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Environmental regulations and standards in Chemistry

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Central Security Risk Prevention Service

The different regulatory sources

- European directives

  Acts binding member states as the results to be achieved, while leaving the choice of means and form

- European regulations

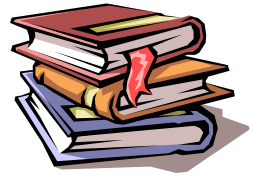
  Have a general scope & are directly applicable and in the same way in all member states, taking precedence over internal provisions

- Laws

  General and permanent rules, drawn up by parliament and promulgated by the president of the republic

- Decrees

  Enforceable decisions of general or individual scope, signed by the president of the republic or the prime minister



The different regulatory sources

- Orders

  Binding decision of general or individual scope emanating from one or more ministry or any other administrative autority (prefects, mayors)

- Circulars

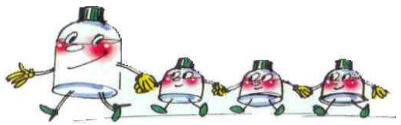
  Serves as a text explanation for decrees & orders. Do not add any rules. No regulatory

- Harmonized European standards & approved French standards

  Translation of the technical requirements set out in the directives into reference documents : Fixing the characteristics of products or procedures. Subject to broad consultation between interested parties (manufacturers, distributors, users, laboratories, administrations)

  Not obligatory, with some exceptions

European REACH Regulation : *Registration, Evaluation and Authorization of CHemicals*



- Implements the registration, evaluation and, in certain cases, the authorization or restriction for the use of chemicals substances to better protect human health and environment against the risks caused by these substances
- Etablishes a new European Chemicals Agency : ECHA
- Adopted by the European Parliament and the Council of the EU in December 2006 – Entered into force since 01.06.2007

→ Aims at improving the knowledge of chemical substances and better controlling the risks for humans and the environment, without undermining the competitiveness of the industry : socio-economic issues

REACH Regulation

- 4 essential steps :
  - A procedure for registering substances produced or imported as such, or contained in preparations, or present in articles when they are intended to be released during use, in quantities ≥ 1 ton/year
    - ✓ Which spanned 10 years from 01.08.2008
    - ✓ Not applicable to radioactive substances, medicines, pesticides, biocides, food additives & substances covered by other regulations
  - The evaluation by ECHA of the dossiers and the evaluation by the competent authorities of the Member States of the substances selected based in particular on tonnage and potential risks
    - ✓ REACH entrusts manufacturers with the burden of proof in terms of risk assessment : it is down to manufacturers and importers to hold the responsability of demonstrating that the substances can be manufactured, used and destroyed without causing any risk to human health and environment
    - ✓ More information required depending on the quantities produced or imported, the potential dangers of the substance and the degree of exposure

REACH Regulation

- An inventory of classifications and labelling of dangerous substances, in order to eliminate discrepancies between manufacturers
  - Priority 1 : all CMRs (category 1, 2 or 3) & respiratory allergens

- A new risk management tool :
  - ✓ Authorization, encouraging manufacturers and users to substitute the substances of greater concern (SVHC or Substance of Very High Concern) before manufacturing or marketing, after examination of the risks involved in these solutions and their technical and economic feasability, in particular :

See established list

CMR category 1 or 2

PBT (Persistent, Bioaccumulable and Toxic) or vPvB (very Persistent, very Bioaccumulable) Substances

Endocrine disruptors

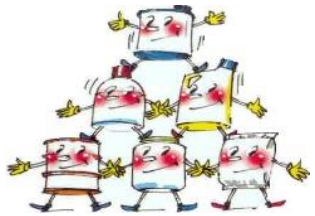
  - ✓ For other substances, possible restriction procedure : total or partial ban
  - ✓ The use of these substances in the context of research and development activities not subject to this procedure

→ Strengthening texts on worker protection which already require employers to eliminate dangerous substances when technically possible or replace them with less dangerous substances

