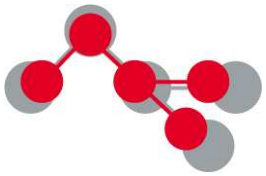
Dr Matteo Dalla Valle
Hong Kong – 17/09/2010



MANAGING REACH
TECHNICAL ASPECTS

WHERE ARE WE NOW?

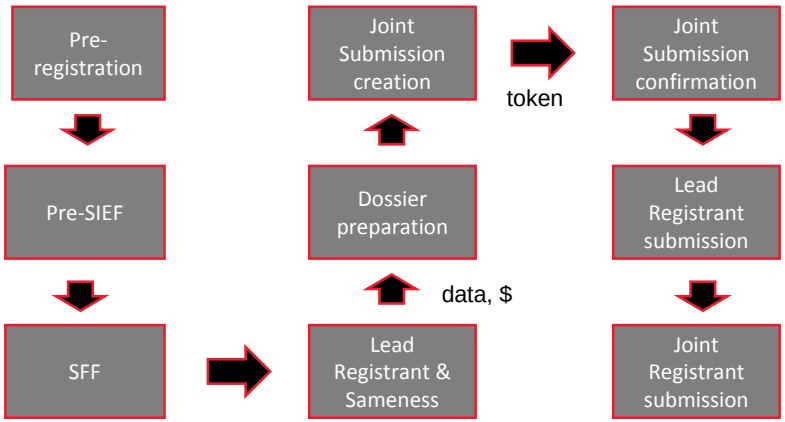
September 2010: Only a few weeks left before the fist REACH registration deadline (1st December)!

SIEFs have been formed and Lead Registrants have been identified

In many cases dossiers have been submitted or are nearly ready for submission by the Lead Registrant

Still a lot of confusion and many SIEFs are behind schedule – big concerns

THE REGISTRATION PROCESS



DOSSIER STRUCTURE

1. Substance ID, contact details, analytical characterization 3. Manufacture, identified uses, exposure	EVERY REGISTRANT (company data)
2. Classification and labelling 4. Physico-chemical properties 5. Environmental fate 6. Ecotoxicity 7. Toxicology	LEAD REGISTRANT ONLY
11. Guidance on safe use 13. Chemical safety report (CSR)	DEPENDING ON THE SIEF IT MAY OR MAY NOT BE PROVIDED BY THE LR

LETTER OF ACCESS

- The LEAD REGISTRANT submits the complete dossier and the other SIEF members should submit only the individual part of the dossier
- The Joint Registrants are then allowed to refer to the LR dossier
- The Letter of Access is a document which allows the JR to refer to the data submitted by the LR on behalf of the SIEF

LETTER OF ACCESS

What does the Letter of Access provide?

- Right to refer to the LR dossier (legal statement + token)
- Classification & Labelling
- Common elements of the SDS and Exposure Scenarios (if required)

Optional

- Copy of the data set
- Right to refer to the CSR
- Copy of the CSR

GOOD PRACTICE

- Joint registrants should be allowed to see in advance what they buy!
- Joint registrants should be provided at least with a copy of the CSR and of a SDS
- The Regulation says that costs should be split in an “equitable and fair” way
- Read carefully what you sign and if not happy with what is provided with LoA you have the right to complain!

REGISTRATION DOSSIER COMPANY SPECIFIC DATA

- Contact details
- Substance identity (including impurities and additives)
- Analytical information on the substance
- Manufacturing process (only for EU manufacturers)
- Estimated annual tonnage
- Sites of production or use (only if in Europe)
- Form in the supply chain (i.e. substance, article, mixture)
- Identified uses
- Uses advised against
- Waste from production and use
- Basic information on exposure

ANALYTICAL INFORMATION

- Detailed substance identity is a requirement of **all** registration dossiers
- The analytical information is necessary to demonstrate that the Joint Registrant's substance is the same as the LR
- Importance of characterization is being underestimated

During the first 5 months of 2009, 450 Inquiries were received by ECHA, 23% of which were rejected

- Incomplete dossiers e.g. missing spectral data
- Substance identity insufficiently described

GENERAL ANALYTICAL REQUIREMENTS

REACH Regulation Annex VI, item 2

2.2.2 Optical activity and isomer ratio
2.2.3 Molecular weight (range) or range
2.3.1 Degree of purity (%)
2.3.2 Nature of impurities, incl by-products
2.3.3 Percentage of main impurities,
2.3.4 Nature and order of magnitude of any additives
2.3.5 Spectral data
2.3.6 High-pressure liquid chromatography or gas chromatography

'SUFFICIENT' AND 'APPROPRIATE' ?

