

# REGISTRATION OF CHEMICAL SUBSTANCES





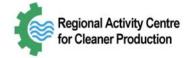
#### REGISTRATION

A technical registration dossier has to be sent to the European Chemicals Agency (ECHA) for each substance manufactured or imported to the EU in more than 1 ton/year.

The information requirements for the registration dossier, on the hazards, use conditions and exposure for chemicals, depends on the manufacture/import volume band (Annex VII to X of REACH)

The hazard information of a chemical substance must be shared among all registering companies in so-called SIEFs (Substance Information Exchange Forums).

If a company uses information owned by another company, the information owner is entitled to compensation.





#### REGISTRATION

- → Manufacturers of substances and manufacturers of transported isolated intermediates in quantities of 1 tonne or more per year need to submit a registration dossier if they are not exempted.
- → Manufacturers of substances that are not intermediate, need to present a registration dossier including all the information required in base of the tonnage band.
- → Manufacturers of intermediates requiring registration can provide reduced registration information, if they can demonstrate the very high strictly conditions in all the cycle life of the intermediate.





# Reduced required information INTERMEDIATES

- The identity of the OR (representing the manufacturer)
- + The identity and classification of the intermediate
- ♣ Any available existing information on the physicochemical, human health or environmental properties of the intermediate.
- → A brief general description of the use
- Information high strictly conditions and on risk management measures

Note: To apply the reduced registration the intermediate manufacturer of non EU Company has to assure that he has received confirmation from the user (inside or outside the EU) that the manufacturing and use takes place on other sites under strictly controlled conditions.

for Cleaner Production





→ If the annual export volume of the substance is less than 1000 tonnes, the information requirements relative to the substance's intrinsic properties (physicochemical, human health and environment properties) are reduced to available data



★ When the substance is exported and used under strictly controlled conditions and the annual quantity of the substance is 1000 tonnes or more, the data requirements on the substance's intrinsic properties are the complete information on physicochemical properties and annex VII.

## BOB



- → If the exporter sells the substance not exclusively for the use as an intermediate, or if the transport and use(s) of the intermediate can not be descripted as under strictly controlled conditions, the exporter (non EU company) needs to submit a "standard" registration dossier (full information based on the tonnage band)
- → If only part of the tonnage exported is for use as intermediate under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirements of the full registration dossier. Nevertheless, use as an intermediate should be documented in the registration dossier, including the volume manufactured or imported for that purpose





If the intermediate is exported and used under strictly controlled conditions during its whole lifecycle (since it is introduced in Europe), the registrant should evaluate and demonstrate whether the following conditions are met:

- The substance is rigorously contained by technical means during its whole lifecycle (transport, storage, sampling, analysis, loading and unloading of equipment or vessels, waste disposal....;
- → Procedural and control technologies shall be used that <u>minimise</u> emission and any resulting exposure;
- Only properly trained and authorised personnel handle the substance;
- ◆ In the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
- In cases of accident and where waste is generated, procedural and/or control technologies are used to.





# IUCLID: International Uniform Chemical Information Database



IUCLID5 is a software with the official format for the registration dossier.

IUCLID5 also allows users to develop pre-registrations, notification on uses, authorizations request, notification on classification and labelling, etc.

Free for download: www.iuclid.eu





Username:	Password:	
		Login
Sign-up new us	ser <u>Password</u>	recovery

English (en) 💌

EUROPEAN COMMISSION

Home IUCLID 5 Project

Get IUCLID 5

Get Support

News

About Us

#### **MECHA**



IUCLID 5 plays a central role in the IT environments of all organisations that have to cope with data submission requirements of REACH and other programmes (OECD HPV, EU Biocides and others). Industry stakeholders, EU Member States, the European Chemicals Agency (ECHA), and any other interested party obtain the IUCLID installation kit from this web site; once installed, the local IUCLIDs are the essential tool to canture & store, submit.

