REACH Authorisation

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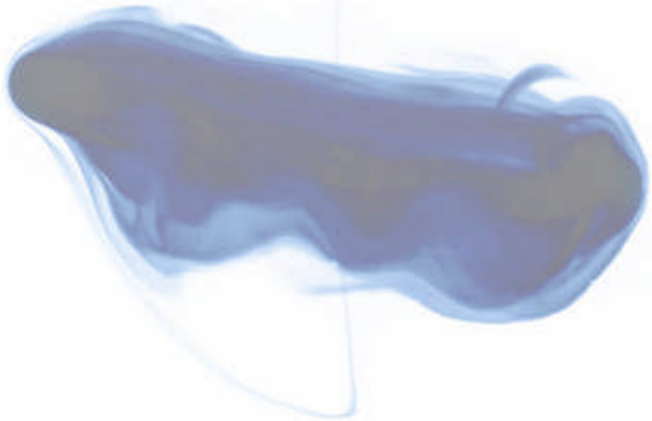
Outline of presentation

- What is authorisation?
- How are substances chosen?
- The Registry of Intentions (ROI).
- The Candidate List.
- Annex XIV.
- How you can propose a substance for authorisation or restriction.



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What is authorisation?

- Authorisation is the mechanism through which REACH will phase out use of the most hazardous chemicals.
- Article 55 "The aim … is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. …"
- Industry must justify the continued use of substances that are subject to the Authorisation regime.
- Uses that are not authorised must cease.

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Which substances are in scope (Art 57)?

- Substances of Very High Concern (SVHCs)
- CMR
  - (a) carcinogenic category 1 or 2;
  - (b) mutagenic category 1 or 2;
  - (c) toxic for reproduction category 1 or 2;
- PBT or vPvB
  - (d) substances which are persistent, bioaccumulative and toxic in accordance with Annex XIII;
  - (e) substances which are very persistent and very bioaccumulative in accordance with Annex XIII;
- Substances of equivalent concern
  - (f) … evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern …
  - Case-by case. Article 57(f) specifically identifies endocrine disruptors and PBTs and vPvBs that do not fulfil the criteria in points (d) or (e). Other effects may qualify.

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Exemptions (1)

- The Authorisation regime does not apply to: (Article 2(5))
  - Human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC
  - Use in food/feedingstuffs in accordance with Regulation (EC) No. 178/2002
- On site isolated intermediates and transported intermediates. (Article 2(9)(b))
- Use for research and development may be exempted. (Article 56(3))
- Other uses that are exempt include: (Article 56(4))
  - Use in plant protection products
  - Use in biocidal products
  - Use as motor fuels or as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems

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Exemptions (2)

- Where substances are subject to authorisation only because they are hazardous to human health: (Article 56(5))
  - Use in cosmetic products within the scope of Directive 76/768/EEC
  - Uses in food contact materials within the scope of Regulation (EC) No. 1935/2004
- When substances are present in preparations: (Article 56(6))
  - For substance meeting the criteria in Article 57(d), (e) and (f) below a concentration limit of 0.1% (w/w)
  - For all other substance below the lowest of the concentration limits specified in 1999/45/EC or Annex I to 67/548/EEC
- Certain uses or categories of use may be exempt if the risks can be shown to be adequately controlled by existing EU legislation. (Article 58(2))

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Authorisation vs Restriction

Authorisation

- Can only be used for substances that meet the criteria in article 57.
- All uses in scope are covered.
- The onus is on industry to demonstrate safe use or that it is currently not economically or technically viable to make changes.
- Industry must reapply for authorisation at regular intervals and pay the accompanying fee.

Restriction

- Can be used for any substance where use creates an unacceptable risk.
- Targeted to specific uses.
- The onus is on MS to demonstrate unacceptable risk and to consider the social and economic implications of the restriction.

