REACH: registration, evaluation & risk management update

Seminar to Japanese Industry on the EU Chemicals Legislation: REACH, CLP & BPR

3 April 2015 / Tokyo, Japan

Geert Dancet
ECHA Executive Director

Content of the update

- ECHA mission and strategic objectives
- REACH main processes and aims
- Registration obligation & 2018 deadline
- Evaluation of registration dossiers
- Communication in the supply chain
- Dissemination
- Authorisation and SVHC 2020 roadmap
- Restrictions
- Substances in articles

ECHA eight years old

- 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 strategic objectives 2014-18

1. Maximising the availability of high **quality information** to enable the safe manufacture and use of chemicals.
2. Mobilising authorities to use information intelligently to identify and **address chemicals of concern**.
3. Addressing scientific challenges by serving as a **hub for building the scientific and regulatory capacity** of Member States, European institutions and other actors.
4. Embracing current and new legislative tasks **efficiently and effectively**, while adapting to upcoming resource constraints.

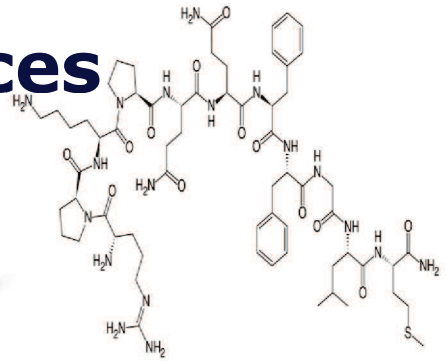
REACH – What it's all about

- Companies to establish safe use of chemicals by **Registration**
- Authorities to **Evaluate** registrations to ensure compliance
- **EU-wide Risk Management** of
  - most hazardous substances through authorisation that promotes substitution and
  - prohibition of unmanageable risk at EU level through restrictions

➢ **Promoting Safety, Competitiveness & Innovation**

What to register

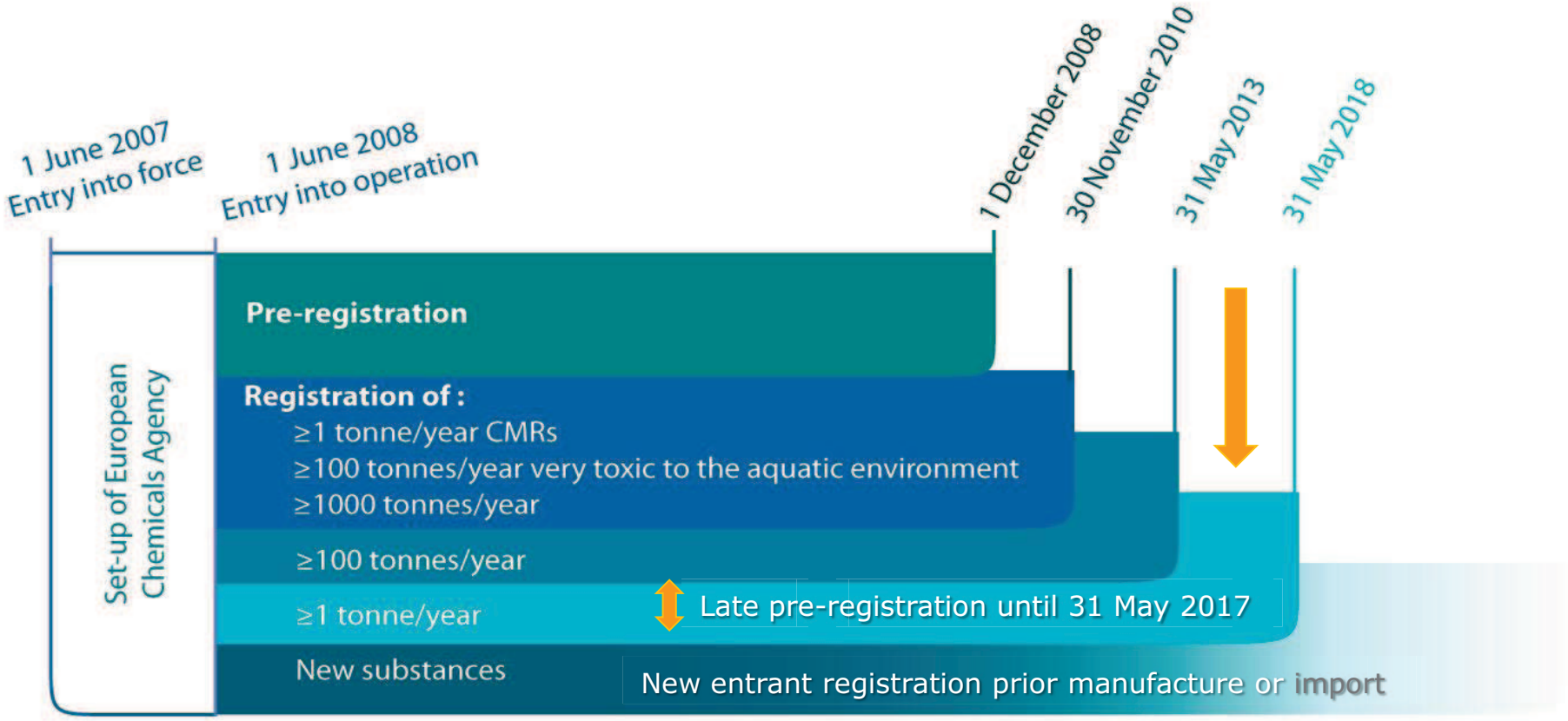
- Registration only concern **Substances**



