



# The National Centre for Chemicals and the chemical risk

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# The National Institute of health (ISS)

- The ***Istituto Superiore di Sanità*** (National Institute of Health), also **ISS**, is a public institution that, as the leading technical-scientific body of the Italian National Health Service (*Servizio Sanitario Nazionale*), performs research, trials, regulatory, control, counseling, documentation and training for public health.
- The Institute is under the supervision of the *Ministero della Salute* (Ministry of Health).
- The official opening of the ISS, called *Istituto di Sanità Pubblica* (Institute of Public Health), took place on April 21, 1934.
- The construction of the main building in Rome, started on July 6, 1931 and it was financed by the American Rockefeller Foundation.
- In 1941 the *Istituto di Sanità Pubblica* assumed its present name of *Istituto Superiore di Sanità*

# Structure and activities

## Departments

- Environment and Primary Prevention
- Cell Biology and Neurosciences
- Haematology, Oncology and Molecular Medicine
- Therapeutic Research and Medicines Evaluation
- Infectious, Parasitic and Immune-Mediated Diseases
- Veterinary Public Health and Food Safety
- Technology and Health

## National centers

- National AIDS Centre
- [National Centre for Chemical Substances, cosmetics and consumer protection](#)
- National Centre for Epidemiology, Surveillance and Health Promotion
- Centre for Immunobiologicals Research and Evaluation
- National Centre for Rare Diseases
- Evaluation and Accreditation Body
- National Blood Centre
- National Transplant Centre

## Technical services

- Service for Biotechnology and Animal Welfare
- Data Management, Documentation, Library and Publishing Activities



# Centre for Chemicals, cosmetics and consumer protection

## **Who are we**

We are the reference point of the national system for chemical risk analysis.

We are the Italian contact point with the European Chemicals Agency (ECHA) for all aspects related to human health.

We do provide technical-scientific support to the Ministry of Health and the Regions, also for authorization of products (biocides and pesticides)

We are also the national network of control laboratories regarding the safety and control of chemical products.



## Our activity

- We provide assessment for hazards and risks related to substances and products, also for marketing, contributes to the evaluation and regulation at European and non-EU level.
- It is the national reference for the plans for the prevention and surveillance of dangerous exposures and intoxication, for biocides, plant protection products, cosmetic and for the safety and control of substances, mixtures, articles, including toys, materials and technologies innovative and emerging for the protection of health.
- The National Reference Laboratory for Chemical Products and Articles implementing the European REACH and CLP Regulation is also in charge of the Center.



# Mission and Vision

## Centro Nazionale Sostanze Chimiche, Prodotti Cosmetici e Protezione del Consumatore

### Mission del Centro

Valuta pericoli e rischi connessi a sostanze e prodotti anche per l'immissione in commercio, contribuisce all'attività di valutazione e regolamentazione a livello europeo e internazionale, è il riferimento nazionale per i piani di prevenzione e sorveglianza delle esposizioni pericolose e delle intossicazioni e per la sicurezza e il controllo di sostanze, miscele, articoli, prodotti cosmetici e prodotti affini, materiali e tecnologie innovative ed emergenti per la tutela della salute della popolazione e del consumatore

Al Centro fa capo il Laboratorio nazionale di riferimento per le sostanze, miscele e articoli in attuazione al regolamento REACH e CLP delle sostanze e delle miscele

