

BFR

Nutzerkonferenz Produktmeldungen

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National Centre for Chemical Substances
ISS – Rome - Italy

Berlin, 5 November 2013

National database:

- ❖ Before CLP regulation
- ❖ Legal requirements following CLP
- ❖ The national database
- ❖ Technical requirements
- ❖ Specific cases
- ❖ Future development
- ❖ EU possible harmonization

EU Directives

1988/379/CE

1999/45/CE

2001/60/CE

National implementations

D.Lgs. 285/1998

D.M.19/4/2000

D.Lgs. 65/2003

Provisions in Art. 45 of CLP similar to Art. 17 DPD

- MS shall appoint body or bodies responsible for receiving information on mixtures classified as hazardous on the basis of their health or physical effects
- Appointed bodies shall keep information confidential
- Harmonization of information

Article 45 (4) (introduced during co-decision procedure)

‘By January 2012, the Commission shall carry out a review to assess the possibility of harmonising the information..., including establishing a format for the submission of information by importers and downstream users to appointed bodies.

Information may be used:

- For medical purposes, in particular in event of emergency
- Art. 17 does not define which information should be notified
- Where requested by MS, for statistical analysis to improve risk management measures, if needed
- Resulted in different provisions by MS
- Different Procedures
- Requirements on composition/concentrations
- Requirements about different info (eg. pH)
- Notification formats
- Tools

Duties resulting from Article 45(4)

- Assessment of possibility of harmonising information to PIC
- Assessment of possibilities to establish a (harmonised) format for submission of information
- No specific reference to a database at EU level
- Consultation with stakeholders, especially EAPCCT
- Legal implementation, if appropriate

Pre-condition for an amendment (if any)

- Avoiding duplication of work
- Ensuring that lessons are learned from discussions in other areas of EU legislation

Links to other EU legislation

Regulation on Plant Protection Products (Regulation (EC) No 1107/2009) Article 68

- very general obligation to adopt a Regulation which amongst others "shall also contain provisions concerning the collection of information and reporting on suspected poisonings

Biocidal Product Regulation (Reg 528/2013)

- very similar provisions than those contained in the Dangerous Preparations Directive (Directive 1999/45/EC)

Regulation on Cosmetic Products (Regulation (EC) No 1223/2009) Article 13

- regulation contains a list of information to be submitted to the Commission
- information has to be submitted electronically
- responsible COM Service has developed the "Cosmetic Products Notification Portal"

Detergents

As requested by Art. 3 comma 1 of national D.P.R 6 Feb 2009, n° 21 concerning implementation of Reg. (CE) n. 648/2004 31 March 2004 about detergents, technical sheets including the list of ingredients should be provided to the national database (Art. 9 Par. 3 Reg. 648/2004 following the specification of Annex VII part C as modified by Reg. 907/2006, 20 June 2006)



National Database of Dangerous Preparations



- Art. 10 of the D.Lgs. N. 285/98 (implementing in Italy dir. 88/379) appoints ISS as the Governmental Organization charged for receiving information on marketed Dangerous Preparations, with particular reference to the full chemical composition.
- This provision is confirmed by the D.Lgs. N. 65/2003 implementing in Italy the Dir. 1999/45/EC.

