INTRODUCTION

Guido Bellomo

- Purpose of the register;
- Information on chemicals and sources of information;
- Chemicals checklists for the national registration;
- Register structure and information exchange;
- Access to the database and confidentiality issues.

PURPOSE OF THE REGISTER

1) Prevention and protection of consumers and workers, accidentally exposed to chemical products;

2) More rapid intervention time in case of accidental poisoning;

3) Monitoring of chemicals on the national market;

4) Management of the application for authorization purposes (biocides);

5) Harmonization (use of chemicals, restrictions, evaluation process)

INFORMATION ON CHEMICALS AND SOURCES

1) Administrative information about company;
2) Industrial sector and production;
3) Administrative information related to the product;
4) Specific information about the product, its properties, classification, use and composition;
5) Information about the evaluation of the information submitted in the context of an application for authorization/registration.

CHEMICALS CHECKLISTS FOR THE NATIONAL REGISTRATION/AUTHORISATION

The complexity of the register depends strictly on its purpose and for this reason it is necessary to understand primarily the function of the database.

1) What is the level of detail in monitoring of chemicals on the market?
2) Monitoring of chemicals, biocides, plant protection products?
3) Management of the application process?
4) Sharing information during the process of evaluation?

REGISTER STRUCTURE AND INFORMATION EXCHANGE

To decide the structure of the register it's important to address the level of detail according to data requirements.

1) What kind of information have to be submitted by the applicant?

2) How to exchange data on chemicals (between applicants and Authority)?

ACCESS TO THE DATABASE AND CONFIDENTIALITY ISSUES

Documentation could be submitted by the applican using preset confidentiality criteria.

1. Public information
2. Restricted information
3. Restricted information to the Authority

Public and restricted information should be treated separately, differentiating accesses to the documentation.

What is considered as Non-Confidential?

- Non-confidential assessment reports by national authorities.

- Updates to the authorisation status of products (amendments, revisions and renewals).

- Summaries of product characteristics, containing key product information, including:
  - product trade names
  - substances in the product and their concentrations
  - biocidal product composition
  - the manufacturer of the product
  - the manufacturer of the active substance
  - hazard and precautionary statements
  - the organism the product is targeted at
  - application methods
  - type of packaging
  - instructions for use

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What is considered as confidential?

- Information that can undermine the protection of the commercial interests or the privacy of the persons concerned.
- This includes details of the full composition of the product and the precise tonnage of the active substance or product manufactured or made available on the market.
- The function of a non-active substance in a biocidal product can be considered confidential.
- The name of a non-active substance can also be considered confidential unless being aware of its existence is essential for the proper use of the product or the substance is of concern.

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TOPICS

- National Register for chemicals
- European Notification System for chemicals
- Management of an application for the authorisation of a biocidal product