Current status of REACH and REACH enforcement

Shanghai Chem Summit 2012

24 October 2012

Kevin Pollard, ECHA - Head of Dossier Submission and Dissemination Unit

REACH status update
REACH进展

- **Dossier and Substance Evaluation**
- Authorisation and Restrictions
- REACH FORUM and Enforcement
  (next session)

- 卷宗和物质评估
- 授权和限制
- REACH论坛和监管
  (下一步计划)

Evaluation: overview

ECHA
EUROPEAN CHEMICALS AGENCY

MSCAs
Member State competent authorities

Dossier evaluation

- Examination of testing proposals
- Compliance check

Substance evaluation

- Examine any information on a substance

ECHA decisions requesting information, quality observation letter (for compliance check) or no further action

Follow-up of decisions

评估概要

ECHA
EUROPEAN CHEMICALS AGENCY

MSCAs
Member State competent authorities

卷宗评估

物质评估

实验方案（TP）检查

符合性审核

物质信息审核

ECHA要求提供进一步信息的决议，质量审查通知或无需进一步动作

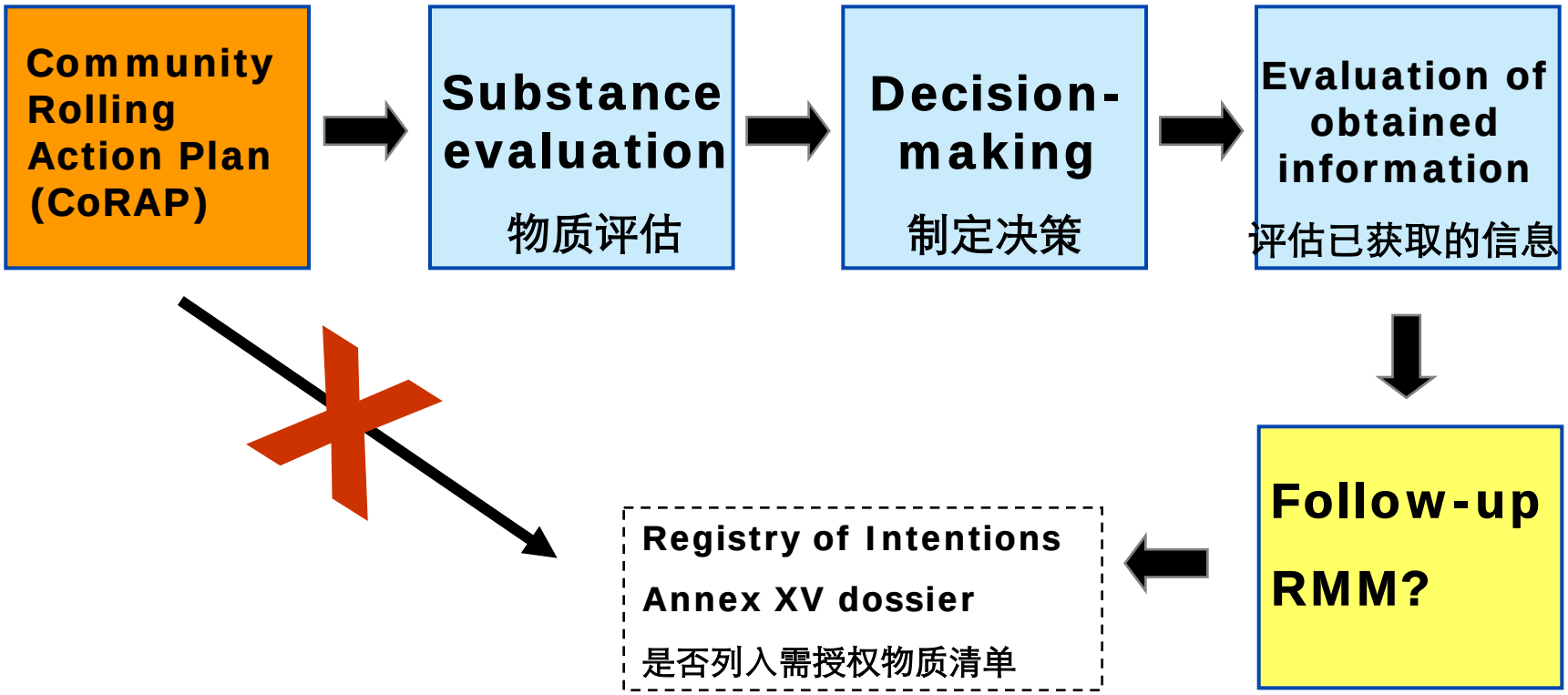
跟进决议

Key messages: Substance evaluation物质评估要点

- Substance evaluation is an important instrument to increase information on chemicals.
- Inclusion in the Community Rolling Action Plan (CoRAP) is just the start of a substance evaluation process.
- MSCAs draft the decisions and request comments and information, by February 2013 at the latest.
- The response requires coordination among registrants of the same substance.
- “What every registrant should know about substance evaluation”: webinar 5 October 2012.
- 物质评估是增加对化学物质信息了解的重要途径
- 欧盟滚动条计划CoRAP是物质评估进程的第一步
- 成员国最迟在2013年2月起草决议并要求提供评议及进一步信息
- 协调同一物质注册人之间的反馈沟通
- 2012.10.5 网络会议：每一位注册这都应该了解物质评估

