Governance europea del REACH, ruolo dell'ECHA nei processi di autorizzazione e restrizione, modalità di coinvolgimento dell'industria nei processi decisionali.

Stavros Georgiou

(Consigliere economico dell'Autorità competente REACH per il Regno Unito
e membro britannico del SEAC)

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REACH
UK Competent Authority

Contents of Presentation

- ECHA: background information on its activities in respect of REACH
- ECHA: activities and regulatory processes concerning potential substances of concern
- Authorisation
- Restriction
- Consultation of industry

REACH
UK Competent Authority

ECHA: Main activities

- Manage REACH, CLP, Biocides and PIC
- Disseminate information on chemicals
- Develop scientific IT tools
- Provide regulatory assistance to industry (helpdesk and guidance)
- Support enforcement
- Advise EU institutions and Member States on chemical safety
- Assist EU's international activities (UNEP and OECD; accession countries)

REACH

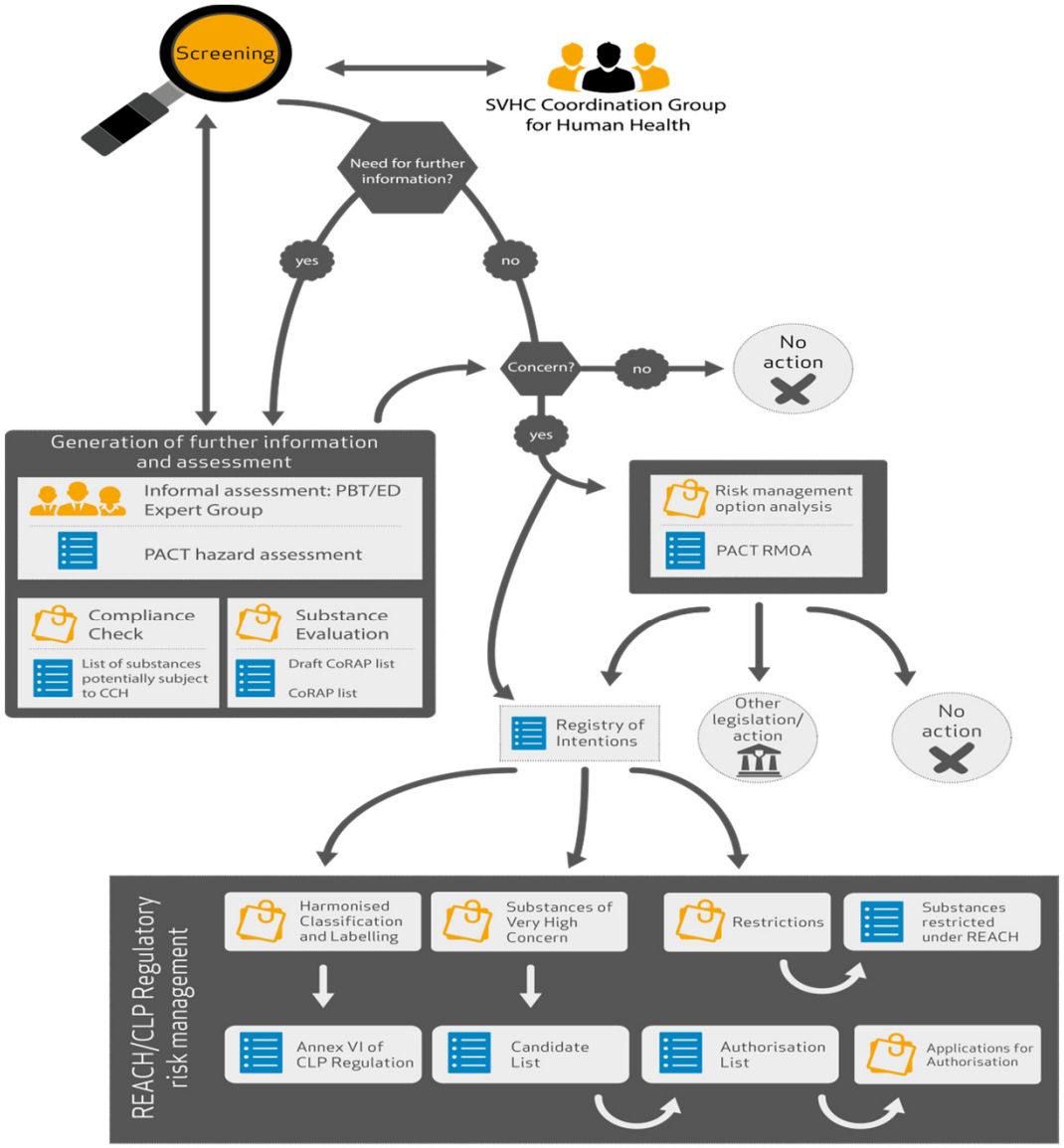
- REACH adopted in 2006
  - **R**egistration of chemicals ["substance
  - **E**valuation of selected registered sub
  - **A**uthorisation of (certain) Chemicals
  - Restriction of (certain) **Ch**emicals

