REACH: ambitions, limites et perspectives

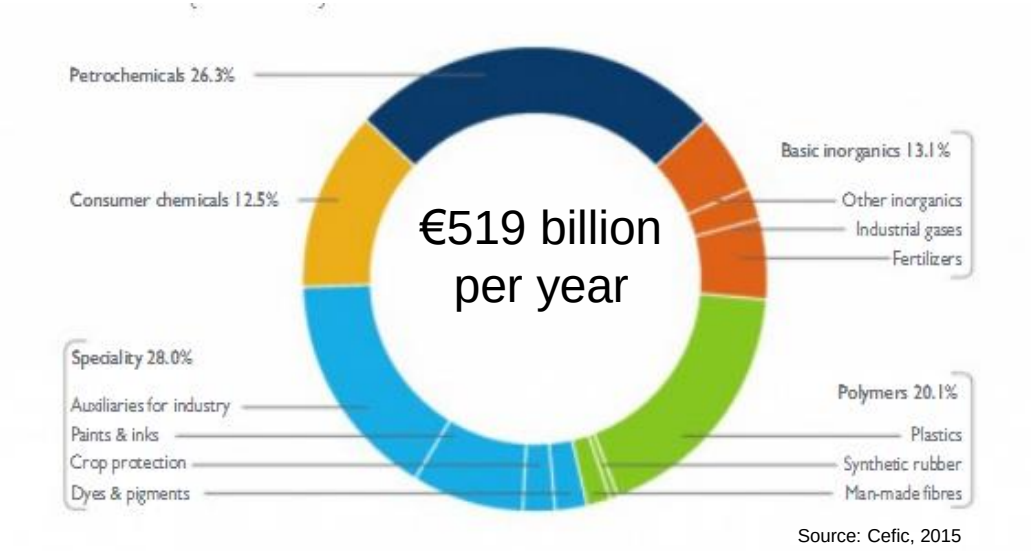
Tony Musu

La Santé des travailleurs, un enjeu politique

Beez, 2 décembre 2016

The EU chemical industry

- 1,2 million workers in the EU chemical industry
- 3,6 million jobs in downstream sectors (building, textile, automotive, electronic, etc...)
- Turnover of the EU chemical industry:



Source: Cefic, 2015

- Chemicals contribute to the EU economic prosperity in terms of trade and jobs

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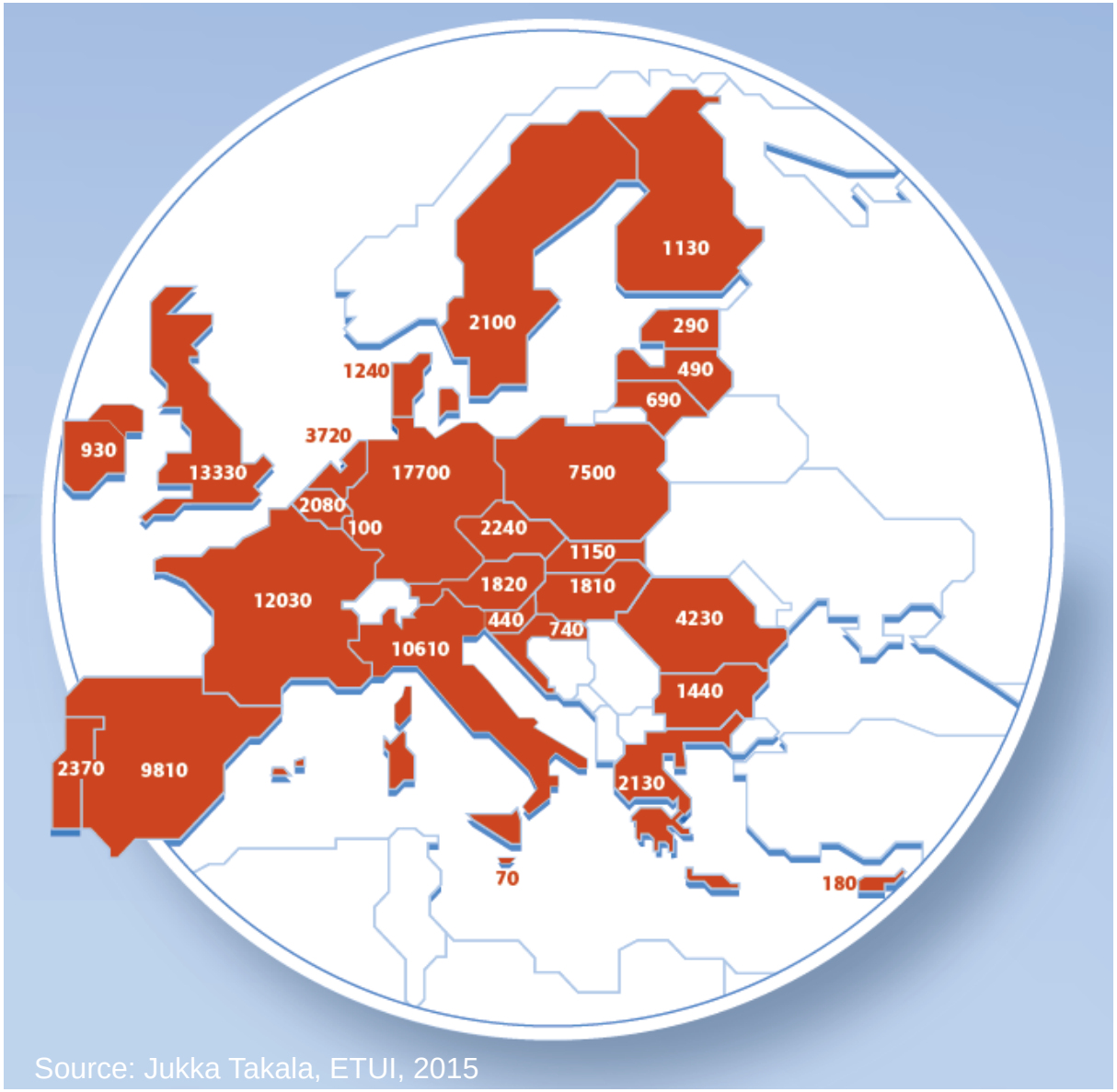
Cancer is the first cause of work-related deaths in the EU-28