  - **… not mixtures** and **articles**
  - **on their own** or **in mixtures**
  - as **monomers in polymers**

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

REACH Registration deadlines



What do we expect in 2018?

	2010	2013	2018 ?
Substances	~ 3 400	~ 3 000	Up to 25 000
Dossiers	~ 20 000	~ 9 000	Up to 70 000

- Multitude of small SIEFs
- Individual registrants
- Higher % of SMEs
- High % of imported substances
- Less information >> need to generate new data
- Different levels of sector organisation
- New economical and political contexts

→ Targeted support needed

2018 Registration Roadmap

- Based on an understanding of 2018 registrants' needs

- The objective is adapt and streamline procedures, IT tools and support to registrants by 2016
- Update guidance especially for avoiding certain animal tests
- Guidance will not change after May 2016
- European Commission is working on mandatory SIEF rules

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
- Make use of REACH 2018 web section

Preparing the registration dossier

- Dossier in **IUCLID** 5 or 6 format for substances at 1 to 100 t.p.a. standard **information linked to tonnage**
- Use **QSAR toolbox** & waiving abilities
- **Chemical Safety Report** for substances ≥ 10 t.p.a. (assisted by Chesar 2 or 3)
- Use the **support tools** (IUCLID Plug-ins) before submitting your dossier
  - TCC, Dossier Quality Assistant …
- Submit with **REACH-IT** 3 from July 2016

chesar → Chemical Safety Report

What IUCLID 5 does and IUCLID 6 will do

- Two versions of the application: desktop and server / Easier installation of the desktop version; easier integration with other systems; enhanced user and data access management; investigation of the possibility to provide IUCLID as a Service
- >110 OECD Harmonised templates for reporting summaries of studies performed according to test guidelines / All existing templates will be updated to the latest version; new templates on Use and Exposure, Assessment Entity, Intermediate Effects, alignment with UN GHS on physicochemical hazards
- Functions available for processing IUCLID data: report generator (e.g. CSR), filtering, fee calculation, data validation (e.g. completeness check), search / All functions updated to the IUCLID 6 format. Enhance capabilities for customisation of these functions (e.g. generation of other types of reports)
- Organisation of the data according to legislation requirements (e.g. REACH, OECD) / Flexible, legislation-dependent updating (legislation-specific parts of the application have been isolated and can be developed and updated separately)

