

Introduction to ECHA's disseminated data: focus on substitution

Webinar: tools to support
substitution to safer chemicals

18 April 2018

Eoin Brennan, ECHA



Outline

- What is dissemination
- Published data
 - Published data – REACH registrations
- Substitution relevant data
 - Live demo – searching and finding data

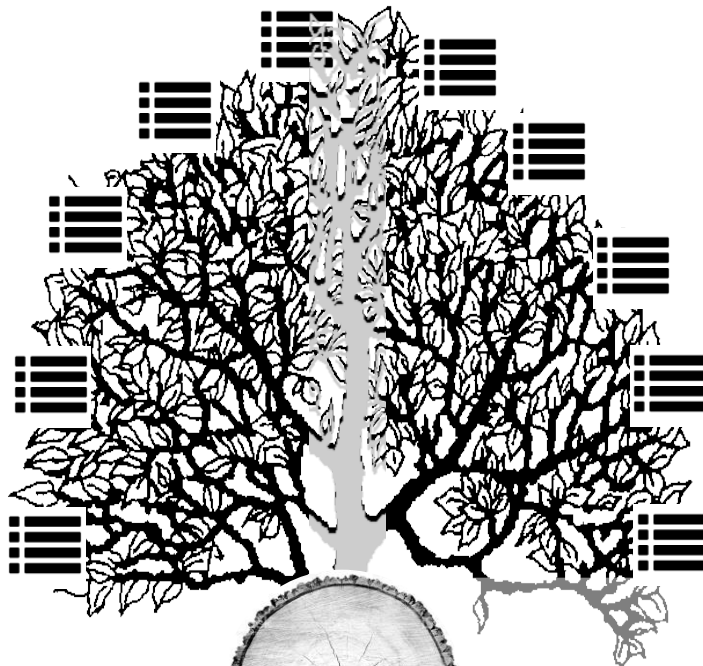
What is dissemination



What we have



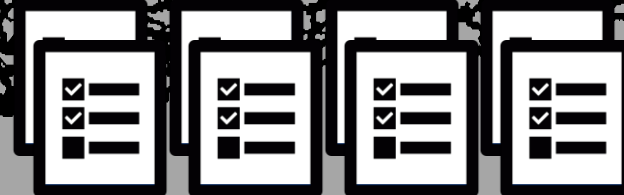
Dissemination



Substance identity



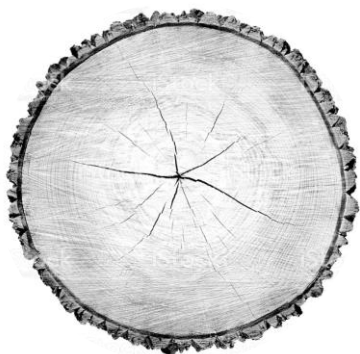
ECHA IT systems



ECHA regulatory lists



Public
ECHA website

Confidential
ECHA internal



Ethanol

Other names: [Regulatory process names \[3\]](#) [Trade names \[177\]](#) [Other names \[1\]](#) [IUPAC names \[50\]](#)

<p>Substance identity</p> <p>EC / List no.: 200-578-6</p> <p>CAS no.: 64-17-5, 97281-11-3</p> <p>Mol. formula: C₂H₆O</p>	<p>Hazard classification & labelling</p> <p></p> <p><i>Danger!</i> According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is a highly flammable liquid and vapour.</p> <p></p> <p>Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is toxic if swallowed, is toxic in contact with skin, is toxic if inhaled, causes damage to organs, causes serious eye damage and causes skin irritation.</p> <p>At least one company has indicated that the substance classification is affected by impurities or additives.</p>	<p>How to use it safely</p> <ul style="list-style-type: none"> Precautionary measures suggested by manufacturers and importers of this substance. Guidance on the safe use of the substance provided by manufacturers and importers of this substance.
<p><chem>CCO</chem></p> <p>About this substance</p> <p>This substance is manufactured and/or imported in the European Economic Area in 1 000 000 - 10 000 000 tonnes per year.</p> <p>This substance is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.</p> <p>Consumer Uses</p> <p>This substance is used in the following products: fuels and inks and toners.</p> <p>Other release to the environment of this substance is likely to occur from: outdoor use, indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives,</p>		

Regulations and regulatory activities

This substance has been found in the following regulatory activities:

