REACH: registration, evaluation & risk management update

The Latest Trends in the EU Chemicals Management: REACH, CLP & BPR

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Outline

- European Chemicals Agency
- Registration
- Supply chain communication
- Risk Management
  - Authorisation
  - Restrictions
  - Substances in articles

ECHA – six years old and growing

- Started on 1 June 2007
- Over 500 staff from 27 countries
- Originally REACH
- Since 2009 Classification and Labelling
- Now also Biocides and Import & Export Regulation

Our mission

Driving force in implementing EU's chemicals legislation for the benefit of human health and the environment as well as competitiveness and innovation

- Help companies to comply
- Advance the safe use of chemicals
- Provide information on chemicals
- Address substances of concern

ECHA's international activities

- Collaboration on **harmonising** chemical management tools and approaches beneficial for authorities and industry
  - **OECD**-related work: e.g. IUCLID, QSAR toolbox, eChemPortal
  - Cooperation with **peer regulatory authorities**: Australia, Canada, Japan & the USA
  - Support to European Commission **multilateral work** e.g. UN Conventions
  - **Awareness raising** on requirements and how to comply in 3rd countries
  - Support to EU **candidate countries**
  - **Presentations** to authorities & industry in third countries

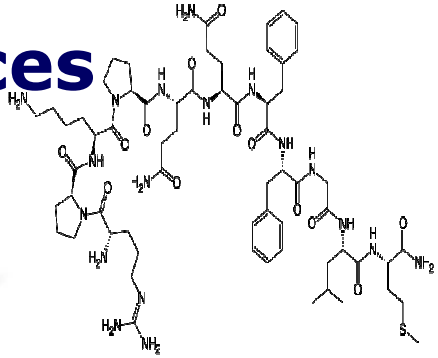
REACH – What it's all about

- Companies to prove safe use of chemicals by **Registration**
- Authorities to **Evaluate** registrations to ensure compliance
- **Risk Management** of most hazardous substances through Authorisation that promotes substitution and prohibition of risky uses through Restrictions

➢ **Safety, Competitiveness & Innovation**

What to register

- Registration only concern **Substances**
  - **… not preparations** and **articles**



- Substances over 1 ton/year
- By EU manufacturers or importers
  - Non-EU manufacturers can nominate an Only Representative

REACH Registration deadlines

Substance Identity

- **Unambiguous** identification is a pre-requisite to most of the REACH processes
- Companies must have **sufficient** information on the identity of their substance
- **Correct** identification enables:
  - Sharing of information
  - Assessment of the applicability of test data, read-across proposals

SIEF agreement (1/2)

- REACH legal requirements
  - Cooperation & communication in the SIEF
  - Data sharing (Ownership of data)
  - Cost compensation (Agreement on cost sharing)
  - Joint submission (except opt-out claim) (Liability)
- Varying number of SIEF participants
- All SIEF participants not familiar with REACH requirements > uncertainty
- SIEF Operating rules are strongly recommended

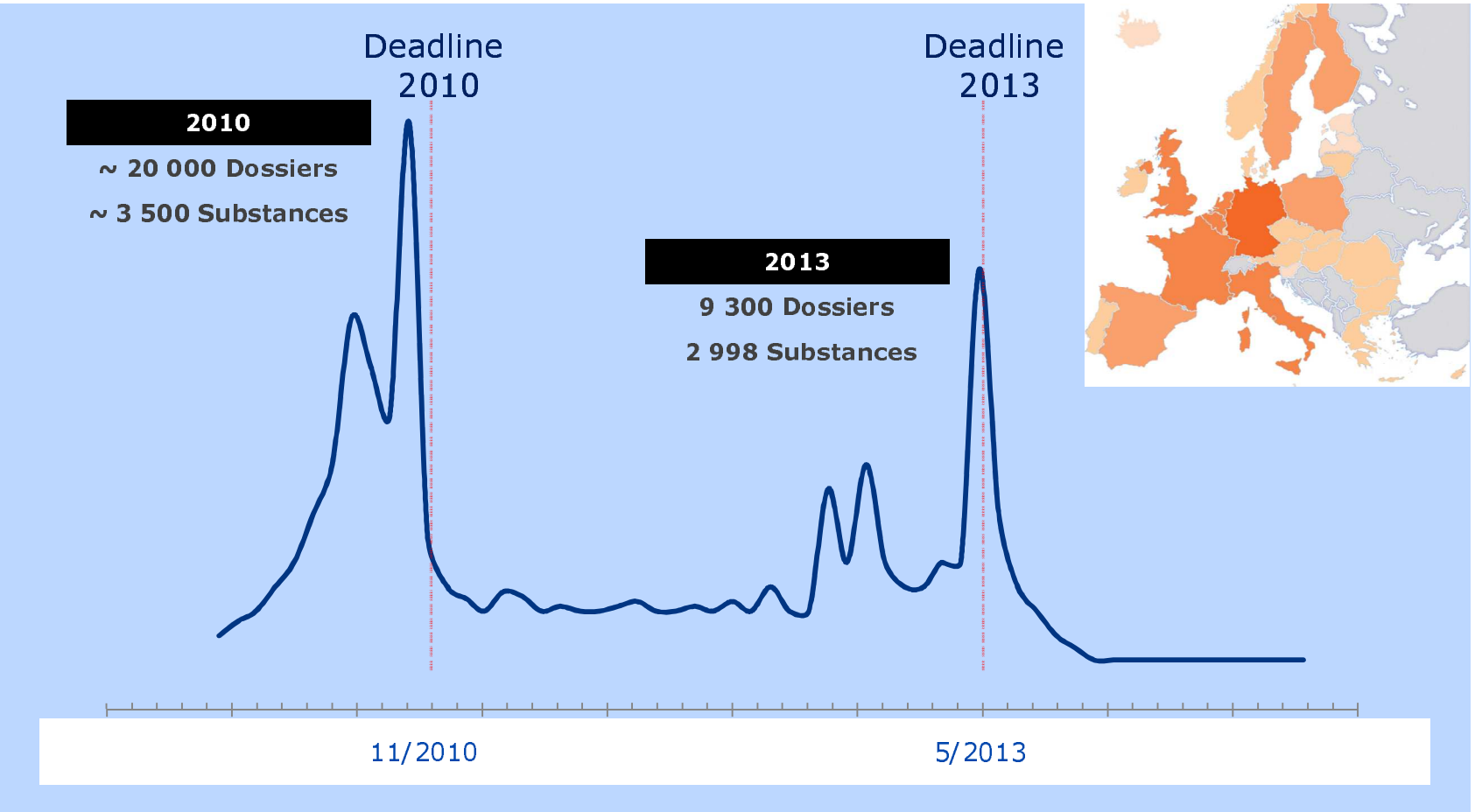
Data sharing

- ECHA has a limited remit regarding data sharing
  - Assists registrants involved in "disputes"
  - Promotes best practice

2010/13 findings

- Data sharing provisions **presented some challenges**
- Around **80%** of the registrations submitted jointly
- The complexity of **substance identification**

Registration milestones



Registration dossiers – overview

	Received	Forecast
Grand total	9 084	~9 300

Registration type	
Standard registrations (all uses)	7 232
Registrations for intermediate uses only	1 798

- Intermediate use: limited data requirements
  - Specific conditions
  - Critical to ensure safe use
- Verification by ECHA

Company Size

Company size	%
Registered by a large company	80%
Registered by an SME	**19**%
Medium company	11%
Small company	5.5%
Micro company	2.5%

Company Type

Role in the supply chain	%
Manufacturer	40%
Manufacturer and importer	12%
Importer	25%
Only Representative of a non-EU manufacturer	23%

Non-EU companies can export to the European Union through two different routes under REACH: either via an importer who has registered the substance, or by appointing an Only Representative.

