Authorisation Applications becoming a reality

Eighth Stakeholders' Day

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Outline

1. Aim of authorisation and status of applications
2. Why and when should you apply?
3. ECHA Committees set the scene
4. Role of applicant, third parties and stakeholders
5. Downstream users will play a key role
6. Take home

Aim of authorisation

- Ensure good functioning of the **internal market**
- Assure **risks from SVHCs** are **properly controlled and**
- Assure SVHCs are:
  - **progressively replaced** by **suitable alternative** substances/technologies
  - where these are **economically and technically viable**

(Art. 55 REACH)

First applications expected in May

	Received notifications to submit	Pre-submission information sessions held	Submitted applications	Names of substances
2012	5	1	0	n.a.
2013*)	2	5	0	n.a.
Total	**7**	**6**	**0**	

*) Situation as of 20 March 2013

- Names of substance(s) public once the application has been submitted.

Why should you apply?

You should apply

- if the use of the substance clearly adds value in the European Union and the risks related to its use are very small…

You should not apply

- if the use of the substance does not add a lot of value in the European Union and the risks are relatively high…

The key question

- What will be the impact on my business if the substance can no longer be used in the EU?

- Relevant question, if
  - the substance is listed in Annex XIV and is subject to authorisation
  - you manufacture the substance, import it, use it in your processes, if it is present in the products you produce or use
  - you want to assess whether the impacts of authorisation would be bigger or smaller than the benefits
  - you need to decide to apply or to substitute

Substitution options and their impacts

- These are core business issues relating to
  - Business strategy
  - Commercial interests
  - Technical possibilities to substitute
- Not only complying with environmental, health or safety regulations
- Look wider
  - Clients, competitors, possible collaborators
  - Direct and indirect costs of downtream users
  - Substitution in short or longer term?

Case for authorisation, if benefits > risks

Benefits

- Avoided cost increases and/or reductions in profit
- Avoided reductions in economic performance, employment, investment
- Avoided environmental impacts: e.g. CO_2, air pollution from energy use, transport

Current risks

- Environmental and health impacts from using the substance

(Can be zero if risks are adequately controlled)

⇒ Authorisation more likely when costs of the alternatives are higher and/or current risks are more controlled

⇒ **Authorisation more likely when the case is clearer – a stronger case is likely to be a simpler case**

Consider also

- Application requires staff and other resources
- Application fee
  - only guarantees an opinion, not authorisation
- Authorisation is temporary
  - application costs have to be incurred again and again,
  - justifying the authorisation might get harder over time
- Competitor, supplier and market trends
  - if everyone else is substituting, will you get left behind?

When should you apply?

- When you are ready
- No need to wait for the latest application window
- ECHA's Committees will start opinion making immediately after the receipt of the payment
- The earlier you apply the earlier you will get the opinions of ECHA's Committees, and the Commission decision

ECHA Committees set the scene

ECHA Committees set the scene

- Established in 2012 how to evaluate applications
  - Key documents published on ECHA's website
- Economic feasibility
  - SEAC published how this will be evaluated
- Setting DNELs and dose-response functions in advance to evaluate remaining risks
  - RAC establishing *reference* DNELs for DEHP and DBP
- Substitution: transparent, efficient and trustworthy involvement of applicants, third parties and stakeholders
  - Publication of comments on ECHA's web (weekly)
  - *Trialogues* with the applicant to clarify proposals for alternatives

Role of applicant, third parties and stakeholders

Public consultation and Trialogue

BIU published

Submitted comments published weekly

Applicant's response published

Public Consultation on Alternatives

Trialogue with the applicant

Week 8

~ Week 13

12-14 months

Date of receipt

SEAC's and RAC's possible additional questions to applicants and third parties

RAC & SEAC opinions

Trialogue

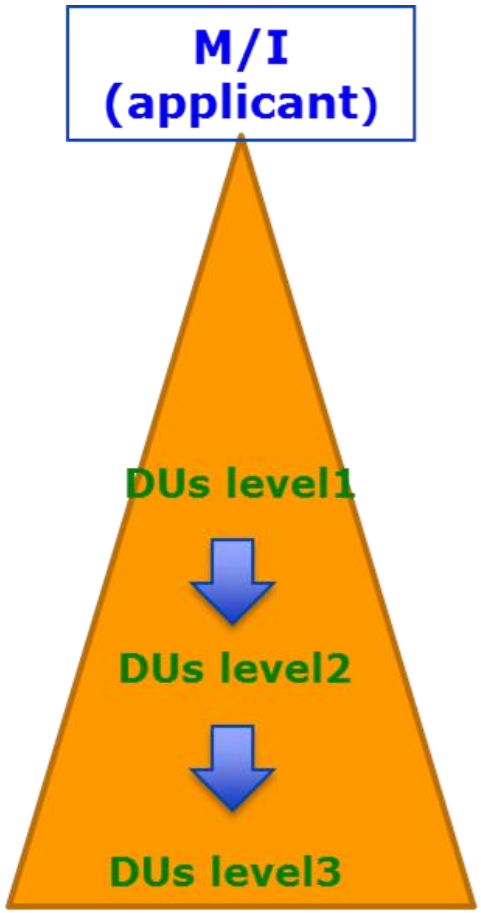
- Opportunity for SEAC and RAC rapporteurs to discuss issues raised by an application
- Open to SEAC and RAC members and observers
- Voluntary
- Held in person or over video or phone
  - Applicant's view
- Will use as input
  - the application
  - comments made during the public consultation
  - questions made by RAC and SEAC and
  - any written responses by the applicant and third parties

