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European Commission (EC) Consultation; REACH Authorisation for Low Volumes/ Legacy Spare Parts

ADS Group Response – April 2015

Background & Rationale

'Authorisation' is a key part of the EU's REACH regulation process. It allows companies and their supply chains to continue to use a chemical which has been selected for controls - by demonstrating the reduction of threat to human health, alongside the ability for that chemical to be replaced by an alternative. However, the process for authorisation is sometimes disproportionate, costly and time consuming.

For the Aerospace, Defence and Security companies, issues with the authorisation process are exacerbated by the unique operating environment of our industries – such as the use of substances in relatively low volumes, the safety and certification requirements for products, and the complexity of the supply chain.

The EC's consultation on simplifying the authorisation procedure for substances use in low volumes, and extending the 'sunset' dates of chemicals used for maintenance operations, provides an opportunity to ensure greater compliance, and protect businesses against safety, regulatory, cost and competitiveness concerns.

Why the 'Authorisation' process should simplified for low volumes/ legacy spare parts =

- **Promoting Safety -** allowing greater flexibility on authorisation for substances used in low volumes on components which are manufactured to qualification and safety standards, and reducing the risk of removing substances from the market which are used in critical maintenance operations.
- **Promoting Compliance -** ensuring suppliers and OEMs can apply for authorisation more effectively, are aware of their responsibilities under REACH, and can comply with both controls and requirements.

How authorisation should be simplified and 'legacy spare parts' transitional period extended =

- **Proportionality –** authorisation requirements should be 'proportionate' against the ability to comply due to certification restrictions, and against the volume of substances used.
- **Expanding Criteria –** define low volume by weight, alongside other criteria such as the need to meet safety standards, their use in anti-corrosion activity, and a company's supplier communication processes.
- **Reducing Documentation –** reduce the requirements in the analysis of socio-economic impacts and alternative substances, focusing on company risk protection and improving time and cost effectiveness.
- **Role for EASA –** where applicable, allow EASA to provide technical information on recertification & safety issues in a simplified procedure; and amend EASA's Basic regulation to highlight REACH as a priority.
- **Extend definition of legacy spare parts** – extend to products where the design and maintenance qualification is fixed and substitutes prevented, not just where production of the component has ended.

What are the consequences of inaction =

- **Supply Chain disruption –** removing chemicals from the marketplace despite qualification standards and low volume use, will impact businesses across the supply chain that are dependent on their use.
- **Diverting Resource –** time/ cost on current authorisation process will continue to increase business resource to meet requirements, and divert funds away from critical business development/ R&D work.
- **Competitiveness and Trade –** reducing security of supply of substances if authorisation is not simplified, will impact on trade, competitiveness and the ability of trading partners to enter the European market.
- **Impact on Maintenance –** day to day maintenance operations on aircraft and components will not be able to take place if substances are removed from market, impacting on safety and business.

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Annex I – ADS Group - Full Response to European Commission (EC) Consultation:

"Consultation on streamlining and simplification of the REACH authorisation application procedure for applications concerning uses of substances in low volumes and on a one-time extension of transitional arrangements for uses of substances in legacy spare parts"

1. REACH Authorisation and AeroSpace, Defence and Security

1.1. AeroSpace, Defence and Security companies in the UK and Europe operate primarily as 'downstream' users of chemicals and substances – using certain substances, mixtures and materials in the maintenance and production process of a wide range of different articles, parts and component.

1.2. These industries rely significantly on a small number of Substances of Very High Concern (SVHC), listed in Annex XIV (the list for Authorisation). This level of reliance means the REACH process has a direct effect on the ability for industry to effectively and efficiently function.

1.3. Alongside the heavy reliance in the production process on the small number of substances which are listed for Authorisation, the Aerospace, Defence and Security industries also have a number of mitigating factors which impact on both the ability to comply with REACH, but also on the effective operation of business.

1.4. Factors such as qualification and certification requirements individual OEMs for our sectors for product safety purposes, the complexity of the supply chain which impacts our ability to manage the REACH Authorisation process, and the long life of operating products, mean that REACH Authorisation is considered 'mission critical' for our industries.

1.5. The obsolescence of chemicals which may be restricted under REACH, and which may not been granted authorisation for continued use before their 'sunset' date of restriction, could cause significant disruption to the supply chain. It could impact on not only the safe operation of aircraft and defence products, and the ability to conduct maintenance activity without interruption in the UK and across Europe, but on the competiveness of our member companies through loss of access to chemicals and increased regulatory costs.

1.6. The factors listed above, and the unique issues faced within our industries as part of REACH, are also made more significant considering the relatively low volumes of chemicals used in the manufacturing and production process of components and products offered by our member companies. Therefore, updating the REACH Authorisation requirements for chemicals used in low volumes, alongside extending transitional arrangements for legacy spare parts, will have a positive impact on the functionality, safety and competitiveness of our industries.