Most of the cancer cases come from chemicals



Source: Jukka Takala, ETUI, 2015

102 500 deaths/year due to work-related cancers

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Negative impact on workers, employers and social-security

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REACH regulation in a nutshell

- Registration: Manufacturers and importers of chemicals > 1 tpa are required to register their substances to demonstrate they can be used safely (no data, no market principle & burden of proof on industry)

- Evaluation of some substances by Member States / European Chemicals Agency

- Authorisation only for substances of very high concern

- Restrictions when risks are unacceptable

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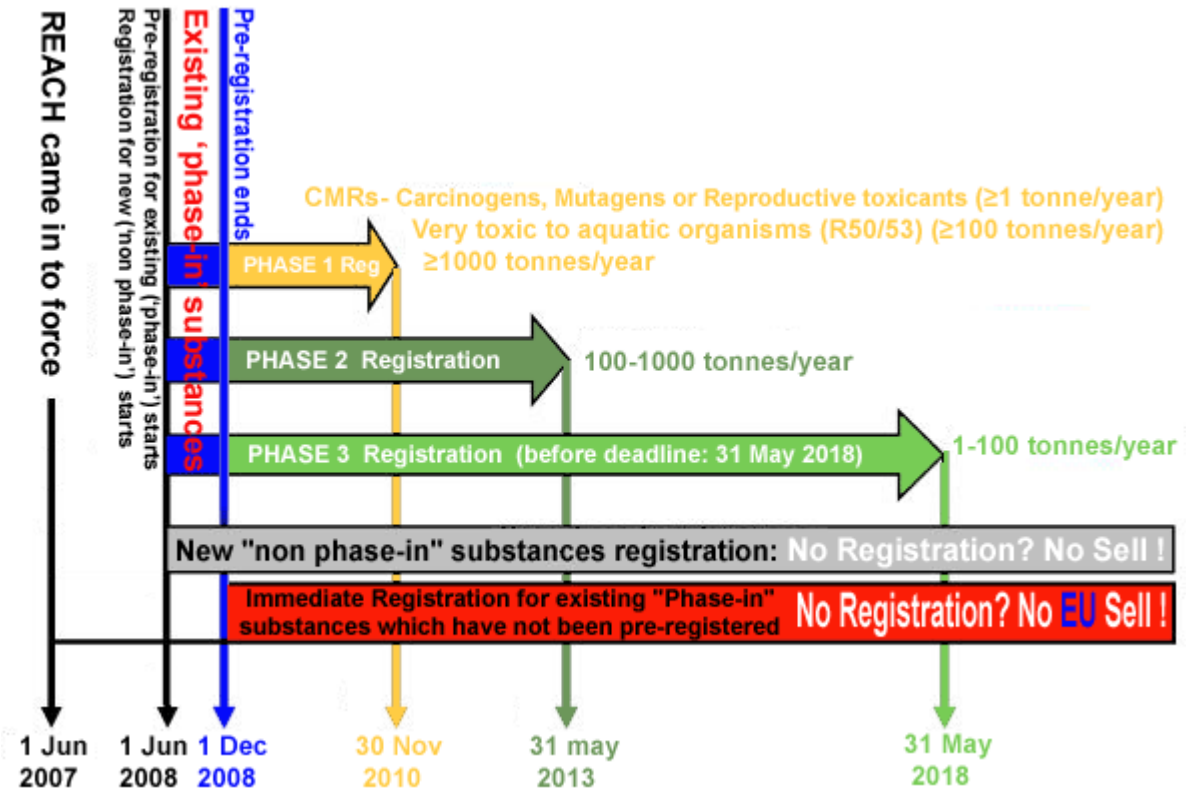
Timeline for REACH registration



