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-Scene Setting-
Authorisation for battery use of lead compounds

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International Lead Association
Eurobat Forum June 2016

Aim of Authorisation

- Assures that the **risks from SVHCs are properly controlled**
- SVHCs are **progressively replaced** by suitable **alternative substances or technologies** where **economically and technically viable**

Authorisation scope

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Why an Authority may wish to initiate the process of an Annex XV dossier for Authorisation

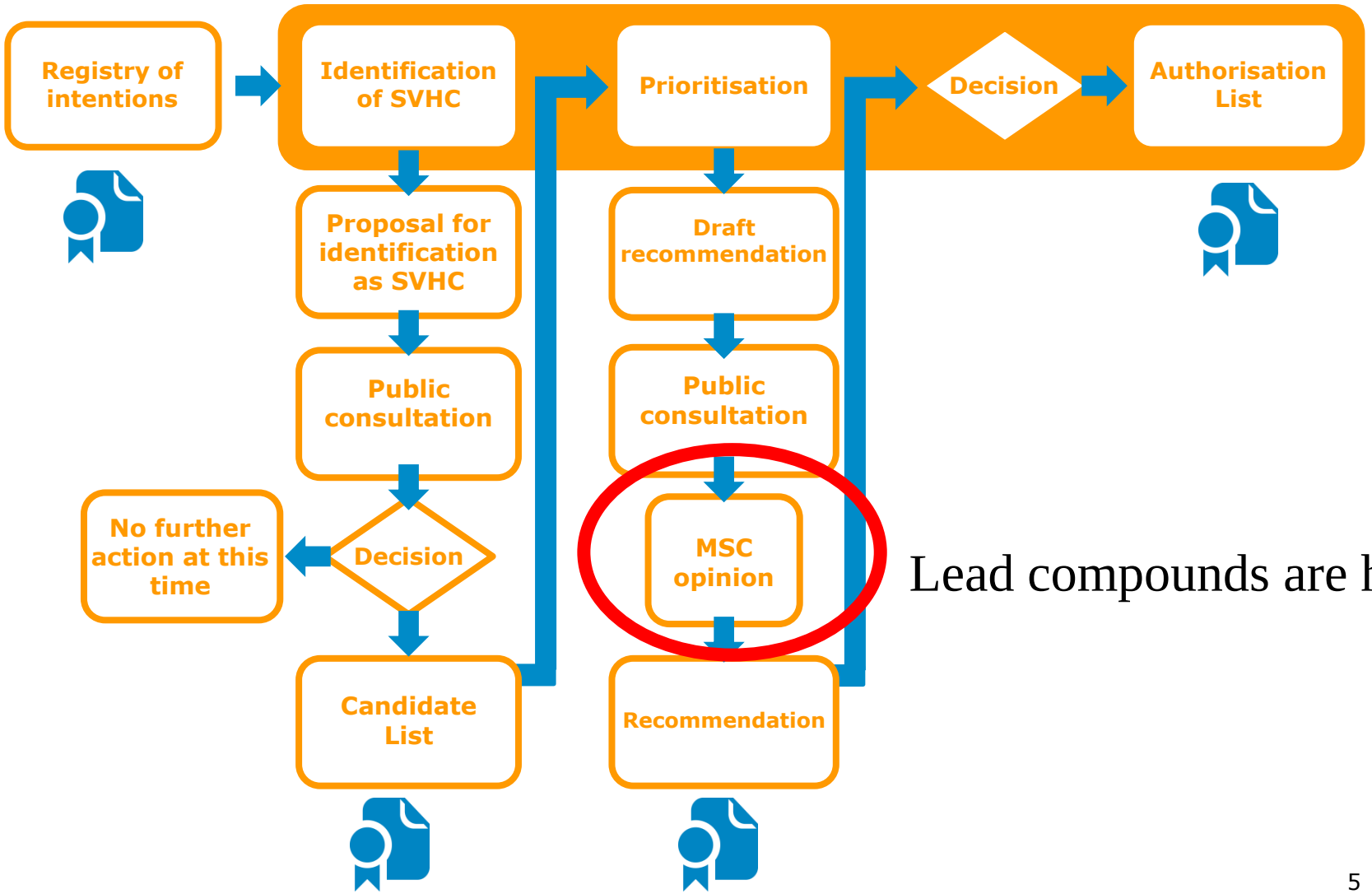
- **Classification criteria:**
  - carcinogenic category 1A and 1B
  - mutagenic category 1A and 1B
  - **toxic for reproduction category 1A and 1B**
  - substances which are persistent, bioaccumulative and toxic (PBT)
  - substances which are very persistent and very bioaccumulative (vPvB)
  - Substances of equivalent concern

