AeroSpace and Defence Industries Association of Europe

ASD19003 Issue 1

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REACH design changes best practices

Guidance document for ASD industries

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Abbreviations

ASD	AeroSpace and Defence Industries Association of Europe
BOM	Bill Of Material
CI	Configuration Index
DAH	Design Approval Holder (TCH, ETSO holder…)
DOA	Design Organization Approval
DOID	Design Organization Interface Document
DS	Design Solution
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EU	European Union
ETSO	Equipment Technical Standard Order
ICY	Interchangeability
Mtl	Material
P/N	Part Number
POA	Production Organization Approval
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EC No. 1907/2006)
TCH	Type Certificate Holder

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Table of Contents

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Foreword

The REACH* regulation has been adopted by the European Union to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry.

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007.

This overview gives a practical position from an Aerospace and Defence perspective aiming to help readers to understand the changes driven by the REACH regulation on their parts, components, equipment which they design to Customer specifications or for catalogues and aiming to provide recommendations to design organizations to reduce design change burden. One area affected by REACH in the Aerospace and Defence industries is corrosion protection used for parts.

REACH regulation highlights some chemical substances through a Candidate List, to identify the substances which use poses a risk to human health or to the environment. Such substances must be communicated to recipients if greater than 0.1% by weight of any component part, for safe use purposes. As a further step, the regulation identifies through the Annex XIV list, substances which should progressively be replaced by less dangerous ones, by setting a sunset date prohibiting their use in the European Economic Area unless that use is Authorised.

The guidance focuses on understanding the REACH challenge, with multiple surface treatments processes changes impacting a very large number of parts. This guidance is designed to illustrate existing processes for design change management and to provide recommendations to minimize design change burden where appropriate in the context of substitution caused by REACH.

This guidance is designed to propose a single EU industry position to illustrate existing processes for REACH design change management and to provide recommendations to Customer and Supplier design organizations to reduce design change burden.

This guidance is intended for REACH correspondents, expert materials engineers, product managers and configuration management specialists, program managers in contact with customers and REACH pilot project managers.

* *REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).*

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Scope

For the purpose of this document, we focus on “surface protections” which have been impacted by REACH, and which cover surface treatments, paints, mastics or sealants that are instructed by equipment, structure or component definition. However, the recommendations of these guidelines also apply to “materials”, covering all type of materials that participate to equipment, structure or component definition, such as structural materials including especially composite, adhesive or soldering ones.

Within this document “surface protections“ and “materials” are all covered by the generic word “materials”.

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Executive summary

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals.

Compliance will force aeronautic industries to substitute many chemical products that can be encountered in various materials, mainly but not only surface protections, on a considerable number of parts. The supply chain is worldwide and is likely to substitute materials in line with local regulation and company priorities, which may generate discrepancy in implementation timeline.

The volume of design changes may be very challenging for change management processes as applied today. There is a real risk of congestion at design organization level, and also cascading up to Design Approval Holders. This could seriously disrupt supply chains if changes could not be approved on time.

This document covers civil and military aviation equipment, structures and components (built to spec or from catalogue), with impact on products inside and offside EU.

It recommends that industries anticipate this wave of change and review their design change processes for simplification, while ensuring they remain compliant with requirements from Authorities and Customers.

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1.0 Context

Reminder on REACH regulation

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007. This European regulation was adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry.

For all chemical substances manufactured or imported in EU above 1 ton per year, the Registration dossiers collect hazard information and risk assessment. Evaluation by ECHA clarifies if the substances constitute a risk to human health or to the environment. The route to Authorization starts when a substance is proposed to be a SVHC (Substance of Very High Concern), and once it is identified as such after public consultation, the substance is included in the Candidate List. The Authorisation process aims to ensure that SVHC's are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. Therefore, ECHA regularly assesses the substances from the Candidate List to determine which ones should be included in the Authorisation List, or Annex XIV, where a sunset date is defined. The sunset date is the date from which the use of the chemical in the EEA is prohibited, unless an authorisation is granted for the specific use. Continued use under an authorisation is subject to periodic review and may have conditions of use associated with it.

