

Regulatory Updates - Chile

Classification, Labelling, and Notification of Chemical Substances (Decree 57)



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Topics

- Scope & Exceptions
- Hazard Classification
- Labeling
- Safety Data Sheet
- Notification of Hazardous Substances
- Risks Assessment
- Implementation Timeline
- Practical Changes



Background

Decree 57

Promulgated on 26 November 2019

Officially published on 09 February 2021

Regulation for Classification, Labeling and Notification of hazardous chemical substances and mixtures

“Reglamento de clasificación, etiquetado y notificación de sustancias químicas y mezclas peligrosas”

<http://bcn.cl/2nluj>

Cooperation between the Ministry of Health and Environment



Contents

It is considered to be a long regulation!

Objective = National Chemical Regulation + GHS standards

Title I: General Provisions

Title II: Hazard Classification

Title III: Hazard Criteria for Classification of Substances

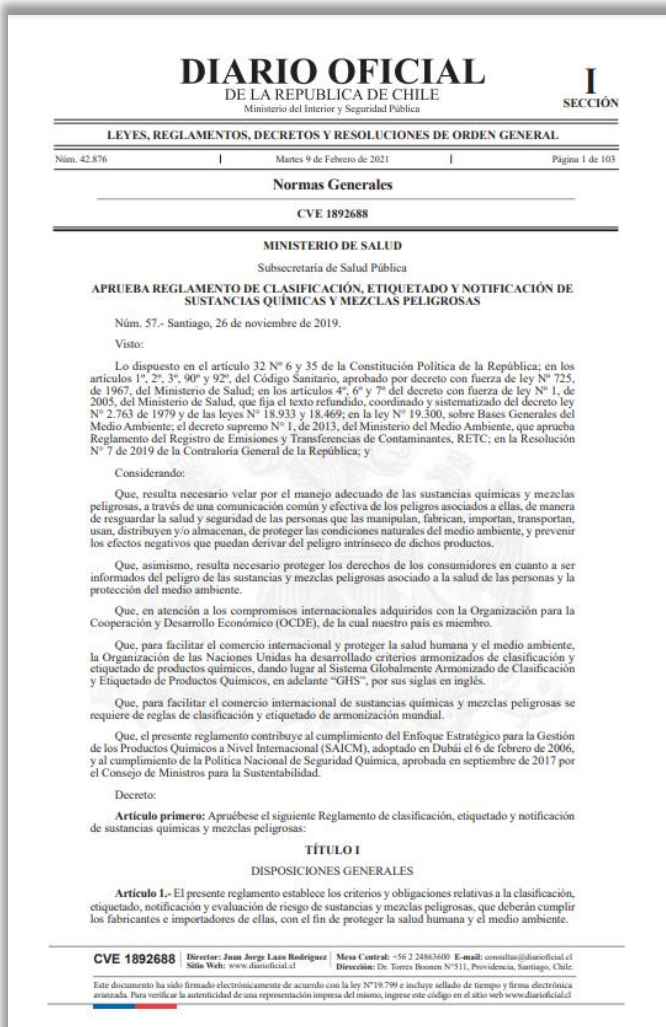
Title IV: Safety Labeling of Substances and Mixtures

Title V: Safety Data Sheets

Title VI: Notification of Hazard Substances

Title VII: Risk Assessment

Title VIII: Oversight and Sanctions





Scope & Exceptions



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


- Classification
- Labeling
- Notification

- Nuclear substances
- Intermediaries
- Substances in warehouses
- Substances used in scientific research and development
- Pharmaceutical, veterinary, cosmetic, and fertilizer products
- Substances contained in Articles
- Food products



Hazard Classification (1/3)