BPR

› Biocidal Active Substances

ESR

› EC Inventory

CLP

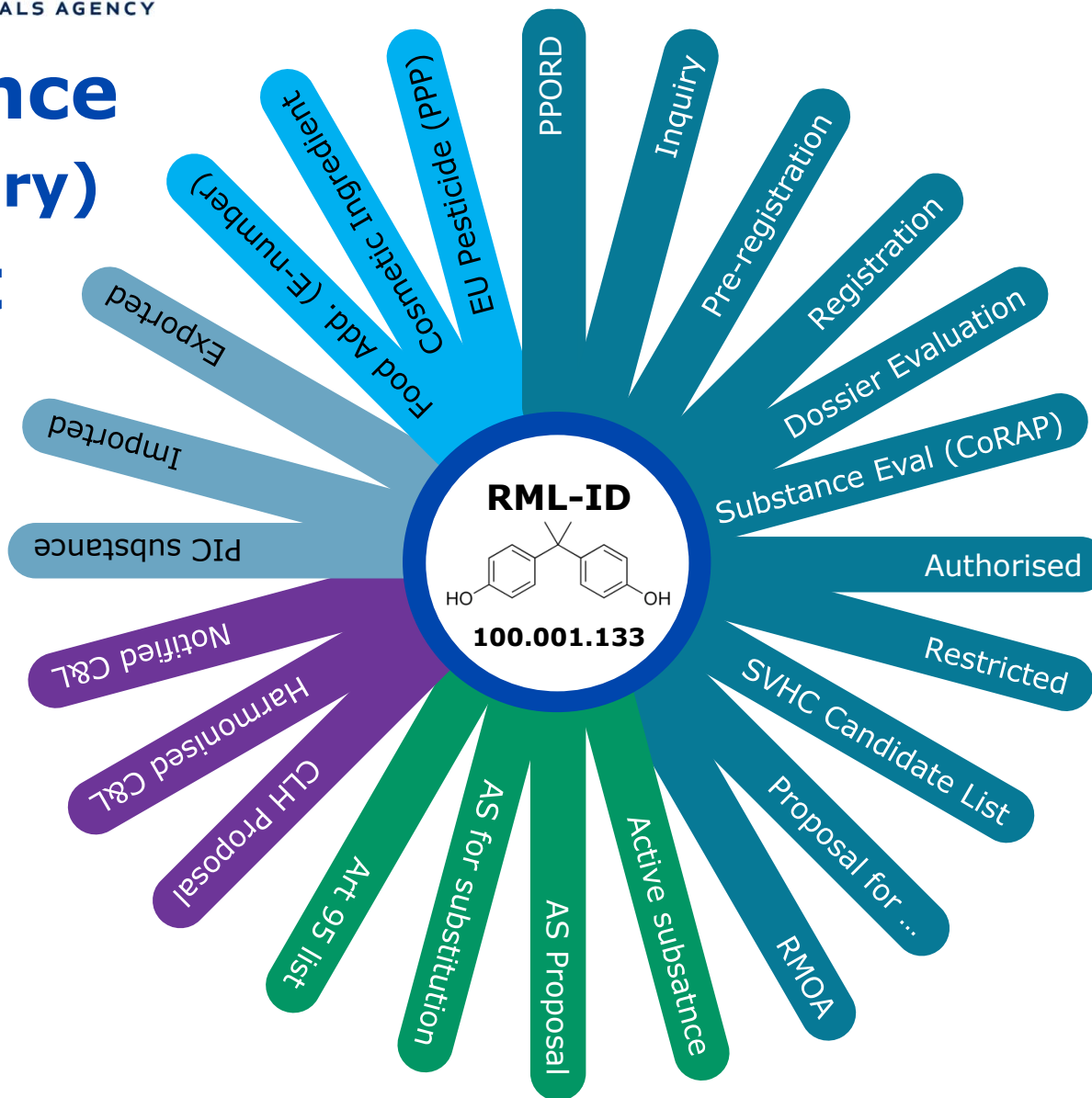
› C&L Inventory

REACH

› Pre-Registration process

› Registration dossier

Substance (regulatory) context



REACH

BPR

CLP

PIC

Other

Published

Infocard



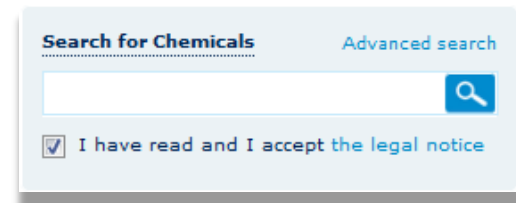
Chemical [X] Infocard

Substance identity: EC No: 203-687-4, CAS No: 133-90-0, Mol formula: C10H12

Physical & chemical properties: Includes hazard pictograms and GHS labels.

Important to know: Substances of very high concern (SVHC) and candidates for substitution.

How to use it safely: Precautionary measures supported by manufacturers and importers of the substance.

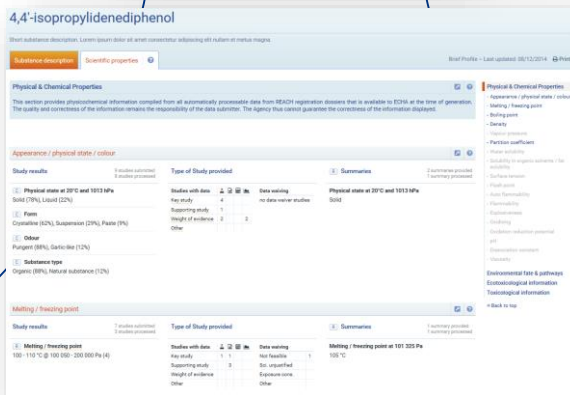



Search for Chemicals Advanced search

I have read and I accept the legal notice

ECHA's homepage:
echa.europa.eu

Brief profile



4,4-isopropylidenediphenol

Physical & Chemical Properties

Appearance / physical state / colour

Study results	Type of Study provided	Summaries
Physical state at 20°C and 1013 hPa	no data were available	Solid
Flash point		
Boiling point		
Freezing point		
Substance type		Organic (98%), Natural substance (1%)

