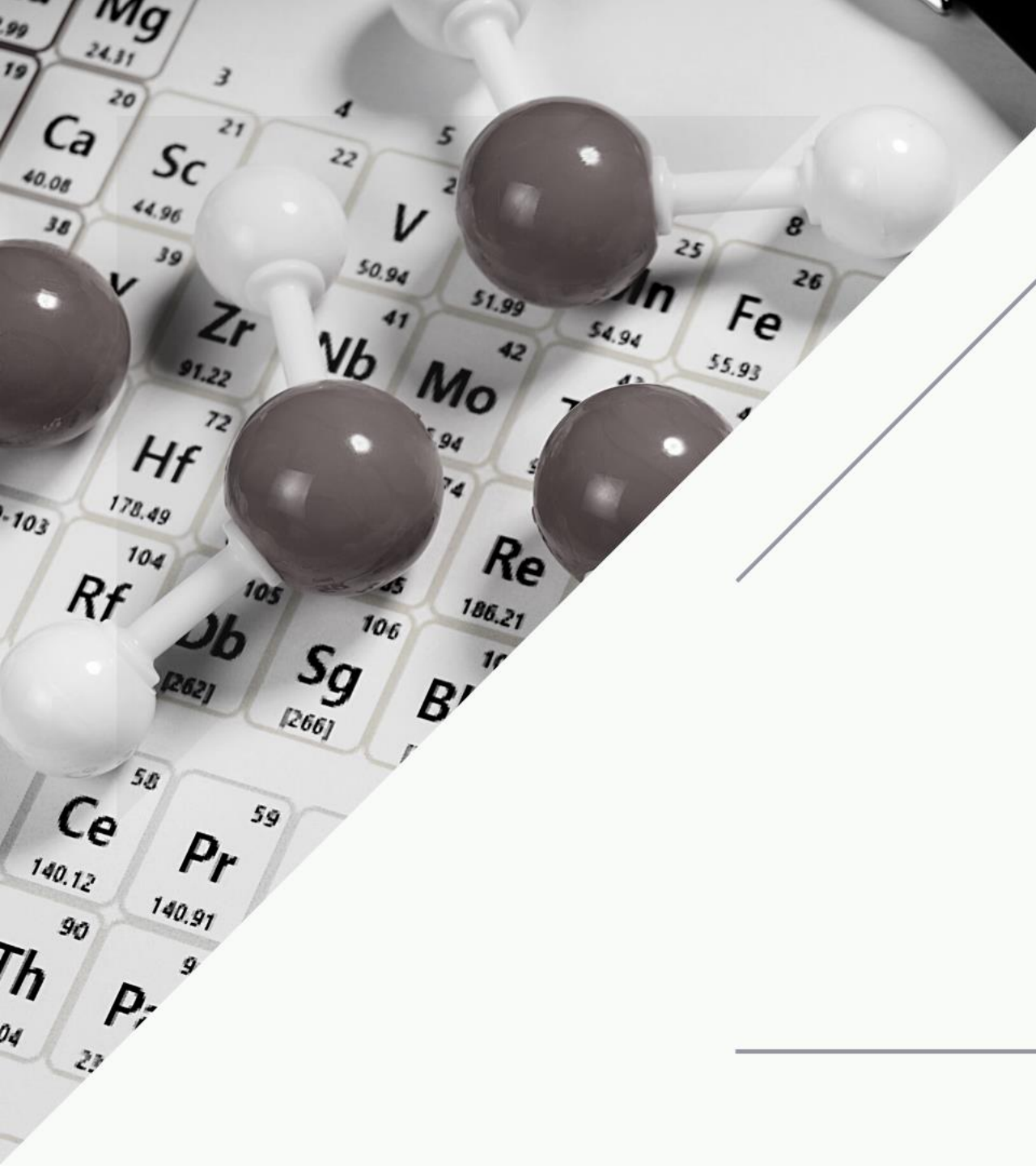


Chemical Management Framework in Colombia: Latest Updates

Implementation of Decrees 1496 (2018) and 1630 (2021)



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Topics

- Background: Framework Decrees
- Implementation of the Decrees: current status and next steps
- General obligations of manufacturers and importers
- National Inventory of Industrial Use Substances: requirements and implementation

Introduction

Colombia is in the process of implementing a comprehensive chemicals management framework.

