SVHC
Authorisation and Restrictions

GPS and REACH Chemicals Legislation
Workshop
11 April 2013
Soporna

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Leo Heezen

Content

- ✓ REACH Title VII and Title VIII
- ✓ SVHC
- ✓ Annex XIV
- ✓ Authorization process
- ✓ Restrictions

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Legal background

- REACH Title VII : Authorisation
  - In principle no placing on the market unless risks of SVHC are properly controlled and these substances are progressively replaced by alternative substances

- REACH Title VIII: Restrictions
  - In Annex XVII specified manufacture, placing on the market and use of specific dangerous substances, preparations and articles is not permitted.

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Principles

Authorisation

- "Banned" unless "authorised"
  - reversal of the burden of the proof
  - Applicant for authorisation

Restrictions

- "Permitted" unless "banned"
  - no reversal of the burden of the proof
  - Member State, ECHA

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Which Substances ?

Authorisation

- Substances of Very High Concern
  - Meeting the criteria of Article 57, identified according to Article 59
  - (Candidate List) and included in the Annex XIV
  - (List of Substances Subject to Authorisation)
  - Article 57 : CMRs 1A & 1B, PBT, vPvB and substances of “equivalent concern”

Restrictions

- Any substance when there is an unacceptable risk which needs to be addressed on a Community-wide basis

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Substances of Very High Concern

Substances with below hazard properties may be identified as SVHC:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances)
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII)
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances

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Substances of Very High Concern

- Member States and ECHA (on request of Commission) can propose SVHC
- This will be followed by a 45 day consultation procedure
- MS and ECHA will respond
- Member State Committee to agree on SVHC
- Publication on Candidate list
- Presently 138 substances on Candidate List (Dec 2012)

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Annex XIV
List of substances subject to Authorisation

- ECHA prioritizes substances from Candidate list for inclusion Annex XIV
  - PBT or vPvB,
  - Wide dispersive use
  - High volume

- ECHA recommends prioritized substances to Commission
  - Sunset date
  - Latest application date
  - Review period certain uses
  - Use exempted from Authorisatiom

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Annex XIV
List of substances subject to Authorisation

- Comments to recommendation in three months after publication
- MSC prepares opinion
- Based on that ECHA prepares recommendation, including exemptions, to European Commission
  - Fourth recommendations published by ECHA (June 2012)
  - In total 53 recommendations
- Commission decides
  - 14 substances now on Authorisation list

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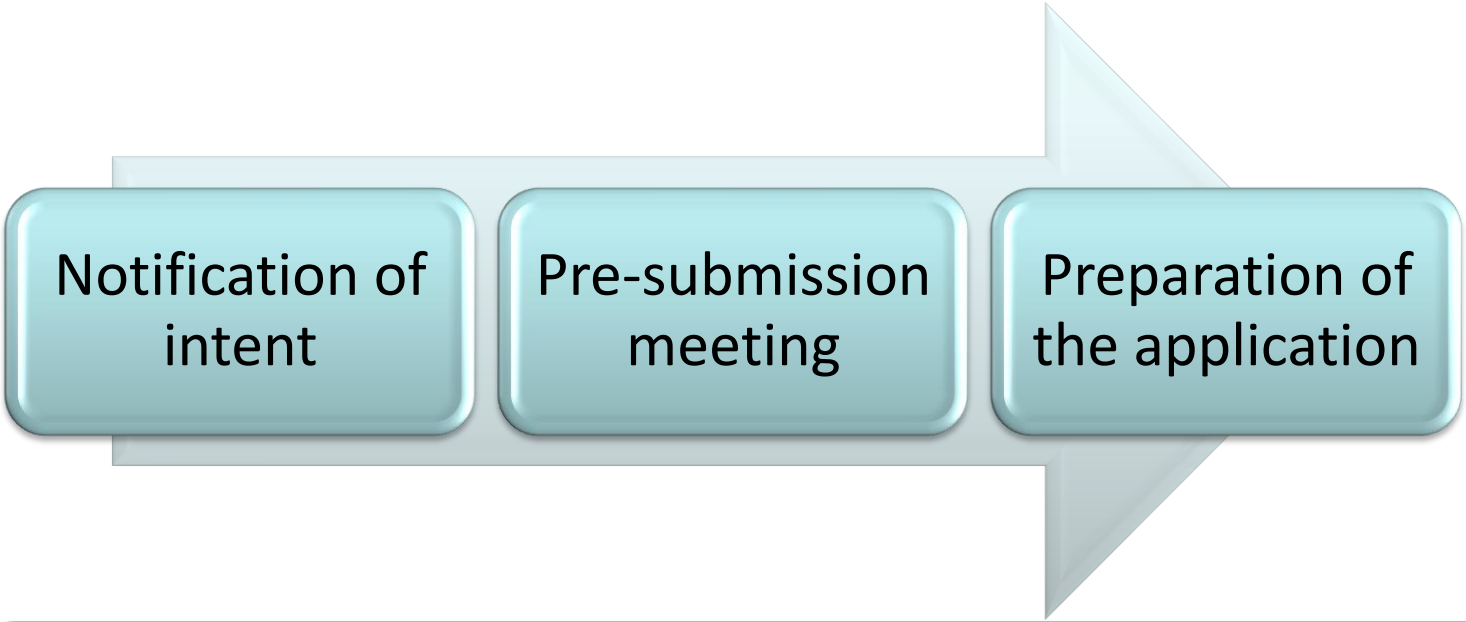
The first industry steps in the process



