



# Legal Requirements for the Use of Recycled Plastic in Food Contact Applications in Latin America

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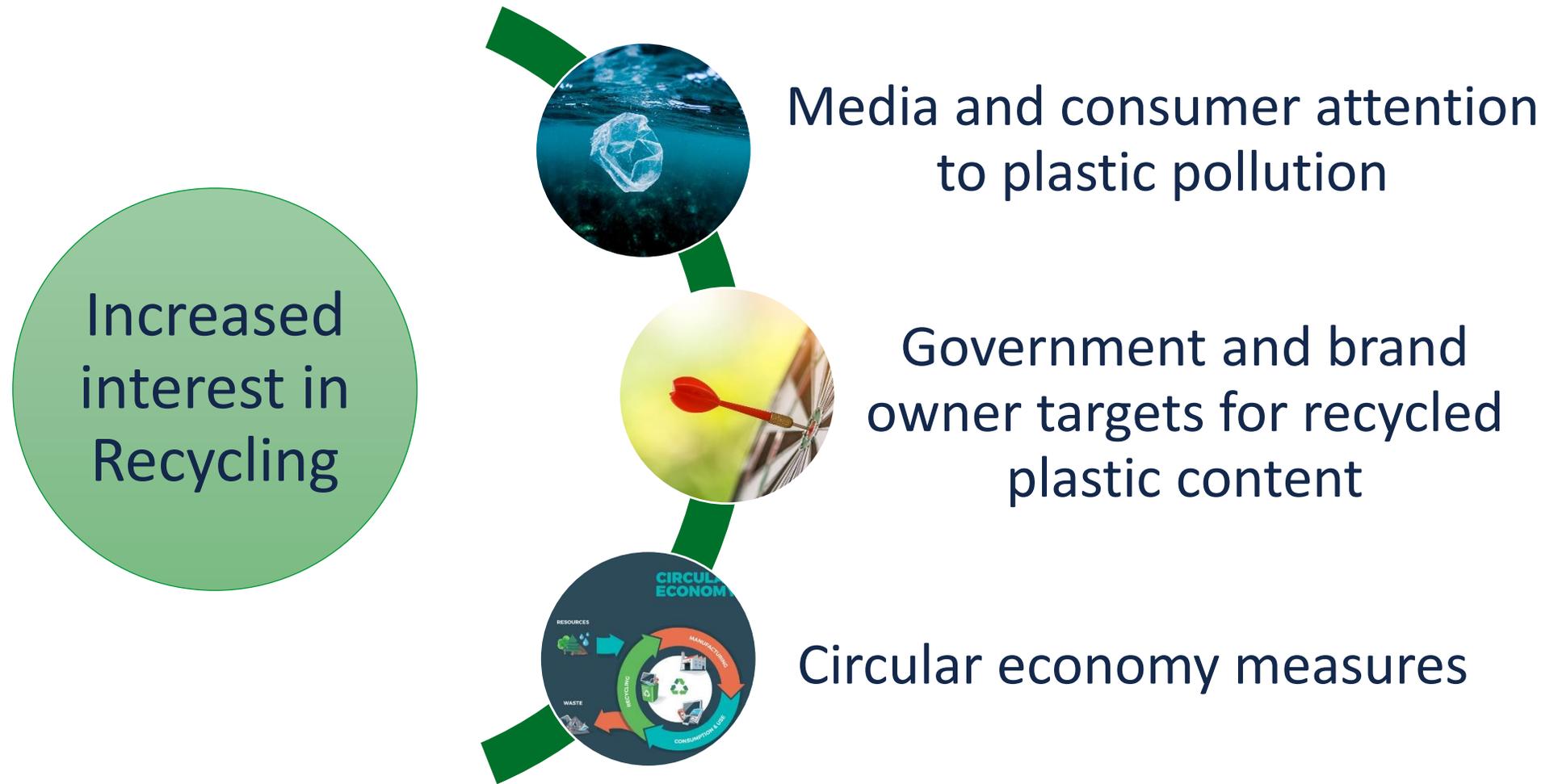