In France, Labor Code, art. L. 4121-2, General principles of prevention

REACH Regulation

- REACH contributions :
  - ➢ Strengthen the principle of substitution for the most dangerous substances
  - ➢ Production of information on the dangers, uses, exposures and risks of substances
    - ✓ The evaluation of toxicological data must allow the declarant to establish the maximum level of exposure to the substance to which humans can be exposed, called Derived No Effect Level (DNEL)
    - ✓ If the substance is dangerous, the declarant must establish exposure scenarios for all exposed populations : workers, consumers, and people indirectly exposed through the environment
  - ➢ Communication of this information in the supply chain, and possibly to the public when these information are deemed necessary for the health and environment protection
    - ✓ *Via* the « Fiches de Données de Sécurité – FDS » (Safety Data Sheets - SDS), defined by Directives 91/155 & 99/45 transcribed in the Labor Code : art. R. 4411-73 & in which appear the DNEL and the « Valeur Limite d'Exposition Professionnelle / VLEP » or Occupational Exposure Limit Value
    - ✓ *Via* the ECHA chemical products information platform
      - ✓ Since 01/30/24 : a new database : ECHA CHED (ECHA chemical database)
  - ➢ Approximately 360 000 substances concerned



REACH Regulation

- A project to reform the REACH regulation which is part of the European Green deal which aims at achieving a 0 level of pollution for an environment free of chemical substances
  - ➢ Absent from the 2024 work program of the European Commission :

    → Reform clearly not carried out before the next European mandate

European CLP Regulation / Classification, Labelling, Packaging

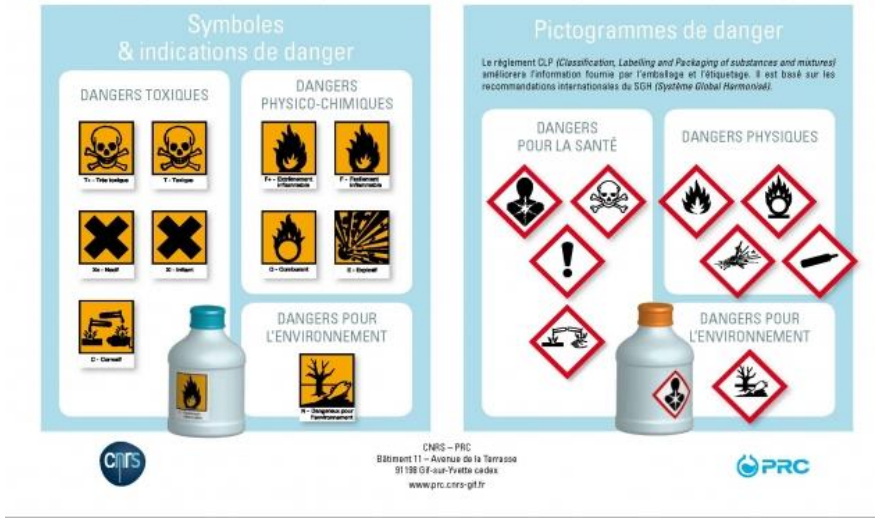
- Recommendations of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), initially adopted by the United Nations Economic and Social Council in 2003 :
  - The risks to humans and the environment related to the storage, transport, use and disposal of chemicals require national programs for safe management ;
  - The laws providing for communication of information to users on the dangers of chemical products present significant divergences depending on the country, or even according to the sectors (transports, workplace, ...) : the dangers are variously defined, the labels and the SDSs meet different requirements ;
  - Many countries lack a classification and labeling system.

CLP Regulation

→Need to harmonize existing systems in order to create a single global system covering the classification and labelling of chemicals as well as SDSs

- Advantages of GHS :
  - Improve the protection of human health and the environment through an easily understood hazard communication system on an international scale ;
  - Harmonization of classification criteria allowing hazards to be identified presented by chemical products & communication elements on these dangers : content of the label and SDS

Old labelling, in France



New labelling GHS (2015)