- Allows a better planning by ECHA
- Indicates for which substances and which uses
- Request for pre-submission meeting to focus on the technical requirements of the dossier, no discussion on the content of the application

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Preparing an application

Who?

- Manufacturer, importer or DU or joint
- Joint application is not a legal obligation!
- Does a DU have sufficient info to apply individually?
- Differring agenda's depending on position in the supply chain

For What?

- One or more uses, one or more legal entities, one or more substances if fulfilling definition of a group (annex XI, sect 1.5)
- Exchange of CBI, potential competition law, legal advice required!
- How to share costs of preparing the application?
- Role for existing consortium/SIEF?

Costs?

- Fee integral part of the application, calculated by use(s), by substances, by size of company
- Joint invoice: how to distribute costs? Advanced payment by one company unlikely?!
- http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_fees_en.asp

Elements of an application

- Main elements – Art 62 of REACH
  - Substance identity
  - Applicants
  - Uses applied for
  - CSR (if not submitted as part of registration)
  - Analysis of Alternatives
  - Substitution Plan (if suitable alternatives available)
  - Additionally (application may include)
    - Socio-economic analysis
    - Justification for not considering certain risks to human health and the environment
  - Fee is part of the application!

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Content : some reflections

USE	CSR/ES	AoA	SP	SEA
• Use descriptor system as a basis • More case specific details may be required • Contact DU?	• CSR of registration dossier • For DU potential issues to get access • Letter of Access may be required?	• Risks, technical and economical feasibility to be considered • CBI & Comp law • What if only little information on (eco)toxicity of alternatives? • Contact DU?	• Ultimate goal is substitution • Realistic timing! • Key to determine time of validity of authorisation • Contact DU?	• Mandatory only for SE route but sometimes advisable for other routes as well • Little expertise available • Resources potential issue!

High level of detail required! Start preparing early!
Highly regulated sectors : substitution is a long process

Possible application packages

Adequate control & No suitable alternative	Adequate control & Suitable alternative	Socio-ec benefits > risks (No adequate control & No suitable alternative)
Threshold substances	Threshold substances	Threshold & Non-threshold substances
CSR Analysis of Alternatives SEA Substance & Applicant info	CSR Analysis of Alternatives Substitution Plan SEA Substance & Applicant info	CSR Analysis of Alternatives SEA Substance & Applicant info

