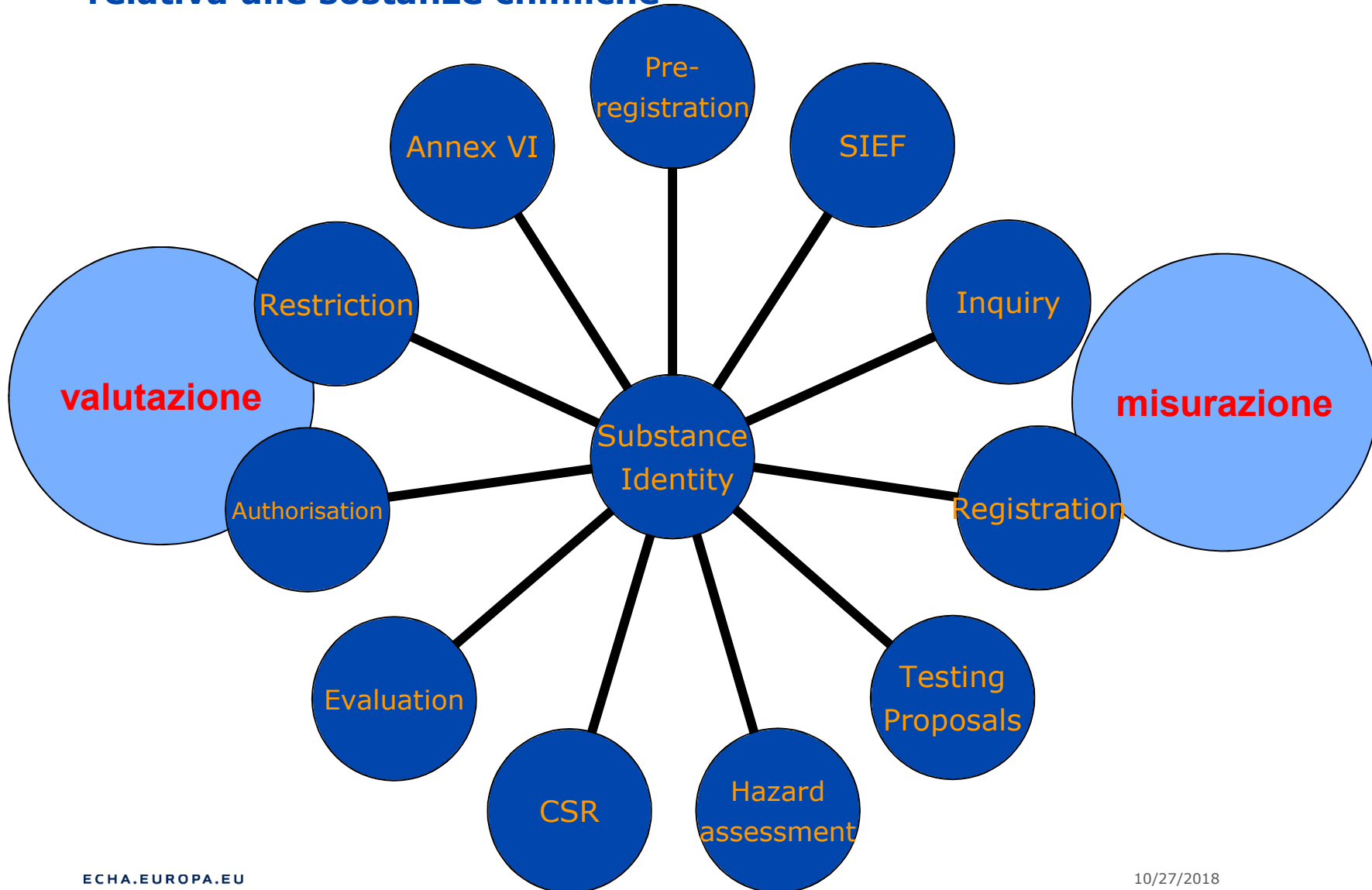


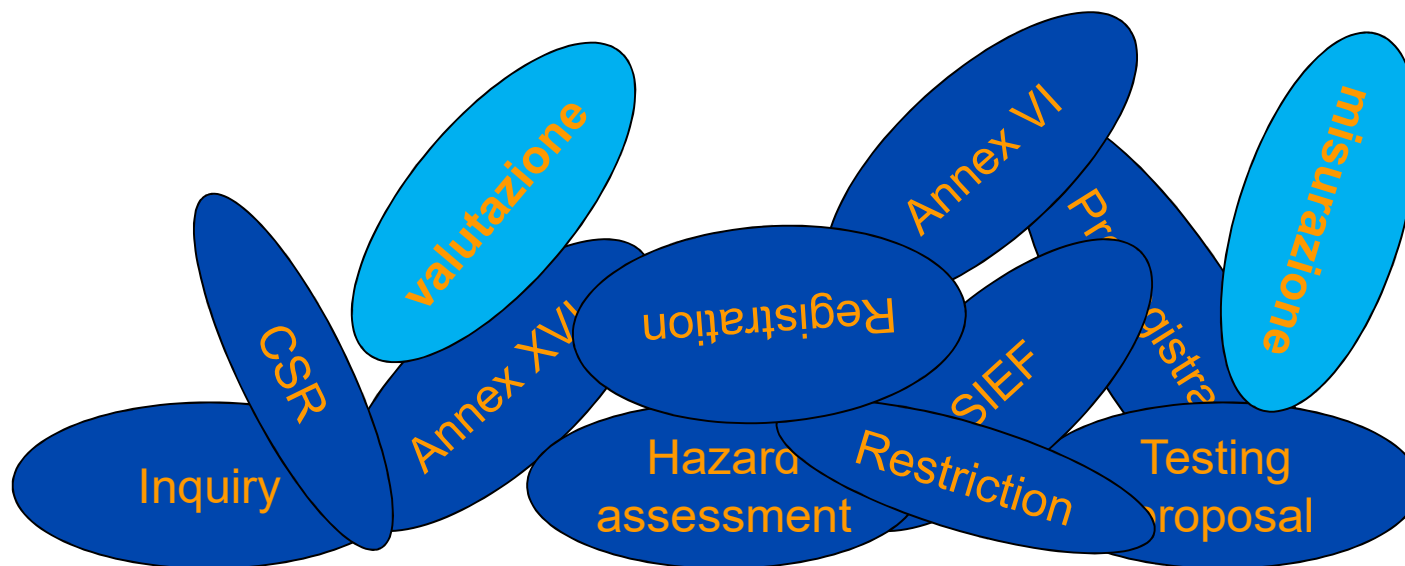
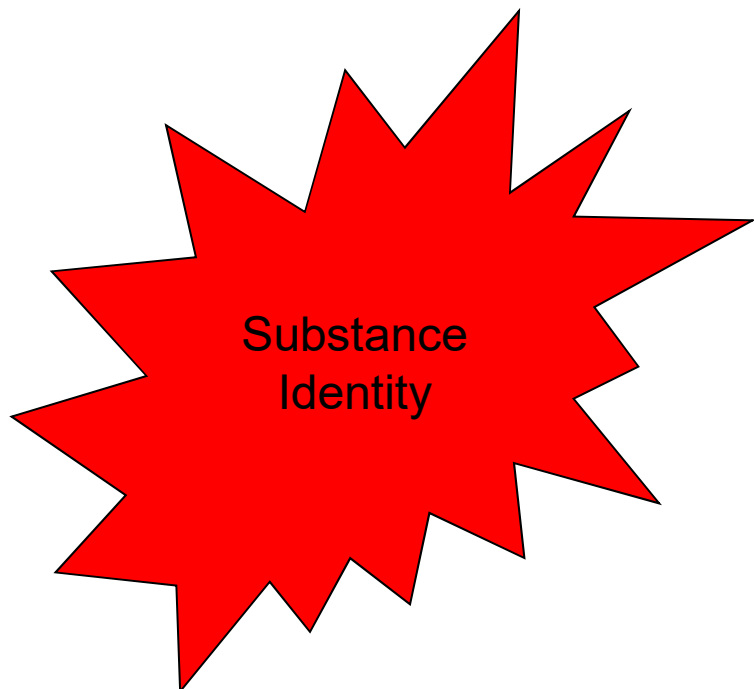
Strumenti per identificare correttamente le sostanze chimiche

Bologna, 18 Ottobre 2018
Convegno Nazionale
REACH 2018

Rossella Demi
Substance Identification &
Data Sharing Unit

L'identità della sostanza e' "il fondamento" per qualsiasi attività relativa alle sostanze chimiche





Cosa e' una sostanza?