Source data



Pre-registration list



Registration dossiers



CoRAP list



Authorisation list



Restriction list



Harmonised C&Ls



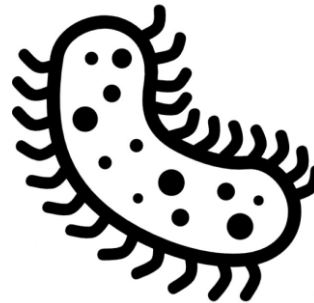
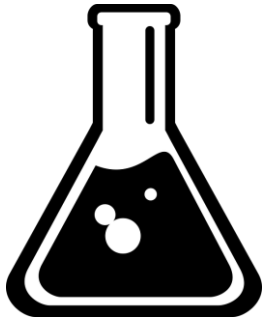
Approved active substances



PIC Annex I

What we have

231 057



Substance centric dissemination

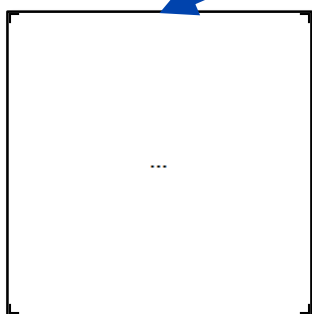
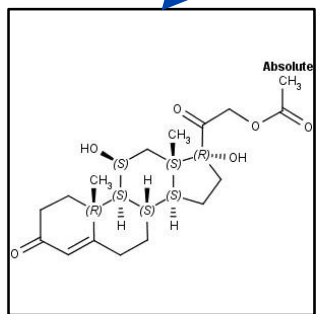
231 057 "substances" under regulation

96 466 assigned structure

95 254 no assigned structure

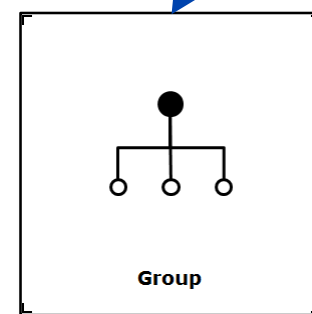
21 012
UVCB

18 125
[Conf]



Complex multi-constituent substance, or UVCB:
Unknown or Variable composition, Complex reaction products or Biological materials

Structure Confidential



Published data



Regulatory lists
What they mean



Published data

REACH

- Registered substances
- Annex III inventory
- Pre-registered substances
- EC Inventory
- Dossier Evaluation decisions
- PACT
- Substance Evaluation - CoRAP
- Information on Candidate List substances in articles
- Substances restricted under REACH
- Authorisation List
- Candidate List of substances of very high concern for Authorisation
- Submitted recommendations
- Adopted opinions on restriction proposals
- Adopted opinions on applications for authorisation
- ECHA's current activities on restrictions
- ECHA's completed activities on restriction
- Registry of intentions

CLP

- C&L Inventory
- Table of harmonised entries in Annex VI to CLP
- Registry of intentions

BPR

- Biocidal Active Substances
- Biocidal Products
- List of active substances and suppliers

PIC

- Chemicals subject to PIC
- Export notifications
- Import notifications
- Explicit consent

EC inventory

Meaning	Existing substance known to be on the EU market before REACH
Key data	<ul style="list-style-type: none">• 106 211 substances• Sub-list context<ul style="list-style-type: none">• EINECS (substance was on market by September 1981)• ELINCS (substance notified between 1981 and entry of REACH in 2007)• NLP (polymer definition was changed and these are substances no longer considered polymers)
Refresh	Never Based on the legal Official Journal of the European Union
Comment	Known issues with limited number of substances

Dossier evaluation decisions

- Meaning** One or more dossiers for this substance have been evaluated by ECHA
- Key data**
- **979 substances**
 - Dossier evaluation decision
 - Link to relevant registered substance factsheet
- Refresh** Daily
- Comment** Decision documents may be of interest. They mention e.g. areas of dossier to be improved

Substance evaluation - CoRAP

Meaning Substance has been or will be evaluated by an EU Member State authority

Key data

- **352 entries**
- Details of evaluation (where concluded)
- Status of evaluation
- Reason(s) for evaluation

Refresh Bi-annually

Comment

Candidate list of SVHC for authorisation

- Meaning**
- 1) Substance is of very high concern
 - 2) Substance will potentially have its use(s) subject to authorisation
- Key data**
- **181 entries**
 - Reason substance is considered SVHC
 - Decision
- Refresh**
- Bi-annually
- Comment**
- Substance of very high concern:
- Carcinogenic
 - Mutagenic
 - Toxic to reproduction
 - Persistent, bio-accumulative, and toxic (PBT)
 - ...

