type Certificate (STC), change approval or repair approval.

It is important to note that, according to the EU Regulation No 216/2008, EASA is the design competent authority for civil aircraft only. Any other aircraft (e.g. military, fire-fighting, state and police aircraft) will have to follow similar rules of the corresponding State of Registry.

To be able to maintain and operate an aircraft the responsible organisations must be approved by the competent authority and compliance is verified on a regular basis. Maintenance of an aircraft requires that the organization complies with specific procedures and materials described in the maintenance manuals which are issued by and the responsibility of the OEMs.

1.2 QUALIFICATION

Qualification precedes certification and is the process under which an organisation determines that a material, process, component or equipment have met or exceeded specific performance requirements as documented in a technical standard or specification. These specifications, often abbreviated as spec(s), contain explicit performance requirements, test methods, acceptance testing, and other characteristics that are based upon the results of research, development and prior product experience.

The industry relies upon standards issued by government-accredited bodies, industry or military organisations, or upon company-developed proprietary specs. Most materials and process specifications include either a "Qualified Products List" (QPL) or "Materials Control" section that identifies products

that have met the requirements. Application and use of these qualified products must be assessed and certification implications addressed before being used on aircraft hardware.

OEMs rely upon the expertise of the chemical formulators to provide viable candidates to test against specific material and process specs. Once candidate(s) are developed, the OEM evaluates candidates by performing screening testing. If the candidate passes screening, testing is expanded to increase the likelihood that the preparation will pass qualification. If the candidate fails, which is often the case, material suppliers may choose to reformulate. It is not uncommon to iterate multiple times before a candidate passes screening. In some technically challenging areas, over 100 formulations have been tested with no success. This phase of development can take multiple years depending upon the material requirements. For those materials that pass screening, production scale-up, development of process control documents, manufacturing site qualifications, and extensive qualification testing is required to demonstrate equivalent or better performance to that which is being replaced. This phase of the process can also result in formulation or manufacturing iterations and may take several additional years. Depending on the complexity of the change and the criticality of the application (for example, fire protection or corrosion prevention have high safety implications and require development and testing against multiple, rigorous performance standards), re-certification may be required. The industry is ultimately limited by the material formulators' willingness to expend their resources to develop alternative materials and technologies to be tested. Not all material formulators are willing to reformulate their materials to eliminate a specific chemical substance. The small volumes of materials sold, demanding performance requirements, and tightly controlled manufacturing processes for aviation customers has proven insufficient incentive for reformulation in some cases.