Substance evaluation leads to risk management measures (RMM)

物质评估引发风险管理措施



ECHA, Commission, MSCAs use the conclusions...ECHA，委员会，成员国决议

- From **substance** evaluation (Article 48)
  - For harmonised classification and labelling
  - For identification of SVHC
  - For restrictions
- 物质评估(Article 48)
  - 统一分类和标签
  - 鉴定高关注度物质
  - 限制

Also other risk management options could be proposed under other legislation than REACH.其他危险管理措施也可通过REACH以外的法规建立

- From **dossier** evaluation (Article 42)
  - For Community Rolling Action Plan (CoRAP) substance identification
  - For identification of SVHC
  - For restrictions
  - For harmonised classification and labelling
- 卷宗评估(Article 42)
  - CoRAP物质鉴定
  - 鉴定高关注度物质
  - 限制
  - 统一分类和标签

Regulatory risk management process is not an automatic continuation. A separate intention has to be submitted.

监管风险管理过程不会自动进行，需要单独提交

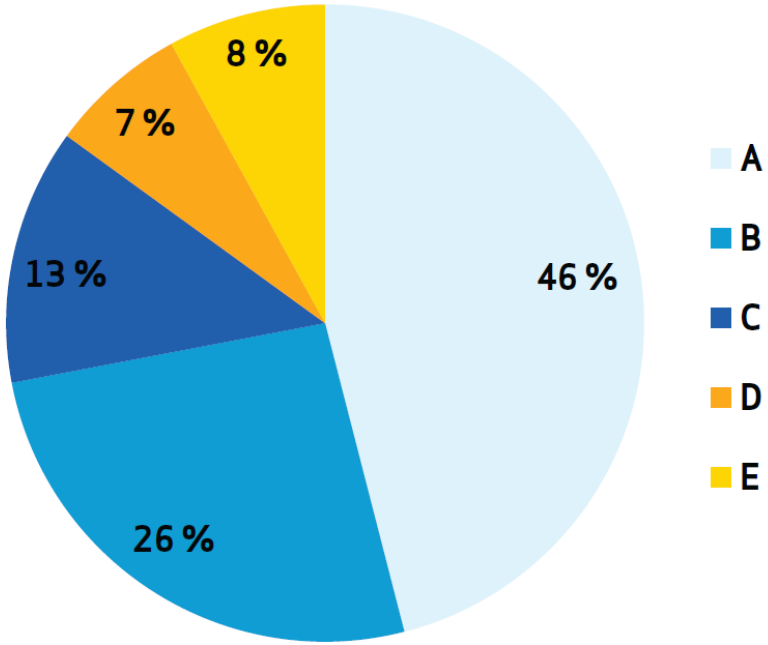
Dossier evaluation卷宗评估

- Good quality (= compliant) dossiers are needed to ensure the safe use of chemicals.
- REACH places the responsibility on companies to ensure safe use of their substances and compliance.
- Evaluation exists to support registrants in their obligation to provide adequate information on registered substances.
- The main findings of the evaluation processes are reported annually in ECHA's Evaluation Progress Reports.
- 高质量的卷宗可以确保化学品的安全使用
- REACH要求从企业层面确保物质的安全使用
- 评估可以让注册者提供更充分的物质信息
- ECHA的评估年报会对评估中主要的问题进行汇总

Evaluation Progress Report 2011

- Annual report
- On ECHA website, now available in 22 languages
- Progress in our activities
- Information on common pitfalls
- **Recommendations**
- All (existing and future) registrants are strongly advised to read this report
- 2012 report – February 2013
- 年报
- ECHA官网提供22种语言
- 行动进展
- 常见错误信息
- **建议**
- 强烈建议所有注册人及潜在注册人阅读此报告
- 2012报告-2013年2月发布

Compliance checks 2011



- The majority of dossiers checked had room for improvement: ECHA took action to notify these registrants
- Almost half of the compliance checks were on **substance identity "roadblocks"** in the course of testing proposal examination
- 大多数卷宗仍需改善：ECHA已告知注册者
- 近一半的符合性评估中，物质鉴别成为了测试方案的拦路虎