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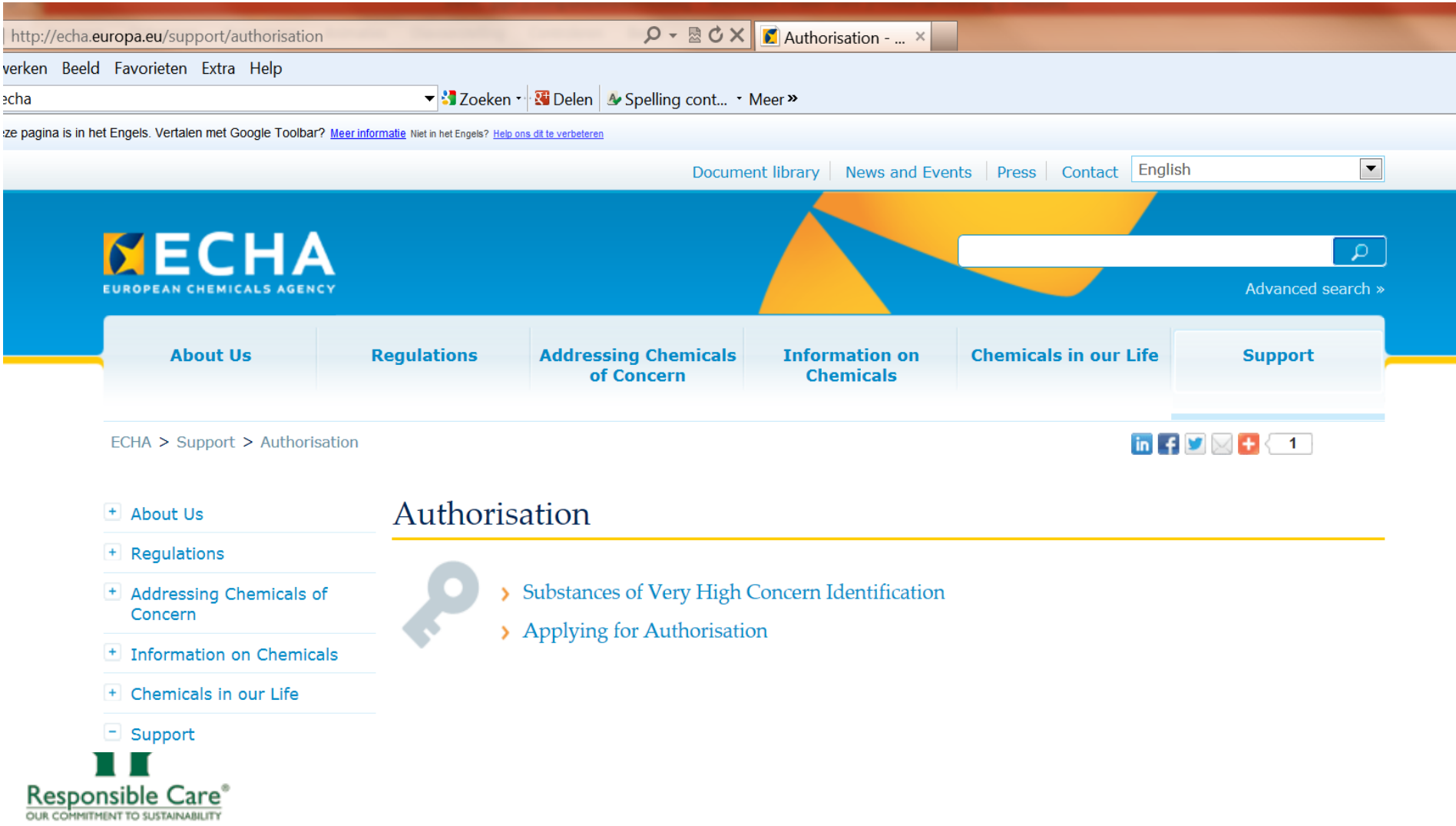
Resources ECHA website