# Overview

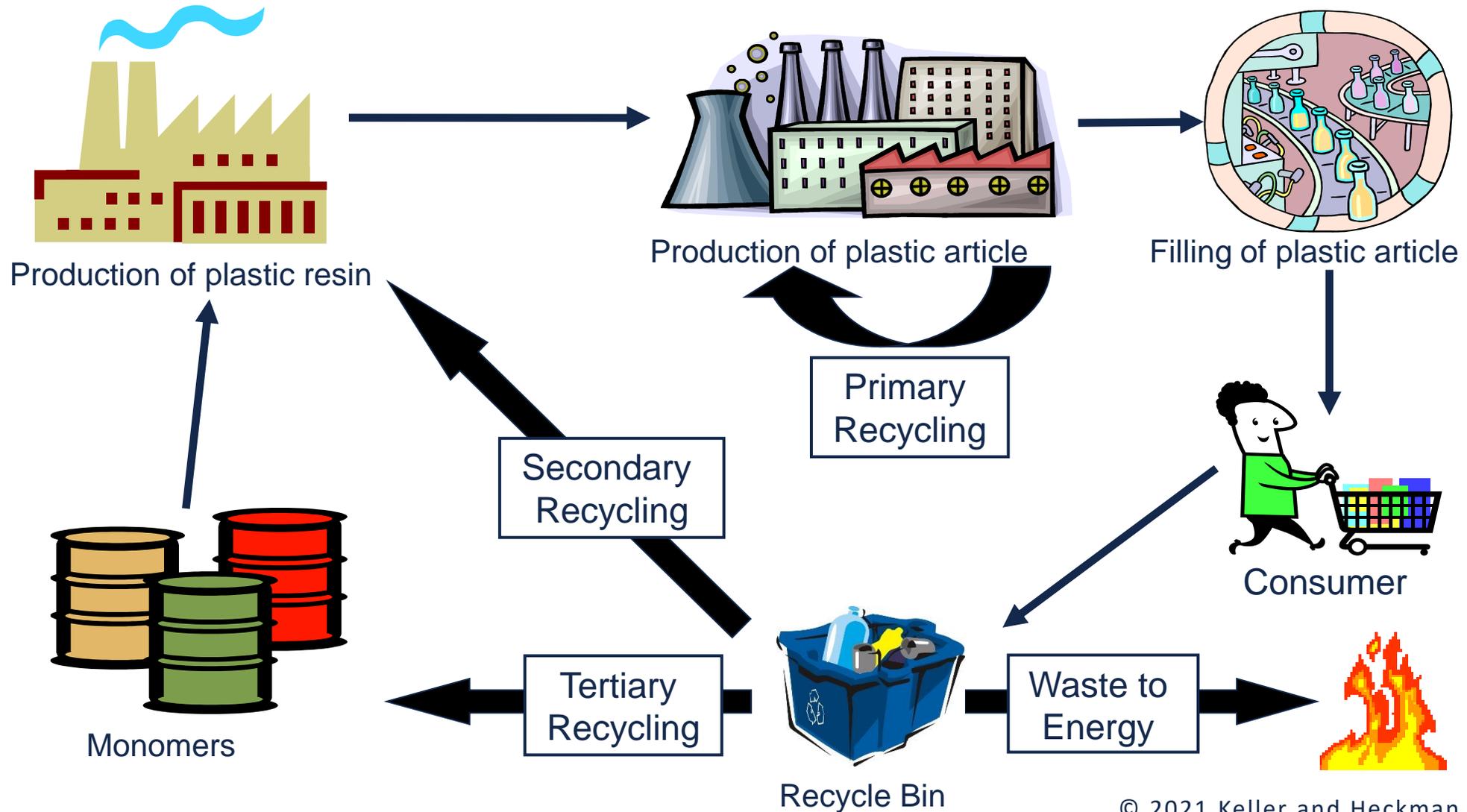
- ◆ Introduction:
  - ◆ Drivers for Recycled Plastic
  - ◆ Recycling Terminology
- ◆ Food Contact Regulations for Recycled Plastic in:
  - ◆ MERCOSUR Countries
  - ◆ Andean Community Countries