Registration Status

- **Two registration deadlines** passed – 2010 - 2013
  - ~7,400 substances registered; ~40,000 dossiers
  - Substances over 100 tpa; most hazardous over 1 tpa
- More than 100,000 substances in the C&L inventory
- Information published on ECHA website
- Eurostat study 5-year update revealed a "*marked increase in quality of data & better control of risk*"
- **From that perspective REACH is delivering**

Registration findings

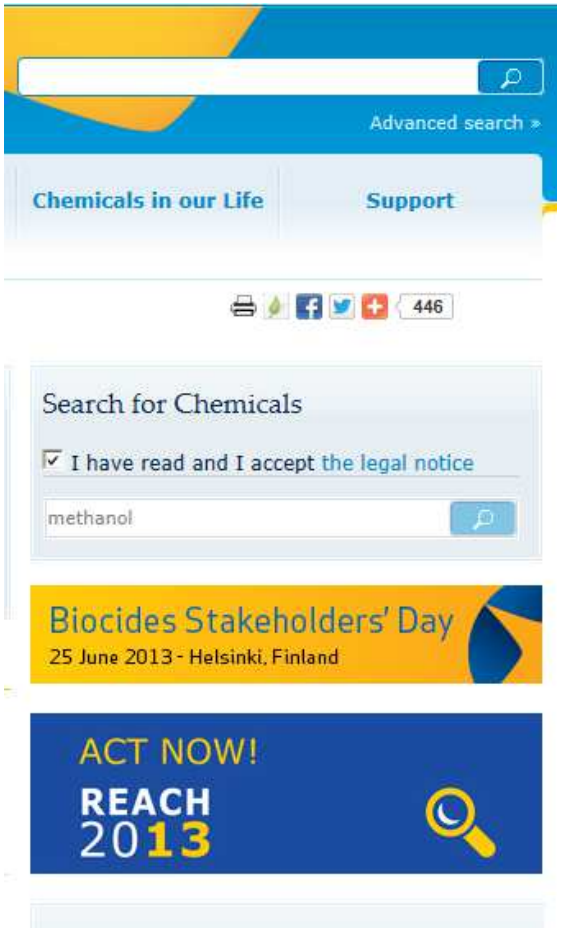
- **Timelines** very challenging but achievable
- **Collaboration** of authorities and industry before the deadline important in achieving a successful result
- The **one substance one registration** concept generally worked well
- **IT systems** critical for functioning of the system

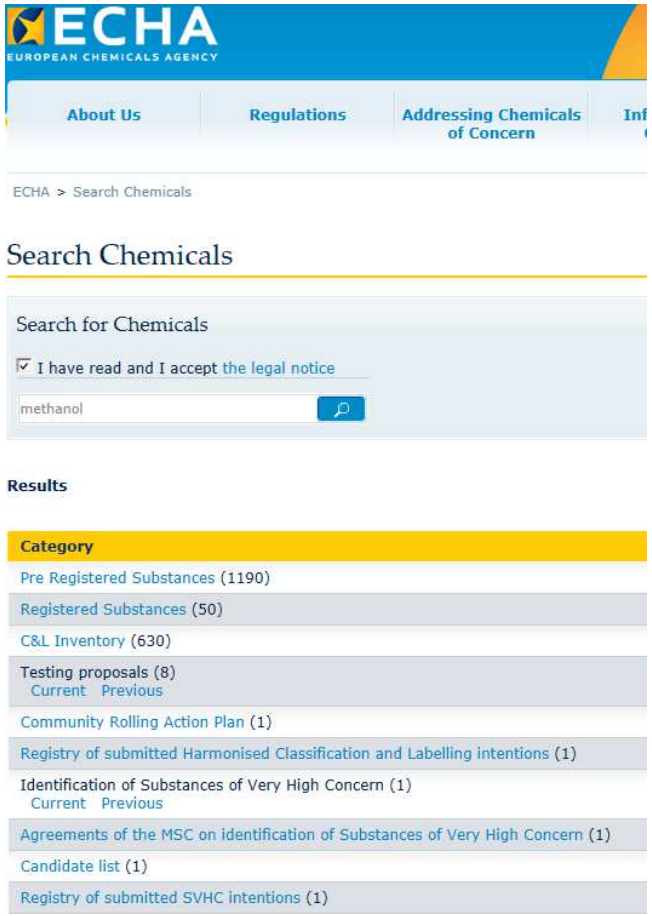
Dissemination

- Information
  - owned by the registrants
  - identical as in registration dossiers
  - Confidential Business Information removed
- Information now available online
  - Over 8,000 substances

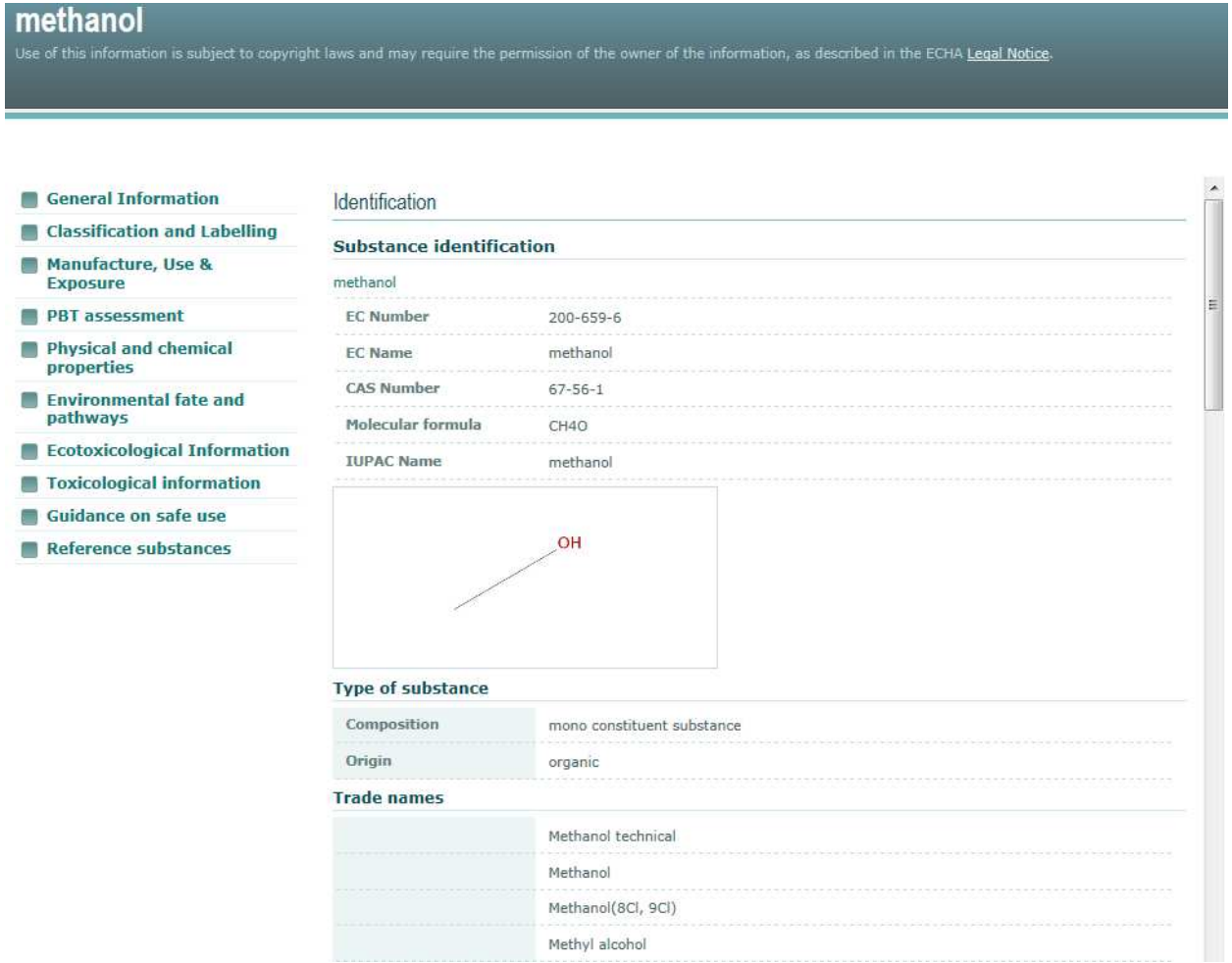
Always published
(a) **name in the IUPAC nomenclature**
(b) **name as given in EINECS**
(c) **classification and labelling**
(d) **physicochemical data**
(e) **toxicological and ecotoxicological data**
(f) **derived no-effect level** (DNEL) or **predicted no-effect concentration** (PNEC)
(g) **guidance on safe use**
(h) **analytical methods**