#### News

#### [18.07.2007] Clarifications concerning License Agreement

The IUCLID 5 Service Support Team has received numerous questions concerning the IUCLID 5 End User License Agreement. This news article provides a number of important clarifications.

#### [19.06.2007] The IUCLID Format (XML) is available

The XML format used to generate export files for data exchange (with worldwide regulatory bodies or between users) is now available and can be downloaded from the web site.

#### [18.06.2007] More than 1000 copies of IUCLID 5 downloaded!

Today, the threshold of 1000 downloads of the IUCLID 5 software has been exceeded

#### [14.06.2007] eChemPortal, the Global Portal to Information on Chemical Substances has been launched!

eChemPortal, the Global Portal to Information on Chemical Substances is now available for public access. To search multiple international databases simultaneously, visit the website http://www.oecd.org/ehs/echemportal.

#### [12.06.2007] IUCLID 5 is now available!

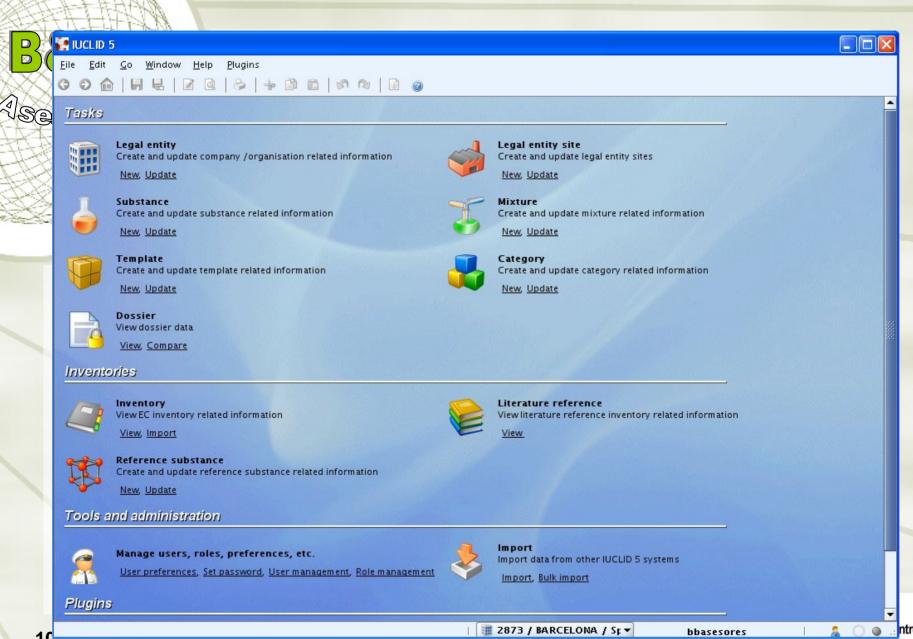
IUCLID 5 can now be obtained free of charge in the "Get IUCLID 5" section. Both the standalone and the distributed versions are available for download.