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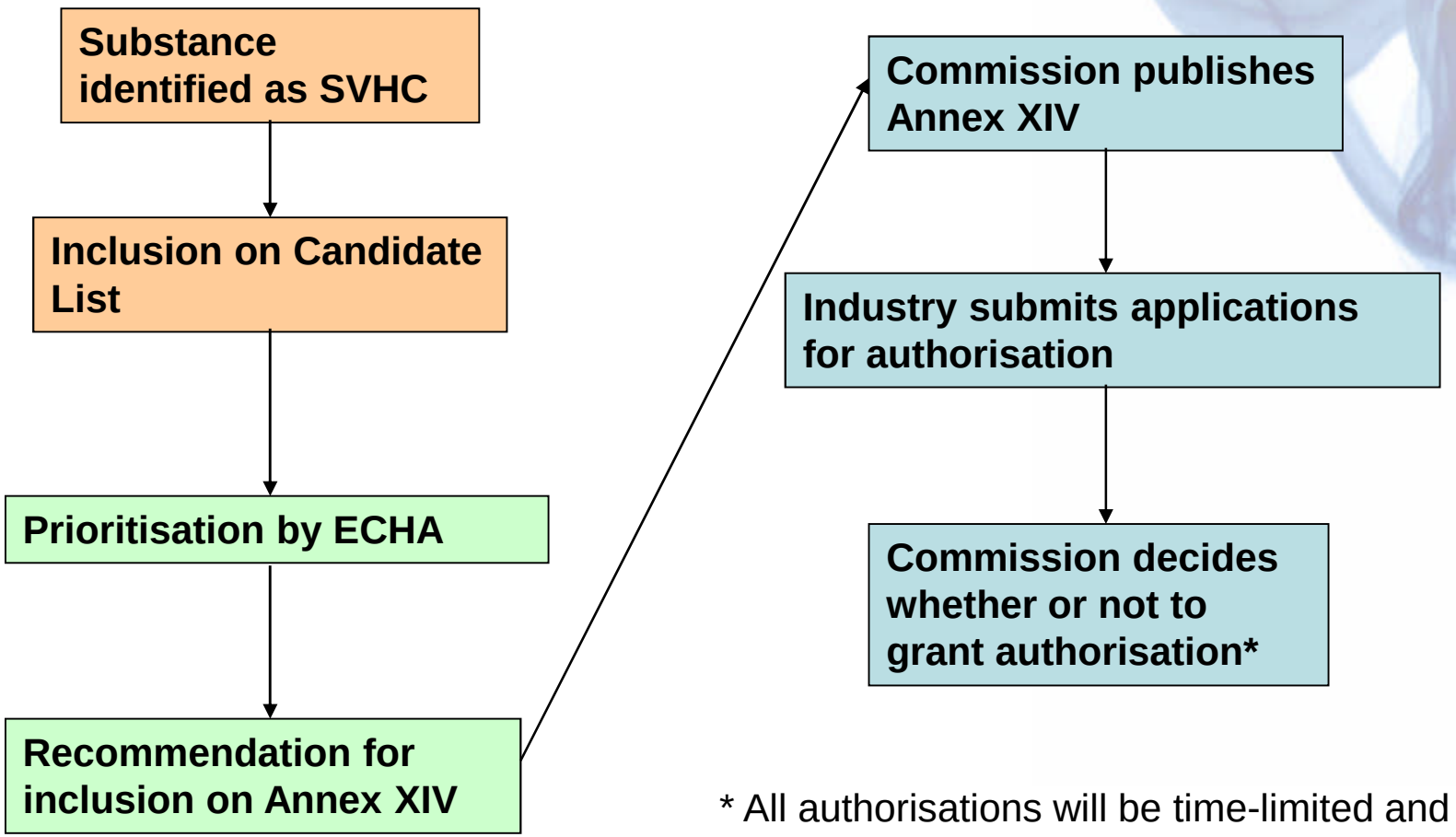
Outline of the Authorisation process



* All authorisations will be time-limited and subject to periodic review (Art. 60(8))

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How are substances chosen?

- Substance must meet SVHC criteria (Article 57) to be considered for Authorisation regime.
- Member States or the Commission (via ECHA) can propose substances.
- MS should prepare an analysis of risk management options (RMOs) to support discussions.
- Dedicated CIRCA site for MS to discuss which regulatory options are the best for specific substances.
- UK Govt departments can participate in discussions via their representatives at the UK Steering Committee.
- Proposal is confirmed when notification is made to the Registry of Intentions (ROI).
- Substance selection criteria for the UK Steering Committee outlined at http://www.hse.gov.uk/reach/substances.htm.