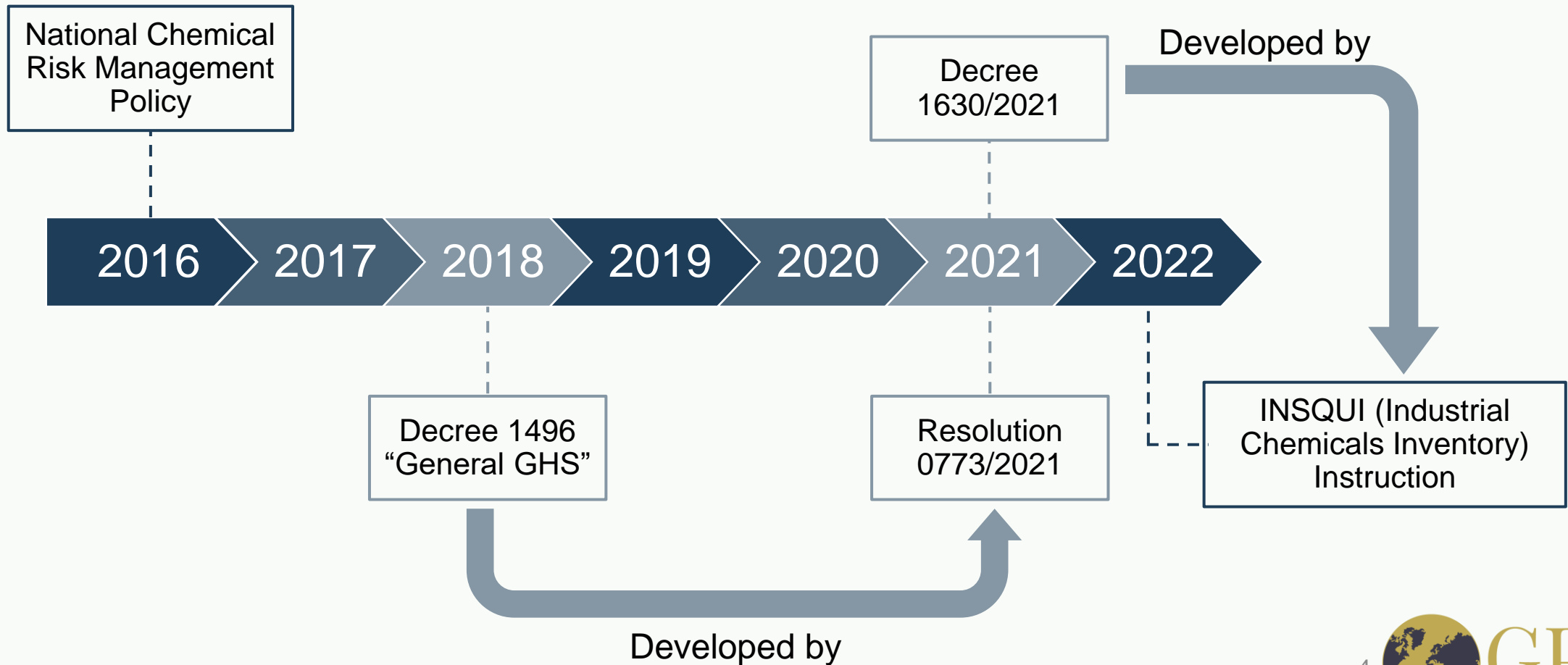
Key drivers:

- National Chemical Risk Management Policy (2016)
- OECD accession (2020), including commitment to implement several OECD legal instruments (9 of them on chemicals)

Two key framework regulations:

- Decree 1496 of 2018 – UN GHS (Revision 6)
- Decree 1630 of 2021 – Chemical Management

Timeline: Chemical Management in Colombia





Decree 1496

UN GHS adoption

Contents

As developed by Resolution 0773, Decree 1496 provides for:

- Mandatory SDSs following GHS Revision 6
- Labelling in accordance with GHS 6
- Cut-off values
- Recommended information sources

Scope and Exceptions

Decree 1496 is an overarching regulation. It applies to:

- All natural and legal persons
- Production, import, storage, transport, distribution, retail and other uses
- Substances and mixtures

Exceptions: pharmaceutical products, pesticide residues in food, cosmetics and food additives

It adopts GHS Revision 6 (2015)

Scope and Exceptions

Special situations:

Agricultural Pesticides (PQUA)

Application of GHS must be in accordance with Andean Community (CAN) law:

- CAN Resolution 630 (from 2002)
- CAN Resolution 2075 (from 2019, with a 5 year transitional period)

Chemicals in consumer products

The following are excepted from GHS application:

- Domestic hygiene products and personal hygiene absorbents – Regulated by CAN Decision 706 (from 2008)
- Domestic and public health pesticides – Regulated by Decree 1843 of 1991

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

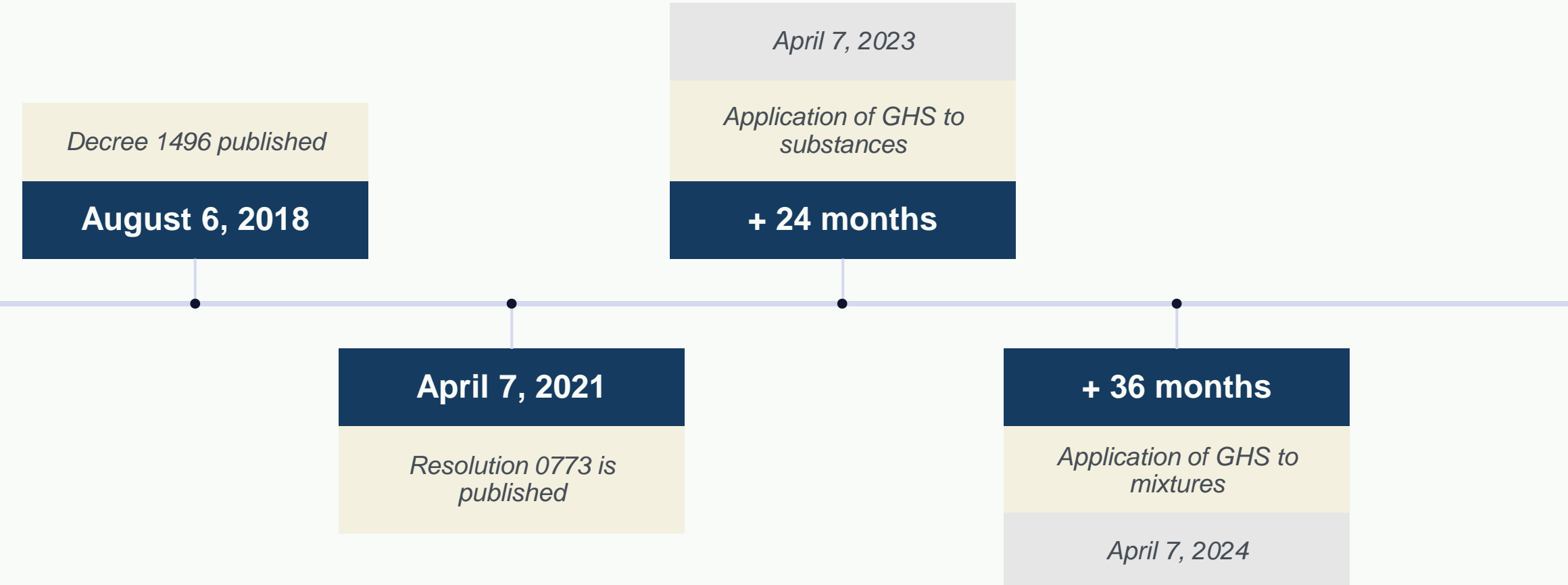


MAD or GLP



ISO/IEC 17025

Timeline: Implementation of GHS



Implementation table

Action	Ministries	Status
Labelling – Specific regulations	Labour Health Agriculture Transport	Resolution 773/2021
SDS – Specific Regulations	Labour Health Agriculture Transport	Resolution 773/2021
Actions by employers to implement GHS	Labour	Resolution 773/2021
Recommended information sources	Labour Health	Resolution 773/2021
PQUA	Agriculture (CAN Bodies)	CAN Resolution 2075/2019



