Cobalt Development Institute

Promoting the Responsible Use of Cobalt in All Forms

Five Cobalt salts

(Co-sulphate, -dichloride, -dinitrate, -carbonate, diacetate)

Restriction versus Authorisation

Recent experience & next steps

February 2013

COBALT REACH CONSORTIUM

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REACH Authorisation – status

- October 2010: the NL MSCA proposed the prioritisation of five cobalt salts for Authorisation.
  The French MSCA had earlier published an Annex XV dossier for cobalt dichloride alone, but the MSC considered that salts should be grouped due to perceived 'interchangeability'of salts.

- December 2011: ECHA proposed to include 5 cobalt salts in Annex XIV (list of substances subject to Authorisation). This triggered unprecedented discussions, and, as a result of the provision of correct information by Industry to ECHA, MS and COM, 8 Member States (MS) opposed the proposal. 2 streams: Co di-acetate alone *versus* All 5 Co salts

- September 2012: the Commission (COM) recommends to postpone Authorisation and instead to prepare a Restriction proposal on the cobalt salts as *'at least one use of the substances (i.e. surface treatment) poses a risk to human health that is not adequately controlled and needs to be addressed.'*

Key success factors for this result

- Organised approach: aligned and consistent message agreed by all EU Associations (and involved companies), but tailored to the national interests of each MS

- Balanced approach: cobalt salts make a very good story (varied uses & benefits -including 'essential micronutrient'- covering many sectors, but disproportionate action as 90% volume is 'out-of-scope')

- Active approach:
  - numerous visits to MS and their Permanent Representations, extending the network to more countries: BG, RO, CZ, AT, IRE, PT; consolidating w/ FR, UK, NL, ES, IT, PL, LT.
  - Meetings with COM DGs: DG ENT (REACH Unit and Raw Materials), DG Research, DG Industry

- Reached out to our DU network (> 100 companies)

REACH Restriction – process & timelines

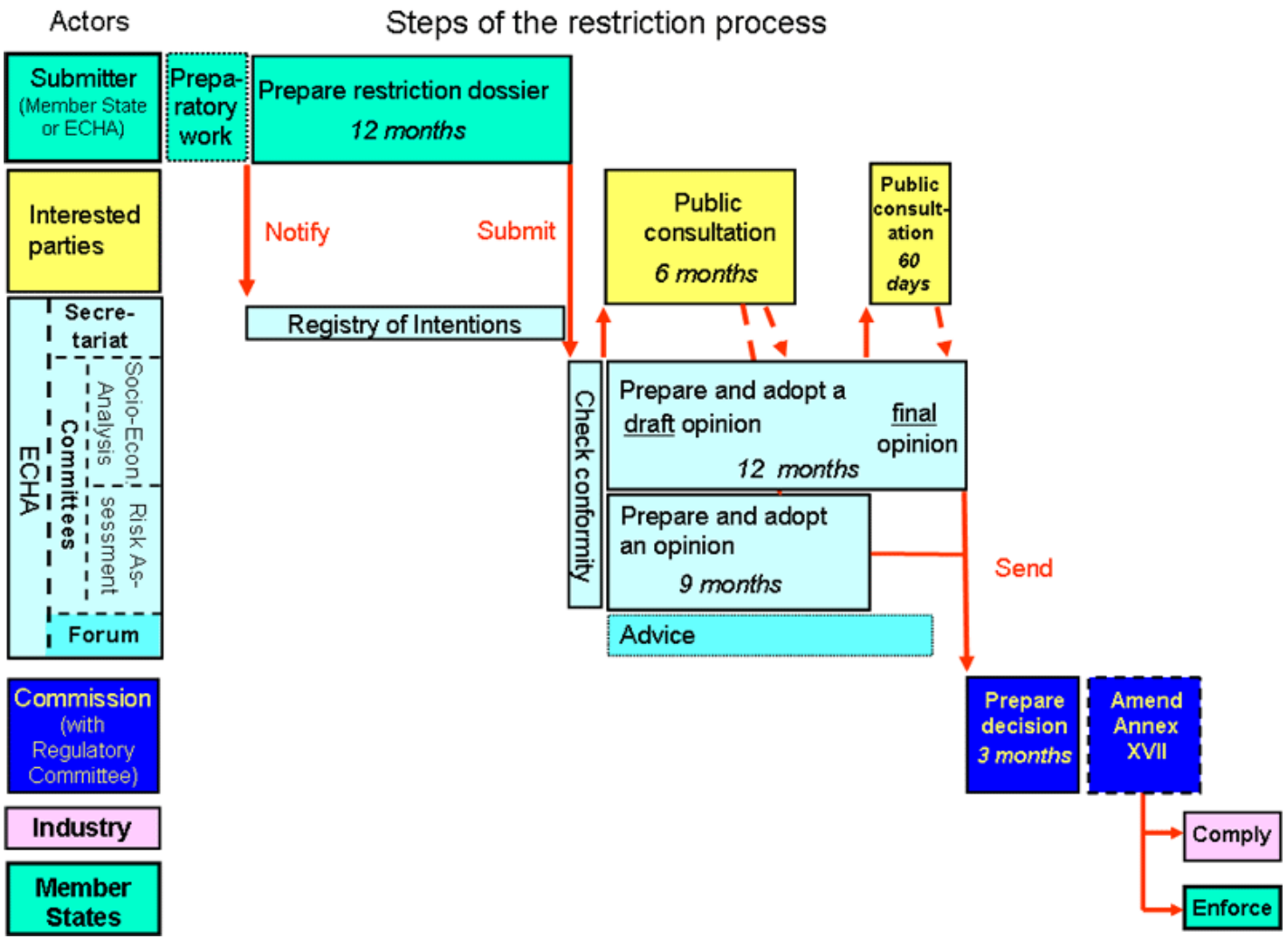
- Jan 2013: COM mandates ECHA to conduct a preliminary investigation on certain uses of cobalt salts, to define the possible scope, i.e. the specific cobalt salts and uses, for a potential restriction. Report due by mid 2013.