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Analysis of Risk Management Options (RMOs)

- Purpose is to identify which legislative tools are the most appropriate to address the concerns.
- Template:
  - Background
  - Objectives for (further) risk management
  - Available information
  - Identification of RMOs to be assessed
  - Assessment of identified RMOs:
    - needs to consider effectiveness, proportionality, practicality and consistency
  - Conclusions on the best (set of) RMOs

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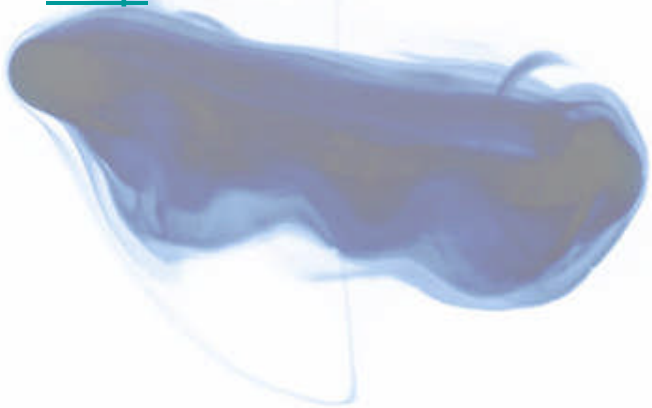
The Registry of Intentions (ROI)

- Identifies which MS are developing which Annex XV dossiers for which substances and the timescales for submission to ECHA.
  - Harmonised C+L
  - Identification of an SVHC
  - Proposals for restrictions
- Note that once a MS has notified an intention to submit an Annex XV restrictions dossier they must submit within 12 months (Art. 69(4)).
- Once dossiers are submitted substances are removed from the ROI.
- The ROI can be accessed at: http://echa.europa.eu/chem_data/reg_int_tables/reg_int_curr_int_en.asp.



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Annex XV SVHC dossier

- **Proposal** – summarises the reasons why the substance is being identified as an SVHC
- **Justification** – discussion of the scientific and technical evidence to support the proposal
- **Information on use, exposure, alternatives and risks** – not required to determine SVHC status but will be used to prioritise substances to be taken forward for inclusion on Annex XIV

- Guidance on the preparation of an Annex XV SVHC dossier is given at: http://guidance.echa.europa.eu/docs/guidance_document/svhc_en.htm?time=1259920627

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Inclusion on the Candidate List

- Member State (MS) submits dossier to ECHA.
- Accordance check (28 days).
- Annex XV dossiers released for public consultation (45 days).
- UK Govt departments can comment on SVHC dossiers via their representatives at the Steering Committee.
- Comments collated and MS prepares a response to comments plus support document (30 days).
- Documents forwarded to Member States Committee (MSC) members (30 day consultation).
- If SVHC status agreed, substance is placed on the Candidate List.
- If MSC cannot reach unanimous agreement then the final decision is made by Commission.
- For 2010, SVHC dossiers will be submitted to ECHA on 8th February and 2nd August.
- Consultations will open on 8th March and 30th August.

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What are the consequences of being on the Candidate List?

- **ARTICLES**
  - From the date of inclusion requirements on the provision of information to customers
  - From 2011 there will be requirements to notify ECHA
- **SUBSTANCES**
  - From the date of inclusion suppliers must provide customers with a safety data sheet
- **PREPARATIONS**
  - From the date of inclusion suppliers of preparations containing at least 0.1% (w/w) of a substance on the Candidate List may have to provide customers with a safety data sheet for the preparation
- For details see: http://echa.europa.eu/doc/candidate_list/candidate_list_obligations.pdf

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Which substances are on the Candidate List?

Currently listed

- Triethyl arsenate
- Anthracene
- 4,4-diaminodiphenyl methane (MDA)
- Dibutyl phthalate (DBP)
- Cobalt dichloride
- Diarsenic pentoxide
- Diarsenic trioxide
- Sodium dichromate
- Musk xylene
- Bis (2-ethylhexyl) phthalate (DEHP)
- Hexabromocyclododecane and (all major diastereoisomers identified, i.e. α-, β-, γ-hexabromocyclododecane (HB-CDD)
- Short chain chlorinated paraffins (SCCPs)
- Bis(tributyltin)oxide (TBTO)
- Lead hydrogen arsenate

Proposed

- 2,4-Dinitrotoluene
- Anthracene oils and pastes (5 separate fractions)
- Diisobutyl phthalate
- Aluminosilicate refractory ceramic fibres
- Zirconium aluminosilicate RCFs
- Lead chromate
- Lead molybdate sulphate red
- Lead sulphochromate yellow
- Acrylamide
- Tris (2-chloroethyl) phosphate
- Coal tar pitch high temperature

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp

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From the Candidate List to Annex XIV

- ECHA (and MSC) identify priority substances.
- Article 58(3) - Priority normally given to substances with:
  - PBT, vPvB properties; or
  - wide dispersive use; or
  - high volumes
- Draft recommendations circulated for public comment (3 months).
- UK Govt department can comment via their representative at the Steering Committee.
- Final recommendations endorsed by MSC and sent to Commission.
- For more details see: http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_prior_set_approach.pdf

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What are the consequences of Annex XIV?