- Meaningful
- 'Orthogonal' analysis - independent and mutually reinforcing
- Consistent
- Accuracy and precision – replicates for high error limits
- Complex cases – 'spike' with known standards
- Fingerprints of complex substances - compare with known spectra

ANALYTICAL TESTS

- Structural information
  - Mass spectroscopy
  - Structural, e.g. *^{1}H and ^{13}C NMR*
  - Vibrational, *e.g. IR, Raman*
  - Electronic, *e.g. UV-Vis, fluorescence,* atomic absorption/emission spectroscopy
- Purity
  - Separation techniques, *e.g. HPLC-MS, GC-MS, ion chromatography*
  - Total substance evaluation, e.g. elemental analysis
- Other defining properties
  - Morphology, usually by XRD
  - Particle size (nano materials)
  - Thermal analysis, typically TGA and DSC

ANALYTICAL DOCUMENTATION

'Description of the analytical methods.....sufficient to allow the methods to be reproduced' (Annex VI)

Spectra/analytical data should clearly show:

- Substance name, structural formula, source, batch #, date etc
- Equipment used (make, model)
- Specific test, conditions and methods used
- Instrument calibration (details, dates)
- Form in which sample was tested
- Purity of solvents and reference standards
- Number of duplicates and whether a mean was quoted

CONCLUSIONS ON ANALYTICAL CHARACTERIZATION

- Substance identity should be demonstrated unequivocally
- Spectra and other analytical work may be meaningless without adequate documentation
- Consistency within the SIEF justifies and facilitates data sharing
- With complex cases, combine other knowledge to strengthen the analytical case
- Take advantage of any registration strategies established by SIEFs/consortia/trade associations that impact on substance characterization

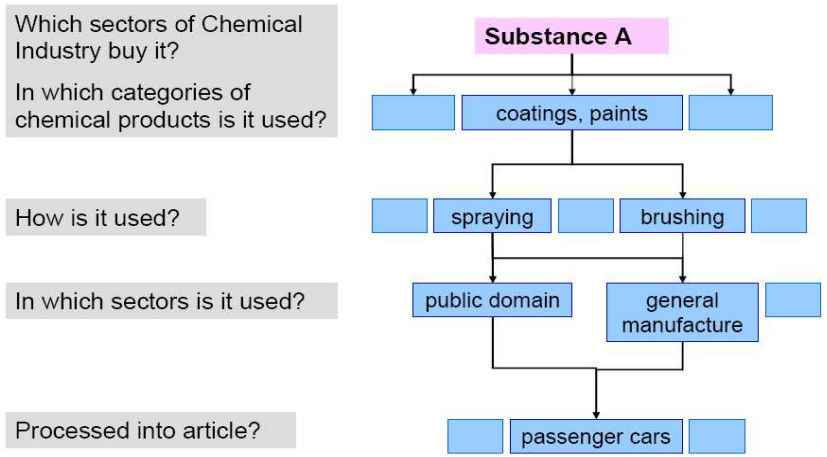
IDENTIFIED USES

REACH requires companies to indicate the uses of the substance they register. All the uses that occur during the life cycle of the substance must be considered.

If a use is not specifically mentioned in the Registration Dossier, that use is not allowed.

Uses are defined by using a standardized system called "use descriptors system". Each identified uses is therefore described by a combination of "descriptors" picked from official lists.

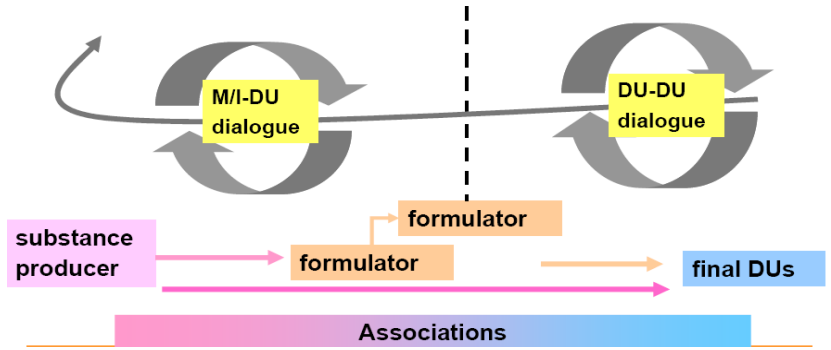
USE DESCRIPTOR SYSTEM



DIALOGUE IN THE SUPPLY CHAIN

- Identify uses
- Build exposure scenarios
- Conduct safety assessment

- Make uses known to M/I
- Inform on conditions of use
- Give feed back to exposure scenarios



ONLY REPRESENTATIVE

- Non EU manufacturers wishing to import into the EU can appoint an '*only representative'* (OR) who for purposes of REACH acts as an importer and registers the substance(s) with the ECHA
- The '*OR*' is not an agent
- Customers of the non EU manufacturer are classed as downstream users and thus avoid registration
- The OR needs to be a legal person or entity within the EU. They make the pre-registration/registration and maintain **records of annual tonnages** to all EU customers of the non-EU manufacturer for the substance(s). They also are the communication link with the ECHA and with customers (in respect of REACH issues e.g. **SDS**).

