Authorisation applications : process, learning lessons and suggestions

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- Learning lessons from industry on AfA
- How to improve the way to apply for an authorization?
  - Streamlining means…
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Introduction

- Eurometaux speaks for the non-ferrous metals industry in the EU. It comprises 12 national federations, 6 sectorial associations and 21 companies.

- Cefic speaks for the European Chemicals industry. It comprises 650 members and affiliates representing 29000 large, medium and small chemical companies in Europe.

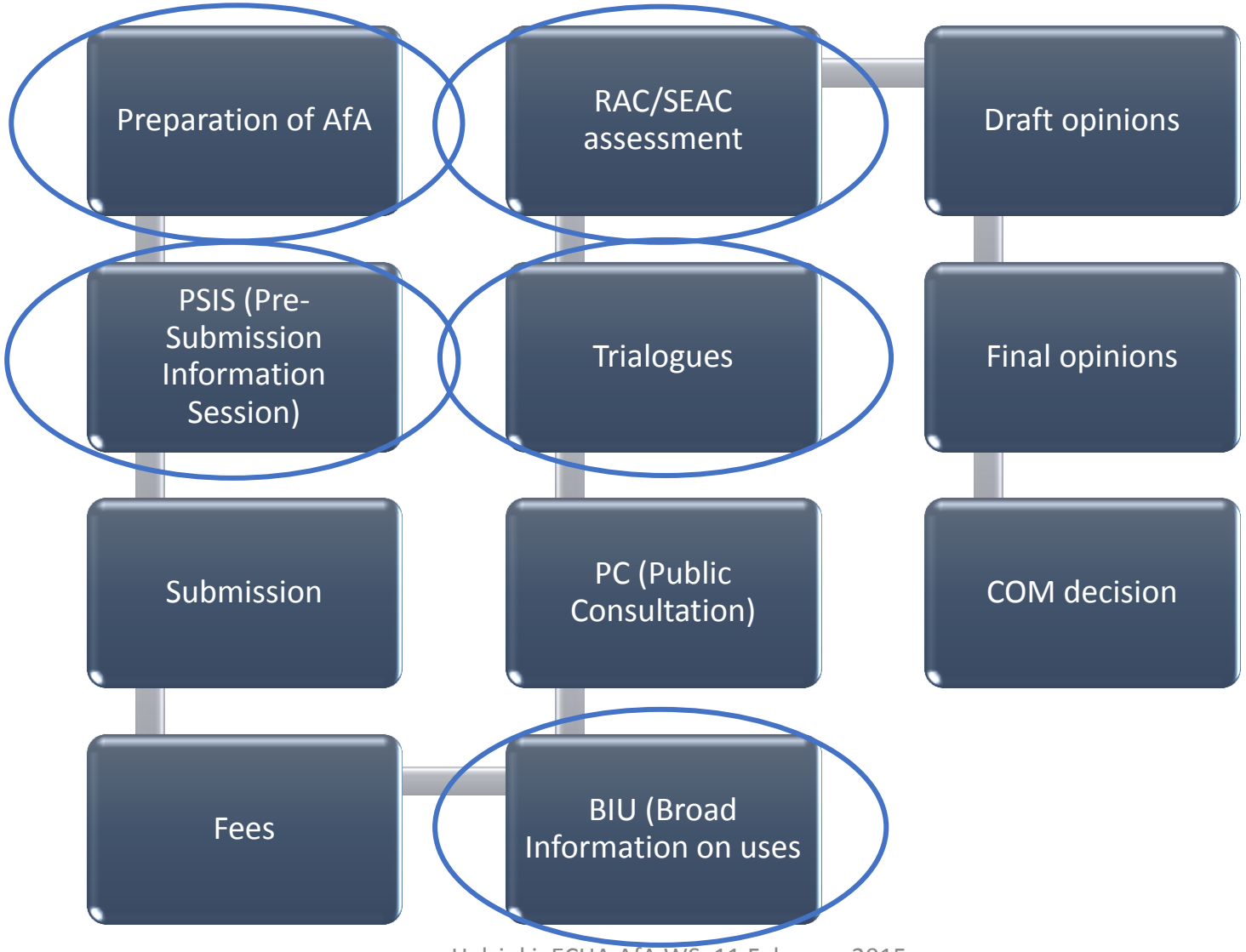
- AmCham EU speaks for American companies based in the EU. This is a unique organisation comprised of 160 companies from a broad range of sectors.

