

SIXTY-SECOND REGULAR SESSION
December 13 - 15 , 2017
Washington, D.C.

OEA/Ser.L/XIV.2.62
CICAD/doc.2338/17
12 December 2017
Original: Español

REFORM TO THE GENERAL HEALTH LAW ON CANNABIS



SALUD

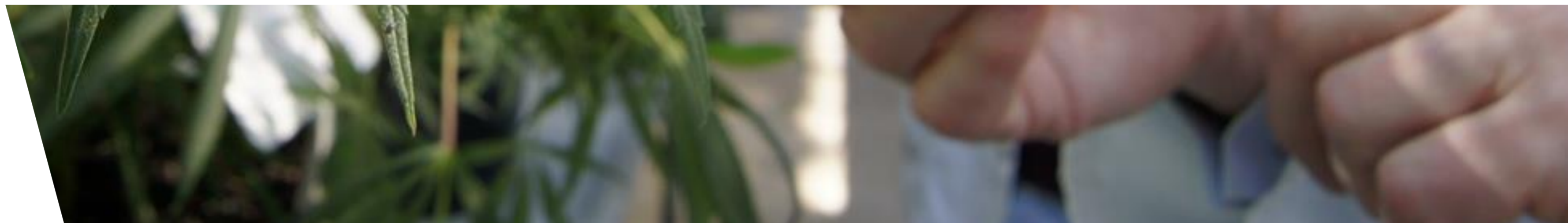
SECRETARÍA DE SALUD



Reform to the General Health Law on Cannabis



Comisión Federal para la Protección
contra Riesgos Sanitarios



INDEX

- 1. Background.**
- 2. Health Reform.**
- 3. Proposed Draft Regulation of the General Health Law, on Health Control of Cannabis and Derivatives of the same.**
- 4. Requirements to request Medical Authorizations.**
- 5. Current Actions.**



SALUD
SECRETARÍA DE SALUD



Cofepris 
Comisión Federal para la Protección
contra Riesgos Sanitarios



BACKGROUND

Import permits for personal use

Case: Girl Grace

Recourse for unconstitutionality of the LGS in the matter of CBD

Judge authorizes import, carry and consumption of CBD

COFEPRIS consigns before the Judge, the import permit in favor of "Grace" for Epidiolex

Judge gives sentence in order to separate the prohibition of cannabis and derivatives for medical purposes of the LGS, in the case of Grace.

july
2015

august
2015

november
2015

january
2016

august
2016

- september 2017:
- **261** CBD import permits
 - **31** preventions
 - **2** denials

COFEPRIS offers two import permits with similar conditions for the RSHO-X Real Scientific Hemp Oil



