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helpdesk REACH
Un service du Centre de Ressources des Technologies pour l'Environnement
En partenariat avec le Ministère du Développement durable et des Infrastructures, le Ministère de l'Economie et du Commerce extérieur et le CRP Henri Tudor

Authorisation Procedure: Basics and Current Status

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Séance d'information: REACH - Quelles sont vos obligations actuelles et futures ?
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Content

1. Introduction
2. Candidate list
3. Annex XIV (Authorization obligations)
4. Authorization application
5. Outlook

1. **Introduction**
2. Candidate list
3. Annex XIV (Authorization obligations)
4. Authorization application
5. Outlook

Authorization – Aim and Exemptions

Aims (Art. 55):

- Risks from substances of very high concern to be properly controlled
- Progressively replaced by suitable alternative substances or technologies where these are economically and technically viable

Exempted (Art. 56):

- Scientific research and development
- Product and process orientated research and development (optional)
- Uses in plant protection products or biocidal products
- Use as motor fuels or fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems
- Under certain conditions: uses in cosmetics and food contact material; in preparation when the content of the substance is small
- General exemptions from REACH (Art. 2)
- But: No tonnage threshold!

Authorization – Procedures

Step 1: Identification of substances of very high concern (SVHC)

Main actors: ECHA and Member States
Result: Candidate list

Step 2: Inclusion of SVHC in Annex XIV

Main actors: ECHA and Member States
Result: Authorization obligation for substances

Step 3: Authorization of uses (for Annex XIV substances)

Main actors: Applicant (manufacturer, importer, downstream user), ECHA and MS
Result: Authorized use

1. Introduction
2. **Candidate list**
3. Annex XIV (Authorization obligations)
4. Authorization application
5. Outlook

Candidate List – Criteria

Criteria for Substances of very high concern - SVHC (Art. 57):

- Classified as carcinogenic, mutagenic or toxic for reproduction (CMR; Cat. 1 or 2)
- PBT (persistent, bio-accumulative and toxic)
- vPvB (very persistent and very bio-accumulative)
- Equivalent level of concern (e.g. endocrine disrupters)

Candidate List – Identification

Identification of substances of very high concern:

1. Dossier prepared by ECHA or a Member State (MS) competent authority
2. Public consultation on dossier and commenting by MS
3. Decision by ECHA's Member States Committee (if comments were received)
4. Identification as substance of very high concern ("substances extrêmement préoccupantes", "besonders besorgniserregender Stoff")

➡ **Inclusion of substance in candidate list (for Annex XIV)**

Candidate List – Consequences

Legal obligations for companies:

- Substances: Supplier to provide Safety Data Sheet
- Preparations not classified as dangerous: Supplier to provide Safety Data Sheet on request, if the preparations contain at least one SVHC (>0.1% (w/w) for non gaseous preparations or >0.2% by volume for gaseous prep.)
- Articles containing >0.1% of an SVHC:
  - Supplier to provide sufficient information for safe use to customers and, on request, to consumers
  - from 2011: Notification to ECHA by producer/importer (under certain conditions)

Non-legal consequences:

- Raised awareness of critical properties of the substance

Candidate List – Current List

Added 2008	Added 2009
Triethyl arsenate	Acrylamide
4,4'- Diaminodiphenylmethane (MDA)	tris(2-chloroethyl)phosphate
Dibutyl phthalate (DBP)	2,4-Dinitrotoluene
Bis (2-ethylhexyl)phthalate (DEHP)	Diisobutyl phthalate (DIP)
Benzyl butyl phthalate (BBP)	Lead chromate
Lead hydrogen arsenate	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)
Cobalt dichloride	Lead sulfochromate yellow (C.I. Pigment Yellow 34)
Diarsenic pentaoxide	Zirconia Aluminosilicate, Refractory Ceramic Fibres
Diarsenic trioxide	Aluminosilicate, Refractory Ceramic Fibres
Sodium dichromate	Pitch, coal tar, high temp.
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	Anthracene oil
Hexabromocyclododecane (HBCDD)	Further four anthracene oil substances
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	
Bis(tributyltin)oxide (TBTO)	
Anthracene	

Candidate List – Current List

Categories of main uses:

- Flame retardants, e.g. short chained chlorinated paraffins (SCCPs) and hexabromocyclododecane (HBCDD)
- Plasticisers, e.g. the four phthalates
- Intermediates, e.g. 2,4-dinitrotoluene, acrylamide and anthracene oils
- Pigments, e.g. lead sulfochromate yellow

Properties leading to identification as SVHC:

- 19 x CMR (carcinogenic, mutagenic or repro-toxic)
- 10 x vPvB (very persistent ad very bio-accumulative) and/or PBTs (persistent, bio-accumulative and toxic)
- 1 x CMR and vPvB/PBT

1. Introduction
2. Candidate list
3. **Annex XIV (Authorization obligations)**
4. Authorization application
5. Outlook

Annex XIV – Procedures and Criteria

“Priority shall normally be given to substances with”:

- ↗ PBT or vPvB properties
- ↗ wide dispersive use
- ↗ high volumes

Inclusion of SVHC into Annex XIV (= list of substances subject to authorization):

1. Draft recommendation by ECHA (= selection of substances from the candidate list)
2. Public consultation
3. Opinion of the Member States Committee (non-binding)
4. Final recommendation by ECHA to Commission
5. Inclusion of substances in Annex XIV via comitology

Annex XIV – Consequences

Annex XIV entry for a substance specifies:

- Uses exempted from authorization obligation, e.g. for product and process orientated R&D
- Sunset date by when a substance can no more be used without authorization (ca. 3.5 to 4 years after inclusion)
- Latest application date (min. 1.5 y before sunset date)
- Possible route of authorization

Legal obligations:

- Manufacturer/importer/downstream user: Authorization needed for every use (that they want to continue)
- Once a use is authorized:
  - Inclusion of authorization number on the label of the substance and preparations including the substance (Art. 65)
  - Downstream users using the substance notify ECHA (Art. 66)

Annex XIV – Current Status

↗ First recommendation by ECHA: 1 June 2009

Substance	Main use	Property
Musk xylene	Fragrance enhancer in detergents, fabric softeners and conditioners	vPvB
4,4`-Diaminodiphenyl-methane (MDA)	Hardener, e.g. in epoxy resins and adhesive	carcinogenic
Hexabromocyclododecane (HBCDD)	Flame retardant, e.g. in polystyrene (used for insolation)	PBT
Bis(2-ethylhexyl)phthalate (DEHP)	Plasticizers used in a wide range of PVC and other polymers applications	Toxic for reproduction
Benzylbutylphthalate (BBP)		
Dibutylphthalate (DBP)		
Short chained chlorinated paraffins (SCCPs)	Flame retardant/plasticizer in rubber, sealants, paints or textile coating	PBT and vPvB

↗ Commission decision via comitology expected 1st half 2010

1. Introduction
2. Candidate list
3. Annex XIV (Authorization obligations)
4. **Authorization application**
5. Outlook

Authorization Application

- **Who applies for an authorization to ECHA?**
  - Manufacturer / importer
  - Downstream user
- **Application for authorization – content:**
  - Identity of the substances
  - Identity of the applicant
  - Uses for which authorization is sought
  - Chemical safety report (if not already submitted with a registration dossier) assessing the risk for human health and the environment
  - Analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, including possible R&D activities
  - Substitution plan, if suitable alternatives are available
  - Socio-economic analysis (optional)

Authorization – Route of Authorization

- **Adequate control route:**
  - CMR substances for which it is possible to determine a threshold
  - Chemical safety report has to show that the risk from the substance is properly controlled
  - Only ECHA's Risk Assessment Committee is involved

- **Socio-economic route**
  - PBTand vPvB substances; CMR substances for which it is not possible to determine a threshold (= exposure level smaller than appropriate DNEL* or PNEC**)
  - The socio-economic analysis has to show:
    - Socio-economic benefits outweigh the risk to human health or the environment, and
    - No suitable alternative substances or technologies available
  - Involvement of the Committee for Risk Assessment and the Committee for Socio-economic Analysis

* Derived No Effect Level ** Predicted No Effect Concentration

Authorization – Authorization Decision

Granting of authorizations:

1. Application by the manufacturer, importer or downstream user to ECHA
2. Public consultation on alternative substances or technologies
3. Conformity check by and opinion of ECHA's Risk Assessment Committee and (if socio-economic analysis included) ECHA's Committee for Socio-economic Analysis
4. Decision by the Commission (via comitology procedure)

The authorization specifies:

- Holder of the authorization
- Identity of the substance
- Authorized uses
- Any conditions under which the authorization is granted
- Time-limited review period
- Any monitoring arrangement

1. Introduction
2. Candidate list
3. Annex XIV (Authorization obligations)
4. Authorization application
5. **Outlook**

Outlook

Candidate list

- Submission dates for dossiers for SVHC identification usually twice a year
- next update fall 2010 (dossier submission in August 2010)
- Starting 2011: Producer/importers of articles to notify ECHA, if (Art. 7):
  - SVHC content > 0.1%
  - Annual amount of SVHC > 1ton
  - Unless producer or importer can exclude exposure to humans or the environment
- Many more substances expected in the future (e.g. 99 substances recently identified as possible candidates)

Outlook

Annex XIV:

- First substances on the Annex most likely mid 2010
  - ➡ first application deadlines: mid 2012
- ECHA recommendation at least every second year
  - ➡ next recommendation June 2011 at the latest

Registry of intention:

- MS or ECHA indicate the substances for which a dossier is planned (for authorization, also for restriction and for harmonized classification and labeling)
- http://echa.europa.eu/chem_data/reg_intentions_en.asp
- Currently on the registry:
  - Arsenic acid and its salts
  - Trichloroethylene
  - Different coal tar substances

Thank you very much for your attention!

Questions?

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