Fecc
EUROPEAN ASSOCIATION OF CHEMICAL DISTRIBUTORS

# *How is REACH Authorisation Changing the Chemicals Market, Implications and Outlook*

## REACH Authorisation Workshop
### Brussels, 7 November 2014

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# Content

- Fecc in a nutshell
- Authorisation basics
- Will authorisation change the market
- Who can apply
- Who should apply
- Learning & experience

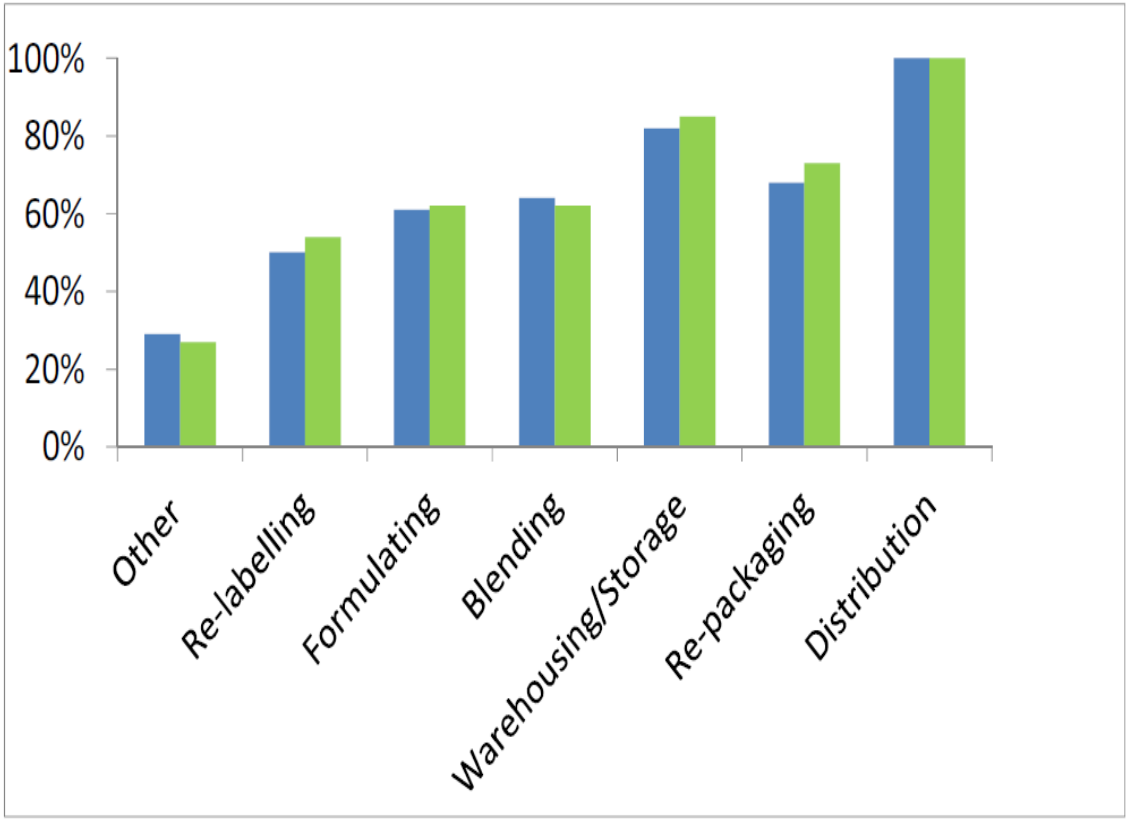
# Fecc Membership

- National Associations: 15
- Company Members: 38
- Associate Members: 9

Fecc represents around 1650 companies of which 830 are distributors with around 30,000 employees annual sales turnover of about 27 billion Euros

