



SALUD
SECRETARÍA DE SALUD



Cofepris 
Comisión Federal para la Protección
contra Riesgos Sanitarios

MEXICO: MEDICAL DEVICES REGULATION

Federal Commission for the Protection against
Sanitary Risk – COFEPRIS

STAKEHOLDER OPEN FORUM

September, 2018.

- The Federal Commission for the Protection against Sanitary Risk (COFEPRIS) is a decentralized entity of the Ministry of Health with technical, administrative and operational autonomy.
- It was conceived by law as a macro sanitary regulator compared to other international sanitary agencies which regulate specific industries individually.

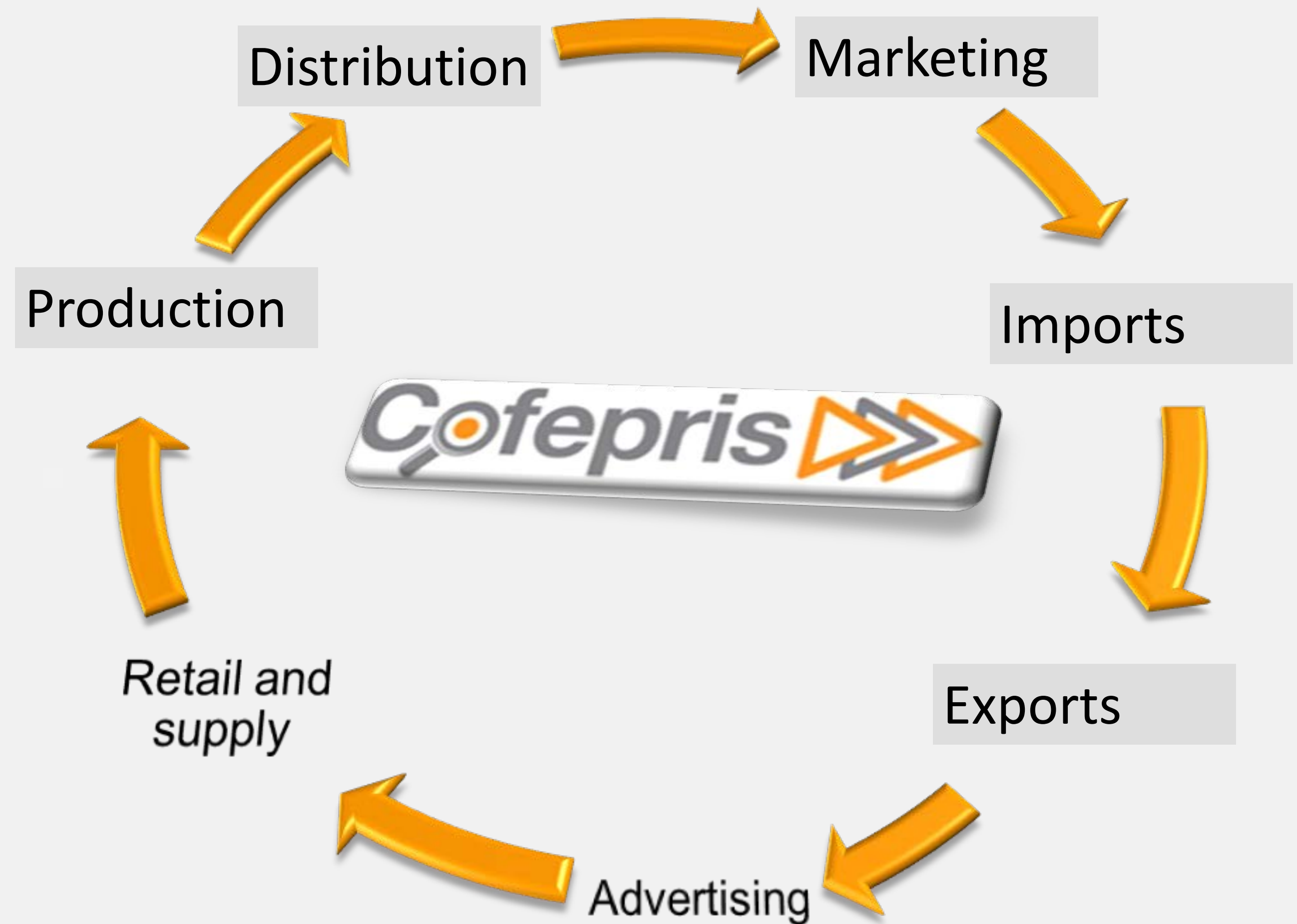


What is COFEPRIS?

COFEPRIS regulates the following industries and business process.