Articolo 3(1) di REACH

Sostanza: significa **elemento chimico** e i suoi **composti** allo stato naturale o ottenuti da un **processo di sintesi**,

Incluso ogni **additivo** necessario a mantenerne la stabilita' e ogni **impurezza** che derivi dal processo utilizzato,

ma escluso ogni **solvente** che possa essere separato senza compromettere la stabilita' della sostanza o cambiarne la composizione

Perche' gli identificatori CAS/EC?

- IUPAC name
 - methyl (3 β ,19 α ,20 α)-16,17-didehydro-10,11-dimethoxy-19-methyloxayohimban-16-carboxylate
- EC # 205-005-3
- CAS # 131-02-2
- Piu' semplici

EC numbers – List numbers

EC Number	Source
2xx-xxx-x 3xx-xxx-x	EINECS (European I nventory of E xisting C ommercial chemical S ubstances) List
4xx-xxx-x	ELINCS (European L ist of N otified C hemical S ubstances) List
5xx-xxx-x	NLP (N o- L onger P olymers) List
List Number	Source
6xx-xxx-x	Automatically assigned, e.g. to pre-registrations of substances with a CAS No.
7xx-xxx-x	Assigned to substances after inquiries by the ECHA Substance ID Team
9xx-xxx-x	Automatically assigned, e.g. to pre-registrations without a CAS No. or other numerical identifier

- Numeri EC:
 - Pubblicati su Official Journal of the European Union
- Numeri List
 - Non hanno valenza legislativa al momento;
 - Sono identificatori tecnici generati da REACH-IT

IDENTITA' SOSTANZA (Annex VI (2) of REACH)

REQUISITI

2.1.1	IUPAC name or other international chemical name
2.1.2	Other names (e.g. trade name)
2.1.3	EINECS or ELINCS number (if available)
2.1.4	CAS name and CAS number (if available)
2.1.5	Other identity code (if available)
2.2.1	Molecular and structural formula (including SMILES, if available)
2.2.2	Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
2.2.3	Molecular weight or molecular weight range
2.3.1	Degree of purity (%)
2.3.2	Nature of impurities, including isomers and by-products
2.3.3	Percentage of (significant) main impurities
2.3.4	Nature and order of magnitude (e.g. ppm) of any additives (e.g. stabilising agents or inhibitors)
2.3.5	Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
2.3.6	High-pressure liquid chromatogram, gas chromatogram
2.3.7	Description of analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

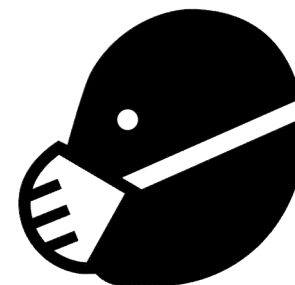
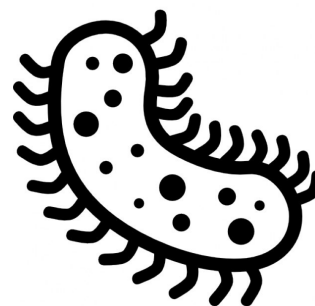
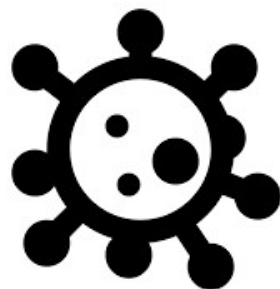
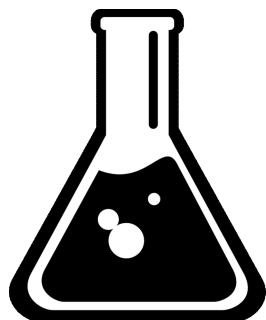
Identita' sostanze in pratica

- Una sostanza e' in generale identificata dal suo nome, dalla sua composizione e dai suoi identificatori numerici
 - Sostanze ben-definite
 - Struttura del costituente(i) e' nota
 - Nome IUPAC e altri identificatori
 - Sostanze UVCB
 - Non puo' essere sufficientemente identificata dalla sua composizione chimica solamente
 - In generale e' denominate sulla base delle materie prime e della tipologia di processo chimico

References

- **Legal reference**
Annex VI item 2 of REACH
- **Guidance for identification and naming of substances under REACH and CLP**
- **Data Submission Manual 18:**
How to report the substance identity in IUCLID 5 for registration under REACH