***Source: Fecc Statistics 2014 (2013 data)***

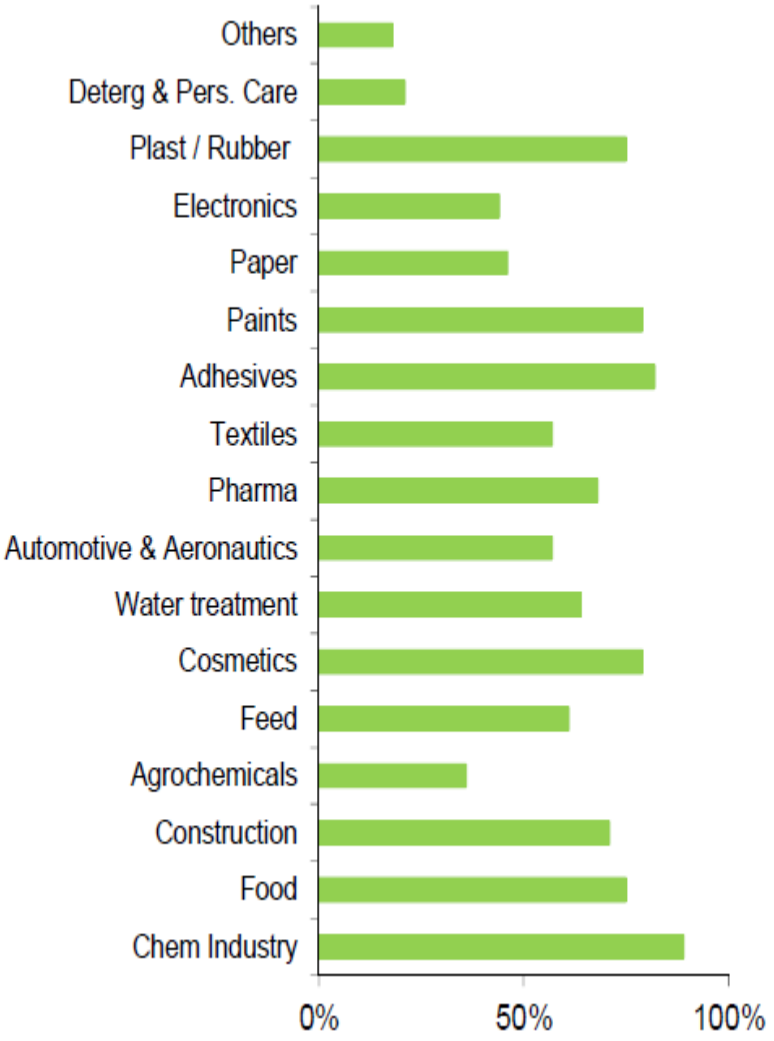
# Chemical distribution sector




2010: % Members with this activity

2011: % Members with this activity

## % Members supplying this sector




*Source: Fecc Statistics 2012 (2011 data)*

# *Distributors roles under REACH & CLP*

Chemical Distributors may have different roles:

- Manufacturer: manufactures a substance within the EU
- Importer: is responsible for imports
- Distributor: (including retailers) only stores and places on the market
- Downstream user: (including re-importers) uses a substance, e.g. formulation, dilution, re-packaging, etc.

# *Authorisation vs Restrictions*

## Authorisation

- Ensure ***risk from SVHC are properly controlled*** & good functioning of the internal market
- Ensure ***progressive replacing of SVHC*** by alternative substances or technologies, when technically and economically viable
- **Scope is limited** to the downstream use of a substance
- Authorisation covers **all uses unless specifically exempted**

## Restriction

- Address a unacceptable risks to human health or Environment that requires ***community wide action***
- **Covers wide scope**
  - Manufacturing
  - Use
  - Placing on the market
  - Substance
  - Substance in mixtures
  - Substances in articles
  - all risks (not limited to SVHC)
- Limited to **uses focused on** by the restriction

# Authorisation basics

## It is a complex, costly and new procedure

- Encourages the development of **safer alternatives**
- Granted for a **limited period**, after which the applicant may re-apply
- The **quality of the application** is key to its success
- Authorisation will only be granted where the application documents show
    - Exposure Scenarios, Risk Management Measures => Chemical Safety Report (CSR)
    - No suitable alternative substances or techniques => Analysis of Alternatives (AoA)
    - Socio-economic benefits > risk to human health => Socio-Economic Analysis (SEA)

# *Authorisation basics*

## Exemptions

- Manufacturing process of a substance
- Substances in articles (only the incorporation of substances in articles in the EU is covered)
- Intermediates uses
- **Certain uses**: R&D, medicinal products, food and feeding stuffs, biocides and pesticides, certain fuels, use in preparations below certain concentration limits

  + cosmetics, food contact materials, medical devices (with regard hazard to human health)

➡ **But what is with substances produced for certain uses which are exempted?**

**Discussion in CARACAL started**

# *Will authorisation change the market?*

- **Extensive communication within the supply chain required to:**

  - Identify/express the needs of a **critical substance** (suppliers are often not aware of critical use down in the chain)
  - Determine **who should apply** for authorisation
  - Exchange information regarding the content of the authorisation dossier (description of uses, substitutes, substance properties etc.)