What Chesar2 does and Chesar3 will do

- Putting together elements relevant for CSA:
  - Substance properties from IUCLID
  - Use description from use maps developed by sector organisations
  - Exposure assessment based on exposure assessment inputs (SpERCs, SCEDs, SWEDs) using imports of extended use maps by use sectors
- Consistent outputs:
  - CSR for monoconstituents and more complex cases ('assessment entities')
  - CSR extract from IUCLID
  - ES for communication in eSDS and exporting to EscomXML format
- Exposure estimation
  - Via the built in exposure tool: ECETOC TRA for consumers and workers; EUSES for environment
  - Possibility to
    - plug in more tools
    - Import output files from tools
    - Manually input output of external tools

QSAR toolbox (OECD tool)

Main features of the QSAR Toolbox:

- ✓ Toolbox contains ~1milion data points for over 80 000 substances
- ✓ Data covers: Phys-Chem., Environmental Fate and (eco)Toxicological properties required by REACH
- ✓ Provides over 100 profiling methods and QSARs combined with 13 metabolism and transformation predictors

Main reasons for using QSAR Toolbox:

- ✓ Allow to fill data gaps by read-across, trend analysis and (Q)SARs for assessing (eco)toxicity hazards of chemicals under REACH
- ✓ Help in reducing the cost and the need for testing on animals;
- ✓ Allows direct data exchange with IUCLID;
- ✓ Is one of the most popular tools used by REACH registrants*;
- ✓ **Is free of charge**, for more information and download please visit: www.qsartoolbox.org

• What REACH-IT 2 does and REACH-IT 3 will do

- Data submission by industry, Representatives and Member states / (1) Help small companies to fulfil their 2018 registration duties by making the application more intuitive and user friendly; (2) Easy online dossier creation for Member of Joint Submission; (3) More intuitive online dossier creation for C&L (GHS)

- Technical processing of the submitted data / Full automation of the technical verification of the data submitted and associated payment to gain efficiency

- Communication and information hub for Industry in relation to submitted data / (1) Easier to retrieve key information (e.g. decisions); (2) Assignment of tasks with deadline; (3) Clear and easy way for Industry to manage its contacts

- Data sharing / Improve the tools to allow industry to easier contact each other and work better together

What happens after registration?

- ECHA
  - **Disseminates** public data of each dossier and registered substance
  - **Verifies confidentiality claims** which may complete the information disseminated
  - **checks compliance** of at least 5% of the submitted 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

Evaluation

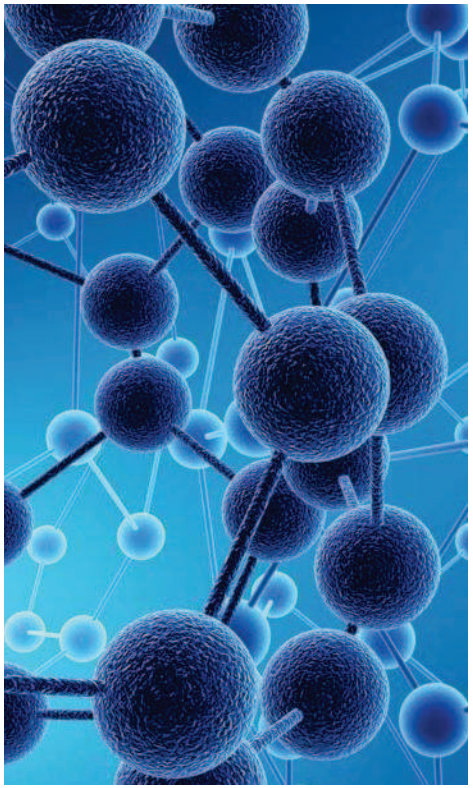
1. Provide **confidence** that registrants are meeting REACH information requirements
2. **Prevent** unnecessary animal testing
3. Build up database for eventual EU-wide **risk management** measures

Compliance Check Strategy 2015 onwards

- high-tonnage registrations with **data gaps in human health** or **environment** endpoints
- **high potential for exposure:** workers, general public or environment
- 'external' information and IT screening used for prioritisation and selection of substances
- some dossiers will still be picked up randomly
- No updating of dossiers allowed after draft decision but companies are encouraged to update dossiers for candidate substances after their have been published
- **other measures** to improve the information on chemicals: dissemination, guidance, IT-tools, webinars, website and **directly contacting registrants** (e.g. screening letters) to incite dossier updates.