- Aims of REACH
  - Ensure a high level of protection of human health and the environment
  - Promote alternatives to animal testing
  - Ensure the free circulation of substances on the internal market
  - Enhance competitiveness and innovation

Principles of REACH

- Industry responsible for safe manufacture and use
- Deal with the ‘burden of the past’ with a systemic program for registration of old chemicals
- Get adequate information on hazards while minimising the use of experimental animals and the costs
- Targeted activities by ECHA, Member States and the European Commission to get maximum effect
- Enforcement at national level

Substances of Potential Concern: Activities and Regulatory Processes



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.

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.

Key players

- Member State Competent Authorities
- ECHA
- Commission
- Member States Committee (MSC)
- Risk Assessment Committee (RAC)
- Socioeconomic Assessment Committee (SEAC)
- Industry and other stakeholders

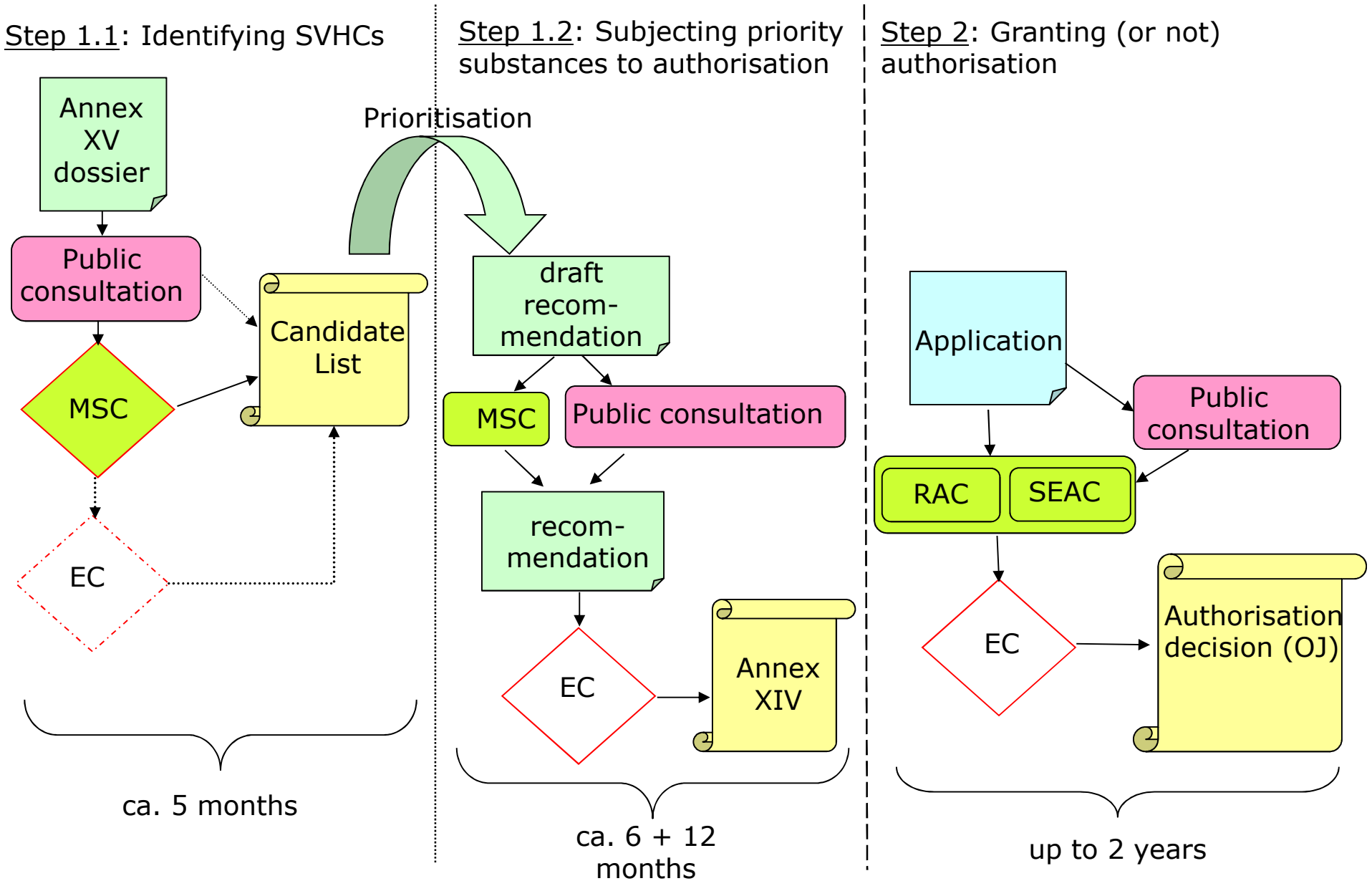
Inclusion on the Candidate List

- Member State (MS) submits dossier to ECHA.
- Accordance check (28 days).
- Annex XV dossiers released for public consultation (45 days).
- 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.