### Vision del Centro

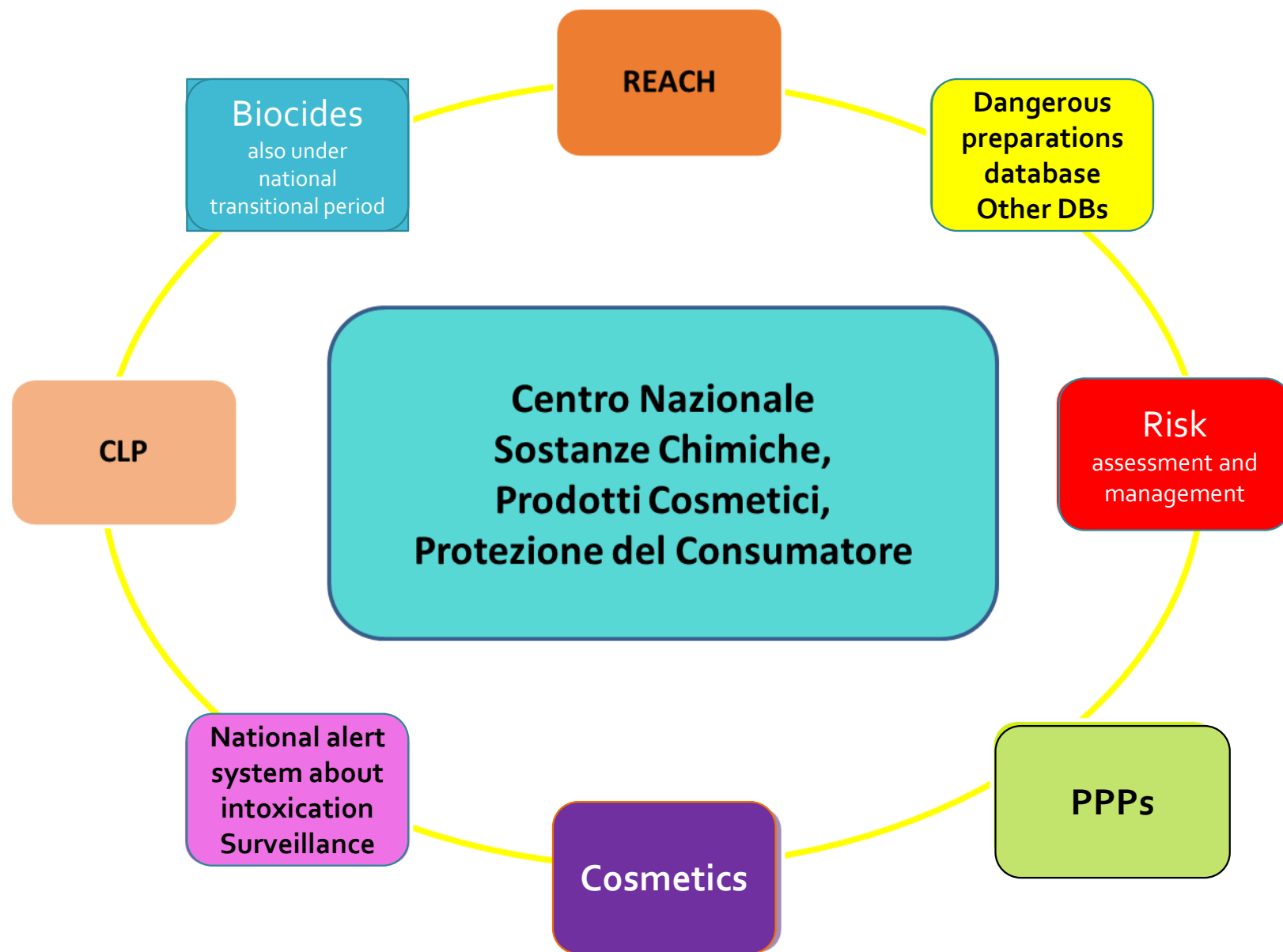
**Produce e promuove le conoscenze** relative alla pericolosità intrinseca di sostanze e miscele attraverso attività di **ricerca** e **valutazione** per l'individuazione delle SVHC. Sviluppa sperimentalmente e valida nuove metodologie analitiche e le **trasferisce** alla rete dei laboratori per il controllo dei prodotti immessi sul mercato.

**Produce conoscenze** relative alla stima dell'esposizione e alla caratterizzazione dei rischi connessi e supporta il sistema autorizzativo per sostanze, miscele, materiali, articoli, prodotti chimici in relazione al rischio per i consumatori e gli utilizzatori professionali.

**Diffonde** attraverso i canali istituzionali (Pubblicazioni scientifiche, Alta Formazione, Convegni/Corsi, ecc.) le conoscenze per supportare decisori politici nazionali ed internazionali, i cittadini e le aziende al fine di tutelare e promuovere la salute e la sicurezza dei prodotti



Our activity according to EU Regulations/Directives



# Our Unit

(Head of Unit:  
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iss.it)

- Unit of substances and products authorization.
- In charge of evaluation and risk assessment of substance and products according to EU Regulations and guidelines.
  