Authorisation list (Annex XIV)

Meaning	Some or all use(s) of the substance are subject to authorisation
Key data	<ul style="list-style-type: none">• 43 entries• Authorisation decision• Relevant dates• Exempted uses
Refresh	Irregular
Comment	

Restriction list (Annex XVII)

Meaning	Some or all use(s) of the substance are restricted in the EU
Key data	<ul style="list-style-type: none">• 66 entries• Conditions of the restriction• Other data such as history of earlier restrictions
Refresh	Irregular
Comment	Restriction report documents give reason for restriction, specific use(s) restricted, and other decision details

Table of harmonised classification and labelling

Meaning	Substance has a harmonised classification and labelling agreed at EU level
Key data	<ul style="list-style-type: none">• 4250 entries• Substance identity• Classification• Labelling
Refresh	Irregular
Comment	File of all harmonised classification and labelling entries

C&L Inventory

- Meaning** Substance has a harmonised classification and labelling agreed at EU level, and/or self-classification(s) notified by companies in the EU
- Key data**
- **139 000 substances**
 - Classification
 - Labelling
 - Seveso data (if applicable)
- Refresh** Weekly
- Comment** Self classifications by industry are not always aligned

Biocidal active substances

- Meaning** Substance is, was, or is sought to be an approved Biocidal active substance in the EU
- Key data**
- **279 substances**
 - Assessment report (if available)
 - Non-confidential scientific data
- Refresh** Frequently but irregularly
- Comment** While there is potentially a lot of data it is not in structured format and is only available as blackened PDF files

Chemicals subject to PIC

- Meaning** Substance is subject to controlled export, or is banned from export
- Key data**
- **1 359 substances**
 - Type of export ban/control(s)
 - Legal text of other legislation(s) relevant to PIC
- Refresh** Annual
- Comment** Also under PIC there is data relating to imports and exports, and the national authorities for all countries signatory to the Rotterdam Convention

Registered substances

Meaning

1. Substance is manufactured or imported to the EEA
2. One or more company(ies) in the EEA have submitted a dossier of information on the substance to ECHA

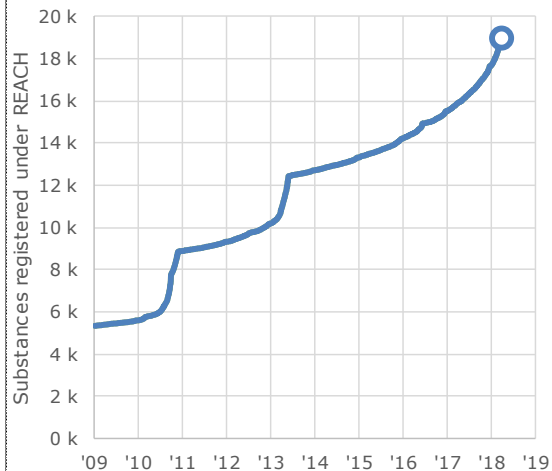
Key data

- **18 800 substances**
 - 60% phase-in substances
 - 65% full registrations (non-intermediates)
- Data as required based on the tonnage registered