REACH COSTS

- Fees payable to ECHA
  - Registration
    - Changes
    - Confidentiality
    - Intermediates
  - PPORD
  - Authorisation
- Dossier preparation
- Data sharing
- Data/information management
- Customer relations
- Safety data sheets

REGISTRATION FEES

Tonnage band (t/y)	Individual registration (€)	Joint registration (€)	Medium enterprise Individual (€)	Small enterprise individual (€)	Micro enterprise individual (€)
1 -10	1600	1200	1120	640	160
10 -100	4300	3225	3010	1720	430
100 - 1000	11500	8625	8050	4600	1150
>1000	31000	23250	21700	12400	3100

TESTING COSTS AND DOSSIER PREPARATION

- How long is a piece of string!!
- Testing costs
  - Annex VII – 60,000 euros
  - Annex VIII – 300,000 euros
  - Annex IX – 900,000 euros
  - Annex X – 1,500,000 euros
- SIEF management costs
  - Consortia membership (100 – 100,000 euros)
- Chemical safety assessment (5,000 - 20,000 euros)

BUSINESS IMPLICATIONS

- Compliance management
- Management of Data sharing/SIEFs/Consortia
- Confidentiality (protection of/ lack of, competitors/general public, competition law)
- Data management
- Costs/financial management
  - Registration fees
  - Testing and dossier preparation costs
  - Reformulation
  - SIEF/Consortia

REACH IT & IUCLID

REACH IT

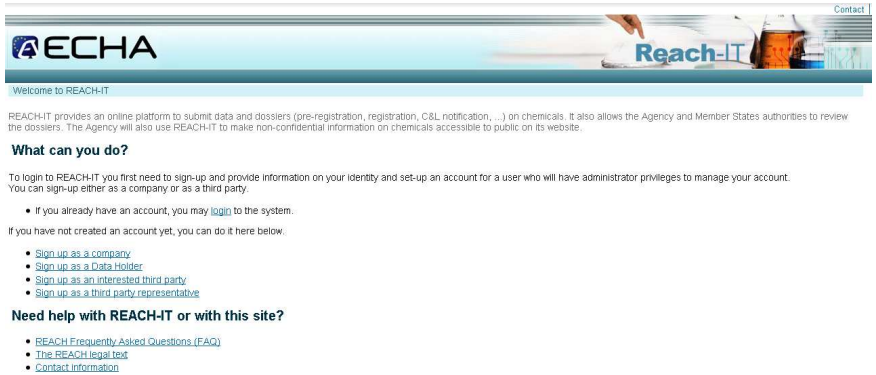
REACH IT Workflow system represents a paperless system whereby 30,000 companies can register 100,000 substances, and then to provide a work flow system for the evaluation and authorisation processes, requiring detailed input from the Member Sates and the ECHA staff.

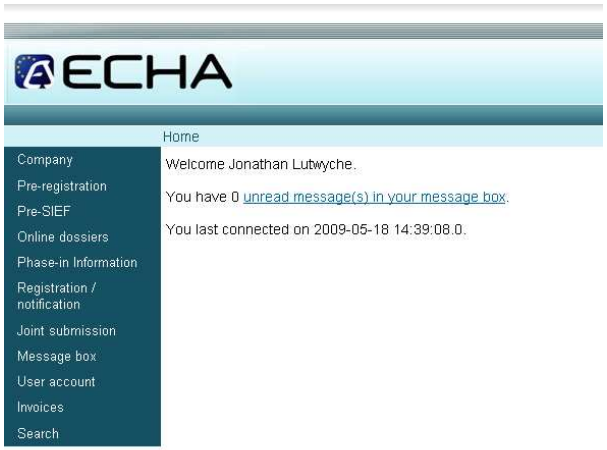
REACH IT

The portal includes 3 main sections:

- **Industry homepage:** where the companies sign up, (pre)register and communicate with ECHA
- **Agency Workflow:** support of the day to day activities of ECHA and Member States Competent Authorities
- **Dissemination website:** useful information, non-confidential documents, guidance documents