- **Extensive communication between competitors!!**
  (for a joint application)

  - Sensitive business info

  (Socio-eco analysis and analysis of alternatives)

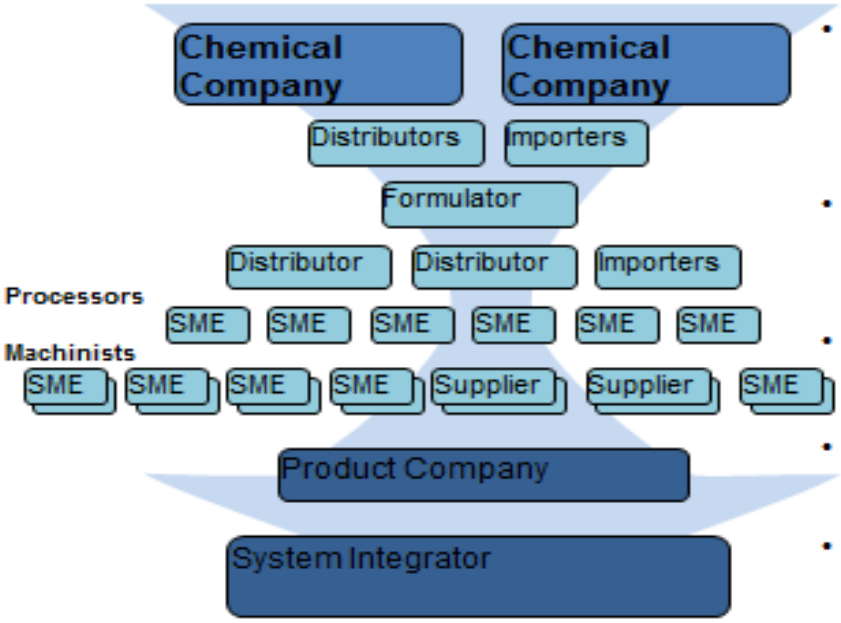
# *Who can apply?*

- **The requests for authorisation may be submitted by:**
  - the manufacturers or importers of the substances
  - the downstream users , which may include formulators and end users of substances or mixtures including Producers of Articles
  - the Only Representative (OR)
  - any combination of these

- **An application for authorisation can be submitted:**
  - for one or several uses
  - for one or a group of (similar) substances

# Who should apply?

## Supply Chain Complexity




- Long and Complex Supply Chains, 8 or more layers
  - Thousands of 1st tier component suppliers
- Many mid-chain players are small
  - SMEs & distributors
- REACH knowledge in mid-supply chain is poor
- No visibility from one end to the other
- Communication through this supply chain is difficult and slow

Source: Aerospace and Defence Industries Association of Europe

# *Who should apply?*

## An authorization application by

- **M/I of substance covers the entire supply chain**
  - All uses should be known
- **DU (formulator) covers the supply by the M/I and the supply chain below the DU**
- **User further downstream only covers own use and his immediate suppliers‘ right to supply the substance**
  Allows his supplier to sell to him, but not supplier‘s uses

**Note: “Distributors” cannot apply unless they are DU or I**

# Who should apply?

## Applicants and Consortium Limitations




**"Λ" Approach**

- M/I is Applicant
- Covers multiple industries with different risks & economic drivers
- Aerospace element potentially inseparable from the rest

**"V" Approach**

- DU is Applicant
- Only Authorises DU and immediate supplier(s)
- Not practical for complex supply chains

**Hybrid/Combinations**

- Other options depending on supply chain and uses
- Structure and stakeholder management are key
- Engagement and cooperation of M/Is paramount