# Drivers for Use of Recycled Plastic



# Recycling Terminology

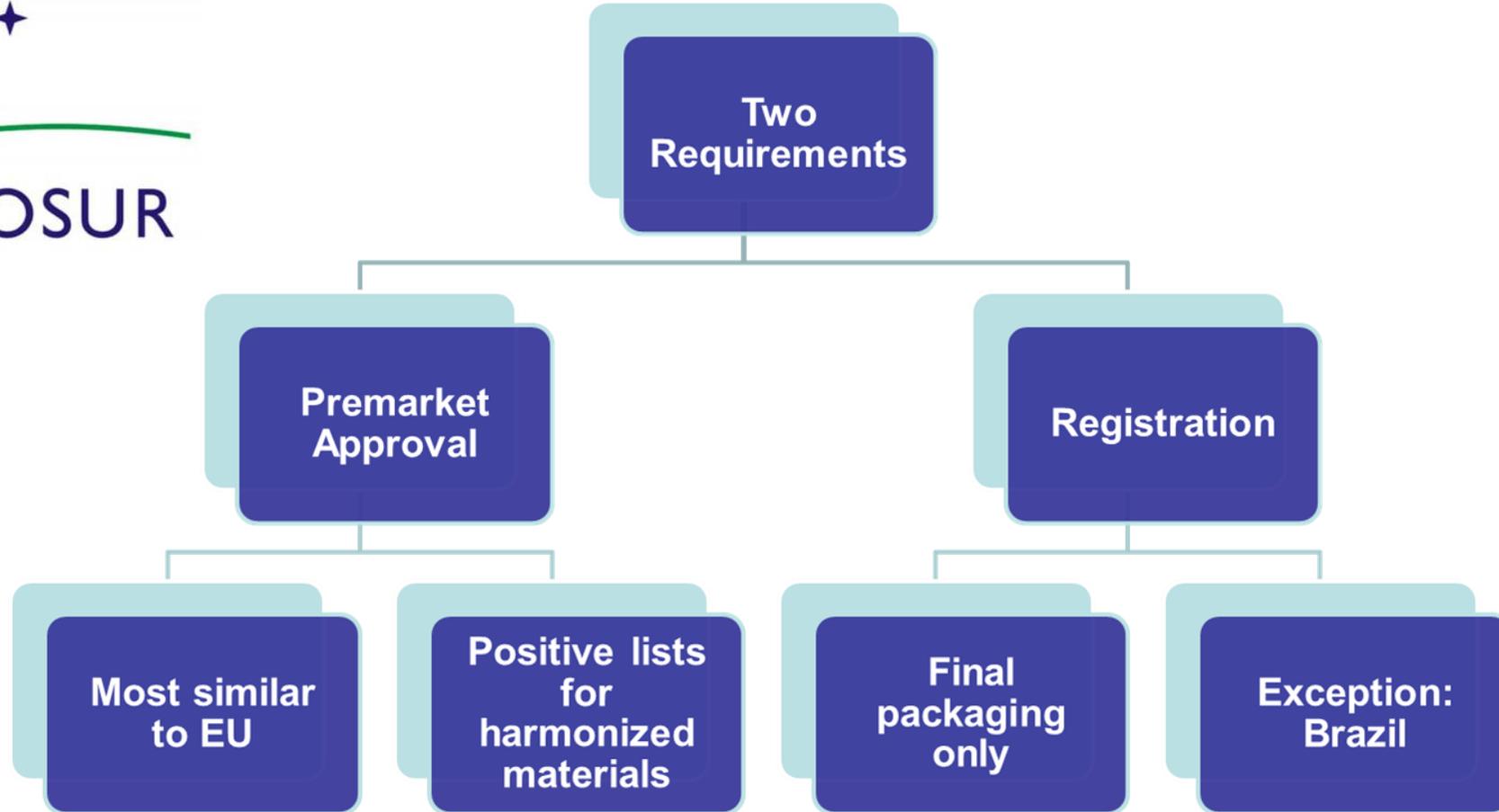


# Mercado Común del Sur (MERCOSUR)



- Trade bloc in South America
- Created by Treaty of Asunción del Paraguay in 1991
- Members: Argentina, Brazil, Paraguay, Uruguay, Bolivia (under integration), Venezuela (suspended)

# What is the Regulatory Framework?



# Recycled Plastics



- ◆ MERCOSUR has adopted several resolutions related to plastics
- ◆ GMC Resolution 56/92 (General requirements for plastics) prohibits recycled plastics unless specifically authorized elsewhere
  - ◇ Excludes in-house reprocessed material or regrind
- ◆ To-date, only specific authorizations for recycled PET



# GMC Resolutions Covering Recycled PET



Refillable PET packages for carbonated non-alcoholic beverages	Res. No. 16/93
Multilayer PET packages, with middle layer containing recycled material, for carbonated non-alcoholic beverages	Res. No. 25/99
Recycled PET for food packages (multilayer and monolayer packages)	Res. No. 30/07



## Requirements for returnable plastic containers

Comply with GMC Resolution 56/92

Register with competent authority

Not transfer substances posing a health concern

Meet applicable microbiological limits

Labeling

## Requirements for establishments that use returnable plastic containers

Authorized by the competent authority

Meet GMP-type requirements (e.g., written procedures, adequate equipment, trained personnel)