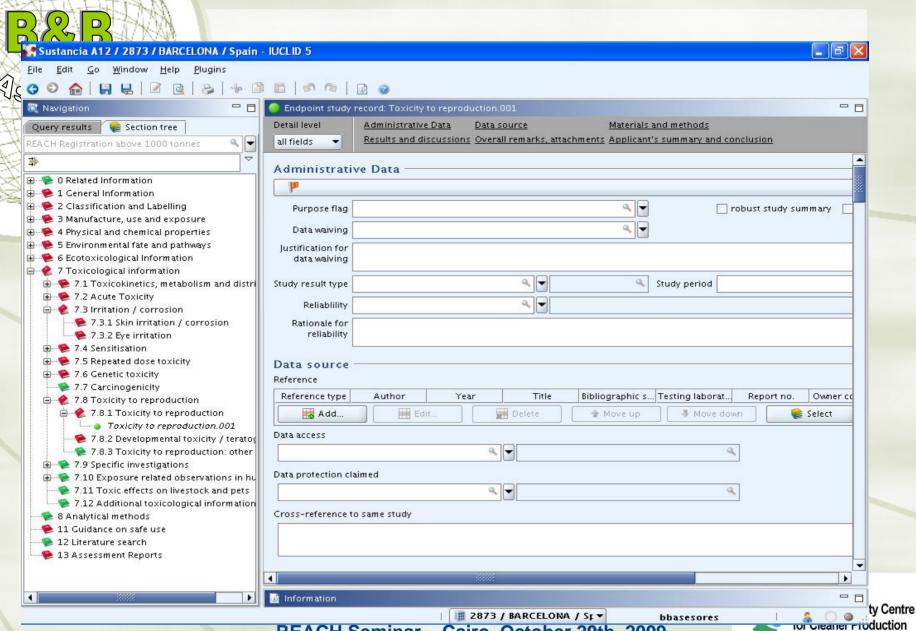
#### [01.06.2007] IUCLID 5 coming soon!

IUCLID 5, the main tool for the Chemical Industry to fulfill their REACH legal obligations, will be

Regional Activity Centre for Cleaner Production

e







## REACH- Description of Uses (I)

## 1) Industry Category:

Information from the industrial economic sector in which the substance is used.



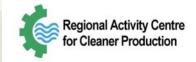
Attachr	nent 1: Descriptor for industry categories
Code 2007	NACE 2007
Α	AGRICULTURE, FORESTRY AND FISHING
В	MINING AND QUARRYING
С	MANUFACTURING
10	Manufacture of food products
13	Manufacture of textiles
14	Industry for clothing and fur
15	Manufacture of leather and related products
16	Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials
17	Manufacture of paper and paper products
18	Printing and reproduction of recorded media
19	Manufacture of coke and refined petroleum products
20	Manufacture of chemicals and chemical products
20.1	Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
20.2	Manufacture of pesticides and other agrochemical products
20.3	Manufacture of paints, varnishes and similar coatings, printing ink and mastics
20.4	Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations
20.5	Manufacture of other chemical products
21	Manufacture of basic pharmaceutical products and pharmaceutical preparations
20.60	Manufacture of man-made fibres
22	Manufacture of rubber and plastic products
22.1	Manufacture of rubber products
22.2	Manufacture of plastics products



## Description of Uses (II)

2) Use category:

Information on the technical functionality of the use of a substance.



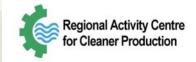
Attachment 2: Descriptor for technical function of substances and end use preparations										
Technical function of substance										
Dust binding agent	Metal surface treatment products, including galvanic and electroplating products,									
Electrolyte	Non-metal-surface treatment products									
Emulsifier	Heat Transfer Fluids									
Emulsion-inhibiting agents	Hydraulic Fluids									
Etchant and acids	Ink and Toners									
Extraction agents	*Inorganic / organic substances and preparations used as ph-regulators, flocculants, precipitants, neutralization agents and comparable unspecific uses									
Filler	Laboratory Chemicals									
Fixing agent	Lawn and Garden Preparations, including fertilizers									
Flame retardant or fire preventing agent	Leather tanning, dye, finishing, impregnation and care products									
Flavouring agent	Lubricants, Greases and Release Products									
Flocullant	Metal Working Fluids									
Flotation agent	Paper and Board dye, finishing and impregnation products									
Flow modifier	Perfumes, Fragrances									
Flux agent	Pharmaceuticals									
Foaming or blowing agent	Photochemicals									
Food and fodder additive	Polishes and Wax Blends									
Friction agent	Polymer Preparations and Compounds									



## Description of Uses (II)

### 3. Application Type

technique / process in which the substance is applied.