Regulated Sectors

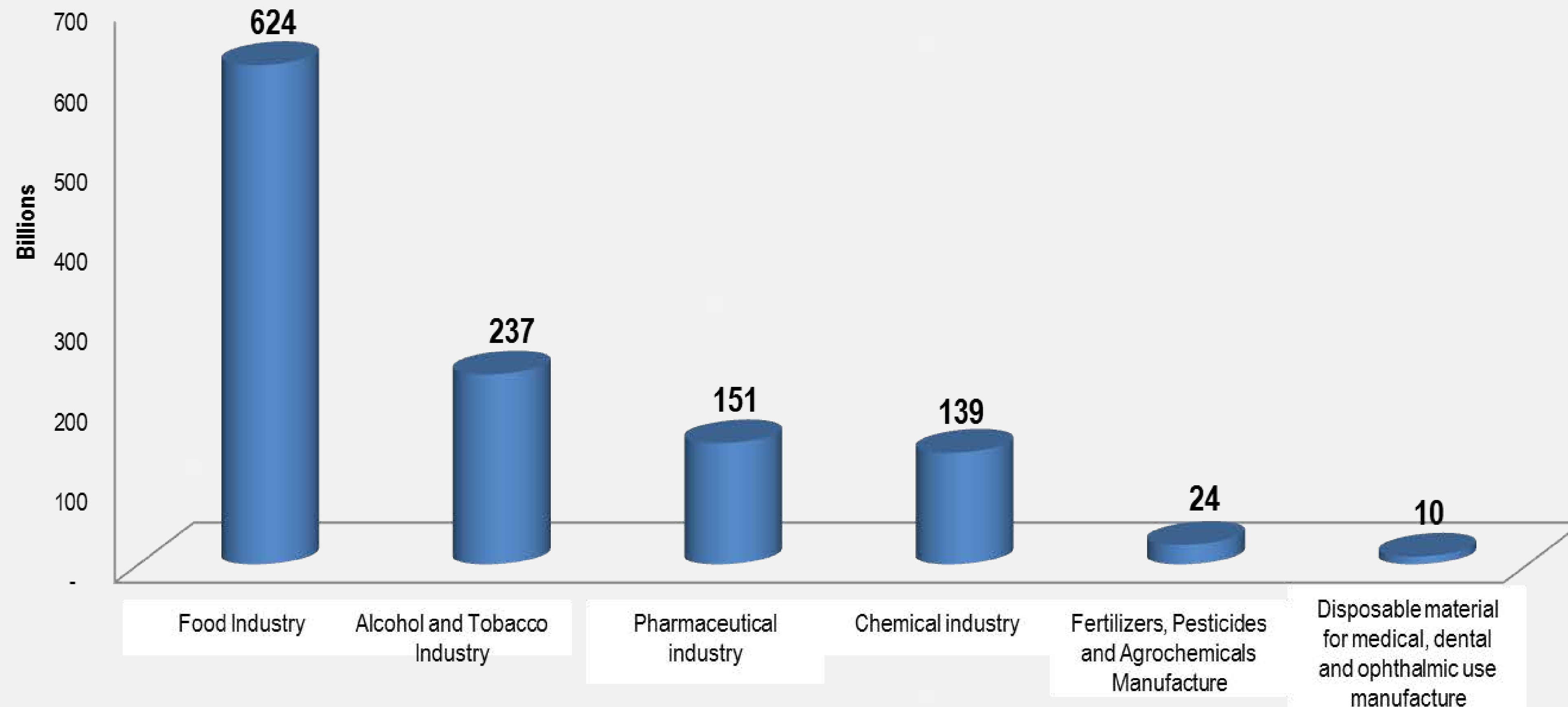
1. Food and Beverages
2. Health Supplies
3. Health Services
4. Cosmetics and beauty products
5. Pesticides, Vegetable nutrients and Toxic substances
6. Emergencies
7. Labor Safety and Health
8. Environmental Risks



