

# Chemical Regulatory Framework in Colombia

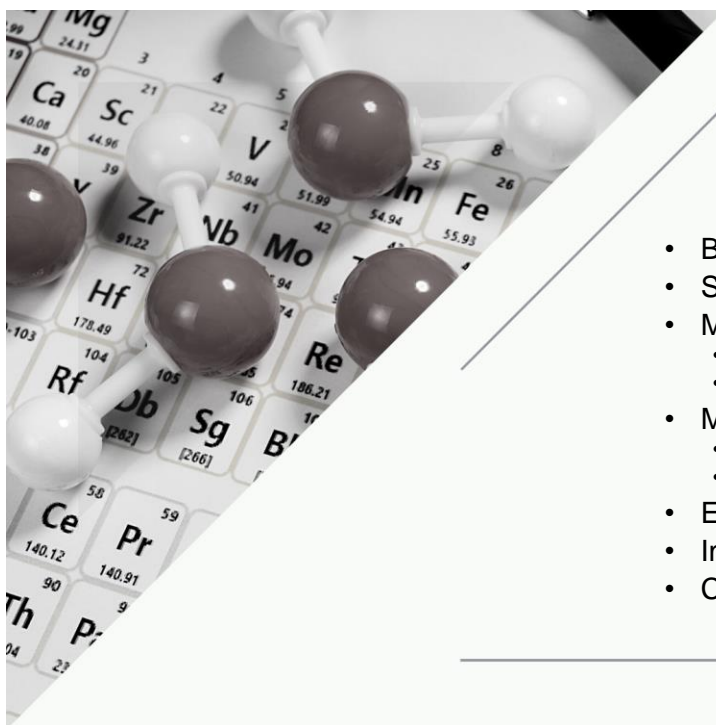
Insights from the Comprehensive Chemical Management of Industrial Substances (Decree 1630)



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## Topics

- Background
- Scope & Exceptions
- Managing Instruments
  - National Inventory
  - Notification
- Monitoring Instruments
  - RETC
  - SGT
- Exchange of Information
- Implementation Timeline
- Compliance strategies

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# Background

## Decree 1630



Promulgated on 30 November 2021



Comprehensive Chemical Management of Industrial Substances, including their risk management

*"Gestión integral de las sustancias químicas de uso industrial, incluida su gestión del riesgo"*



Governmental Website ([FuincionPublica](#))

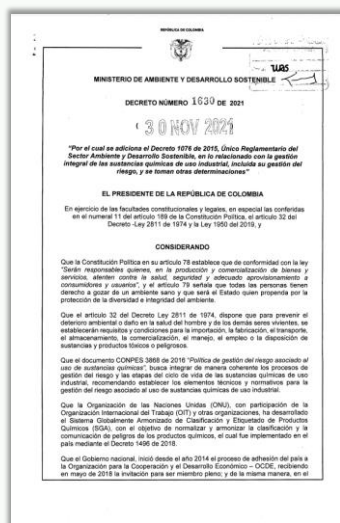


Cooperation between several ministries (Ministry of Commerce, Labor, Health, and Environment)



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# Contents



## Decree 1630 of 30 November 2021

Objective = National Chemical Regulation + Instruments

### A new title to the Decree 1076 (Environment Code)

Section I: General Provisions

Section II: Management Instruments

Section III: Obligations

Section IV: Monitoring

Section V: Institutional Coordination

Section VI: Information handling

Section VII: Inspection and Control



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## Key Definitions

- **Industrial Use:** It refers to any transformation, formulation, consumption, storage, conservation, treatment, packaging, transfer, mixing, production of an article, or any other use of a chemical substance or mixture in industry.
- **User of Industrial Chemicals:** Any natural or legal entity established in the country, who uses a substance, either mono-constituent, multi-constituent, or in the form of a mixture, for its industrial activities.
- **Mono-constituent Substance:** It is one in which a constituent is present at a minimum concentration of 80% (w/w) and contains up to 20% (w/w) of impurities. A mono-constituent substance is named based on the main constituent.
- **Multi-constituent Substance:** Defined by its quantitative composition, it presents more than one constituent with concentration  $\geq 10\%$  (w/w) and  $< 80\%$  (w/w). The multi-constituent substance is the result of a chemical reaction in the manufacturing process.
- **Mixture:** It is a solution that is obtained by intentionally joining two or more substances without producing a chemical reaction.