- Biocides
- Agricultural pesticides
- Cosmetics
- National database of dangerous products



## *HEALTH RISK ASSESSMENT*



# Risk assessment

## 4 steps:

- Hazard evaluation (intrinsic properties of the substance or mixture)
- Determination of the dose / response curve
- Determination of non-effect levels
- Risk characterization

## 2 steps:

- Risk communication
- Risk management (or the definition of specific measures to contain / manage risks)



# Hazard evaluation

Evaluation of intrinsic properties:

- Physical and chemical properties
- Toxicological
- Eco-toxicological
- Fate and behaviour



• Classification and labelling



CLP

## Exposure

Sources of exposure to chemicals

- Environmental, including home and school
- Occupational
- Therapeutic
- Dietary
- Accidental
- Deliberate



# Exposure

## Under use condition Worker

Consumer

Bystander

Resident

## Accidental:

Spill

Break the container

Fire, explosion, fumigation

Spill during transport

PPE breakdown

Accidental contamination of clothing

Ingestion of contaminated food

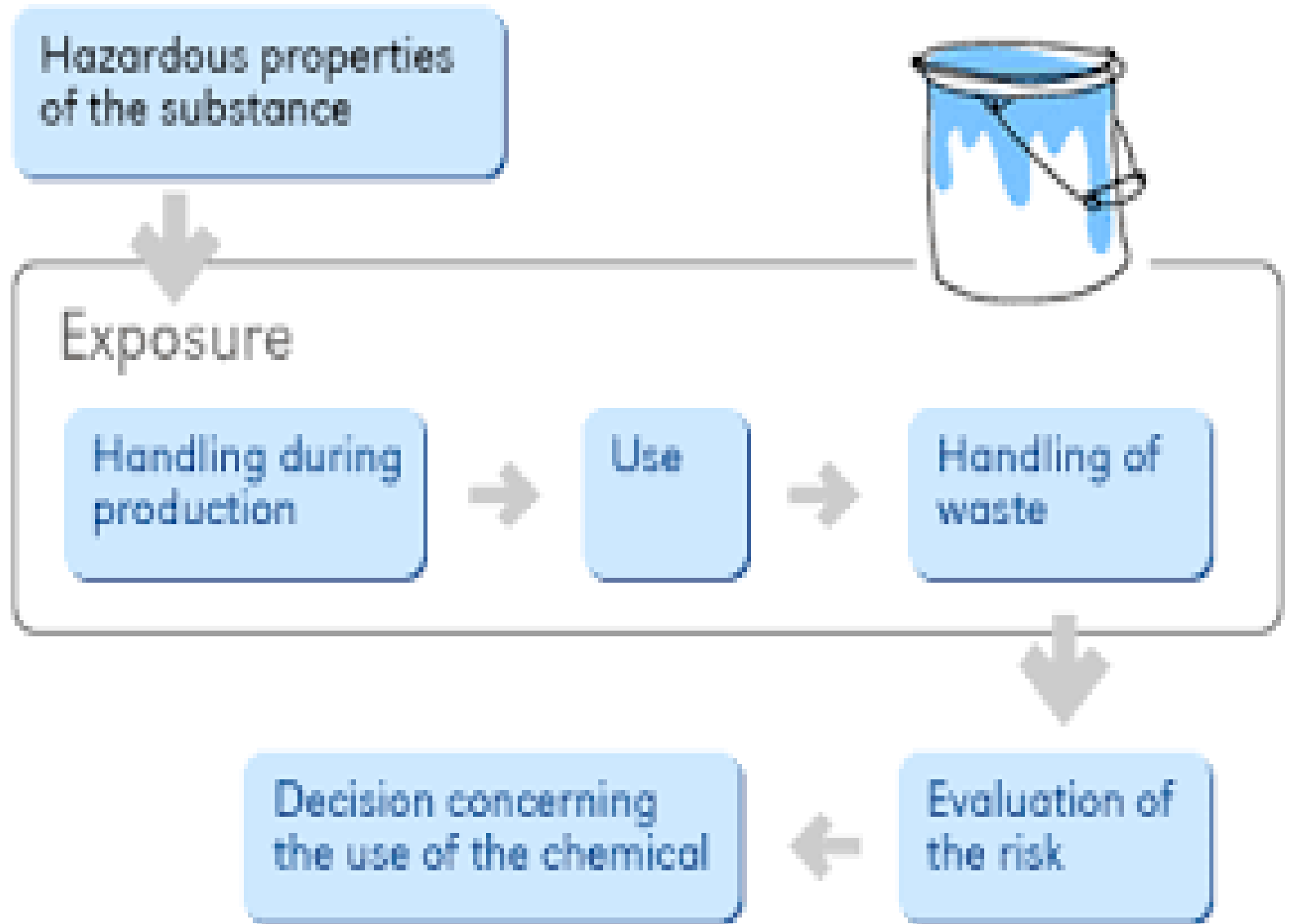
Improper use (misuse), use of improper containers

