Risk management measures under REACH

- Authorisation and Restriction

Study visit of Brazilian Authorities to the European Chemicals Agency

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Content

- Risk Management of Chemicals under REACH
  - Overview
  - Authorisation
  - Restrictions
- Conclusions

Introduction

REACH Regulation (EC) No. 1907/2006

Registration,

Evaluation

Authorisation and Restriction of CHemicals

REACH does not stand on its own (1)

- Other sectoral chemicals legislation exists:
  - Plant Protection Products - pesticides
  - Biocidal Products - biocides

- Other important policy areas where links in terms of chemicals management exist:
  - Environment:
    - Water (e.g. priority hazardous substances)
    - Waste (e.g. use of hazardous substances in electronic equipment)
    - Air (e.g. quality objectives, paints directive (solvent use))

REACH does not stand on its own (2)

- Worker protection legislation:
  - Framework Directive on Health and Safety at Work
  - Setting of occupational exposure limits (OELs)
  - Carcinogens and Mutagens Directive
- Consumer Protection:
  - General Product Safety Directive
  - Toys (includes chemical requirements)
  - Cosmetics
- Health:
  - Medicinal products and medical devices
- Food:
  - Food contact materials

Risk Management of chemicals under REACH

REACH Processes

- **Data sharing**
- **Registration**

Industry gathers information and ensures responsible and well-informed management of the risks

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MSs

- **Evaluation**
  - **Dossier evaluation**
  - **Substance evaluation**

ECHA and MSCAs control and request for further info

- **(Classification & labelling – CLP Regulation)**
- **Authorisation**
- **Restriction**

Commission, with support of ECHA and MS-CAs, applies community wide risk management systems

Authorisation

One of main regulatory instruments available for authorities under REACH to manage risks from chemicals

Main principles of authorisation (1/2)

- Focus on:
  - most hazardous substances = **S**ubstances of **V**ery **H**igh **C**oncern (SVHC)
    - Carcinogens, Mutagens and toxic for Reproduction: CMRs → Human Health
    - Persistent, Bioaccumulative and Toxic for the environment: PBTs → Environment
    - very Persistent and very Bioaccumulative: vPvBs → Environment
    - Substances of "e*quivalent level of concern*" (e.g. endocrine disruptors, potent respiratory sensitisers)
  - for which uses may lead to significant exposure

- Principle: after a certain date ("*sunset date*") the use of an Annex XIV substance is forbidden unless specifically authorised (or exempted)

- Ultimate goal: substitution by safer alternatives

Main principles of authorisation (2/2)

- Some general exemptions:
  - scientific Research & Development
  - all intermediates
  - substances for which management of risks for human health and/or environment are already covered by other relevant Community legislation (medicinal products, cosmetic products, food and feed, food contact material, biocides and pesticides, fuels)
  - …

- **NOT** covered by the authorisation requirement:
  - manufacturing processes
  - imported articles containing the substance

The authorisation procedure: a two-step approach

- Step 1: subjecting substances to the authorisation requirement

  Step 1.a: Identification of SVHCs → ***"candidate list"***

  Step 1.b: Prioritisation of substance ("recommendation") and Inclusion in Annex XIV → ***"authorisation list"***

Public authorities (mainly)

- Step 2: authorisation applications and decisions

Industry

Authorisation – Step 1a

- Step 1a: Identification of substance as a SVHC
  Consequence: substance gets placed on the Candidate List

Substances of Very High Concern (SVHC)

- Carcinogens, mutagens, reproductive toxins (CMRs) cat 1A and 1B
- Persistent, Bioaccumulative and Toxic (PBT)
- Very Persistent and Very Bioaccumulative (vPvB)
- Substances of equivalent concern to the above

Step 1a: Candidate List

138 Substances

ECHA website

Examples:

- **Phthalates**
- **Arsenates**
- **Cobalt compounds**
- **Lead compounds**
- **(Di)chromates**

Step 1a: Candidate List - Implications

- Directly after inclusion in the Candidate List:
  - Suppliers of the substance:

    → provide their customers with a safety data sheet
  - Suppliers of articles containing the substance:

    → provide information to allow safe use of the article to customers or to consumers, upon request (45 days!)