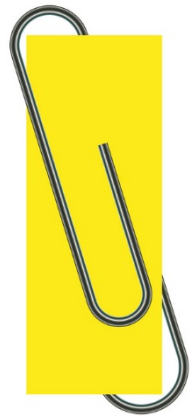
Source: Aerospace and Defence Industries Association of Europe

# *Additional duties*

- In cases where a DU uses the substance on the basis of the authorisation granted to his supplier, **the DU shall notify ECHA within three months of the first supply** of the substance (Art. 66(1))

- If none of the companies in the supply chain holds an authorisation, **all users must cease use** immediately after the sunset date

- Holders of an authorisation including DU must include the **authorisation number on the label**



# *Applying or not?*

## Applying or not remains a company decision

- **Key question is?**
  - What will be the impact on my business? Is it a core business?
  - Analysing options and impacts probably provides an answer
  - A company should apply, if:
    - the use of the substance clearly adds value
    - and the remaining risks are calculable
- **Authorisation concerns the "core business", do not leave it to others**
- **A strong case probably mean an easier application**
- **Preparation needs to start early**
- **Involvement of the supply chain essential**

# *Learning & experience*

**The complexity / length of the supply chain remain a key challenging issue!**

- Challenge to identify all actors having different priorities
- Challenge to identify other sectors having the same use
- Combination of sales
- Challenge to set up a strategic plan
- Challenge to respect the timeline

**It is recommended to involve your business unit to map your supply chain!**

- Via early communication campaign
- Via open / active / passive communication website

# *Learning & experience*

## Inform about:

- The **changes** that may appear in the supply chain for chemicals and articles used
- Willingness to withdraw a substance/article
  - ⇒ inform on time your supply chain for further adequate actions
- Willingness to continue
  - ⇒ will request significant additional resource and time costs linked to the development/qualification of alternatives
  - ⇒ and where authorisation is needed, find and nominate a lead applicant

# *Distributors' experience*

- Authorisation is seen as too expensive/too heavy/too complicated
  - ✓ Reluctance to commit to requests by customers
  - ✓ Lack of own data
- Some distributors have stopped the supply of some substances e.g. ethylen oxide, propylene oxide, 1,2 dichloroethane
  - ✓ Communication letter with some DUs/Cefic/Fecc
- Some distributors developped an open substitution policy in cooperation with customers but customers involvment is required to test the substitutes for instance

# Example - ADCA

- Manufacturer outside EU – no EU production
- Importers/DUs were getting aware too late about the process
- **Process too fast** – no possibility to set up a communication strategy
- Difficulity to raise awareness of the whole supply chain

| Timeline | |
|---|---|
| August 2012 | Registration of Intention |
| September 2012 | Annex XV dossier |
| December 2012 | Inclusion in candidate list |
| June 2013 | Draft authorisation |
| Spring 2013 | Set up ADCA TF by REACHCentrum with M/I//DU |
| June – Sept. 2013 | Commenting period |
| Feb. 2014 | Inclusion in 5th Recommendation List of ECHA – List on hold |

# *"Simplified authorisation"*

## Thoughts ongoing to think about simplification of the authorisation process:

- Who will benefit from a simplified procedure?
  - Small volumes
  - High social/economic value
  - Controlled conditions/existance of an OEL
  - Downstream user SMEs
  - .....

⇨ But this relates to simplify the granting of authorisations, NOT getting rid of authorisation

# Recommendations

- ⇒ Consider forming **alliances** of various associations to determine high level common aligned messages to Regulators
- ⇒ Try to get agreement to share ONE VOICE messages
- ⇒ Look for **other management measure** to reduce risk
- ⇒ Prepare a **robust application**
  - Only **"one chance"** for industry to make a good application
    - Risk of overloading the application
    - Risk of depending from others

# *Support documents*

- Industry guidance on authorization for DU - guidance co-signed by Cefic , ACEA, ASD, CEPE, Eurofer, Eurometaux, ORO, UEAPME – currently under revision

  http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/REACH-Authorisation-Guidance-for-Downstream-Users.pdf

- ECHA website
- Industry association websites

# *Thank you for your attention!*

**Visit our website**

**www.fecc.org**