Value of the products regulated by COFEPRIS

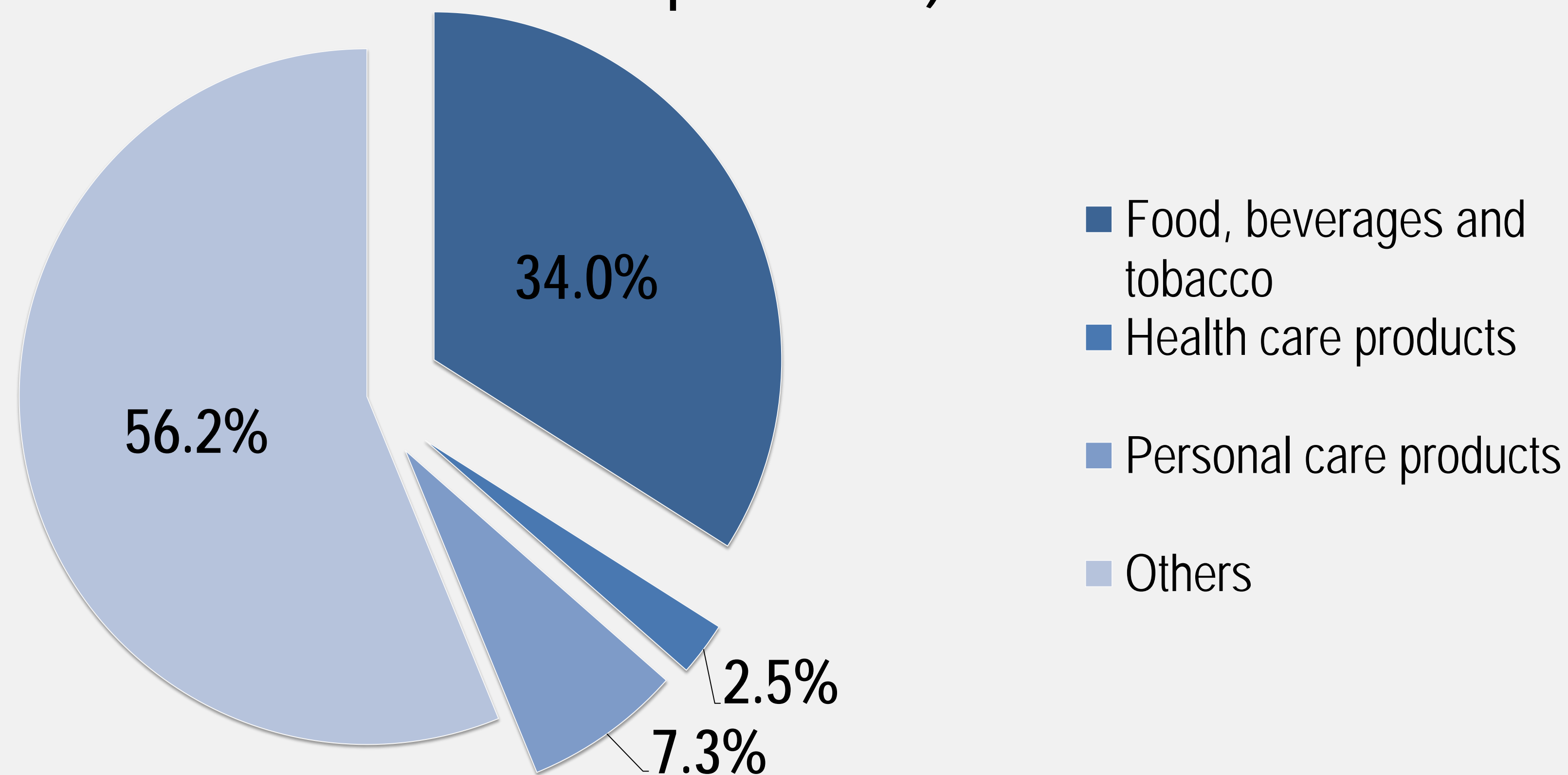
These industries represent **9.8% of Mexican GDP.**

Industries Regulated by COFEPRIS (2009 last available year)



COFEPRIS regulates 44 cents out of every Mexican peso spent by households in Mexico through 3 categories: Food, beverages; health care; and personal care products.

Household Expenditures per Category (as a % of total household expenditures)*



Source: Encuesta Nacional de Ingresos y Gastos de los Hogares (ENIGH, 2012). INEGI (2013).

* Only current monetary expenditures are considered.



Characteristics of health regulatory policy

- Its main objective is to improve population access to health products
- Rests on four fundamental pillars and the pillars are aligned with the **3 priorities of health** policy established by the Federal Government.

Government's Health Policy Priorities

1. Effective Access
2. Service Quality
3. Prevention

Pillars of Health Regulatory Policy

Ensuring the safety, quality and efficacy of all drugs.

Offering a reliable and predictable scheme.

Removal of barriers to entry of safe and of high quality products.