~ 30 000 substances expected to be registered by May 2018

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Registration statistics (10 Nov 2016)

	Nb unique substances	Nb dossiers
Total	**14 817**	**56 431**

What information is submitted in the registration dossiers ?

Hazard

- Physical and chemical properties
- Classification and labelling
- Environmental and human health hazard assessment

Exposure/Risk

- How much is used
- How and where it is used
- How risk is controlled
- Environmental and human health exposure assessment

The data are available on ECHA's website:
http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

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What is REACH registration information used for ?

Regulatory Decisions	• Authorisation • Restriction • Harmonised classification
Information to users of Chemicals	• Safety data sheets and exposure scenarios • Uses that are advised against • Advice to consumers • Dissemination advice on ECHA website

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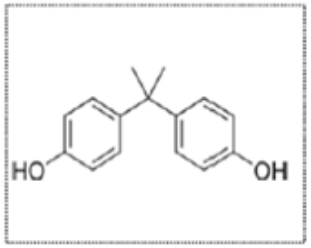
Dissemination of REACH information on ECHA's website ?

4,4'-isopropylidenediphenol — DRAFT — *Infocard* – last updated 03/06/2014

2,2-bis (4-hydroxyphenol) propane; 2,2-di(4-hydroxyphenyl)propane; 4,4' isopropylidinediphenol; Biphenol A; Bisferol A; **BPA**; C006780; DIAN; ...

Substance Identity

EC Number	201-245-8
CAS Number	80-05-7
Molecular Formula	C15H16O2



Critical properties

Sensitiser

Safety classification & labelling

Danger! This substance causes serious eye damage, is suspected of damaging fertility or the unborn child, may cause respiratory irritation, may cause an allergic skin reaction and *is toxic to aquatic life with long lasting effects.*

The above is based on the Harmonised Classification and Labelling (ATP1) approved by the European Union and *Classification and Labelling provided by companies to ECHA in REACH registrations.*

Regulatory actions

Substance included in the Community Rolling Action Plan (CoRAP).

About this substance

This substance is a High Production Volume chemical; per year 1,000,000+ tonnes are manufactures and/or imported in the European Economic Area.

This substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones), and paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper).

This substance is used in the following products: coating products, fillers, putties, plasters, modelling clay, and adhesives and sealants. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in the following areas: formulation of mixtures and/or re-packaging, and building & construction work. This substance is used in for the manufacture of: plastic products, electrical, electronic and optical equipment, bulk chemicals, machinery and vehicles, and pulp, paper and paper products.

Release to the environment of this substance is likely to occur from industrial use: in the production of articles, formulation in materials, as an intermediate step in further manufacturing of another substance (use of intermediates), formulation of mixtures, and manufacturing of the substance. Other release to the environment of this substance is likely to occur from: indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment), outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials), indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners), and outdoor use.

Precautions and Safe Use

Precautions suggested by manufacturers and importers of this substance can be found here; Guidance provided by manufactures and importers on the safe use of the substance can be found here.

