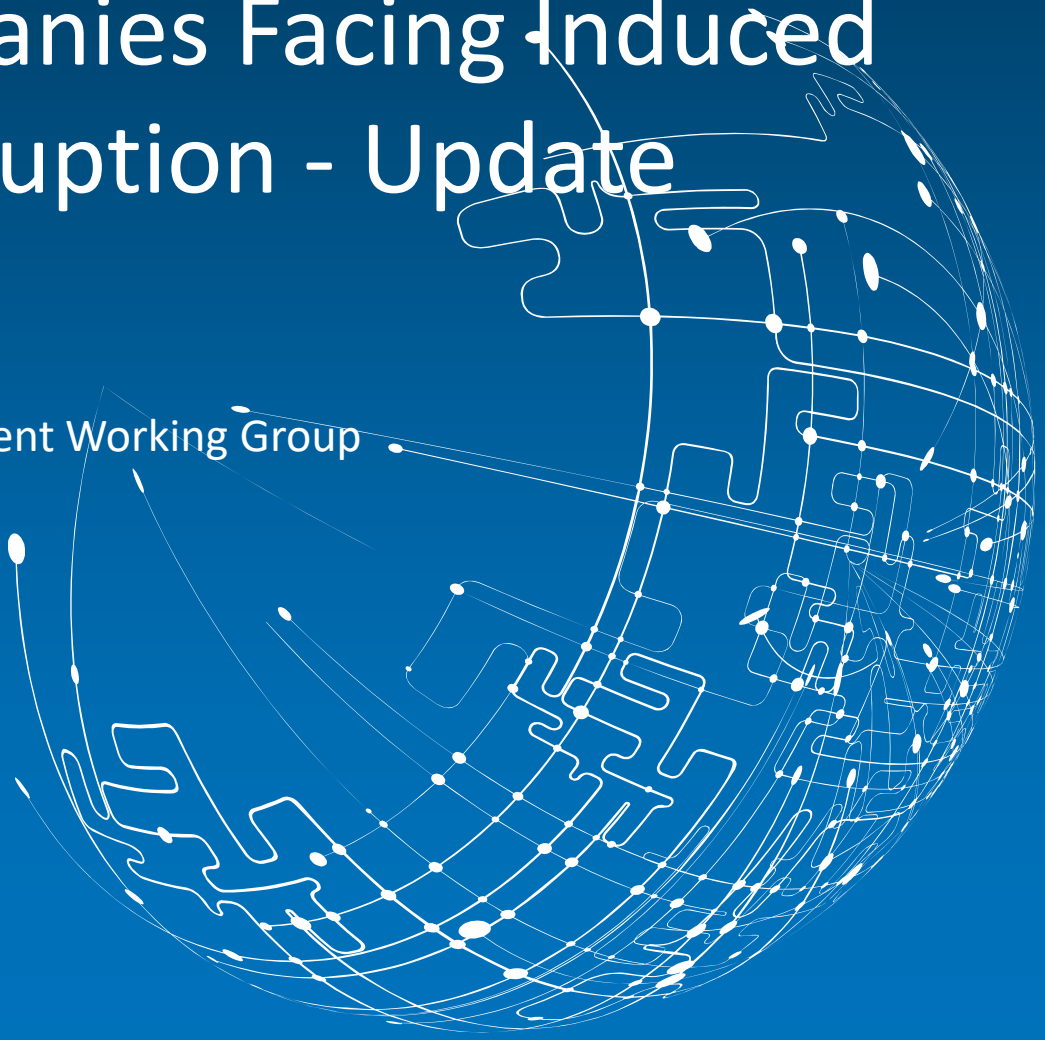
ECHA Forum Open Session

Support to Companies Facing Induced Supply Chain Disruption - Update

Steve George,
Chair REACH and Chemicals Management Working Group

November 2019

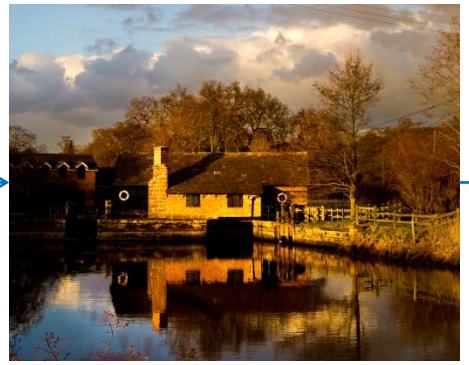


ASD
AeroSpace and Defence Industries
Association of Europe

A simple supply chain of a Commodity Substance

Manufacturer

DISTRIBUTOR

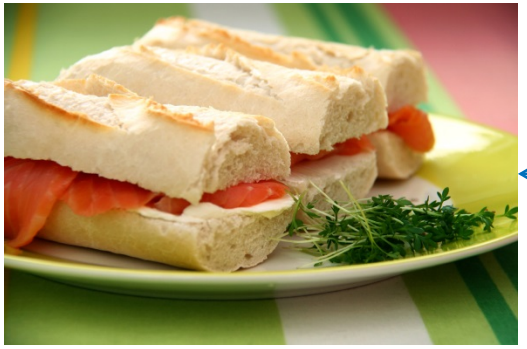


Processor

DISTRIBUTOR

Formulator

Article Manufacture



OEM

Don’t expect a farmer to know a baker… or a sandwich maker

Key messages from November 2017

- A summary of last time
  - Supply chains are complex
  - Producers do not know their ultimate customer
  - We cannot know all the substances in supply chains due to process uses, CBI etc.
  - We are dependent on communication via small companies who struggle with complexity of REACH
  - Decisions are made in the commercial interests of each individual supply chain actor
  - Substitution is never instant, especially for some safety focused industries
- A particular concern then was 2018 Registration
- The request was to:
  - Recognise companies can be forced into non-compliance through no fault of their own
  - Consider each case on its merits

- This time: A revisit to refresh the point for newly developing issues

As shown in November 2017

Example scenarios where helpful MS EAs are needed

Upstream market dynamics	Chemical withdrawn from market (Registration or authorisation costs, business decision, communication failure, formulation and end-uses/ sectors impacted)	Formulation withdrawn from market (Ingredient withdrawn, Registration/ authorisation costs, EU market non-viable – business decision, end-use impact)
Authorisation planning failure	Unreported Supplier Need (e.g. supplier did not advise process use, not included in customer authorisation planning)	Rare Chemical Use Case (E.g. Repair use in legacy products, need not anticipated until an unusual failure happens)
Use coverage	Final authorisation did not cover a downstream use (Upstream authorisation, applicant clarification during dossier development, e.g in response to committee review)	Unexpected use conditions not easily met (Authorisation decision, communication failure. For example RAC ask for additional technical controls. Also eSDS requirements)
Authorisation need unexpected (afterward)	Substitution Plans Failed (Did not apply for authorisation because expected substitution, too late to apply)	Wrong lifetime buy size (Last batch for article manufacture too small e.g. due to quality or reliability issues)

All of these cases can happen without any non-compliance.
Resolution may require short term relief from obligations

Authorisation Issue 1 – Scope of Application

- Issue
  - Scope of authorisation is challenged by committee review process
  - Conditions or clarifications are made which restrict the application
  - Downstream users continue to believe they are covered
- Result
  - Non-coverage of downstream use is discovered only after a decision is made.