- Annex XIV entry will specify:
  - Sunset date (3½ - 4 years after inclusion for first list)
  - Date by which applications for authorisation must be made (at least 18 months before the sunset date)
  - Review periods
  - Exemptions for uses adequately controlled by existing legislation
- After the sunset date has passed:
  - Art. 56(1) M/I and DU must not place on the market or use a substance unless authorisation has been granted for that use, the use is exempt from authorisation, or where you are supplying to an immediate DU who has authorisation granted for their use.
  - Art. 56(2) DUs must ensure they use substances within the conditions of an authorisation.
- Provision of information:
  - Authorisation numbers must be made available on product labels (Art. 65)
  - DUs must notify ECHA within 3 months of first supply (Art. 66(1)) and ECHA will keep a register of DUs making such notifications (Art 66(2)).

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Which substances are currently proposed for inclusion on Annex XIV?

- First recommendations sent to the Commission on 1 June 2009:
  - Musk xylene
  - 4,4-diaminodiphenyl methane (MDA)
  - Short chain chlorinated paraffins (SCCPs)
  - Hexabromocyclododecane (and all major diastereoisomers, i.e. α-, β-, γ-hexabromocyclododecane) (HB-CDD)
  - Bis (2-ethylhexyl) phthalate (DEHP)
  - Benzyl butyl phthalate (BBP)
  - Dibutyl phthalate (DBP)
- Further recommendations to be made at least every 2 years.
- See: http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec_en.asp

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What could this mean for the supply chain?

- If authorisations for certain uses are not granted or companies do not apply, the use must cease after the sunset date.
- This could mean a halt to the supply of chemicals that are relevant for areas that you regulate.
- Examples of uses not automatically exempted:
  - DEHP – use as a plasticiser in medical devices.
  - DBP – use in a 2-part epoxy compound which prevents moisture migrating into the electronics of pressure transmitters used in the nuclear power installations.
  - DBP – use in military propellants and military propelling charges [MS can request specific exemptions in the interests of national defence (Art.2(3))].
- For more information see the response to comments documents at: http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/subst_spec_docs_en.asp
- Check that supplies of key chemicals will not be affected by authorisation decisions.

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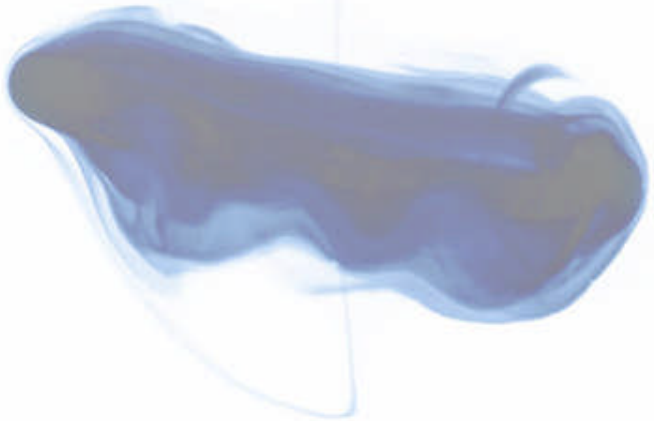
Removal from Annex XIV

- Substances can be removed from Annex XIV in the following circumstances:
  - Substances for which all uses have been prohibited under Title VIII – restrictions (Article 58(7)).
  - Substances which on the basis of new information no longer meet the criteria of Article 57 (Article 58(8)).



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What does industry have to do to apply for an authorisation?

- Applications may be made by a Manufacturer or Importer or a Downstream User (DU).
- Applications must be made at least 18 months before the sunset date.
- The dossier must include:
  - a Chemical Safety Report (CSR) covering risks related to SVHC properties (unless submitted).
  - an analysis of alternative substances or technologies considering the risks and technical and economic feasibility of substitutes (may include information on R+D activities of the applicant).
  - where suitable alternatives exist, a substitution plan.
  - if the applicant can not demonstrate adequate control and no suitable alternative exists, the applicant must include a socio-economic analysis.
- A fee has to be paid for each application.
- Authorisations are time-limited and industry must reapply (with the appropriate fee).

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How can you propose substances for authorisation or restriction?

- Identify a concern.
  - Does the substance meet the criteria for an SVHC?
  - What evidence is there to indicate an unacceptable risk?
- Carry out some initial scoping work based on the information required for the analysis of RMOs.
  - Background
  - How does EU legislation currently address the issue?
  - What more do you hope to achieve?
- Forward your information to your departmental representative on the REACH Steering Committee.
- Steering Committee meetings are held 4 times per year.

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