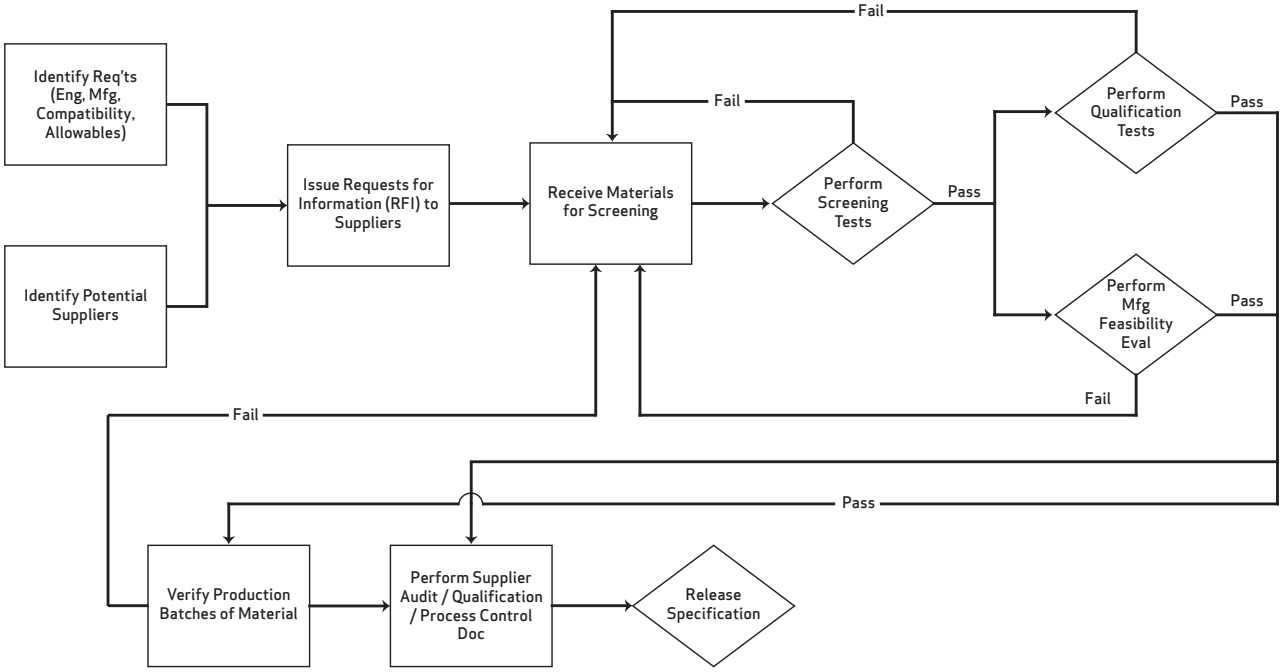

FIGURE 6: QUALIFICATION PROCESS

This process is an extensive internal approval process with many different steps from basic technology research up to technology demonstration in a lab environment. Depending upon the difficulty of the technical requirements, these initial steps can easily take 3-5 years. After initial laboratory testing, each specific

application must be reviewed, which means additional testing for specific applications / parts. Airworthiness Certification begins at this same time, this certification can take from 6 months to years. Additional time is needed for production scale-up and development of a supply chain.

1.3 LABORATORY TESTING CANNOT FULLY SIMULATE IN-FLIGHT PERFORMANCE

Standard laboratory testing accelerates environmental factors. Lab tests are typically idealized test components / test panels under a limited set of conditions; they cannot duplicate all relevant physics of in-service environments. Limited capability to duplicate actual environmental conditions (i.e., vibration, temperature (freeze/thaw) and pressure cycling, ultraviolet (UV) exposure) can limit predictive power of lab tests. Results from outdoor exposure testing of corrosion panels are very different from lab chambers. However, this kind of testing takes years rather than weeks to complete. It is common practice to validate laboratory performance with outdoor testing and monitoring under representative conditions over several years. These evaluations must also be reviewed and approved by airworthiness authorities before hardware can be placed on an aircraft and can take years to obtain depending upon the application.

Confidence in an alternative's performance is critical, as some aerospace hardware is in locations that cannot be readily inspected, sometimes for the life of the aircraft. Extreme caution must be exercised and risks understood before replacing a material which has proven field experience.

1.4 INDUSTRIALISATION

Industrialisation is an extensive step-by-step methodology followed in order to implement a qualified material or process throughout the manufacturing, supply chain and maintenance operations, leading to the final certification of the aerospace product. This includes re-negotiation with suppliers, investment in process implementation and final audit in order to qualify the processor to the qualified process.

Taking into account that an aircraft is assembled from several million parts provided by several thousand suppliers, this provides an indication of the complexity for the industrialisation stage of replacement materials/processes, and the supply chain which provides these parts.

Special challenges are:

- Low volumes limit influence on changes to suppliers' materials / processes
- Procurement & insertion of new equipment
- Scale-up & certification of new process
- Incompatibility of coatings could be a risk.
- Re-negotiation of long term agreements with suppliers.
- Increased complexity of repairs – Multiple different solutions for different applications as a substitute for a single, robust process. For example, currently all aluminum parts can be repaired with one chromated conversion coating. In some specific cases, the future state could require different conversion coatings for each aluminum alloy and application environment. Since different alloys are not easily distinguishable on the shop floor, ensuring that the proper repair procedures are used will be much more difficult. If alternate means of compliance approvals are requested for repair facilities or airlines, regulatory agencies are unlikely to have adequate knowledge or technical data to make informed assessments.

The operating environment, longevity of the aircraft, supply chain complexity, performance and above all airworthiness requirements are some of the considerations which can constrain the ability of the industry to make changes and adopt substitutes in the short, medium or long term.

2. Developing applications for authorisation

2.1 REACH AUTHORISATION REQUIREMENTS

Under REACH, authorisation is required if an SVHC listed in Annex XIV of the regulation is to be used past the substance's "sunset date". Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled ("adequate control" route) or that the socio-economic benefits of using the substance outweigh the risks and there are no suitable alternative substances or technologies ("SEA route"). All applications must include an analysis of alternatives (AoA) and they may also include a socio-economic analysis (SEA). Applications are submitted to the European Chemicals Agency (ECHA), whose two independent scientific committees (the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)) develop opinions on whether the application is justified, and give recommendations on the 'review period' duration and possible conditions of the authorisation. These opinions are then submitted to the European Commission, which grants (or rejects) the authorisation.