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
- **Community Rolling Action Plan** lists of substances & evaluating Member States and initial concerns
- Duration **3 years**, renewed each year
- Substance evaluation performed by Member States within 12 months

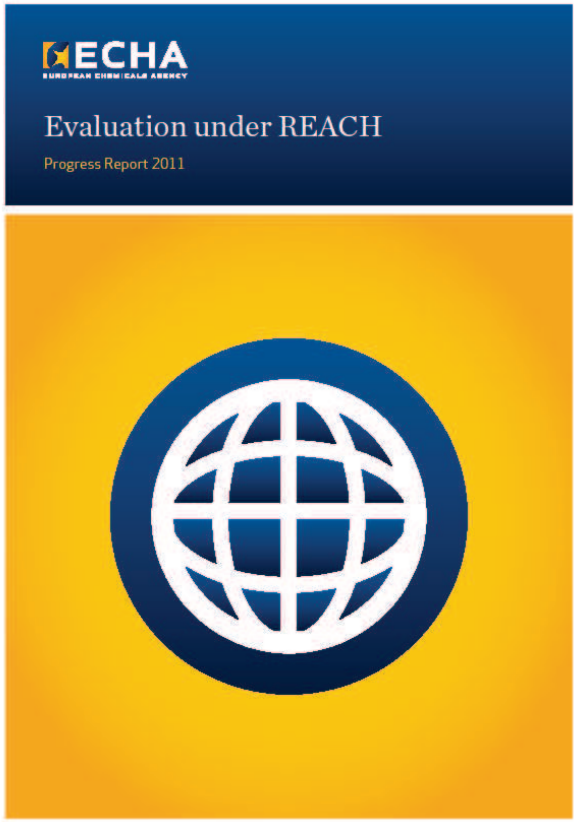


Substance Evaluation substances

- 201 substances listed on CoRAP
  - 13 concluded without decision
  - 26 Decisions taken (waiting on information from IND)
  - 94 Ongoing
  - 68 Not started
- In tabular form on ECHA website:
  - SID – Initial grounds for concern – status
- Available reports:
  - Justification document (why substance was placed on CoRAP)
  - Decision on required information
  - Final conclusion when information is received

Reporting

- Annual Evaluation reports since 2008
- Information on:
  - common pitfalls
  - ECHA recommendations
- All registrants should read
- 2011 & 2013 Reports on animal testing
  - Use of alternative methods