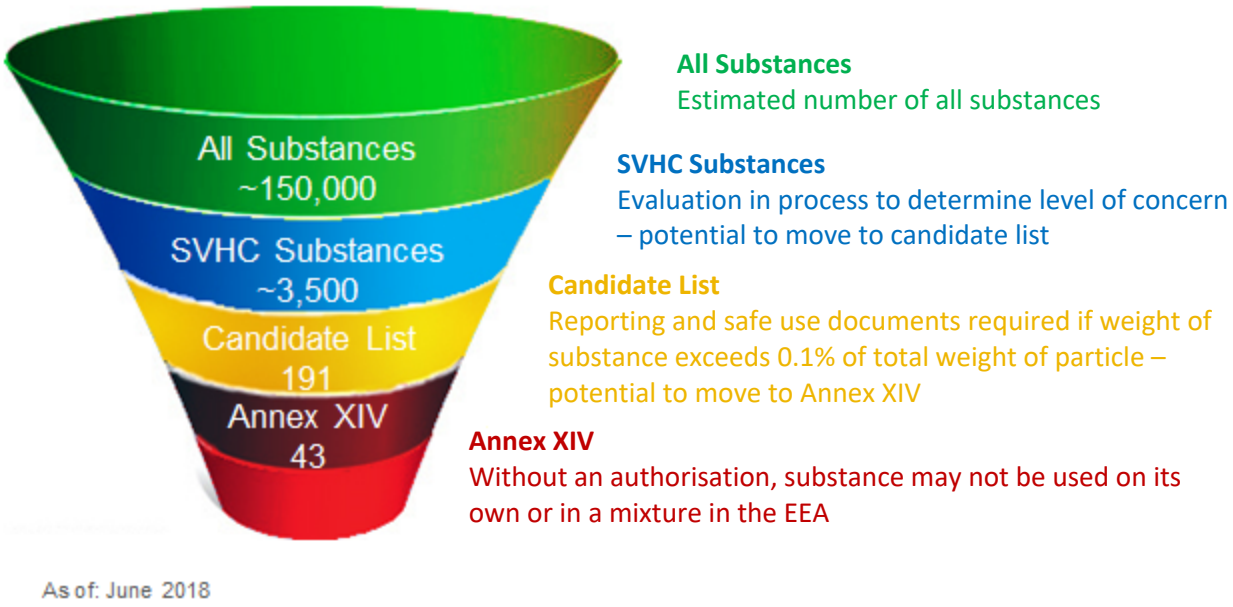

Figure 1.1 REACH Regulation Lists

For the substances of the Candidate List, suppliers of articles which contain such a substance in a concentration above 0.1% (weight by weight) have to provide enough information to allow the safe use of the article to the recipients of the article. The concentration criteria of 0.1% (weight by weight) is to be determined at each piece part level. The regulatory context for substance declaration continues to develop, for example in the context of amendments to the Waste Framework Directive made in 2018. Candidate list substances are reportable to downstream recipients for the purposes of safe use by all users including customers, operators, workers in maintenance, repair or overhaul activities, or end-of-life management. The presence of such substances in component parts >0.1% of component weight or where users may be exposed to such substances in foreseeable conditions of use is therefore a key concern in configuration and change management.

The Candidate List and the Authorisation List are regularly updated to include additional substances.

Candidate List: https://echa.europa.eu/candidate-list-table

Authorization List or Annex XIV: https://echa.europa.eu/authorisation-list

Authorization and Applications for Authorisations: https://echa.europa.eu/regulations/reach/authorisation/applications-for-authorisation.

2.0 Existing change management processes

Scope

This guidance document is applicable to design changes only. It covers changes initiated by the Design Approval Holder or by the design organizations of its suppliers.

It is not applicable to the implementation of these changes in the Production file.