The AoA of an authorisation application examines whether there are any suitable alternative substances or technologies to the substance subject to authorisation. This includes an assessment of technical and economic feasibility, and of the availability of the alternatives. An authorisation application's SEA (if one is included) compares the risks of continuing to use the Annex XIV substance with the costs of whatever the applicant would do if he was not authorised to use it. This alternative course of action is called the non-use scenario – the future scenario in which the substance is 'not used' by the applicant. It is expected that this alternative will generally have higher costs and/or lower functionality (or other disadvantages) than the Annex XIV substance – if it was somehow better overall, the applicant would not be applying for authorisation. If no such alternative substance or technology is available or feasible, the non-use scenario is whatever strategy the applicant would adopt to cope with not being able to use the Annex XIV substance. In the end, the non-use scenario might be the complete cessation of a line of commercial activity.

The development of the non-use scenario is an essential part of the SEA and considers the following questions:

- What options are available if the current substance cannot be used anymore? (Some of these options might be identified through the AoA, others within the SEA itself.)
- What is the estimated cost of each option? (Orders of magnitude might only be estimable in some cases, but estimates should be reliable enough to support strategic planning for non-authorisation.)
- Which option would be selected by the applicant? This decision might be decided on the basis of cost, but also on timescales and other non-financial considerations. This selected option is the non-use scenario.

The SEA then describes how the cost of the selected option (if authorisation is not granted) would compare with the risk associated with continuing to use the Annex XIV substance (if authorisation is granted).

In many cases the use of Annex XIV substances in the aviation industry involves small volumes and takes places in tightly controlled environments by highly trained workers, so risks to the environment and human health is expected to be low. If this is the case, it should be clearly demonstrated in the application, as it supports the application under both the adequate control and socio-economic routes.

2.2 TYPICAL CHARACTERISTICS OF THE AVIATION INDUSTRY WHICH ARE RELEVANT FOR THE AOA AND SEA

The following describes what specific characteristics might be relevant when developing an application for authorisation in the aviation industry, taking into account what is needed to justify the authorisation and the

information which is relevant to establishing the review period (duration) for the authorisation. However, each individual application will need to reflect the circumstances pertaining to the particular substance and intended use.

2.2.1 AoA: Regulatory characteristics of the substitution process: Qualification, certification and industrialisation process and the `lifecycle´ stage of an aircraft type: Legacy – operating – future aircraft

As described above, components, equipment, materials and processes incorporated in an aircraft must be qualified, certified and industrialised, with these processes requiring resources and time. Furthermore, aircraft that are exported to other countries will have to be certified (validated) also by the authority of the "State of Registry".

A representative lifecycle of a typical aircraft product is expected to exceed decades, as illustrated in the following figure:

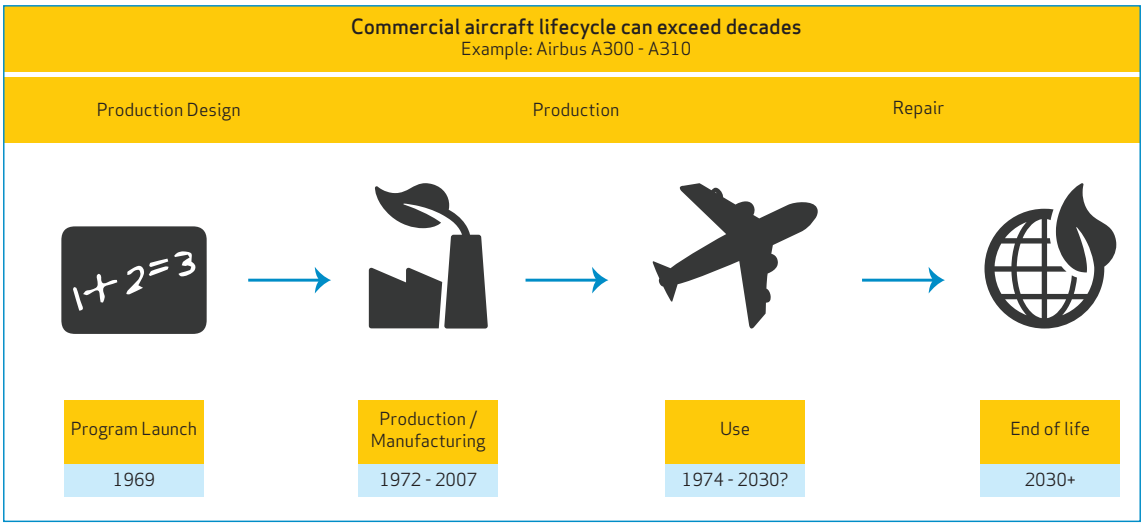

FIGURE 7: AIRCRAFT LIFECYCLE

Some key figures to be considered are the following:

- The development of a new aircraft can take up to 15 years.
- The production of one type of aircraft may last more than 50 years
- The lifespan of an aircraft is typically 20-30 years.
- Therefore, typical aircraft categories to be considered in an application are the following:
- Legacy aircraft in operation (the aircraft type is not being produced anymore).
- Operating aircraft of a type which is still in production.
- Future aircraft for which a Type Certificate has not been issued yet.

In specific cases, the suitability of alternatives can differ between different aircraft categories. For each application and category, the qualification, certification and industrialisation process must be performed in order to determine a suitable alternative.

These validation processes, which may include changes to the type design, are often as intensive as the original primary certification process, which makes the introduction of new materials even more complicated, expensive and time consuming. This information is clearly relevant for an authorisation application, and the AoA should describe:

- At what stage the applicant is in the analysis of alternatives and what is still required (qualification, certification and industrialisation)?
- How long does the rest of the process take and why? Some aspects which may be considered are the following:
    - Is it major or minor change of design?
    - Is it a critical or non-critical function?
    - Who is the certification authority - EASA or Design Organisation Approval (DOA))? (Depends on the significance of the change)
    - Is it a certification for a limited application (only in certain visible areas of the aircraft, which may be easily inspected) or for full-scale application in the aircraft. This is important because the inspection of hidden areas may be difficult or even impossible for the current design of the aircraft. Introducing new alternatives on hidden areas poses higher risks if there is not sufficient in-service experience.
        - A long period of in-service experience may be required (how long is it expected?).
        - Certification for full-scale application in the aircraft (visible and hidden areas).

This information might sometimes only be known by the OEMs and it is therefore important that the non-OEM applicant collaborates with them while developing an Application for Authorisation.

If an alternative material or process has not passed OEM testing to be qualified and the associated aircraft parts or components are not certified, it is not a suitable alternative substance or technology for the aviation industry. Airline Operators and MROs have to comply with maintenance procedures and substances and processes not incorporated in these procedures are not considered suitable alternatives.

A case specific presentation of impacts of the regulatory airworthiness requirements alone may be sufficient to justify that technically feasible alternatives are not currently available. Furthermore, this information is relevant for setting the non-use scenario, and has clear implications for the review period.

2.2.2 SEA, non-use scenarios

2.2.2.1 Non-use scenarios when qualified and certified alternatives do not exist

The aviation industry uses substances for different purposes in the aircraft. A substance might be used to manufacture, operate or maintain an aircraft. Because of the complexity of the processes involved, different scenarios exist among the different purposes (production, operation, maintenance) and stakeholders when a qualified and certified alternative is not available. Some possible scenarios are as follows:

- Production of the aircraft and components in the EU would have to be stopped, and relocated outside the EU (if capacity is available) or suspended (until capacity is made available). This is because no change is possible in the short-term to the manufacture of current aircraft, which is based on approved designs and certification. This would apply across the whole range of SHVCs used in the aircraft industry;
- Operation of aircraft would not be affected directly by the unavailability of a substance since aircraft can be treated as articles under REACH and would therefore not be subject to the authorisation requirement. However, their operation might be prevented indirectly if maintenance (leading to the use of a substance under REACH, as part of the 'restoration' or 'remanufacture' of an article) is not possible. The possible impacts of this are considered below;

