

Welcome to Today's Webinar:

Bisphenol A and HHPA / MHPA

REACH Authorisation Regulatory Implications
and Supply Chain Mapping by IAEG WG5
4 December 2018

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Today's webinar - aims



- Provide an overview of the REACH Authorisation procedure
- Set out the typical practical options for actors in the supply chain
- Explain the challenges faced by the aerospace sector
- Overview BPA & HHPA/MHHPA regulatory status in the context of REACH Authorisation
- Outline the activities the IAEG REACH Authorisation Work Group 'WG5' is undertaking, explain why we are undertaking them and why we need your support!

Who are we?

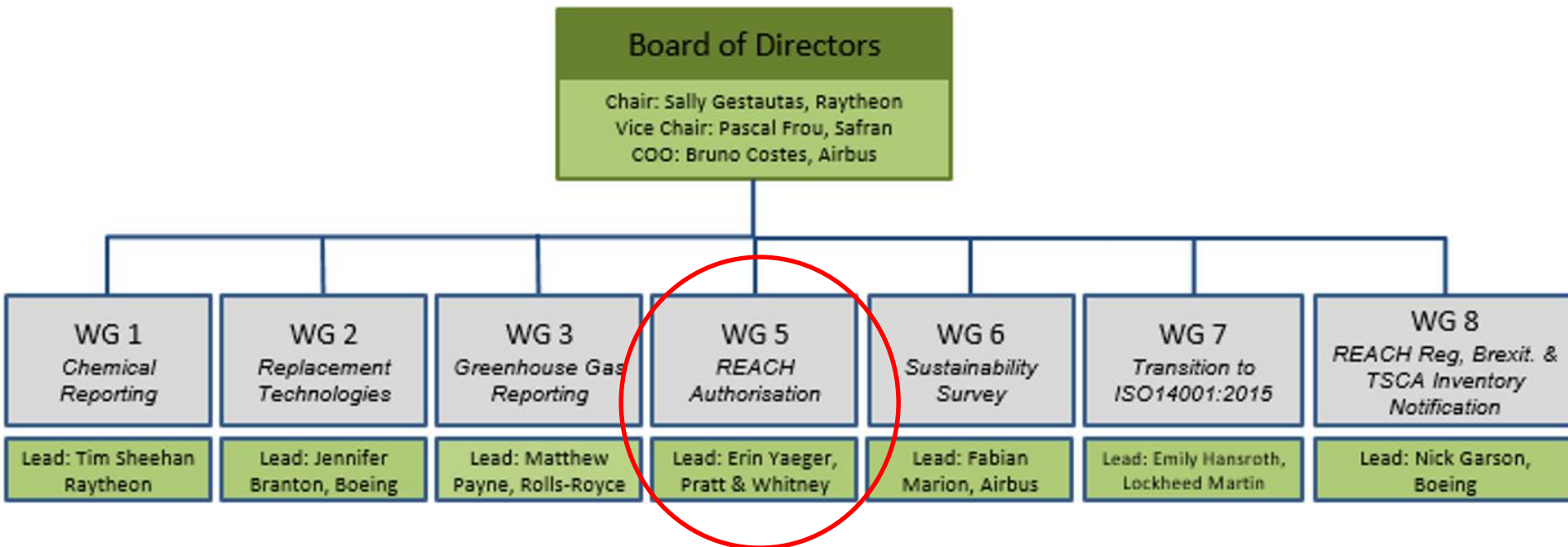


- Trade association formed by major aerospace companies – formally incorporated June 2011
- Focussed on the multitude of global laws and regulations impacting health and the environment
- Formed to address the complexity and variability of these requirements and associated impact on the Aerospace industry (Civil & Defence) and its supply chain