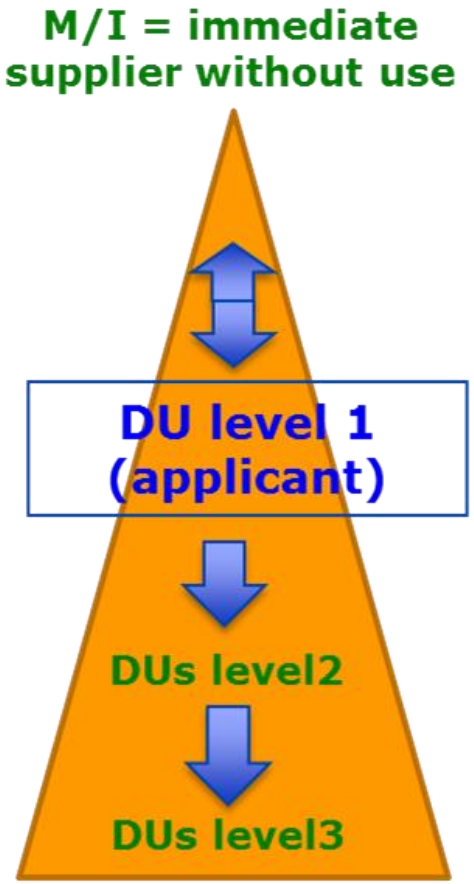
Downstream users will play a key role

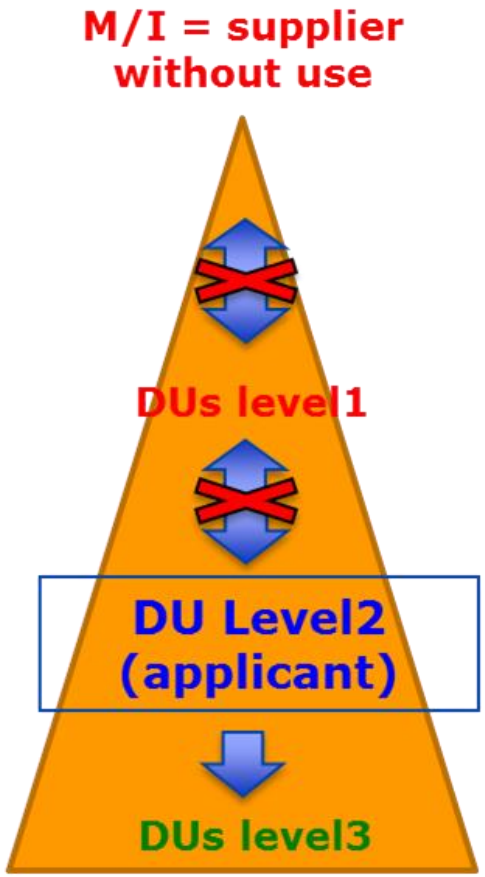
Demand pull: Downstream users are in key role

- Downstream user needs often drive the application
- Downstream user: be sure that your supplier applies
  - otherwise, you will have to apply yourself
- In 2013, ECHA focuses on how downstream users can be better informed
  - Cannot do this alone. Needs help.
- Supply-chain coverage in REACH:
  - Top-down but not bottom-up!

Supply-chain coverage: three examples







Take home

Key messages

- Apply if the use of the substance clearly adds value and the remaining risks are small: one aim of Authorisation is substitution
- The question is *what will happen to my business if the Annex XIV substance can no longer be used in the EU?*
- Authorisation concerns your 'core business': Own it!
  - Think outside your business
- A strong case for authorisation probably means an easier application
  - The more marginal the case becomes, the more resources, time, analysis etc. the application will need
- You may know more than you thought
  - Your challenge is to persuade independent, scientific Committees
  - Understand how the Committees formulate their opinions

Advice

- Start to prepare early
- No need to wait for the latest date!
- Get familiarised with:
  - How RAC and SEAC will evaluate the applications
  - Questions and Answers (currently 54)
  - Guidance Documents (content / procedure)
  - Submission tools and user manuals
  - Formats and templates
- Involve your supply chain (up and down)
- Be «use-oriented»
  - Your definition may differ from how REACH defines the use
- Notify ECHA, and request for a «*pre-submission information session*» (six to seven months before), if needed
- Ask ECHA for technical advice (e.g. through Helpdesk)
  - make suggestions too.

Thank you