Official list of classification of substances


Ministerio de Salud
 Gobierno de Chile

Resolution 777
on August 2021

SUBSECRETARIA DE SALUD PÚBLICA
 DIVISIÓN DE POLÍTICAS PÚBLICAS SALUDABLES Y PROMOCIÓN
 DEPARTAMENTO DE SALUD AMBIENTAL

LISTADO OFICIAL DE CLASIFICACIÓN DE SUSTANCIAS

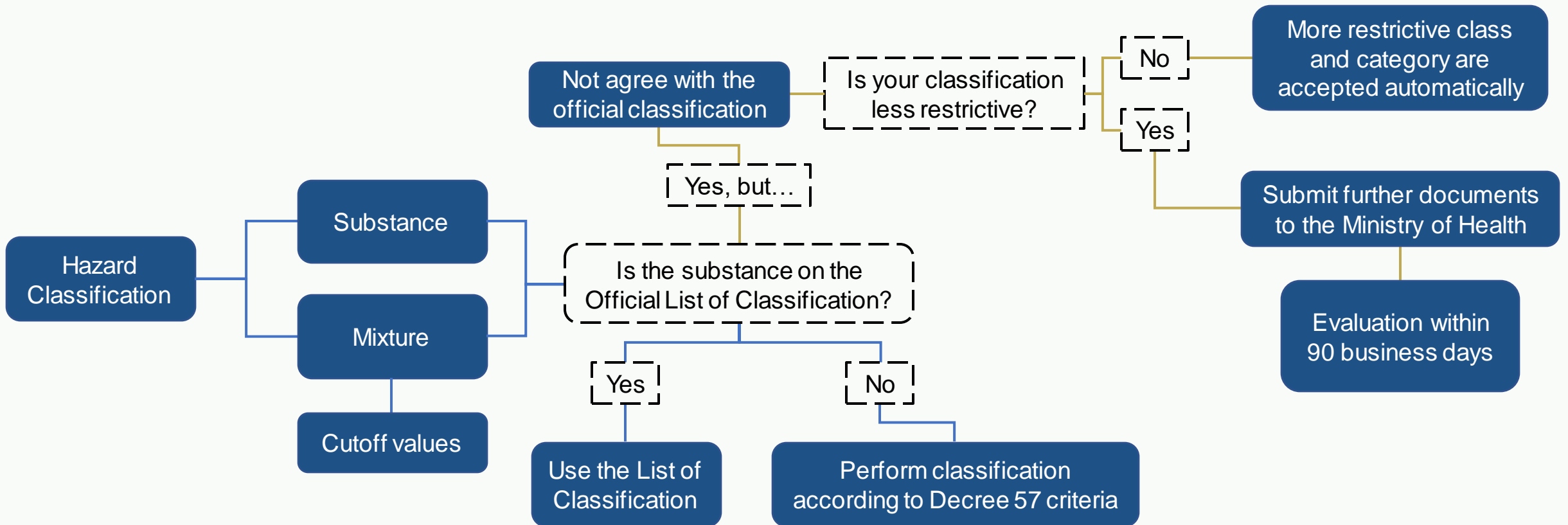
Nombre químico	N.o CAS	Clasificación	Clasificación	Límites de concentración específicos y factores M	Notas
		Códigos de clase y categoría de peligro	Códigos de indicaciones de peligro		
((4-(5-Oxo-3-propilisoaxazolidin-4-ilidenmetin)fenil)propoxicarbo-nilmetilnamino)acetato de pro-pilo	198705-81-6	Aquatic Chronic 4	H413		
((N-(3-Trimetilamoniopropil)sulfamoil)metilsulfonatoftalocianina- to)cobre (II) de sodio	124719-24-0	Eye Dam. 1	H318		

This list

- Allows additional classes to NCh. 382/2004
- Works as a minimum classification reference
- Less restrictive categories need to submit documents to the Ministry of Health
- Manufacturers and importers must keep information updated (within 6 months)