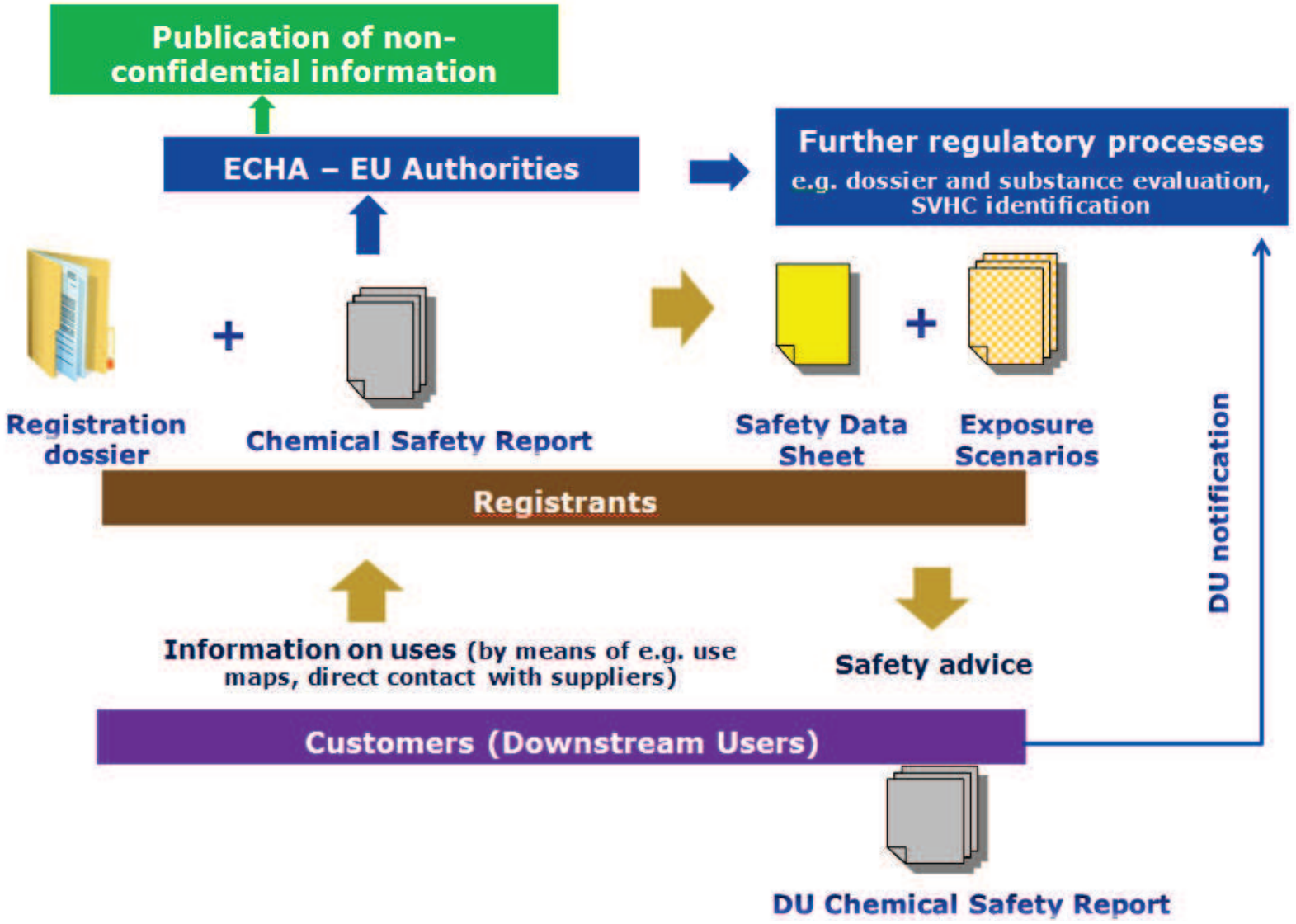


http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports

REACH and CLP – benefits for downstream users

- Registration process generates **more and better information** on chemical hazards and uses
- Regulatory Process leads to substitution of substances of concern and **Safer Products**
- Chemical safety assessment leads to **improved information** in the supply chain regarding safe use

Process overview



Chemical Safety Report Roadmap

FOCUS AREAS

Main driver: Increase efficiency and effectiveness of communication by harmonising and standardising

- *Information up – use maps:* developing template and content on how the substances are used in practice
- *Information down - exposure scenarios:* templates and examples. ESCom catalogue of standard phrases and XML for electronic communication of ES. Methodologies to consolidate ES information for safe use of mixtures.

Main driver: Raise awareness and knowledge of downstream users

- *Range of supports:* Webpages, webinars, standard presentations, articles, conferences, guidance, practical guides, eGuides

ECHA, industry and member states working together:

- CSR/ES Roadmap defines common priorities and areas of work
- ENES is a network of several hundred who meet biannually to identify and promote good practices

Dissemination of information on chemicals

- Information
  - owned by the registrants
  - identical as in submitted dossiers
  - Confidential Business Information removed