- Six months after the inclusion:
  - Producers/importers of articles have to notify ECHA if their article contains a substance on the Candidate List

Authorisation – Step 1b

- Step 1b: SVHC substance on Candidate List gets placed on Authorisation List (Annex XIV to REACH)

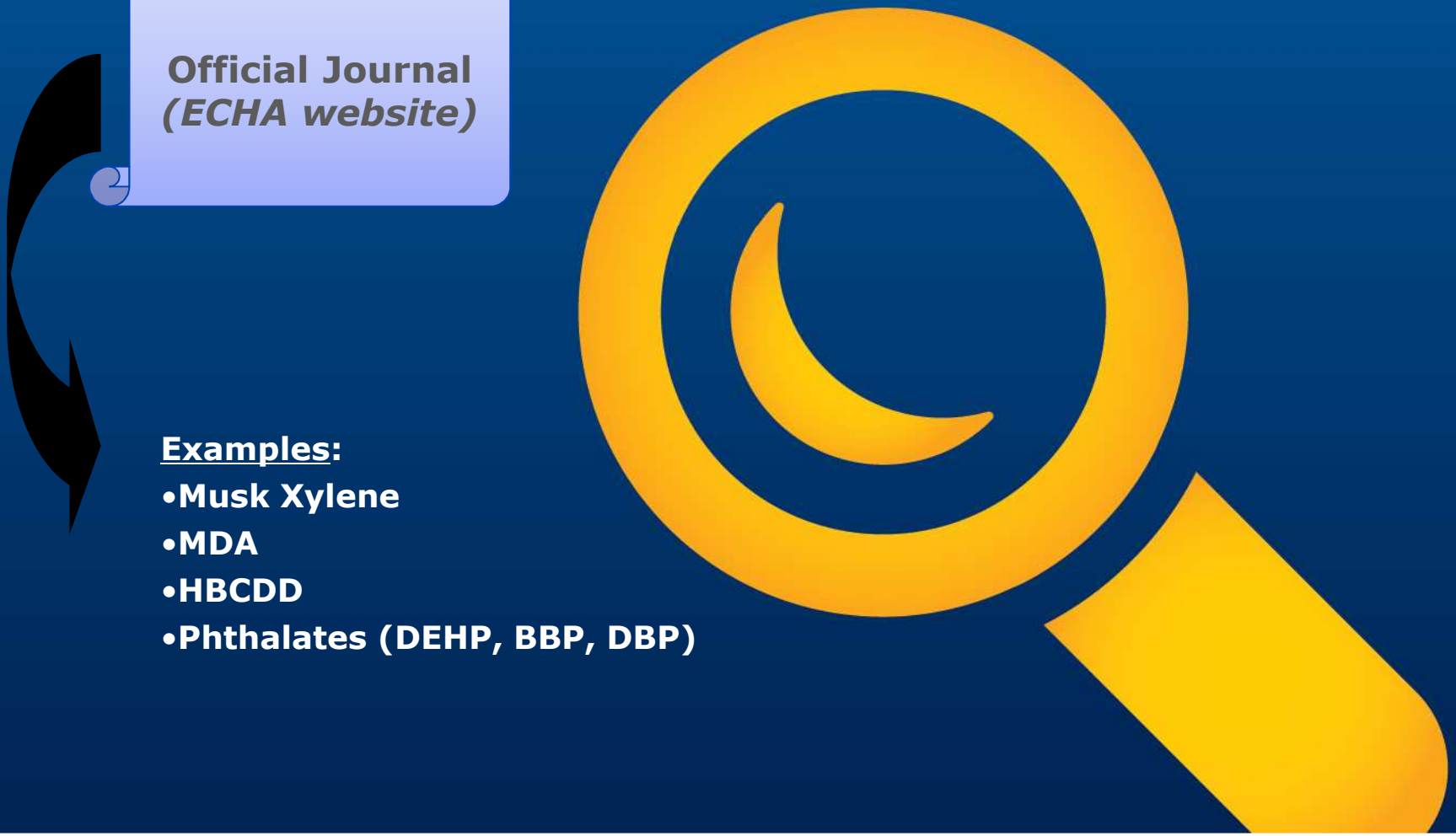
  Consequence: substance becomes subject to authorisation

  → User must apply for authorisation in order to be able to use that substance after the 'sunset date'

Step 1b: Authorisation List (Annex XIV)