Authorisation scope

- Manufacturers, importers or downstream users **shall not place a substance on the market for a use** or use it themselves **if that substance is included in Annex XIV**, unless:
  - ✓ The **use** has been **exempted**
    - ✓ Isolated intermediates
    - ✓ **Specific exemptions**
      - ✓ **e.g. REACH Article 58(2)**
  - ✓ The **use has been authorised**

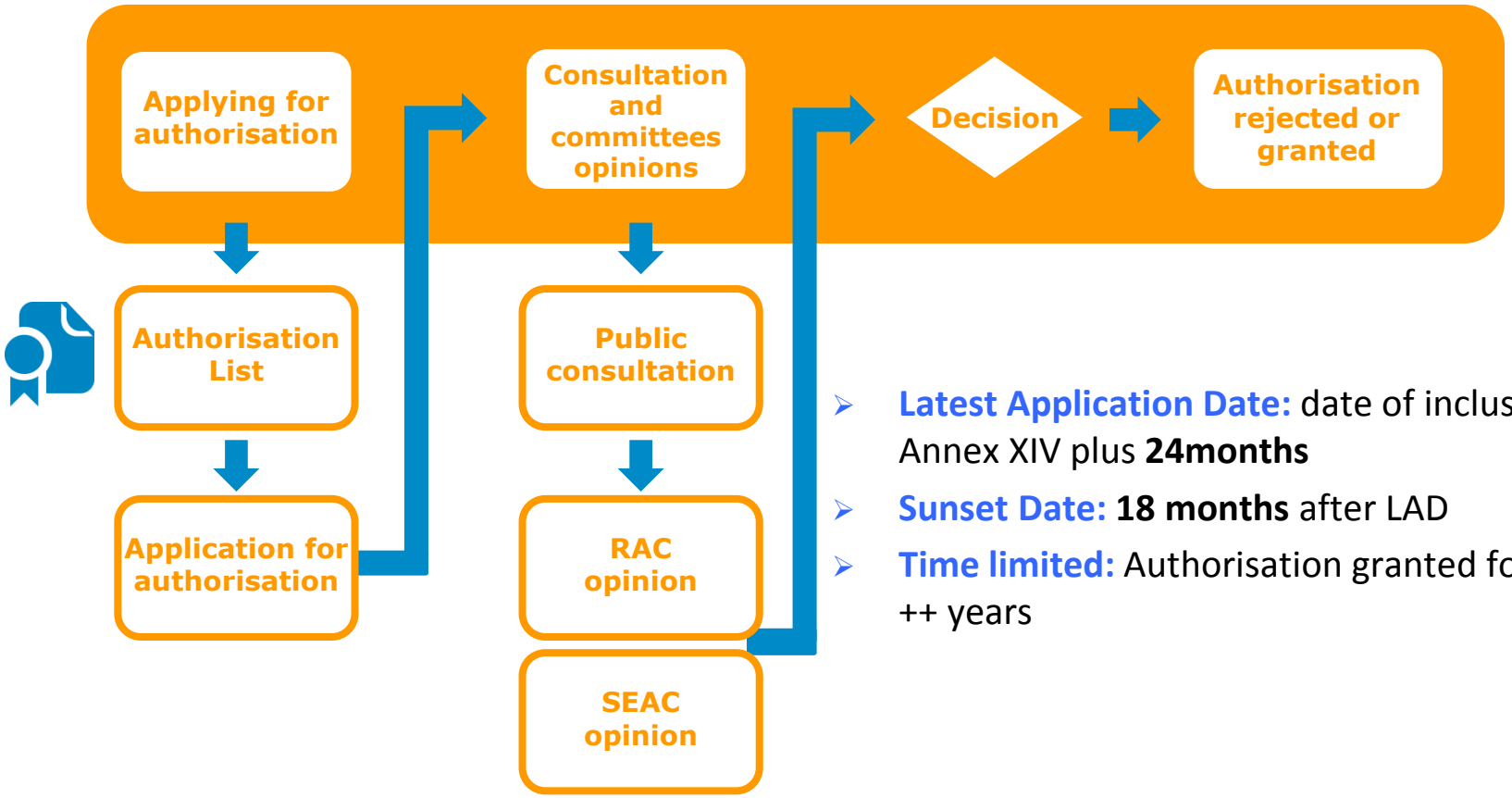
Does not cover the presence of substance in **imported articles**