COMPLIANCE CHECKS

A	Final decision - substance identity checked for a dossier with a testing proposal;
B	Final decision - a dossier without testing proposal;
C	Quality observation letter;
D	Closed - upon dossier update after draft decision;
E	Closed - no regulatory action

Recommendations: Substance Identity

建议：物质鉴别

- Define your substance precisely and unambiguously. The identity and composition specified in the registration dossier needs to be supported by appropriate analytical information on the substance manufactured.
- Make sure that the substance identity and the test materials used in studies are representative for the registered substance.
- 在注册卷宗中，需要借以实验分析手段明确物质的识别信息及组分信息
- 确认物质同一性，测试物质需具有代表性

Recommendations: Use of Read Across
建议：采用read-across

- Justify your read across approaches with sound reasoning, scientific evidence and available experimental data.
- 通过充分的理由、科学依据和已有的实验数据阐明read across方法的合理性及有效性

Recommendations: Chemical Safety Assessment
建议：化学品安全评估

- Be thorough in completing the chemical safety assessment.
- Classify the substance according to the CLP Regulation.
- Cover all identified hazards and uses in the **exposure scenarios.**
- Demonstrate the safe use of your substances in the **chemical safety report.**
- Provide advice on the safe use of your substances and communicate it to your customers in complete **safety data sheets**.
- 详尽地开展化学品安全评估
- 依据CLP法规对物质进行分类
- **暴露场景应包含已确定的所有危害及用途**
- **化学品安全报告应提供物质的安全使用说明**
- 安全数据表中提供充分的物质安全使用建议并传递给下游

Compliance check 符合性评估

- ECHA uses compliance checks (CCH) to see if information from registrants fulfils the legal requirements.
- At least 5 % of all registration dossiers received within each tonnage band need to be checked.
- ECHA can decide which dossiers to check.
- Dossiers can be randomly selected or based on concern-driven criteria.
- Mix of approaches allows different aspects of poor quality to be addressed (e.g. all or specific aspects of a selected dossier).
- ECHA通过开展符合性评估来检查注册人申报的信息是否符合法规要求
- 各吨位级至少抽取5%的注册卷宗进行评估
- ECHA有权决定哪些卷宗需要审核
- 可随机抽取或根据关注程度选择需被核查的卷宗
- 各方法的综合使用可以全面审核低质量卷宗 （卷宗的所有部分或特定部分）

Improving dossier compliance by targeted compliance checks

通过定向的符合性评估提高卷宗质量

- Complements current compliance check activities.
- Aims at having maximum impact on safe use of chemicals.
- ECHA targets compliance checks to specific dossier issues (endpoints), where safety matters.
- Poor information on these endpoints affects safety and reliability of the chemical safety assessment.
- Rewards companies that do a good job – by addressing poorly performing companies effectively.
- The chances of poor quality dossiers being picked up for compliance check are much higher with the new approach.
- 完善现有的符合性评估进程
- 目的在于最大程度保证化学品的安全使用
- ECHA对卷宗中有关安全性的特定部分进行定向符合性评估
- 节点信息的缺失会影响CSA的可靠性
- 不合规的公司会受到ECHA惩罚，这也可视为对合规公司的奖赏
- 新方法中，低质量的卷宗更容易被选中接受符合

And how will it work?

通过定向的符合性评估提高卷宗质量

- ECHA and Member State Competent Authorities identify Areas of Concern (AoC) = dossier issues (endpoints) where safety matters.
- **IT tools** screen **all** submitted registration dossiers to identify suspicious dossiers with respect to the AoC (endpoint).
- Criteria for automatic selection for checking will include, *inter alia*:
  - i) Individual registrations outside of a joint registration;
  - ii) Dossiers where the Chemical Safety Report is missing.
- The specific endpoints in selected dossiers are then evaluated **by ECHA staff** under a REACH compliance check.
- If non-compliant, the registrant receives a compliance check decision from ECHA.
- Registrants may receive multiple decisions.
- 完善现有的符合性评估进程
- 目的在于最大程度保证化学品的安全使用
- ECHA对卷宗中有关安全性的特定部分进行定向符合性评估
- 节点信息的缺失会影响CSA的可靠性
- 不合规的公司会受到ECHA惩罚，这也可视为对合规公司的奖赏
- 新方法中，低质量的卷宗更容易被选中接受符合性评估