- For maintenance operations, the non-use scenario might vary. Unexpected and regular maintenance involving the replacement of aircraft components (e.g. wheels) could continue since, as mentioned for operation, components would be treated as articles under REACH and hence not subject to an authorisation requirement, (assuming component manufacture is not affected). The repair and maintenance of aircraft components using SVHCs would, however, need to occur outside of the EU, since these activities do involve 'use' as defined in REACH. There would likely be a significant increase in the size of inventories of these components held at maintenance facilities in the EU, because of the inability to continue on-site maintenance using SVHCs. No maintenance, routine or unexpected, would be possible of airframes, so this would have to be undertaken outside of the EU – for unexpected maintenance, the aircraft would have to be grounded and physically shipped, or flown with a special permit (Permit to Fly) issued by the State of Registry of the aircraft. Clearly, with only component replacement and non-SVHC maintenance of components and aircraft being possible in the EU, this would significantly affect the economic viability of EU-based maintenance operations, and the most likely scenario would be that all maintenance facilities in the EU would be closed (at least eventually) and relocated.

Although moving 'base maintenance activities' (major maintenance checks) to a location outside the EU is a comparatively easy step to make, as repair facilities exist in numerous other regions, this could never be justified in the case of "line maintenance activities" (day-to-day activities, including defect rectification). This is because being unable to undertake these activities where an aircraft lands would basically imply suspending the operation of the aircraft every time there is a defect, with the need to ship or fly it outside of the EU for repair. Normal operation of revenue aircraft would be impossible under these circumstances, with consequent drastic implications for the entire commercial aviation industry.

2.2.2.1.1 The cost of this non-use scenario

Important considerations for the estimation of the cost associated with a relocation of production or maintenance outside the EU include:

- Cost of the relocation itself, including the closure of current facilities, issues related to the cancellation of employment contracts with the existing workforce, adaptation in size and capability of non-EU facilities to take on board the planned activities, higher rejection rates in manufacturing, possible increase of prices outside of the EU due to the unavailability of the process in the EU etc;
- If one step of the repair process is no longer permitted, the whole process is likely to be outsourced, since it will likely not be economically viable to undertake such closely related tasks in separate and distant geographical locations. Ultimately, the entire repair process of the article will probably be shipped elsewhere (complete engine/component);
- Production disruption and additional logistical costs involved in shipping large quantities of components into and around the EU, and large aircraft structures out of the EU;
- Impacts on long and complex supply chains, since if some work has to be moved outside the EU, it might be more economical to align the supply chains within this new region, with knock-on effects on the original locations in terms of loss of employment and reductions in economic activity;

2.2.2.1.2 Options for applicants

Where no technical alternatives exist for materials, preparations, formulations etc. containing a SVHC, the manufacture and maintenance of the associated aircraft and components could not take place if use of the SVHC was not permitted in the EU. This means manufacture would have to cease or be relocated outside of the EU, inventories of spare parts might have to increase significantly, and aircraft would need to be physically transported from the EU (or flown under permit) for even day-to-day maintenance. The short- and long-run costs of these actions can be expected to be considerable, and in some cases dramatic, both for companies and the wider industry and economy. In comparison, the volumes of SVHCs used in these materials are in many cases small, conditions relatively controlled, and hence risks to human health and the environment 'low'. Under REACH, authorisation can be granted if the benefits of authorisation exceed the

risks of continued use of the SVHC in question. These conditions would appear to be fulfilled in principle in this case, and hence it would appear feasible to prepare an appropriately argued and evidenced application to continue the use of a SVHC.

The scenario described in this section relates to a situation where no qualified and certified alternative currently exists for a SVHC subject to authorisation. However, feasible alternatives might already exist which have not yet been qualified and certified, or due to factors such as technical progress and the pressure on e.g. formulators, alternatives might become available over time. In these situations, the relocation of entire maintenance and manufacturing facilities outside of the EU might be the only option in the short-run if a SVHC cannot be used, but in the longer term an alternative might be useable once the development, qualification, certification and industrialisation process had been completed. If this is the case, the analysis of alternatives should describe such situations and how long it would take for this process to be completed for any possible alternative. For some SVHCs and uses, there might be alternatives which are already mature and are in the final stages of certification, in which case authorisation might only be required for a relatively short time. For other substances, there might be no viable known candidates and the process is at the initial R&D stage, implying an extended period before adoption of an alternative could ever be adopted, and hence an argument in favour of a relatively long authorisation period. It can be seen that the authorisation is in these cases designed to ensure that the business operation of the applicant can continue unhindered until an alternative can be adopted. Note, however, that just because an alternative is technically feasible and has been certified, this does not necessarily mean that it will be economically feasible – this scenario is considered in the next section.