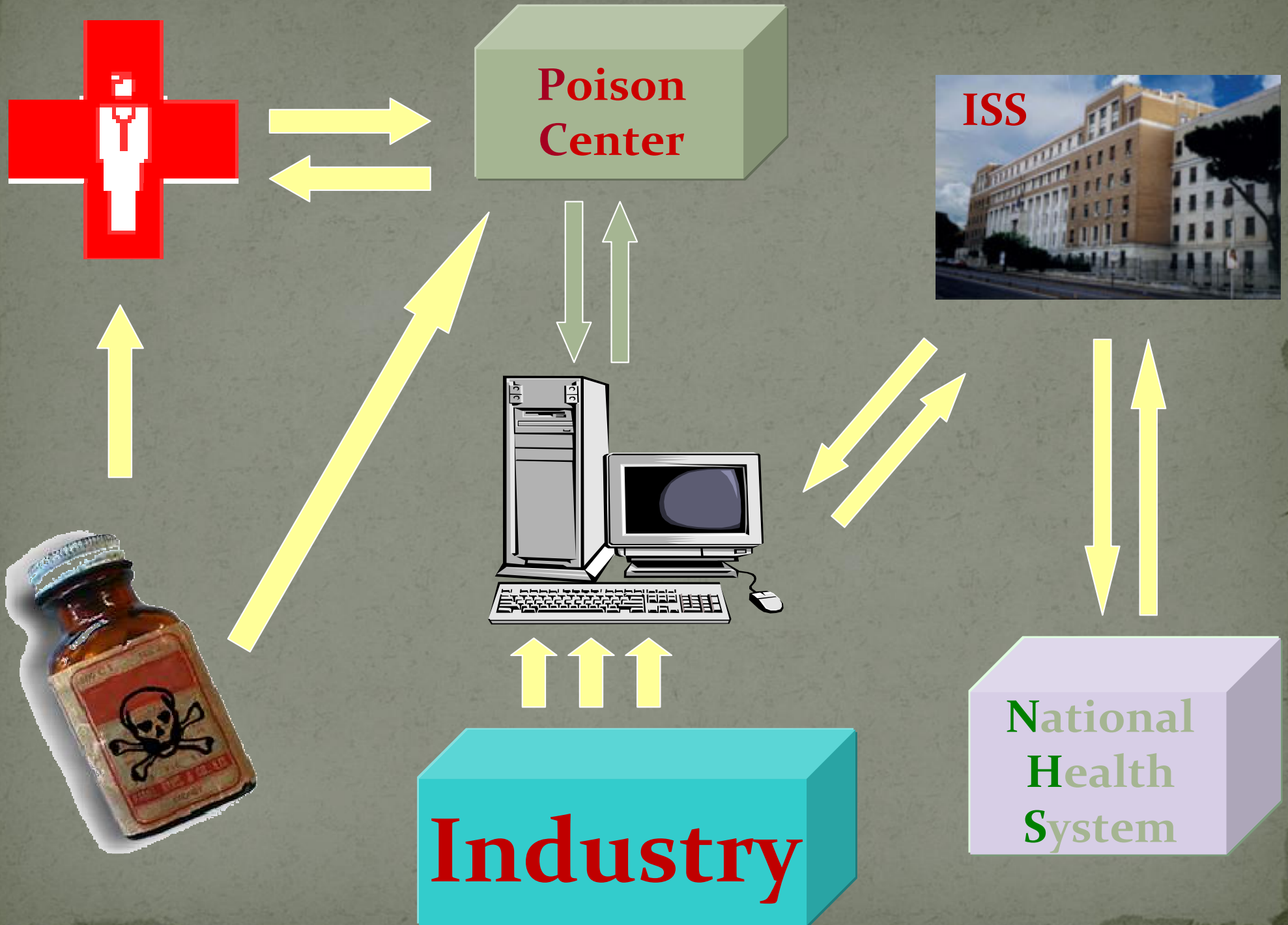
National Database of Dangerous Preparations”

Establishing a Database of Dangerous Preparations listing the dangerous preparations present on National market, to be used only in view of preventive or therapeutic measures, particularly in emergency;

Allowing the on-line consultation of the data bank only to the Poison Centres certified as suitable by fulfilling specific criteria concerning their structural and human resources, and being able to ensure the confidentiality of the sensitive data with the use of personalized keys of access ; all the other Poison Centres can access the information through ISS or the certified Poison Centres;

Constitution of a Permanent Working Group ISS-Poison Centres (PCs)





ELEMENTS OF THE DATABASE



- **Location:** ISS - National Centre for Chemical Substances
- **Scope:** Collecting the full chemical composition for all dangerous preparations marketed in Italy and falling in the scope of DPD.
Detergents included later (art. 9 of reg. 648/2004)
- The registration to the database is free of charge

PURPOSES OF THE DATABASE

“The information contained in the database are confidential and will be used only for health purposes in view of preventive or therapeutic measures to be adopted, particularly, in emergency”.

WHO ARE THE USERS

The system is operational 24 h/day and 7 days/week.

Direct connection for consultation is granted only to the national **Poison Centres** certified by the Ministry of Health as suitable by fulfilling specific criteria concerning their structural and human resources, and being able to ensure confidentiality about data contained in the database.

On a case by case basis, the ISS may give the information to **other central or regional bodies for their institutional tasks (e.g. inspections, control, prevention, accidents etc.)**.

Currently, **9 Italian Poison Centres** have been granted direct access to the database

WHO MUST REGISTER

Those responsible for marketing in Italy dangerous preparations -according to DPD definitions- and detergents (classified or not as dangerous) **must send** to the ISS information on these preparations (mainly the **full chemical composition**).

Actors:

- **Producers** (even those who produce elsewhere in the EU and market in Italy directly without traders)
- **Importers** from third Countries (even those who import elsewhere in the EU and market in Italy directly without traders)
- **Traders** of preparations produced in the EU who change the label for the Italian market (e.g. including their name)

ISS guarantees the industry, about the confidentiality of the information stored in the database.

WHICH KIND OF INFORMATION IS REQUIRED

- Name/Address, Tel./Fax., e-mail of Registrant (mandatory)
- Trade name of the products (mandatory)
- Intended uses (mandatory)
- Physical state (mandatory)
- Other physico-chemical properties (optional)
- Full quali-quantitative chemical composition (mandatory)
- C&L (optional)
- Packaging description (optional)

Each registrant has assigned a “company code” and each preparation has assigned a “product code”

HOW TO REGISTER

A fully electronic procedure is foreseen:

• 1° step:

registration of the Company to the web site www.preparatipericolosi.iss.it
(English version available).