14 Substances

Official Journal
(ECHA website)



Examples:

- **Musk Xylene**
- **MDA**
- **HBCDD**
- **Phthalates (DEHP, BBP, DBP)**

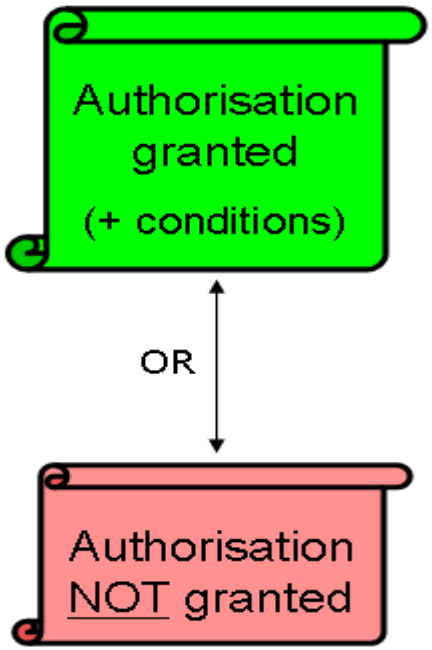
Step 1b: Annex XIV listing - implications

- After the « *sunset date* », industry is not allowed to place an Annex XIV substance on the market or use it unless industry has an authorisation granted by the Commission

- An authorisation is substance, use and supply-chain specific, but can be applied for jointly (M/I/DU(S))

Authorisation – Step 2

- Step 2: Applications for Authorisation
  Consequence: authorisation may/may not be granted



Step 2: Applications for authorisation

- An applicant can be:
  - a manufacturer,
  - an importer,
  - a downstream user,
  - any combination of these.

- An application for authorisation can be submitted:
  - for one or several uses
  - for one or a «*group of*» substance(s)

- «*an application for authorisation shall be accompanied by a fee*» (see Fee Regulation)

When will an authorisation be granted?

The Commission shall grant an authorisation if:

- **risks are adequately controlled *(« adequate control route »)***

***!**NB:* *not applicable for substances with PBT, vPvB properties and non-threshold CMRs*

The Commission may grant an authorisation if:

- **socio-economic benefits outweigh the risks**

and

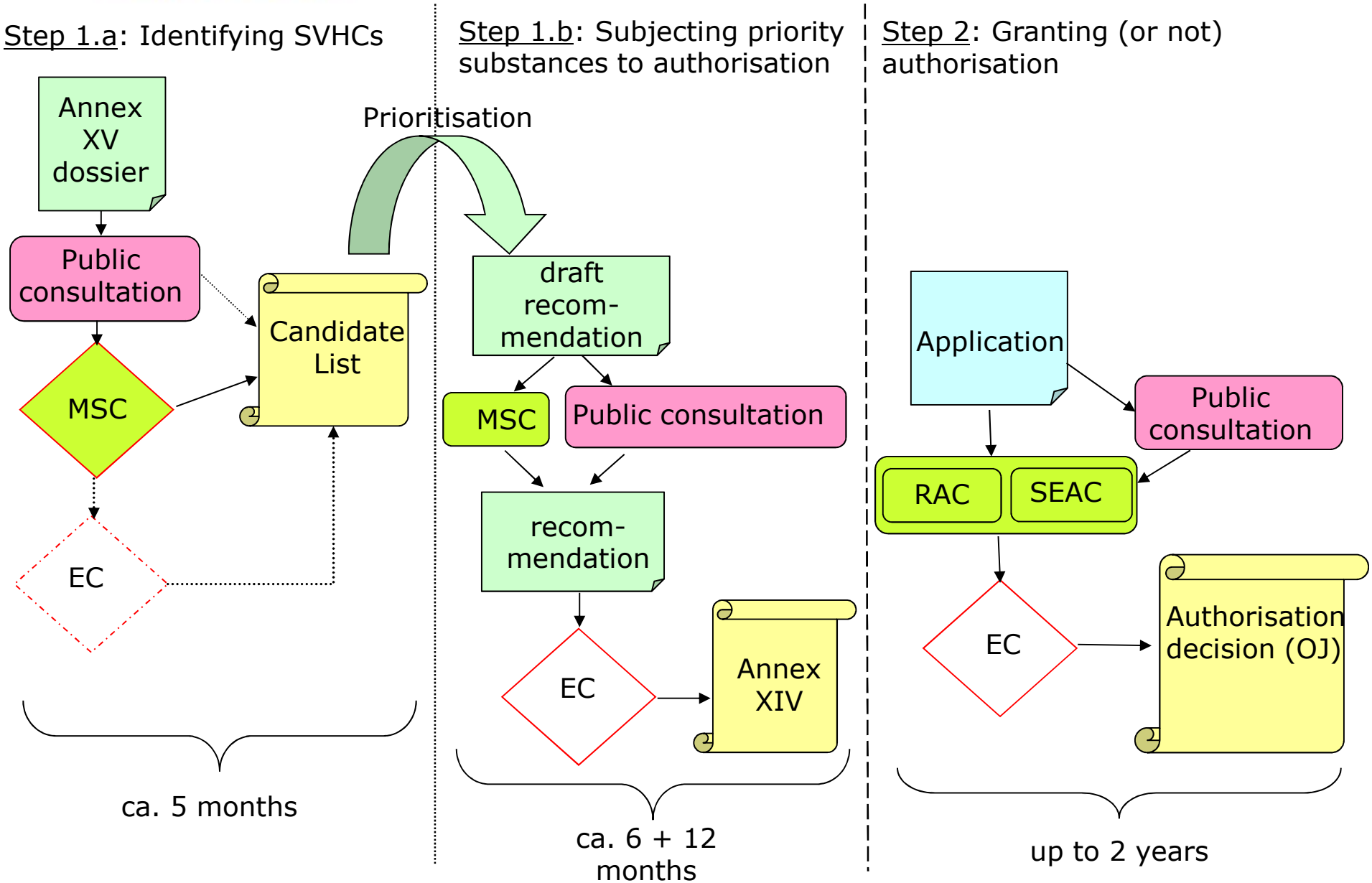
- **there are no alternatives available that (1) reduce the overall risk and (2) are technically and economically feasible for the applicant(s) *(« socio-economic route »)***

Authorisation decisions

- An authorisation is substance, use and supply-chain specific

- Commission decisions will specify:
  - the identity of the substance(s)
  - the person(s) to whom the authorisation is granted
  - the use(s) for which it is granted
  - any conditions under which it is granted, incl. any monitoring arrangement
  - a time-limited review period (case-by-case approach)

The authorisation overall procedure



Impacts of Listings

- Legal obligations:
  - Candidate List:
    - Substance in Articles Notification (Article 7(2)): EU producers and importers of articles shall notify substances in articles to ECHA
    - Communication to supply chain/consumers (Article 33)
  - Annex XIV (« *Authorisation List* »):
    - Application for authorisation for continued use
- Market forces for substitution

Further general information on authorisation

- About the process, steps and actors:
  http://www.echa.europa.eu/web/guest/**regulations/reach/authorisation**

- About the different lists, opinions/decisions, and public consultations:
  http://www.echa.europa.eu/web/guest/**addressing-chemicals-of-concern/authorisation**

- About the practical details of dossier development and submission:
  http://www.echa.europa.eu/web/guest/**support/authorisation**

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Thank you for your attention.

Restriction

Another main regulatory instrument available for authorities under REACH to manage risks to chemicals

Restrictions: aim and scope

- Ensure protection of human health and or the environment, where
  - Manufacturing, placing on the market or use causes unacceptable risk
  - These risks need to be addressed on Community-wide basis
- Ensure good functioning of the internal market

Can cover
- any substance on its own, in mixtures and/or in articles
- manufacturing of substances
- Import of articles containing substance

Main principles of restrictions

- Some general exemptions:
  - Scientific research and development
  - Risks to human health due to use in cosmetic products
  - On site isolated intermediates

- Restriction entries (Annex XVII)
  - Inherited from the Directive 76/769/EEC
  - New restrictions (amendments of existing restrictions and new entries)

Restriction procedure - 1

- Registry of Intentions (RoI)
  - MSs have to notify their intentions to prepare Annex XV restriction dossier (ECHA from the request of the Commission)
- Annex XV dossier (technical dossier and Annex XV report) submission to ECHA
  - MSs within 12 months from the notification
  - ECHA within 12 months from the request
- Conformity check
  - Legal requirement for Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) to check if the dossier conforms with the requirements

Restriction procedure - 2

- Consultation of interested parties
  - Conforming Annex XV reports on ECHA's website
  - Interested parties have 6 months to provide comments

- Developing the opinions
  - RAC has to give it's opinion in 9 months from publication – Is the suggested restriction appropriate in reducing the risk?
  - SEAC gives first draft opinion, interested parties have 2 months time to comment on the draft opinion, final opinion within 12 months – Are the costs as a result of a restrictions proportionate to the reduced risk?