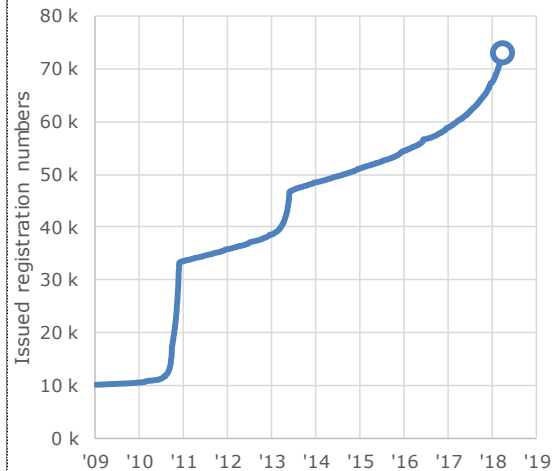
Refresh Daily

Comment All above 1 tonne expected by end May 2018

Substances Registered



Dossiers Registered



2018 April

Substances

Registered	18 928
Published	99.42%

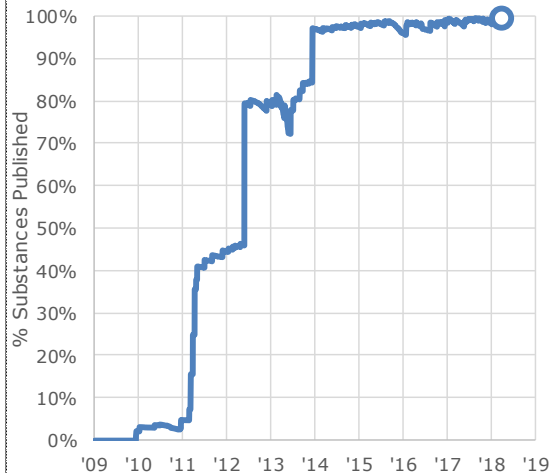
Registration Dossiers

Registered	72 863
Published	99.37%

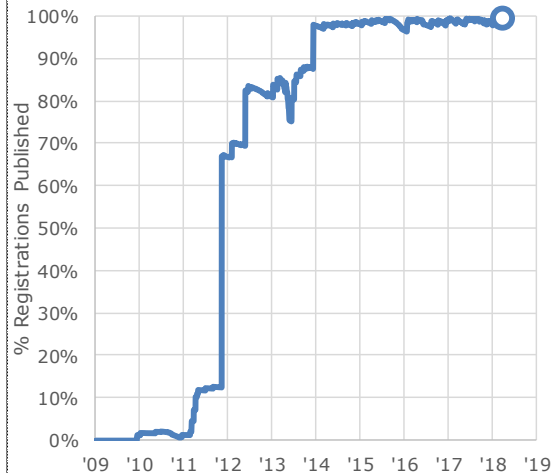
Data Published

(Gigabytes)	230.5
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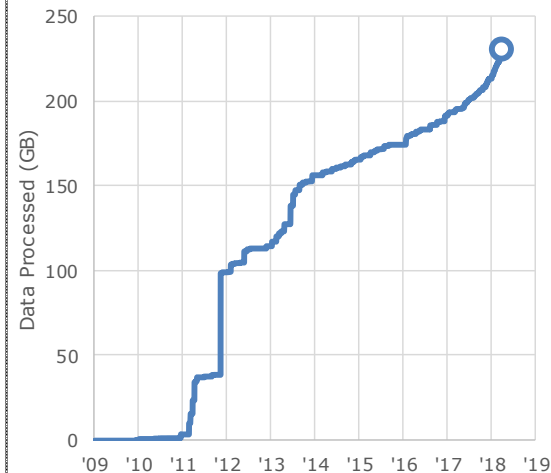
Substances Published