Search substances on ECHA home page





Dissemination of information



methanol

- General Information
- Classification and Labelling
- Manufacture, Use & Exposure
- PBT assessment
- Physical and chemical properties
- Environmental fate and pathways
- Ecotoxicological Information
- Toxicological information
- Guidance on safe use
- Reference substances

Identification

Substance identification

methanol

EC Number	200-659-6
EC Name	methanol
CAS Number	67-56-1
Molecular formula	CH4O
IUPAC Name	methanol

Type of substance

Composition	mono constituent substance
Origin	organic

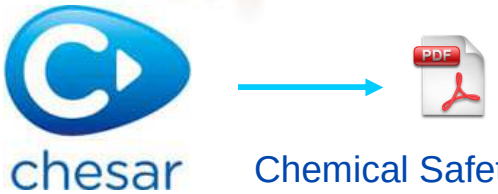
Trade names

	Methanol technical
	Methanol
	Methanol(8CI, 9CI)
	Methyl alcohol

Tips for 2018

- Registration is a big but manageable task
  - Thousands of companies have already done it
- Check if your substance is already registered
  - **Already registered:** contact the lead registrant to verify substance sameness, make the SIEF agreement and to obtain your REACH-IT member token
  - **Not yet registered:** contact (pre)SIEF to establish sameness and agree on a lead registrant
- Substance Identity
  - **Unambiguous** identification is a pre-requisite to most of the REACH processes

Preparing the registration dossier



- Dossier in **IUCLID** 5 format for substances at 1 t.p.a. submitted using **REACH-IT**
- Standard **information linked to tonnage**
- **Chemical Safety Report** for substances ≥ 10 t.p.a.
- Use the **support tools** (Plug-ins) before submitting your dossier
  - TCC, Dossier Quality Assistant …

Only Representatives – Concept

- A **non-EU manufacturer can appoint** an Only Representative to carry out the registration obligations of the importers
- Non-EU manufacturer then **needs to inform all importers** about the Only Representative
- Only Representative can be any legal entity **established in the EU** with **sufficient skills & knowledge**
- A non-EU manufacturer can only **appoint one** Only Representative per substance

Only Representatives – Responsibilities

Need to:

- **comply with** all obligations of importers under REACH (pre-registration, data-sharing,…)
- **keep up-to-date information** on EU importers and the quantities imported which are covered by the registration
- cover in the dossier **all uses** of the substance by the importers included in the registration
- If an **OR represents different** non-EU **manufacturers**, separate registrations are needed (trough separate accounts in REACH-IT)

What happens after registration?

- ECHA
  - **Verify confidentiality claims**
  - **examine proposals for new tests** on the 2013 substances by 1 June 2016
  - **check compliance** of at least 5% of dossiers per tonnage band (target end 2016)
- Member States: **substance evaluation**
- Screening for authorisation/restriction as part of **2020 Roadmap**
- **Enforcement**: no registration, no market

Requirement to spontaneously updates

- Change in substance status
- Changes in tonnage band
- Change from intermediate to “normal” registration
- Change in composition
- New identified uses/uses advised against
- New knowledge on risks
- Change in classification and labelling
- CSR/Safe Use amendments
- Testing proposal needed

Evaluation

1. Provide **confidence** that industry is meeting obligations
2. **Prevent** unnecessary animal testing
3. Build up information basis for eventual **risk management** measures at EU level