Take-home messages: Dossier evaluation

充分理解：卷宗评估

- Keep yourself up-to-date with Evaluation Progress Reports and act to avoid common pitfalls.
- Keep your dossiers up-to-date.
- Webinar – planned for 27 September 2012 – on how to create a compliant dossier
- Joint submission is not an option. It is a legal obligation.
- Do not wait for a draft decision – **improve your dossier now**!
- 实时关注评估进展报告，避免常规错误
- 及时更新卷宗
- 2012-9-27网络会议：主题：如何制作合规的卷宗
- 联合提交不是一种选择，而是法律义务
- 不要等到收到决议草案才行动，趁早更新卷宗

Relevant links

- Join our webinars and workshops: http://www.echa.europa.eu/en/web/guest/support/training-material/webinars
- Substance evaluation: http://www.echa.europa.eu/web/guest/regulations/reach/evaluation/substance-evaluation
- Dossier evaluation (Evaluation Progress Reports): http://www.echa.europa.eu/web/guest/regulations/reach/evaluation

REACH status update

- Introduction
- Dossier and Substance Evaluation
- **Authorisation and Restrictions**
- REACH FORUM and Enforcement

- 简介
- 卷宗和物质评估
- **授权和限制**
- REACH 论坛和监管）

Authorisation 授权

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

（REACH下主管当局管理化学品风险的主要手段之一）

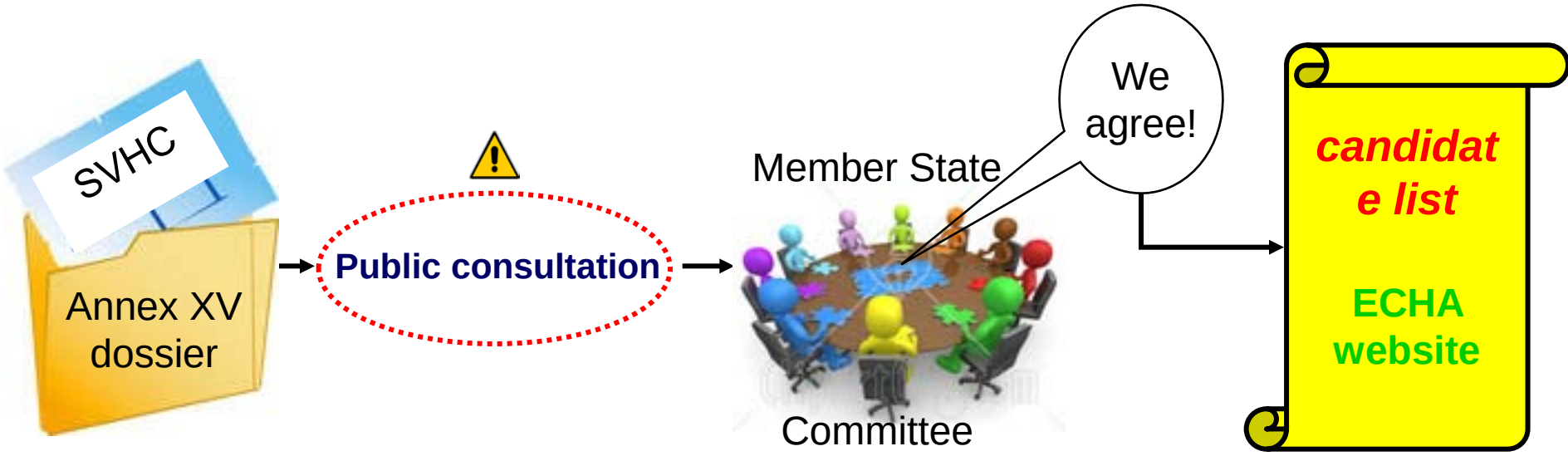
Authorisation - Aim and Scope授权-目的和范围

Substances of Very High Concern (SVHC)

- Carcinogens, mutagens, reproductive toxins (CMRs) cat 1A and 1B 致畸、致癌、致突变1A，1B类物质
- Persistent, Bioaccumulative and Toxic (PBT)持久性、生物累积性和有毒物质
- Very Persistent and Very Bioaccumulative (vPvB)高度持久、高度生物累积物质
- Substances of equivalent concern to the above与以上物质关注度相仿的物质

- Ensure risks from SVHC are properly controlled 确保合理控制SVHC物质引发的风险
- Ensure SVHCs are progressively replaced where alternatives:确保SVHCs能逐渐被取代
  - reduce the overall risk and降低整体风险
  - are economically and technically viable经济可行和技术可行
- Ensure good functioning of the internal market确保国际市场的良性运作

Step 1A – The Candidate List



http://echa.europa.eu

Authorisation – 2 step process (1a)
授权 – 分两个步骤(1a)