Dossiers Published



Data Published



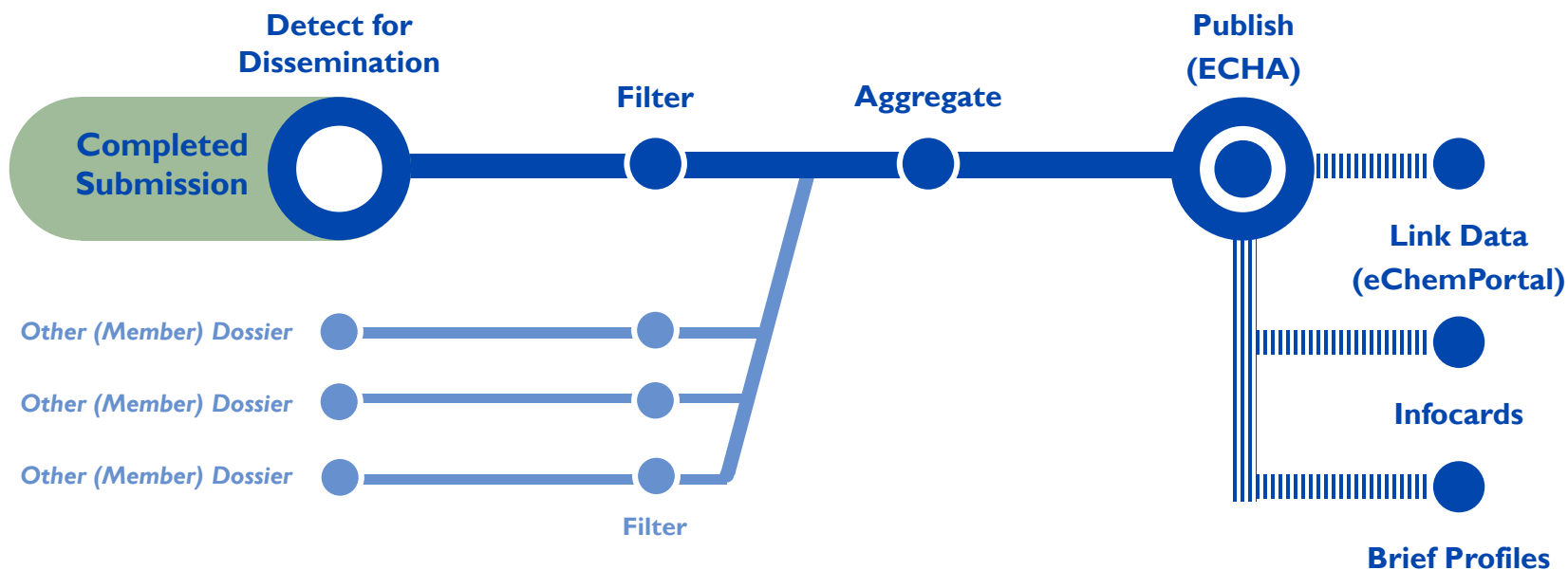
Published data



Publication process



Registered substances

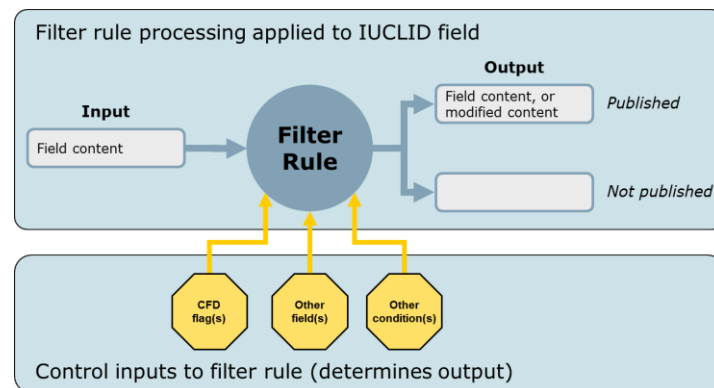
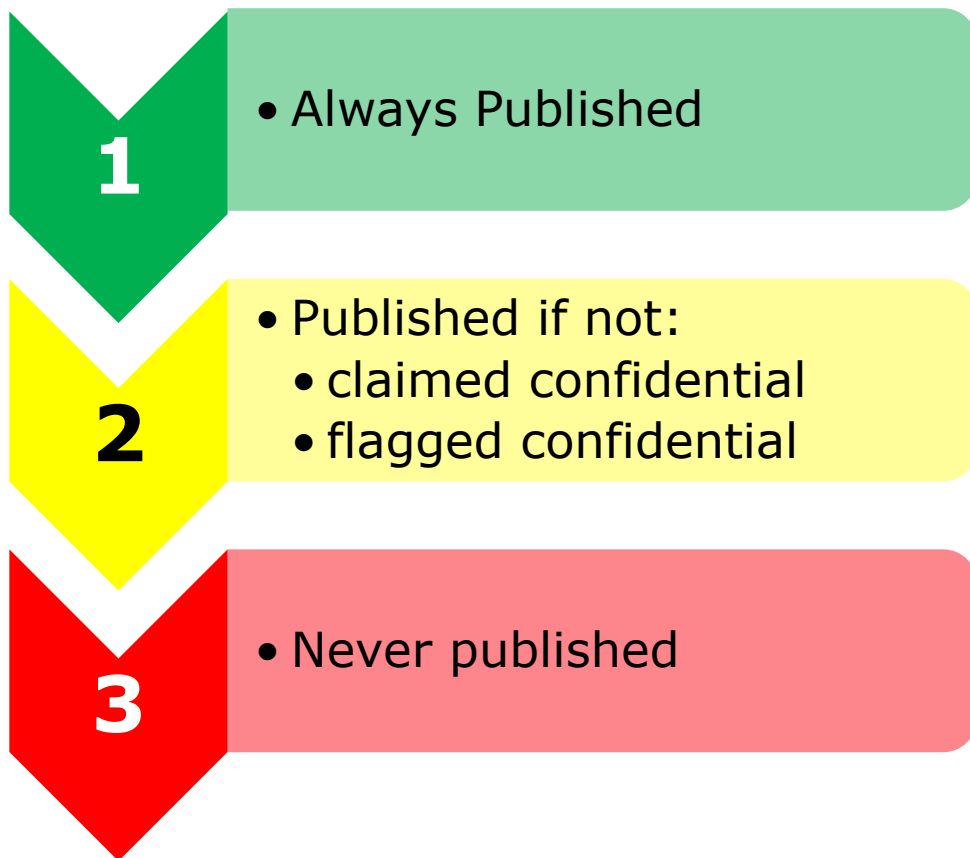




Source of data

- REACH Regulation
- Policy decisions
- Low level implementation
- Technical details

Per field



Always published



Article 119(1)

- (a) without prejudice to paragraph 2(f) and (g) of this Article, the **name in the IUPAC nomenclature** for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
- (b) if applicable, the **name of the substance** as given in EINECS;
- (c) the **classification and labelling** of the substance;
- (d) **physicochemical data** concerning the substance and on pathways and environmental fate;
- (e) the result of each **toxicological and ecotoxicological study**;
- (f) any **derived no-effect level (DNEL)** or **predicted no-effect concentration (PNEC)** established in accordance with Annex I;
- (g) the **guidance on safe use** provided in accordance with sections 4 and 5 of Annex VI;
- (h) **analytical methods** if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

Unless confidential



Article 119(2)

- (a) if essential to classification and labelling, the **degree of purity** of the substance and the **identity of impurities and/or additives** which are known to be dangerous;
- (b) the **total tonnage band** (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;
- (c) the **study summaries** or **robust study summaries** of the information referred to in paragraph 1(d) and (e);
- (d) **information**, other than that listed in paragraph 1, contained in the **safety data sheet**;
- (e) the **trade name(s)** of the substance;
- (f) subject to Article 24 of Regulation (EC) No 1272/2008, the **name in the IUPAC nomenclature** for non-phase-in substances referred to in paragraph 1(a) of this Article for a period of six years;
- (g) subject to Article 24 of Regulation (EC) No 1272/2008, the **name in the IUPAC nomenclature** for substances referred to in paragraph 1(a) of this Article that are only used as one or more of the following:
 - (i) as an intermediate;
 - (ii) in scientific research and development;
 - (iii) in PPORD

Unless confidential



'Volunteered' information

If not claimed confidential, information not specifically excluded from dissemination but not explicitly covered by REACH Article 119 is considered to be 'volunteered' for publication by the registrant.