Decree 1630

Chemical Management

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

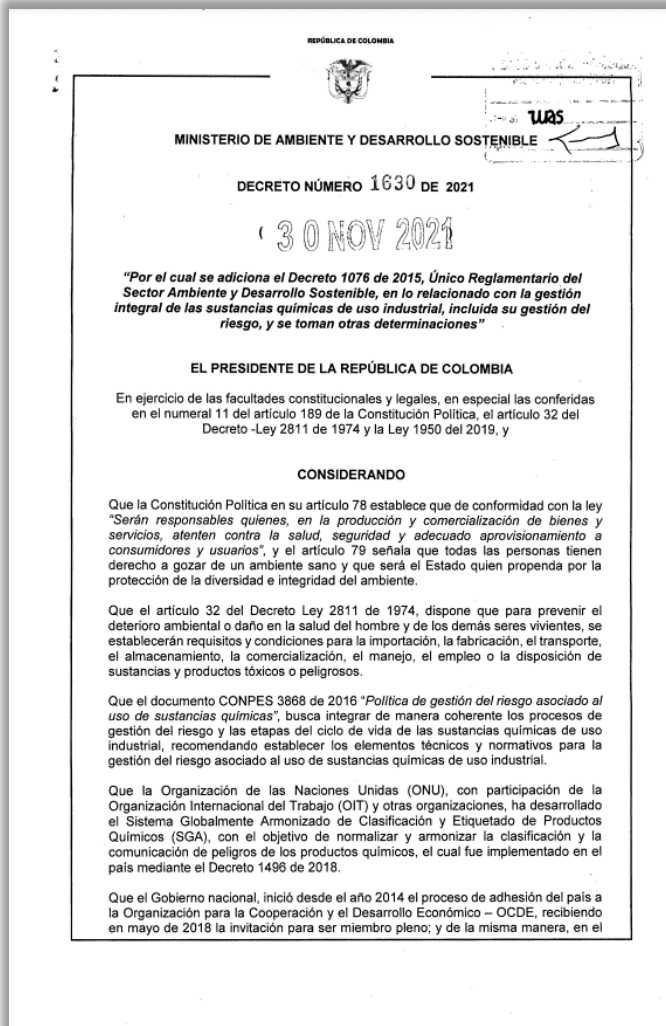
Section III: Obligations

Section IV: Monitoring

Section V: Institutional Coordination

Section VI: Information handling

Section VII: Inspection and Control



Scope and Exceptions – 1

Decree 1630 is an overarching regulation. It applies to:

- Industrial use substances
- All natural and legal persons (industrial users)
- Production, import, use, retail, distribution and transport

Industrial use refers to any use of a substance or mixture in industry.

Scope and Exceptions – 2

However, Decree 1630 contains significant exceptions:

Specifically regulated

- Pesticides
- Medicines, cosmetics and cleaning products
- Food additives
- Explosives or substances for their manufacturing
- Radioactive substances
- Agricultural products (including fertilisers)
- Mercury
- Asbestos

Technical exceptions

- Articles
- Impurities
- UVCB substances
- Polymers

Intentional or safe

- Natural origin substances with no chemical processing
- Non-isolated intermediates
- Substances in transit
- Samples with no commercial value
- Substance hydrates
- Unintentionally generated substances

New Instruments

Managing
Instruments



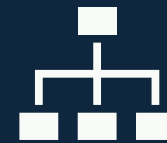
National Inventory of
Chemical Substances