National debate on marijuana use

SALUD
SECRETARÍA DE SALUD



Cofepris
Comisión Federal para la Protección
contra Riesgos Sanitarios

5 Fora

+200 speakers &
+ 4 k participants

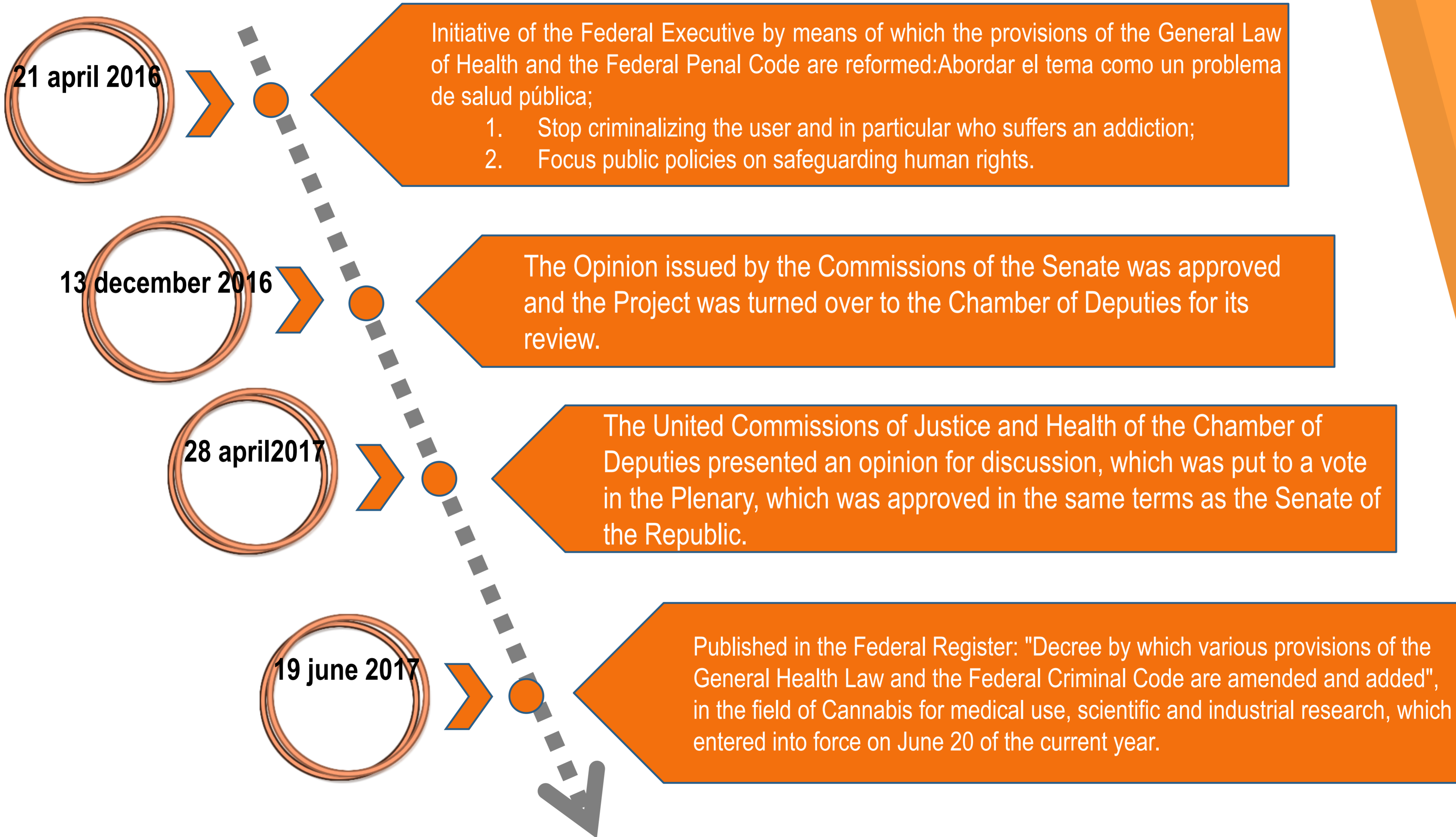
- I. Public health and prevention. January 2016, Cancun, Quintana Roo.*
- II. Ethics and human rights. February 2016, Ciudad Juárez, Chihuahua.*
- III. Economic and regulatory aspects. February 2016, Saltillo, Coahuila.*
- IV. Citizen security. March 2016, Guadalajara, Jalisco.*
- V. Public health and prevention, ethics and human rights, economic and regulatory aspects, citizen security. April 2016, CDMX.*

Conclusiones

1. Address the issue of drugs and marijuana, from the perspective of human rights.
2. The use of marijuana should be addressed from a public health perspective.
3. Addictions should be treated with prevention and comprehensive therapeutic solutions, without criminalizing consumers.
4. Strengthen actions to prevent the consumption of drugs, including marijuana, especially campaigns aimed at children and young people.
5. Access to controlled substances for therapeutic purposes and scientific research of the Mexican population should be facilitated.



Federal Executive Reform Initiative



SALUD
SECRETARÍA DE SALUD



Cofepris 
Comisión Federal para la Protección
contra Riesgos Sanitarios

HEALTH LAW REFORM



Cannabis Reform

Reform

Effects

artículo 235 bis added:

"Design and execute public policies that regulate the medicinal use of the pharmacological derivatives of cannabis sativa, Indica and American, ... Tetrahydrocannabinol, ... as well as regulate the research and national production of the same."