Never published



Not Disseminated

Information covered by Article 118

Specific details of manufacturing processes, sites

Personal data – names, email addresses

Dossier administrative data (UUIIDs, Submission numbers, dates, creators)

Etc

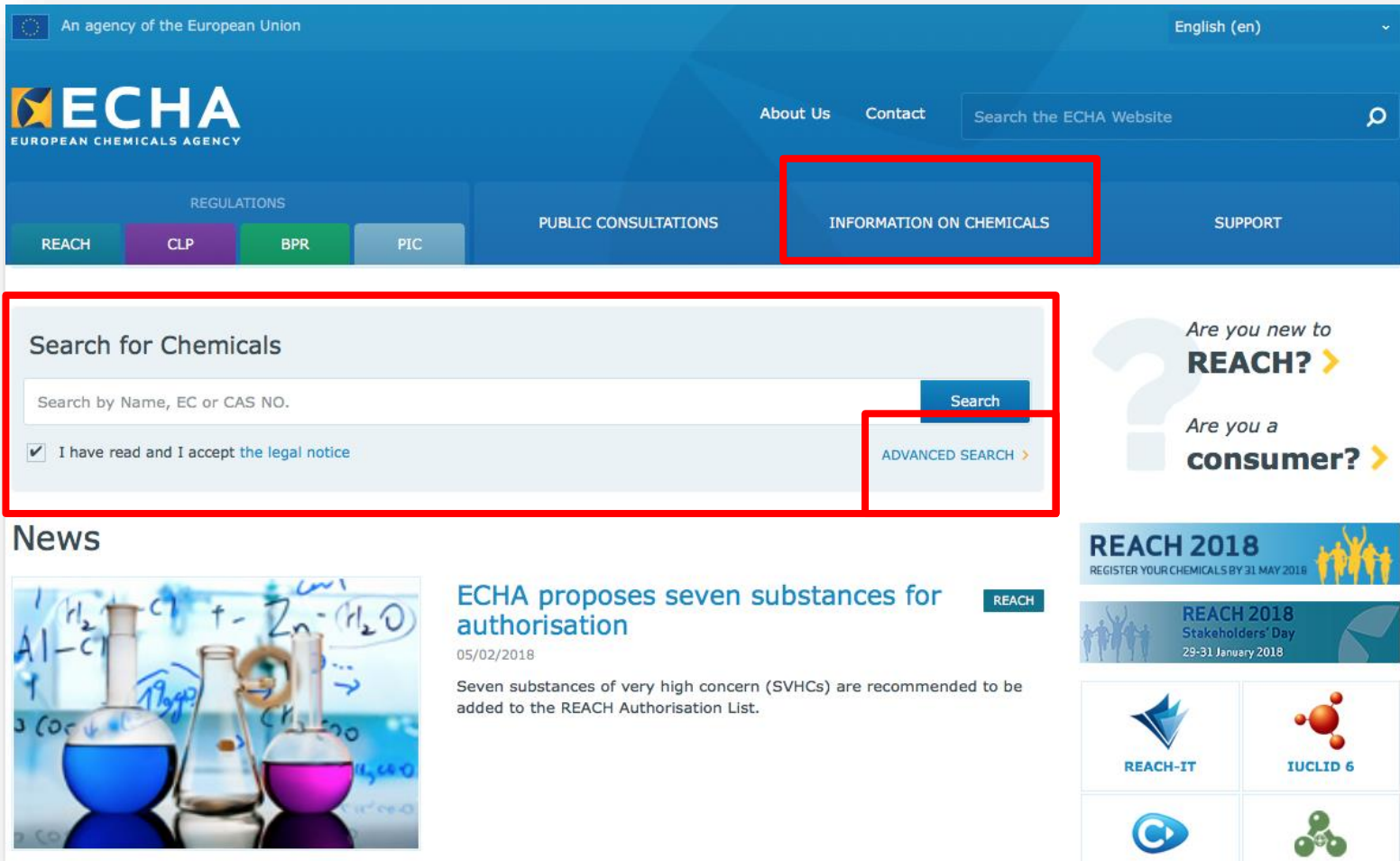
Substitution relevant data



Where to find it
How to search



Where to find it



An agency of the European Union English (en)