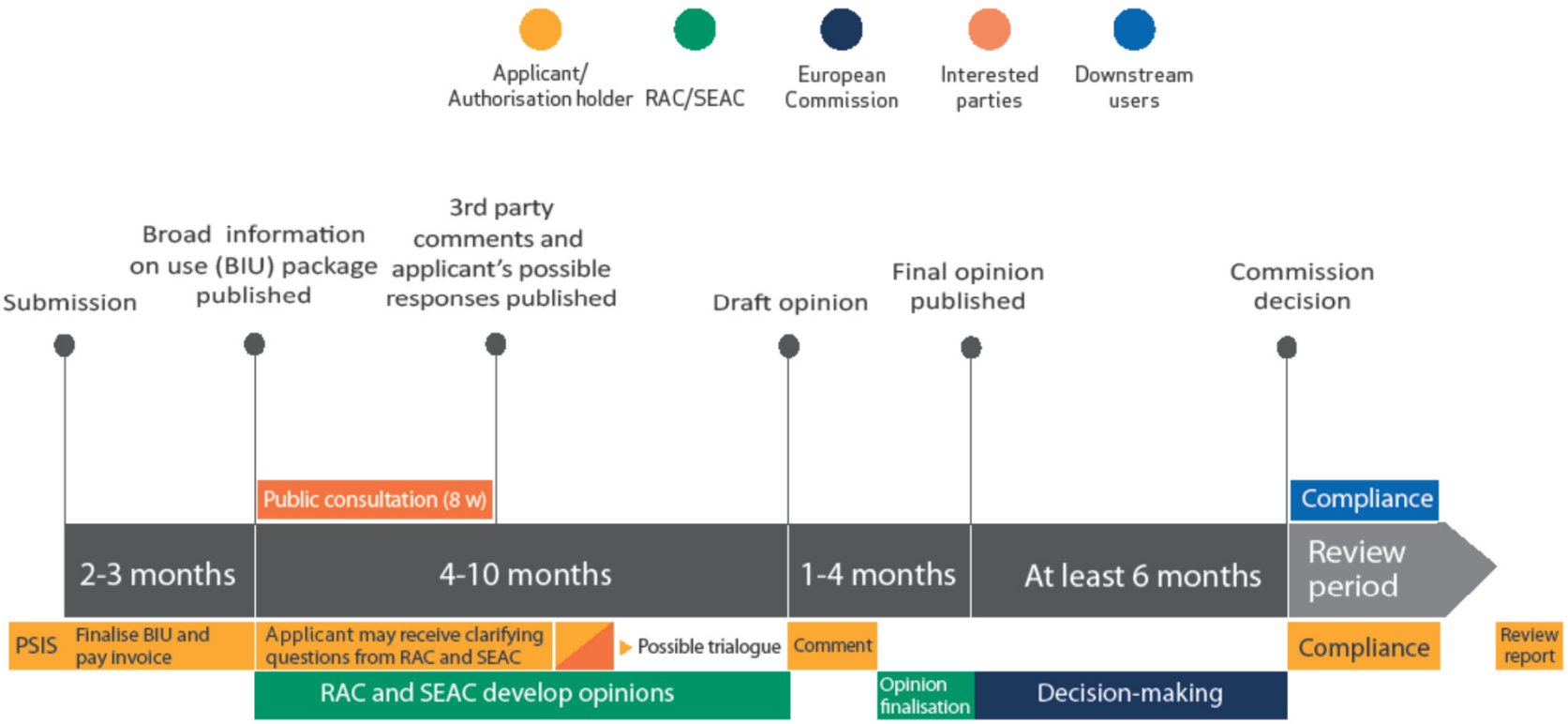
From the Candidate List to Annex XIV

- 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).
- Companies may request exemptions for uses adequately controlled under current legislation.
- Final recommendations endorsed by MSC and sent to Commission.
- Recommendations to be made at least every 2 years.
- For more details see: http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_prior_set_approach.pdf

Authorisation: Overall Procedure



Authorisation: Application procedure



REACH restriction: the framework

- Continues the work done under Directive 76/769/EEC
- A safety net:
  - authorisation/other Community actions are not more appropriate
  - other REACH processes do not ensure adequate control of risks

- Any condition for or prohibition of the manufacture, use or placing on the market:
  - an unacceptable risk to human health or the environment
  - this risk needs to be addressed on a Community-wide basis

- Restrictions may be imposed on:
  - manufacture, use and/or placing on the market
  - a substance on its own, in preparation or in an article, when there is an unacceptable risk to HH or Env that needs addressing EU wide basis

- General exemptions:
  - scientific research and development
  - risks to human health due to use in cosmetic products (dir 76/768/EEC)
  - on-site isolated intermediates

Key players

- Member State Competent Authorities
- ECHA
- Commission