The Ministry of Health is authorized to design and execute public policies that regulate the medicinal use of pharmacological derivatives of cannabis, including THC.

artículo 237 eliminates:

"cannabis sativa, indica, americana o marihuana"

Cultivation, harvesting, processing, preparation, conditioning, acquisition, possession, trade, transportation, medical prescription, supply, employment, use, consumption of cannabis, shall be permitted only for medical and scientific purposes, with the prior authorization of the Secretary of Health

THC is eliminated from fraction I of article 245, establishing itself in fraction II, when it has concentrations higher than 1%.

It allows the registration, commercialization, import and export of medicines that contain pharmacological derivatives of cannabis in these concentrations.



Cannabis Reform

Reform

Effects

THC is classified in fraction IV of article 245, when it has concentrations equal to or less than 1%.

It allows the registration, commercialization, import and export of medicines that contain pharmacological derivatives of cannabis in these concentrations.

Section V of article 245: products containing cannabis derivatives in concentrations of 1% or less than THC, with extensive industrial uses.

The commercialization, importation and exportation of various products of cannabis derivatives that due to their concentration of THC do not imply a risk to health are allowed.

Article 290 establishes that drugstores and establishments destined to the production of medicines may import pharmacological derivatives of cannabis, including THC, with prior authorization issued by the SSA.

These establishments are allowed to import and market these substances in order to produce medicines with pharmacological derivatives of cannabis.



Cannabis Reform

SALUD
SECRETARÍA DE SALUD



Transitional Articles

Second.- The SSA, through CONADIC, will reinforce the Program against Drug Dependence, with emphasis on the prevention, treatment, rehabilitation, social reintegration and control of the consumption of cannabis and its derivatives, as well as the treatment of people with addictions.

Fourth.- The SSA will have 180 days from the entry into force of this Decree, to harmonize the regulations and regulations in the therapeutic use of THC.

- Option 1. Reforms to various Regulations, Official Mexican Standards, Agreements.
- Option 2. Issue a new Regulation on Cannabis. ✓

Cofepris
Comisión Federal para la Protección
contra Riesgos Sanitarios



SALUD
SECRETARÍA DE SALUD



Cofepris 
Comisión Federal para la Protección
contra Riesgos Sanitarios

PROPOSED DRAFT REGULATION GENERAL HEALTH LAW



Proposed Draft Regulation on Sanitary Control of Cannabis and Derivatives thereof

FIRST TITLE . General disposition.

- **Single Chapter. Purpose of the Regulation, Definitions, Supplementation of the standard and application and interpretation of the Regulation. Articles 1 – 4**

SECOND TITLE. On Research for Medical and Scientific Purposes.

- **First chapter. Research Protocols. Articles 5 - 11.**
- **Chapter Two. Of the Investigation for Medical and Scientific Purposes. Articles 12 - 17.**

THIRD TITLE. Of the Medical Use of Cannabis and its Pharmacological Derivatives.

- **First chapter. Of the Process of Medicines Containing Pharmacological Derivatives of Cannabis. Articles 18 - 20**
- **Chapter Two. Import of Medicines Containing Pharmacological Derivatives of Cannabis or Raw Material that Intervenes in its Preparation. Articles 21 - 30.**



Proposed Draft Regulation on Sanitary Control of Cannabis and Derivatives thereof

SALUD
SECRETARÍA DE SALUD



Cofepris
Comisión Federal para la Protección
contra Riesgos Sanitarios

TITLE FOUR. Of the Requirements to Market, Import and Export Products other than Medicines, which contain Cannabis Derivatives in Concentrations of 1.00% or less of THC.

- **First chapter. Of the Industrial Products in General. Articles 31-34.**
- **Chapter Two. Of Food, Food Supplements, Non-Alcoholic Drinks and Alcoholic Beverages. Articles 35-36.**
- **Chapter Three. Of the Import and Export Permits. Articles 37 – 39**

TITLE FIVE. Of Advertising and Promotion.