CLP Regulation

- GHS Advantages :
  - Reduce the need for testing and evaluation of chemicals ;
  - Provide a recognized framework for countries that do not have a system ;
  - Facilitate international trade in chemicals whose dangers have been properly assessed and identified internationally.
- The GHS is implemented in Europe via the so-called « CLP regulation » / regulation (EC) n° 1272/2008 of the European Parliament and of the Council of 16.12.2008 relating to classification, labelling and packaging of substances and mixtures
- Covers all chemicals, except :
  - Radioactive products, medicines, cosmetic products, foodstuffs,
  - Waste,
  - The transport of dangerous materials, …

CLP Regulation

- The main requirements of the CLP regulation :
  - Criteria for classification of dangerous substances & mixtures ;
  - The procedure for notifying ECHA of classifications and labelling of substances ;
  - Rules relating to labelling and packaging ;
  - The obligations of Member States related expecially to the etablishment of national technical assistance services and the designation of organizations responsible for receiving information concerning the response to be provided in the event of a health emergency.

Environmental guidelines in chemistry

Directive 2010/75/EU related to industrial emissions, *known as IED and revised in April 2024* , for prevent and reduce **chronic emissions (emissions of small quantities, but repeated over time)** of pollutants from industrial and agricultural activities at European level (discharges into water, air and earth) :

- Industrial installations (production and processing of metals ; mineral industry ; chemistry - Installations and activities using organic solvents - Installations producing titanium dioxyde),
- Combustion installations & refineries,
- Incineration and waste treatment installations,
- The food industry, paper mills and intensive poultry and pig farming.

- Seven separate pre-existing directives related to industrial emissions are put together into a single text.

The IED Directive

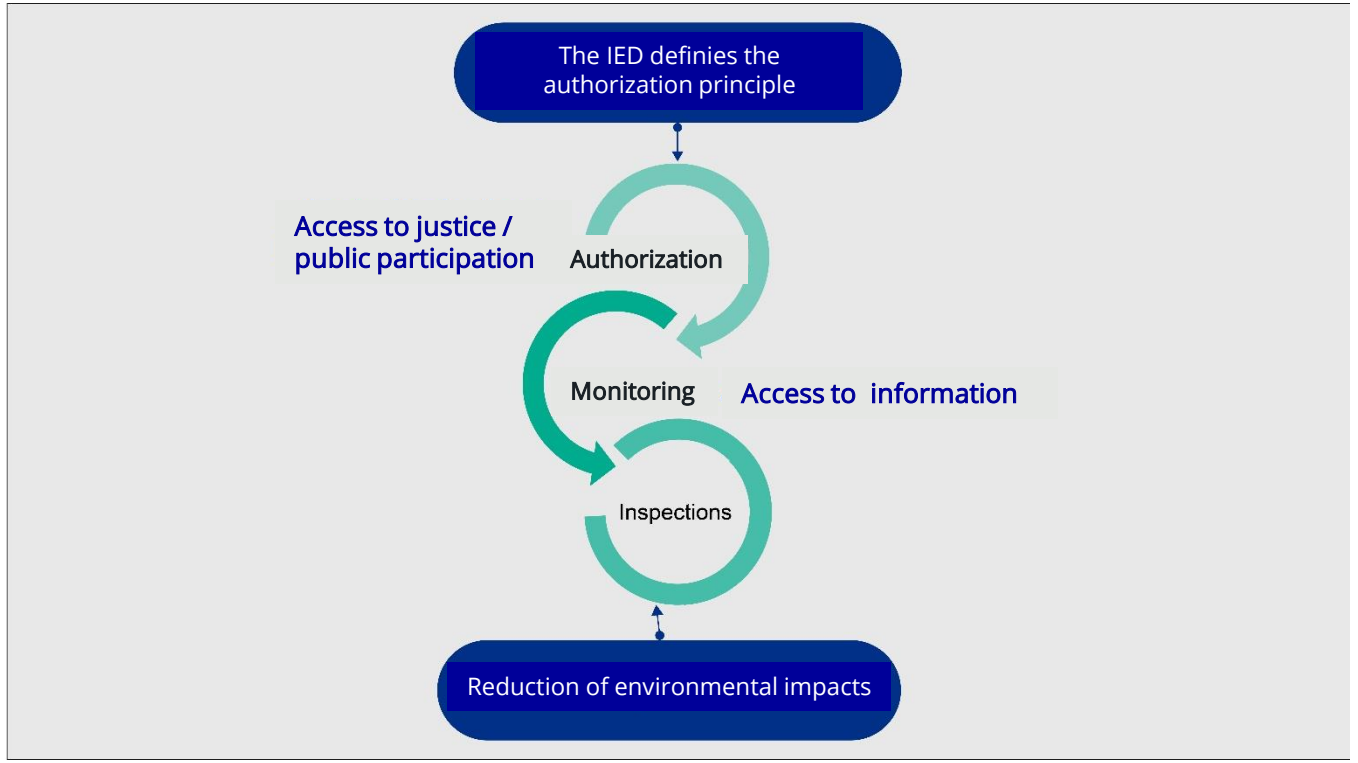
- The main principles of IED are :
  - Pollution prevention & reduction of pollutant emissions into air, water and earth, waste management, energy efficiency, circular economy, decarbonization and prevention of accidents.
  - The obligation to hold an operating authorization (*which already existed in France*),
  - Implementation of Best Available Techniques (BAT *or MTD in French*).
  - Emission limit values.