Introduction

Aims

- Share experience from industry on Application for Authorisation
- Provide some recommendations
- Review the overall Authorisation process

Authorisation process



Learning lessons from industry on AfA

Key questions on how to prepare an application:

- Do you need to apply?
- Who to involve and who will apply?
- How to define a use?
- How much time do you need?
- Which kind of information is needed?

Learning lessons from industry on AfA (1)

Do you need to apply?

ISSUE

- Identification of targeted/exempted use
  - Intermediates
  - Article 58 (2)
  - Others?

N.B.: Outcome of the RMOA is key!

PROPOSAL

- **Very early and consistent RMOA**
  - Consistency between legislations
  - Harmonization at EU level
  - Early consideration of RMOA
  - Start retroactive RMOA for CL substances
- **Exemptions**
  - Clarify upfront which use can be exempted: better use of existing regulations - Art 58 (2)
  - Consider de-selection from CL
  - ECHA opinion: to ensure better harmony and reduce uncertainty

How to define the use?

ISSUE

- A "use" in the Registration dossier can be different from a "use" in Authorisation
- Supply chain communication
  - Need to identify and reach potentially impacted companies

PROPOSAL

- **Keep it simple**: translate use descriptors into a simple wording describing the use process
- Review the use based on the **AoA** (Analysis of Alternatives)
- Contact ENTIRE supply chain as soon as possible

Learning lessons from industry on AfA (2)

Who to involve?

ISSUE

- Supply chain Communication
  - Supply chain complexity
  - Producers, Importers, Distributors, Formulators, DUs, End Users
  - Users not using the SVHC as such but depending on

PROPOSAL

- Identification of key players upfront
- Need time to contact all actors
- Early communication during the RMO (Risk Management Option) process

Who will apply?

ISSUE

- Supply chain complexity
- Incoherence in Regulation: cover all steps down, but only one step up

PROPOSAL

- Identify the submitter based on the complexity of the supply
  - 2 applications could be required (e.g. at formulator and DU level)
  - 2 applications might be clearer
- Allow DU to cover several steps up in the supply chain – steps relevant for his use.

Learning lessons from industry on AfA (3)

By when do you need to apply?

ISSUE

- LAD (Last Application Dates) and SSD (Sunset Dates): set by the Commission when SVHC are included into the Annex XIV
- LAD and SSD not always realistic

PROPOSAL

- **Adapt LAD and SSD** to supply chain complexity and sector impacted
- LAD - take into account **applicants needs** and not only authorities needs
- **Consistency between legislations** Harmonization at EU level

How much time do you need?

ISSUE

- Supply chain complexity
- Supply chain awareness
- Application strategy:
  - who, what, when, how?
- Data sharing issue

PROPOSAL

- **Start as soon as possible**: ideally during the potential SVHC screening… at the latest when the substance is included into the Candidate List
- Ensure publicly available data are shared on a legal basis

Learning lessons from industry on AfA (4)

Which kind of information is needed?

ISSUE	PROPOSAL
• Hazard • Exposure • Substitution • SEA • Which data considered as Relevant for the assessment? • …	• Provide a **"check list"** focusing on most critical data needed and how to gather them • Give access to anonymized **"best cases"** as examples

Learning lessons from industry on AfA (5)

After the AfA submission:

- Communication with authorities
- RAC and SEAC assessment
- Quality of the Afa

Communication with authorities

Learning lessons from industry on AfA (6)

PSIS

- Very useful
- Best timing: 6 months before applying
- Use it!!

Trialogue

- Depends on remaining questions (… or not!) of the Rapporteur
- Maintain Trialogue to always give a chance to applicants to clarify potential remaining issues

And then…

Lack of exchanges during the Committee assessment

- Increase transparency – AfA remains a 1 shot exercise!
- Important to ensure input from Applicants during this process

Learning lessons from industry on AfA (7)

CSR

- How to manage and meet RAC expectations?
- Level of scrutiny of non-threshold sustances?