Chemical Prioritization



Risk Evaluation

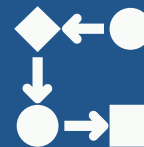


Risk Reduction and
Management Programs

Monitoring
Programs

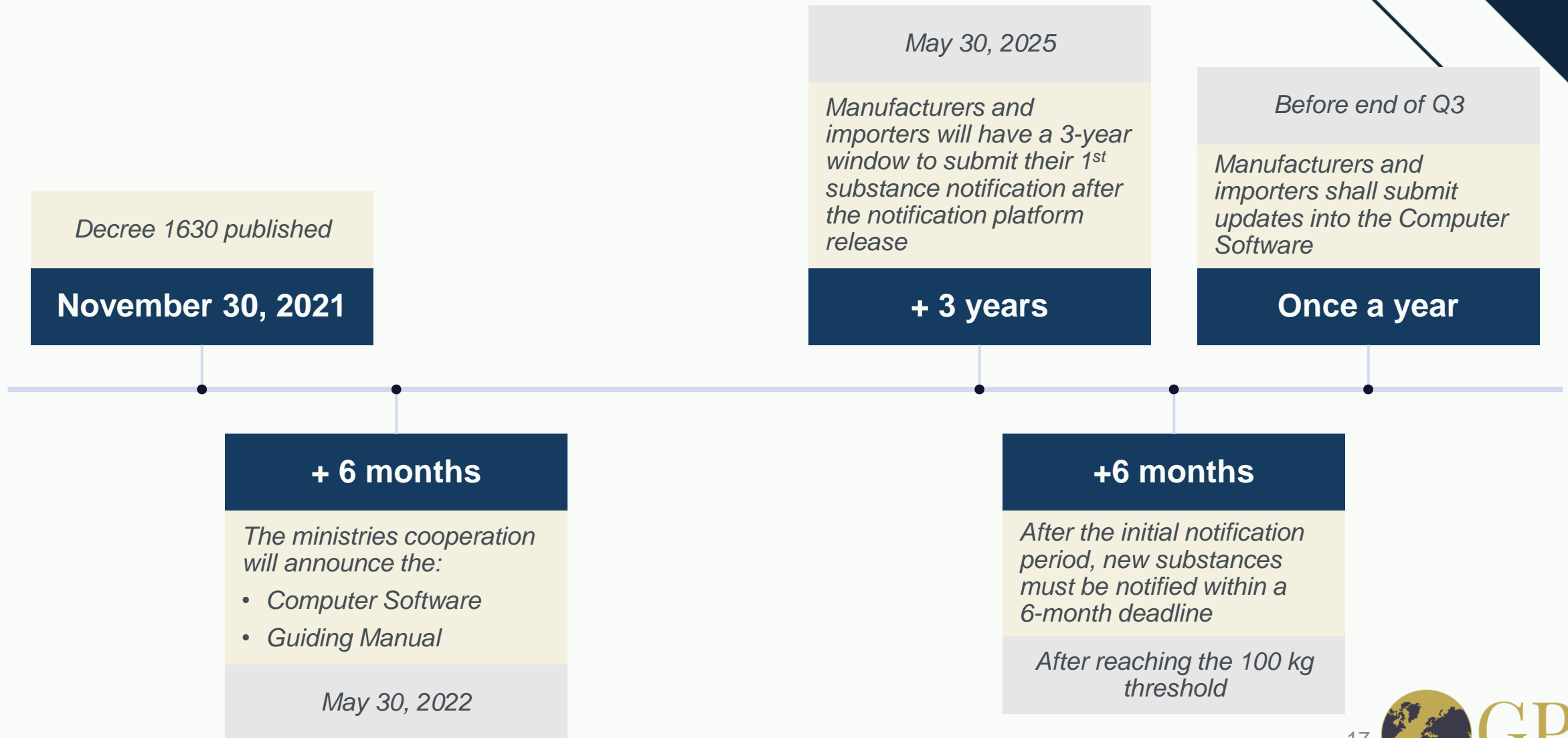


Pollutant Release and
Transfer Register (RETC)




Toxicological Management
System (SGT)

Timeline: Implementation of National Inventory



Implementation table

Action	Ministries	Status
Development of notification platform and use instructions	Trade Labour Health Environment	Published – latest version: May 2022
Substance prioritization: criteria, conditions and information requirements	Environment Health	To be done on the basis of inventory
Risk Assessment Guidelines	Environment Health	Under development
Risk Reduction and Management Programmes	Environment Health	Under development
Establishment of RETC (TRPR)	Environment	Under development
SGT (Toxicological Management System)	Health Labour	Under development

A photograph of three pieces of laboratory glassware: a small Erlenmeyer flask, a large Erlenmeyer flask, and a test tube, all containing a dark liquid. The glassware is set against a plain white background.