More

4,4'-isopropylidenediphenol – European Chemicals Agency Infocard – last updated 18/02/2014

- Infocard gives simple high level overview of a substance
- Understandable to the broadest possible audience
- More detailed profiles will also be available

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Classification, Labelling & Packaging (CLP) Regulation

Harmonised Classification and Labelling for carcinogens:

Category of carcinogen	Number of substances
1A	336
1B	681
2	198
Total	1215

C&L Notifications:

- covering ~123 000 individual substances
- of which ~ 3 000 self-classified as Carc. cat 1A or 1B or 2
- C&L inventory database available on ECHA website (including substances in Annex VI of CLP with harmonized classification):

http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

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Evaluation

- 2 types of evaluation:
  - Dossier evaluation (animal testing/compliance checks) is performed by ECHA
  - Substance evaluation when a substance may present a risk to human health or the environment is done by the Member States (with ECHA as coordinator)
- Results of evaluation:
  - No further action
  - Industry can be asked for more info
  - Substance needs to be regulated further

    Eg: authorisation or restriction procedures

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State of play on Evaluation ?

- Dossier evaluation:

ECHA's's findings : 61% of dossiers examined so far were not in compliance = data quality problem

most frequently found shortcomings ?

- substance identity (SID)
- exposure assessment
- risk characterization
- prenatal developmental toxicity study
- sub-chronic toxicity study

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Consequences of bad quality data in registration dossiers:

- not possible to ensure that the risks are properly controlled for workers, consumers & environment
- in particular for workers: Risk Management Measures and conditions of use in extended Safety Data Sheet not reliable
- no confidence amongst citizens in the REACH system
- bad image for the Chemical industry
- questions about ECHA's efficiency

See also the ECHA's progress report on Evaluation under REACH:
https://echa.europa.eu/fr/regulations/reach/evaluation

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Authorisation

- For each use of substances of very high concern (CMRs (1A & 1B), PBTs, vPvBs, equivalent concerns) included in the Authorisation list (= REACH Annex XIV)

- Aim of authorisation (Art 55):

"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".