Restriction procedure - 3

- Commission decision
  - Commission will have 3 months to draft its decision
  - Final decision: Comitology procedure with scrutinity involving Member States and the European Parliament

Specific restriction cases

- Carcinogenic, mutagenic and toxic to reproduction (CMR substances) category 1A and 1B used by consumers (substance as such, in mixture or in articles)
  - Commission proposes the restriction without ECHA involvement

- Annex XIV substances (authorisation list)
  - After sunset date ECHA considers if the use of the substance in articles causes risk that is not adequately controlled and prepares an Annex XV proposal

Restrictions

- All restrictions listed in Annex XVII
  - Full ban or ban on certain uses
  - Certain derogated uses
  - Specific conditions of use
  - Currently 63 entries in Annex XVII
  - New/revised entries under scrutinity and under consideration

- Obligation to:
  - Comply with any conditions set out in Annex XVII
  - Update Safety Data Sheet

Recently adopted restrictions

- Lead and its compounds in jewellery articles
- Dimethylfumarate in articles
- Mercury in measuring devices
- 4 Phenylmercury compounds
- Cadmium and its compounds

Restrictions under consideration

- Opinions submitted to the Commission
  - 4 classified phthalates in certain articles (opinions: no basis for restriction)
  - Chromium VI in leather articles

- Under consideration in ECHA/Committees
  - 1,4 -dichlorobenzene in toilet blocks
  - Lead and its compounds in consumer articles

- Notified intentions to submit a restriction dossier
  - 1-methyl-2-pyrrolidone (NMP) (April 2013)