	Operation unit	Examples or explanation
13.*	Drying	Tray drying over, spray drying
14.	Storage	General and open bulk storage
15.1*	Passive release of substances from articles in service life: long-life, large surface, outdoor 12	E.g. construction material
15.2*	Passive release of substances from articles in service life. Abrasive use processes	Tyres, brake pads, road surface, shoe soles
15.3*	Passive release of substances from articles in service life: indoor with permanent or repeated skin and/or mouth contact	E.g. dyes in textiles
15.4*	Passive release of substances from articles in service life: other indoor	Floor coatings and coverings;
16.*	Burning of fuels including waste incineration; limited exposure to the fuel in its unburned form.	Heat and power generation, incineration of waste, pyrolysis
17.1	Biological, chemical or physical treatment of waste in open tanks, bunkers or basins	Neutralization, reducing, oxidizing, oil/water separation
17.2	Mechanical crushing and/or sorting of waste (manually or semi-automated)	
17.3	Landfilling of substances in waste	

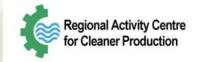


## Description of Uses (II)

# 4. Article category in which a substance has been used::

Unintended release-

Deliberate release-



TRA Category	Pick-list for article types	TARIC category				
	Rubber products: footwear	Section XII Chapter 64				
	Rubber products: toys	Section XX Chapter 95				
C17	Wood and wood furniture: flooring	Section IX Chapter 44				
	Wood and wood furniture: furniture	Section XX Chapter 94				
	Wood and wood furniture: toys	Section XX Chapter 95				
C18	Other <sup>13</sup> :					
C19.1	Constructional articles and building material for indoor use <sup>14</sup> : wall construction material ceramic, metal, plastic and wood construction material, insulating material.	Glass, ceramic, cement: 6806, 6810, 6815,				
C19.2	Constructional articles and building material for outdoor use <sup>15</sup> : wall construction material, road surface material, ceramic, metal, plastic and wood construction material, insulating material.	6901, 6902,7016, 7018,7019,7308 Wood: 4407- 4413,4418				
C20	Commercial and consumer plastic products like disposable dinner ware, food storage, food packaging, baby bottles	Section VII Chapter 39 Code 3923, 3924				
	Plastic products: Flooring	Section VII Code 3918				
	Plastic products: Toys	Section XX Chapter 95				

Scented articles	
Clothes	
Ernser	
Candle	
Toys	
Paper articles	
CD	
Other scented articles; please specify	
Articles for printing and writing	
Crayon	
Type writer ribbon	
Printer certridge	
Pons	
Correction rollers and pens	
Other articles for printing and writing	
Articles releasing polishes and cleaners	
Polishing textiles	
Cleaning wipes	
Cleaning sponge	
Shoe polishing sponge	
Other articles; please specify	
Articles releasing grease and/or corresion inhibitors	
Packaging material for metal parts	
Other articles; please specify	
Hygiene products and medical articles releasing scent, lotions and notified as medicinal product, cosmetic product and/or blocide pro-	
Diapers with scents or lotion	
Wet wipes with scents or lotion	
Plasters releasing substances	
Other articles; please specify	



# RISK INFORMATION ALONG THE SUPPLY CHAIN

The downstream user in the use chain must receive manufacturer information on how to handle a product with hazardous substances

Health Risk = Toxicity • Exposure

This user must communicate to the next actor the use and exposure of the products containing hazardous substances to the humans and the environment.

The Safety Data Sheet will serve as an information platform in the use chain, extended with:

- The identified uses and
- Measures for a safe handling during their use.







#### What uses cover?

Strategic decision of the Operating Unit

What Markets / Customers / Applications should be covered?