= substitution of SVHCs

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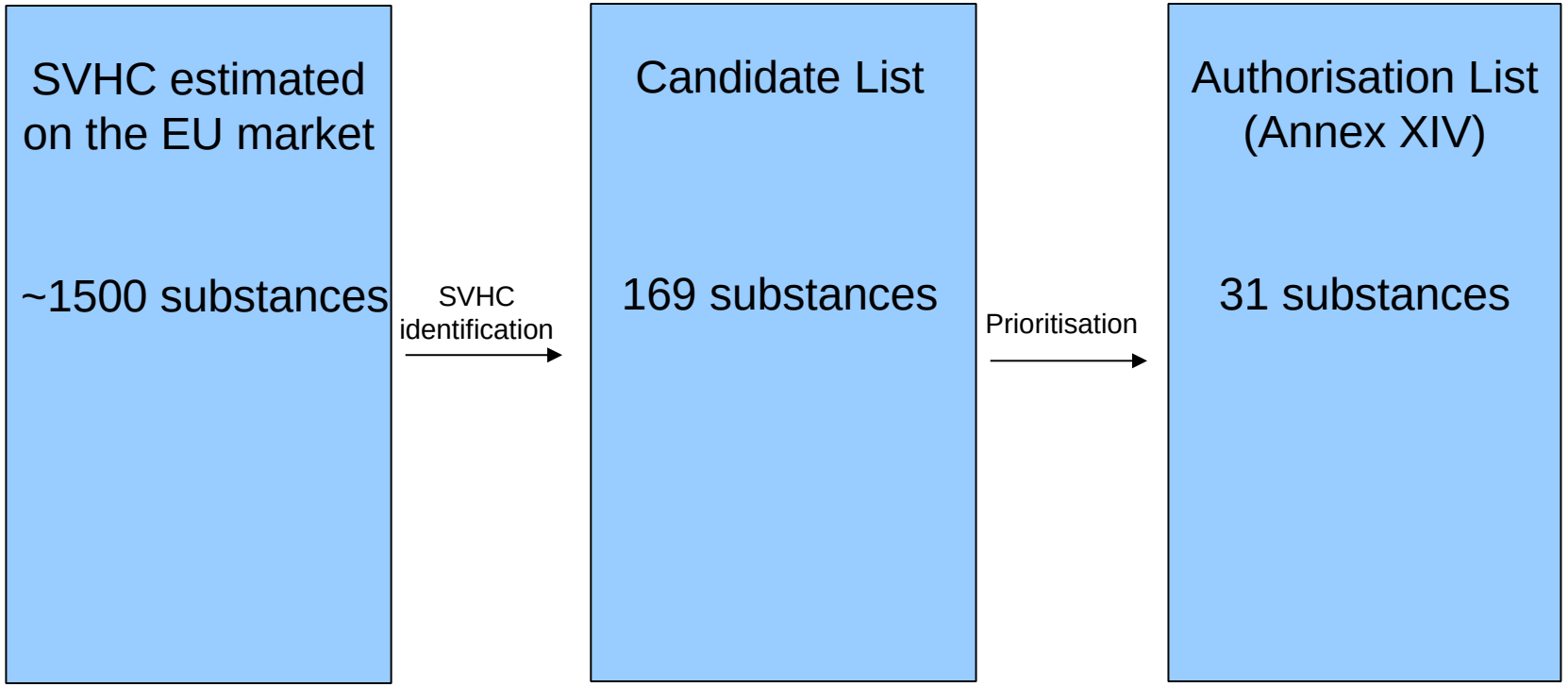
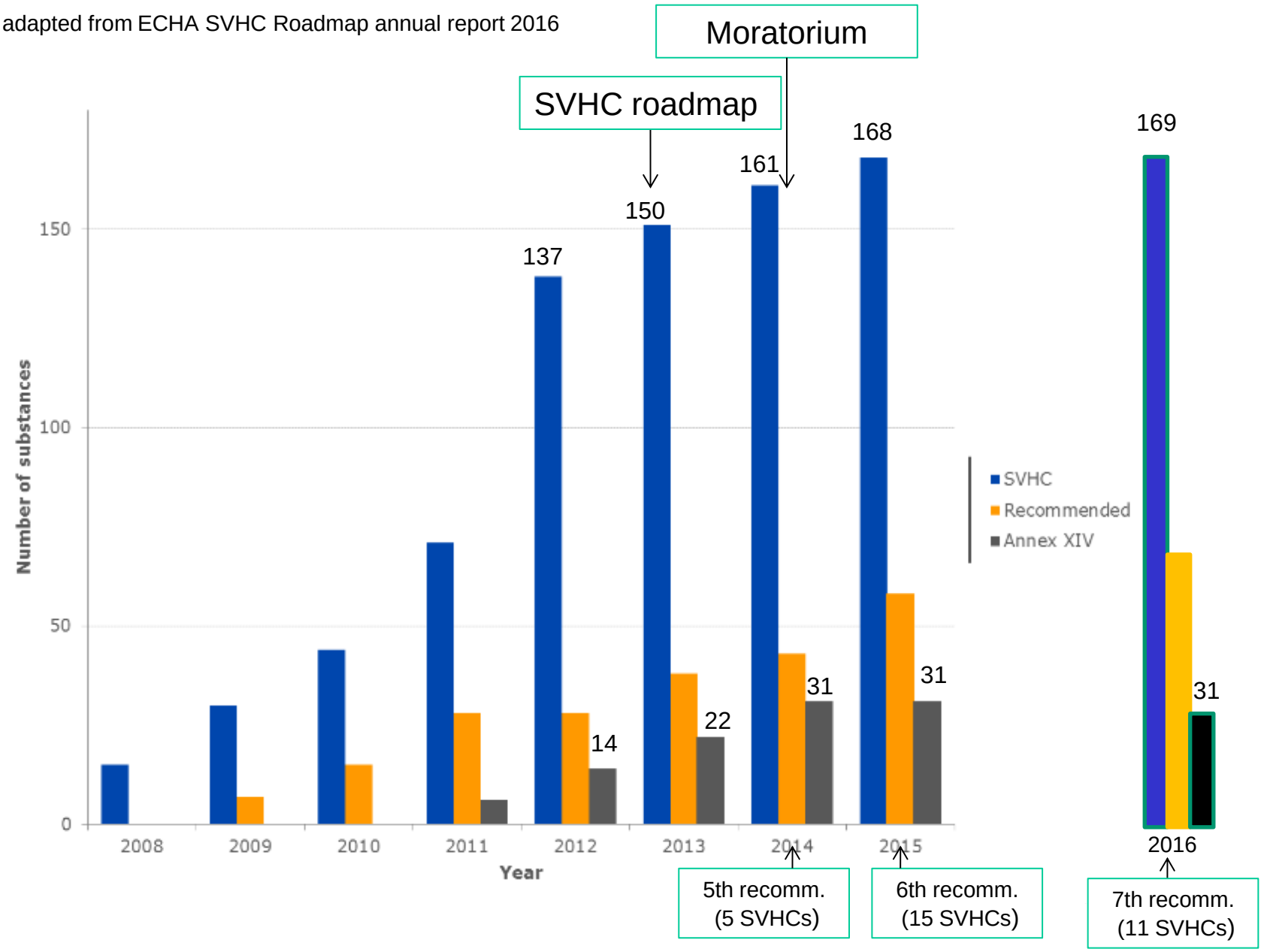
State of play on authorisation under REACH (Nov 2016)?