PROPOSAL:

Provide a « fit for purpose » template based on RAC requirements

Exposure assessment

- Need monitoring data and not only modelling data
- When modelling can be used?
- What level of scrutiny can be expected on the exposure cases of non-threshold substances?

PROPOSAL:

RAC is invited to provide clarifications

RAC and SEAC assessment

Learning lessons from industry on AfA (8)

SEA

- What level of detail is required?
- Needs to be linked to AoA
- Too complex SEA (or AfA) does not work
- Avoid generic statements without strong data support (e.g.: relocalisation outside the EU)

PROPOSAL:

Keep it simple, focused and credible to ensure a good understanding by non-industry experts

”Adequate control” route… or not…

There is a risk that this route is not accepted by RAC (e.g.: disagreement on DNELs)

PROPOSAL:

Develop reference DNEL on time!

Need a Plan B?

Learning lessons from industry on AfA (9)

Review period

Based on applicants request mainly focused on availability of alternatives

Quality of the Afa is key: poor quality = short review period

PROPOSAL: Ensure that

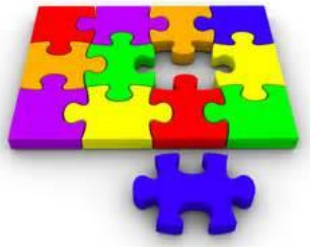
- Exposure is taken into account (.e.g: no or minimized exposure = long review period)
- Very long review periods are set in specific cases (e.g.: recycling, spare parts)

Suggestions on how to improve application for authorisation process

Improve the AfA Process through the improvement of Authorisation

Streamlining

Streamlining means…



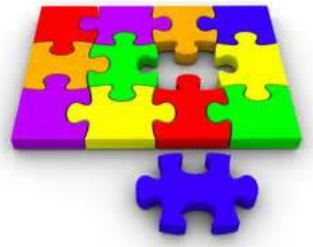
A good communication and coordination throughout the supply chain

- E.g.: link between SVHC and final product (not always containing the SVHC)

A “simple” application

- Avoid disproportionate application focusing on direct socio economic impact, realistic analysis of alternatives and well defined uses: stay focus!
- Application should be fit for purpose

Streamlining means…



FAfA = full application with better tools helping to submit adequate info

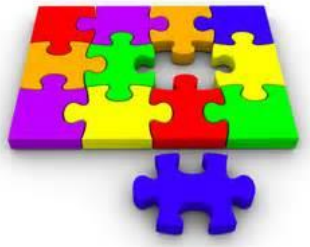
- Develop standard boxes – “not applicable”, “not relevant”, etc..

SAfA = simplified application according to the specific use targeted

- Applicant = Provide figures, schemes, table to explain entire exposure assessment
- Authorities = Consider a longer RP for uses with very limited or no exposure. A longer RP would stimulate companies to invest.
- Focus SEA doc only on use and non-use scenario if no alternative exists.

eSAfA = extraordinary simplified application in specific cases (e.g.: spare parts , low volumes)

Streamlining means…



Develop & Clarify model argument/template for

- Close system, highly regulated environment, bridging application
- Multilingual application

Statement for specific cases

- Low volumes, spare parts, end product subject to approval scheme
- Partly exempted uses, recycling, etc…

Find the balance between streamlining and relevancy of data!

Applicants interest and needs

Interest:

- To continue **business** in the EU in compliance with EU regulation
- To minimize uncertainty on the **market**
- To see his application for **authorisation granted**

Needs:

- Consistency between legislations
- Clarity on managing and understanding Committees expectations
- Clarity on level of details required

Conclusions

- Industry and authorities have a common interest: ensure a workable system!
- Close collaboration between Industry, ECHA, Committees and Commission is need to streamline the Authorisation application
- Streamlining application will request consistency from industry and authorities
- **Proactivity is key in the entire Application process!**
- Authorisation application is part of the overall Risk Management System which needs to be effective, transparent and efficient