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**

ECHA information on chemicals

- Registered substances information (13 000 substances; **> 2 million study summaries** on properties and effects of chemicals)
- Public C&L inventory (120 500 substances; > 6 million notifications)
- EC Inventory (106 213 substances)
- Candidate list of Substances of Very High Concern (SVHC) (161 substances) and Substances in Articles (SiA) notifications
- Registry of intentions for risk management proposals (Restriction, SVHC and Harmonised C&L)
- Information on active substances (113 substances) and biocidal products
- Notifications and explicit consent under Rotterdam Convention (PIC) (e.g. 71 explicit consents and waivers from Japan)

What to expect in 2015

- Enhanced advance search capabilities on substance uses and hazards
- Integration of multiple regulatory activities in one single integrated search – facilitate substance regulatory activities follow-up
- Graphic design of Registered substances pages (including study records) improved with enhanced navigation capabilities
- Tiered approach to information
  - Infocards
  - Brief Profiles

Tiered Approach to Information

Infocard *(1st tier)*

Allow users to further identify the substance

Provide high-level information to concerned citizens on:

- substance's critical properties
- classification and hazards
- uses and exposures

Provide an overview of main regulatory processes on-going for the substance

Substance Brief Profile *(2nd tier)*

Extend Infocard information

Provide information on scientific properties:

- Physical chemical properties,
- Environmental fate and pathways
- Ecotoxicological Information (including PNEC)
- Toxicological Information (including DNEL)
- Study records type overview

Provide links to the source data

Substances of Very High Concern

- EU policy commitment
  - **To have all relevant currently known SVHCs included in the Candidate List by 2020**

➢ The Commission finalised **the SVHC Roadmap** in March 2013

  ➢ Actions needed to achieve this policy goal

http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT

➢ ECHA draw up the **Roadmap Implementation Plan** in November 2013

  ➢ How to carry out the required actions

http://www.echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan

  - ECHA published its first report in March 2015
  - Results covering activities of 2013 and 2014

2020 SVHC Roadmap - Objectives

- **Build a common understanding** between EU Commission, Member States and ECHA of the main principles
- **Share responsibilities** for an effective management of resources
- **Set priorities:** in which order should we process relevant substances?
- **Ensure transparency** for stakeholders by communicating authorities intentions
- **Increase predictability** for Industry for planning and resources management E.g. “Substitution or application for authorisation?”

Substances addressed

Substances of very high concern (SVHC)

- **CMR**: carcinogenic, mutagenic or toxic for reproduction
  - Category 1A or 1B in accordance with the CLP Regulation (EC) 1272/2008
- **PBT, vPvB**: (very) persistent, (very) bioaccumulative and toxic for the environment (PBT or vPvB)
  - According to REACH (Annex XIII)
- **Equivalent level of concern**: identified on a case-by-case basis, cause an equivalent level of concern as with CMR or PBT/vPvB substances
  - e.g. endocrine disruptors, sensitisers

[Article 57 REACH]

Public Activities Coordination Tool (PACT)

- Informs on **authorities selection** of substances for:
  - assessment of the hazard properties (to be included in PACT next year) or
  - analysis of the Risk Management Options
- Inclusion in the PACT **does not mean confirmed concern** or firm regulatory action
- In March 2015 **116 substances** with RMOA intentions in PACT
- In SVHC Roadmap preliminary worst case assumption of **maximum 440 known SVHCs** to be RMO assessed between 2013-2020 but new SVHCs may be identified

Authorisation

- Focus on:
  - most hazardous substances = Substances of Very High Concern (**SVHC**)
  - For which uses may lead to exposure
- Principle: after a certain date "***sunset date***"
  the use of an Annex XIV substance is forbidden unless specifically authorised
- Ultimate goal: **substitution** by safer alternatives

The authorisation procedure: a two-step approach

- **Step 1**: **subjecting substances** to the authorisation requirement

  Step 1.1: Identification of SVHCs → **"*candidate list*"**

  Step 1.2: Prioritisation of substance ("recommendation") and Inclusion in Annex XIV
  → **"*authorisation list*"**