Harmonized with best international practices

Global Harmonization Initiatives

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World Health
Organization



IMDRF
International Medical
Device Regulators Forum

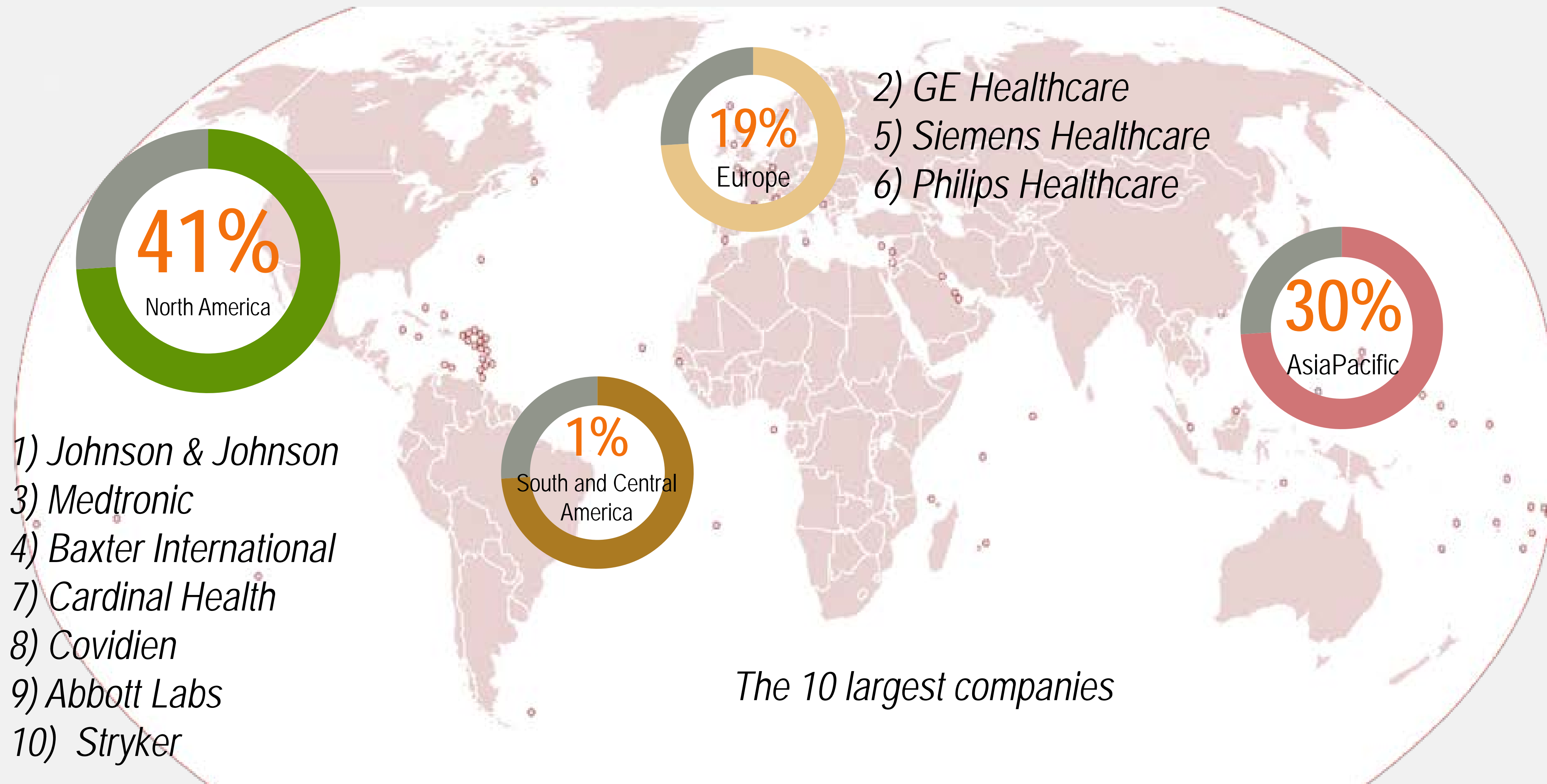