This decision should be based on economics reasons and also it should be taking into account: :

- → How is cover the product value chain?
- The number of applications covered (uses)





### What applications cover?

Preparation of the information

- For each intended application:
  - → Prioritization according to economic criteria
  - → Determination of the quantities of substances commercialized
  - → Identify those customers with typical applications that are willing to provide exposure data.
  - → If possible, identification of the use type
  - → intermediate, monomer
  - → Industrial use, professional use, final consumer
  - → Uses development and exposure scenarios
  - → It must be developed during the process of preparing the registration dossier
- → Dialogue between manufacturer ← → Customer

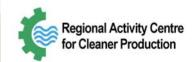






## Why the applications are important?

- Companies that register shall describe how to control the exposure to humans and the environment for all the uses of the substance.
- → Downstream users are not authorized to use a substance in their products if the user exposure scenarios are not defined for that substance





#### Risk evaluation

**WHO** WHERE indoor outdoor HOW **AMOUNT FREQUENCY DURATION** 

Who uses the product?

- Consumer
- Professional
- •Industrial

Closed or open system?

#### Inside or outside?

Application type?
Directly or not
Type of equipment used

Amount of product used?

<1Kg

Frequency of use? < once a year

Duration of use? <1h

#### **Preventive Measures**

**Waste Management** 







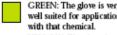


#### **Preventive Measures**

#### **Waste Management**

- •Facilitate the recycling,,
- Proper handling
- Plant treatment or authorized manager

The first square in each column for each glove type is color coded. This is an easy-to-read indication of how we rate this type of glove in relation to its applicability for each chemical listed. The color represents an overall rating for both degradation and permeation. The letter in each square is for Degradation alone...
GREEN: The glove is very

















square is for Degradation alone  CREEN: The glove is very well suited for application with that chemical.  YELLOW: The glove is suitable for that application under		FILM			NITRILE UNSUPPORTED NEOPRENE  SOL-VEX 29-865			SUPPORTED POLYVINYL ALCOHOL PVA			C	OLYVINY HLORID (Vinyl)	E	d	NATURAI RUBBER ANNER: HANDLE	5	NEOPRENE/ NATURAL RUBBER BLEND CHEMI-PRO*				
careful control of its use.  RED: Avoid use of the glove with this chemical.	Degradation Rating	Permeation: Breakthrough	Permeation: Rate	Degradation Rating	Permeation: Breakthrough	Permeation: Rate	Degradation Rating	Permeation: Breakthrough	Permeation: Rate	Degradation Rating	Permeation: Breakthrough	Permeation: Rate	Degradation Rating	Permeation: Breakthrough	Permeation: Rate	Degradation Rating	Permeation: Breakthrough	Permeation: Rate	Degradation Rating	Permeation: Breakthrough	Permeation: Rate
CHEMICAL					9.2	88					9 g	ææ		a a	88						
Acetaldehyde	•	380	E	Р	_	_	Е	10	F	NR		_	NR		_	Е	7	F	Е	10	F
2. Acetic Acid	•	150	_	G	270	_	Е	60	_	NR		_	F	180	_	Е	110	_	Е	260	_
3. Acetone	<b>A</b>	>480	E	NR	_	_	Е	10	F	Р	_	_	NR	_	_	Е	10	F	G	10	G
4. Acetonitrile	<b>A</b>	>480	E	F	30	F	Е	20	G	•	150	G	NR	_	_	Е	4	VG	Е	10	VG
5. Acrylic Acid	_	_	_	G	120	_	Е	390	_	NR	_	_	NR	_	_	Е	80	_	Е	65	_
6. Acrylonitrile	Ε	>480	Е	-	-	_	_	-	_	I	_	_	1	_	_	_	_	_	_	_	_
7. Allyl Alcohol	•	>480	Е	F	140	F	Е	140	VG	Р	_	_	Р	60	G	Е	>10	VG	Е	20	VG
8. Ammonia Gas		19	Е	•	>480	_	•	>480	_	_	_	-	•	6	VG	<b> </b>	_	_	•	27	VG
9. Ammonium Fluoride, 40%	_	_	_	Ε	>360	_	Е	>480		NR	_		Ε	>360	_	E	>360	_	E	>360	_
10. Ammonium Hydroxide	Ε	30	_	Ε	>360	_	Е	250	_	NR	_	_	Ε	240	_	Е	90	_	Е	240	_
11. Amyl Acetate	<b>A</b>	>480	E	Е	60	G	NR	_	_	G	>360	Е	Р	_	_	NR	_	_	Р	_	_
12. Amyl Alcohol	_	_	_	Е	30	E	Е	290	VG	G	180	G	G	12	Е	Е	25	VG	Е	45	VG
13. Aniline	•	>480	Е	NR	_	_	Е	100	Р	F	>360	Е	F	180	VG	Е	25	VG	Е	50	G
14. Aqua Regia	_	_	_	F	>360	_	G	>480	_	NR	_	_	G	120	_	NR	_	_	G	180	_
15. Benzaldehyde	•	>480	Е	NR	_	_	NR	_	_	G	>360	Ε	NR	_	_	G	10	VG	G	25	F
16. Benzene, Benzol	<b>A</b>	>480	Е	Р	_	_	NR	_	_	Е	>360	Е	NR	_	_	NR	_	_	NR	_	_
17. Benzotrichloride	_	_	_	Ε	>480	Е	NR	_	_	_	_	_	_	_	_	NR	_	_	NR	_	_
18. Benzotrifluoride	_	_	_	Е	170	G	F	_	_	Е	_	_	G	<10	F	Р	50	G	_	_	_
19. Bromine Water	_	_	_	Е	>480	Е	Е	>480	E	_	_	_	_	_	_	_	_	_	_	_	_