## Voluntary:

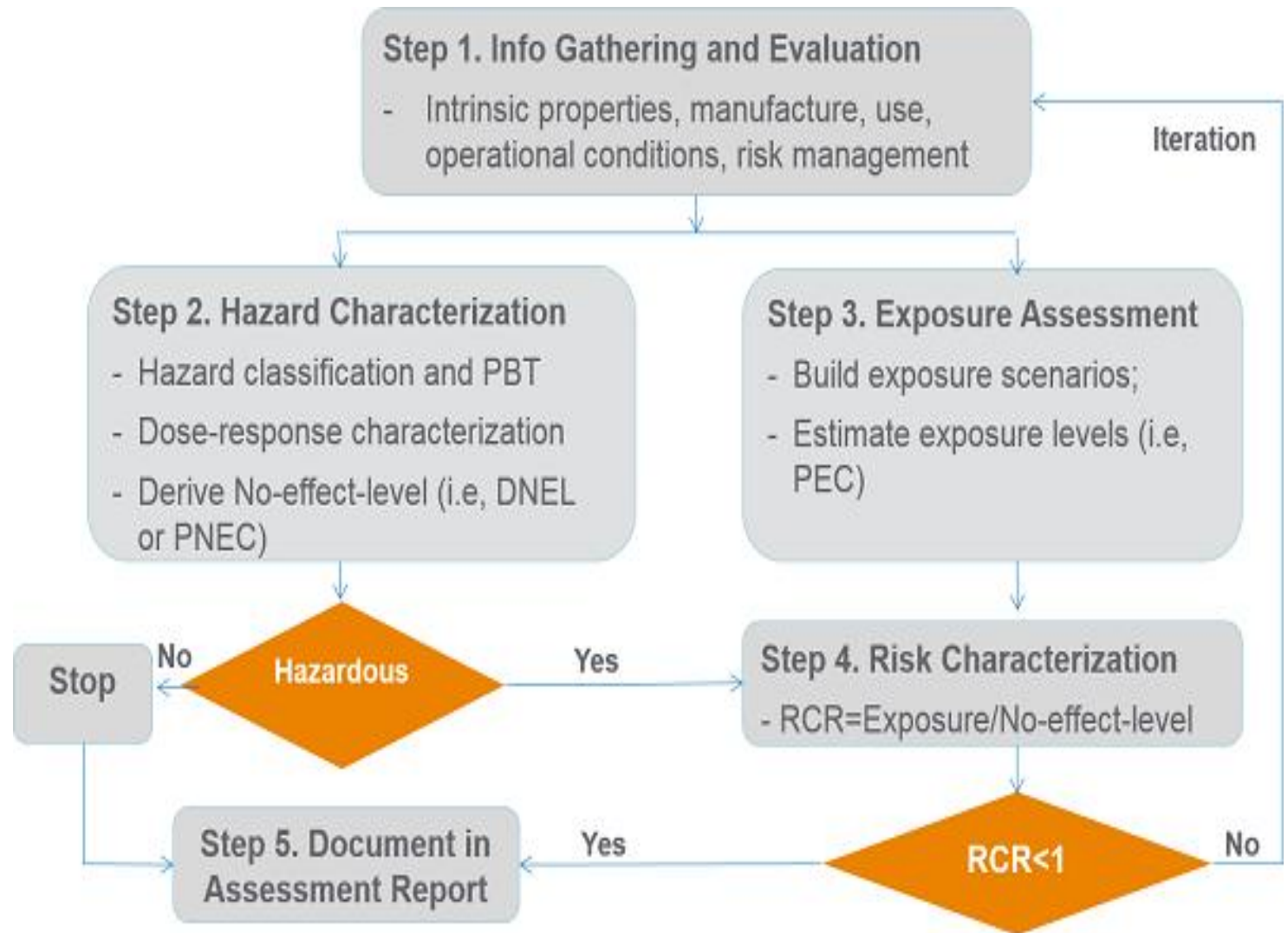
Suicide

Abuse

# Lifecycle of a chemical



# Chemical risk

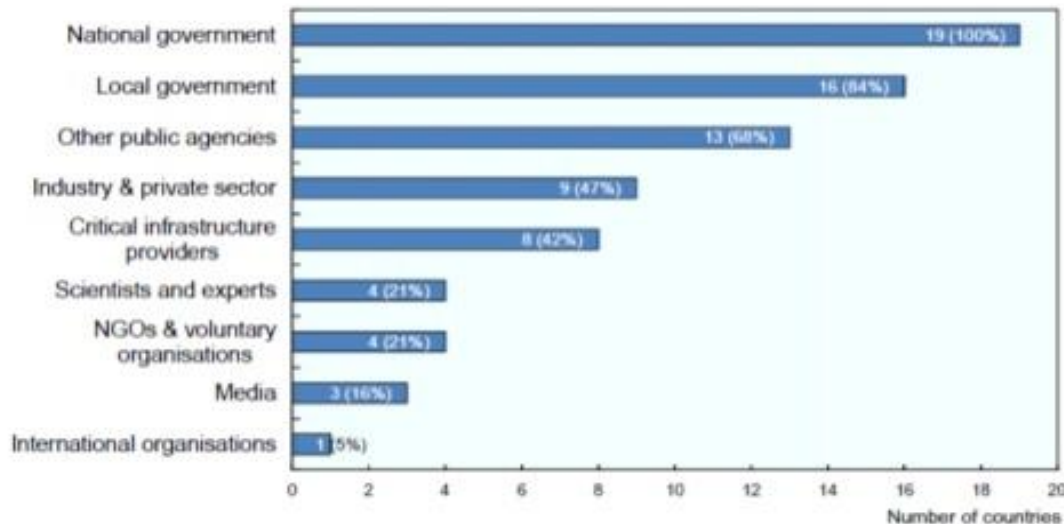




# Risk communication

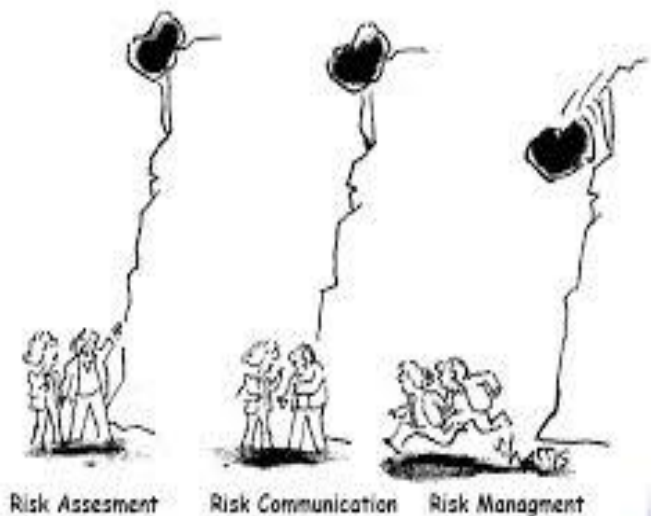


## Which actors have legal or formal responsibilities for risk communication?



➔ *Risk communication could improve by more effectively including stakeholders*

- label
- sds
- notification to dangerous mixture database



# Label

## Old label



**NOCIVO**

**FRASI DI RISCHIO**  
Nocivo per inalazione e ingestione.  
Nocivo: pericolo di gravi danni alla salute in caso di esposizione prolungata per inalazione e ingestione



**PERICOLOSO PER L'AMBIENTE**

Altamente tossico per gli organismi acquatici, può provocare a lungo termine effetti negativi per l'ambiente acquatico

**CONSIGLI DI PRUDENZA** - Conservare fuori della portata dei bambini. Conservare lontano da alimenti o mangimi e da bevande. Non mangiare, né bere, né fumare durante l'impiego. Non gettare i residui nelle fognature. In caso d'ingestione consultare immediatamente il medico e mostrargli il contenitore o l'etichetta. Questo materiale e/o il suo contenitore devono essere smaltiti come rifiuti pericolosi. Non disperdere nell'ambiente. Riferirsi alle istruzioni speciali/schede informative in materia di sicurezza.