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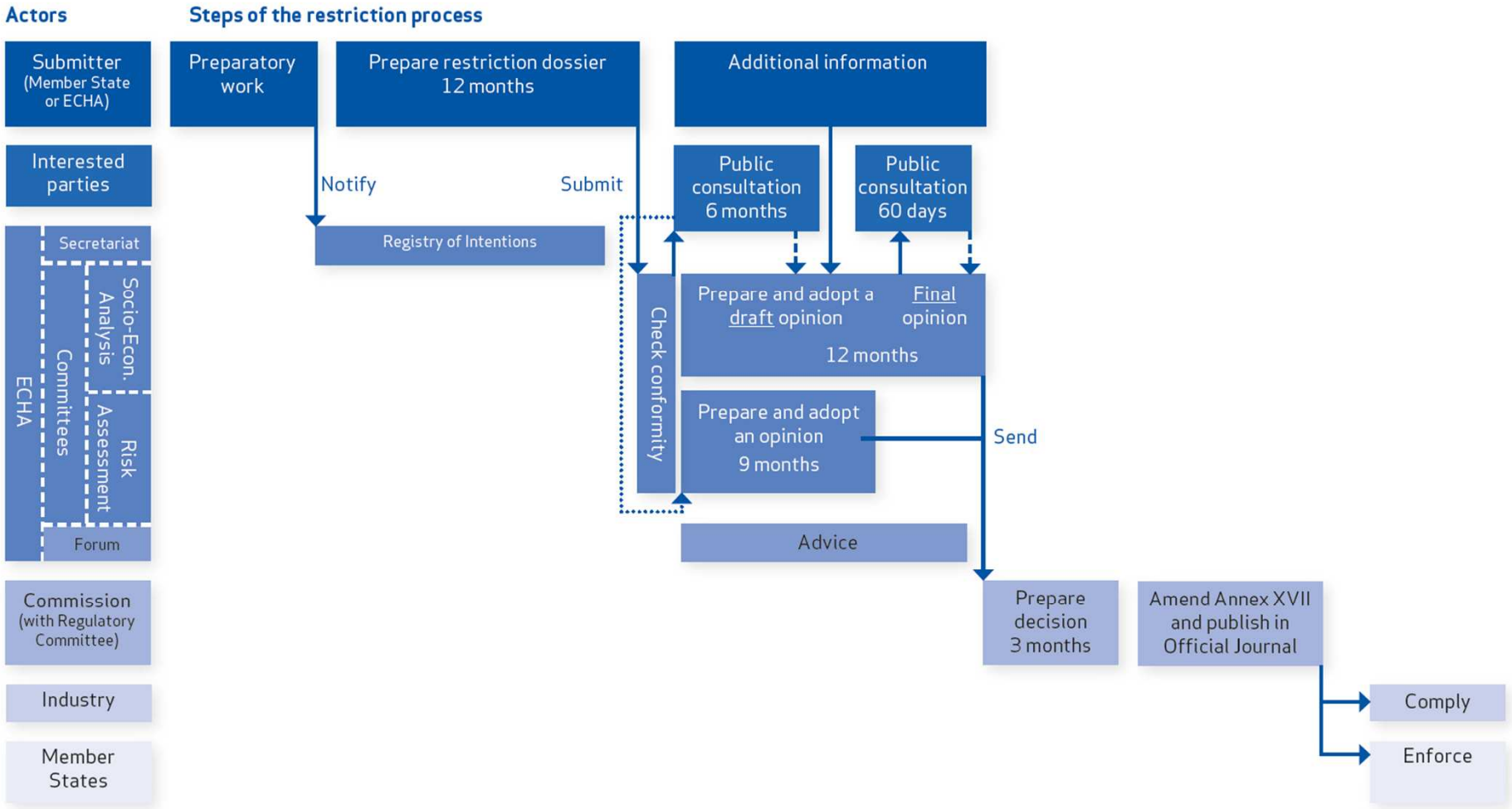
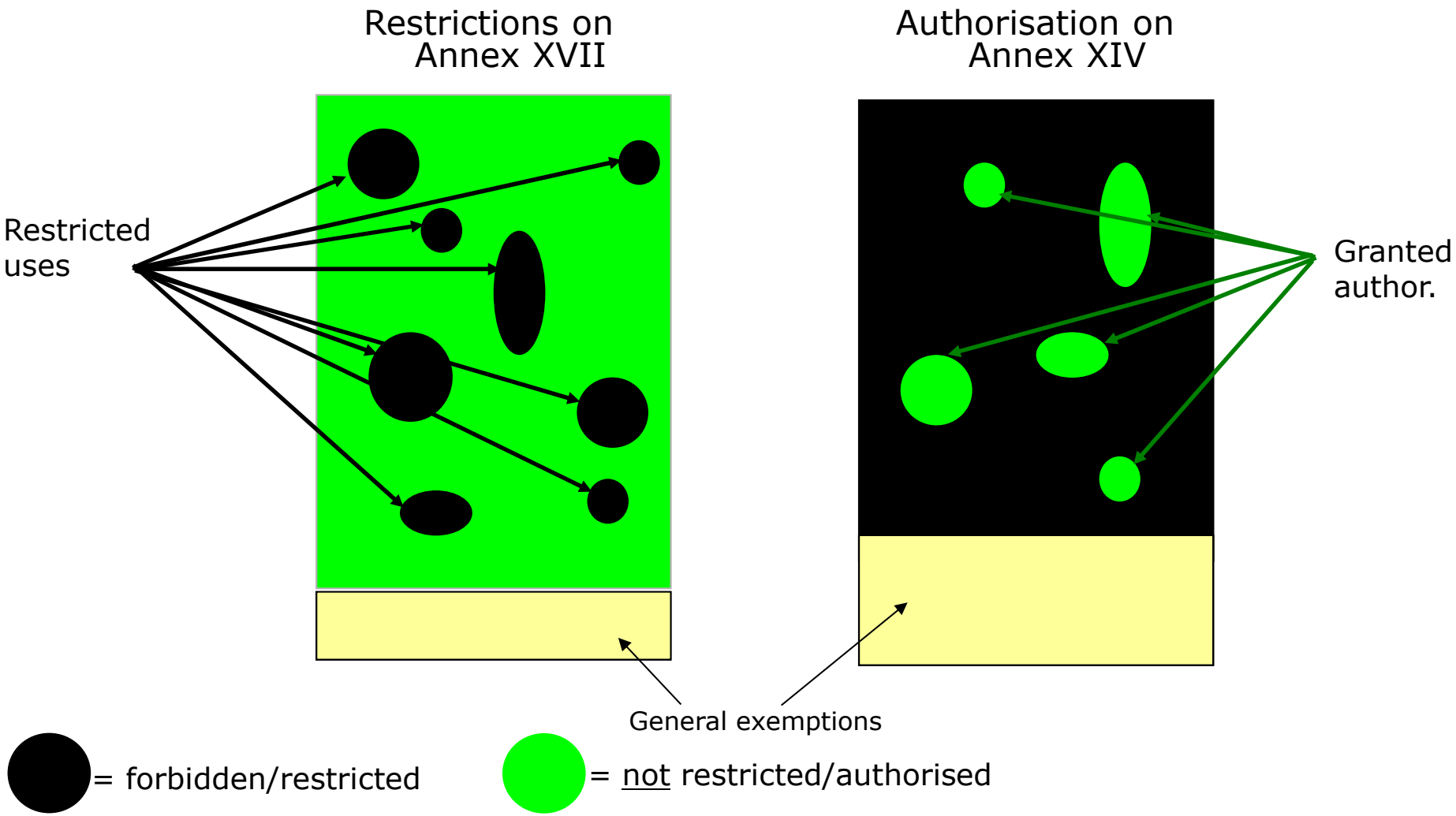