- July/September 2013: COM will then confirm their request to ECHA to prepare a restriction dossier (from October 2013) specifying the scope of the restriction dossier to be prepared based on the results of the initial investigation.

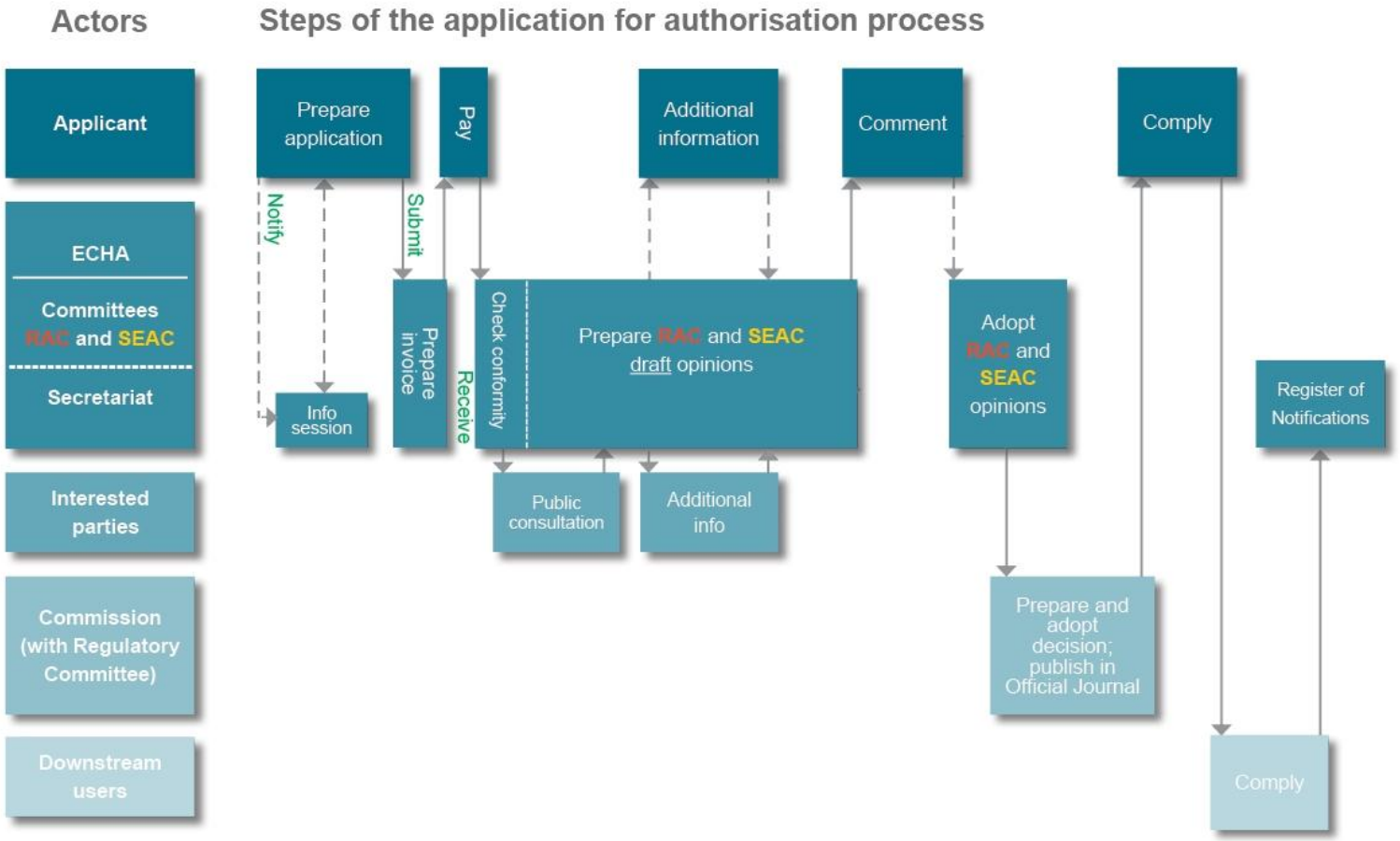
- 2014-2015 - Restriction procedure, which includes ECHA preparing a Restriction dossier (Oct 2013-Oct 2014) and an Socio-Economic Analysis (SEA) and Risk Analysis (RA) conducted by the SEAC and RAC Committees (Oct 2014-Oct 2015)