- Risk Assessment Committee (RAC)
- Socioeconomic Assessment Committee (SEAC)
- Industry and other stakeholders

REACH restriction: Main steps and timelines

RMOA

Prep. work

Prepare Annex XV Restriction Dossier 12 months

Notify

Submit

Registry of Intentions

Comments 6 months

Com-ments 60 days

Check conformity

SEAC opinion 12 months

Finalise

Extend-able up to 3 months

RAC opinion 9 months

Draft amendm. 3 months

Amend Annex XVII

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 the benefits to society outweigh the risks.
- 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.

Public consultation (Authorisation)

- Identification as an SVHC
  - Provide information to MS drafting of Annex XV dossier
  - Consultation on identification as an SVHC
- Inclusion on Annex XIV
  - Consultation on priorities recommended for inclusion on Annex XIV
  - Lobby commission during discussions on Annex XIV
- Granting authorisations
  - Interested parties have the opportunity to submit information based on broad information on uses for which applications have been received
  - Lobby commission during discussions on authorisation decisions

Public consultation (Restriction)

- Provide information to MS drafting of Annex XV dossier
- During public consultation on Annex XV dossier
- Consultation on draft SEA opinion
- Lobby commission during drafting of Annex XVII

Thank You!

(Acknowledgement: ECHA - Risk Management Implementation Unit)