- Step 1a: Identification of substance as a SVHC SVHC物质的鉴定
  - Consequence: substance gets placed on the Candidate List
  - 结果：物质被列入候选物质名单
  - Public consultation - ensure that comments are well reasoned and relevant
  - 公众评议：确保评论合理且相关

Substances of Very High Concern (SVHC)

- Carcinogens, mutagens, reproductive toxins (CMRs) cat 1A and 1B CMR1A，1B类物质
- Persistent, Bioaccumulative and Toxic (PBT) PBT物质
- Very Persistent and Very Bioaccumulative (vPvB) vPvB物质
- Substances of equivalent concern to the above 与以上关注度相仿的物质

Step 1a: Candidate List 候选物质清单

138 Substances
ECHA website
ECHA目前公布138种物质

例如：

- Phthalates（邻苯二甲酸盐）
- Arsenates（砷酸盐）
- Cobalt compounds（钴化合物）
- Pigments（染料）
- (Di)chromates（重铬酸盐）

Step 1a: Candidate List – Implications

Step 1a: 候选清单 – 补充信息

- Directly after inclusion in the Candidate List:进入候选名单后：
  - Suppliers of the substance:物质供应商

    → provide their customers with a safety data sheet 提供用户SDS
  - Suppliers of articles containing the substance: 物品供应商

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

    主动提供，或应用户要求在45天内提供物品安全使用信息
- Six months after the inclusion:进入候选名单后六个月：
  - Producers/importers of articles have to notify ECHA if their article contains a substance on the Candidate List

    物品的生产商/进口商需告知ECHA物品中是否含有清单上的物质

http://echa.europa.eu

The Candidate List – State of Play (1/2)

候选清单 – 进展情况(1/2)

- First substances included in Oct 2008
- 2008年10月第一批物质进入清单目录
- Two updates per year (June and December)每年6月和12月更新
- Now 138 substances 目前共138种物质

(http://echa.europa.eu/web/guest/candidate-list-table)

The Candidate List – State of Play (2/2)
候选清单 – 进展情况(2/2)

- To get an indication of the potential new substances to be included in the Candidate List, follow the Registry of Intentions
- 通过注册意向，可获得可能被列入名单的潜在物质

- (http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions)'

Step 1B – Prioritising substances for authorisation

candidate list

ECHA website

→ Prioritisation (ECHA) →

Annex XIV recom-mendation (ECHA)

→ Decision (Commission) =

Annex XIV (“authorisation list”)

Official Journal

opinion

Public consultation

MSC

http://echa.europa.eu

Authorisation – 2 step process
授权 – 分两个步骤

- Step 1b: SVHC substance on Candidate List gets prioritised to placed on Authorisation List (Annex XIV to REACH)候选名单上的SVHC物质优先列入授权物质清单，即附件XIV
  - Consequence: substance becomes subject to authorisation结果：物质需要申请授权

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

在'日落时间'后如要使用名单上的物质必须申请授权）

Step 1b: Authorisation List授权物质清单 (Annex XIV)

Examples: （举例）

- HBCDD（六溴环十二烷）
- Phthalates (DEHP, BBP, DBP)（邻苯二甲酸盐）
- TCEP（磷酸三（β-氯乙基)酯）
- Diarsenic compounds(三氧化二砷化合物)
- Lead compounds（铅化合物）

Step 1b: Annex XIV listing – implications

补充信息

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

Some uses are exempted
- by Titles I and VII in REACH (general exemptions) or
- through Annex XIV substance-specific entries (specific exemptions)

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

- ‘日落时间’后，未经欧盟委员会批准和授权，附加XIV中的物质不允许在市场上流通）

某些用途被豁免
- 附件法规中I至VII所列的常规豁免
- 附件XIV中的特殊豁免

- 授权工作依物质，用途及特定供应链开展，但是生产商/进口商/下游用户/OR可联合申请

http://echa.europa.eu

The Authorisation List – state of play

授权物质清单 – 进展情况

- The current list contains 14 substances (6 substances included in Feb 2011 and 8 substances in Feb 2012)
- ECHA's 3rd recommendation (submitted to COM in Dec 2011)
  - 7 chromium substances
  - 5 cobalt substance
  - Trichloroethylene
- A new recommendation (and update of Annex XIV) is currently foreseen once a year
- 目前的清单包括14种物质，其中2011年2月提交了6种，2012年2月提交了8种
- ECHA在2011年12月向COM提交第三批建议列入清单的物质
  - 7种铬类物质
  - 5种钴类物质
  - 三氯乙烯
- 预计建议列入清单和附件XIV的更新将每年进行一次

(Recommendations: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list
and
Annex XIV: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

Step 2: Authorisation Application 授权的申请

Authorisation granted

(+ conditions)