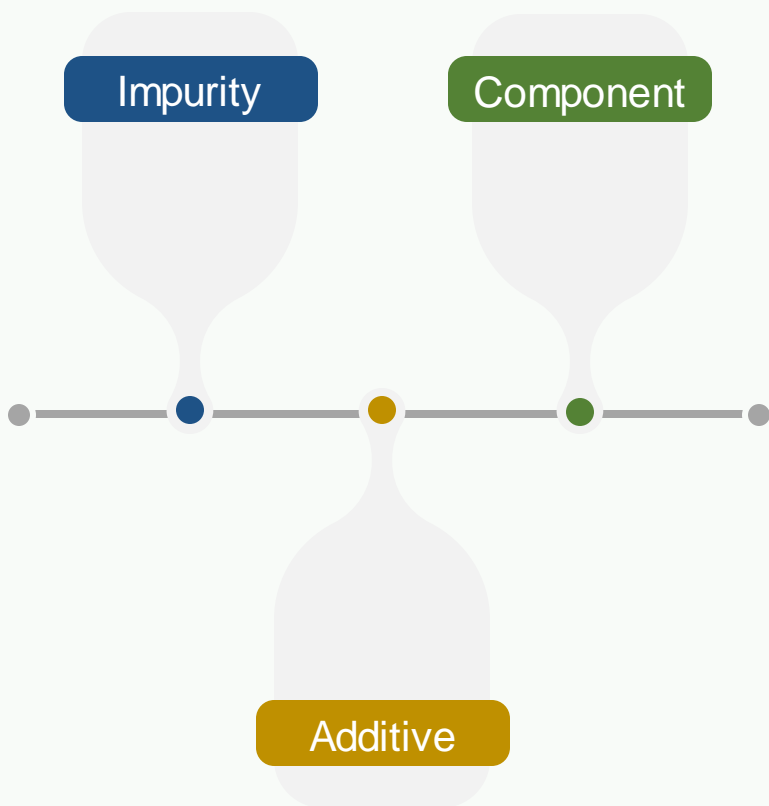
Identify, classify, and label the substances according to their hazardous prior to marketing or use, regardless of quantity imported or manufactured!

Hazard Classification (2/3)



— Main
— Alternative

Hazard Classification (3/3)



Hazard Class	Cutoff Value
Acute toxicity	≥ 1,0%
Skin corrosion/ irritation	≥ 1,0%
Serious eye damage / eye irritation	≥ 1,0%
Respiratory/ skin sensitization	≥ 0,1%
Germ cell mutagenicity: Category 1	≥ 0,1%
Germ cell mutagenicity: Category 2	≥ 1,0%
Carcinogenicity	≥ 0,1%
Reproductive toxicity	≥ 0,1%
Specific target organ toxicity (single exposure)	≥ 1,0%
Specific target organ toxicity (multiple exposure)	≥ 1,0%
Aspiration hazard: category 1	≥ 1,0%
Aspiration hazard: category 2	≥ 1,0%
Toxicity to the aquatic environment	≥ 1,0%

expressed in percentage by weight, except for gasogenous mixtures (by volume)

Hazard Classification Criteria



Physical



Health



Environmental

28 hazard classes

#	Hazard class	Article
1	Explosives	Arts. 23 - 29
2	Flammable gases	Arts. 30 - 32
3	Aerosols	Arts. 33 - 34
4	Oxidizing gases	Art. 35
5	Pressurized gases	Art. 36
6	Flammable liquids	Arts. 37 - 40
7	Flammable solids	Arts. 41 - 43
8	Spontaneously reacting substances and mixtures	Arts. 44 - 49
9	Pyrophoric liquids	Arts. 50 - 51
10	Pyrophoric solids	Arts. 52 - 53
11	Substances and mixtures under spontaneous heating	Arts. 54 - 58
12	substances which, in contact with water, emit flammable gases	Arts. 59 - 63
13	Oxidizing liquids	Arts. 64 - 65
14	Oxidizing solids	Arts. 66 - 68
15	Organic peroxides	Arts. 69 - 73
16	Corrosive substances and mixtures for metals	Arts. 74 - 75
17	Acute toxicity	Arts. 76 - 87
18	Skin corrosion or irritation	Arts. 88 - 100
19	Serious eye injury or eye irritation	Arts. 101 - 112
20	Respiratory or skin sensitization	Arts. 113 - 139
21	Germ cell mutagenicity	Arts. 140 - 145
22	Carcinogenicity	Arts. 146 - 155
23	Reproductive toxicity	Arts. 156 - 178
24	Target organ specific toxicity – single exposure	Arts. 179 - 194
25	Target organ specific toxicity – multiple exposure	Arts. 195 - 206
26	Aspiration hazard	Arts. 207 - 214
27	Hazards for the aquatic environment	Arts. 215 - 241
28	Hazards for the ozone layer	Arts. 242 - 243

