

COSTA RICA CHEMICALS REGULATIONS

By: Cristina Caro Tovar
International Regulatory Attorney
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COSTA RICA AGENDA

1. GHS IMPLEMENTATION

2. REGISTRATION

3. NOTIFICATION

4. COSTA RICA: CENTRAL
AMERICA REGULATIONS

I. GHS IMPLEMENTATION

COSTA RICA ADOPTS UN-GHS SIXTH REVISED EDITION

- CLASSIFICATION
- LABELLING
- SAFETY DATA SHEET

Competitive markets

OCDE: member adopting GHS



GHS IMPLEMENTATION

Costa Rica implemented GHS by Decree 40457-S approving RTCR 481:2015 “Chemical Products. Hazardous Chemical Products. Labelling”.

Costa Rica adopted 6th Revision of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals.

Additional Requirements

Labelling:

- “In case of intoxication see a physician and provide this label”
- “Keep out of children’s reach”
- Include phone number of the National Center of Intoxications
- Supplemental label: if the label of the chemical is in a language other than Spanish then include a supplemental label in **Spanish**.

Mandatory since December 2017.

Transitional Period: Five-year period

By December 30, 2022, products must comply with GHS classification, label, and SDS.

2. REGISTRATION

- Technical Regulation RTCR 478:2015 “Hazardous Chemical Products. Registration, Imports and Control.”
- It's effective since May 3, 2018. This regulation was approved by Decree 40705-S.

Purpose

to establish the requirements and procedures to register and import hazardous chemical substances to protect human health and the environment.

Registration

approval by the Ministry of Health as prior requirement to import or distribute a hazardous chemical product (substances and mixtures), once the chemicals have been evaluated regarding their danger (classification), label and specific uses.

CHEMICAL
MANAGEMENT

What is covered by the regulation?

RTCR 478:2015

Hazardous Chemicals

Non-Hazardous Chemicals

Consumer Products – finished products

Industrial Products – raw materials – unfinished products

CHEMICAL MANAGEMENT

- Production – Processing chemicals (substances and mixtures)
- Storage
- Use at the Workplace
- Use - Consumer Products
- Distribution
- Retail
- Transportation



REGISTRATION: REQUIREMENTS

1. State product use
2. Application
3. Legal presentative
4. Applicant-broker
5. Chemical name
6. Classification of chemical – GHS
7. Label
8. Safety Data Sheet
9. Toxicological information
10. Formula – Components and CAS#
11. Name of manufacturer
12. Name of distributors
13. Responsible technician
14. Fee payment (no fee for raw materials)

HOW IS THE REGISTRATION DONE?
COSTA RICA USES AN INTERNET PLATFORM IS CALLED “REGISTRELO”
AND IS MANDATORY
WWW.REGISTRELO.GO.CR

The screenshot shows the Registrelo website interface. At the top left is the Registrelo logo with icons for a person, a house, a flame, a person with a plus sign, and a person with a minus sign. To the right is the logo for the Ministerio de Salud Costa Rica, featuring a map of Costa Rica. Below the logos is a navigation bar with the text: INICIO | INFORMACIÓN | MAPA DEL SITIO | CONTÁCTENOS.

The main content area is divided into several sections:

- FIRMA DIGITAL:** A blue box containing two red buttons: "Inicie Sesión" and "Regístrese". Below the "Inicie Sesión" button, it says "Para Iniciar Sesión debe de estar registrado a Registrelo.go.cr".
- Estimado Usuario:** A large blue banner with a background image of a person in a white lab coat. The text reads: "Para los trámites de medicamentos radiofármacos deberán presentarse en ventanilla de la Dirección de Atención al Cliente y la solicitud debe estar dirigida a la Dirección de Protección al Ambiente Humano de acuerdo al procedimiento establecido." A small "1 de 3" indicator is in the bottom right corner.
- CONSULTAS:** A grey box with a globe icon. Text: "Realice sus consultas sobre Productos, Usuarios, Registros Sanitarios."
- SERVICIOS:** A grey box with an icon of three people. Text: "Acceda al área de trámites del registro sanitario del sistema."
- NORMATIVAS:** A grey box with a clipboard icon. Text: "Información de leyes sobre registros sanitarios."
- Información (Left):** A grey box with a "NOTICIAS" icon and a list of links:
 - Programa de Capacitación PYMES
 - Invitación a Ciclo de Conferencias sobre Registro de Medicamentos.
 - CIRCULAR MS-DRPIS-613-04-2020 Empresas, personas fabricantes, importadoras, distribuidoras y compradoras de equipo y material biomédico (EMB)
- Información (Right):** A grey box with a "NOTICIAS" icon and a list of links:
 - DM-RM-5351-2020 (REFORMA DISPOSICIONES ADMINISTRATIVAS TRÁMITE DE INSCRIPCIÓN RENOVACIÓN Y CAMBIOS POST REGISTRO DE PRODUCTOS DE INTERÉS SANITARIO EN LA PLATAFORMA REGISTRELO
 - DM-RM-2934-2020 DISPOSICIONES ADMINISTRATIVAS TRÁMITE DE INSCRIPCIÓN RENOVACIÓN Y CAMBIOS

REGISTRATION: RENEWALS – AMENDMENTS

The registrations already done need renewals and these need to comply with Requirement of RTCR 478:2015 “Hazardous Chemical Products. Registration, Imports and Control.”

Raw chemicals: no payment for registration

Finished product: hazardous chemical manufactured product that is for consumption or to be used by another entity.

New chemical:

When there is a change in the hazard classification is considered a new chemical. must apply for a new registration.

Can a producer or importer use the same registry for several chemicals? Yes

Section 7.1.7 of the regulation provides the cases in which the same registry may be used for several products and this is when the products comply with the same characteristics as long as the use does not change and they are:

- a) Dilutions of same product; different concentrations, with same CAS number and hazardous classification doesn't change.
- b) Products of the same company: same composition but different commercial name
- c) A kit of products
- d) A Family of products

3. NOTIFICATION

REQUIREMENTS FOR NOTIFICATION

- a) Application – “Registrelo” (company’s name)
- b) Legal representative
- c) Cas Number
- d) NO CAS No.? SDS
- e) Name of chemical
- f) Label
- g) Manufacturer
- h) Responsible technician

- Non-Hazardous Chemicals
- Notification (not registration)
- No fee is required

If after new studies is found that the product is classified as hazardous then the product must be registered.

Concept or Service	Regulation	Duration
Registry or Renewal of hazardous chemicals	40769-S	5 years
Notification of chemical products (raw materials -unfinished products)	42061-S	5 years
Notification of non-hazardous chemical products*	40705-S	Do not expire

FOR HOW LONG REGISTRATION OR NOTIFICATION IS VALID?

WHAT IS NOT COVERED
BY THE REGULATION ON
REGISTRATION OF
CHEMICALS?

- Pharmaceuticals
- Cosmetics
- Food Additives
- Pesticides: domestic and industrial use.
- Fertilizers: domestic use
- Narcotics and Psychotropics
- Hygiene products -RTCA of 2007 Registration of Hygiene Products
- Veterinarian products
- Others

COSTA RICA: CHEMICAL REGULATIONS

RTCR 478:2015 will be applied along with the regulations that are already enacted in specific chemical substances or products mostly Decrees concerning for example:

- Use of aerosols included in the Montreal Protocol
- Use of lead and mercury in paints
- Controlled use of asbestos
- Pyrotechnic materials
- Others: RTCA- Central American Technical Regulations an economic bloc that Costa Rica is part of and that I'll explain a little bit later in this presentation.