• 2° step:

download the client program (ISSFormula)

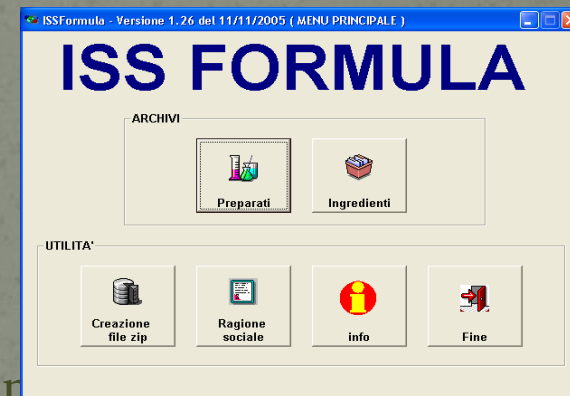
• 3° step:

Fill up an electronic form for each preparation using the ISSFormula program (User Guide available), and generate the .zip file. It is possible to use other programs if the .zip files generated are IT compatible.

• 4° step:

Send electronically the .zip file to the database.

Data may be checked by using the web site (a Company can see only its own data)



www.preparatipericolosi.iss.it

OR:

www.iss.it → CSC →
Archivio preparati pericolosi

Home Page - Windows Internet Explorer
http://www.preparatipericolosi.iss.it/iss/index_en.phtml
Live Search
Home Page
ISS - Archivio Preparati Pericolosi
Tuesday, Oct 2, 2007 6:20:49 PM

Archivio Preparati Pericolosi Home Page

Requires IE 5, cookies enabled - Best viewed at 1024x768

Versione Italiana

New version of ISSFormula: 1.26 (published December 05 2005)

- Introduction
(Archivio Preparati Pericolosi was prepared to comply with Article 15 of Legislative Decree No. 65 of March 14th, 2003)
- Registration
- Download
(Download and technical documents)
- Login
- Contact
- News

English version available

Istituto Superiore di Sanità: Centro Nazionale Sostanze Chimiche - Microsoft Internet Explorer
File Modifica Visualizza Preferiti Strumenti ?
Indirizzo http://www.iss.it/cnsc/
Google Effettua la ricerca + + + + + Segnalibri Controllo + + + + + Vai Collegamenti + + + + +

Www.iss.it Centro Nazionale Sostanze Chimiche

Responsabile: Roberto Binetti

Chi siamo
In questa sezione vengono sinteticamente descritte la struttura, l'organizzazione interna e le attribuzioni del Centro Nazionale Sostanze Chimiche (CSC).

Normative
Il Regolamento n° 1907/2006 (REACH)
Il Regolamento n° 1272/2008 (CLP)
Il Regolamento n° 440/2008 (I Metodi di prova)
La Direttiva n° 1999/45 (Preparati pericolosi)
La Direttiva n° 67/548 e gli Allegati
Gli ATP della Direttiva n° 67/548
La Direttiva n° 98/8/CE (Biocidi)

Appuntamenti
01 Luglio 2009 Workshop: Aspetti applicativi dei regolamenti REACH e CLP: i laboratori di saggio, i metodi alternativi, confronto fra le classificazioni ambientali

Corsi
25 - 26 Novembre 2009 Corso di formazione per ispettori su sostanze e preparati pericolosi
Scheda [PDF - 115.46 KBytes]
Iscrizione [PDF - 185.85 KBytes]

Basi di dati
BaseDati Sostanze Chimiche
Entra nella BaseDati Sostanze Chimiche
Banca Dati Cancerogeni
Entra nella Banca Dati Cancerogeni
Banca Dati Bonifiche
Entra nella Banca Dati Bonifiche
Archivio Preparati Pericolosi
Entra nell'Archivio Preparati Pericolosi
Banca Dati Sensibilizzanti
Entra nella Banca Dati

THE WEB SITE - Personal Page, Personal Search

INITIAL RESULT(S) - Microsoft Internet Explorer

File Modifica Visualizza Preferiti Strumenti ?

Indietro Avanti Termina Aggiorna Pagina iniziale Cerca Preferiti Cronologia Posta Stampa Modifica Discussione Copernic

Ingrinzito https://www.preparatipericolosi.iss.it/iss/query1_accept_en.phtml Vai Collegamenti Elenco telefonico Hotmail gratuita

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ISS - Archivio Preparati Pericolosi Thursday, Aug 29, 2002 11:33:52 AM

Search criteria

Product name	Magic Unkork
Product code	-----
Company	UNITED NEW CHEMISTRY LTD.
Company code	0123456789

No.	Company code	Company	Product code	Product name	Synonym(s)	Dang.
1	0123456789	United New Chemistry Ltd.	AUT1	Magic Unkork	Rocky IV Terminator Conan	Si

Results: 1 - 1

Top

Operazione completata Internet

Avvio ISS - Outlook Express Berlino Microsoft PowerPoint... Microsoft® Design Ga... INITIAL RESULT... Microsoft Photo Editor 11.33

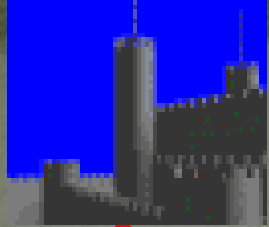
DEADLINES

New preparations:

For the dangerous preparations put on market for the first time in Italy, the registration to the database must be performed within **30 days** as from the date of introduction into the Italian market.