Cosa abbiamo



“Substance Centric Dissemination”

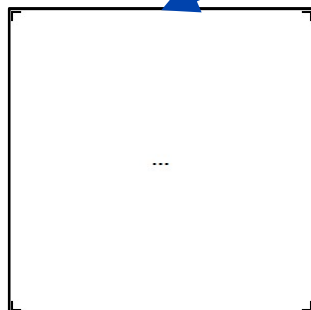
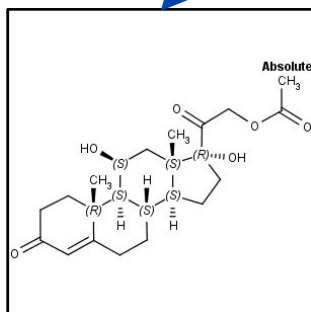
231 057 “sostanze” regolate

96 466 w/assigned structure

95 254 no assigned structure

21 012
UVCB

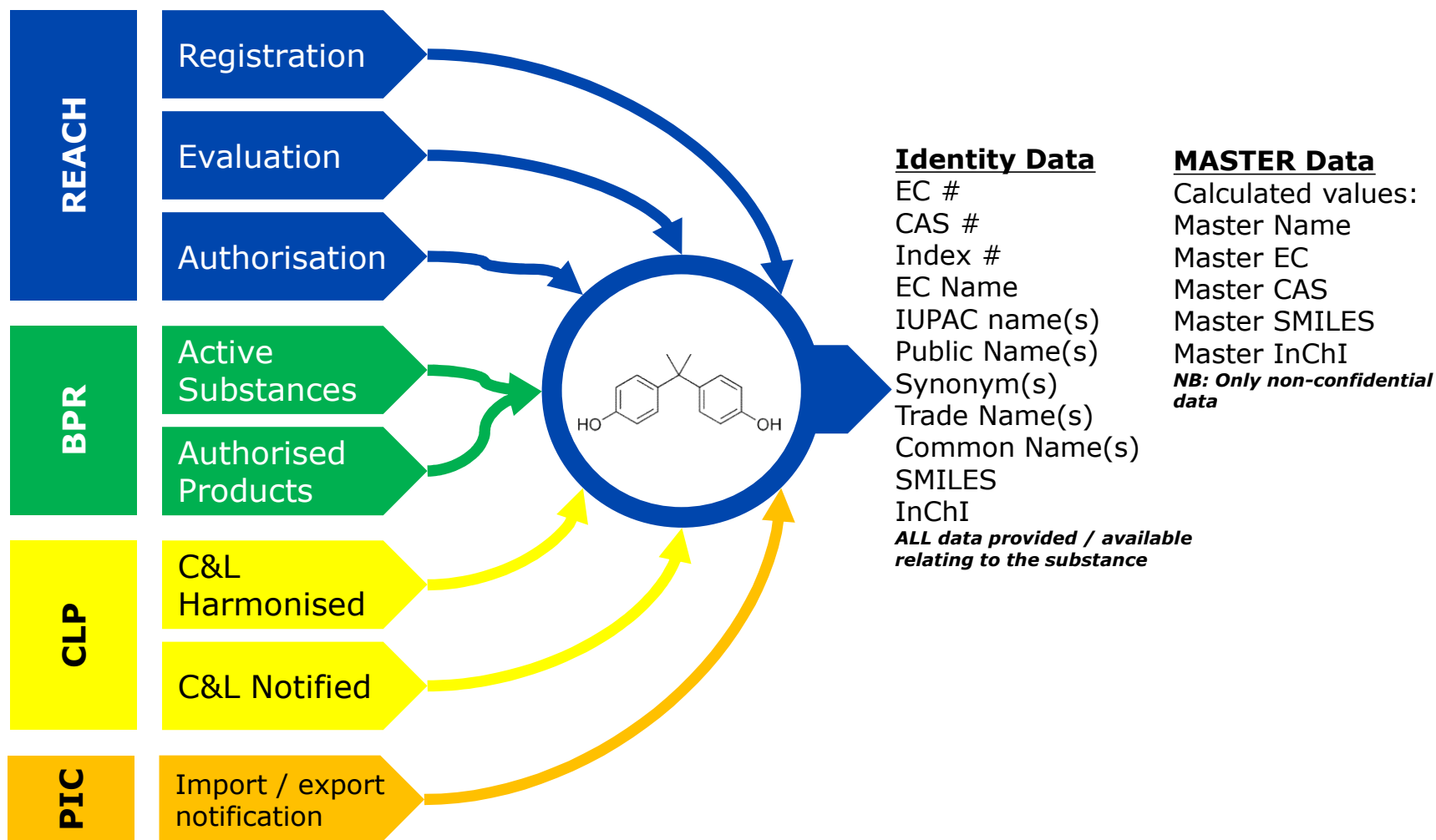
18 125
[Conf]