Pan American
Health
Organization

i-p-r-f.org
International Pharmaceutical
Regulators Forum



Global production in 2015 663 billion USD

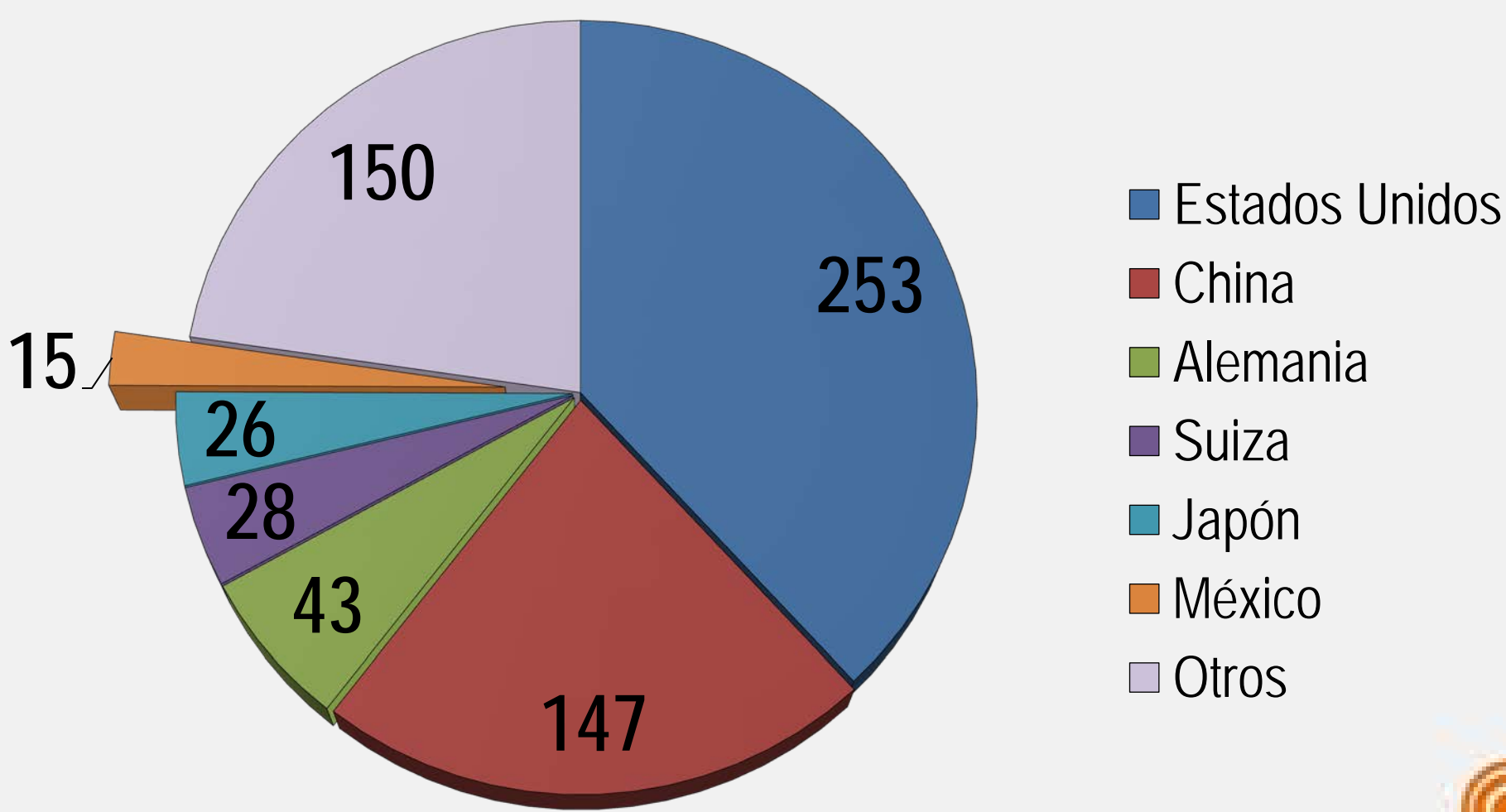


Growth estimate 2015-2020



Expected Annual growth : **6.2%**