REACH - Evaluation

Member States

Dossier evaluation

Substance evaluation

Testing proposal examination

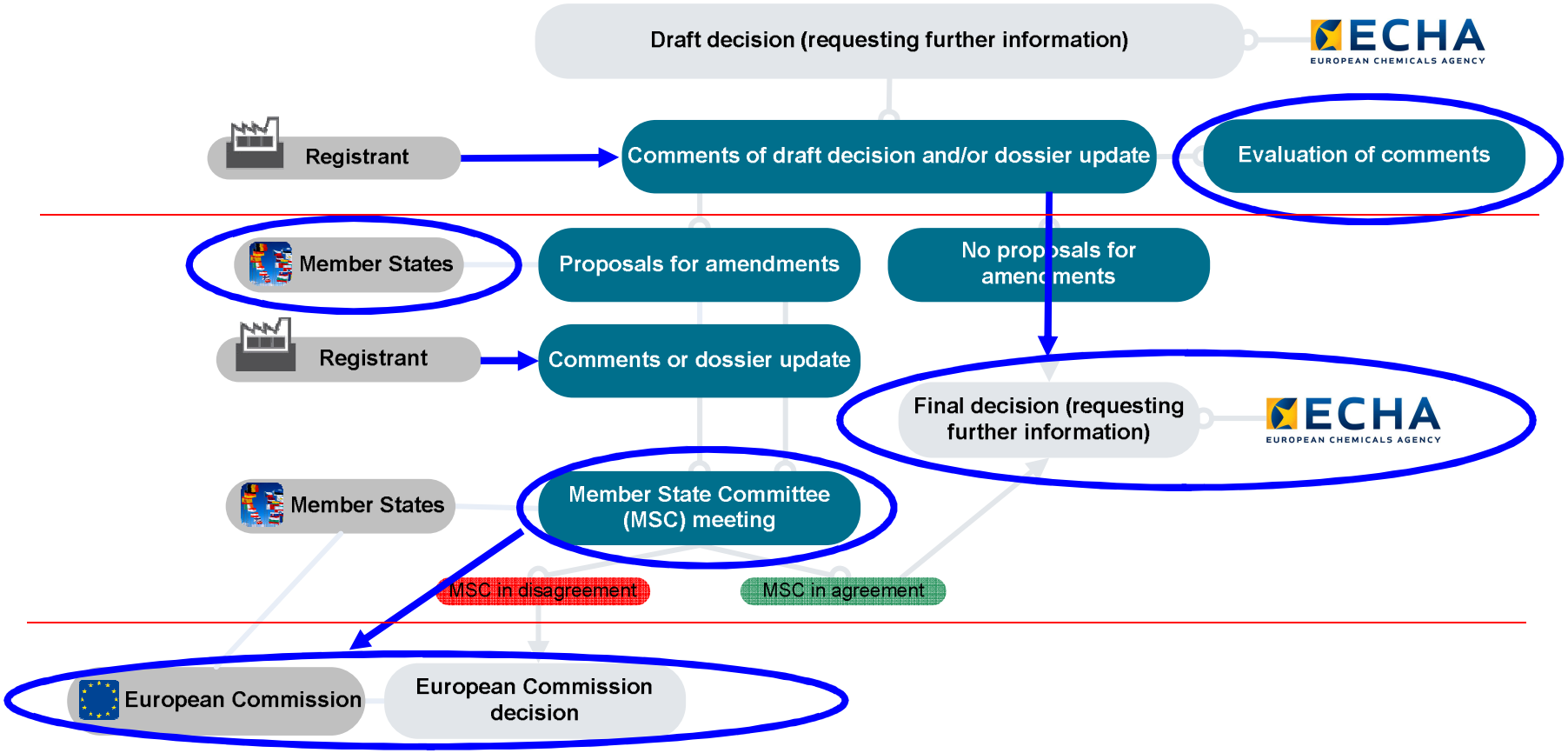
Compliance check

Examine any information on a substance

Output

- accept/reject a testing proposal
- request of information, because the dossier is not compliant (CC) or the potential risk needs clarification (SEV)

Evaluation – the mechanics



Dossier Evaluation: compliance check

ECHA questions	ECHA examination conclusions	Numbers and timelines
Info requirements adequately fulfilled? **Adaptations** adequately justified? **CSA & CSR** comply with Annex I? **Risk Management** Measures are adequate? **Explanations** for separate submission	Decision: 1. Request further information 2. No further action	Select at least **5%** of total received for each tonnage band Draft decision within **12 months** from starting the evaluation

1,200 registration dossiers from 2010 deadline will be checked for compliance by end of 2013

Compliance Check

- The Agency may perform on any registration dossier
- Some **priority setting** is suggested in the legislation:
  - Dossiers submitted separately (opting-out of joint submission)
  - Dossiers [1, 10t], not fully falling under Annex VII
  - Substance is on Community Rolling Action Plan
- **Random** selection
- **Concern-driven** selection

Compliance Check Findings

Common shortcomings in dossiers

- Substance identity **(66 %)**
- Exposure assessment & risk characterisation **(23 %)**
- Prenatal developmental toxicity study **(26 %)**
- Sub-chronic toxicity study **(18 %)**

2013 Dossier Information Quality

- Detailed information not yet available
- ECHA's actions to improve quality:
  - New IT tools e.g. Dossier Quality Assistant
  - IT screening: personalised advice for registrants
  - More experience
  - More support available
- Screening will be done on key issues
  - Substance identification
  - Use as intermediate

Dossier Evaluation: testing proposals

ECHA questions	ECHA examination conclusions	Numbers and timelines
Proposed test **adequate** and justified? **Unnecessary** animal testing avoided? 3rd party **info** valid?	Decision: 1. Accept testing 2. Reject testing 3. Change test conditions 4. Request additional testing	**All testing proposals** •**Non phase-in**: draft decision in 6 months •**Phase-in** submitted according to schedule

Over 1,100 testing proposals from 2010 have been processed

Testing Proposal Assessment

- **Stimulates** and supports industry towards efficient testing
- **Ensures** that testing conducted only if needed, in particular on vertebrate animal testing

Testing Proposal Assessment

- Required by REACH Annexes IX & X:
  - Registrants identify a data gap and cannot otherwise fulfil the REACH information requirements;
  - Additional testing is triggered by risk:
    - available information of the substance is inconclusive;
    - further investigation is needed
- Deadlines:
  - for **non phase-in** substances: 180 days after receipt
  - for **phase-in** substances:
    - by 1 Dec 2012 (if received by 1 Dec 2010)
    - by 1 Jun 2016 (if received by 1 Jun 2013)
    - by 1 Jun 2022 (if received by 1 Jun 2018)

Substance Evaluation

MSCA questions	MSCA examination conclusions	Numbers and timelines
Is there a **suspected risk**? Would **further data cla**rify the concern related to the substance?	Decision: • Request additional testing Other outcomes: • Substance evaluation report • Conclusions for further actions (risk management)	**Substances in the CoRAP; about 50 per year** Draft decision within **12** months from the publication of the CoRAP

CoRAP = Community Rolling Action Plan

Substance Evaluation

- Selected **in collaboration** with the Member States
- Based on the agreed **risk-based** criteria or other risk-based national priorities
- **Criteria** cover:
  - hazard information
  - exposure information
  - tonnage (incl. aggregated tonnage)
- **Ways** to find substances:
  - IT-based screening
  - Member States make notifications
  - Via dossier evaluation

Community Rolling Action Plan

- Duration **3 years**
- **CoRAP lists** of substances & evaluating Member States and initial concerns
- Substance specific **justification** documents published (from 2013)
- **Consequences** of inclusion into CoRAP
  - No legal impact on the substance/registrant
  - Substances need to be evaluated within 12 months from the publication of the CoRAP
  - Evaluation of substances listed for the 2nd and the 3rd year only starts from the publication of CoRAP updates in those years

Substances in the CoRAP

CoRAP 2012-14	CoRAP 2013-15	Draft CoRAP 2014-16
Published 29 Feb 2012	Published 20 March 2013	To be published in March 2014
Contains **90** substances: •36 for 2012; •23 for 2013; •31 for 2014	Contains **115** substances: •46 for 2013; •46 for 2014; •23 for 2015	Contains **125** substances: •56 for 2014; •49 for 2015; •20 for 2016
Draft decisions for 32 substances 17 Member States	21 Member States	20 Member States

Interaction with Registrants

Formally – opportunity to comment on a draft decision
Value of a co-ordinated response from registrants

Informally – Registrants can contact the Member States (details on the CoRAP)

– Member States can contact registrant(s) (issues with submission of updates/pending studies)