DPD

## New CLP label

**ATTENZIONE**

**AVVERTENZA**



**PITTOGRAMMI**

**INDICAZIONI DI PERICOLO** • Nocivo se ingerito. Nocivo se inalato. Può provocare danni agli organi in caso di esposizione prolungata o ripetuta. Molto tossico per gli organismi acquatici con effetti di lunga durata. Per evitare rischi per la salute umana e per l'ambiente, seguire le istruzioni per l'uso.

**FRASI H**  
**FRASI EUH**

**CONSIGLI DI PRUDENZA** • Tenere fuori dalla portata dei bambini. Non respirare la polvere/i fumi/i gas/la nebbia/i vapori/gli aerosol. Non mangiare, né bere, né fumare durante l'uso. Utilizzare soltanto all'aperto o in luogo ben ventilato. In caso di inalazione: trasportare l'infortunato all'aria aperta e mantenerlo a riposo in posizione che favorisca la respirazione. In caso di malessere, contattare un **CENTRO ANTIVELENI** o un medico. Raccogliere il materiale fuoriuscito. Smaltire il prodotto/recipiente in conformità alla normativa vigente.

**FRASI P**

CLP





KEEP CALM AND

LEARN GOOD

RISK COMMUNICATION

KeepCalmandLearnGood.com

SDS

# SAFETY DATA SHEET

Airgas

Aqua Ammonia (5-19.9%)

## Section 1. Identification

<b>GHS product identifier</b>	: Aqua Ammonia (5-19.9%)
<b>Other means of identification</b>	: Aqua Ammonia, Ammonium Hydroxide
<b>Product use</b>	: Synthetic/Analytical chemistry.
<b>Synonym</b>	: Aqua Ammonia, Ammonium Hydroxide
<b>SDS #</b>	: 001196
<b>Supplier's details</b>	: Airgas USA, LLC and its affiliates 259 North Radnor-Chester Road Suite 100 Radnor, PA 19087-5283 1-610-687-5253
<b>Emergency telephone number (with hours of operation)</b>	: 1-866-734-3438

## Section 2. Hazards identification

<b>OSHA/HCS status</b>	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
<b>Classification of the substance or mixture</b>	: SKIN CORROSION/IRRITATION - Category 1B SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 AQUATIC HAZARD (ACUTE) - Category 1

**GHS label elements**  
Hazard pictograms



<b>Signal word</b>	: Danger
<b>Hazard statements</b>	: May displace oxygen and cause rapid suffocation. Causes severe skin burns and eye damage. May cause respiratory irritation. Very toxic to aquatic life.