- 4Q2015-1Q2016: COM Decision on Restriction by comitology.

REACH Restriction process



REACH Authorisation process



REACH Restriction vs Authorisation

- Authorisation:
  - all uses would be impacted e.g. all (non-intermediate) uses would have had to apply for Authorisation (positive listing)
  - no exemptions were foreseen (e.g. even as essential element?)
  - manufacture not in scope, and imported articles not in scope
  - authorisation application reviewed at regular intervals – can be renewed
  - final phase-out of the uses where substitution possible

- Restriction:
  - only the uses of concern or under consideration will be impacted (tbd)
  - imported articles can be in scope, so can manufacturing
  - scope of a restriction is very ‘flexible’ e.g. total ban or narrowed scope (negative listing)
  - timing of the procedure for Restriction is the same for the substances of the Third Prioritisation List (e.g. Decision early 2016)
  - timing is flexible: later enforcement dates and derogations can be set to allow Industry/MS to adopt the necessary implementation steps

Restriction versus *Authorisation*

RESTRICTION

- **Risk driven** and selective scope (but all risks considered i.e. Human Health & Environment)
- **SEA**: required
  - Study done by MS or ECHA
  - IND input best before start
  - Focus on Risk Benefit
- **AofA:** required (by MS)
  - IND input best before start
  - Comparative assessment for all relevant/hazard endpoints

AUTHORISATION

- **Substance driven** & applicable to all uses (but Human Health-only focused)
- **SEA**: depending on route
  - Study done by the Applicant
  - IND in control
  - Focus on Cost outweighting risk
- **AofA**: required by AA
  - IND in control
  - Comparative assessment on Technical feasibility

REACH Authorisation- Remaining threats

- Cobalt salts are *no longer* included in the 3rd Priority list for Authorisation, but have been set aside…

However:

- *remain on the **Candidate list***
- there is currently no mechanism for their removal
- they will continue to be reviewed periodically by ECHA for potential prioritisation (as will all substances on the Candidate List)

- COM has left open the option for **Authorisation** for which the final Decision is only ‘postponed’ until the Restriction procedure is ‘concluded’.

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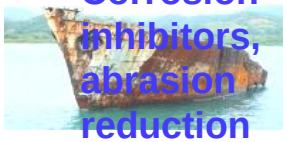
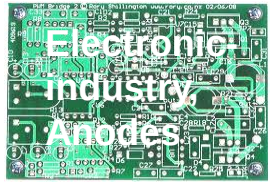
Restriction: same uses considered as under Authorisation…

- Use as catalyst (6% of total): only cobalt acetate and used under strictly controlled conditions
- Cobalt diacetate as pigment in PET
- Surface treatment (3% of total): passivation and plating
- Essential Element (<2%):
  - Biotechnology/biomedical
  - Animal feed, Fertilizers
  - Biogas
- Anticorrosion agent/water treatment (< 1%)
- Humidity indicator cells (<<1%)


Polymers


Synthetic fibres


Corrosion inhibitors, abrasion reduction


Electronic industry, Anodes


Military, Aerospace


Fermentation


Enzymes


Corrosion inhibitors, abrasion reduction


Military, Aerospace

Restriction in practice: next steps

- Jan and Feb 2013: two meetings between ECHA and CoRC to discuss industry stakeholder contacts and data gathering for their preliminary investigation on certain uses of cobalt salts, to help them define the scope for potential restriction

- A kick-off webinar will be launched by ECHA via a Press Release and is planned for 20 March.