2.2.2.2 Non-use scenario when certified alternatives are economically infeasible

If an alternative is technically feasible for use in a particular application, and it has been (or could be) qualified and certified, it can be expected that the industry will adopt it if the additional costs of doing so (compared with the existing substance) – including any remaining development and approval costs – are less than the costs of applying for authorisation. However, in some cases, implementing an alternative could have very significant associated costs, due to technical or economic limitations. Some examples are the following:

- Even if technically feasible, the alternative might exhibit reduced performance compared with the existing substance, which might result in the need to introduce more frequent inspections or even new inspection methods/areas. The addition of new inspection methods/areas increases cost and may disrupt normal aircraft operation. It might not even be physically feasible to follow the new inspection methods with particular aircraft designs (e.g. due to lack of access for inspection);
- Similarly, even if the alternative is technically feasible for a particular use, gaining certification to use it on an existing aircraft type (particularly a legacy design) and then retrofitting it across the existing fleet could be extremely costly, and in some cases/uses practically impossible, e.g. due to the location of the existing component (encases within the airframe, for instance);
- One substance is often used in the aviation industry for several technical applications, and industry experience has been that very few one-to-one replacements have been found for any given substance. This has meant that it has often been necessary to introduce several alternatives simultaneously to cover the range of functions provided by a single existing substance. This results in the added complexity of having to qualify and certify multiple alternatives to replace a single substance. This may also lead to significant delay in starting industrialisation. Implementation of multiple materials/processes to replace a material/process which contains a SVHC also increases production and maintenance complexity, and thereby costs;
- Even if a technically feasible alternative is available, it might still need to go through further development, certification and industrialisation before it is practically available for use in future aircraft. As explained above, this can be an extended process which can take several years, whereas the time between a substance being listed in Annex XIV of REACH and its sunset date can be relatively short. In this case, there is no alternative effectively available to the applicant, and the scenario becomes similar to the

first one discussed, with an inability to continue use of the substance leading to significant disruption to manufacturing, operation and maintenance activities, and possible relocation. However, once the alternative has been proven to perform well and once it has been certified it will become available to the applicant and thus the justification for an application, if the product containing SVHC was still needed, would need to be made on a different premise.

2.2.2.2.1 Cost of this non-use scenario

The different alternatives developed by each OEM would need to be implemented by their numerous suppliers, which in many cases are Small and Medium-sized Enterprises (SMEs). SMEs which support multiple OEMs have the increased financial burden of implementing multiple OEM-specific materials/ processes, which might not be economically viable for them. If this is the case, OEMs and airline operators might be forced to seek processors (potentially outside the EU) who would be willing or able to accommodate OEM-specific processes limited to a single company's parts, with consequent implications for the industry and local economies.

The cost of introducing a new product on an existing fleet could be very high. Possible costs include engineering hours to change the design, inspection methods and access for such inspections, as well as the time and cost of re-certification. Retrofitting multiple parts into legacy aircraft could be extremely complex and in some cases equivalent to rebuilding the aircraft completely. However, the case for introducing alternatives can dramatically improve when introduced during new product development as it becomes an integral part of the new test programme and the design can be adapted to the new inspection methods. In these cases, costs manifest themselves more in terms of the time taken to adopt the alternative, or any interim measures which need to be adopted after the sunset date.

2.2.2.2.2 Options for applicants

It might take considerable time and resources to develop technical alternatives to a SVHC in an aviation use. If and when this process is completed, adopting the alternative for the development in future aircraft is possible but could entail significant increases in cost. For current and legacy aircraft, it might be necessary to retrofit the alternative throughout the existing fleets. As with the non-availability scenario, the manufacture and maintenance of the associated aircraft and components could not take place after the sunset date unless and until these changes are made, and manufacturing and maintenance activities would be likely to be relocated outside the EU. The short- and long-run costs of these actions can be expected to be considerable for companies and the wider industry and economy. However, as before, the volumes of SVHCs used are n many cases small, conditions relatively controlled, and hence risks to human health and the environment 'low'.