Prod	duct	XX

PLANTA DE KREXOXIM-METIL									×		8	Equipos de Proteccción Individua!					
		Muy Táxico	Táxico	Nocivo	el Medio	Corriosivo	Muy inflamable	inflamable	Irritante	Explosivo	Comburente						
O-CRESOL	Fundido	4	X									B2	A2				
CLORURO DE TIONILO	líquido			3	X	X	<u> </u>	3			3 3	B1	A2	F3	3.		
HIDROCLORURO DE	líquido			3	1000	X		3			3	B1	A2	Secretary .	3		
FORMALDEHÍDO	líquido		X				į,					B2	A1	F3			
TOLUENO	líquido	-	0000	X		E.	1	X				B1	A1	F3	Same -		
METANOL	líquido		Х			· ·		X				B2	A1	F3	D1		
ACIDO CLORHÍDRICO	líquido	}		8		X	15	3			3	B1	A3	F3	3		
METILATO SÓDICO	polvo		Х	Š i		X					E t	B2	A3	250.000	3		
HIDRÓXIDO DE SÓDIO	líquido					X						B1	A2				
ACIDO SULFÚRICO	líquido		i i	8		X		7 7			F	B1	A1	F3	D1		
CIANURO SÓDICO	sólido	X	1	3								B2	A2	F1			
KREXOXIM-METIL	polvo	1	1	X	X	3-1-	2	3 3			8 - 8	B2	A2	F2	Same		
DIMETILFORMAMIDA	liquido		X	0.00			i i	8 8		1	E :	B1	A1	Sec. Learner	D1		
TETRABUTILAMONIO-	líquido			X								B2	A2	F1			
RESIDUE DE CONTROL VI			Х	No. of the last of				X		1	F	1					
DEC MICA O ODE DI M	10.0			w	•					1	100	54					