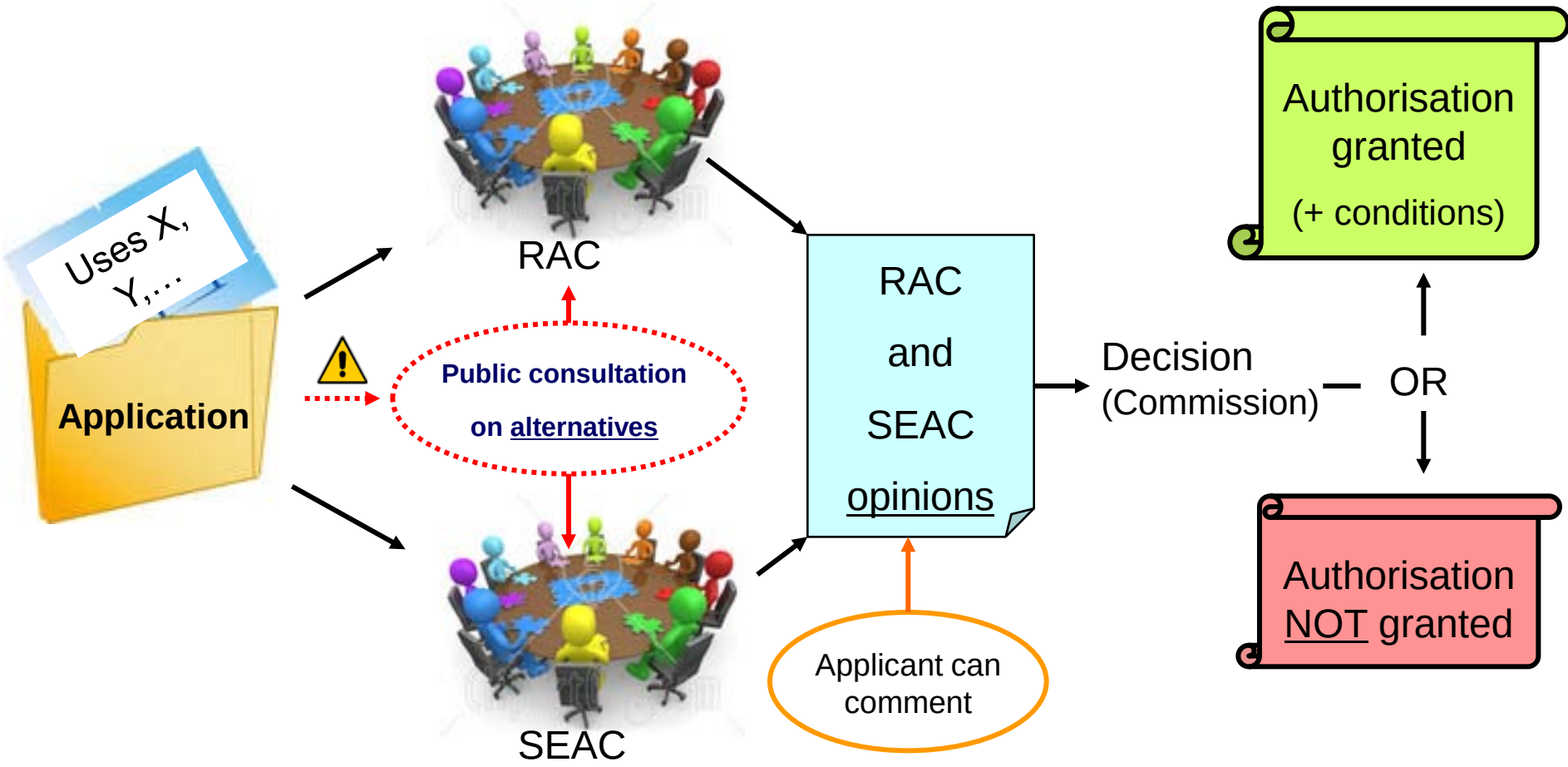
有条件的批准授权

OR

Authorisation NOT granted

授权不予批准

Step 2 – Authorisation applications - Procedure

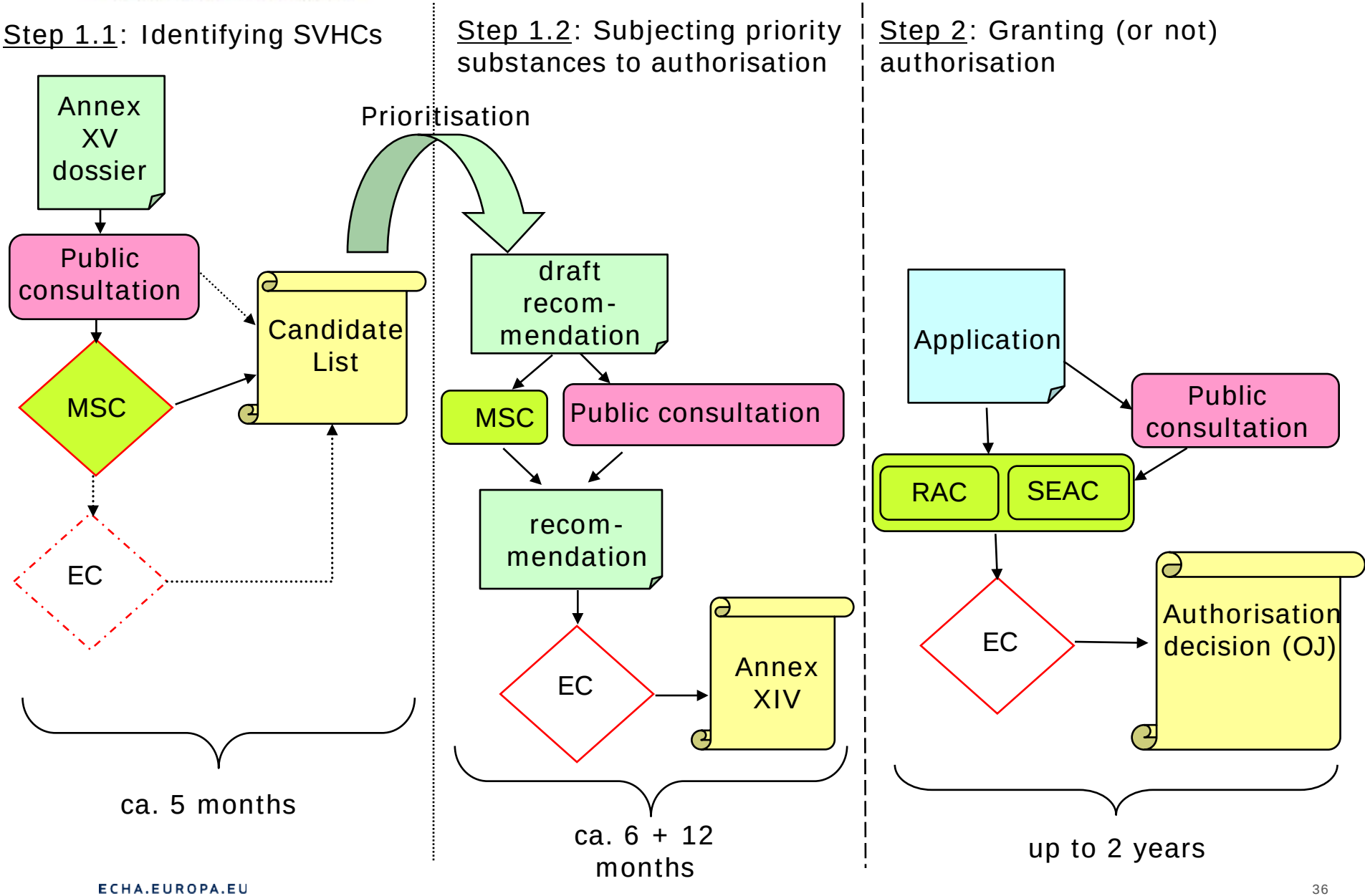


http://echa.europa.eu

Step 2: Applications for authorisation授权申请

- An applicant can be:
  - a manufacturer,
  - an importer,
  - an only representative
  - 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)
- 申请人必须是:
  - 生产商
  - 进口商
  - 唯一代表（OR）
  - 下游用户
  - 以上角色任意组合
- 授权申请可以提交:
  - 一种或多种用途
  - 一种或一组物质
- 授权申请费，详见Fee Regulation

The authorisation overall procedure



Restriction限制

Other main regulatory instruments available for authorities under REACH to manage risk to chemicals

（REACH下主管当局管理化学品风险的其他主要手段）

Restrictions: aim and scope限制：目的和范围

- 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
- 确保环境与人类健康
  - 生产，销售或使用中产生的不被接受的风险
  - 需在委员会基础上处理这些风险
- 确保国际市场的良性运作

Can cover
- any substance on its own, in mixtures and/or in articles
- manufacturing of substances
- Import of articles containing substance
- 物质本身，混合物或物品中的物质
- 物质的制造生产
- 进口包含这些物质的物品