- LIST OF CHEMICALS
REGISTRATION
NOTIFICATION
PROHIBITED
RESTRICTED**

**SOURCE: MINISTRY OF
HEALTH OF COSTA RICA**

The screenshot shows the website of the Costa Rican Ministry of Health. The header includes the logo and name of the 'Ministerio de Salud Costa Rica'. A navigation menu contains links for 'Inicio', 'Sobre Ministerio', 'Trámites', 'Información', 'Centro de información', 'Centro de prensa', and 'Contáctenos'. Below the navigation is a search bar with the text 'MEJORADO POR Google'. The main content area is titled 'INFORMACIÓN' and features a sidebar with a list of categories: 'Guía de requisitos de importación', 'Manipulación de alimentos', 'Medicamentos', 'Productos registrados', 'Tabaco', 'Tratamiento de lodos', 'Gestores de residuos', 'Garantías en custodia vencidas', and 'Unidades de Cumplimiento'. The 'Productos registrados' category is selected, displaying a list of documents. The list is sorted by 'El más reciente primero' and includes the following items:

Documento	Tamaño	Descargas	Popular	Fecha
DRPIS_REPORTE_FERTILIZANTES_APROBADOS_2020	53 KB	1564	Popular	15 Mar 2021
DRPIS QUIMICOS PELIGROSOS DESPUES DEL 2007	5.33 MB	127280	Popular	11 Mar 2021
Vinculación de patentes y protección de datos de prueba	72 KB	36949	Popular	22 Feb 2021
LISTADO DE RADIOFARMACOS REGISTRADOS	23 KB	11684	Popular	10 Feb 2021
DRPIS PRODUCTOS NATURALES	87 KB	79728	Popular	27 Ene 2021
DRPIS PRODUCTOS QUIMICOS NO PELIGROSOS	196 KB	139582	Popular	27 Ene 2021
DRPIS QUIMICOS PELIGROSOS ANTES DEL 2007	3.79 MB	119280	Popular	27 Ene 2021
DRPIS PRODUCTOS PARA EL HIGIENE	531 KB	91039	Popular	27 Ene 2021
Listado de Tintas y Pigmentos para Tatuajes	12 KB	9149	Popular	27 Ene 2021
DRPIS REPORTE EQUIPO Y MATERIAL BIOMEDICO	14 KB	41027	Popular	27 Ene 2021
LISTADO PRINCIPIOS ACTIVOS BIOLOGICOS	37 KB	15199	Popular	27 Ene 2021

4. COSTA RICA: CENTRAL AMERICA REGULATIONS

SIECA – TRADE BLOC

Costa Rica is part of the Secretariat for Central American Economic Integration (SIECA, per Spanish acronym). SIECA is the technical and administrative body of the central American Economic Integration Process. One of their functions is to enact Resolutions that country members must adopt into their national regulatory framework

- **The country members are:**
 1. Costa Rica
 2. El Salvador
 3. Guatemala
 4. Honduras
 5. Nicaragua
 6. Panama





CHEMICAL REGULATIONS: COSMETICS

Costa Rica adopts the Resolutions issued by the Central American Economic Integration by Executive Decrees for example:

Cosmetics

Costa Rica issued Decree 35031 of 2008 approving and incorporating into their regulatory framework the Central American Technical Regulations:

- RTCA 71.03.49.08 Cosmetic Products. Good Manufacturing Practices.
- RTCA 71.01.35:06 Cosmetic Products. Registration and Notification of Cosmetic Products.
- RTCA 71.03.36:07 Cosmetic Products. Labelling.
- RTCA 71.03.45:07 Cosmetic Products. Quality Surveillance.



**CHEMICALS:
OTHER
REGULATIONS**

For Food Additives

Costa Rica in Decree 37294 of 2012 approved:
RTCA 67.04.54:10 Processed Food and Beverages. Food Additives.

For Pesticides

Costa Rica in Decree 36630 adopted:
RTCA 65.03.44:07 Pesticides. Registration

Other chemical products/substances

- Decree 24334. Lead and Mercury in Paints
- Decree 24715. Land transportation of Hazardous Products.
- Decree 25056. Products with asbestos

COSTA RICA:
**INTERNATIONAL
CONVENTIONS**



Minamata
Convention

Paris
Agreement

Rotterdam
Convention

Stockholm
Convention

Montreal
Protocol

Basel
Convention

NEXT STEPS IN CHEMICAL MANAGEMENT

Enact or amend
regulations in
chemicals

Create guideless
or process for
risk evaluations
and risk
management

Prioritization of
Chemicals

Creation of an
inventory of
chemicals

Public Awareness

Provide for a
budget

THANK YOU

Cristina Caro
International Regulatory Attorney
Cristina.carotovar@gmail.com

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