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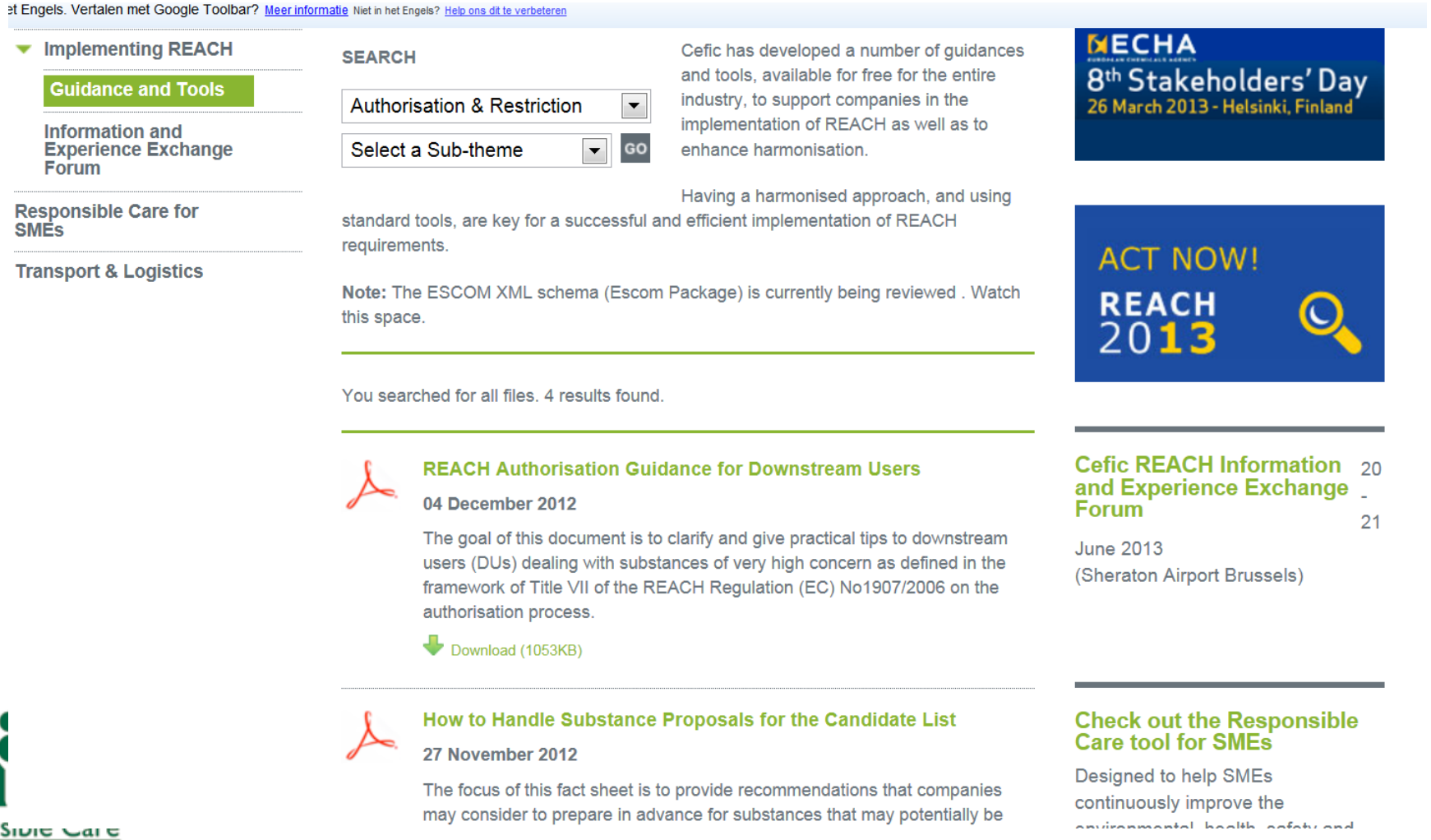
Resources: CEFIC website