Importers and manufacturers: general obligations

Obligations

Importers & Producers

- Identify, classify, and label substances according to GHS Revision 6
- Keep updated SDS in accordance with GHS Revision 6
- 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

Labelling contents

Contents	Notes
Product identification	Must be the same as in SDS.
Identification of the manufacturer, importer or distributor: <ul style="list-style-type: none">• Name• Address• Phone number	Not required for small containers (under 30 ml).
Hazard communication elements: <ul style="list-style-type: none">• Pictograms• Signal word• Hazard statements	Not applicable to non-hazardous products. All hazard communication elements must be together in the label. Only pictograms required for small containers.
Precautionary statements	As chosen by the labelling responsible (most relevant). Not required for small containers.
Additional information: <ul style="list-style-type: none">• Nominal quantity• Lot number	Optional.

Labelling of mixtures

Labelling must indicate all components displaying the following hazards:

Carcinogenicity	Acute toxicity
Germ cell mutagenicity	Skin corrosion
Toxicity to reproduction	Serious eye damage
Single target organ toxicity (STOT)	Skin or respiratory sensitization

Labelling size is established by reference to Regulation (EU) 1272/2008, on classification, labelling and packaging of substances and mixtures

Labelling of mixtures – Cut-off values

Additionally, for some hazards, the presence of substances displaying them above cut-off values will determine the application of that hazard to the mixture:

Hazard	Cut-off value	Labelling mandatory (in addition to SDS)
Carcinogenicity	0.1% (included)	0.1% (included) for Category 1 1.0% (included) for Category 2
Toxicity to reproduction	0.1% (included)	0.3% (included) for Category 1 or effects on/through breastfeeding 3.0% (included) for Category 2
STOT	1.0% (included)	10.0% (included) for all

Safety Data Sheets – Contents

- Must follow Revision 6 of the GHS (Annex 4)
- Must be in Spanish
- A local emergency phone number must be included (or a free number with 24/7 availability)

Safety Data Sheets – Requirements

- **Access** by public authorities to the **underlying technical and scientific information** must be guaranteed
- SDSs and labels **must be updated** after changes in information or in a mixture's composition. At a minimum, they must be updated every **5 years**.

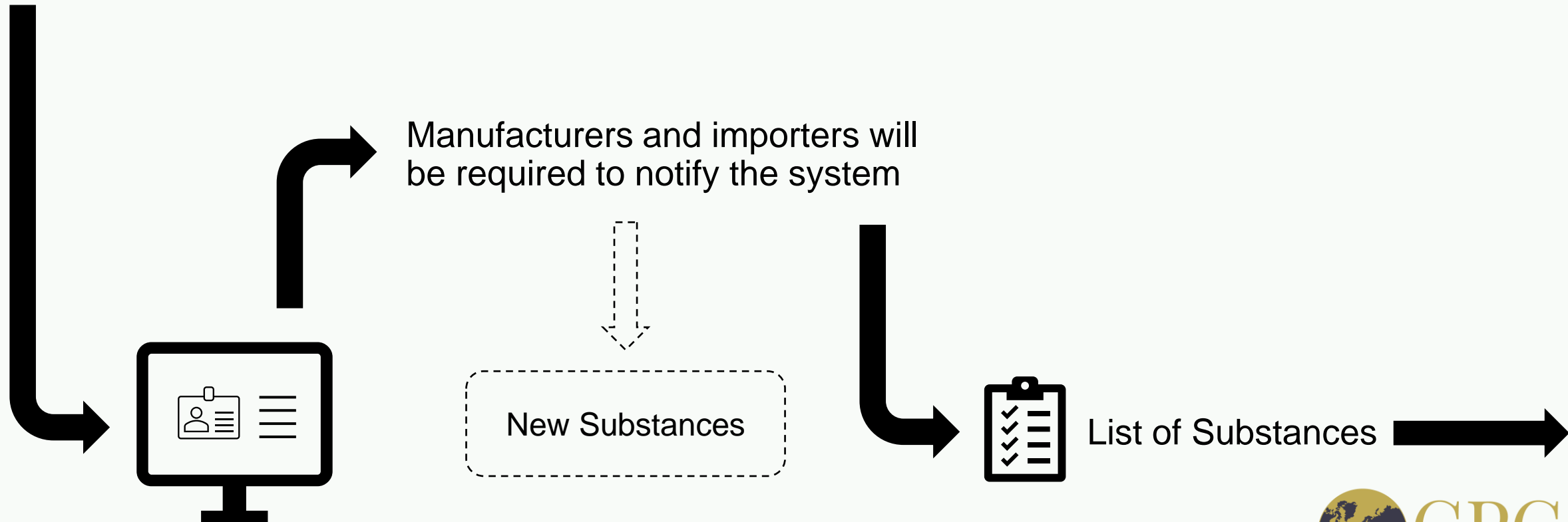


National Inventory of Industrial Use Substances

Requirements and
Implementation

The National Inventory

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



Notification basics



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!