- **Single Chapter. Articles 40-42.**

TITLE SIX. Verification, Security Measures and Sanctions.

- **Single Chapter. First. Articles 43 and 44**



SALUD
SECRETARÍA DE SALUD



Cofepris 
Comisión Federal para la Protección
contra Riesgos Sanitarios

REQUIREMENTS TO REQUEST MEDICAL AUTHORIZATIONS



REGULATED PRODUCTS

The Ministry of Health, through COFEPRIS, exercises sanitary control based on the risk of the following products and services:

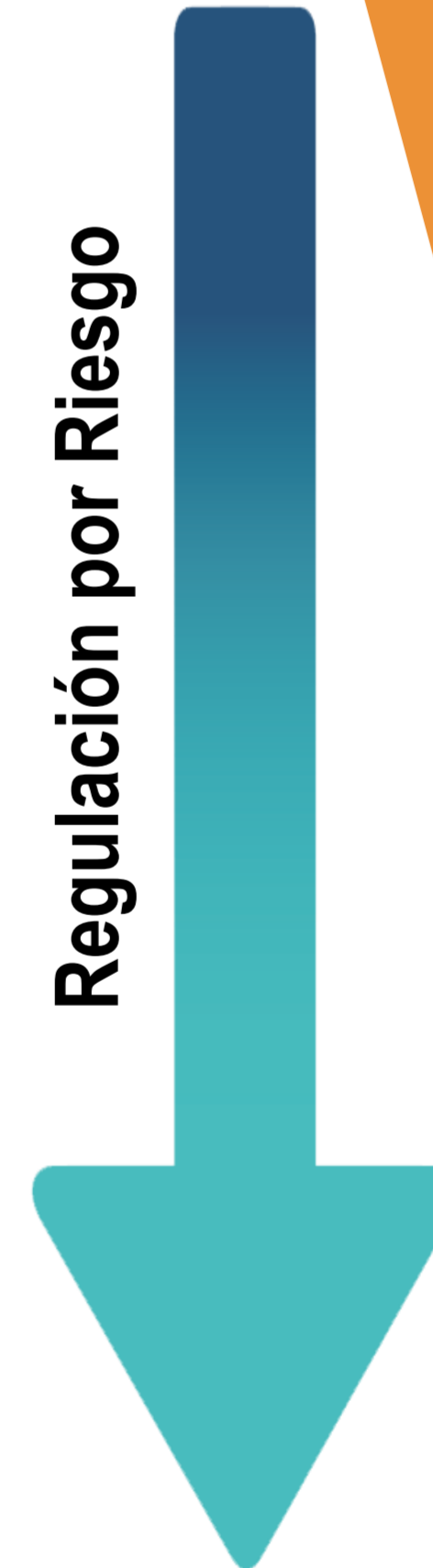
PRECURSORS

- 1. Allopathic medication
- 2. Herbal medicine
- 3. Herbal remedy
- 4. Medical device
- 5. Herbicide
- 6. Alcohol
- 7. Base
- 8. Nutritional supplement
- 9. Food
- 10. Cosmetics

THC CONTENT

- Over 1%
- Over 1%
- Lower than 1%
- Lower than 1%
- Doesn't apply
- Lower than 1%
- Lower than 1%
- Lower than 1%
- Lower than 1%
- Lower than 1%

Regulación por Riesgo



Sujeto a vigilancia

SALUD
SECRETARÍA DE SALUD



Cofepris 
Comisión Federal para la Protección
contra Riesgos Sanitarios



CURRENT ACTIONS

Current Actions

1

Review of Issuance of Comments to the Proposed Draft Regulation by the Participating Dependencies and Institutions.

2

Meeting with the Secretary of Health and Heads of the Dependencies of the Federal Public Administration.





SALUD

SECRETARÍA DE SALUD



Reform to the General Law of Health on Cannabis



Comisión Federal para la Protección
contra Riesgos Sanitarios

