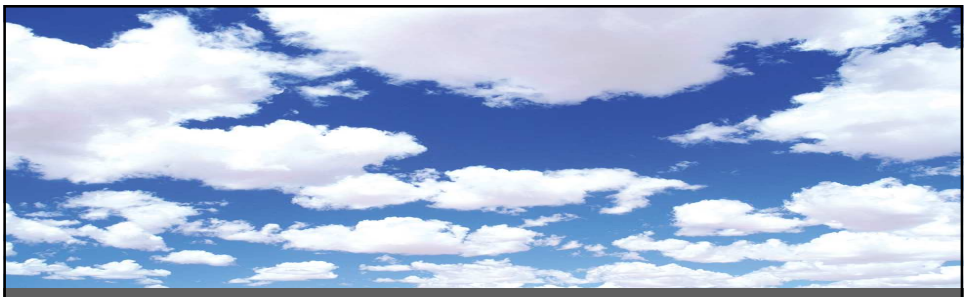


REACH – Pre-Registration - Registration and Authorization

Lena Perenius – Director REACH/Chemicals Policy

cefic

Content

- Pre-registration
- Registration
- Authorisation

Why, What, How, Who

New concepts in REACH

- **Shift of responsibility from Authorities to Industry**
- **Animal welfare considerations strengthened**

Content

- **Pre-registration**
- Registration
- Authorisation

Why, What, How, Who

Pre-registration

➢ **Why ?**

- **To facilitate data sharing and avoid unnecessary animal testing**
- **To benefit from phase-in status (e.g. transitional period for registration)**

Pre-registration

➢ **What ?**

- **Name and address of the potential registrant (or third party)**
- **Substance name & EINECs and CAS n°(if available)**
- **Substance name (as previously) of substances intended for either (Q)SARs or read-across purposes**
- **Envisaged deadline for the registration**
- **Tonnage band**

➢ **When ?**

- **Pre-registration phase: between 1 June – 1 December 2008**

Pre-registration

Pre-registration of phase-in substances ⇨ database

Agency publishes the list of substances on 1 January 2009

- Names of the substances
- EINECS or CAS N°s or other identity code
- First envisaged registration deadline

A DU using a substance not appearing on the list may notify the Agency of his interest in the substance and give the details of his current supplier. The Agency shall publish on its website the name of the substance and on request provide contact details of the downstream user to a potential registrant.

Content

- Pre-registration
- **Registration**
- Authorisation

Why, What, How, Who

Data sharing for Registration

Substance Info Exchange Forum (SIEF)

- Aim
- Potential registrants :
  - Exchange information to minimise duplication of tests and to agree on classification and labelling for the same substance
  - SIEF participants provide others with existing studies, react to requests by others, identify needs for further studies and arrange to carry them out.
- M/I of substances < 1 t/yr, DU and 3rd parties may submit information to the Agency to take part in the SIEF

SIEF

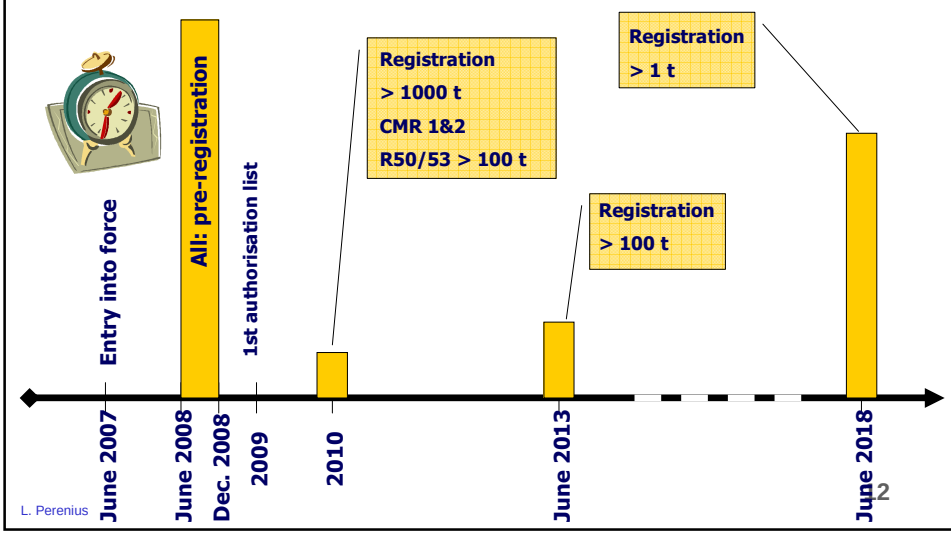
- Sharing of tests involving vertebrate animals mandatory
  - If participant refuses to share => stop proceeding registration and sanctions
  - rest of SIEF proceeds without fulfilling this requirement
- Study available: participants agree on sharing cost, otherwise equal share.
- Study not available: participants agree who performs it, otherwise Agency appoints the one.
- Sharing of tests involving non vertebrate animals and phys-chem data obligatory at request of another potential registrant.
  - If participant refuses to share => sanction
  - rest of SIEF proceeds as if no relevant study was available in the SIEF

Registration

➢Why ?