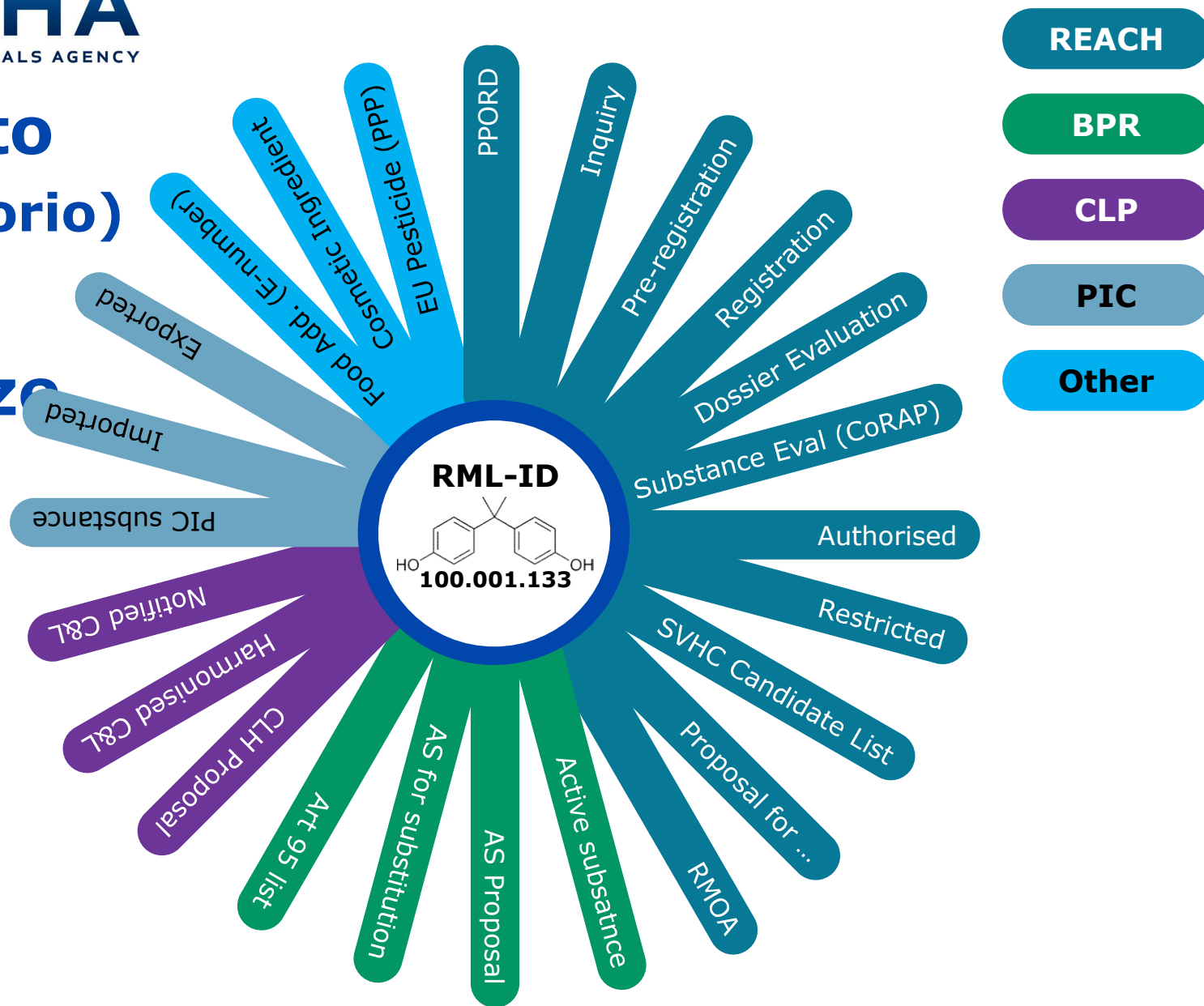
Complex multi-constituent substance, or UVCB:
Unknown or Variable composition, Complex reaction products or Biological materials