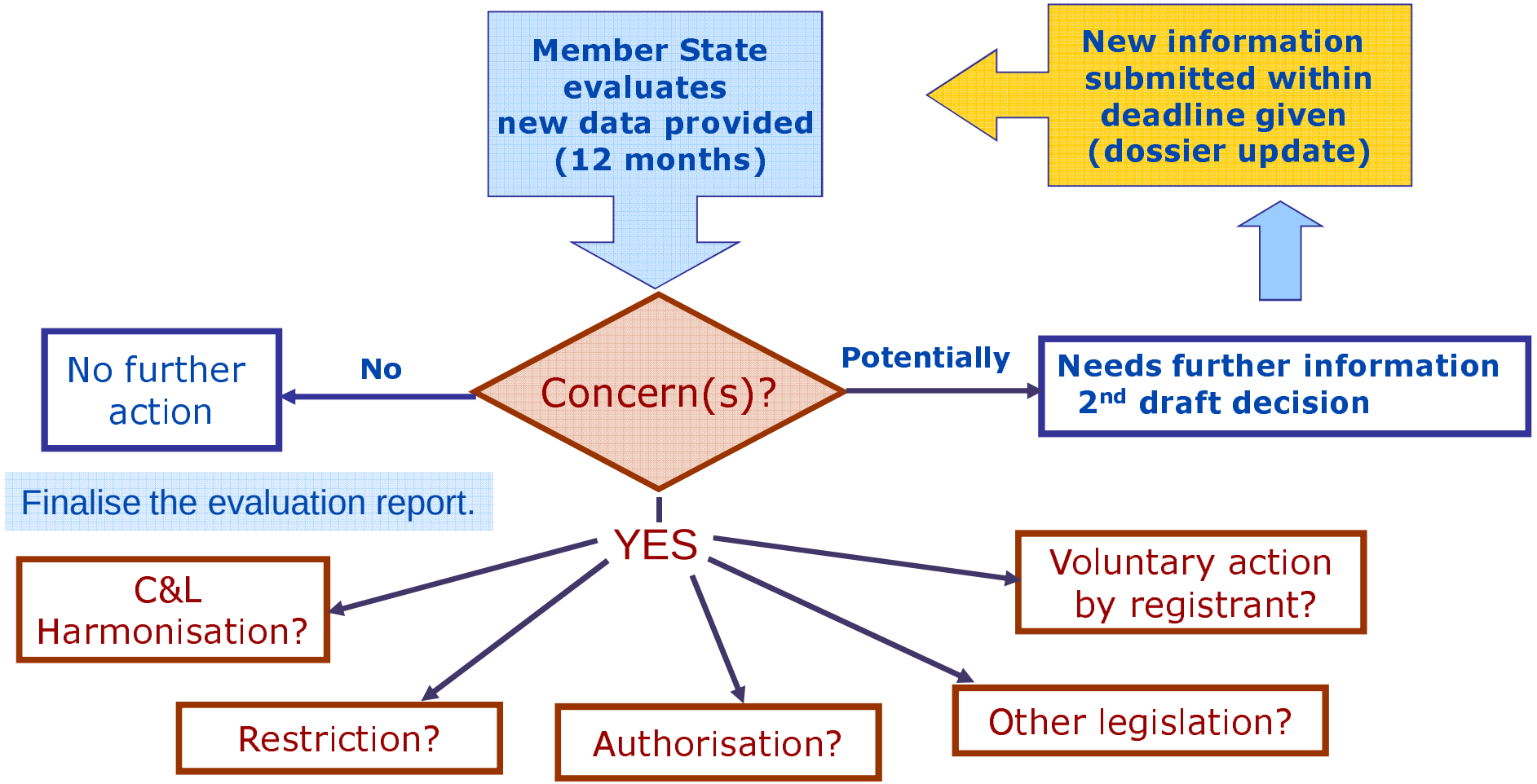
Communication to the registrants and Downstream Users on how to act during Substance Evaluation

A leaflet Substance Evaluation:

Tips for Registrants and Downstream Users

Work on-going on a harmonised policy across Member States

Follow up to Substance evaluation



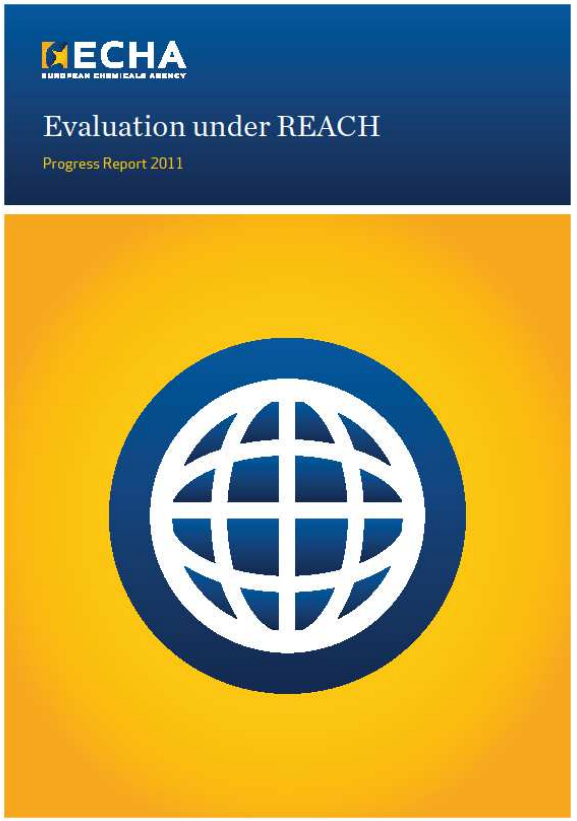
The MSCA informs ECHA of its conclusions as to whether or how to use the information obtained **(Art. 48 – Follow-up).** ECHA informs the Commission, the Rregistrant and the other MSCAs.

New factsheet on *Dossier Evaluation Decisions*

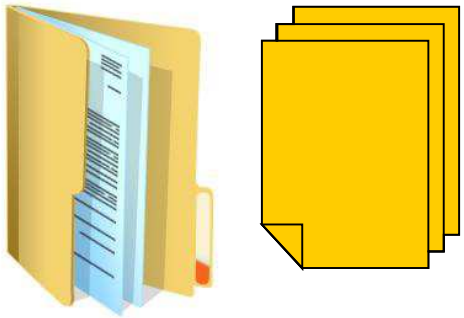
- Published on 15 October
- Describes the process steps and the possible outcome documents
- Addresses communication issues after the decision has been received
- Provides useful reminders for registrants

Reporting

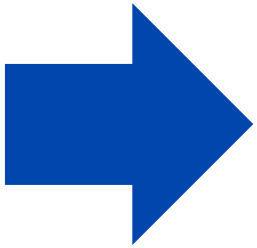
- Annual Evaluation reports since 2008
- Reports available on ECHA website
- Informs registrants on
  - common pitfalls
  - ECHA recommendations
- All registrants should read
- 2011 Report on animal testing
  - Use of alternative methods