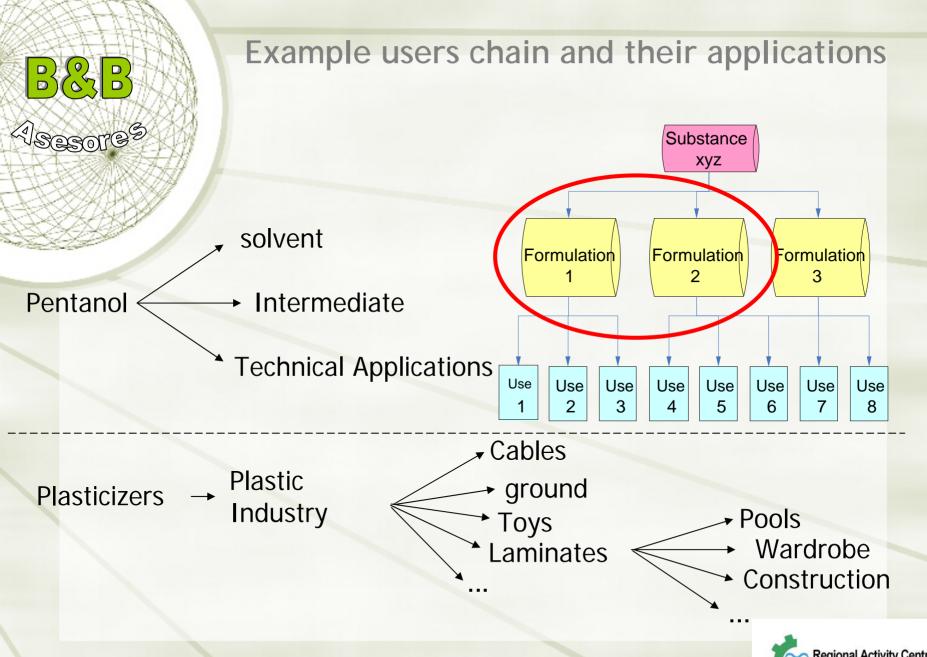


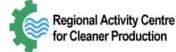






rional Activity Centre er Production

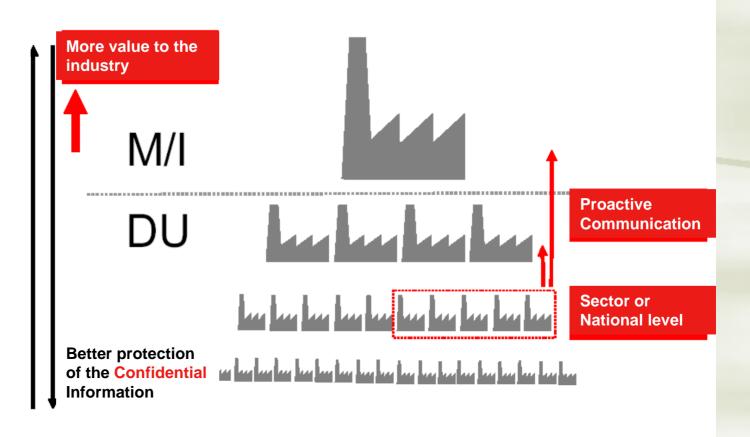




## B&B

## Applications and scenarios of exposures:

Complexity increase



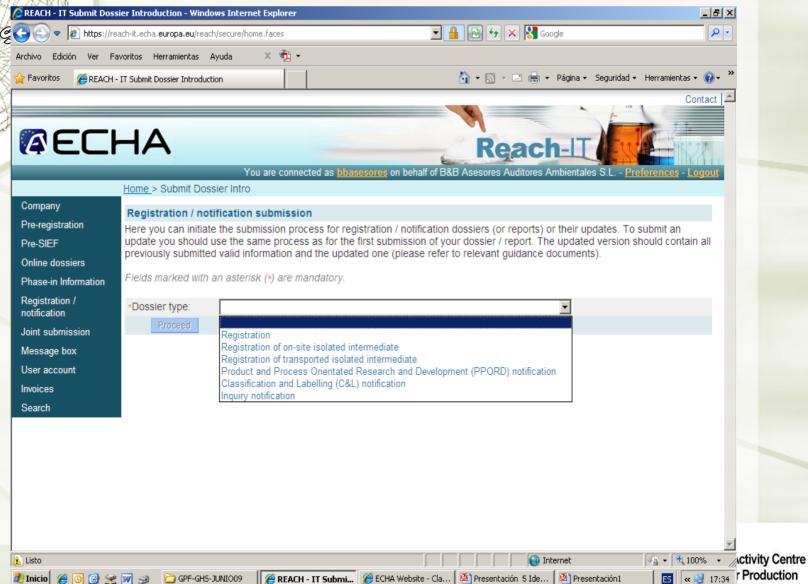
- The registration information should be elaborated the more upstream possible in the use chain.
- •It is important that the downstream user participate actively in defining the standard uses.