REACH IT Portal





IUCLID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

IUCLID
(International Uniform ChemicaL Information Database)

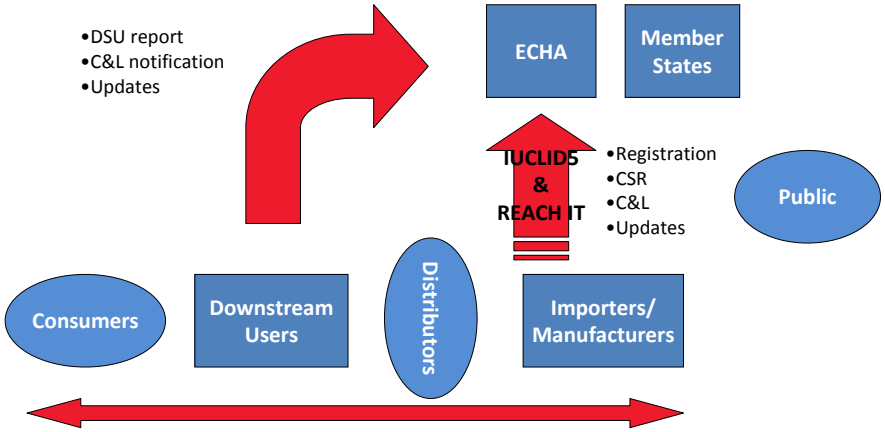
- IUCLID 5 (currently version 5.2.2) is an IT application that is used to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances.
- It is a sophisticated database tool that is used for the preparation of substance dossiers and chemical safety reports
- It is also the key communication tool (via ReachIT) between the chemical industry and the ECHA.
- It is, therefore, a key software application essential for chemical industry to comply with the new legislation

http://iuclid.echa.europa.eu/

WHAT IS IUCLID5?

- **Industry**:
  - Chemicals inventory
  - Database
  - Preparation of dossiers
  - Submission of dossiers
  - Platform for sharing data
- **ECHA & Member states**:
  - Central data repository
  - Basis for data evaluation

REACH DATA FLOWS



•SDS
•Hazard labelling

•Use data
•Exposure scenarios

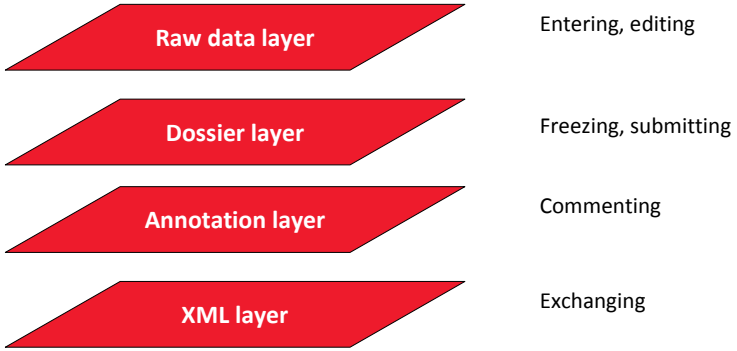
INSTALLATION

1. Webpage registration (http://iuclid.eu)
2. Installing IUCLID-5 software
3. Creating and importing a LEOX (Legal Entity File)
4. Importing EC Inventory and reference substances
5. Install the necessary plug-ins

