Authorisation and Annex XIV

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Authorisation and Annex XIV of REACH - Overview

Authorisation:

- **Why?** History and aim of authorisation
- **What?** Authorisation requirement & scope
- **How?** Routes to authorisation

Annex XIV to REACH Regulation:

- Annex XIV: Regulation (EU) No 143/2011
- Next steps

Some conclusions

Authorisation: Why?

- **Substances of Very High Concern (SVHCs):**
  - **CMRs cat. 1A or 1B**: very serious effects on human health, cannot be normally reversed
  - **PBTs, vPvBs**: accumulate in living organisms, accumulation cannot be reversed
  - Other **substances of equivalent concern**

  → their effects have to be prevented rather than remedied
- Authorisation ensures that **risks** related to the use of an SVHCs are **adequately controlled** or **outweighed by socio-economic benefits**
- **Burden of proof** is on the **applicant**

Authorisation: Why?

Aim of authorisation (Art. 55 REACH):

- 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**

Authorisation: What?

Authorisation requirement:

Substances subject to authorisation **may not be placed on the market for a use or be used unless the use has been authorised**

- Authorisation is always related to a **use**
- **All uses** are covered unless
  - excluded from the scope
  - exemption is foreseen in Annex XIV
- Authorisation is linked to the **applicant**
- **Imported articles** are not subject to authorisation
- No **volume** threshold
- **Time dimension**: transitional periods (latest application date and sunset date), review period (general / specific)

Authorisation: What?

Excluded uses:

- Intermediates
- Medicinal products
- Food and feedingstuffs
- Scientific R&D
- Plant protection products and biocidal products
- Motor fuels and fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems
- Only with regard to hazards to human health:
  - cosmetic products
  - food contact materials
  - medical devices
- In mixtures when presence below certain %

Authorisation: How?

Two “routes” to authorisation:

- **“Adequate control”**:
  if the risks are **adequately controlled** as documented in CSR
  - NOTE: does not apply to PBTs, vPvBs and to other substances for which it is not possible to determine a threshold
- **“Socio-economic”**:
  if the **socio-economic benefits outweigh the risk and**
  there are **no suitable alternative substances or technologies**

Authorisation: How?

Applying for authorisation:

- By **M, I and/or DU (by 1 or more persons)**
  - DU may use substance in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use
- For **1 or more uses**
- For **1 or several substances** that belong to the same group
- **Content**:
  - CSR (unless already submitted)
  - Analysis of alternatives
  - Socio-economic analysis (de facto required in applications under socio-economic route)
  - Substitution plan (if suitable alternatives available; not for socio-economic route)
  - Justification for not considering risk (optional)
- Must be submitted to ECHA. Commission takes the final decision.

Authorisation: How?

Commission decision granting an authorisation:

- Authorisation holder(s)
- Identity of substance(s)
- Use(s) for which authorisation is granted
- Any conditions under which authorisation is granted
- Time-limited review period
- Any monitoring arrangement

Authorisation: How?

Review:

- **Review report**:
  - must be submitted at least 18 months before expiry of review period
  - must include updates of: analysis of alternatives
    if suitable alternatives:
    → substitution plan
    CSR
    socio-economic analysis
- **Authorisation may be reviewed at any time** if:
  - changes in risks to human health or environment, or in socio-economic impact, or
  - new information on possible substitutes
- **Outcome**:
  extension / amendment / withdrawal of authorisation

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Commission Regulation (EU) No 143/2011:

Substance	Intrinsic property (ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
		Latest application date	Sunset date		
5-tert-butyl-2,4,6-trinitro-m-xylene **(Musk xylene)**	vPvB	21 February 2013	21 August 2014	-	-
4,4'-Diaminodiphenylmethane **(MDA)**	Carcinogenic (category 1B)	21 February 2013	21 August 2014	-	-
Hexabromocyclododecane (**HBCDD**)	PBT	21 February 2014	21 August 2015	-	-
Bis(2-ethylhexyl) phthalate (**DEHP**)	Toxic for reproduction (category 1B)	21 August 2013	21 February 2015	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	
Benzyl butyl phthalate (**BBP**)	Toxic for reproduction (category 1B)	21 August 2013	21 February 2015	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	
Dibutyl phthalate (**DBP**)	Toxic for reproduction (category 1B)	21 August 2013	21 February 2015	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	

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Next steps:

- Annual updates of Annex XIV (following ECHA recommendations)
- Next update:

  ECHA recommendation of 17/12/2010:

  - proposes inclusion of 8 additional substances (diisobutyl phthalate, diarsenic trioxide, diarsenic pentaoxide, lead chromate, lead sulfochromate yellow, lead chromate molybdate sulfate red, tris (2-chloroethyl) phosphate, 2,4 – dinitrotoluene)
  - proposed transitional arrangements:
    18-24 months (latest application date),
    LAD + 18 months (sunset date)
  - no exemptions are recommended

Some conclusions

- The aim of authorisation, whatever the route, is to **progressively replace SVHCs:**

  

  It is important that the application provides sufficient evidence on:
  - availability and suitability of alternatives
  - activities aiming at developing / switching to suitable alternatives
- Authorisation under **socio-economic route** will de facto require a sound socio-economic analysis showing that **socio-economic benefits > risks to hh/env**
- Authorisation is a new process for all players (potential applicants, stakeholders, ECHA and Commission): communication is crucial