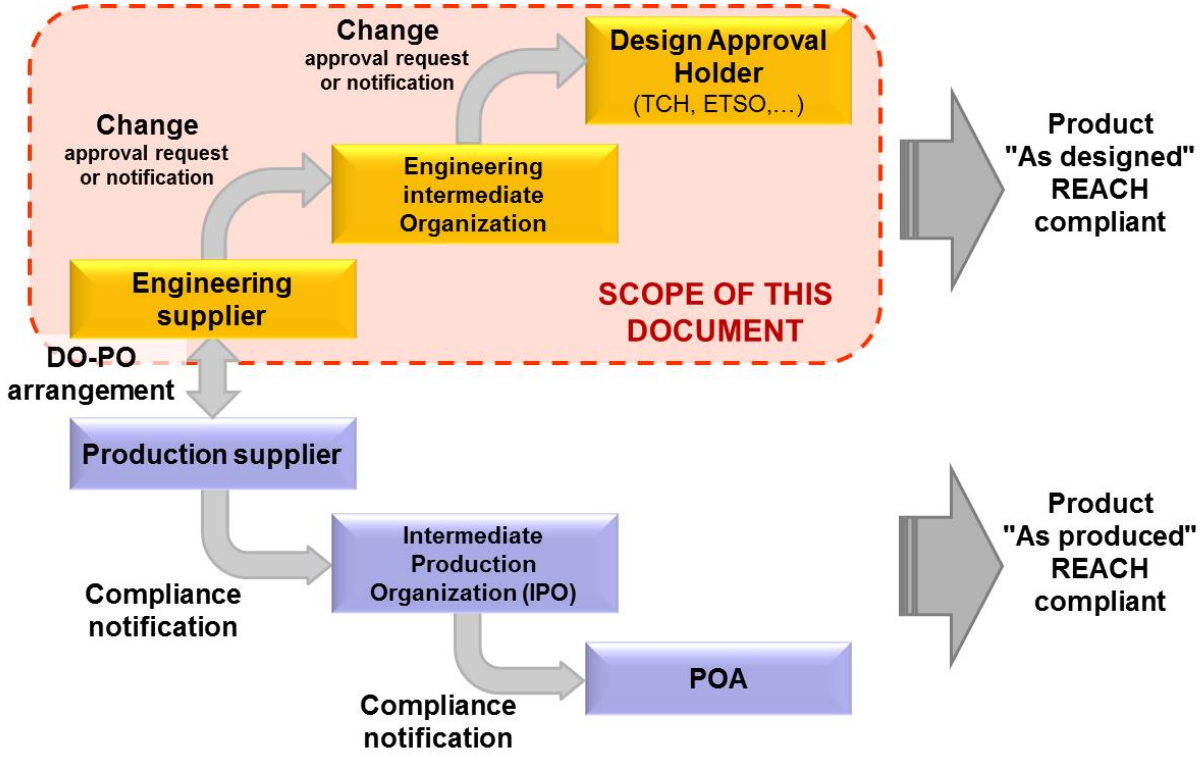

Figure 2.1 REACH changes in Design and Production files

Processes

Noncompliance to a mandatory requirement (REACH for instance) drives the need for a design change. Each design organization owns design change procedures.
These procedures define the appropriate path to be selected, based mainly on:

- Parts functions, including criticality and operating environments
- External change requirements (Authorities / Customers)

As a result, a material can be changed with three main design change processes, as illustrated below:

❶ Alternate in the specification

❷ Alternate in the part drawing

❸ New part(s) design with relevant material called-out

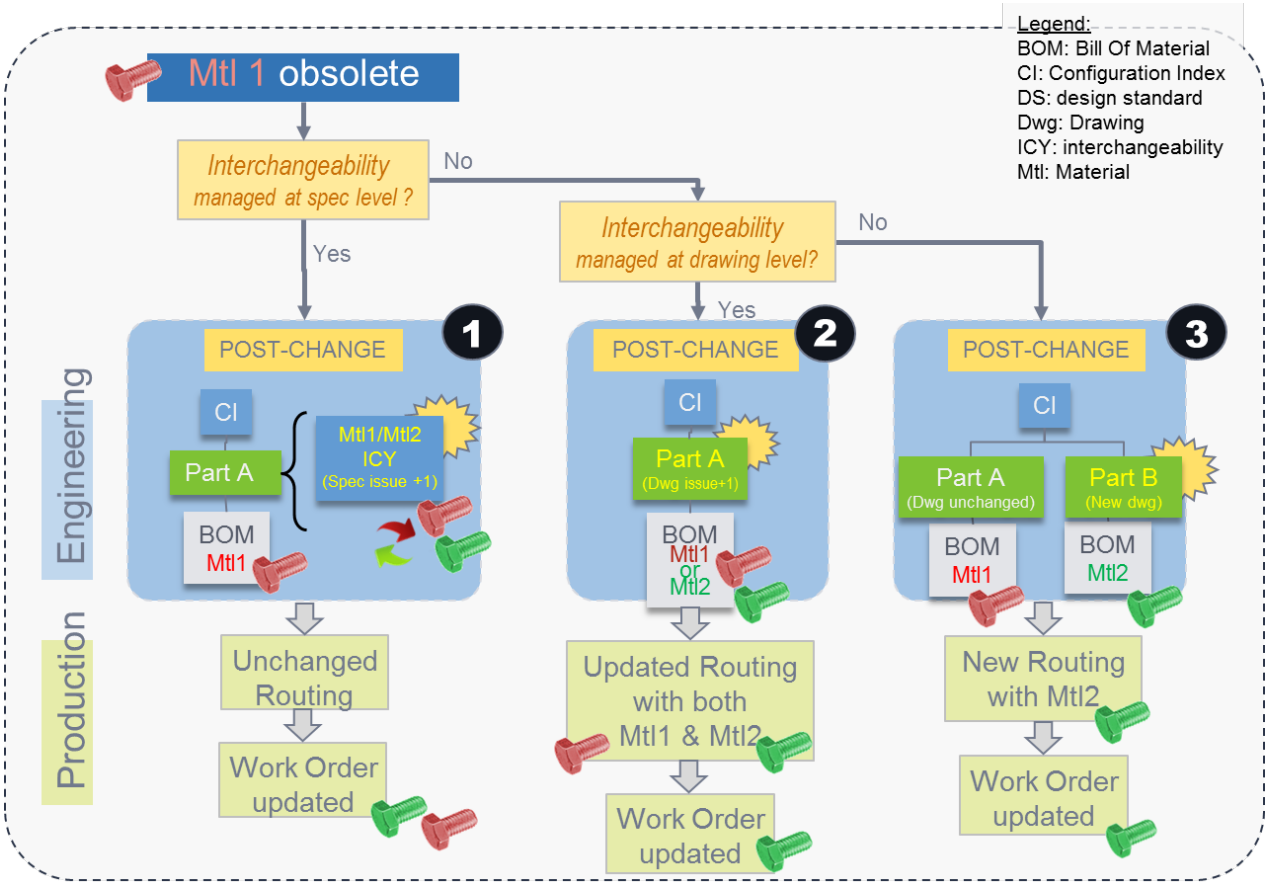

Figure 2.2
Existing product change management processes

In path 1, pre and post-change materials will appear interchangeable within material specification without any condition.

In path 2 and 3, material change will appear as a change of the part drawing with:

- Proposed Design Solution (DS)
- Impact on BOM (part-lists, drawings, specifications…)

All paths shall be supported by substantiation versus applicable requirements.

3.0 Management of Material specifications

To date the REACH regulation has a strong impact on the Aerospace and Defence Industry Surface Treatment processes, paints and sealants. Many manufacturers have started to turn to alternative solutions to replace their materials impacted by REACH.

The key item for implementation of the REACH compliant materials is to understand whether or not those substitution materials can be demonstrated as alternatives to the initial ones.

Therefore, demonstration of level of interchangeability is required according to internal procedures and Customer rules. Interchangeability can be understood, for example, as absence of impact on Form, Fit, Function. A change to a component where a Substance of Very High Concern at reportable levels (>0,1% weight for safe use purposes) is removed should not be considered as fully interchangeable, since this causes a difference which affects actions or obligations by downstream customers or users.

This demonstration should be performed on a back to back basis with the existing material solution, in order to demonstrate that there is no regression of the new material performances.

Material substitution with no impact on interchangeability

When non regression of the new material is demonstrated by the back to back tests with the existing material, then the substitution solution can be added as an alternative in the existing material specification (= universal interchangeability).

Both alternatives can be used, the back to back demonstration proves that the interchangeability of the material, and thus the interchangeability of the concerned parts is unchanged.

It must be highlighted here that visual aspect of a part with its REACH compliant material may be changed. Indeed, usually color is not a function. Whereas homogeneity of color for a batch is a key driver for the quality of anodizing for example, the color itself is not a requirement, unless explicitly specified (such as red removable plugs). Color variations will become a usual fact in the coming months with implementation of material alternatives to comply to REACH. The same applies to harmony (such as surface finishing). For example surface finishing can matter, especially in cabin.