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## Scope & Exceptions

Decree 1630 addresses the production, import, use, marketing, distribution or transport of industrial substances identified and classified according to the GHS → (6th version) Decree 1496 of 2018



Hazardous substances and mixtures, which are not regulated by other special regulations:

- Managements Instruments
- Monitoring Programs



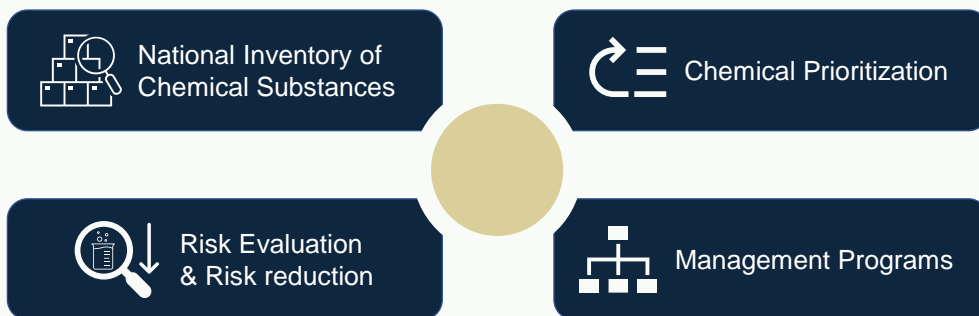
UVCB substances

- Impurities
- Articles
- Natural Substances
- Polymers and Monomers
- Intermediaries
- In customs transit



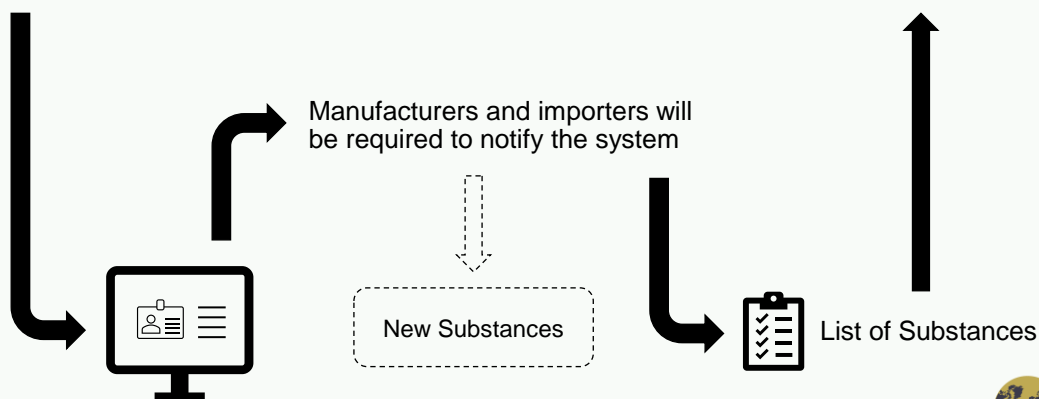
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# Managing Instruments



# The National Inventory

A database that allows to identify each substance, respective manufactured or imported quantities, uses, and substances' hazardous characteristics.



## Notification (1/3)



### Who?

All manufacturers and importers dealing with hazard substances over 100 kg per year



### What?

All Mono-constituent Substance, Multi-constituent Substance or Mixtures above the threshold



### How?

Through a computer software being developed in cooperation by the ministries



### When?

Within 3-years after the software is officially published

Yearly update!