# GMC Resolution 25/99



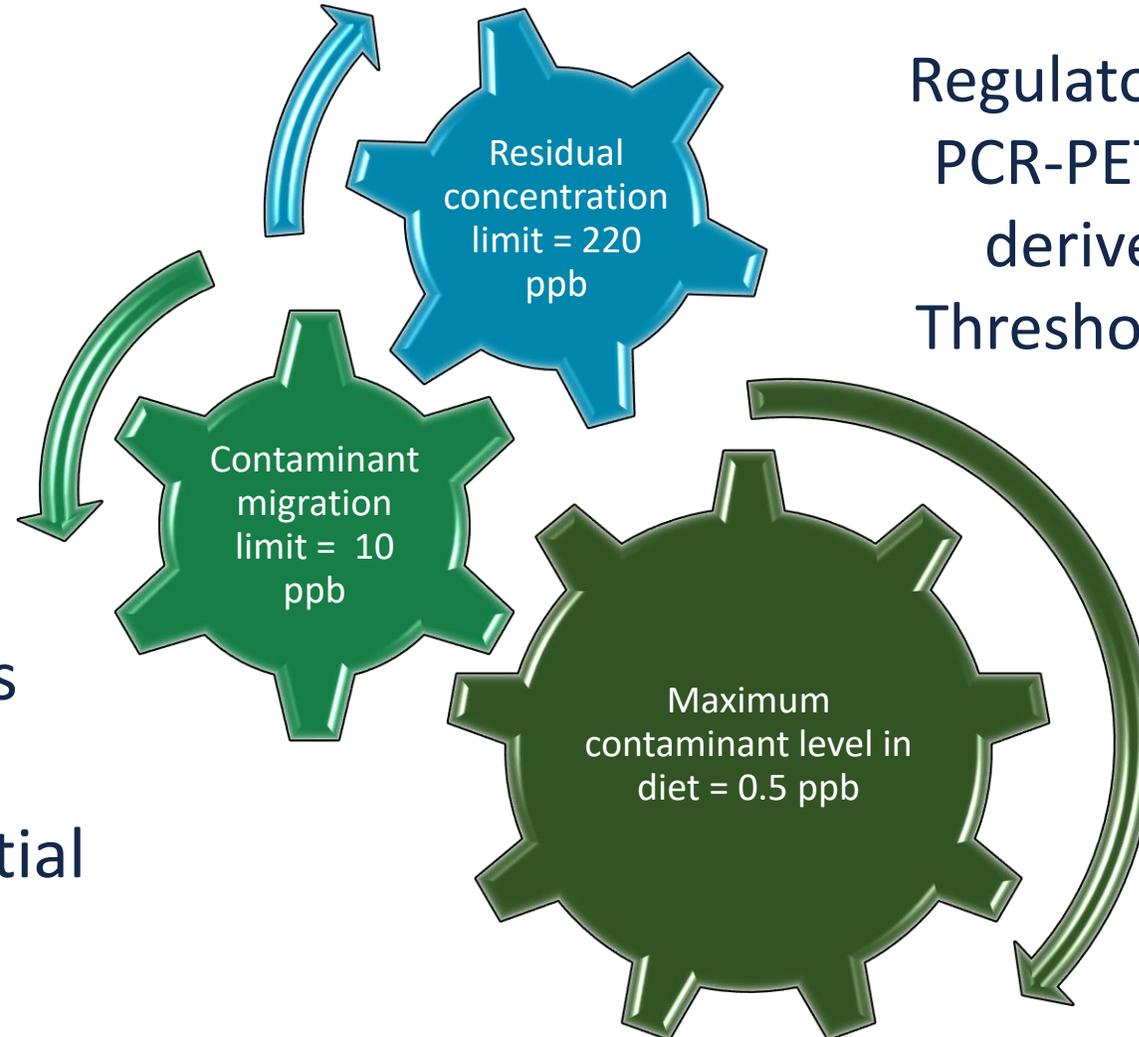
## Requirements for multilayer PET bottles for non-alcoholic carbonated beverages

- ◆ PCR-PET:
  - ◇ Specifications for decontaminated PET flake (e.g., intrinsic viscosity)
  - ◇ Authorization/approval by the Competent Health Authority
- ◆ Multilayer PET container:
  - ◇ Thickness: virgin, food contact layer >25 microns; inner recycled layer <200 microns
  - ◇ Must be safe and not alter organoleptic qualities of food
  - ◇ Useful life of the packaged product should not be longer than 1 year
  - ◇ Meet other applicable MERCOSUR legislation and be authorized/approved by the Competent Health Authority
  - ◇ Labeling