Structure Confidential

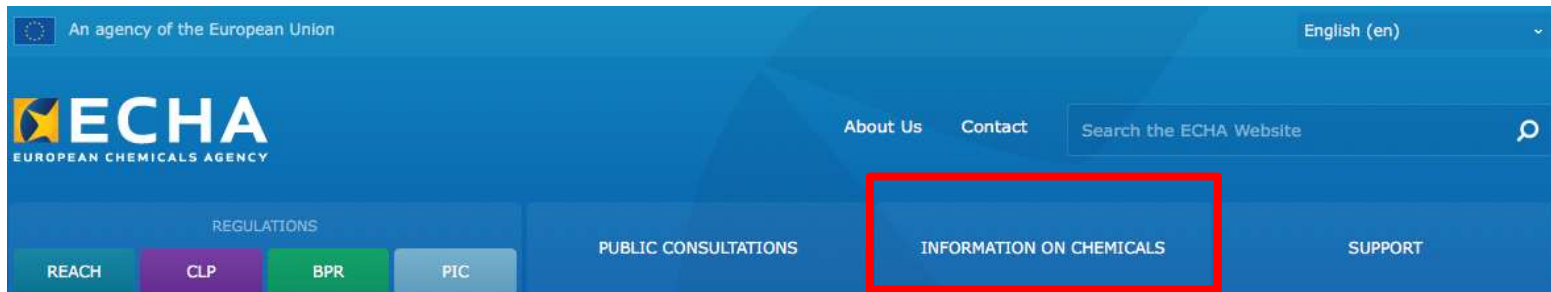
Substance centric – Approccio scelto



Contesto (Regolatorio) delle Sostanze



Dove trovare le informazioni



The screenshot shows the top navigation bar of the ECHA website. It includes the ECHA logo, the text 'An agency of the European Union', and a language selector set to 'English (en)'. Below this is a search bar labeled 'Search the ECHA Website'. A horizontal menu contains several categories: 'REGULATIONS' (with sub-items REACH, CLP, BPR, PIC), 'PUBLIC CONSULTATIONS', 'INFORMATION ON CHEMICALS' (highlighted with a red box), and 'SUPPORT'. There are also links for 'About Us' and 'Contact'.



The screenshot shows the 'Search for Chemicals' form. It features a search input field with the placeholder text 'Search by Name, EC or CAS NO.' and a 'Search' button. Below the input field is a checkbox labeled 'I have read and I accept the legal notice'. To the right of the search area is a link for 'ADVANCED SEARCH >'. The entire search form is enclosed in a red border.

Are you new to **REACH?** >
Are you a **consumer?** >

News



ECHA proposes seven substances for authorisation

05/02/2018

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

REACH

REACH 2018
REGISTER YOUR CHEMICALS BY 31 MAY 2018

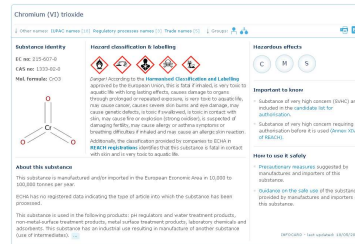
REACH 2018
Stakeholders' Day
29-31 January 2018



A grid of four logos: 'REACH-IT' (a blue stylized 'R'), 'IUCLID 6' (a cluster of red and orange spheres), a blue circular logo with a white 'C', and a green logo with three spheres.

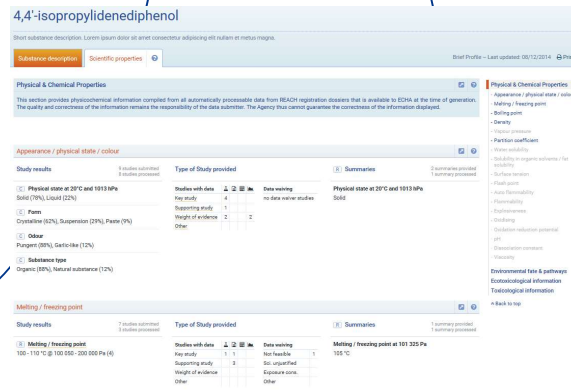
Livelli di Informazione (tiered approach)