Under REACH, authorisation can be granted if the benefits of authorisation exceed the risks of continued use of the SVHC in question. These conditions would appear to be fulfilled if there is no certified alternative. This appears also to be the case when a certified alternative exists but for particular reasons (known by the applicant) it would not be possible or very expensive to use it. Hence, it should be possible to construct an appropriately argued and evidenced application to continue the use of a SVHC, if the costs of not getting the authorisation are demonstrated to be high.

Section 3: Concluding remarks

The use of some SVHCs in the aviation industry is extensive, and often plays a critical role in meeting performance and safety standards, particularly those relating to airworthiness set by EASA. In many cases the volumes used are relatively low, and used in well-controlled industrial or professional settings. The risks to human health and the environment from the use of these SVHCs might also therefore be expected to be relatively low.

The authorisation requirement for SVHCs listed in Annex XIV of REACH is often seen as a ban on the use of these chemicals, but this is incorrect. Rather, REACH allows the use of these chemicals to continue after their sunset dates, but only –as the name suggests – if that use is authorised. The use can continue so long as it can be demonstrated that risks are adequately controlled (for threshold substances) or that the costs of switching to alternatives are greater than the risks of continued use.

In general, neither the REACH regulation implemented by ECHA nor those governing airworthiness and overseen by EASA take precedent over the other. The aviation industry therefore needs to seek authorisation to continue to use SVHCs listed in Annex XIV, but existing airworthiness requirements and procedures must still be met. At the very least, if the time taken to develop and adopt alternatives is relatively long, this would be the basis for applying, and granting, equally long review periods.

However, the structure of the aviation industry, the need to impose rigorous standards across aircraft fleets, and to ensure that standards are met at all times, mean that the costs of adopting alternatives could well be significant, even if alternatives exist. In the extreme, it might actually be cheaper in the shorter run to relocate all manufacturing and maintenance activities outside of the EU so that use of the SVHCs in question can continue. The costs of such a non-use scenario would undoubtedly be very high for the industry, customers and the European economy. These costs need to be compared with the relatively low risks expected from SVHC use. On balance, this suggests a strong prima facie justification case for authorisation for aviation industry in general; and an even stronger justification for legacy aircraft, as recertification is particularly challenging.

One of the principal objectives of the authorisation requirement of REACH is to encourage the progressive substitution of SVHCs with safer alternatives, whilst allowing use to continue where it is safe and/or of high value. As such, given the conditions of use and characteristics of the aviation industry described in this section, it might be expected that the use of SVHCs can continue under REACH, but that extra effort will be made by the all operators in the supply chain to identify viable alternatives which do not need to be authorised. When this search is successful in finding safe alternatives which perform cost-effectively, SVHCs and authorisation will no longer be needed. Until then, however, REACH is designed to permit use to continue where it is justified, based on authorisation applications which are evaluated and approved on a case-by-case basis.

Whilst this document and the activities that preceded it help in understanding who should apply for authorisation, it does not guarantee that the authorisations the industry needs will be sought. Applications for Authorisation therefore need to be made by Manufacturers and Importers of chemicals, and by Formulators. Applications by end-users are useful or relevant in very few circumstances, such as where the end-user is using a substance on its own, or has a unique use of an imported mixture. Upstream vendors and sub-contractors need to ensure that their upstream suppliers are applying for authorisations where needed.

Appendices

Appendix 1: Letter from the aviation industry to their members who may be selling products containing Annex XIV substances (September 2013)

Appendix 2: Mapping of a typical production supply chains and ongoing maintenance/repair uses using the guidance supplied by ECHA

Appendix 1

Letter from the aviation industry to their members who may be selling products containing Annex XIV substances (2 pages)

Ref: 201309_AXIV communication letter-M/DU
Date : September 2013

To: All European Chemical Manufacturers and Distributors

Dear Sir,

As you know, more and more substances have been or will be identified as SVHC under REACH with a potential outcome to be selected for prioritization, and to ultimately end up on the REACH Annex XIV (authorisation list). Substances listed on Annex XIV cannot be used or placed on the market in Europe after the sunset date if no authorisation has been granted.

This can impact the entire downstream supply chain using an Annex XIV substance.

In this case, several options might be envisaged:

- Phasing out of the substance
- Looking for potential alternative
- Submission of an application for authorization

In order to avoid any market disruption, each actor of the supply chain should start to organise themselves and develop a strategy to pursue their activities.