Partially aligned with GHS 7 revision

Labeling (1/2)

Labels must clearly and visibly include

- Manufacturer or importer identification
- Product identifiers
- Hazard pictogram(s)
- Signal word
- Hazard statements
- Appropriate precautionary statements
- Nominal quantity of the substance
- Toxicological center (24/7 service) in Chile

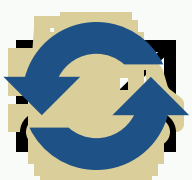
The supplier, manufacturer, or importers may decide the order in which the hazard statements and precautionary statements appears on the label

Labeling (2/2)

Labels must be

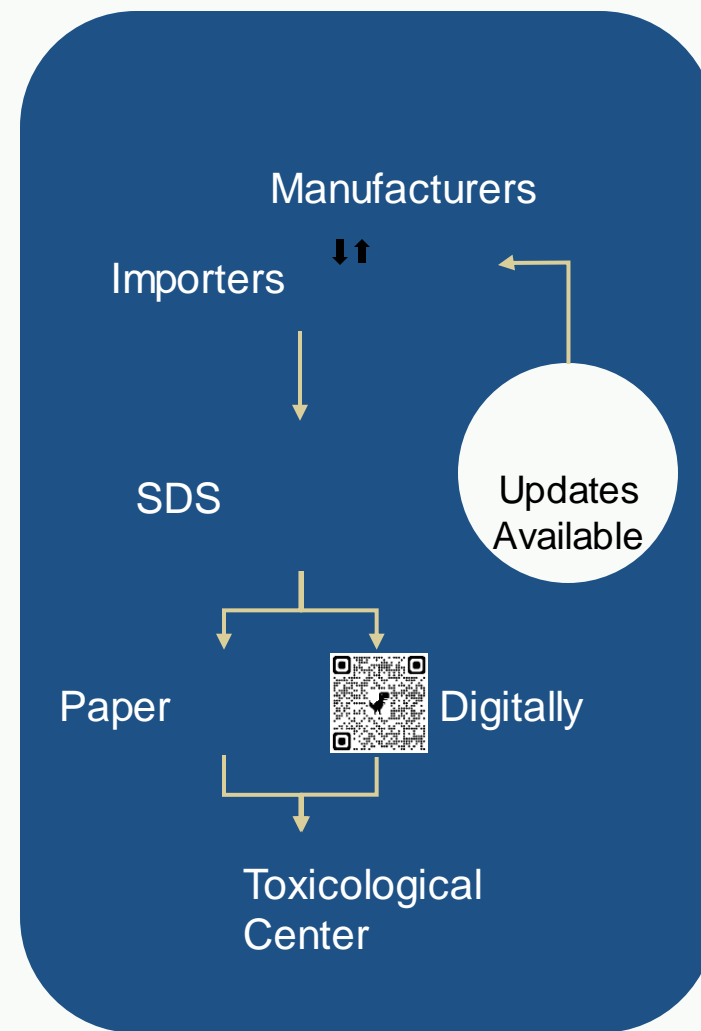
- firmly attached or printed in the container (indelibly)
- the color used should prevail the contrast of hazard pictograms
- text should stand out from the background

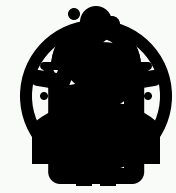
Container size	Minimum label surface (cm²)	Minimum pictogram side dimension (cm)
< 50 ml	Not applicable	0,5 x 0,5
≥ 50 and < 125 ml	Not applicable	0,5 x 0,5
≥ 125 ml and < 250 ml	25	Not less than 1,0 x 1,0
≥ 250 ml and < 1 L	50	Not less than 1,5 x 1,5
≥ 1 L and < 5 L	100	Not less than 2,0 x 2,0
≥ 5 L and < 50 L	200	Not less than 2,5 x 2,5
≥ 50 L and < 500 L	400	At least 3,5 x 3,5
> 500 L	600	At least 6,0 x 6,0



Safety Data Sheet

- 1) Identification of the substance or mixture and of the company or company;
- 2) Identification of the hazard(s);
- 3) Composition/ information on ingredients;
- 4) First aid;
- 5) Fire fighting measures;
- 6) Measures to be taken in the event of accidental spillage / spillage;
- 7) Handling and storage;
- 8) Exposure controls / personal protection;
- 9) Physical and chemical properties;
- 10) Stability and reactivity;
- 11) Toxicological information;
- 12) Ecotoxicological information;
- 13) Information regarding the disposal of the substance or mixture;
- 14) Information regarding transportation;
- 15) Regulatory information;
- 16) Other information.