http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/



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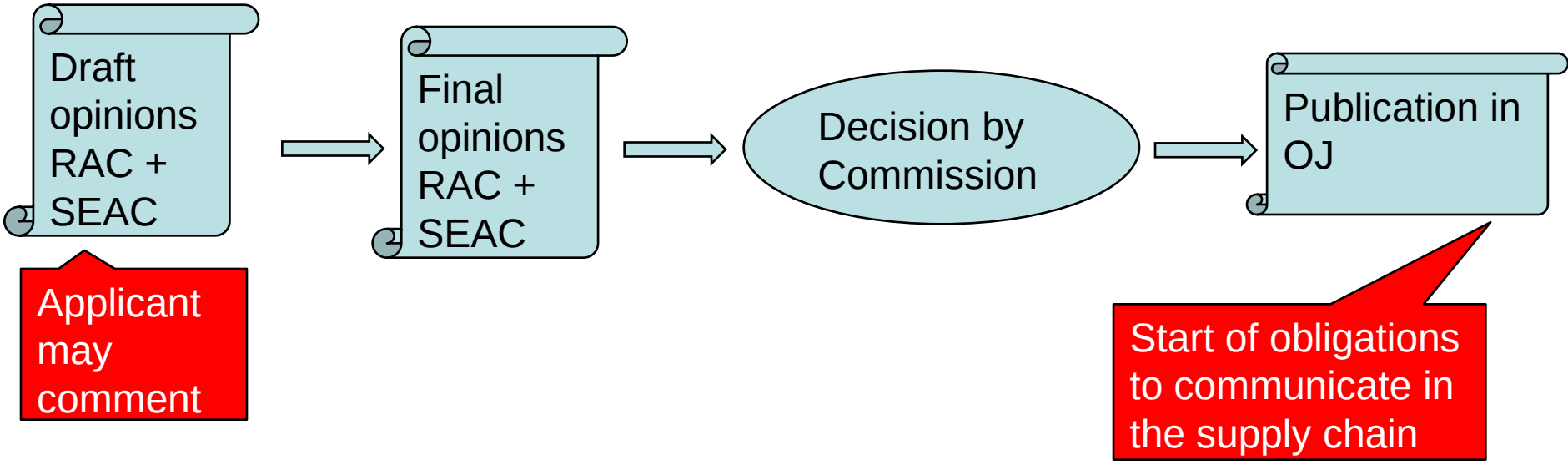
After submission



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Authorization: consider that...

- It is a lengthy, costly and labour intensive process with a large degree of uncertainty
- Alternatives available for all applications?
- Can you (and your customers) switch before the application date? (concerted action → need to consider competition law issues)
- If not, do you want to continue this business in Europe? Cost vs benefit?
- Communicate with your customers / suppliers
- 'Living process': authorisation granted for a limited time → re-submission

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Conclusions

- Applying for authorisation is new to everyone
- Data sharing not a legal obligation
- Large risk of infringement of anti-trust law
- High level of detail required in the application dossier
- Early start recommended!
- Make use of opportunities to communicate with ECHA

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Restrictions

- Safety net in REACH, manage risks not sufficiently addressed by other processes
- All uses of a restricted substance not specifically restricted under Annex XVII are allowed under REACH (except if also listed on Annex XIV or subject to other legislation) within the limits of the Exposure Scenarios of manufacturers'/importers' registration.
- Decision for the restriction based on the two following cumulative elements:
- a) an unacceptable risk to human health or environment, and
- b) the risk needs to be addressed at a community wide basis level.
- List of all restricted substances (specifying restricted uses) in Annex XVII of REACH

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Restrictions

- Not a new concept!
  - » Existing restrictions in the Marketing and Use Directive (76/769/EEC) carried over to REACH.
    - Directive 76/769/EEC was repealed on 1 June 2009.
  - » Pay attention to Article 67(3) referring to more severe national restrictions, to be maintained until 1 June 2013, provided they have been notified.
- Broad scope:
  - » Any substance on its own, in a preparation or in an article may be subject, where justified, to restrictions.
  - » Can apply to manufacturing, placing on the market (including importing) and/or all uses or to specific uses.
  - » No tonnage threshold for a substance subject to restriction provisions.