Works in progress to improve the system

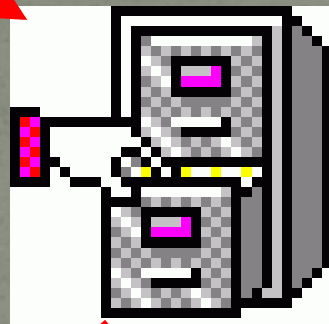
- A new platform has recently been created to increase the research's speedness
- The new platform is now fully operating, possibility of on line registrations avoiding the need to download and install the client ISS Formula (XML records will be created).
- The old procedure will remain available for those who prefer to work off-line before uploading the final .zip file
- Possibility to turn to mandatory some optional info (e.g. pH of the mixture, labelling data) and to add new info (e.g. picture of the packaging).
- Find out resources to perform the completeness check on a systematic basis (presently random). The not complete registrations (e.g. not covering 100% of the components) will be anyway uploaded but considered as not fulfilling the legal requirements
- Company will receive a statement of compliance/non compliance on the registrations made
- Improving the list of use category/ kind of formulation
- Involvement of the local inspectors
- Start to accepting CLP revised C&L for mixtures



Local and regional authorities
(enforcement)

communications

check

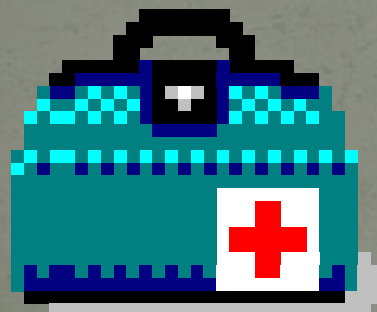


ADMINISTRATORS

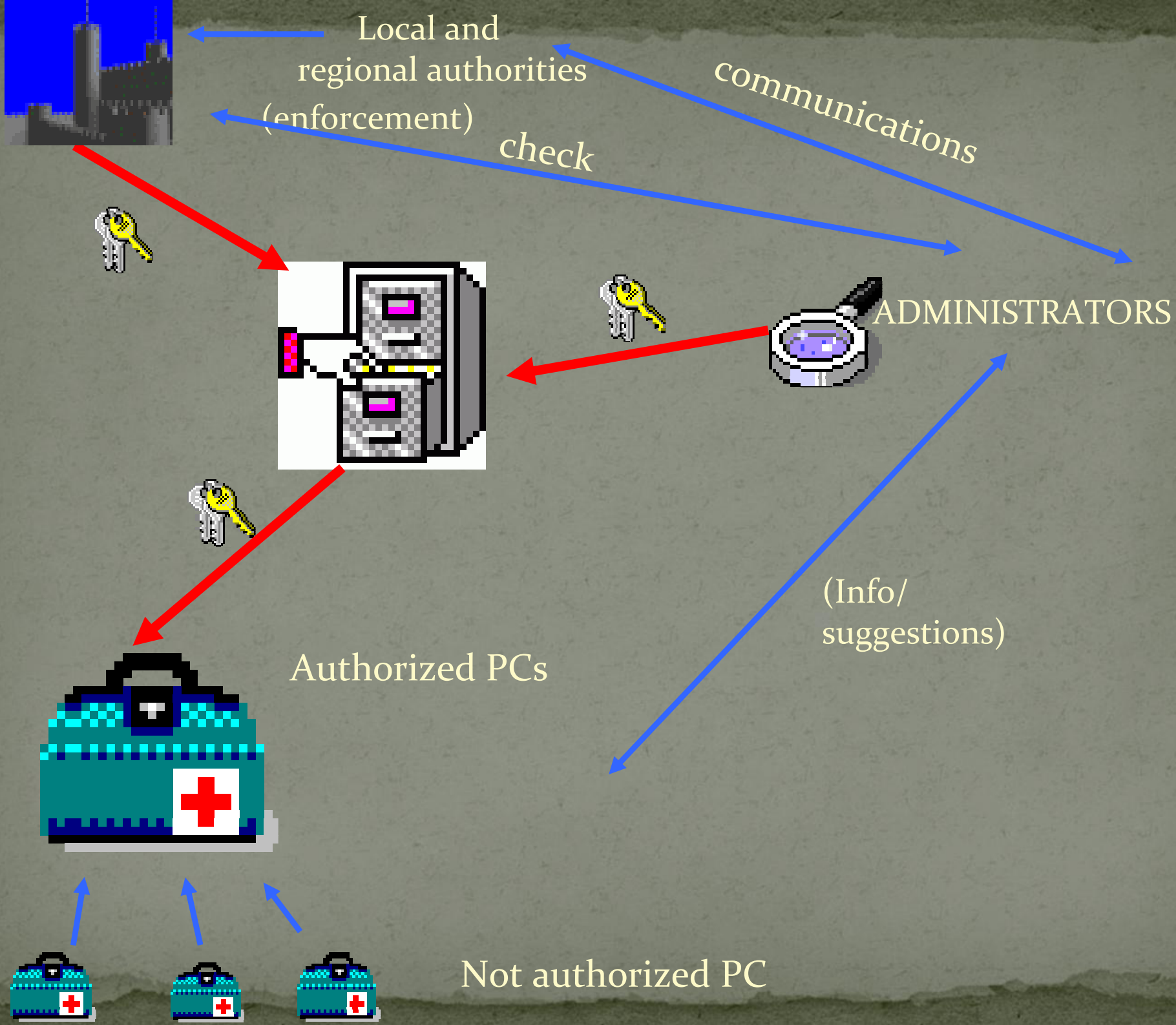


Authorized PCs

(Info/
suggestions)