Notification (1/3)

Who?

All manufacturers and importers dealing with hazard substances over 1 ton per year

How?

Through the Environmental Authority Portal

{<http://plataformasqi.mma.gob.cl>}

What?

All hazard substances and mixtures

Substances in mixtures only when above the threshold

When?

Before August 30, 2024

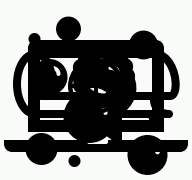
Every two years!



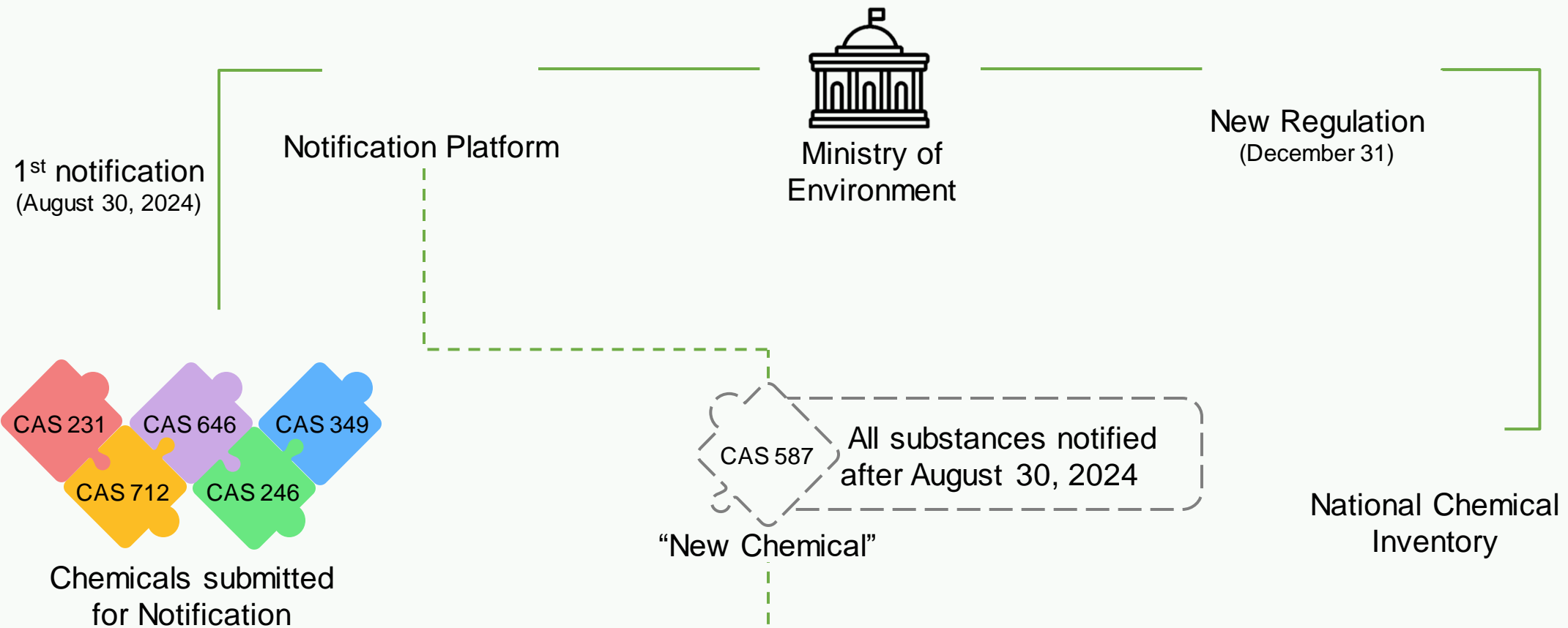
Notification (2/3)

Which information?