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Restrictions

Exemptions:

- in scientific research and development,
- for on-site isolated and non-isolated intermediates,
- in PPORD, if this as well as the exempted quantities are specified in the Annex XVII,
- for the use of substances in cosmetic products, with regard to risks to human health within the scope of the Cosmetics Directive

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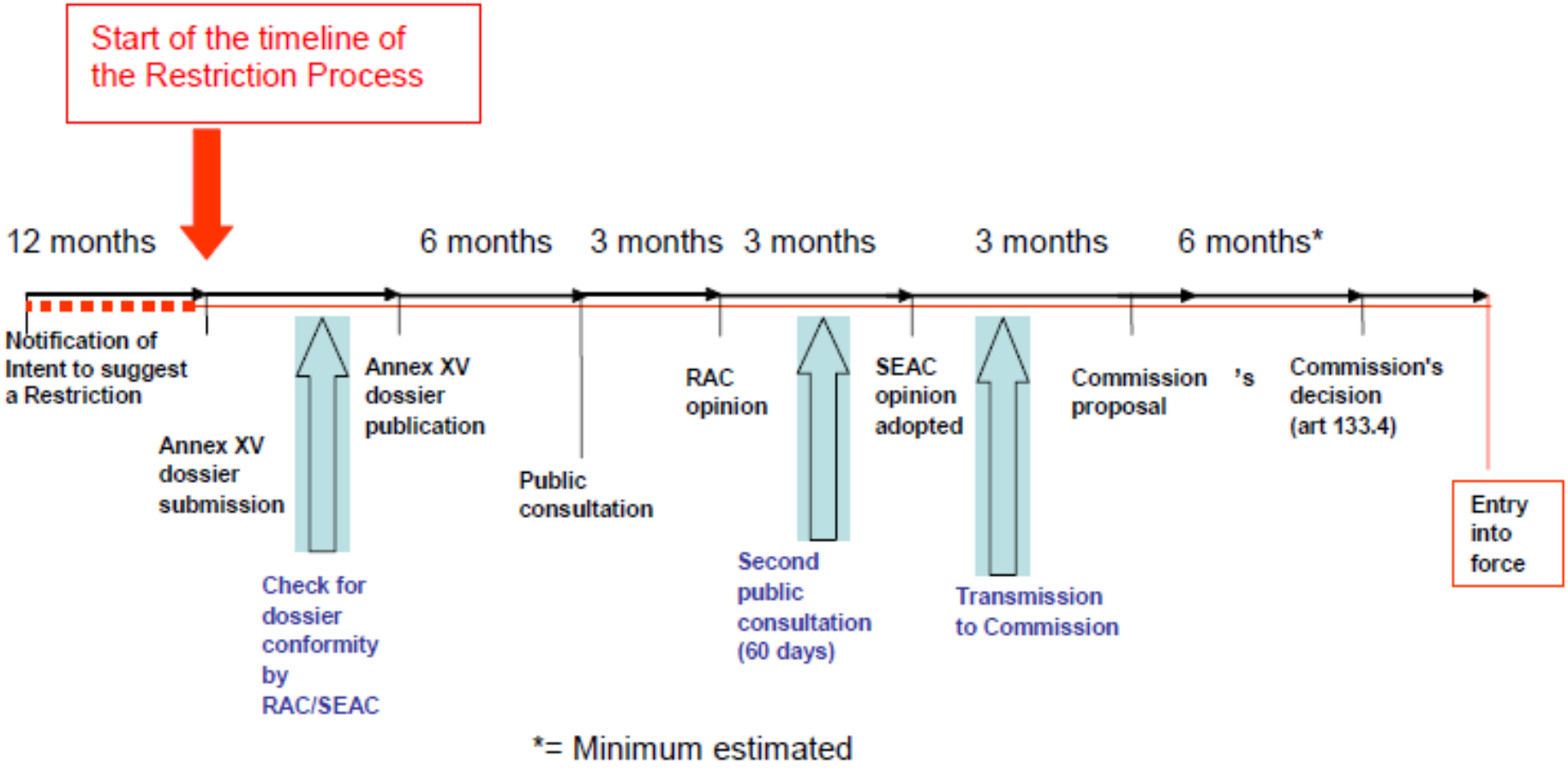
Restrictions- process and timeline