Relationship between Restrictions and Authorisation



Further general information on restrictions

- About current restriction entries (Annex XVII of REACH): http://echa.europa.eu/regulations/reach/legislation
- About the process, steps and actors: http://echa.europa.eu/web/guest/regulations/reach/restriction
- About restriction proposals, public consultations and opinions: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restriction
- About the practical details of dossier development and submission: http://echa.europa.eu/web/guest/support/restriction

Risk Management under REACH - Summary

- Chemical Safety Assessment
  - First level risk management measures at company level
- Authorisation & Restriction
  - Main regulatory instruments available for authorities under REACH to manage risk to chemicals at EU level
  - Complement each others
  - Authorisation is a complex and totally new process: we are all learning by doing!

Implications for non-EU actors

How to prepare for EU customers requirements?

Obligations for EU importers of substances on their own or mixtures

From Registration:

1. Registration requirement

From Candidate List:

2. Provision of Safety Data Sheets (SDS) to EU downstream users (Art. 31(1))

From Authorisation List (Annex XIV):

3. Authorisation requirement

From Restriction (Annex XVII):

4. Comply with existing restrictions

Effects of Restrictions (Annex XVII) on non-EU suppliers

- Substances in articles may be subject to restrictions
- Examples:
  - Cadmium content in plastic materials (entry 23)
  - Nickel in articles intended to come into direct and prolonged contact with the skin (entry 27)
  - Azocolourants in textile and leather articles (entry 43)
  - Penta- and octa-BDE in articles (entries 44-45)
  - 6 phtalates in toys and childcare articles (entries 51-52)
  - Dibutyl- and dioctyltin compounds in consumer articles (entry 20)
- Articles imported in EU shall be in line with these restrictions!

Other impacts of Candidate Listing

- Market pressure and opportunities
- « On the way to substitution »

Conclusions

Message to non-EU suppliers

- EU importers have legal obligations
  → non-EU suppliers can/should provide information to meet their needs
  → being ready to provide EU customers with the information they need/require can be a (pro-active) way to secure markets

- Market forces: EU customers may go further in their requirements (e.g. “no SVHCs in articles!”)

- Be prepared
  - Make inventories
  - Keep track of EU regulatory developments (Candidate List, Authorisation List, Restrictions – Annex XVII)
  - Consider substitution

- Actively communicate up and down the supply chain

More details

ECHA website: http://www.echa.europa.eu

- Requirements and procedures desciptions
- Access to guidance documents and ”fact sheets”
- Latest news (eg. new substances listed)
- Frequently Asked Questions/Questions and answers
- Access to ECHA Helpdesk

- Sign up for ECHA’s News Alerts (for updates of RoI, C&L Harmonisation proposals, Restriction proposals, SVHC proposals and Candidate Listing,…) http://echa.europa.eu/news_en.asp

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