✓ The terms **«best available techniques»** (BAT) are defined in the directive :

- The term **« best »** corresponds to the most effective techniques in terms of protecting the environment as a whole.
- The notion of **« techniques »** covers, for example, production processes, waste treatment facilities, the substitution of chemical products and even organizational arrangements.
- The notion of **« available »** requires both that operators in a given industrial or agricultural sector have the possibility to obtain the technique, that it is actually implemented on an industrial scale, and that its cost (purchase but especially operation and maintenance) is acceptable with regard to the considered sector.

The IED Directive

- The harmonization of requirements in terms of environmental assessment of industrial installations promotes homogeneous conditions of competition in the European Union.



Source : www.ineris.fr

The IED Directive

- It is the counterpart for chronic risks of Directive 2012/18/EU of July 4, 2012, known as the Seveso 3 Directive.
- The transposition into national/French law takes as closely as possible the provisions of the IED directive. It naturally falls within the framework of the regulation of classified facilities, through the creation of « 3000 » sections, generally with a minimum theshold expressed in volumes of production.
- The revision of the IED intends to promote the use of less toxic or non-toxic chemicals in industrial processes.
  - To this end, the role of ECHA in the document review process (the « BREF »), coming from the exchange of information between Member States, industry and non-governmental organizations, describing techniques, emissions and consumptions as well as what will be considered as the Best Available Techniques (BAT) for a given sector of activity, could be strengthened in the years to come, in order to improve the interface between IED and the REACH regulation.

Environmental guidelines in chemistry

Directive 2012/18/EU, known as the Seveso 3 directive, related to major accidents involving dangerous substances :

- A major technological risk is an accidental event occurring on a site industrial and leading to serious immediate consequences for workers, neighboring populations, properties or environment.
- The consequences of an accident in industry are grouped under three typologies of effects :
  - ✓ The thermal effects of a fire or an explosion ;
  - ✓ The effects of overpressure generated by an explosion blast ;
  - ✓ Toxic effects, consequences of the accidental release of polluting products in the form of gas clouds.
- The prevention of technological risks brings together all the provisions to be put in place to reduce the probability of occurence and the consequences of an accident. It relies on four tools :
  - ✓ Controlling the risk at source by the operator ;
  - ✓ Controlling urbanization (keeping populations away from danger) ;
  - ✓ The organization of emergency resources ;
  - ✓ Public information.
- The study of dangers is at the heart of the prevention of technological risks. Its exploitation will allow the implementation of all the tools provided for by the legislation.

The Seveso 3 Directive

- The list of substances concerned by the Seveso 3 directive is aligned with the new classification system for dangerous substances in the CLP regulation.

- The transposition of these new provisions into French regulations led to substantial modifications to the nomenclature of classified installations which was adapted to this new architecture.