Production by Country, 2015
Billion USD



International Trade

431 Billion USD

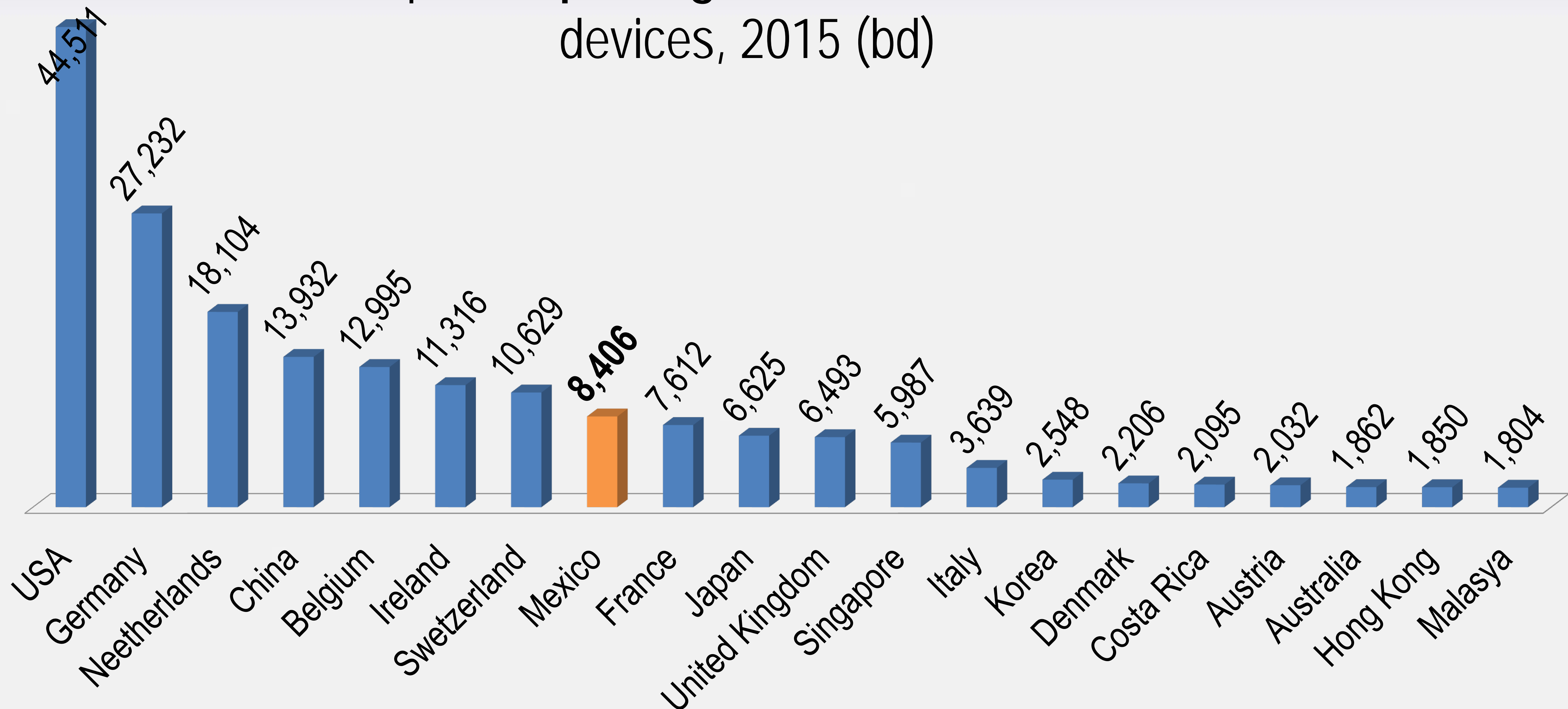
Exports
219.9 B USD



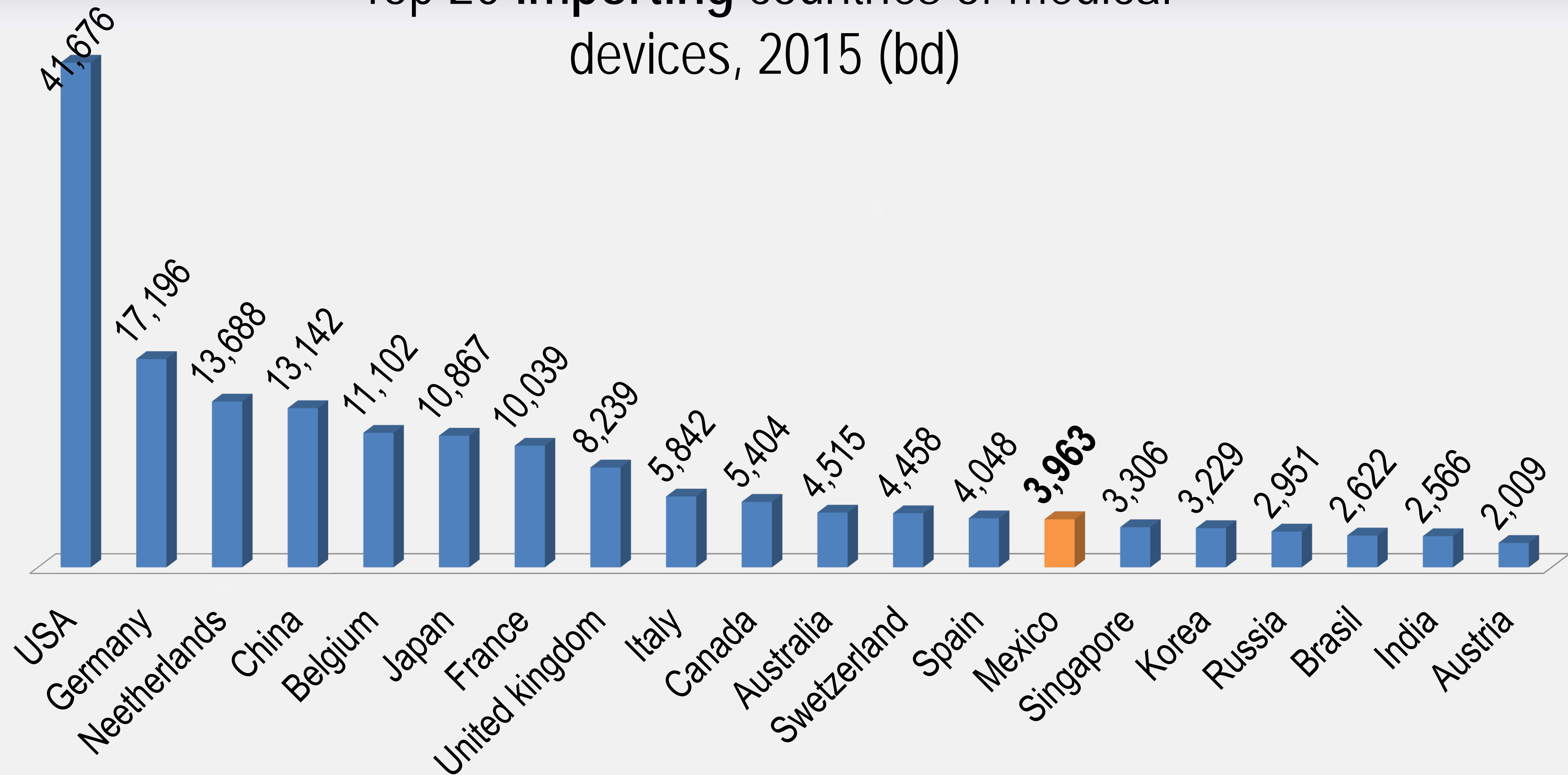
Imports
210.9 B USD



Top 20 exporting countries of medical devices, 2015 (bd)