- Notifier information
 - Name, address, phone, and email of the notifier
 - Name, address, phone, and email from the legal representative
 - Name, address, phone, and email of the contact person
 - Manufacturers must indicate the address of the manufacturing plant
- Data about the substance
 - Substance names (IUPAC, commercial, common, etc.)
 - CAS number
 - Hazard classification (with hazard class and category)
 - Manufactured or imported amounts per year (expressed in mass)
 - Substance intended uses
 - Attach the substance SDS



Notification (3/3)



Risk Assessment

Still have to be defined
by the Ministry of Health
and Environment

Risk Assessment

Present a resolution determining

- Modalities & Technical Criteria
- Criteria for choosing which substances undergo the risk assessment
- Further requirements

The Miniseries have
18 months to present
such resolution

This deadline ends
on August 9, 2022

Other provisions

Oversight

State Health Secretariats

(Secretarías Regionales Ministeriales de Salud)

Application

Compliance

Revocations

Decree 44 of 1985, article 4

that regulates the production, distribution, sale and use of indicated organic solvents

Decree 43 of 2015, Title XII

that regulates the Storage of Hazardous Substances

Transitional Period

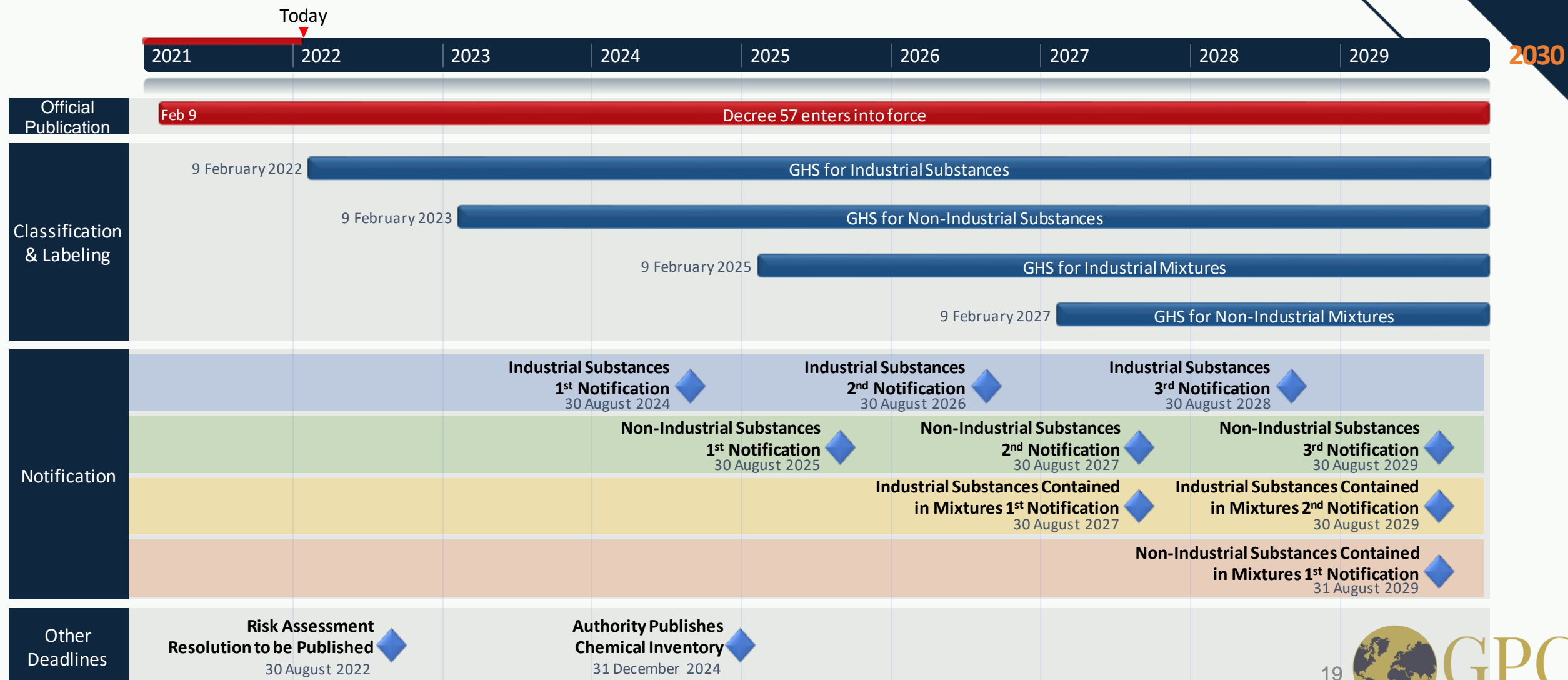
Industrial Substances → 2022

Non-industrial Substances → 2023

Industrial Mixtures → 2025

Non-industrial Mixtures → 2027

Implementation Timeline





Practical Changes