IAEG Work Group 5 Members

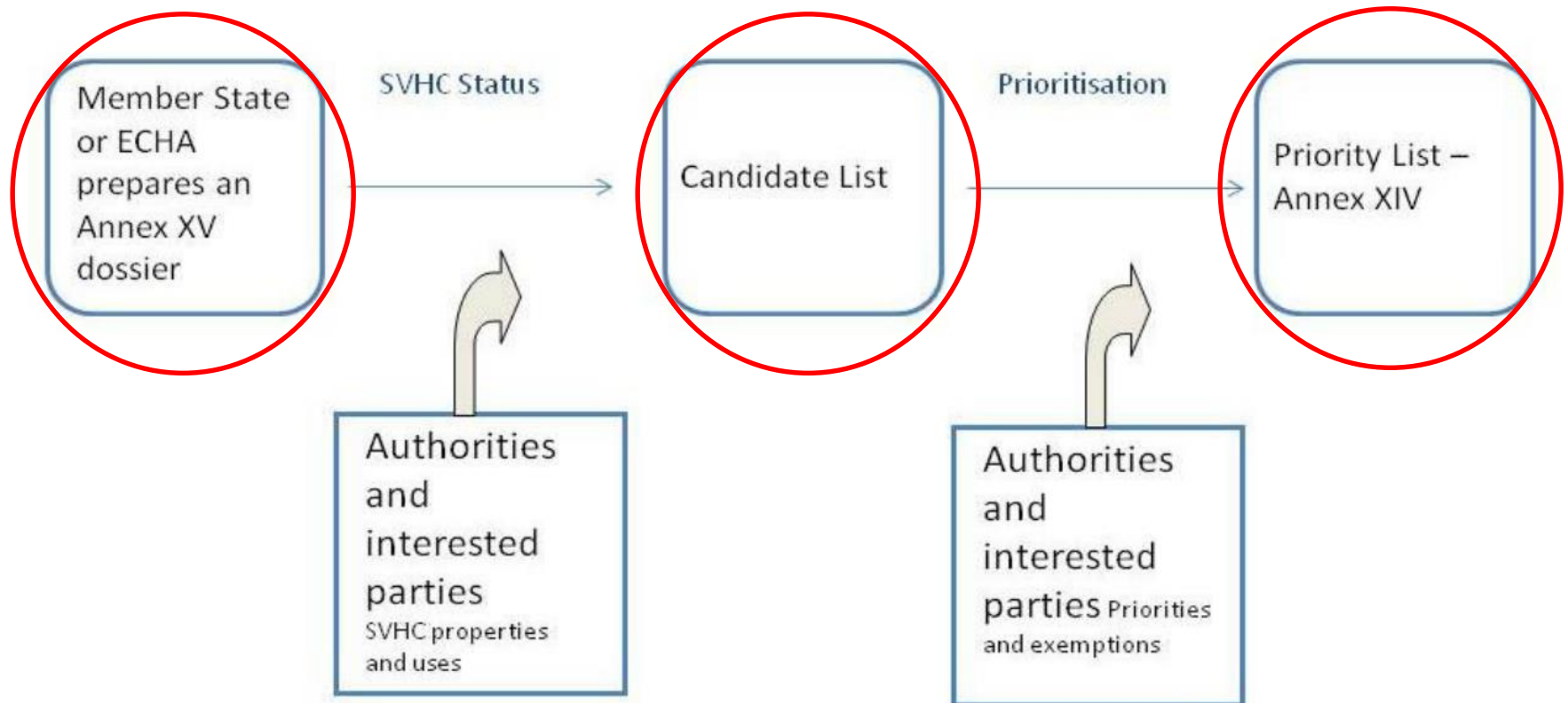
Aviall Services, Inc. (Boeing Company)	Lockheed Martin
Airbus	Mitsubishi Aircraft Corporation
Airbus Helicopters	Northrop Grumman
BAE Systems	Pratt & Whitney (UTC)
Boeing Company	Pratt & Whitney Canada (UTC)
Bombardier Aerospace	Raytheon Company
Cobham Plc.	Rolls-Royce
Dassault	Safran
Embraer S/A	Textron Aviation
GE Aviation	Thales
Gulfstream Aerospace Corp	UTC Aerospace Systems
Honeywell	

IAEG at a glance



- After a two-step regulatory process, SVHCs may be included in the Authorisation List
- These substances cannot be placed on the market or used after a given date (the 'Sunset Date'), unless an authorisation is granted for their specific use, or the use is exempted from authorisation
- Authorisation list = **43 entries (substance or family of substances)**
- Candidate list = **191 entries (substance or family of substances)**
- Authorisations are time limited (typically 4, 7 or 12 years) and review reports are required. They are granted per substance and per use