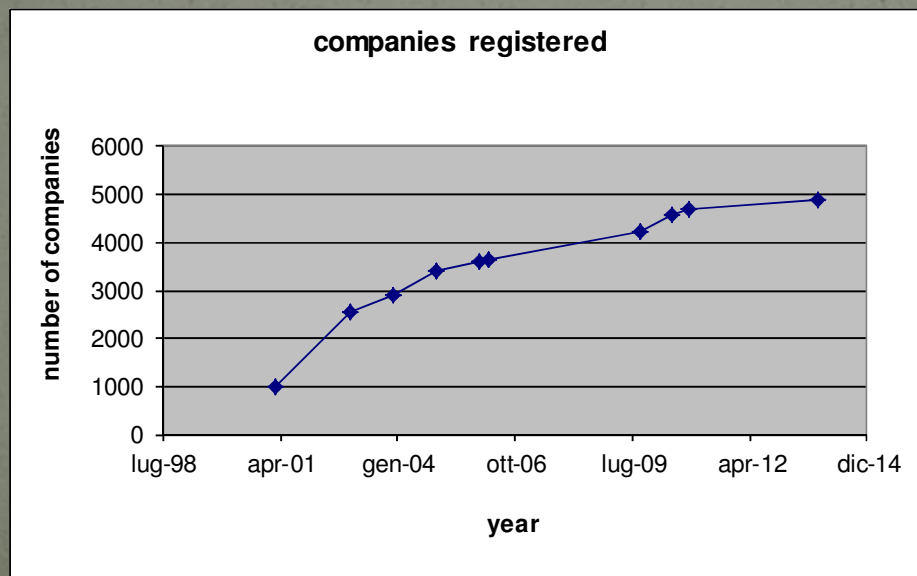
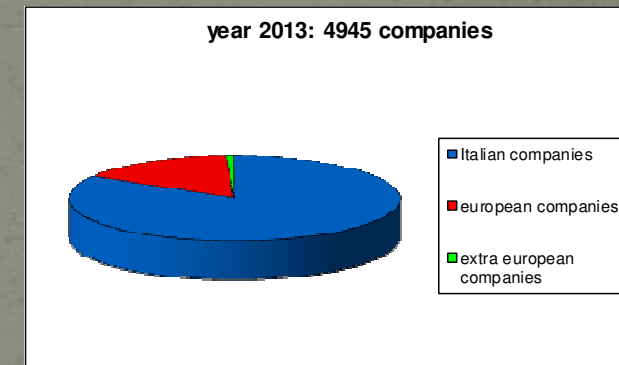