Legislation & Normative

Previously

Decree
43/2015

NCh.
2245/2015

NCh.
382/2004

NCh.
2190/2019

»

Currently



Decree
57/2019

Hazard Classification(1/2)

Differences between full GHS and Decree 57

Hazard Classes	Hazard Category	Full GHS	Decree57
Flammable Gases			
	Category 1a	✓	✓
	Category 1b	✓	✗
	Category 2	✓	✓
Gas Under Pressure			
	Compressed Gas	✓	✗
	Liquified Gas	✓	✗
	Refrigerated Gas	✓	✗
	Dissolved Gas	✓	✗
Flammable Liquids			
	Category 1	✓	✓
	Category 2	✓	✓
	Category 3	✓	✓
	Category 4	✓	✗
Desensitized Explosives			
	Category 1	✓	✗
	Category 2	✓	✗
	Category 3	✓	✗
	Category 4	✓	✗

»

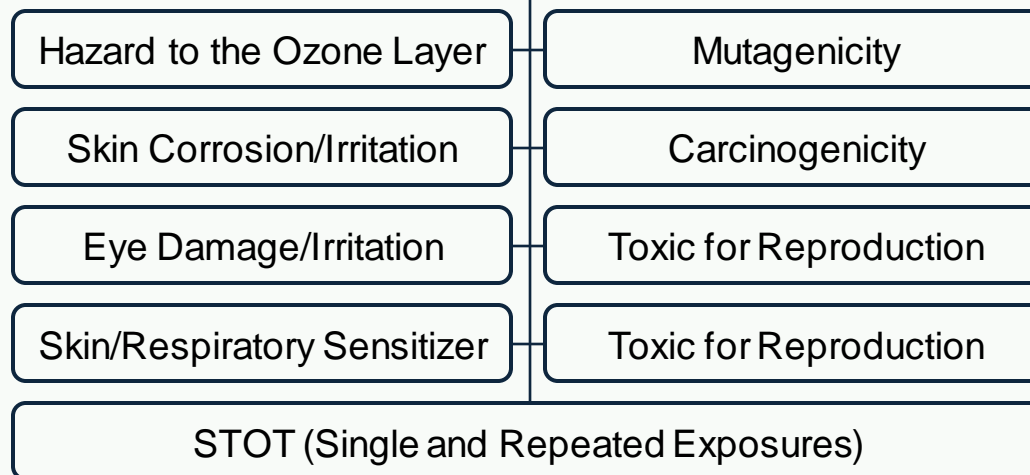
Hazard Classes	Hazard Category	Full GHS	Decree57
Acute Toxicity			
	Category 1	✓	✓
	Category 2	✓	✓
	Category 3	✓	✓
	Category 4	✓	✓
	Category 5	✓	✗
Skin Irritation			
	Category 1	✓	✓
	Category 2	✓	✓
	Category 3	✓	✗
Eye Irritation			
	Category 1	✓	✓
	Category 2a	✓	✓
	Category 2b	✓	✗
Aspiration Hazard			
	Category 1	✓	✓
	Category 1	✓	✗

Hazard Classification(2/2)

Differences between full GHS and Decree 57

Hazard Classes	Hazard Category	Full GHS	Decree57
Acute Hazard (aquatic environment)			
	Acute 1	✓	✓
	Acute 2	✓	✗
	Acute 3	✓	✗
	Chronic 1	✓	✓
	Chronic 2	✓	✓
	Chronic 3	✓	✓
	Chronic 4	✓	✓

+11 Hazard Classes if compared to NCh. 382/2004



Labels

Previously

- Nch 2190/2019



ALCOHOL ISOPROPILICO

Medidas de Primeros Auxilios

Inhalación: Sacar a la persona al aire libre y ayudarla a respirar. Si es necesario, dar respiración artificial. Solicitar ayuda médica.