- ECHA seem keen to collaborate with CoRC and Industry stakeholders for information gathering.
  They will then draw their conclusions independently.

- The more data we can provide, the better ECHA will understand the uses, and the more ‘tailored’ will be the restriction that is developed.

ECHA investigation study

- **Initial contact with specific sectors**
  End February: ECHA will contact (by e-mail) sectors where potential 'quick wins' were identified to arrange meetings/teleconference to discuss uses
- **20 March: ECHA webinar** (Open to the public)
  This will be to explain the procedure - this will focus only on the procedure.
- **Survey of certain sectors**
  mid-March: ECHA will launch a series of surveys specific to some sectors where they feel more information is require
  mid-March to mid April: 4- (to 6?) week window Industry to provide responses
  mid-April: close of survey
  mid-April to early May: ECHA analyse the results
- **Meetings between ECHA and (some specific) industry sectors**
  7-8 May (Brussels): to discuss potential remaining concerns and way forward
  mid-to end-May: time for Industry to provide further input to ECHA
- **Investigation report**
  June: ECHA writes a report (no opportunity for industry comments)
  End June: Investigation report is submitted to the Commission.

Restriction- work continues for Industry

ECHA (or MS) are responsible for the Restriction dossier

- It is in the interest of Industry to be proactive by providing *early* inputs into the process- and the clock is ticking (only 4 months to mid 2013)

- Current Industry activities in preparation for the Restriction:
  - *Short Restriction Roadmap document* for COM and ECHA outlining Industry suggestions for providing support to ECHA (with data collection and more data) during the process
  - Cobalt Industry will work in collaboration with the sectors concerned by the restriction
  - *In 2013: continue to refine the Exposure assessment/scenarios*
  - *In 2014: inputs for the Annex XV, RMO assessment, Analysis of Alternatives, Socio-economic Analysis*

Restriction: scope and wording

Aim to reduce identified risks without compromising uses:

- Provide enough information to ECHA to ‘screen-out’ as many uses as possible in the initial phase
- Maintain communication with ECHA on the scoping during the investigation (in 2013) and the preparation of the Annex XV Restriction dossier (in 2014)
- Proposal a general wording of the Restriction
- Some examples have been cited, e.g. dichloromethane

<u>For the Surface treatment sector specifically</u>

- mobilise the Surface Engineering sector to participate in the necessary related activities and funding
- ES refinement: see EBRC outline & project
- On-going discussions with Surface Treatment Sector

Restriction Road Map

Aim to maximise engagement of industry stakeholders

- To be prepared by Consultant (wca environment) as per Technical Toolkit for previous public consultations.
- Would span the 24 months of the restriction process.
- Stages:
  1. Define strategy
  2. Identify all uses and potential alternatives > Toolkit
  3. Refine exposure scenarios > Best practice (EBRC)
  4. Refine (and influence) proposed scope of restriction
  5. SEA dossier and toolkit for each relevant use
  6. Risk Management Options (RMO): analysis + toolkit
  7. Response to Public Consultation (analysis- summary)

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Summary of current exposure scenarios

- For REACH dossier, the CSR and ES are developed in order to show Safe Use in each application, however... for some uses (e.g. surface treatment) further data is required.
- Exposure estimates were based on analogous data (i.e. Data from similiar processes with the same substances)
- Generic „workplaces“ were defined including generic descriptions of operational conditions (OC) and risk management measures (RMM)
- Exposure assessment represents combined assessment of exposure to all used cobalt substances (measurements analysed for Co, stoichiometrically transformed to substance exposure)

Strategy for Refinement of ES

Re-definition of AC/WP*

- Telephone interviews
- Conduct of site visits and suggest sampling strategy
- Improve knowledge on OCs and RMMs

Anticipated timeline: 3 months (already started)

Exposure database

- Define AC/WP according to above
- Circulate tailored questionnaire within entire sector
- Collate database

Anticipated timeline: 2.5 months (5.5 months)

Re-Conduct of EA**

- Re-conduct of exposure assessment
- Update ES based on gathered knowledge (more specific)
- Refine guidance for downstream users

Anticipated timeline: 3 months (8.5 months)

*AC/WP: Activity Classes/Workplaces; **EA: Exposure Assessment