Authorisation, regulatory process summary



Lead compounds are here

Application for authorisation, process summary



- **Latest Application Date:** date of inclusion in Annex XIV plus **24months**
- **Sunset Date:** **18 months** after LAD
- **Time limited:** Authorisation granted for 5,7,12 ++ years

Cost of Authorisation

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Authorisation Costs

Base fee covers the application for an authorisation for **one substance, one use, and one applicant**

STANDARD FEES	
Base fee	€ 50 000
Additional fee per substance	€ 10 000
Additional fee per use	€ 10 000
Additional fee per applicant	Additional applicant is not an SME: € 37 500
	Additional applicant is a medium enterprise: € 30 000
	Additional applicant is a small enterprise: € 18 750
	Additional applicant is a medium enterprise: € 5 625

The Agency shall levy an **additional fee** for

- **each additional use**
- **each additional substance** meeting definition of a group of substances
- **each additional applicant** that is party to the application

Status of Lead Compounds

- Lead monoxide
- Lead tetroxide
- Pentalead tetraoxide sulphate
- Tetralead trioxide sulphate

- Initially included in ECHA 6th priority list but in July 2015 ECHA indicated that they would not include in final recommendation to Commission to “balance workload”.
- Now included in **7th priority list** that is currently being reviewed by MSC and **scheduled to be submitted to Commission in Oct 2016**

Exemptions from Authorisation

- The lead compounds will very likely be included in the 7th priority list recommendation from ECHA to Commission

- **Key is for Commission to grant exemption for battery use**

- **Article 58(2) REACH**: "**Uses** or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the **existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled**"

The case for exemption of battery use of lead compounds

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- The **use is restricted to manufacturing of lead-based batteries** as all four compounds are transformed into other substances during the manufacturing process such that only trace amounts (<0.1%) are present in the finished battery (which is in any case a sealed unit and operates in a closed loop)
- This **existing workplace legislation provides binding and enforceable requirements for the control of risks** from industrial use of lead in battery manufacturing. In having a binding occupational exposure and biological limit for lead and lead compounds, supported by additional measures such as medical surveillance, Council Directive 98/24/EC ensures that **harmonised EU wide standards operate that constitute minimum requirements relating to the protection of health**
- Employee **health surveillance** (in the form of routine blood lead measurements) **demonstrates the effectiveness of the measures already in place** under the existing EU workplace legislation in controlling the risk to human health
- Provisions already exist in both the EU **ELV and Battery Directives** to **encourage substitution** of heavy metals (including lead) in batteries where technically feasible

Comitology Procedure

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REACH Committee ⟹ Qualified Majority Voting

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Commission proposal for Annex XIV

Belgium	12	Luxembourg	4
Bulgaria	10	Hungary	12
Czech Republic	12	Malta	3
Denmark	7	Netherlands	13
Germany	29	Austria	10
Estonia	4	Poland	27
Ireland	7	Portugal	12
Greece	12	Romania	14
Spain	27	Slovenia	4
France	29	Slovakia	7
Italy	29	Finland	7
Cyprus	4	Sweden	10
Latvia	4	United Kingdom	29
Lithuania	7		

Parliament and Council then have three months to examine proposals

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adopted if there are at least 255 votes in favour