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## Notification (2/3)

### Which information is needed?

- Manufacturer or importer information
- Substance amounts manufactured or imported
- Substance identification, including CAS number
- Substance hazard classification in accordance with the GHS 6<sup>th</sup> revision
- Identified substance uses



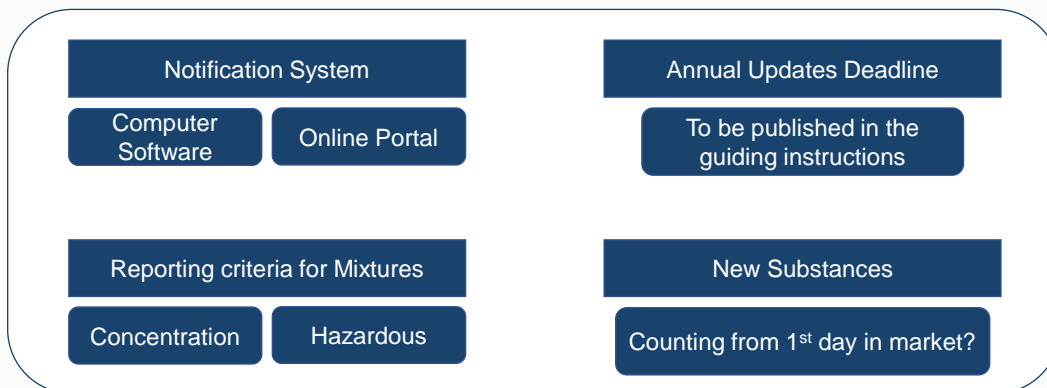
It is possible to submit information on a voluntary basis for manufacturer or importers dealing with lower thresholds of 100 kg per annum.



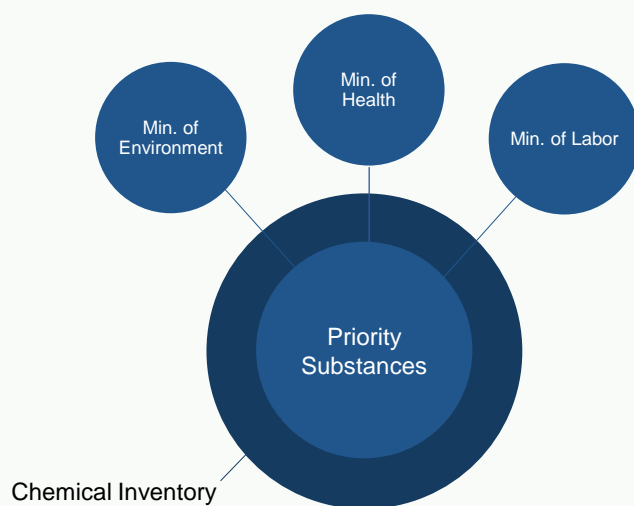
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## Notification (3/3)

Points to be clarified



## Chemical Prioritization

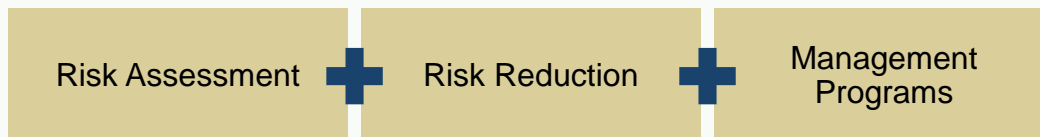


Priority substances are requested to provide detailed or specific information via the Online Portal.

Still to define:

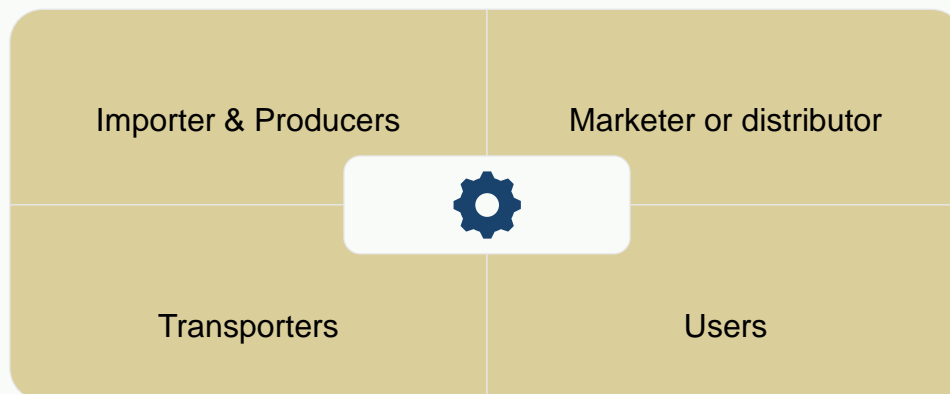
- Modalities & Technical Criteria
- Assessment Criteria
- Further requirements

## Risk Measures



- Cooperation between Ministries of Health and Environment
- Guidelines should address the preparation and implementation of programs
- Manufacturer & Importers need to subject priority substances to activities
  - Substance current identified use
  - Substance new identified use

## Obligations (1/5)



## Obligations (2/5)

### Importers & Producers

- Identify, classify, and label substances according to the GHS
- Provide information to the National Inventory for Prioritization and Risk Assessment
- Make the risk assessment and risk reductions information available to the end-user
- Support and participate in the processes of risk management
- Observe directives for ground transportation (Decree 1079/2015) when transporting chemical substances

## Obligations (3/5)

### Marketer or distributor

- Provide an accurate label and SDS
- Follow risk reduction programs defined by the manufacturer or importer
- Follow the safe handling instructions provided by the manufacturer or importer
- Observe directives for ground transportation (Decree 1079/2015) when transporting chemical substances



## Obligations (4/5)

### Transporters

- Observe directives for ground transportation (Decree 1079/2015) when transporting chemical substances

Decree 1079/2015, Book 2, Title 1, Chapter 7, section 8

*"Automotive land transport of dangerous goods by road"*

Objective to establish technical and safety requirements for handling and transporting dangerous goods by road through the national territory.



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## Obligations (5/5)

### Users

- Certify an accurate label and SDS
- Inform the manufacturer or importer about the new uses of the substance. In case the new use is accepted by the manufacturer or importer, provide the information required for the risk assessment and management program related to the new use.
- Support the manufacturers and importers in the reduction and management of risks by providing additional relevant information.
- Follow the request activities imposed by the risk reduction programs defined by the manufacturer or importer
- Report to the authorities any uncompliant information, whether the reduction and management programs are not available or present inconsistencies



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# Monitoring Instruments

Min. of  
Environment

A Registry for Emission and Transfer of  
Contaminants (RETC)

Record and provide information to the public on emissions and transfers of pollutants to water, air and soil, as well as on residues or hazardous waste.

Min. of Health



Min. of Labor

Toxicological Management System (SGT)

The system will support the prevention, mitigation, reduction and control of poisoning risks, and assist in the prevention, diagnosis, and treatment of adverse health effects.

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# Information Acceptance

## OECD

Mutual Acceptance of  
Data (MAD)

OECD test methods or  
equivalents

Good Laboratory  
Practices (GLP)