Not authorized PC

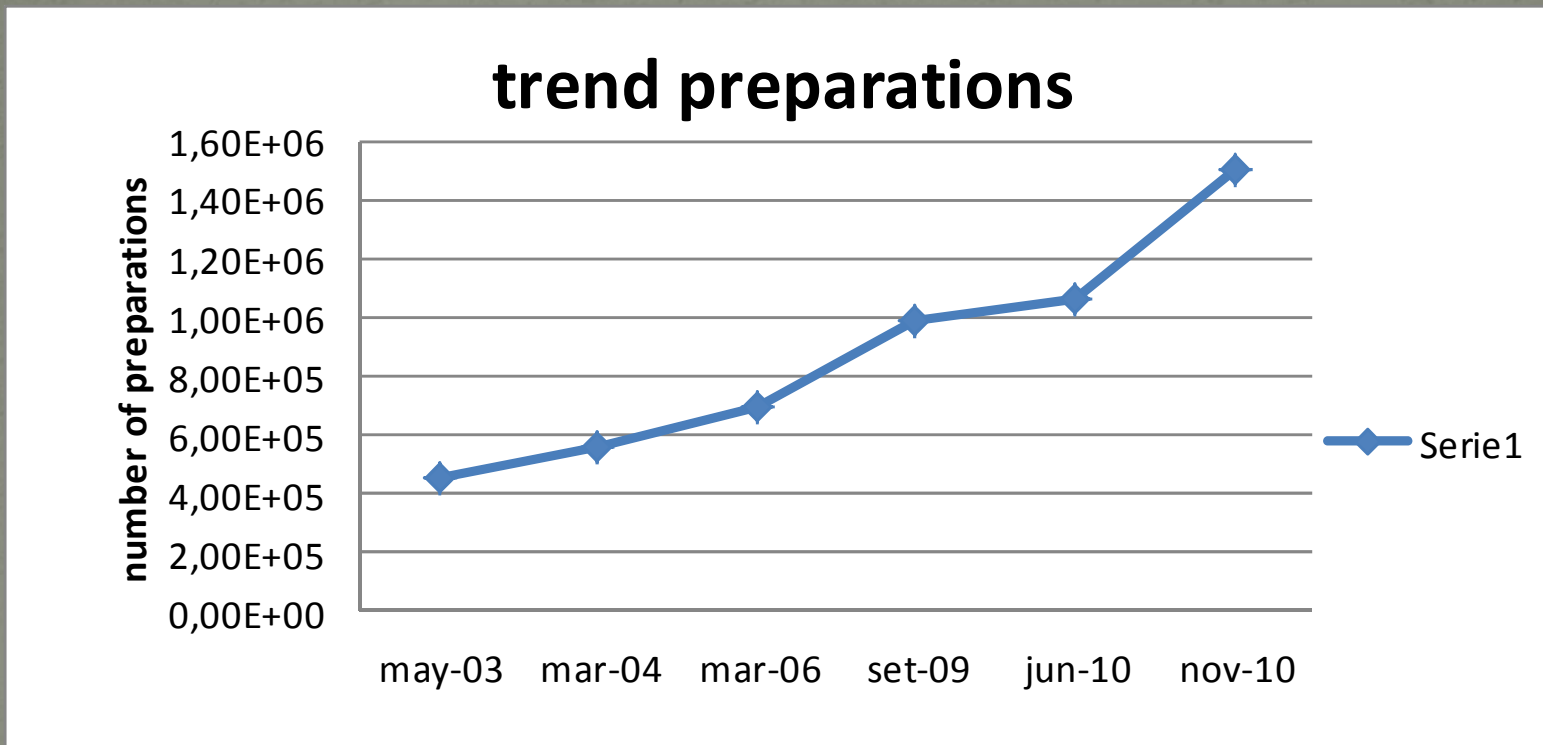


Companies registred up to now

- Total: 4945
- Italian: 4190
- EU-located: 726
- Non EU : 29



PREPARATIONS trend



N. Preparations

In total	1.575.777
Detergents	31.132
Non Detergents	1.544.645
Dangerous	1.311.246
Not dangerous	233.399

European Notifiers



AUSTRIA	18
BELGIUM	52
BULGARIA	1
CROATIA	1
CZECH REPUBLIC	3
DENMARK	8
ESTONIA	1
FINLAND	5
FRANCE	96
GERMANY	330
GREECE	1
HUNGARY	2
IRELAND	4
ITALY	4190
LUXEMBOURG	2
NETHERLANDS	76
NORWAY	1
POLAND	1
PORTUGAL	1
SAN MARINO	4
ROMANIA	1
SLOVENIA	1
SPAIN	52
SWEDEN	8
SWITZERLAND	32
TURKEY	1
UNITED KINGDOM	85

Extra UE



USA	20
ARGENTINA	1
JAPAN	2
CHINA	1
INDIA	2
CANADA	3



BUGS

- Mixtures where compositions does not reach 100%
- Mixtures where some ingredients are linked to ingredients directly notified by producers (confidentiality) but this link does not work
- Mistake due to wrong C&L of the ingredients
- Mistake due to wrong responsibility of notifiers/importers
- Mixture in mixture

New commercial cases



New commercial mixtures for refilling e-cigarette



- Mixtures mainly imported from UE
- 36 notification during 2013
- Infractons
- Ignorance about legal requirements, mostly from simple importers
- Some accidents due to accidental ingestion (mistake due to similarity to pharmaceutical products), mainly children

Commercial mixtures newly included in the database

Klinker – Concrete

- Different mixtures, very often linked to availability of ingredients
- High variability of mixture
- Million of producers
- Different degrees of dangerousness, linked to % dangerous components

<u>Percentage</u>	<u>Mixture</u> <u>DPD Classification</u> (concrete)	<u>Indication of danger</u>
Clinker concrete > 5 % and < 10 % by weight	Xi R36 – R43 	R36 – Eye irritant R43 – Can cause skin sensitization.
Clinker concrete > 10 % and < 20 % by weight	Xi R41 – R43 	R41 – Severe eye damage R43 – Can cause skin sensitization.

<u>Percentage</u>	<u>Mixture</u> <u>CLP Classification</u> (concrete)	<u>Indication of danger</u>
Clinker concrete > 5 % and < 20 % by weight	Eye Dam. 1; H318 Skin Irrit. 2; H315 Skin Sens. 1; H317	H318 Severe eye damage H315 Skin irritant H317 Can cause skin sensitization  

CLP impact on databases workload

It is therefore highly likely that the impact resulting from the application of the CLP also inevitably leads to an increase of the items mentioned in the national databases for poison centers

Category of Danger	Concentration limit for classification
Acute oral toxicity 1*	0.025%**
Acute oral toxicity 2*	0.25%
Acute oral toxicity 3*	5%
Acute oral toxicity 4*	25%
STOT 1	1%
STOT 2	10% (but needs SDS on request at 1%)
Skin corrosion 1	5% (becomes Cat 2 skin)
Skin corrosion 1	3% (becomes Cat 1 eye)
Skin corrosion 1	1% (no classification)
Skin irritation 2	10%
Skin or respiratory sensitiser	1% (but needs SDS on request at 0.1%)
CM Cat 1a, 1b	0.1%
R Cat 1a and 1b	0.3% (but needs SDS on request at 0.1%)
CM Cat 2	1% (but needs SDS on request at 0.1%)
R Cat 2	3% (but needs SDS on request at 0.1%)
Aquatic acute 1	0.1% ****
Aquatic chronic 1	0.1% ****
Aquatic chronic 2	1%
Aquatic chronic 3	10%
Aquatic chronic 4	1 %***
* Based on ATE point estimate in Table 3.1.2,	
** Note that if below limit of concern of 0.1% for Cat 1, the legal text implies that substances can be ignored unless it is known to be of concern. Rather vague !	
*** Consider on case-by-case, especially if potential vPvB or PBT.	
**** Note M factor	

-DPD : 20 %

-DPD : 5 %

Note that the text of the CLP Regulation covers this in detail and this is a summary of limited endpoints.