•To document/make available the Chemical Safety Assessment (CSA) and recommend risk management

When do I have to register



Obligation to register

Manufacturer
Importer
EU Representative of non-EU manufacturer

more than 1 t/yr

Exemptions for

Substances to the extent they are used for a specific use covered by other legislation (art. 2)

Polymers

PPORD (time limited)

Re-importation

Registered substances being recovered in the Community

Well known substance (Annex IVI)

Inappropriate (Annex V)

COM reviews Annex IV and V within one year after entry into force

General : Full Dossier	Special : Reduced Dossier	Deemed to be Registered
Substances on its own or in preparation	Isolated intermediates	Notified substances (67/548/EEC)
Monomers, even if intermediates	on-site (under strictly controlled conditions)	Substances in plant protection and biocidal products (art. 15)
Substances in articles (conditions apply)	transported (confirmation from user that use takes place under strictly controlled conditions)	

Which information?

Tonnage band	*1-10*	*10-100*	*100-1,000*	*> 1,000*
TECHNICAL DOSSIER Data – Annex	✓ VII	✓ VII & VIII	✓ VII -IX	✓ VII-X
CSR	No	✓	✓	✓

Registration Information Requirements 1-10 t

- TECHNICAL DOSSIER

Phase-in substances: ⇨ prioritisation according to Annex III

- If prioritised: Annex VII
- If not: Only information on phys-chem properties

Non phase-in substances: Annex VII

Registration Information Requirements

Prioritisation criteria according to Annex III

- The substance is likely to be CMR category 1 or 2 or PBT or vPvB (according to criteria in Annex XII) on basis of QSAR or other evidence,
  or
- The substance has dispersive or diffuse use(s), particularly in consumer preparations or consumer articles
  and
- The substance is likely to be hazardous (under Directive 67/548/EEC) on basis of QSAR or other evidence.

Registration Information Requirements

- TECHNICAL DOSSIER
- Common information for all registrations
  - Identity of manufacturer or importer, identity of substance
  - Information about manufacturing process and produced quantity incl. all identified use(s)
  - Classification and labelling
  - Guidance on safe use (storage, disposal, first aid measures)
  - All relevant and available test data (incl. a literature search)
  - Indication as to which information has been reviewed by an independent assessor
  - Request for confidentiality in accordance to art. 118 (2)
- Information depending on the tonnage
  - Annexes VII to X
  - Testing proposal

Registration Information Requirements

Technical Annexes

Annex VII

- Physicochemical properties
- Basic human health data
- Short term aquatic toxicity

Annex VIII

- Human health data (including *in vivo*)
- Ecotoxicological data

Annex IX and Annex X

- Long term, repeat dose, chronic, fate etc

Annex XI

- Adaptations of the testing regimes (exposure waiving, read-across, QSARs,)

Registration Information Requirements

What is the Chemical Safety Assessment/Report?

Only obligatory for substances > 10 t/y

Shall consider all stages of the life-cycle of a substance as defined by the identified uses and will contain the following information:

1. Human health hazard assessment
2. Human health hazard assessment of physico-chemical properties
3. Environmental hazard assessment
4. PBT and vPvB assessment

- - - - if dangerous or a PBT or vPvB - - - -

5. Exposure assessment
6. Risk characterization

CSR rules defined in Annex I

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Regulatory Framework
Joint submission of data between multiple registrants

SEPARATELY	CHOICE	JOINT
Identification of manufacturer or importer Identification of substance Information on manufacture and use For substances 1 to 10 t, exposure information (section 6 of Annex IV) Indication about review by an assessor	Guidance on safe use (section 5 of Annex IV) Chemical Safety Report Indication about review by an assessor	Classification and labelling Study summaries and robust study summaries of information derived from application of Annexes VII to XI Proposals for testing where listed in Annexes IX and X Indications about review by an assessor

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Opt-out possibilities from joint submission

M/I can opt-out the joint submission of data if:

- A joint submission would be disproportionately costly, or
- A joint submission would lead to disclosure of commercially sensitive information, or
- Disagreement with the lead registrant on the selection of this information.