Material substitution with possible impact on interchangeability

In the case interchangeability would be impacted at the article level; the substitution material should be defined by a dedicated specification (one way or two way interchangeability limited case by case).

4.0 Appropriate use of change management processes

Prior to focus on potential process improvement, it is important to understand the respective impact of each of the 3 change paths introduced in Chapter 2.

Change process characteristics

The table below illustrates the main characteristics of these 3 paths.
Especially, Part Number change is not always required for REACH related changes, and normal change principles apply. A new part number is always required when the previous and new parts are not fully interchangeable, or where the change is significant from a customer or user perspective, such as due to REACH "Article 33" substance reporting obligation

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

* Two ways of managing this multi-material specification:

- two materials defined in the specification
- or, one material defined, and the other one referenced (spec. referencing another spec.)

Figure 4.1 – Characteristics of change management processes

This table highlights the progressive complexity from path 1 to 3.

Change authorization

Change authorization from customer is also a key parameter: it can have significant impact on the change approval cycle.

In all the cases, agreement with customer (as reported usually in Contract, DOID or Configuration Management Plan) shall prevail to define this authorization process.

The table below indicates the minimum communication to customer for its configuration management consistency and its information.

Impacted level	Process spec 1	Drawing 2	Part 3
Equipment, specified item or build to spec	Change **notification**	Change **notification**	Change **request**
Component design and build, i.e. DAH proprietary part	Authorization notified by DAH Change implementation **notification** to DAH	**Generic** change **request** submitted to DAH	Change **request** submitted to DAH

Figure 4.2 – Minimum change authorization to customer

5.0 Recommendations

Industry design change management processes are heavily constrained by configuration management requirements imposed by regulations and customers.
Nevertheless, these processes should be suitable for REACH wave changes, if used appropriately.

This chapter is not proposing new change processes or new configuration management rules.
It identifies areas for improving existing ones, with objective to ease design change management, especially but not only for REACH compliance.

Recommendations:

a) Limit P/N changes:

A Part Number change impacts the part documentation over its whole life cycle.
It is anticipated that many material or process chemicals changes resulting from REACH can be managed without requiring part number changes:

- at specification level, i.e. a specification referencing pre-change and post-change material as interchangeable
- at drawing level, i.e. drawing or part-list referencing pre-change and post-change material as alternatives.

b) Use of the lighter change process:

Previous chapters illustrated the different processes available for design changes due to REACH regulation.
Change workload and approval cycle are highly dependent on the process selected.
The change process selected should be the least burdensome appropriate for the nature of the change in accordance with contractual and supplier quality requirements.

c) Group the changes:

Many chemicals affected by REACH authorisation affect parts and technologies across a wide range of applications and products.
Except for the ones where part function or environment impact interchangeability, the design change substantiation should be the same.
Changes should be grouped where possible to reduce the number of changes that need to be processed, provided they are sufficiently similar after considering technology, application, functional constraints, program and change authority.
Change procedure may need an update to allow for group of changes.

d) Deliver generic change authorization to suppliers:

When the impacts on the parts are very limited, and products interchangeability is established for the concerned range of usage, its implementation in supplier design may not require systematic customer review for acceptance.
It may be helpful for a customer to provide its supplier(s) with a generic change authorization for a set of parts (i.e. thanks to a letter or Coordination memorandum).

Each time the supplier will process a change due to this product replacement on one of these parts, it could rely on this document for customer acceptance, rather than providing each change proposal to customer review.

e) Implement design approval delegation:

Reminder: a supplier cannot approve any design change on his own, except when an agreement is in place with its customer.
When possible, customer and supplier should work together to agree and formalize change approval delegations. This could allow supplier to classify and approve some type of design changes, based on specified customer criteria.

Documentation:

Implementation of the above recommendations must drive the update of configuration management requirements: Applicable internal and/or interface documents should be revised and agreed, such as:

- Configuration management plan(s)
- Configuration management procedure(s)
- Design Organization Interface Document(s)
- (…)

Depending on the document impacted and Design Organization level, this may require internal, customer(s) and/or Authority(ies) acceptance.