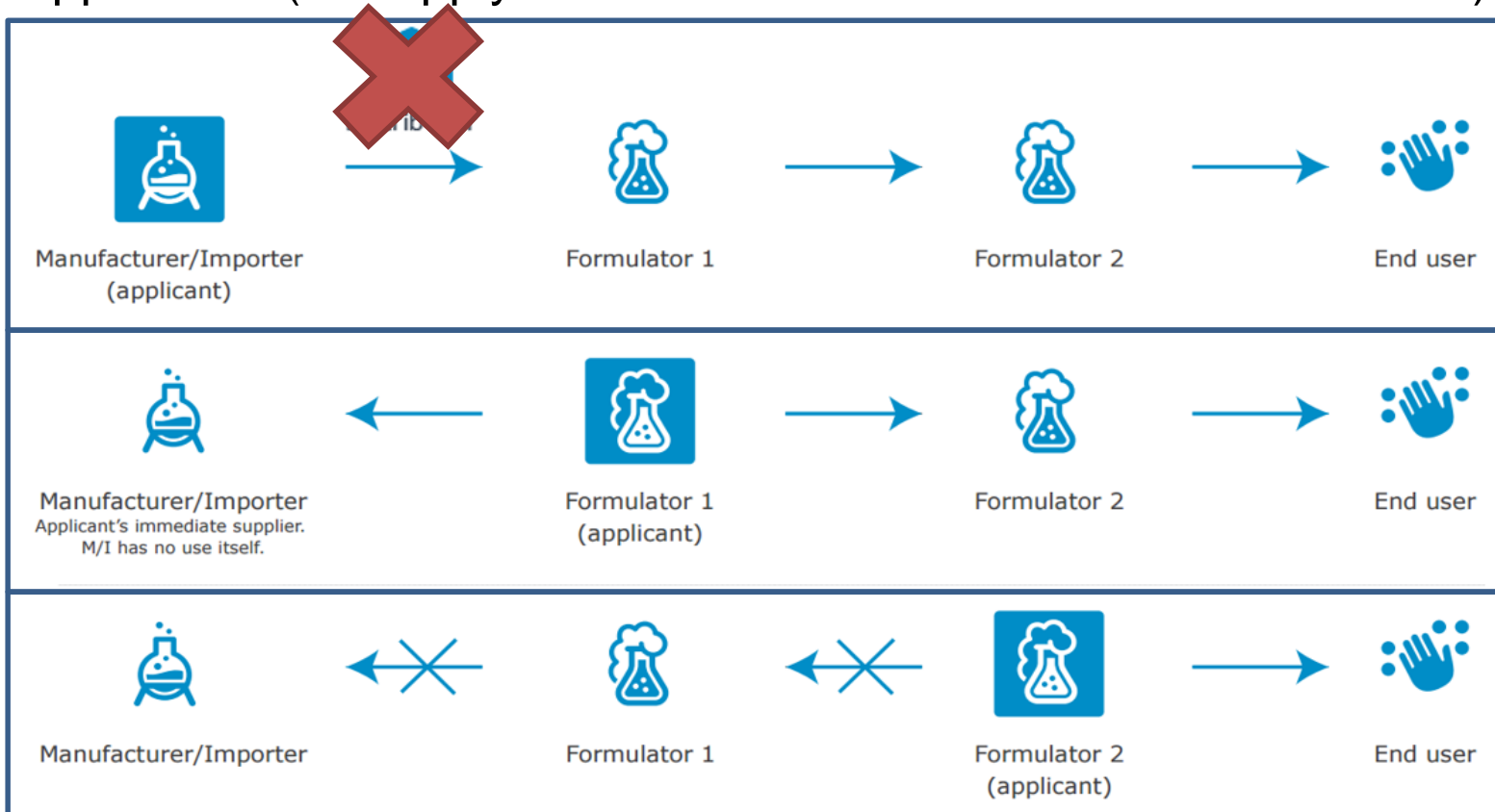
Journey to Annex XIV



*Ref1

Supply chain coverage

- Use coverage is top-down, not bottom-up – there is a potential for supply chain disruption
- ‘The best’ way: substance manufacturer or importer submits application (all supply chain can be covered if uses are included)



*Ref2

An evolving process...

- ECHA's templates and guidance materials can change
- As do committee evaluation methods
- ECHA's Authorisation Q&A's regularly updated
- Important to stay on top of the current 'best practises'

Given that large dossiers can take 2 years+ to develop, applicants must be ready to exhibit flexibility in their approach to Authorisation

Authorisation from a business perspective

1. Replace the substance with a suitable alternative or adapt your process to avoid its use
2. Redesign products (articles) to avoid the use of the substance
3. Consider applying for authorisation or joining a consortium to support the applicants
4. Ensure your use is covered by another authorisation.
5. Cease use in the EU.



Challenges for the aerospace sector

- Industry's dependence on certain SVHCs to meet functional requirements, in particular high standards of safety over long product lives
- Reg. 216/2008 on qualification, etc. of alternatives
- Relatively small volumes of chemicals used by sector or its suppliers
- Complexity of the supply chain



*Ref4

Before we begin creating key authorisation documents, we need to know

- What are the uses?
- Are potential alternatives available?
- Who should apply for authorisation?