Contacto con la piel: Lavar la zona afectada con abundante agua. Retirar ropa contaminada. Si la irritación persiste consultar con un médico.

Contacto con los ojos: Lavar inmediatamente con abundante agua a lo menos por 15 minutos. Acudir al médico.

Ingestión: No inducir vomitos. Solicitar ayuda medica de inmediato.

Información Toxicologica: Irritante moderado de ojos y piel. No inhalar los vapores.

Manipulación y Almacenamiento: No inhalar los vapores. Usar mascar de protección respiratoria con filtro para solventes. Usar guantes de nitrilo. Usar lentes con protección lateral. Almacenar en lugar limpio y seco, lejos de fuentes de calor. Mantener el producto en su envase original y cerrado.

NU 1219

Centro de Información Toxicológica
+562 2635 3800

Currently

- Decree 57

Identificación del Producto
Identificación de Ingredientes Peligrosos

Pictograma
(Símbolo en Marco Rojo)

Palabra de Advertencia
(Atención)

Indicación de Peligro(s)
(Nocivo si se inhala)

Consejo(s) de Prudencia
(Utilizar sólo al aire libre o en un lugar bien ventilado)

Nombre y dirección de la compañía
Número del teléfono



Pictograms

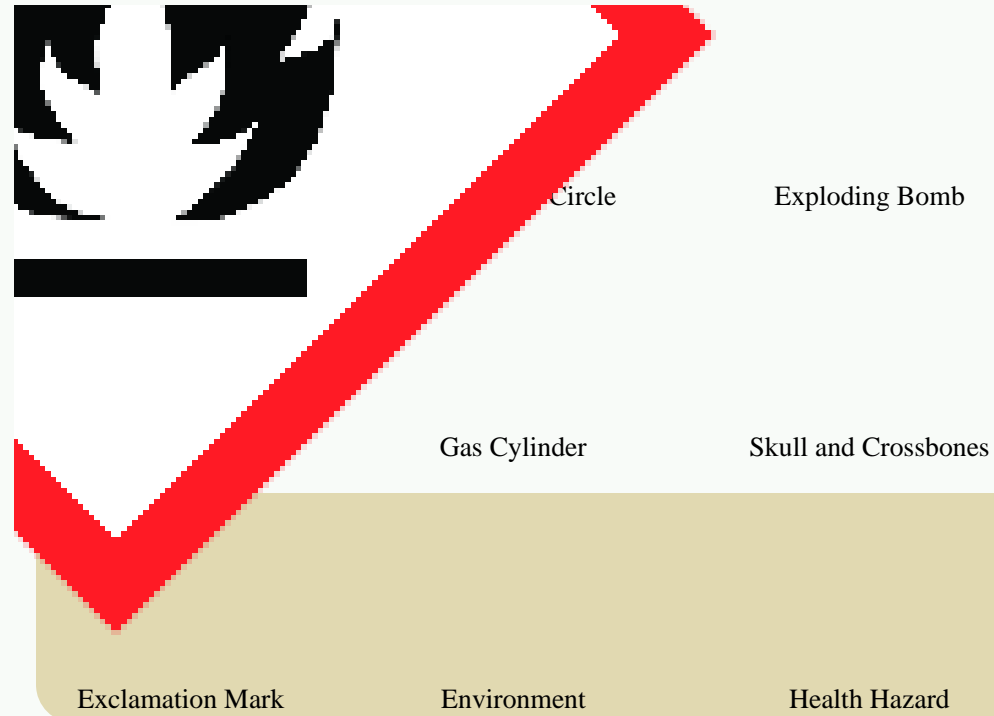
Previously

- Nch 2190/2019



Currently

- Decree 57



New Pictograms
to NCh. 382

What business should consider?

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

Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



Global Product Compliance (GPC)



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