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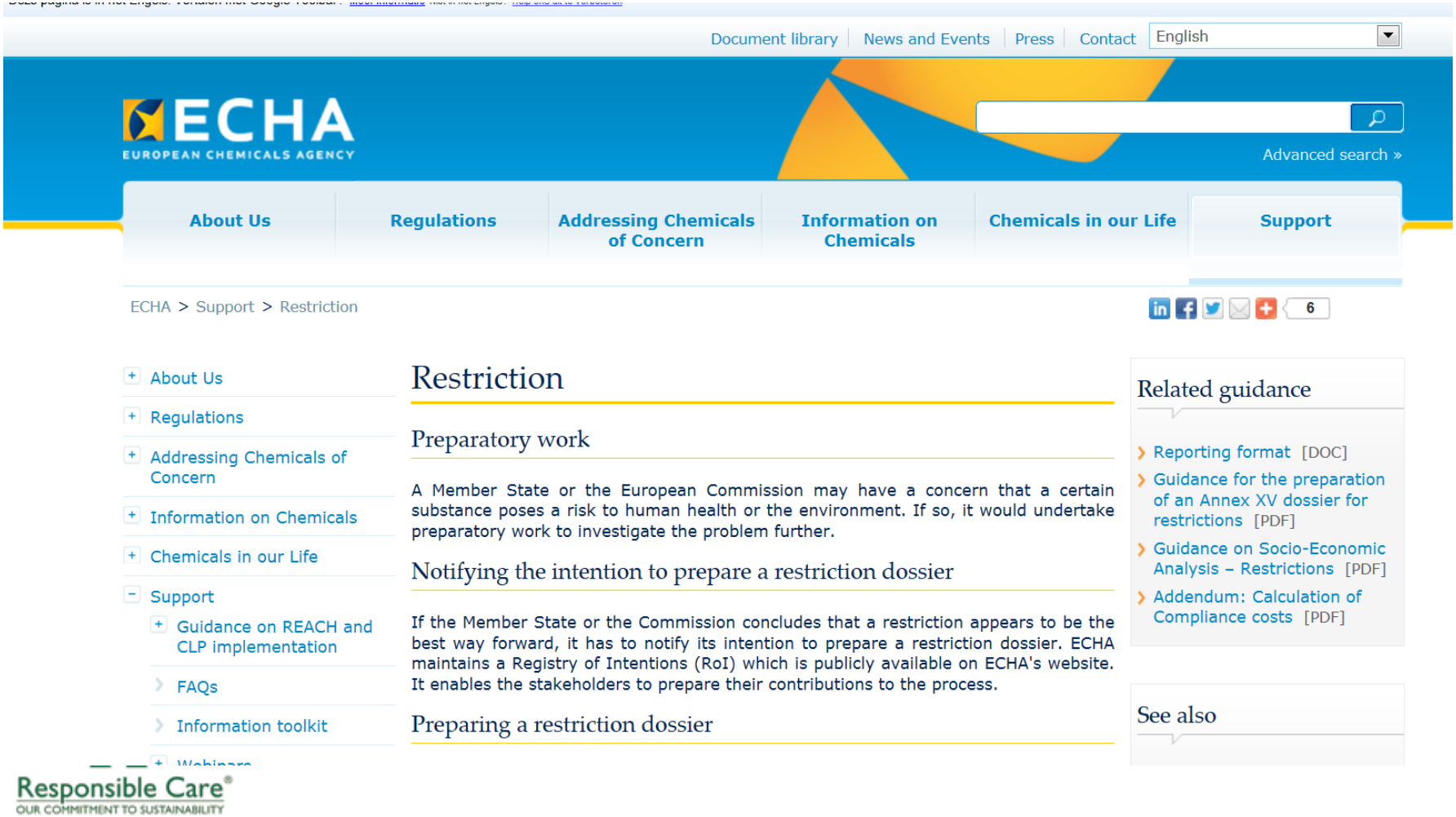
Restrictions- stay up-to-date!

http://echa.europa.eu/web/guest/support/restriction



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Thank You!

Leo Heezen

(reachheezen@caiway.net)

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