2. Aerospace, Defence and Security and Updating Authorisation for Low Volumes

2.1. As discussed, the regulatory environment in which our industries operate mean that products are subject to strict certification and qualification checks and standards, and are therefore under significant amounts of oversight and scrutiny. In addition, our industries often use chemicals in very low volumes in comparison with other users and other industries. As an example, a substance used in surface treatment or metal treatment on certain components, may be present in the final product at a concentration of less than 0.1 per cent by weight. Alongside this, industry already takes the protection of workers using such chemicals very seriously, despite these low volumes, taking appropriate chemical risk control measures to ensure employees are protected from exposure and that substances are used safely.

2.2. Despite the use of chemicals listed under REACH's SVHC in comparatively low volumes, reducing the overall risk to human health, the approaching 'sunset' date may lead to such chemicals at any weight or concentration bot being used at all at any weight or concentration. This may have a critical impact not only on the ability of businesses to use such chemicals in their production processes for components, but also on the ability of industry to use chemicals in low volumes for the critical maintenance and repair of aircraft and defence products in operation. The current authorisation process is sometimes burdensome, costly and time consuming for companies, and does not differentiate substances which are used in much lower levels, than those which cause potentially harmful effects.

2.3. Simplifying the Authorisation procedure for chemicals used low volumes, so that there are fewer requirements under socio-economic analysis (SEA) and analysis of alternatives (AoA) will therefore be beneficial to industry. Firstly, it will help to promote safety – by simplifying authorisation for low volume uses, it will impact on those substances used for the continued use Parts and Products subject to extensive Qualification and Certification requirements. This ensures products can continue to be manufactured to the high safety standards which have been set and agreed by European authorities (e.g. EASA), and not removed from the accessible market altogether. This also reduces the risk of the potential removal of chemicals used in critical components for maintenance operations – which may require authorisation and recertification at late notice, but where the exact chemical for repair is not initially known.

2.4. Simplifying the Authorisation process for Low Volumes will also help to promote more applications for use across the supply chain, fostering a greater level of compliance of REACH from industry – and subsequent analysis of alternative substances. Developing greater awareness of the authorisation process through simplification and communication will ensure both suppliers and OEMs are more aware of their responsibilities under REACH, and also factor in risk mitigation to ensure continued supply of products and components.

3. Improvements in the REACH Authorisation procedure

3.1. *Proportionality* – The key driver behind improving the REACH Authorisation procedure should be a focus on 'proportionality'. This includes ensuring that requirements as part of the authorisation process are proportionate to the levels/ weights of chemical used, and the ability for manufacturers to effectively comply with the process. This is important for aerospace and defence industries, who use chemicals in low volumes but are subject to qualification or certification, or similar procedures – meaning there are certain constraints on areas such as analysing alternatives. For example, many suppliers who build parts and components to print, and which are subject to certification, do not on most instances have design control. It is therefore not proportionate in this instance to request AoA. Alongside these factors, a similar approach should be taken to low volumes in registration – where reduced information is requested.

3.2. *Expanding Criteria* – ADS believe that if ECHA are seeking to use weight as the key criterion for establishing what constitutes 'low volumes', then 100kg should be the maximum volume per legal entity. However, weight should not be deemed the only and defining criterion by which to measure low volumes. Certain chemicals may be used at over 100kg in their initial production processes, but become only a small fraction of the substances composition in the final product. ADS believe that 100kg should be part of a number of criteria in determining low volume applications – including their qualification to meet safety specifications, their use in anti-corrosion operations, and whether there is a company mechanism in place to communicate through the supply chain to minimise risk.

3.3. *Time and Cost* – After defining the criteria for low volumes, a simplified authorisation procedure should also include a mechanism whereby a company can be confident that it can be granted authorisation in a timely and cost effective manner to the business. The current process, which has no clear, defined and accepted duration levels, incurs significant resource amongst business, is disproportionate for substances

used in low volumes and can take away vital funding from business development, export and R&D activity which is vital for competitiveness.

3.4. *Reducing documentation* – As discussed, many component manufacturers that are subject to qualification or certification do not have design control. Therefore they are unable to assess alternative chemicals as this is fixed in the production process. For applications for low volume authorisation, and where there is significant certification procedures surrounding these substances, the requirement for Socio-Economic analysis and Analysis of Alternatives should be reduced – and the focus shifted onto whether the company in question has sufficient protection control in place for its employees when using the substance.

3.5. In reducing the overall levels of alternative assessments in an authorisation for substances used at low volumes, a simplified procedure should also seek to include relevant agencies such as the European Aviation Safety Agency (EASA), alongside companies who have to comply with safety requirements.

4. The Role of EASA and Amending the Basic Regulation

4.1. As highlighted, the civil Aerospace industry in Europe must follow strict regulations and guidelines, set by European authorities, to ensure a high degree of safety, reliability and performance. Certification processes ensure new components and materials are able to operate in a wide range of different operating environments – with any change in the composition or material used to produce these components, subject by law for assessment by EASA.