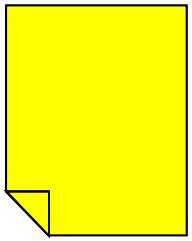


Elements of supply chain communication

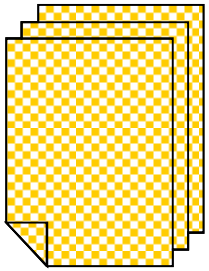


Chemical safety report including exposure scenarios





Safety data sheet



Exposure scenarios

Appropriate and relevant information to protect human health and the environment

Improving quality CSR & ES quality

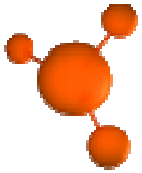


ENES: Exchange Network for Exposure Scenarios

ENES-5 - 21-22 November 2013

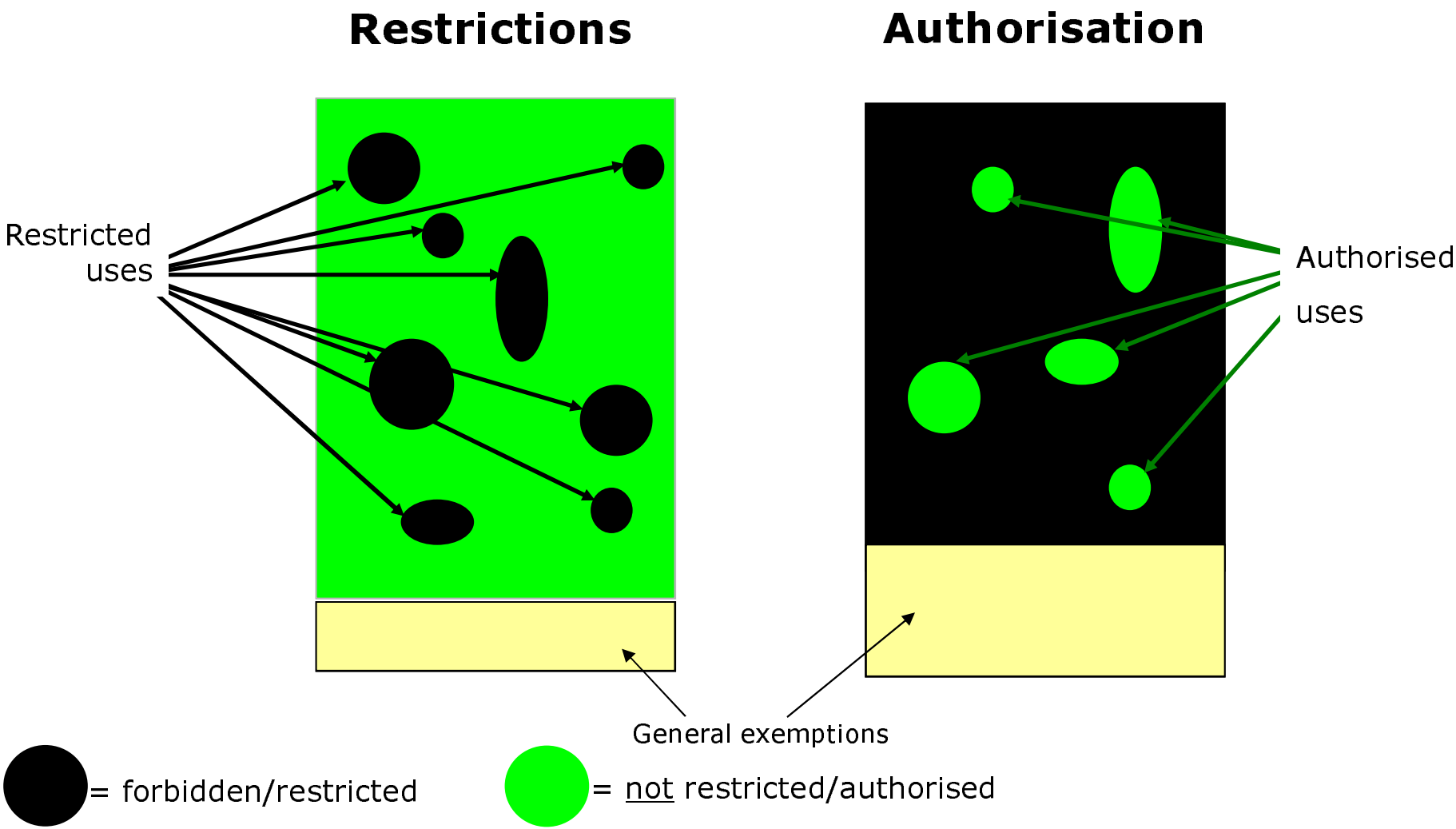
http://echa.europa.eu/enes

Improving quality of chemical safety report - Illustrative example CSR



- **Part 1:** General advice (8 pages)
- **Part 2:** Worked example of chemical safety report
- **Part 3:** IUCLID dataset for chemical safety report
- **Part 4:** Chesar dataset for generating CSR

Difference between Restrictions & Authorisation



REACH does not stand on its own

- Other sectoral chemicals legislation exists:
  - Plant Protection Products - pesticides
  - Biocidal Products - biocides
- Other important policy areas with links to chemicals management:
  - **Environment** (Water - priority hazardous substances, Waste -use of hazardous substances in electronic equipment, Air - quality objectives)
  - **Worker protection legislation** (Framework Directive on Health and Safety at Work, Occupational exposure limits, Carcinogens and Mutagens Directive)
  - **Consumer Protection** (General Product Safety Directive, Toys, Cosmetics)
  - **Health** (Medicinal products and medical devices)
  - **Food** (Food contact materials)

Authorisation (1/2)

- Focus on:
  - most hazardous substances = Substances of Very High Concern (**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

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

Substances of Very High Concern (SVHC)

ECHA MS

Preparation of Annex XV SVHC dossier [Art.59(2),(3)]

Public consultation

Identification of SVHC & Candidate list inclusion [Art.59(1)]

'Candidate list' of SVHC for Annex XIV inclusion

ECHA MS

Prioritisation of Candidate list substances [Art.58(3)]

Public consultation

Inclusion of Candidate list SVHC in Annex XIV [Art.58(1)]

'Authorisation list' of SVHC **(Annex XIV)**

ECHA MS

Application for Authorisation to use Annex XIV SVHC [Art.62]

Public consultation

RAC & SEAC Committees draft opinions

COM decision

Authorisation granted (or not) for a use of an SVHC [Art.60]

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:

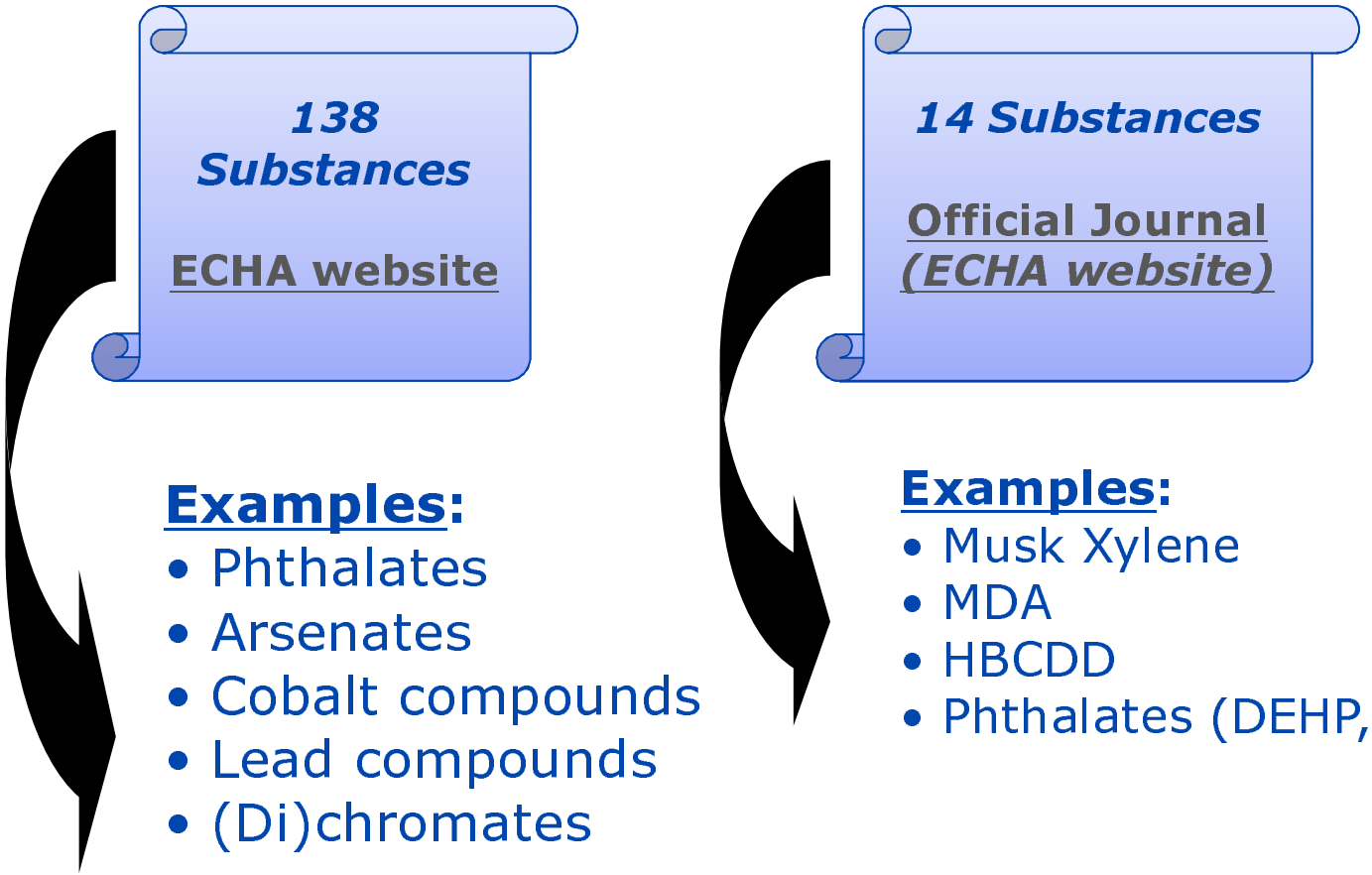
    → provide information to allow safe use of the article to customers or to consumers, upon request (45 days!)