GETTING SUPPORT

IUCLID5 STRUCTURE

The data in IUCLID5 is organized in multiple layers



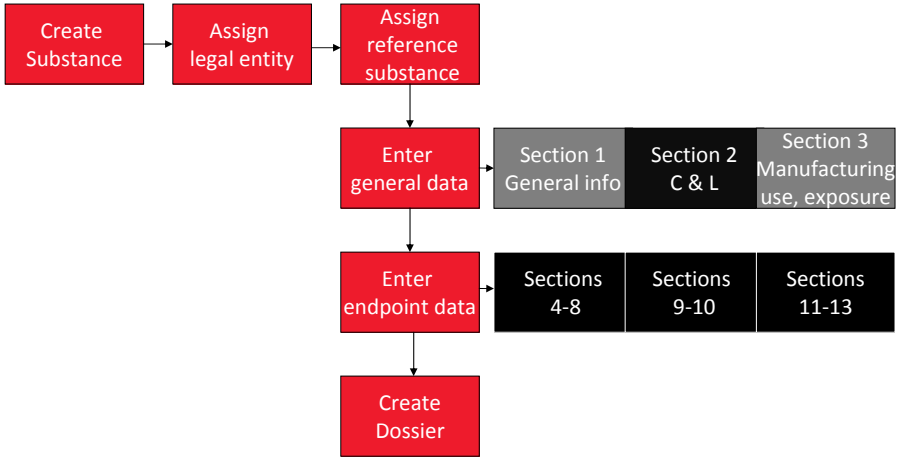
Entering, editing

Freezing, submitting

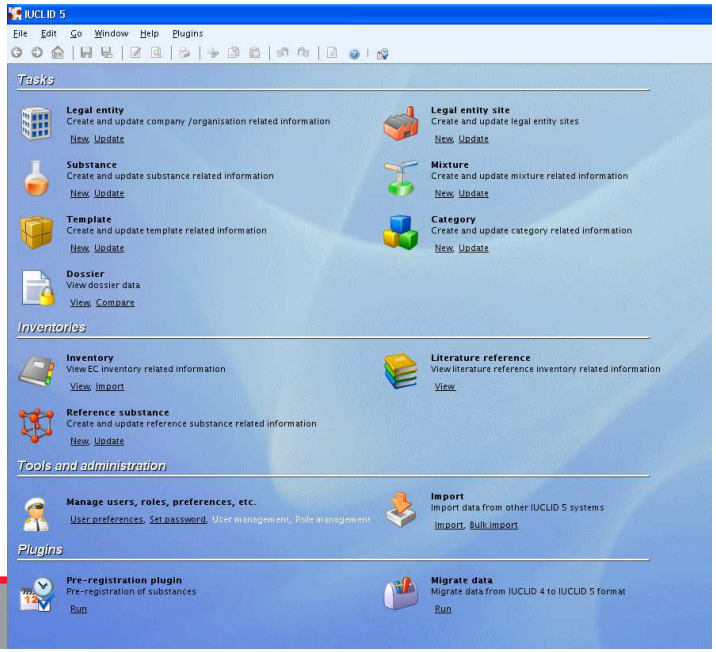
Commenting

Exchanging

CREATING A DOSSIER

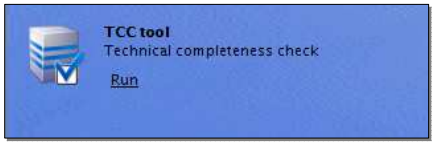


HOME PAGE

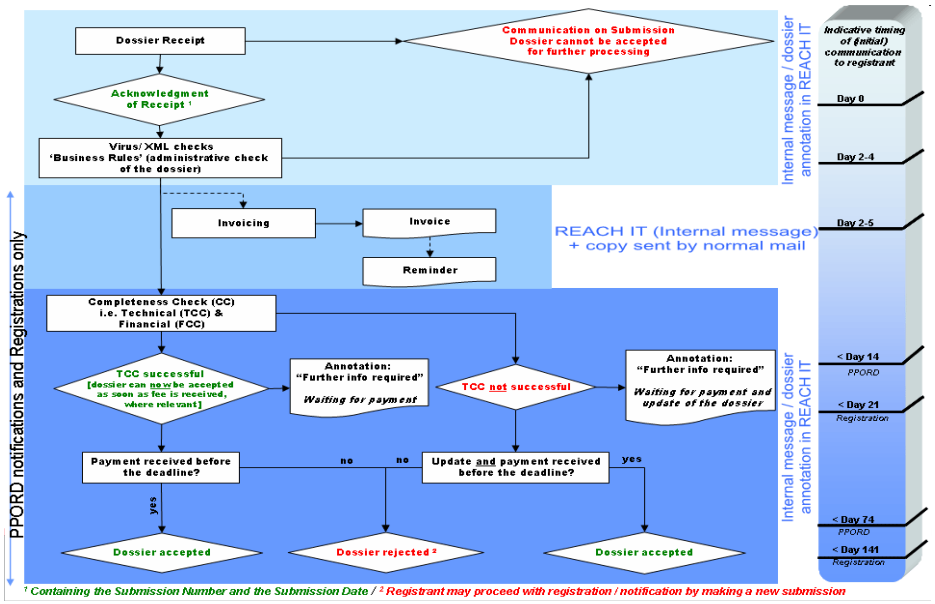


TECHNICAL COMPLETENESS CHECK (TCC) TOOL

The aim of the Technical Completeness Check (TCC) plugin is to enable registrants and PPORD notifiers to check within their IUCLID installation (or database) the technical completeness of their dossiers (or datasets) prior a submission to ECHA via REACH-IT. The plugin also checks that the dossier (or substance) will be able to pass some of the business rules that can be found in REACH-IT



POST-SUBMISSION



[1] Containing the Submission Number and the Submission Date / [2] Registrant may proceed with registration / notification by making a new submission