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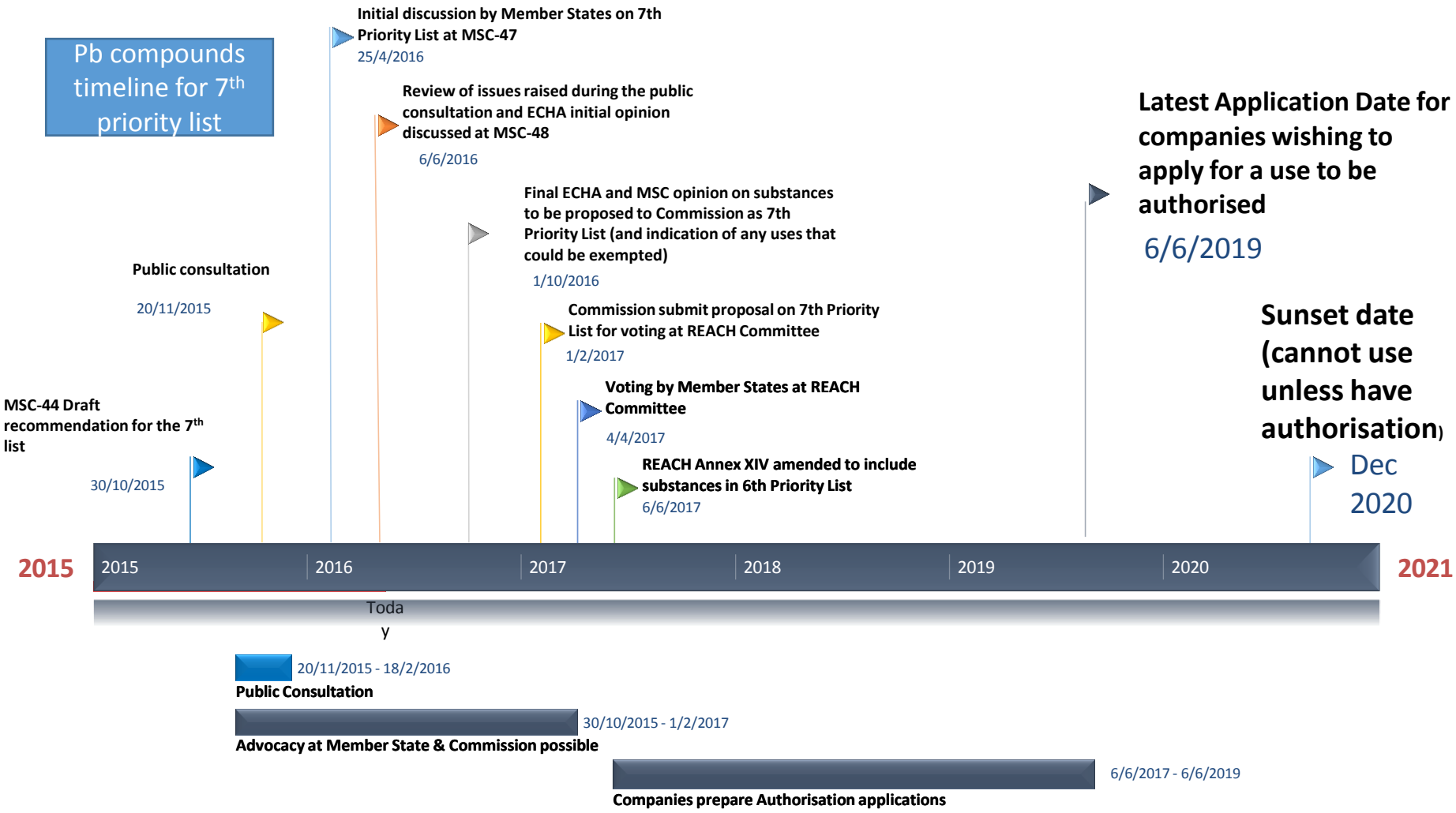
Pb compounds timeline for 7th priority list
Initial discussion by Member States on 7th Priority List at MSC-47
25/4/2016
Review of issues raised during the public consultation and ECHA initial opinion discussed at MSC-48
6/6/2016
Final ECHA and MSC opinion on substances to be proposed to Commission as 7th Priority List (and indication of any uses that could be exempted)
1/10/2016
Latest Application Date for companies wishing to apply for a use to be authorised
6/6/2019
Public consultation
20/11/2015
Commission submit proposal on 7th Priority List for voting at REACH Committee
1/2/2017
Sunset date (cannot use unless have authorisation)
Dec 2020
MSC-44 Draft recommendation for the 7th list
30/10/2015
Voting by Member States at REACH Committee
4/4/2017
REACH Annex XIV amended to include substances in 6th Priority List
6/6/2017
2015
2015
2016
2017
2018
2019
2020
2021
Today
20/11/2015 - 18/2/2016
Public Consultation
30/10/2015 - 1/2/2017
Advocacy at Member State & Commission possible
6/6/2017 - 6/6/2019
Companies prepare Authorisation applications