- **Step 2**: authorisation applications and decisions

Lessons learnt on Applications for Authorisation

- Application system works!
  - Incentive to industry to substitute towards safer substances
  - Leads to further improvement of risk management measures
  - Transparent and predictable
- Room for further improvement exist
  - Costs have reduced (by over 30%) but for certain cases the process is too burdensome
  - Finding balance in “upstream” broad applications
- Work ongoing/planned to further simplify/streamline process

Restrictions

- **Ensure protection** of human health and or the environment, where
  - Manufacturing, placing on the market or specific use cause 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
  - Member States have the initiative

Substances in Articles

- A key objective of REACH: to ensure the safe use of chemicals (workers, consumers, environment)
- Articles can contain a broad range of chemicals
  - some of them being hazardous
  - exposure may occur during the service-life or waste phase
- A substantial share of articles on the EU market are imported from outside EU
- REACH obligations on the EU importers have an impact on non-EU article producers

http://echa.europa.eu/web/guest/regulations/reach/candidate-list-substances-in-articles

Legal obligations for EU importers of articles (1/2)

- When articles contain substances which are on the REACH Candidate List:
  - Notify substances in articles
  - Communicate in the supply chain sufficient information to allow safe use of the article

➢ EU importer needs to know how to comply with his obligation
  - whether the article includes Candidate List substances and
  - brief description of **use of the substance in the article** (technical function) and, the **uses of the article** and how to **use them safely**

Legal obligations for EU importers of articles (2/2)

- To comply with existing restrictions (Annex XVII)

Examples:

- Nickel in articles intended to come into direct and prolonged contact with the skin / Lead and its compounds in jewellery

- Azocolourants in textile and leather articles

- 6 phthalates in toys and childcare articles

- Dimethylfumarate (DMFu) in articles

- PAHs in consumer products

How to prepare for customer requirements

- Actively **communicate with your EU clients** to ensure that they can comply with their legal obligations

- Actively **communicate with your own suppliers**: they (or their suppliers) have the relevant information on the substances contained in your final articles

- Plan for the future:
  - Follow PACT and the Candidate List
  - Consider substitution of (potential future) Candidate List substances

Nanomaterials

- **Covered by the EU legislation but scientific and policy challenges remain**
- ECHA **addresses nanomaterials through REACH and Biocides regulation** and is an **active dialogue partner** in discussions on risk assessment of nanomaterials also at international level
  - No explicit reference in REACH but need to demonstrate the safe use of substance including nano form
  - Biocides regulation has specific references
- **Compliance check**
  - Insufficient information on nanomaterials > data requested mainly on *granulometry*
- **Substance evaluation**
  - Selected: Silicon dioxide (2012 by The Netherlands), Silver (2015 by The Netherlands) & Titanium dioxide (2015 by France)
- **ECHA support to industry**
  - Webinar, workshops , info sessions and contacts with individual registrants

Endocrine disruptors

- REACH, Biocides and Plant Protection Products address Endocrine Disruptors and under CLP endocrine disruption is a mode of action that may lead to CMR classification
  - **REACH:** authorisation, Safety Data Sheet & Safety Report – PBT assessment
  - **Biocides:** exclusion criteria for approval of active substances and Authorisation of biocidal products (some exceptions apply)
  - **Plant Protection Products** EDs authorised only exceptionally
- Once the criteria for Endocrine Disruptor identification has been established on the Community level, ECHA will apply the criteria for the REACH and the Biocide Regulations
- Substance evaluation under REACH is best suited to investigate ED properties
- ECHA ED Expert Group supports selection of substances for Substance evaluation and Authorisation
- Currently:
  - **Substance evaluation:** 47 substances with suspected ED properties in CoRAP
  - **Authorisation:** 4 substances on the Candidate List of SVHC due to ED properties

Worth to Remember

- **Preparations for 2018** deadline ongoing & s**ubmit** from mid-2016
- **Supply chain communication** is essential
- **Learn from evaluation** & update dossiers proactively
- **Dissemination** more transparent & informative from Dec 2015
- **Authorisation** applications work
- Follow **Candidate List** & **PACT** for substances of (potential)concern in articles
  - geert.dancet@echa.europa.eu

Thank you !