Substances of very high concern:
CMRs (1A & 1B), PBTs, vPvBs, equivalent concerns



Roadmap has slowed down Candidate & Annex XIV listing

Source: adapted from ECHA SVHC Roadmap annual report 2016



Granting of Authorisation

- Authorisation is granted by the Commission if
  - Route 1 :Industry can prove the risk is adequately controlled
  - Route 2: Socio-economic benefits > risks and no suitable alternatives are available
- No Authorisation granted if:
  - Use is not considered to be adequately controlled
  - Benefits are smaller compared to risks
  - Suitable substitutes are available (for route 2 only)
- All authorisations are time-limited and have to be reviewed (review periods vary between 2 and 12 years)

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State of play applications for authorisation (Nov 2016)

Substance	Number of received[1] applications (applicants)	Number of uses	RAC-SEAC opinions per use [2]	RAC-SEAC opinions per use and per applicant[3]	Commission decisions per use and per applicant[4]
Bis(2-ethylhexyl) phthalate (DEHP)	5 (7)	10	10	14	7
Dibutyl phthalate (DBP)	2 (2)	4	4	4	4
Bis(2-ethylhexyl) phthalate (DEHP) and Dibutyl phthalate (DBP)	1 (1)	3	3	3	3
Lead sulfochromate yellow (C.I. Pigment Yellow 34) and Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	1 (1)	12	12	12	12
Hexabromocyclododecane (HBCDD)	1 (13)	2	2	26	26
Diarsenic trioxide	4 (4)	5	5	5	5
Trichloroethylene	13 (15)	19	19	21	2
Lead chromate	1 (1)	1	1	1	
Chromium trioxide	25 (61)	41	13	49	
Sodium dichromate	17 (23)	23	7	7	
Chromium trioxide, Sodium dichromate and Potassium dichromate	1 (6)	3			

Source:https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications

REACH authorisations & substitution, does it work ?

- Candidate List is the main driver for innovation/substitution for industry (including DUs)
- Candidate List is a cost-effective incentive for companies to move towards safer alternatives even in SMEs (Glass making in Murano –IT)
- Commission & MS have slowed down the inclusion of SVHCs in the Candidate List (SVHC roadmap & moratorium)
- Up to know all authorisations are granted (no example of refusal yet)
- Commission prefers “short review periods” instead of not granting authorisations when applications are of bad quality

European Chemicals Agency (ECHA)

- ECHA's main task is to manage the technical, scientific and administrative aspects of the REACH & CLP regulations
- In 2016, ECHA has a staff of ~ 600 people
- ECHA's budget 2016 ~ € 107 million
- Since 2013, ECHA is also managing the implementation of
  - the new Biocide Products Regulation
  - the recasted PIC Regulation on the export and import of dangerous chemicals
- ECHA aspires to become the world's leading regulatory authority on the safety of chemicals
- Friendly to industry…..

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Longer term perspectives

- Changes needed to maximise REACH benefits ?
  - More balanced role of ECHA (new General director soon)
  - Measures to improve quality of registration data
  - Speed up the inclusion of SVHCs in Candidate List & Annex XIV
  - Synergies between REACH and other EU legislations need to be worked on and developed further (i.e. OSH, Waste legislation)
  - Enforcement
- Policy against work-related cancers
  - Revision of the Carcinogens & Mutagens Directive
  - Collecting systematic data on exposures (Hazchem@work)
  - Collecting reliable data on cancer and occupations
  - Consistent regulatory framework for Substances toxic for reproduction & Endocrine Disruptor Chemicals
  - Pay more attention to gender
- Industry needs to be convinced that the only way forward is safer chemicals and products containing them (mind-set change)

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Thank you for your attention !

More info available in ETUI publications (2016):

1) Eliminating occupational cancer in Europe and globally

http://www.etui.org/en/Publications2/Working-Papers/Eliminating-occupational-cancer-in-Europe-and-globally

2) Cancer risks in the workplace, better regulation, stronger protection

http://www.etui.org/fr/Publications2/Working-Papers/Cancer-risks-in-the-workplace-better-regulation-stronger-protection

3) Carcinogens that should be subject to binding limits on workers exposure

http://www.etui.org/fr/Publications2/Rapports/Carcinogens-that-should-be-subject-to-binding-limits-on-workers-exposure

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