Environmental Code and Nomenclature for classified installations

- Any industrial or agricultural operation likely to create risks for local residents and/or cause pollution or nuisance to environment is potentially an Installation Classified for Environmental Protection (ICPE).
- An ICPE is defined in **article L. 511-1 of the Environmental Code**.
- The regulation relating to ICPE aim in particular to :
  - **Prevent**, on the one hand, **accidental risks** (explosion, fire, accidental release, leak of toxic products, etc.) and on the other hand, **chronic risks** (prolonged exposure to very small quantities of pollutants likely to have an impact on the health of populations) ;
  - **Protect** the different components of the environment (water, air, earths, landscapes, …) or reduce the impacts linked to noise and olfactory pollutions … ;
  - **Preserve** biodiversity (fauna, flora, ecosystem…) and the use of resources ;
  - **Fight** against the effects of climate change (environmental sobriety and energy transition, decarbonization…).

ICPEs

- ICPEs can be very different, ranging from agricultural breeding of around fifty head of cattle, to glassworks or foundries, including factories, workshops, construction sites, waste storage, incinerators, methanizers, wind turbines or quarries ...
- Not all installations present the same risk or the same degree of danger.
- This is why the activities covered by ICPE legislation are listed in a **nomenclature** that includes **three classification regimes** (declaration, registration or authorization) and requiring prior administrative procedures for the operator.
- For each activity, the nomenclature therefore provides classification thresholds within these regimes.
- The nomenclature is divised into four parts :

ICPEs

- **Substances – "1XXX" type section**
(combustible, flammable, radioactive … - for example : section no. 1435 relating to service stations)

- **Activities –"2XXX" type section**
(agrifood, wood, waste, … - for example : section no. 2980 related to the operation of a wind farm)

- **Facilities classified as IED – "3XXX" type section**
(for example : section no. 3660 related to the operation of intensive livestock farming)

- **Dangerous substances and mixtures** falling under the Seveso 3 Directive – **"4XXX" type section**
(for example : section no. 4331 related to the storage of flammable liquids)

ICPEs

- The different sections of the ICPE nomenclature :
  - ✓ Sections relating to substances :
    - 11XX : Greenhouse gases
    - 13XX : Explosibles,
    - 14XX : Flammables,
    - 15XX : Fuels,
    - 16XX : Corrosives,
    - 17XX : Radioactives.

    Harmful, irritating or sensitizing characteristics have not yet been the subject of specific sections.
  - ✓ Sections relating to activities :
    - 21XX : Agricultural activities, animals,
    - 22XX : Agri-food, agro-industry,
    - 23XX : Textiles, leathers, skins,
    - 24XX : Wood, paper, cardboard, printing,
    - 25XX : Materials, ores and metals,
    - 26XX : Chemistry, parachemistry, rubber and plastics,
    - 27XX : Waste,
    - 29XX : Miscellaneous.

ICPEs

- **The different sections of the ICPE nomenclature :**
  - ✓ Sections relating to activities covered by the Industrial Emissions Directive :
    - 3xxx
  - ✓ Sections relating to substances covered by the Seveso 3 directive :
    - 41xx : Toxic
    - 42xx : Explosives
    - 43xx : Gas
    - 44xx : Oxidizing
    - 45xx : Dangerous for the environment
    - 46xx : Reacting with water
    - 47xx : Named
    - 48xx : Other properties

  These 4000 sections specify, depending on the quantity of products, whether the installation is a low or a high threshold.

  →Nomenclature-ICPE-juil24.pdf

ICPEs

- An ICPE can be covered by several sections.
  - ✓ Each section is identified by a 4-digit number, the first 2 characterizing the substance or activity family (e.g. : 1110 very toxic substances, 22XX agri-food, ...). Each section provides a description of the activity as well as the possible thesholds for which a classification regime is defined.
- <u>The declaration regime</u>
  - ✓ For **the least polluting and least dangerous activities**, a simple **declaration** (with a relatively simple file to be filled ouf by the petitioner) is necessary.
  - ✓ Certain activities linked to this "declaration" regime are subject to periodic control to be carried out by an approved body.
- <u>The registration regime</u>
  - ✓ **For standardized installations** (service station, warehouse, poultry industry, etc.), whose risks are known and can be regulated by generic requirements, the **registration regime** (simplified authorization) applies ; except in the case of strong impact.
  - ✓ Before exploitation, the petitioner must submit a registration application file.
  - ✓ The related public and the municipal councils are consulted during the procedure.
  - ✓ If an authorization is issued, the operator must notably comply with the regulatory requirements issued by the ministerial decree specific to the sector of activity concerned.