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Content

- Pre-registration
- Registration
- **Authorisation**

Why, What, How, Who

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Authorisation

- **Why ?**

- **Aim:**

  To ensure that risks from substances of very high concern are adequately controlled and that they are progressively teplaced if technically and economically and economically feasible

The Scope of authorisation

- Authorisation applies to each manufacturer/ importer or downstream user who markets or uses himself a substance (as such, in preparations, or articles) listed in Annex XIV
- No volume threshold
- A series of exemptions for some regulated products (e.g. Food-contact materials and cosmetics are exempted from the human health assessment part of the process)

Authorisation: targeted substances

- Carcinogenic cat. 1&2
- Mutagenic cat. 1&2
- Reprotoxic cat. 1&2

CMRs 1&2

- Persistant and Bioacumulative and Toxic – PBTs (Annex XIII Criteria).
- very Persistant and very Bioacumulative – vPvBs (Annex XIII Criteria)
- identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case-by-case basis, such as endocrine disrupters or other PBTs/vPvBs

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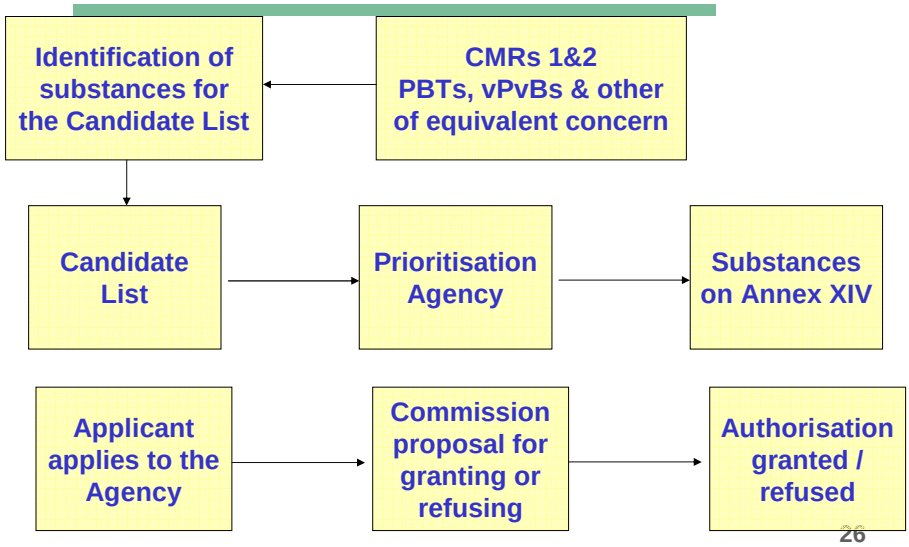
The Authorisation process – general overview



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What do I have to do to apply for an authorisation?

- Application to the Agency to include:
  a) the identity of the substance(s) and name/contact of the M/I
  b) for which use(s) authorisation is sought
  c) CSR, unless already submitted as part of the registration;
  d) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, and including information about any relevant research and development activities by the applicant, if appropriate;
  e) where the analysis referred to in paragraph (d) shows that suitable alternatives are available, a substitution plan including a timetable for proposed actions by the applicant
- Agency Committees opinions, open for comments by third parties

Commission decision on the Authorisation (Comitology)

What is “suitable alternative”?

Besides other relevant aspects, the following:

(a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;

(b) technical and economic feasibility of alternatives for the applicant.

In which cases I will get an authorisation and for how long?

- Granting of authorisation
  - if the risks are adequately controlled except for:
    - PBTs & vPvBs according to Annex XIII
    - Substances of equivalent concern having PBTs & vPvBs properties
    - Other substances for which it is not possible to determine a threshold (Annex I, section 6.4),
  - if the socio-economic benefits outweigh the risk and if there are no suitable alternative substances or technologies.
- Duration: time limited review on a case by case basis based on all relevant information including the following elements:
    - The risk posed by the substance including RRM and SE benefits
    - Analysis of alternatives or substitution plan submitted