- ◆ Requirements for PCR-PET obtained from physical and chemical processes for use in food packaging
  - ◇ PCR-PET decontamination must be validated through challenge testing using surrogate contaminants
  - ◇ Supported by a no objection letter from FDA or positive EU opinion
  - ◇ Approved and registered by relevant National Sanitary Authority
  - ◇ Must be safe and not alter organoleptic qualities of food
  - ◇ Also addresses GMP, recordkeeping, and labeling



# GMC Resolution 30/07 continued



Regulatory threshold for PCR-PET contaminants derived from FDA's Threshold of Regulation

Challenge test validates efficiency of recycling process to remove potential contaminants

# Who are the Sanitary Authorities?



## Argentina

- National Food Institute/Instituto Nacional de Alimentos (INAL)
- National Wine Institute/Instituto Nacional de Vitivinicultura (INV)
- National Service of Agricultural Food Health and Quality/Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA)



## Brazil – generally exempt from registration

- Recycled materials must be registered with the National Agency of Sanitation Surveillance (ANVISA)
- ANVISA must be notified when FCMs are imported



## Paraguay

- National Institute of Food and Nutrition (INAN)
- National Institute of Technology, Standardization and Metrology (INTN) – performs sanitary evaluations



## Uruguay

- Ministry of Public Health – registrations
- Uruguay Technological Laboratory (LATU) – performs sanitary evaluations

# Comunidad Andina/Andean Community (CAN)

- ◆ Second largest trade bloc in South America
- ◆ Members: Bolivia, Colombia, Ecuador, Peru
- ◆ Unlike MERCOSUR, no harmonized regulations for food contact materials
- ◆ Must look to the national law of each CAN member state





# Bolivia

- ◆ Member of CAN, but in the process of integrating into MERCOSUR
- ◆ Supreme Decree 2887/2016
  - ◇ Promotes recycling of food grade PCR-PET
  - ◇ Mandatory minimum of 30% PCR-PET in PET bottles
- ◆ Administrative Resolution No. 47/2018 requirements for food grade PCR-PET:
  - ◇ Must be safe and not alter sensory characteristics of food
  - ◇ Use decontaminated PCR-PET validated through challenge tests to meet a regulatory threshold of 0.5 ppb in diet
  - ◇ Registration of companies producing/importing PCR-PET containers (SENASAG)
  - ◇ References Bolivian Standard NB 716002:2009



# Colombia

- ◆ Resolution 4143/2012 (“Requisites for plastic and elastomeric materials”)
- ◆ Article 13, generally prohibits recycled plastic, unless:
  - ◆ (1) there is a functional barrier that reduces migration to levels that are toxicologically safe, sensory insignificant, and technologically unavoidable; or
  - ◆ (2) manufactured with recycled material subjected to validated decontamination or ultra-cleaning
  - ◆ Competent health authority (INVIMA) must verify requirements and issue authorization



# Ecuador

- ◆ RTE INEN 291:2016 (“Recycled plastic materials intended to contact food (PCR PET)”)
  - ◇ Excludes industrial scrap, plastic materials made from returnable bottles, materials used behind a functional barrier, and chemical depolymerization
  - ◇ Requires FDA or EU no objection letter
  - ◇ PCR-PET must comply with global and specific migration limits and not exceed a residual limonene content (volatile organic pollutant) of 120 µg/kg of resin
- ◆ Registration required (ARCOSA)



# Peru

- ◆ Supreme Decree 038/2014 amended Supreme Decree 7/1998 to permit the use of PCR-PET meeting specific requirements, including:
  - ◇ Certificate of conformity (INDECOPI) and registration (DIGESA)
- ◆ Law 30884/2018 on single use plastics requires at least 15% PCR in PET bottles for beverages and personal care products

# Who are the Sanitary Authorities?



**Colombia:** National Institute of Drug and Food Surveillance (INVIMA)



**Bolivia:** National Service of Agriculture and Livestock Health and Food Safety (SENASAG)



**Ecuador:** National Agency for Regulation, Control and Sanitary Surveillance (ARCSA)



**Peru:** Environmental Health Directorate General – Ministry of Health (DIGESA);  
National Institute for the Defense of Competition and Intellectual Property (INDECOPI)



# Thank You

**Any questions?**

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