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

Step 1b: Annex XIV listing - implications

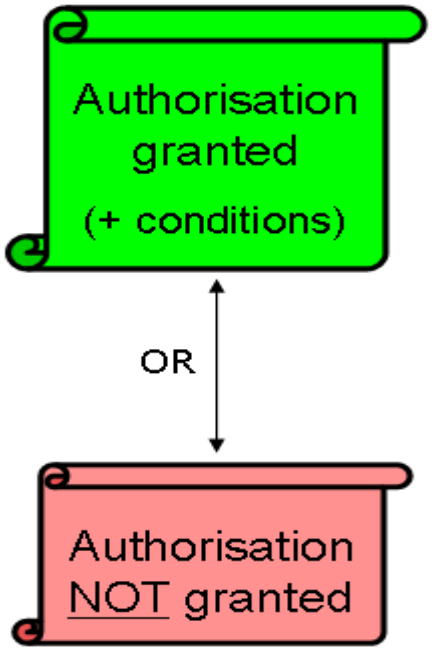
- **After the « sunset date »,** industry is not allowed to place an Authorisation Annex (XIV) substance on the market or use it unless companies have an authorisation granted by the Commission

Step 1a: Candidate List & 1b: Authorisation List



Step 2: Applications for authorisation

- An **applicant** can be:
  - manufacturer
  - importer
  - downstream user
  - any combination of these
- An **application** can be submitted:
  - for one or several uses
  - for one or a «group of» substance(s)



Fee » Fee Regulation

Factsheet published in late 2013

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 applicants *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 **persons** to whom the authorisation is granted
  - the **uses** 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)

Authorisation

Procedure includes public consultations

Step 1a

Identification of Substances of Very High Concern

5 months

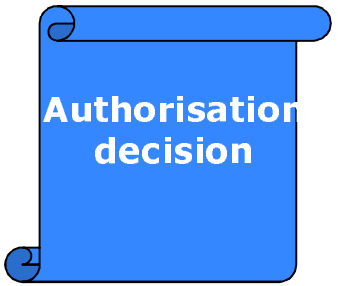
Step 1b

Subjecting priority substances to authorisation

6 + 12 months

Step 2

Granting authorisation



up to 2 years

Restrictions

- **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 **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

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 previous legislation (Dir 76/769/EEC)
  - New restrictions (amendments of existing restrictions and new entries)

Restriction procedure (1/2)

- Registry of Intentions (**RoI**)
  - Member States have to notify their intentions to prepare a 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 (2/2)

- **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 its 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?
- Commission **decision**

Specific restrictions

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

- **Authorisation list** substances (Annex XIV)
  - 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 scrutiny and under consideration
- Obligation to:
  - Comply with any conditions set out in Annex XVII
  - Update Safety Data Sheet

Recently adopted restrictions

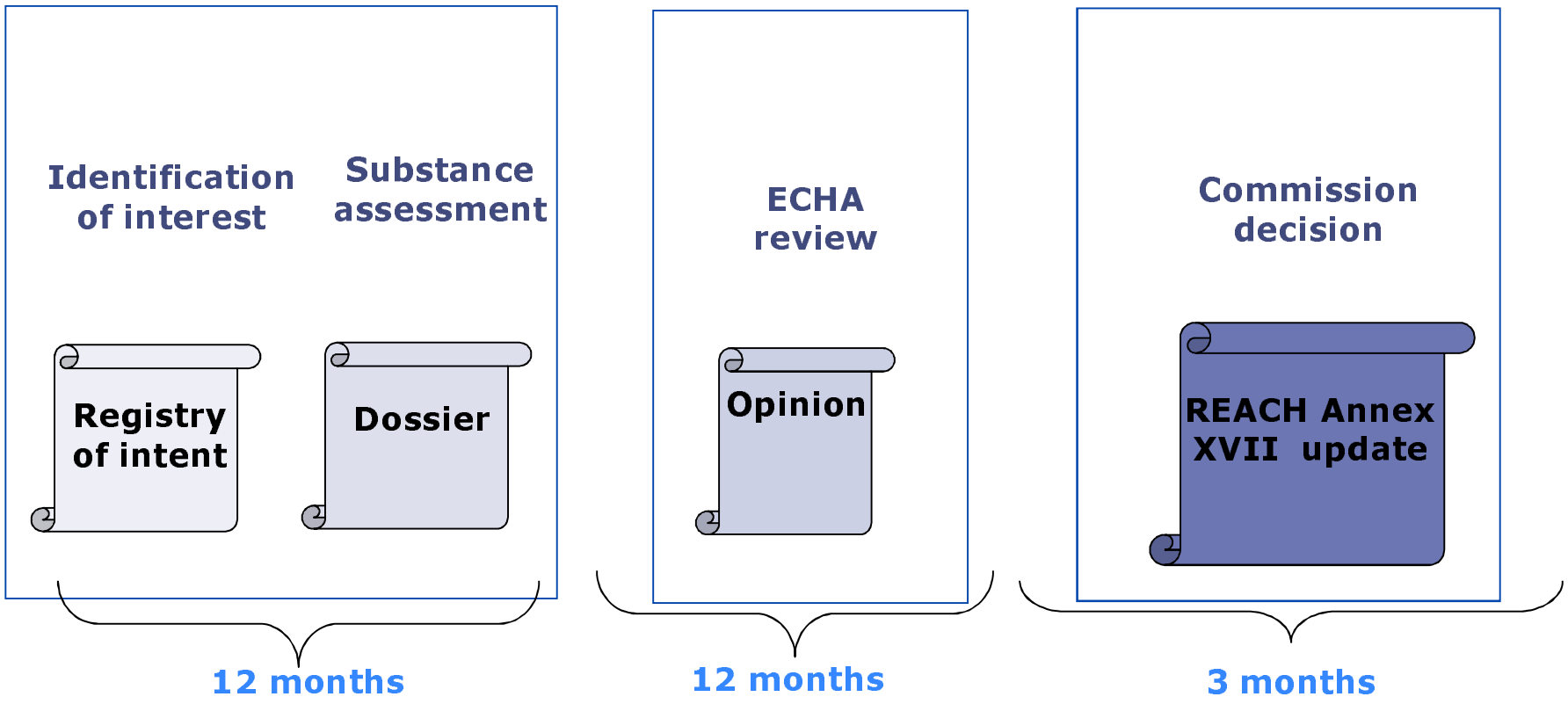
- Lead and its compounds in jewellery articles
- Dimethylfumarate in articles
- Mercury in measuring devices
- 4 Phenylmercury compounds
- Cadmium and its compounds