Disclose Information:  
- OECD LEGAL 0205  
- OECD LEGAL 0204

## Outside Data



MAD or GLP



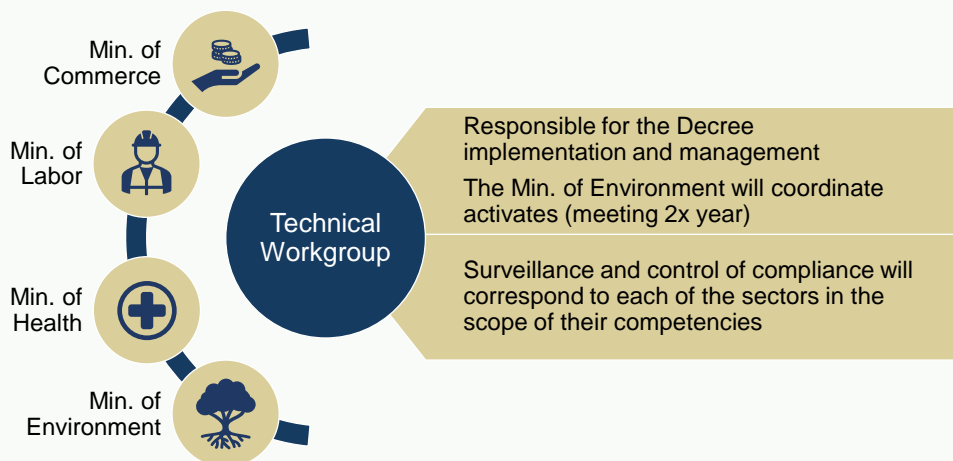
ISO/IEC 17025

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# Implementation



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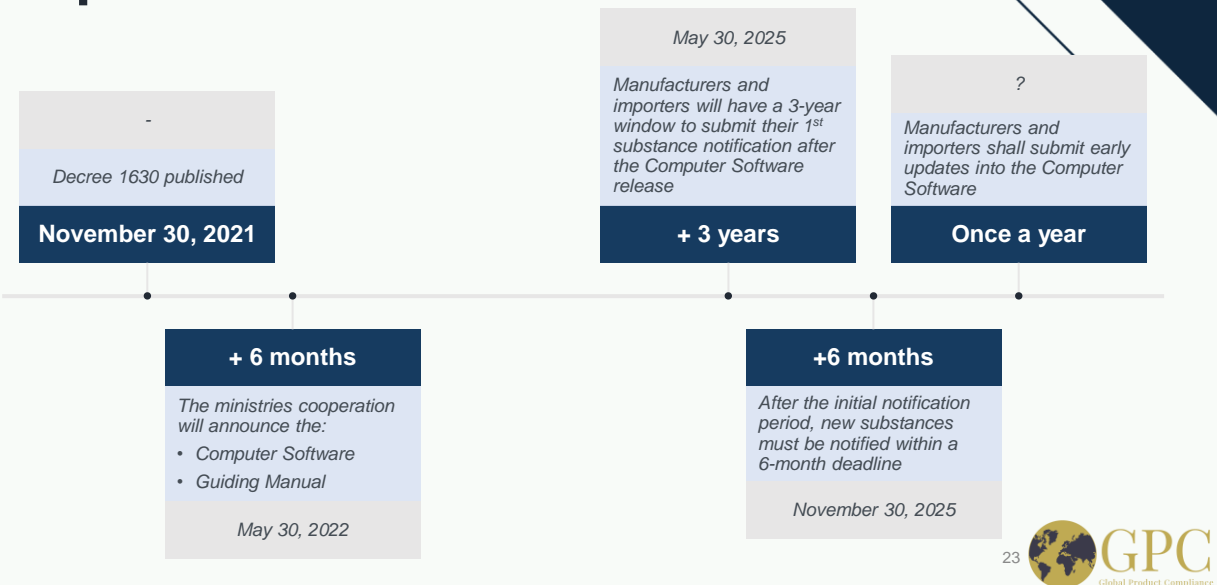
# Ministerial Responsibilities

Activities	Min. of Commerce	Min. of Health	Min. of Labor	Min. of Environment
Computer Software	✓	✓	✓	✓
Chemical Inventory	✓*	✓	✓	✓
Chemical Prioritization	-	✓	✓	✓
Risk Assessment	-	✓	-	✓
Risk Reduction	-	✓	-	✓
Management Programs	-	✓	-	✓
RECT	-	-	-	✓
Toxicological Management System	-	✓	✓	-
Chemical Substance Group	✓	✓	✓	✓*

\*Once officially published/created, the ministry is responsible for the operational coordination/administration

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# Implementation Timeline



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## What should business consider?

- Set up a regulatory team
- Identify substances and amounts placed in Colombia
- Update labels
- Update SDS information
- Update their substance hazardous classification
- Do not forget to notify your substance!

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# Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



Global Product Compliance (GPC)



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