CLP: impact on detergents

Household products	EU	CLP (all cats.)
Laundry detergent (powder)		
Skin irritant	22%	100%
Eye irritant	100%	100%
Laundry detergent (liquid)		
Skin irritant	84%	100%
Eye irritant	100%	100%
Cleaning fluids		
Skin irritant	15%	100%
Eye irritant	65%	100%
Dishwashing liquid		
Skin irritant	88%	100%
Eye irritant	100%	100%

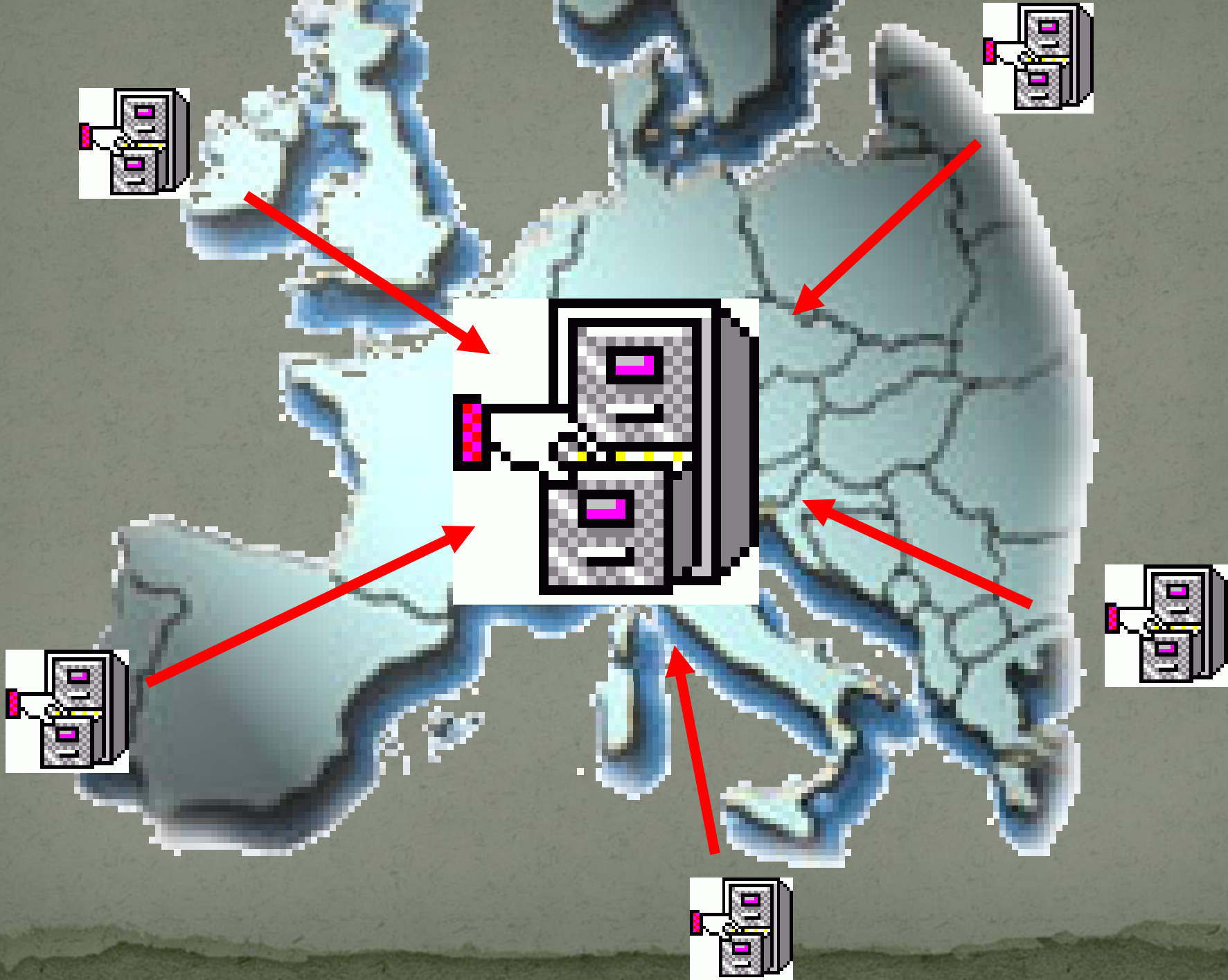
**Serious Eye Damage / Eye Irritation:
Implications of CLP**