4.2. If any change has a possible effect on the safe use of a certified aircraft, the components or parts used may require requalification. Until this qualification process is completed, any alternative substance is not actively permitted for use on a component – which is designed for an aircraft granted type certification by EASA, and awarded to the Original Equipment Manufacturer (OEM).

4.3. Therefore, due to the impact a change of substance may have on the safe operating use of a certified component and aircraft, EASA should have a role within a simplified authorisation procedure. Where applicable, EASA's role would be to work with industry; review substances listed for authorisation by ECHA; and provide technical information on recertification & safety issues for authorisation applications. EASA would also help to review the analysis of alternative work undertaken as part of the authorisation procedure, in order to reduce the impact on removing a product from the market. The key focus for EASA would be to understand the potential consequences for both safety and competitiveness – which is particularly important as EASA are in direct contact with the Original Equipment Manufacturers (OEMs) in setting the essential performance criteria of aerospace products.

4.4. Increasing EASA's involvement in a simplified authorisation procedure should also be mirrored by ensuring REACH is identified as a key priority in EASA's own roles and responsibilities. Under the current European Commission initiative to update EASA's Basic Regulation (the legislation that defines its responsibilities), ADS believes provisions should be made to ensure REACH is listed as an area where EASA should seek to ensure there are no adverse effects on aviation safety. For example, where a special or low volume authorisation is requested in the framework of REACH implementation, EASA should provide ECHA with all necessary expertise and justifications regarding recertification and safety impacts.

4.5. It should also be noted however, that a greater understanding of the impact of REACH on defence, security and space operations should also be taken into account during simplified authorisation applications – with the key focus on EC/ ECHA working with industry to identify the potential impacts.

5. Legacy Spare Parts: Definition and Sunset Dates

5.1. As outlined in the consultation documentation, ADS supports the intent to identify details of chemicals/ substances which may require an extension of their sunset dates in circumstances where they are used in the production of legacy spare parts. In addition, industry supports the definition of 'legacy spare part' and 'spare part' but also believe that it should not be limited to repair of Articles no longer in production. This would limit the potential benefits to be gained by extending sunset dates.

5.2. The definition of 'legacy spare parts' should also be extended to spare parts for products where the designs and maintenance applications are certified and substitutes prevented (i.e. still in production but with fixed designs). In the production of 'spare parts', there is no differentiation between those made for on-going production and those destined to be used for repair of out of production platforms. In both cases, a repair/ maintenance organisation for example, is required to use the materials already specified and and does not have the capability or authority to assess and qualify an alternative. In the long term, ADS welcomes an approach to a more simplified procedure for legacy spare parts – however, the focus on longer term sunset dates for substances in Annex XIV and that are used in legacy processes and parts is more urgent, and requires attention.

6. Consequences of Inaction

6.1. *Disruption on Supply Chain* – The obsolescence of substances from the marketplace due to upcoming REACH deadlines, but which are used in relatively low volumes, may not be made available for manufacturers in the EU, due to the cost and complexity of the Authorisation procedure. If authorisation procedures for chemicals used in low volumes, and for those with significant certification and qualification, is not simplified it may disrupt supply chains - leading to increased manufacturing costs and in some instances, the reduction of business in the UK and EU. This will hit SMEs in particular, as many companies will be unaware of their responsibilities and of the authorisation process, but may be forced out of business or leave the aerospace industry altogether.

6.2. *Burdens and Costs* – The level of administrative support required for REACH authorisation, and the time taken to form consortia to share best practice, can be significant. For SMEs in particular, the cost of compliance is focused on seeking to comply with their customers REACH processes and initiatives. The level of documents, forms and surveys requires SMEs to include significance compliance costs into business plans – all of which are affected by a further complex REACH authorisation process.

6.3. *Trade and Competitiveness* – Without the ability for users of substances in low volumes to apply for a simplified authorisation procedure, the threat of chemicals being made unavailable for use in the supply chain may also impact on the competitiveness of European industry. Without security of supply, trading partners may not enter the EU market, and costs associated with authorisation may take money away from innovation and R&D funding for business improvement projects. This is despite the fact that the volumes of SVHCs used in these materials are in many cases small, conditions for their use ARE controlled to the agreed and acceptable criteria levels, and the risks to human health & environment 'low'.

6.4. *Impact on Maintenance activities* - Simplified authorisation procedures, alongside extending 'sunset' dates for legacy spare parts will help to ensure certain areas of industry are able to function effectively and efficiently, without disruption of its operations. Critical and routine safety and maintenance operations for example, depend on access to certain chemicals – however, where no technical alternatives exist for materials containing a SVHC, maintenance of the associated aircraft and components could not take place if use of the SVHC was not permitted in the EU. This has the potential not only to affect day to day maintenance operations which ensure the safe operation of aircraft, but could also see in the longer term, relocation of maintenance operations outside the EU – reducing EU competitiveness.