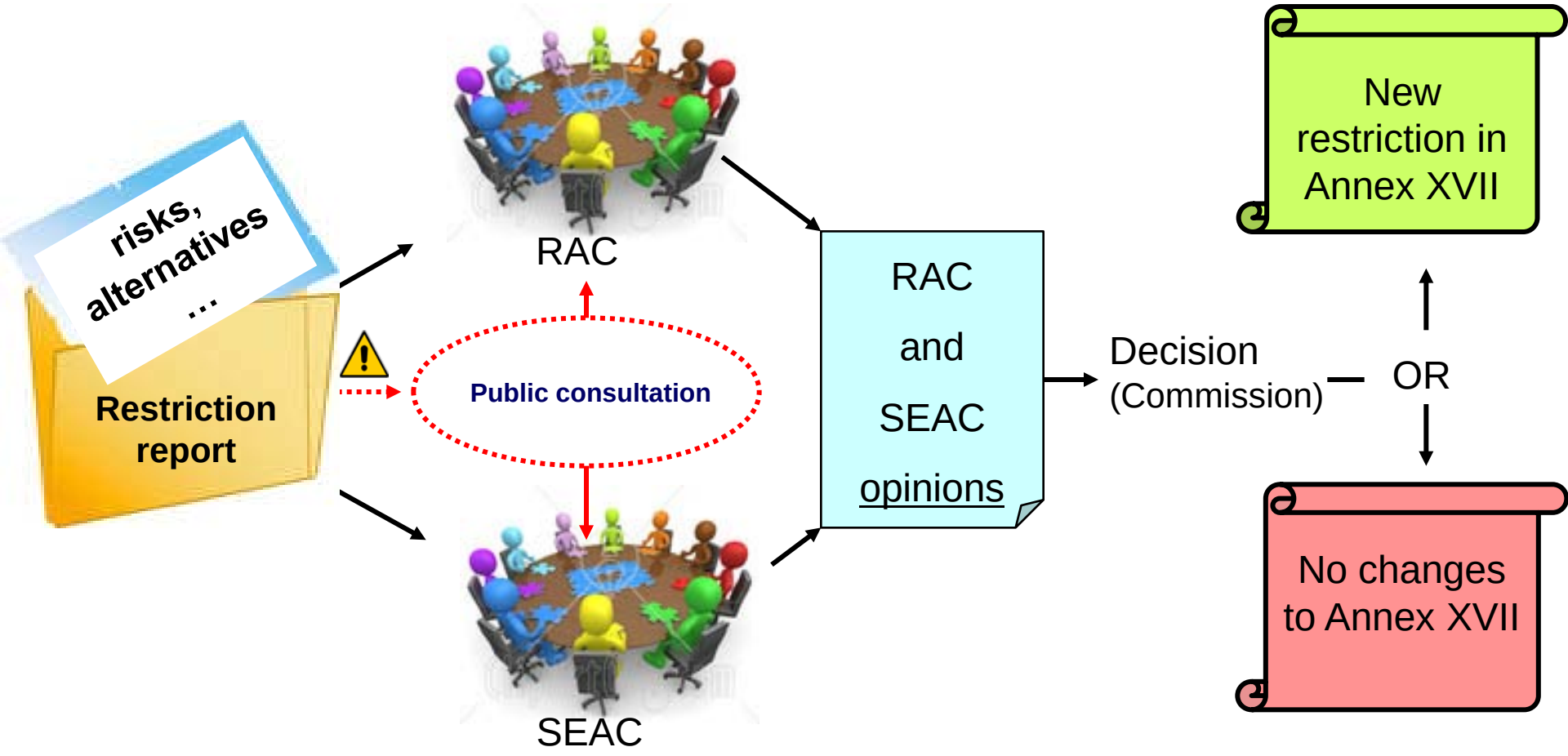
http://echa.europa.eu

Restrictions限制

- All restrictions listed in Annex XVII (currently 60+ entries)
  - Full ban or ban on certain uses
  - Certain derogated uses
  - Specific conditions of use
- Obligation to:
  - comply with any conditions set out in Annex XVII
  - Update Safety Data Sheet
- 附件XVII中的限制名单（目前有60多种物质）
  - 所有用途或某些用途被禁止
  - 某些限制用途
  - 特定条件下的用途
- 义务：
  - 符合附件XVII中的条件要求）
  - SDS更新

http://echa.europa.eu

Restrictions - Procedure



http://echa.europa.eu

- **ECHA Website**

  http://www.echa.europa.eu

- **Candidate List and Annex XIV**

  http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation

- **Restrictions**

  http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/restriction

http://echa.europa.eu

REACH status update REACH 进展

- Introduction
- Dossier and Substance Evaluation
- Authorisation and Restrictions
- **REACH FORUM and Enforcement**
- 简介
- 卷宗和物质评估
- 授权和限制
- REACH论坛和执行

See next ECHA presentation

Thank you.

Kevin Pollard