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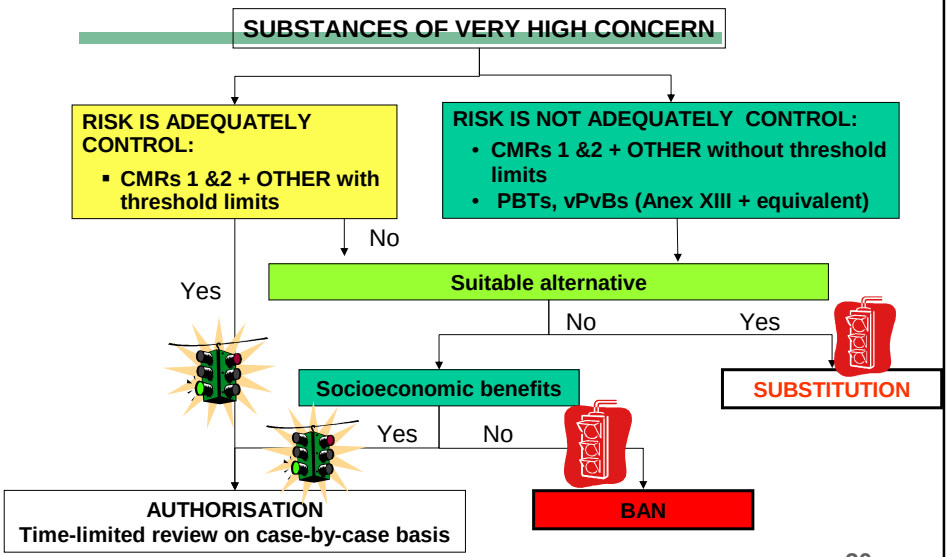
In which cases I will get an authorisation?



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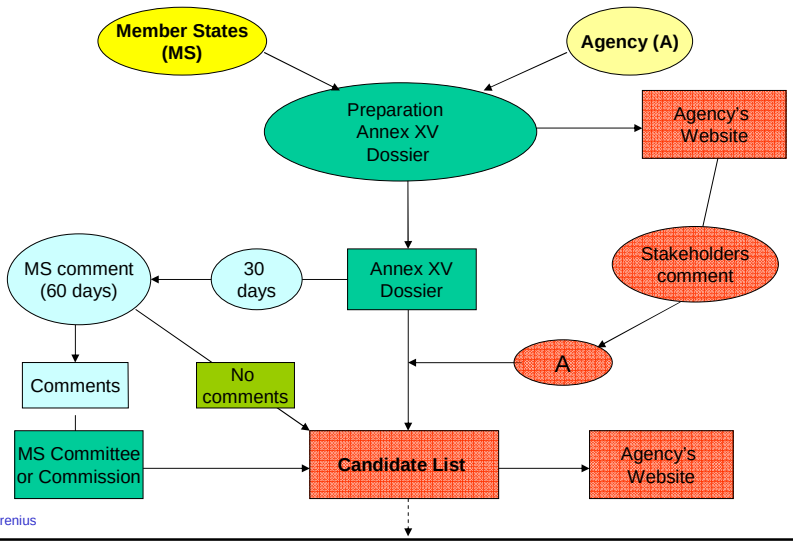
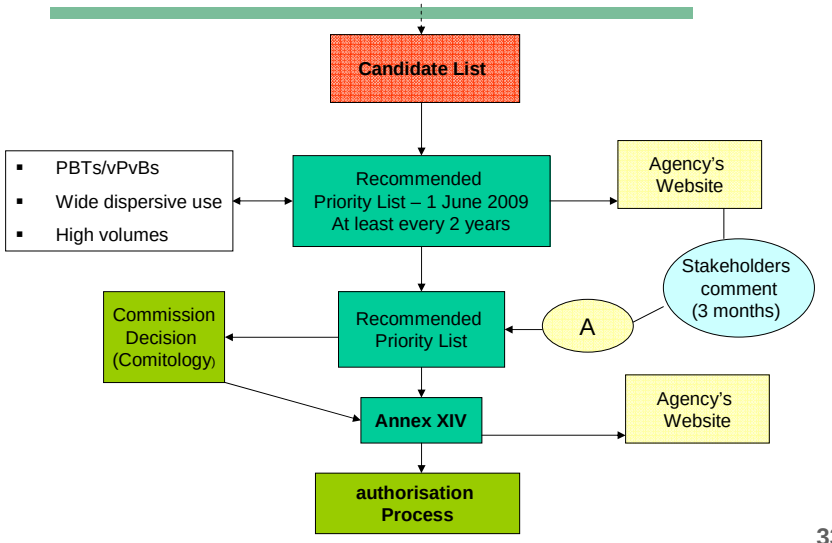
Back-up

Authorisation process - Identification of SVHC



Authorisation process - Prioritisation of SVHC



List of Acronyms

CAS#	Chemical Abstracts Service number
CMR	Carcinogen, Mutagen, or Reproductive Toxicant
DU	Downstream User
EINECS	European Inventory of Existing Commercial Substances
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
PBT	Persistent, Bioaccumulative and Toxic substance
PPORD	Product and Process Orientated Research and Development
(Q)SAR	Qualitative Structure Activity Relationship
SIEF	Substance Information Exchange Forum
vPvB	Very Persistent and very Bioaccumulative