  - A new application would be required to cover the gap made without the user's knowledge, taking > 2 years

Authorisation Issue 2 – Conditions of Use

- Issue
  - Conditions of use are imposed on an Authorisation application during committee review
  - The downstream user is unaware of this, but it takes time to meet those conditions
  - Alternatively, the conditions imposed are impractical/impossible to achieve
- Result
  - The downstream user has to interpret the intent of the conditions and meet them as close as he/she can
  - The user is potentially in non-compliance until a review report or new application can correct the issue

Authorisation Issue 3 – Business Failure

- Issue
  - A supplier has a Downstream User authorisation
  - The supplier chooses to stop supplying, or the business fails e.g. due to quality or financial reasons
  - The customer has to source from elsewhere
  - The Authorisation sunset date is in the past, and a new application take >2 years to be made and decided
  - Either the customer is unwilling to source from outside the EEA, or this is impractical
- Result
  - A new supply source is needed, and there would be a long period of time without Authorisation coverage

Other supply chain shocks

- The 2018 Registration is in past

- However, there continues to be obsolescence or supplier threats as a result of
  - Legislative changes
  - Commercial choices

Issues Requiring High Expertise

- REACH is incredibly technical
- Most downstream users do not employ chemistry experts
- Understanding of what substances are / are not in scope of a list entry is therefore very difficult for Downstream Users
  - Industry works using CAS/EC numbers, but some list entries are defined by molecular structure
- Examples:
  - Annex XIV entry 43 NPE – 22 substances in the “non-exhaustive” list
  - CL proposal Perfluorobutane sulfonic acid (PFBS) and its salts – many! It uncertain how many this covers

- There is risk that a downstream user is unknowingly using a substance affected by legislative limitations but does not have the expertise to know
  - May be using old stock or have limited time to react

Summary and Requests Revisit

- Summary
  - Industry expects and seeks compliance, but recognises that sometimes non-compliant situations may be forced upon them
  - If a company finds themselves in difficulties resulting in non-compliance, self-reporting should be the best option

- Therefore ASD requests:
  1. EA's to encourage companies with concerns to contact their Enforcement Authority
     - EA's to understand the underlying issues before applying penalties
     - EA's to agree with concerned companies a plan that aims to maintain trade and return to compliant state, with follow up checks as required
  2. EA recognition that recovery from issues can take particularly long where due to Authorisation gaps

Thank you

AeroSpace and Defence Industries
Association of Europe

ASD
rue Montoyer 10 I 1000 Brussels, Belgium
info@asd-europe.org I www.asd-europe.org