ICPEs

- The authorization regime
  - ✓ For **installations presenting the greatest risks and impacts**, the operator must apply for **environmental authorization** including in-depth studies, such as :
    - A hazard study aimed at assessing technological risks ;
    - A incidence study or an impact study, with a view to reducing environmental nuisances and the risks of associated pollution.
  - ✓ This process must be carried out before any commissioning.
  - ✓ The related public and the municipal councils are consulted during the procedure.
  - ✓ Ultimately, the department prefect may authorize the installation under specific conditions or reject / refuse putting the installation into operation.
- Some establishments are particulary sensitive : the ones that use and handle substances which, in the event of an accident, can be particulary dangerous for humans and their environment (gases, chemicals, explosives, phytosanitary products, ...). These sites subject to the authorization regime are classified **"Seveso"** (*in reference to the European Directive of the same name : Directive n° 2012/18/EU concerning the control of dangers linking to major accidents involving hazardous substances*).
  - ✓ Their activities are classified in France in the fourth part of the classified installation nomenclature (dangerous substances and mixtures - "4XXX« type section).

ICPEs linked to chemistry at Paris-Saclay University

- Laboratories or external storage holds, subject to Declaration with regard to :
  - ✓ Sections 4330 & 4331 : Storage or use of flammable liquids
  - ✓ Sections 4110 to 4140 : Storage or use of substances or mixtures presenting an acute toxicity
  - ✓ Section 1185 : Use of fluorinated greenhouse gases or substances that deplete the ozone layer

- Henri Moissan site, subject to Authorization with regard to :
  - ✓ Section 1450-1 : Storage or use of flammables solids
  - ✓ Section 4110-2 : Storage or use of acute toxic liquid substances or mixtures

  And to Declaration :
  - ✓ Section 4110-1 : Storage or use of acute toxic solid substances and mixtures
  - ✓ Section 4330 : Storage or use of flammable liquids
  - ✓ Section 4714 : Storage or use of Formaldehyde

The Environmental Code and chemical waste management / *Remimber*

Book V / Prevention of pollution, risks and nuisances

- Title IV / Waste (art. L541-1 to L542-14)
  - ✓ Chapter I / art. L541-1 to 50 / Waste prevention and management
  - ✓ Chapter II / art. L542-1 to 14 / Special provisions for the sustainable management of radioactive materials and waste

The international environmental certification standard ISO 14001

- Standard defined by the International Standard Organization (ISO), which is a global federation of national standards organizations bringing together approximately 140 countries.
- The ISO 14001 standard constitutes a framework that defines rules for integrating environmental concerns into the organization's activities, in order to control the impacts on the environment and thus reconcile the imperatives of the organization's operation and the respect for the environment.
- It applies to all types of organizations.
- It concerns the environmental aspects linked to activities, products and services of this organization (interactions between activities, products and services and the components of the environment).
- Compliance with these requirements requires the implementation of an environmental management system according to the ISO 14 001 standard, which is based on a voluntary approach and must allow :

The international environmental certification standard ISO 14001

- To better understand the environmental impacts generated by the organization's activities ;
- To guarantee compliance with regulations and be able to anticipate future developments therein ;
- To be able to improve practices in a logic of continuous progress and reducing environmental impacts.
  The environmental management system places the company's activities into a logic of sustainable development.

- Certification according to the ISO 14 001 standard of an environmental management system, applicable to whole or part of a site, is obtained following an audit carried out by an independent approve organization.
- Subsequent maintenance of the certification is subject to the annual verification of the conformity of the system with the standard and the renewal (every 3 years) of the certification by an independent organization.


Merci!