Notification information

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 6th revision
- Identified substance uses



It is possible to submit information on a voluntary basis for substances below the 100kg threshold.

Notification platform

- The Ministries for Trade, Labour, Health, and the Environment have published the official guide for Decree 1630's Notification Portal.
- Online portal: insqui.sical.gov.co
- Responsible:
 - Manufacturers
 - Importers (Colombian)
 - Foreign Representatives (*"Representantes Exclusivos del Exterior"*)

Notification – Confidentiality

- Foreign Representatives can be used by foreign manufacturers to keep their confidential information from Colombian importers
- Additionally, confidentiality claims can be submitted in the platform for:
 - Name (commercial, common, IUPAC)
 - CAS Number
 - Chemical formula and molecular weight

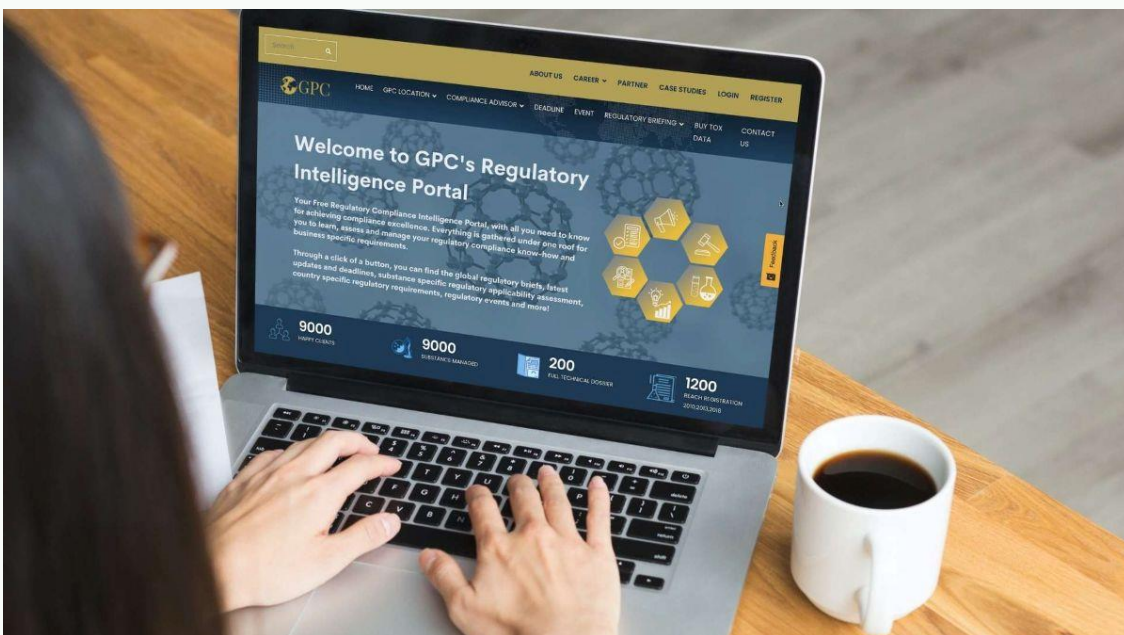
Notification – Timelines

- Notification of Existing Substances by May 30, 2025 (years 2021, 2022 and 2023)
- Annual update by the end of Q3 (September 30)
- New Substances: 6 months after reaching the 100kg threshold

Next steps for business



- Set up a regulatory team
- Identify substances and amounts placed in Colombia
- Establish contact with local partners
- Update hazard classification
- Update SDSs
- Update labels
- Initial notification (mandatory or optional)
- Annual updates and further information
- Contact with authorities



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