Any action will have some impact on your customers, suppliers, etc... Therefore communication within the supply chain remains very important.
The purpose of this communication step is to encourage communication between manufacturers, importers, distributors, formulators and downstream users.

Aerospace companies are interested in continued supply of some of those hazardous substances.

An application for authorization can be made by every downstream user or by the manufacturer.
However, within complex supply chains, application for authorisation by several end-users:

- is impractical (due to insufficient experience or capacity to manage the process for SMEs),
- only covers their immediate suppliers and not the whole supply chain

Therefore, application by the manufacturer, importer or formulator seems to be the best option.

A top-down approach, with strong support from end-users (since they have a strong knowledge on the alternatives and associated impacts), could be applied to cover several uses in a limited number of applications.

By sending this letter, we would like to let you know that the European aerospace industry have an interest in substances listed on Annex XIV [(1)] and in the list of recommendations for inclusion in Annex

1

XIV [2]. The Aerospace and Defence manufacturing industry is represented in Europe by ASD and the Airlines maintenance and repair industry by AEA.

(1) http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
(2) http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list

If any Annex XIV substances are part of your portfolio, please contact the Aerospace industry and let us know if you supply the substances today. In return we will advise if there is a known potential Aerospace use. All correspondence will remain confidential between you and the Aerospace associations.

For this purpose, we have set up a unique mailbox: chemicals@asd-europe.org

We remain at your disposal for more information and to establish further cooperation.

Regards,

On behalf of

ASD and AEA REACH Working Groups

Appendix 2

Mapping of a typical production supply chains and ongoing maintenance/repair uses using the guidance supplied by ECHA

Chromate	Supply Chain Activity	SU	PC	PROC	ERC	AC	Function
Chemical importer	Packaging	17,0 + agreed aerospace or defece description	14	8a,8b,9	n/a	n/a	Corrision Inhibitors
Formulator	Mixing	17,0 + agreed aerospace or defece description	14	5	2	n/a	
	Packaging	17,0 + agreed aerospace or defece description	14	8a,8b,9	n/a	n/a	
Formulation Distributor	Packaging	17,0 + agreed aerospace or defece description	14	8a,8b,9	n/a	n/a	
Processing plate shop	Coating articles	17,0 + agreed aerospace or defece description	14	7,10	5	1	
Sub-component manufacturer	drilling/ machining	Include effect in CSR only					
Sub-Assembly	drilling/ machining						
Sub System OEM	Coating articles, drilling-machining	17,0 + agreed aerospace or defece description	14	7,10,24,25	5	1	
Platform Integrator	Coating articles, drilling-machining	17,0 + agreed aerospace or defece description	14	7,10,24,25	5	1	
Customer	In article n/a	17,0 + agreed aerospace or defece description	n/a	n/a	n/a	n/a	
Maintenance Repair & Overhaul	Repair/ maintenance	17,0 + agreed aerospace or defece description	14	7,10,24,25	5	1	
NB. Distributor in this case would potentially re-bottle (if not authorisation not required)							
PC14	Metal surface treatment products, including galvanic and electroplating products						
PROC2	Used in closed, continuous process with occasional controlled exposure						
PROC3	Used in closed batch process (synthesis of formulation)						
PROC4	Used in batch and other process (synthesis) where opportunity for exposure arises						
PROC5	Mixing or blending in batch processes						
PROC7	Industrial spraying						
PROC8a	Transfer of substance or preparation (charging/discharing) from/to vessels/large containers at non-dedicated facilities						
PROC8b	Transfer of substance or preparation (charging/discharing) from/to vessels/large containers at dedicated facilities						

PROC9	Transfer of substance of preparation into small containers (dedicated filling line, including weighing)
PROC10	Roller application or brushing
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles
PRC35	Other hot work operations with metals
EFC1	Manufacture of substances
EFC2	Formulation of preparations*
EFC5	Industrial use resulting in inclusion into or onto a matrix
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment
SU0	Other + in the manufacture, maintenance, repair and overhaul of Aerospace Products to ensure continued airworthiness
SU0	Other + in the manufacture and maintenance of Defence Products
AC1	Vehicles

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ECHA-14-R-09-EN - ED-01-14-353-EN-N - ISBN: 978-92-9244-490-7 - DOI: 10.2823/9437