

**TOXICOLOGICAL INFORMATION  
AND DATA NETWORK.  
AN EUROPEAN CHALLENGE ?**

**RISK ASSESSMENT ON THE BASIS OF  
POISON CENTRE DATA**

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**RISK ASSESSMENT ON THE BASIS OF  
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Historically, medical toxicologists and risk assessment toxicologists have existed in two parallel worlds.

Actually, human data from Poison Centres are not used in the risk assessment process.

**RISK ASSESSMENT ON THE BASIS OF  
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**Risk assessment for risk management  
(regulatory work)**

- Objective : to prevent harmfulness of chemicals
  - for consumers
  - for workers
  - for environment
- Data come mainly from standardized animal studies, and published human data.
- Challenging is how to act with the uncertainty of using animal model to evaluate human health effects.
- Example : data like « NOAEL » (No-Observed Adverse Effect) is an information of importance.

**RISK ASSESSMENT ON THE BASIS OF  
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**Risk assessment for poisoning management  
(Poison Centre work)**

- Objective : to evaluate after acute or chronic exposure to chemicals the potentiality of harmfulness, to give advise to treat the patient and to prevent complications.
- Data come mainly from clinical experience (published and own cases).
- Challenging is how to act in absence of human clinical experience : chemical industrial accident, new product.

**RISK ASSESSMENT ON THE BASIS OF  
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- These two disciplines have developed strategies to act in the absence of information on the health effects and potentiality of exposure.
- There is a need for these two disciplines to try to share experience.

**RISK ASSESSMENT ON THE BASIS OF  
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- In France, the need to involve Poison Centres in the risk assessment for regulatory purpose has been identified, some years ago :
  - in 1996, the french law has redefined the role of Poison Centre, set up a national toxicovigilance network ;
  - in 1997, several Poison Centre toxicologists were involved in the process of risk assessment for regulatory purpose.

### RISK ASSESSMENT ON THE BASIS OF POISON CENTRE DATA

■ The role of Poison Centres has been expanded including :

- continuous surveillance of human exposure,
- risk assessment of health effects of chemicals,
- expertise to authorities after environmental pollution, indoors and outdoors.

### RISK ASSESSMENT ON THE BASIS OF POISON CENTRE DATA

Example : the Lille Poison Centre surveillance programme of human exposures to chemicals

- Network of case recording in several toxicovigilance collaborating hospitals in the region.
- Cases come from :
  - Poison Information Unit
  - Adults and Pediatric Emergency Department from different hospitals,
  - Forensic Institute.
- All cases are followed and Poison Severity Score is scored.

### RISK ASSESSMENT ON THE BASIS OF POISON CENTRE DATA

- Case data base is linked to the product and substance data base.
- Analysis is done continuously :
  - to identify the most harmful products and substances, the population at risk, and the circumstances ;
  - to alert the National Toxicovigilance Network, Ministry of Health and the Consumption Authorities ;
  - to identify priorities and to evaluate prevention programmes.

### RISK ASSESSMENT ON THE BASIS OF POISON CENTRE DATA

- In our experience, there is a great challenge for Poison Centres to contribute to the regulatory risk assessment by providing their knowledge on human health effects of chemicals in their daily life :
  - epidemiological « non published » data,
  - effects after accidental or occupational exposures,
  - information on acute toxicity : cutaneous, ocular, respiratory,
  - information on sensitization : cutaneous, respiratory.

### RISK ASSESSMENT ON THE BASIS OF POISON CENTRE DATA

This could contribute to :

- the hazard assessment by identifying and confirming the information on toxicity of chemicals predicted by animal studies (target organs) ;
- dose or concentration for critical effect, for NOAEL (data from acute exposure, suicide may also be useful) ;
- circumstance of exposure (normal / over exposure / accident) ;
- population exposed ;
- identification of priorities in the selection of substances to be assessed by regulator.

### RISK ASSESSMENT ON THE BASIS OF POISON CENTRE DATA

In this perspective, we did a study.

- Objective : to identify high frequency and high severity substances in the home environment.
- Method :
  - 1997 - 2001
  - data collected from Poison Centre, emergency department,...
  - non intentional (home accident and misuse)
  - severity using the « poison severity score » after follow up
  - household and leisure products

**RISK ASSESSMENT ON THE BASIS OF  
POISON CENTRE DATA**

**Results (1)**

- 1997 - 2001
- 58401 cases of accidental exposures (home, misuse)
- 23054 cases with 1934 household and leisure products

**RISK ASSESSMENT ON THE BASIS OF  
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**Results (2)**

15 most frequent substances contained in products involved toxic exposures in home environment

1	SODIUM HYPOCHLORITE	4017
2	WHITE SPIRIT (petroleum distillate)	1646
3	ETHANOL	850
4	SODIUM CARBONATE	790
5	ETHOXYLATED ALCOHOLS	733
6	SODIUM HYDROXIDE	514
7	ISOPROPANOL	483
8	SODIUM SULFATE	459

**RISK ASSESSMENT ON THE BASIS OF  
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**Results (2) (suite)**

9	CITRIC ACID	435
10	SODIUM ALKYL BENZENE SULFONATE	418
11	HYDROGEN PEROXYDE	386
12	AMMONIAC	374
13	ETHYLENE GLYCOL	354
14	METHANOL	353
15	SODIUM SILICATE	351

**RISK ASSESSMENT ON THE BASIS OF  
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**Results (3)**

15 most frequent ingredients in products by high severity (PSS > or = 2)

1	SODIUM HYPOCHLORITE	62
2	WHITE SPIRIT (petroleum distillate)	56
3	SODIUM HYDROXIDE	35
4	AMMONIAC	18
5	HYDROGEN PEROXYDE	17
6	BUTYL ACETATE	13
7	SODIUM PERBORATE	12
8	ETHOXYLATED ALCOHOLS	11

**RISK ASSESSMENT ON THE BASIS OF  
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**Results (3) (suite)**

9	QUATERNARY AMMONIUM	10
10	SODIUM CARBONATE	10
11	ETHANOL	10
12	ISOPROPANOL	10
13	POTASSE	10
14	ETHYL ACETATE	9
15	BUTYL GLYCOL	8

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**Results (4)**

10 most frequent categories of products involved in severe cases

1	CLEANER/POLISH	104
2	BLEACH/DISINFECTANT/STERILIZER	75
3	SOLVENT	53
4	REMOVER	44
5	FUEL/SOURCE OF IGNITION	31
6	WOOD PRESERVATIVE PRODUCT	18
7	TEXTILE CHEMICAL	15
8	PAINT/PRINTING MATERIAL	10
9	VEHICLE MAINTENANCE	9
10	ADHESIVE/GLUE	9

**RISK ASSESSMENT ON THE BASIS OF  
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**CONCLUSION (1)**

- Information on human health effects and exposures to chemicals coming from Poison Centres could be useful for risk assessment for regulatory purposes.
- But Poison Centres cannot solve all existing problems and difficulties still exists to obtain useful human data (uncontrolled variables, incomplete exposure estimations, differences between individuals).

**RISK ASSESSMENT ON THE BASIS OF  
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**CONCLUSION (2)**

- So Poison Centres have a key role to play in risk assessment.
- But Poison Centres should focus on the **QUALITY** and the **ADEQUACY** of the data collected to allow their use for risk assessment.
- E.U. support should be given to conduct feasibility studies in this perspective.