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)

Restrictions

Procedure includes public consultations

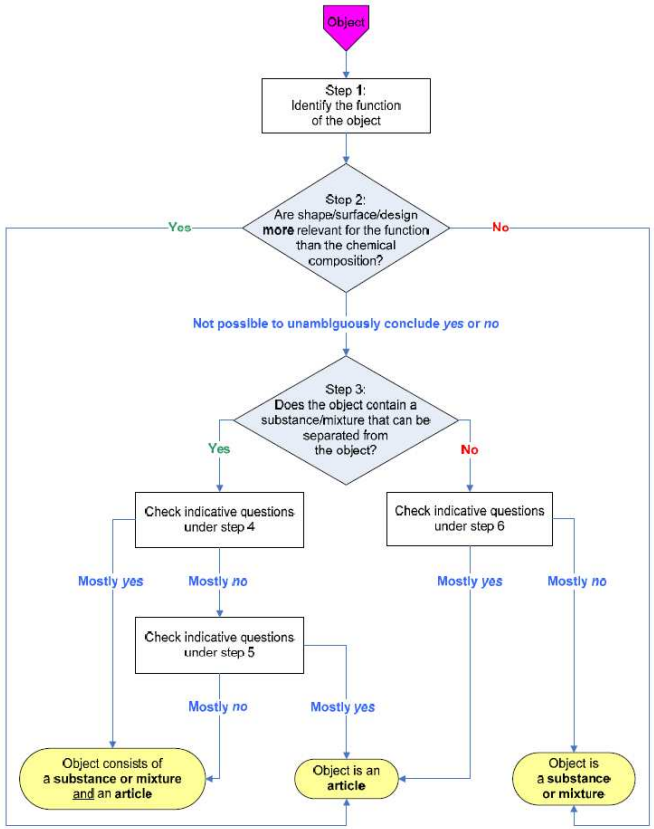


Substances of Very High Concern in Articles

'Article' Definition - REACH

"an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition"

Producers, importers or suppliers of articles may have legal obligations under REACH if a Candidate List substance (SVHC) is contained in their articles



Notification of substances in articles

Purpose of notification:

-Ensure that sufficient information is available on use of substances of very high concern (SVHCs) in articles not covered by registrations

-To support the identification of cases which may require regulatory risk management

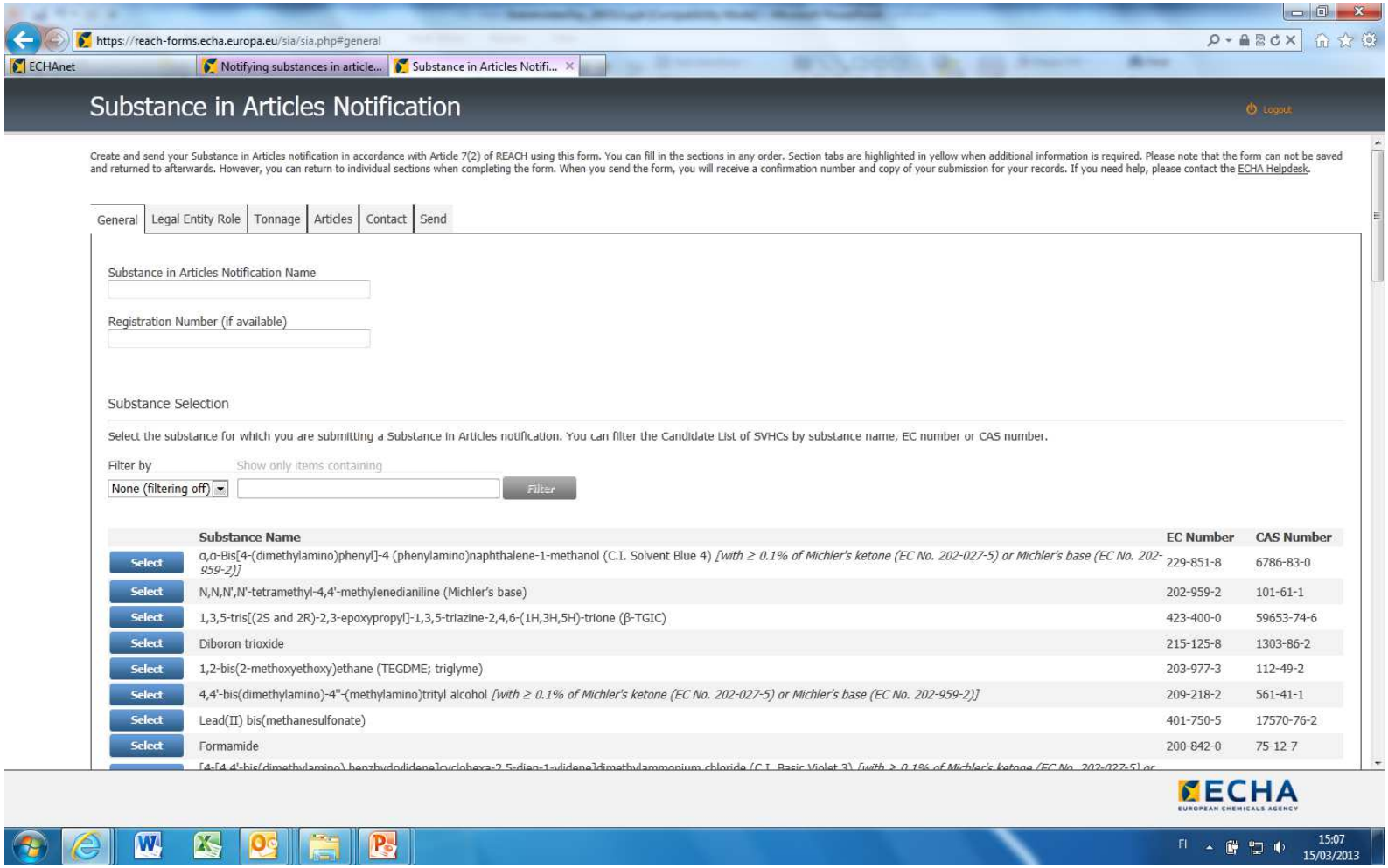
ECHA must consider restriction of Annex XIV substances in articles after the sunset date

→ Information on SVHCs in imported articles important to allow ECHA to understand possible needs for derogations from such restrictions

Only a few notifications received (xxx by December 2013)

→Need for improvement

Online notification webform



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Worth to Remember

- Registration is a way to ensure safe use of chemicals
- 1-substance-1-registration applies
- A wealth of registration information is available online
- Authorisation & Restriction are regulatory instruments for risk management at EU level
- Candidate Listing of a substance creates compliance requirements

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Thank you !