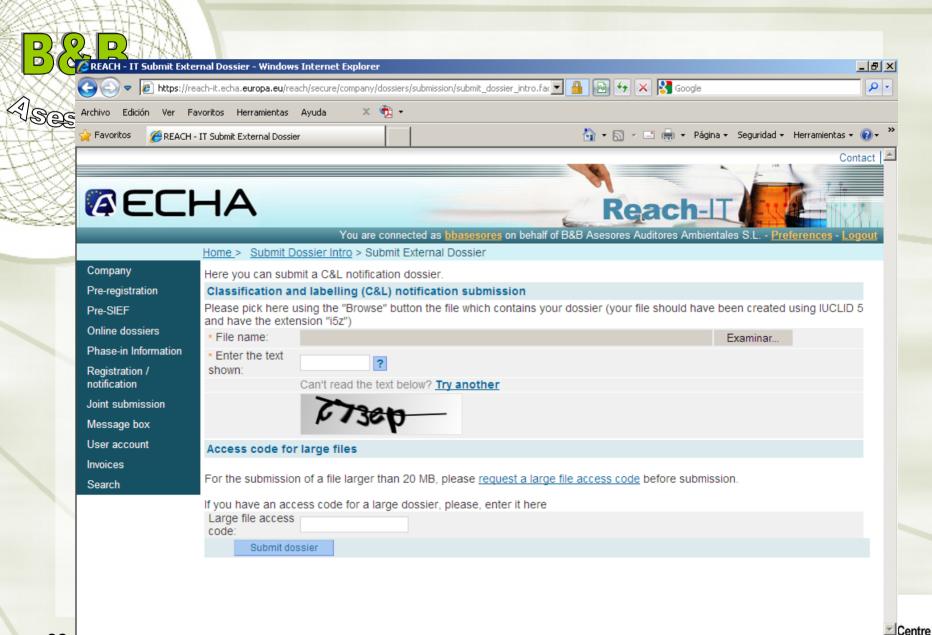
https://reach-it.echa.europa.eu/reach/secure/home.faces#

🏄 Inicio 🥖 🗿 🧭 💥 🕡 🧀 Curso REACH

Internet



GPF-GHS-JUNIO09



REACH - IT Submi... 🏉 ECHA Website - Cla... 🏻 Presentación 5 Ide... 🕍 Presentación1

4 + 100% - ction

ES « 🗾 17:35

🏄 Inicio 🥖 🗿 🚱 🔀 📝 🥥 🗀 GPF-GHS-JUNIO09



#### MORE INFORMATION

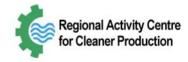
The REACH section on the website of the European Chemicals Agency (ECHA) gives an overview of the Regulation.

The website also provides:

- → A Navigator tool which will assist importers and Only Representatives to find out their obligations and how to fulfil them
- ★ Extensive guidance on REACH provisions
- → IT tools for REACH uses and how to operate them

Please see the ECHA website:

http://echa.europa.eu





# Thank you

Pedro Guerra
B&B Asesores
C/Ganduxer 5-15, L. 5
08021 Barcelona (Spain)
Tel 932414118
bb@bbasesores.com

Regional Activity Centre for Cleaner Production Mediterranean Action Plan Dr. Roux, 80; 08017 Barcelona Tel: +34 93 553 87 90

http://www.cprac.org