Infocard

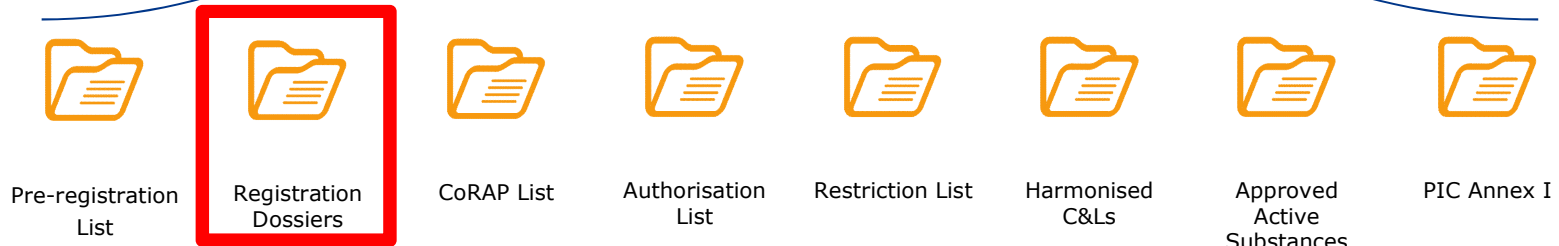



ECHA's homepage:
<http://echa.europa.eu>

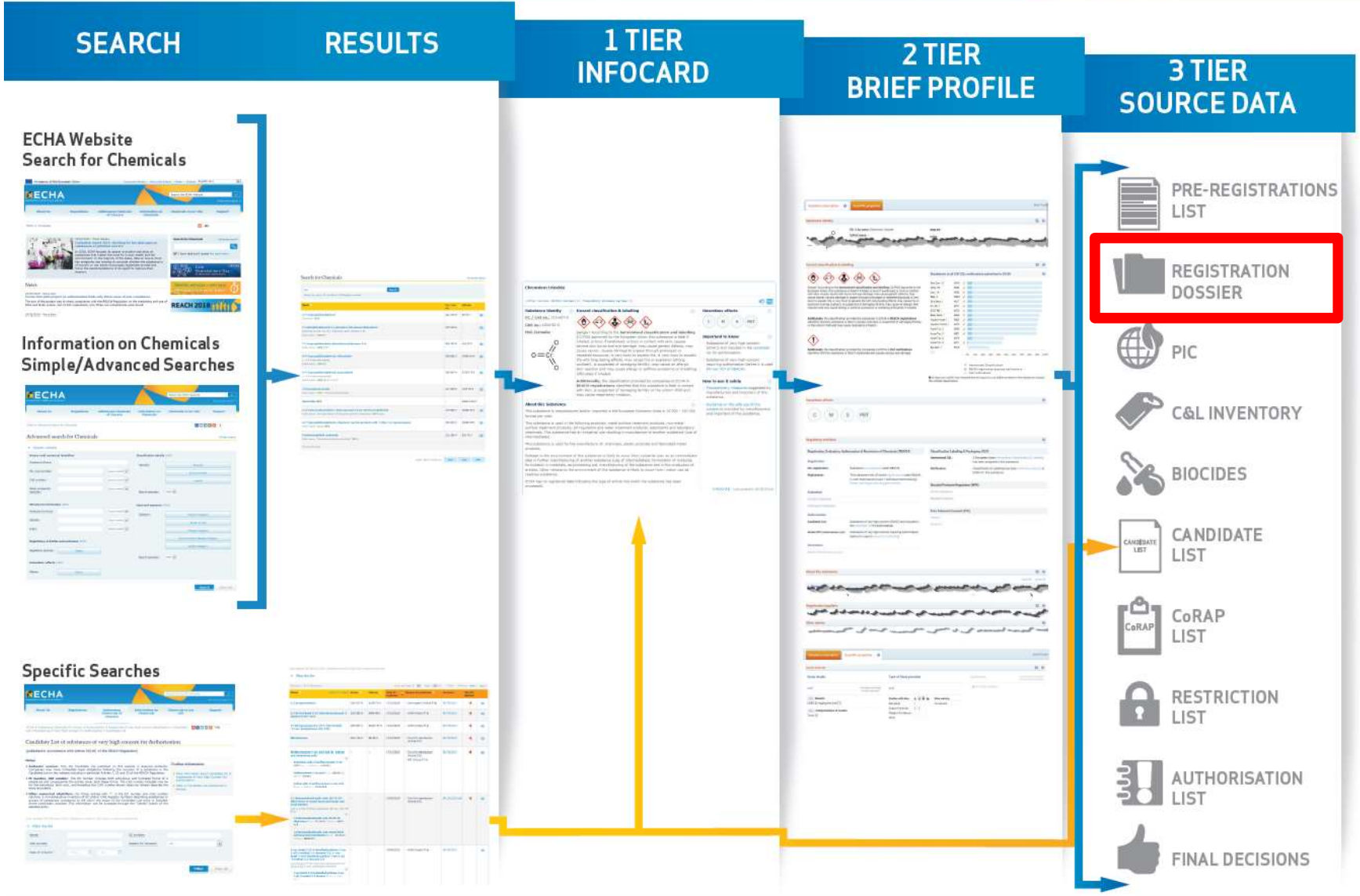
Brief Profile



Source Data

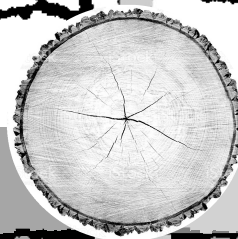
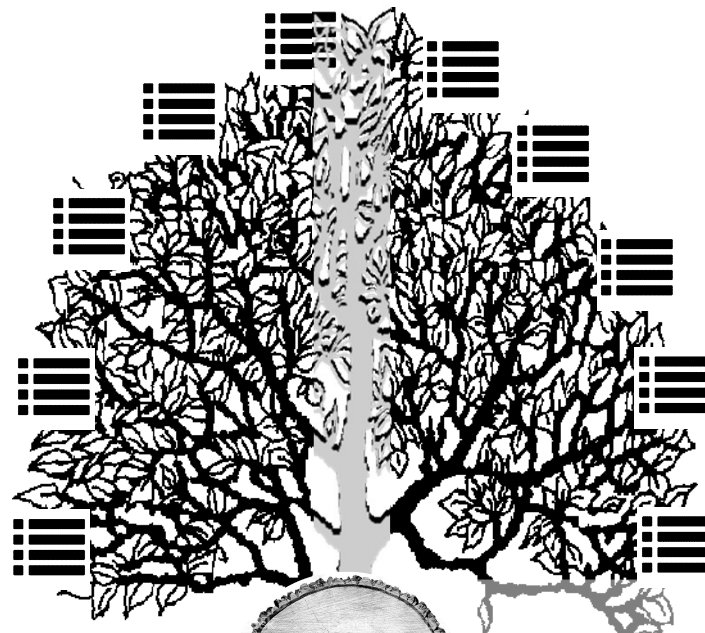


TIERED APPROACH TO INFORMATION



Public
ECHA Website

Dissemination

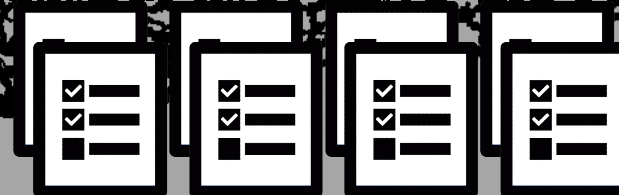


RML

Confidential
ECHA Internal



ECHA IT systems



ECHA Regulatory Lists

Processo CCH : problemi di “incompliance”

- Deviazione dalla regola dell' 80 %
- Sostanze con additivi che non sono stabilizzanti
- Dati analitici che contraddicono le informazioni sull'identità della sostanza
- Dati analitici a supporto dell' identità della sostanza non sufficienti/illegibili/parziali
- Contro ione not identificato/quantificato
- Informazione sulla stechiometria non riportata
- Informazione sulla stereoisomeria non riportata

Conclusioni

- L'identità della sostanza è il primo passo per la gestione dei rischi, nei processi come nella valutazione del rischio per uomo e ambiente.
- (E)Valutazione: assicura che l'identità sia chiara e che i dati di pericolosità siano connessi alla sostanza effettivamente sintetizzata.
- ECHA controlla le informazioni sull'identità della sostanza riportate in IUCLID 5 (consistent, correct and compliant)
- One registration, one substance

Grazie