Source: AISE

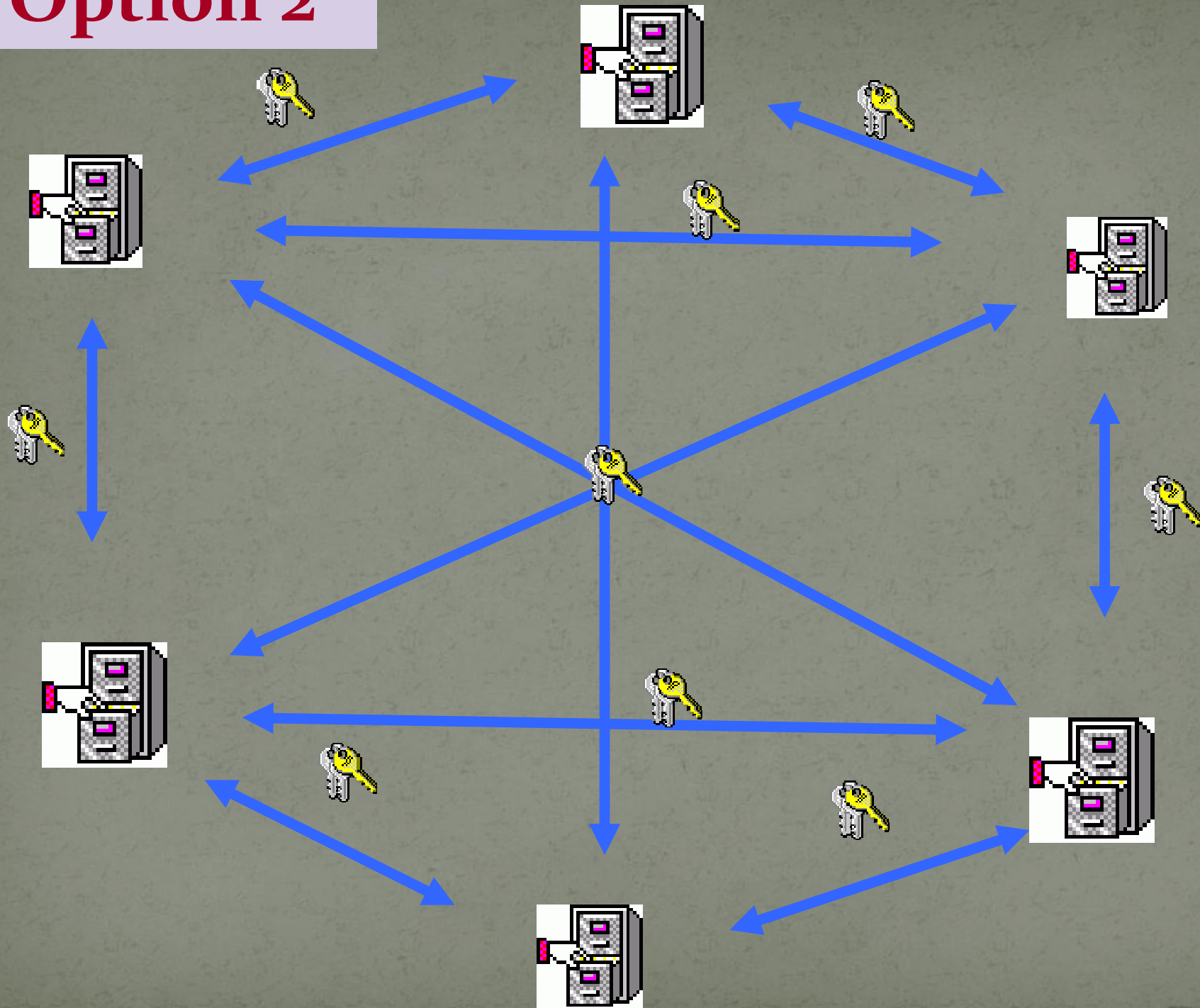
HOW WE SEE THE FUTURE OF THE NATIONAL DATABASE

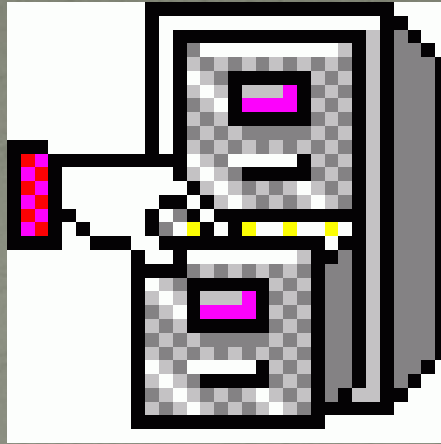
- The Poison Centres usually don't need extended info on the preparations (e.g. the full content of SDS), and prefer to get an essential and quick info useful for their institutional activity
- Need to identify a core set of data which are essential for the Poison Centre and which are present in the different national databases
- On the basis of such "core set of data" elaborate a common format in an electronic platform compatible with all the systems adopted in the different MS
- Such common format could be adopted with the aim of satisfying the requirements of all national databases, so avoiding for the industry to be obliged to fill up different forms for the different national databases
- A more long-term project could aim at allowing the different national databases to be connected with each other in an European Network so as to widen for the Poison Centres the research possibilities in case of need.

Option 1



Option 2





Many thanks for your
attention!

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