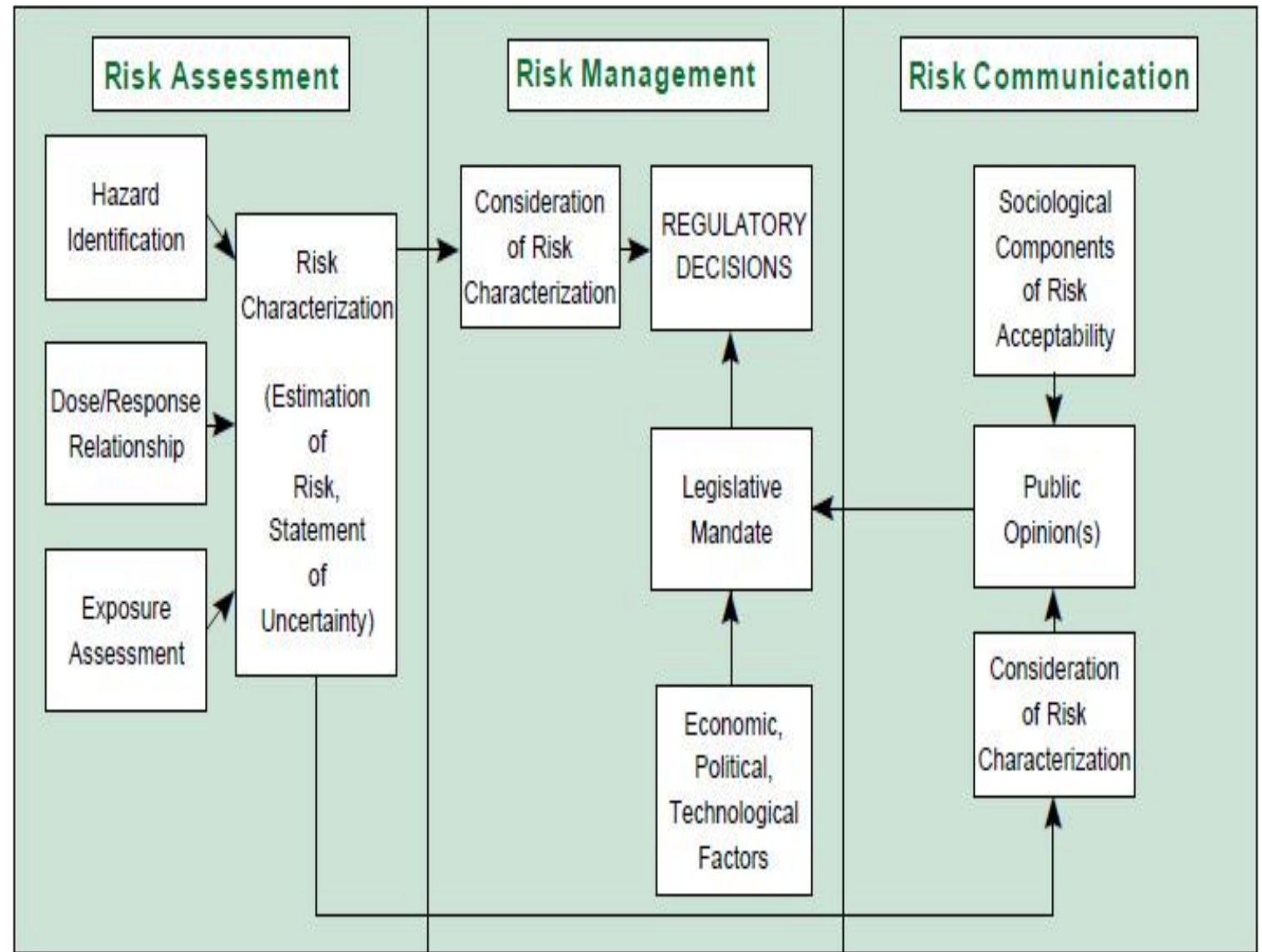
### Precautionary statements

<b>General</b>	: Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
<b>Prevention</b>	: Wear protective gloves. Wear eye or face protection. Wear protective clothing. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Avoid breathing vapor. Wash hands thoroughly after handling.
<b>Response</b>	: Collect spillage. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or physician. IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Wash contaminated clothing before reuse. Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or physician.

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# Risk assessment, Risk management, Risk Communication





# The surveillance

## Surveillance of exposures and poisonings by chemical products

- Collection of information on cases of exposure to chemicals and intoxication as a result of use and improper uses in domestic and professional environments.
- Regulatory references: regulation (EU) 545/2017 and ISS functions on the subject
- Products of interest: detergents, plant protection products, biocides, mixtures and articles containing dangerous substances (eg: electronic cigarette, dyes, glues, products for the treatment of surfaces, etc.)

### Tools:

- data and information from the dangerous product database;
- survey format prepared including EC new requests and made it available to PCs;
- Setting a new database on exposures and poisonings from chemical products available to the Competent authority REACH – CLP and to EU COM
- annual reporting

# The risk mitigation measures

- Based on the surveillance data, proper risk mitigation measures could be revised/added to a mixture which have caused accident in order to mitigate exposure risk , specially for sensitive population (elder, pregnant women, children)

# The Chemical Safety Assessment