ECHA
EUROPEAN CHEMICALS AGENCY

About Us Contact Search the ECHA Website

REGULATIONS PUBLIC CONSULTATIONS **INFORMATION ON CHEMICALS** SUPPORT

REACH CLP BPR PIC

Search for Chemicals

Search by Name, EC or CAS NO. Search

I have read and I accept the legal notice **ADVANCED SEARCH >**

News

ECHA proposes seven substances for authorisation REACH

05/02/2018

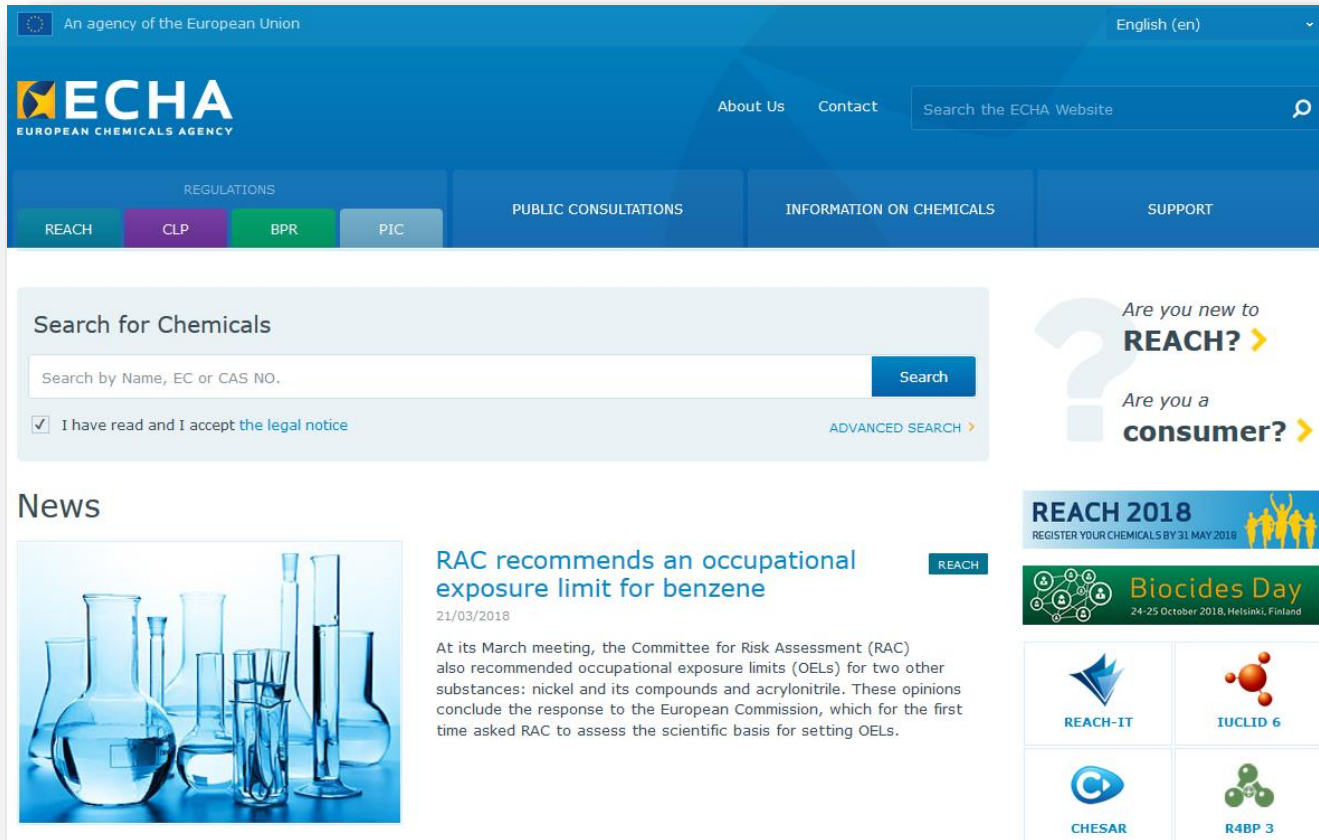
Seven substances of very high concern (SVHCs) are recommended to be added to the REACH Authorisation List.

REACH 2018
REGISTER YOUR CHEMICALS BY 31 MAY 2018

REACH 2018
Stakeholders' Day
29-31 January 2018

REACH-IT **IUCLID 6**

Live demonstration



The screenshot shows the ECHA website homepage. At the top, it says "An agency of the European Union" and "English (en)". The ECHA logo and name are prominently displayed. Navigation links for "About Us" and "Contact" are present, along with a search bar. A menu for "REGULATIONS" includes "REACH", "CLP", "BPR", and "PIC". Other sections include "PUBLIC CONSULTATIONS", "INFORMATION ON CHEMICALS", and "SUPPORT".

Search for Chemicals

Search by Name, EC or CAS NO.

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News

RAC recommends an occupational exposure limit for benzene REACH

21/03/2018

At its March meeting, the Committee for Risk Assessment (RAC) also recommended occupational exposure limits (OELs) for two other substances: nickel and its compounds and acrylonitrile. These opinions conclude the response to the European Commission, which for the first time asked RAC to assess the scientific basis for setting OELs.

REACH 2018
REGISTER YOUR CHEMICALS BY 31 MAY 2018

Biocides Day
24-25 October 2018, Helsinki, Finland

REACH-IT **IUCLID 6**

CHESAR **R4BP 3**

Future

- Policy review
- Focus on substitution
 - Promotion
 - Data requirements
 - Searches
 - ...



Thank you!

eoin.brennan@echa.europa.eu

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