Top 20 importing countries of medical devices, 2015 (bd)



México

Total
Production
15,220
million USD

**Largest
Producer**
in Latin
America

8°
largest
world
exporter

14°
largest
world
importer

156,831
persons
employed in
2015



Main investment clusters in Mexico



Medical device production in Mexico, 2010-2016*

(million USD)



Growth
rate
6.1%

México:
**Important
supplier of**
the United
States



General Health Act

17 bis: **COFEPRIS** competences
194, 262: **Terms and Definitions**
263-268 bis, 295: **Imports**
310: **Advertising**
376: **Market Authorization**
398-400: **Inspections**

Health Supplies Bylaw
(RIS)

82: **Market Authorization**
83: **Classification**
224-225: **Safety measures**

United States of Mexico
Pharmacopoeia (FEUM)

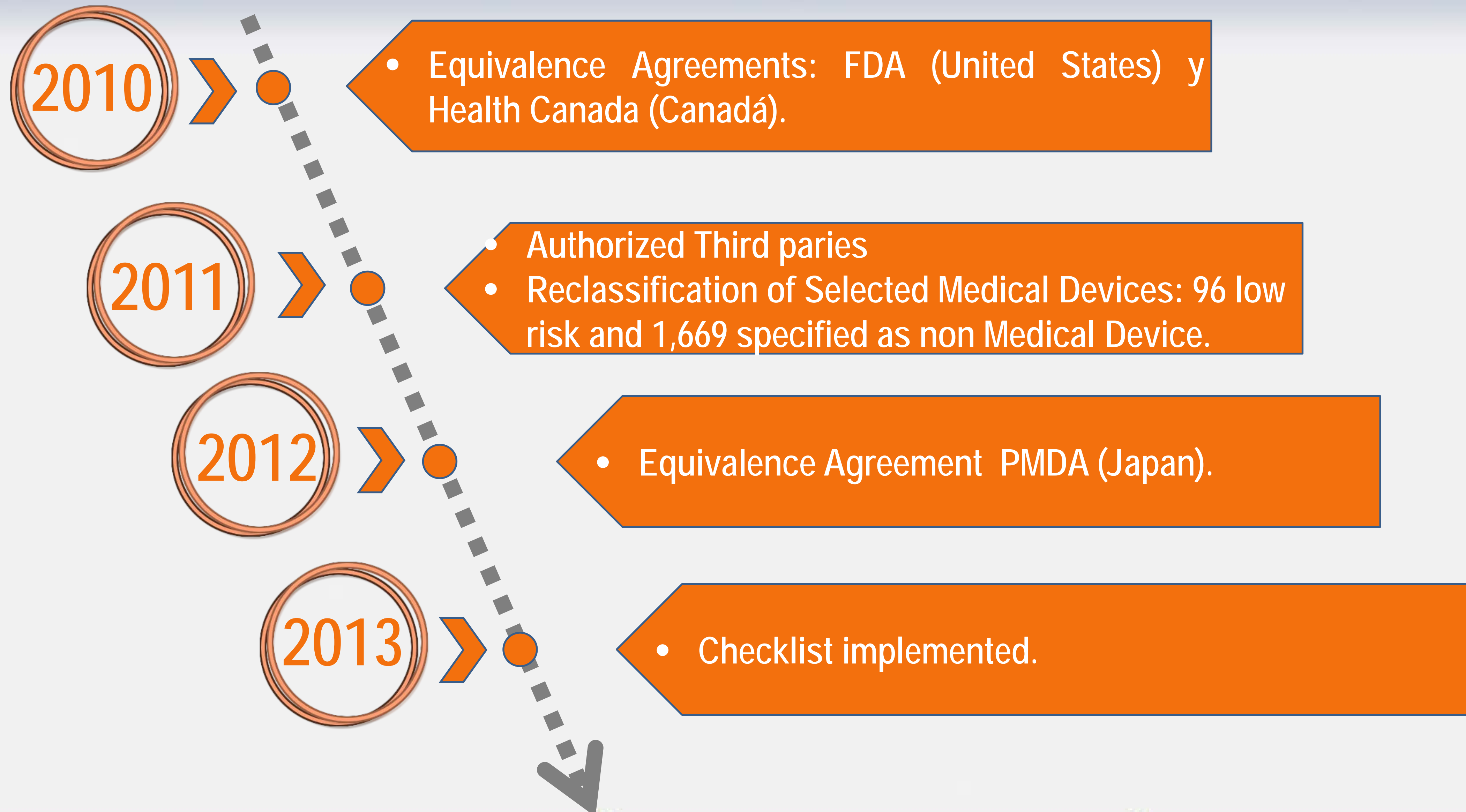
MD Supplement: it defines and establishes the specifications and methods of analysis for its verification to guarantee the quality and optimal functioning.