...Situation complicated by different commercial interests of supply chain actors

Supply chain mapping – process overview



1. IAEG Member survey

- Identify known uses

2. Supplier Survey

- Webinar (today)
- Two-phased survey

3. Supply Chain Report (Members)

- Reporting of results / additional findings from market analysis

4. Recommendation

- e.g... Spin-off consortium?
- Joint other consortium?
- Individual action by members?

Information collected through the Work Group's research and supply chain queries allows each member company to perform their own business risk assessment

Supply chain mapping for BPA, HHPA and MHHPA (1/4)



- BPA, HHPA and MHHPA included on ECHA's 9th draft recommendation for inclusion on Annex XIV;
- Potential Authorisation timescales uncertain

Substance identity (in ECHA Candidate List)	Relevant CAS Number(s)	Relevant EC Number(s)
4,4'-isopropylidenediphenol (bisphenol A; BPA)	80-05-7;	201-245-8
HHPA: Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	85-42-7 13149-00-3 14166-21-3	201-604-9 236-086-3 238-009-9
MHHPA: Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	25550-51-0 19438-60-9 48122-14-1 57110-29-9	247-094-1 243-072-0 256-356-4 260-566-1

Supply chain mapping for BPA, HHPA and MHHPA (2/4)



- Very well established in critical aerospace applications
- BPA used to produce polycarbonate and epoxy resins
- Polycarbonate uses include
 - Windows for aeroplanes;
 - Covers for position lights etc;
 - Personal protection equipment for civil and military usage (goggles, visors of helmets);
 - Electrical insulation; and
 - Modern communication equipment with optical technology.
- Epoxy resin uses include
 - Composite materials for structural components for weight and CO₂ emission saving;
 - Potting compounds for the majority of electrical components used on printed circuit boards;
 - Adhesives and primers for modern manufacturing techniques;
 - Paints and varnishes for long-life products.

Supply chain mapping for BPA, HHPA and MHHPA (3/4)



- BPA:
 - Majority (but not all) use understood to be intermediate but there are significant data gaps in the supply chain
 - Concerns exist regarding processing steps and residual BPA content in polymers
- HHPA and MHHPA:
 - Used almost exclusively in curing agents for epoxy resins
 - If listed on Annex XIV, the uses will be subject to authorisation

Supply chain mapping is vital!

Supply chain mapping for BPA, HHPA and MHPA (4/4)



- Two-part survey being undertaken
 1. A short (one page) initial questionnaire to help with use identification
 2. A more detailed follow-up questionnaire to obtain key information
- **Information is treated confidentially, and is aggregated and anonymised before being shared with work group members** (supply chain information cannot be linked back to individual respondents)

Your support is essential!



- Please complete and pass on our short questionnaires to your suppliers (even if you are not a user!)
- The more information we receive, the better the picture of the supply chain
 - This will allow for a more informed, structured and comprehensive approach to potential future Authorisation activities
- You may help to make certain that your use can continue and your concerns can be taken on board
- Outside the EU? Authorisation can still affect you!

References

- ***Ref1.** Nickel Institute (2012): The REACH Authorisation Process – Key Questions and Answers. Available at <http://www.nickelconsortia.eu/assets/files/consortia/Authorisation%20QA%20May%202012.pdf>.
- ***Ref2.** ECHA (2013): Factsheet – Applications for authorisation under REACH. Available at https://echa.europa.eu/documents/10162/13637/factsheet_applications_authorisation_en.pdf.
- ***Ref3.** ECHA (undated): Getting started – Distributor. Available at <https://echa.europa.eu/support/getting-started/distributor>.
- ***Ref4.** ECHA – EASA (2014): An elaboration of key aspects of the authorisation process in the context of aviation industry. Available at https://echa.europa.eu/documents/10162/13552/aviation_authorisation_final_en.pdf.
- ***Ref5.** GIFAS (2017): Reaction products of Bisphenol A for aeronautics and space applications. Available in ECHA RCOM at <https://echa.europa.eu/documents/10162/ffc0a157-d90e-05f9-aa7b-d300d81bb6e7>.

Useful links



- ECHA Authorisations Page; <https://echa.europa.eu/regulations/reach/authorisation>
- ECHA Q&As on Authorisation; <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation>
- Authorisation List; <https://echa.europa.eu/authorisation-list>
- IAEG Work Group 5 website: <http://www.iaeg.com/workgroups/wg5/>