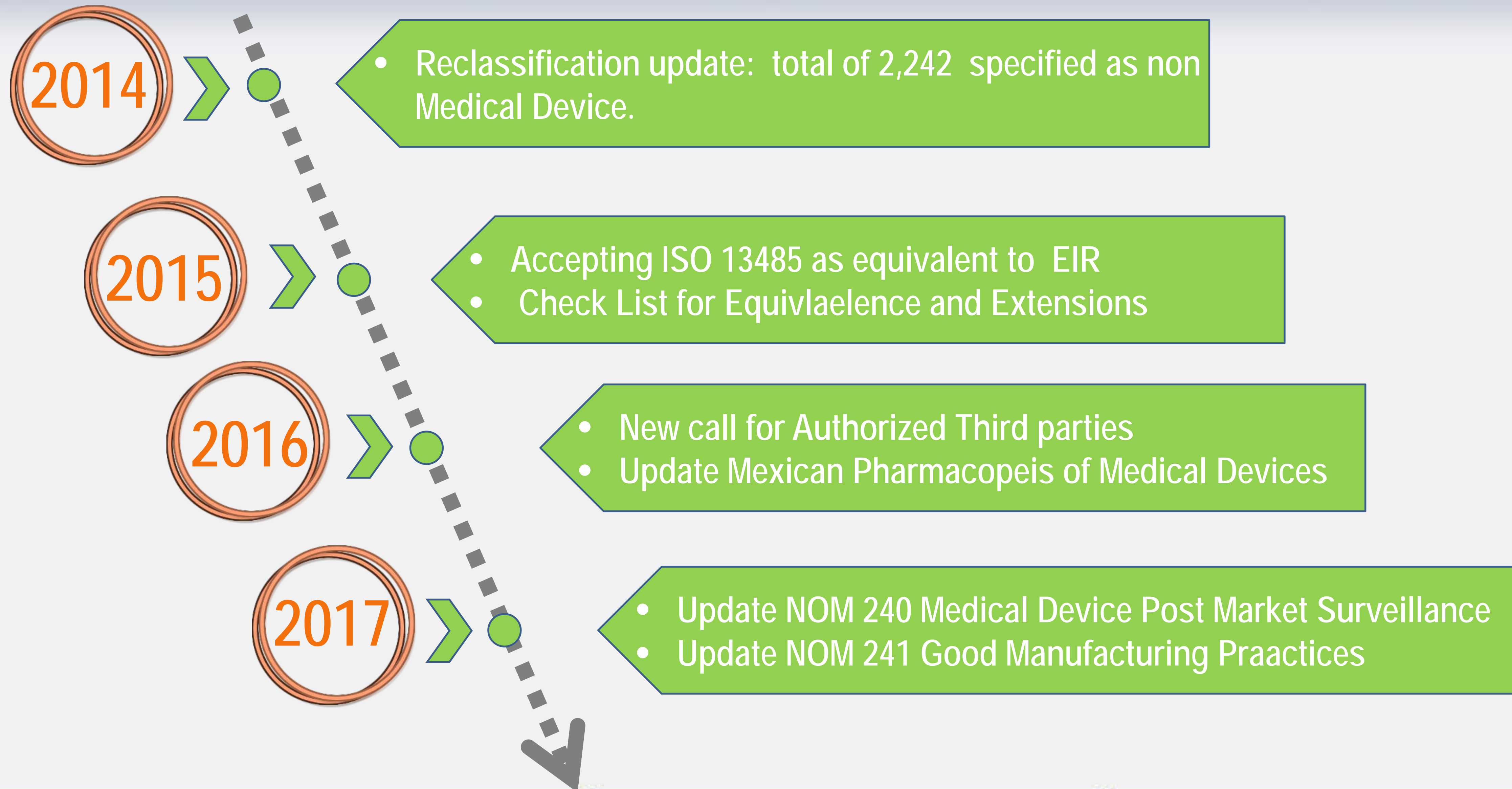
Official Resolutions and
Norms

NOM-241-SSA1-2012: GMP.
NOM-137-SSA1-2008: Labelling.
NOM-240-SSA1-2012: Technovigilance.

**GHTF and IMDRF foundations and principles*







TRADE NEGOTIATIONS

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- Pharmaceutical Annex
- Medical Devices Annex



Colombia



Chile



Peru



Mexico



- Pharmaceutical Annex

EU



Mexico



- Pharmaceutical Annex
- Medical Devices Annex



US



Canada



Mexico



- Mexico is the **largest exporter** of medical devices in Latin America, with a production equivalent to **15 billion dollars**.
- Mexico is ranked approximately **8th world exporter** and within of the **20 largest world importers**.
- The sector generates more than **130 thousand jobs**.
- Mexico has robust regulatory structure
- Mexico is strongly committed to advance in international regulatory harmonization





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**Somos COFEPRIS,
somos ARN**

THANK YOU

Mario Alanís Garza

General Director of International Affairs
malanis@cofepris.gob.mx



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