

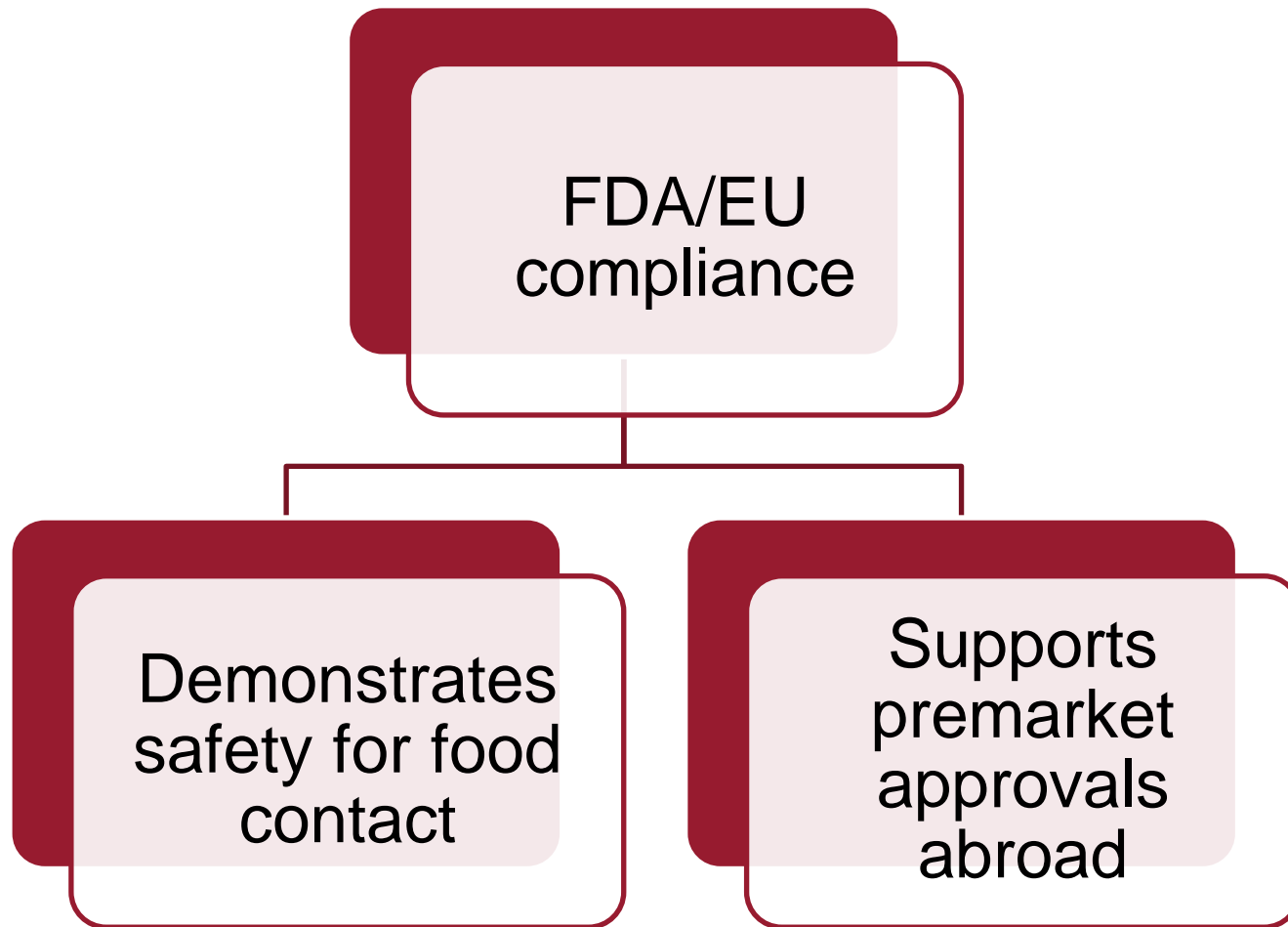


# Premarket Approval Jurisdictions China & MERCOSUR

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2017 SPE International Polyolefins Conference  
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# Leveraging Your FDA and EU\* Compliance



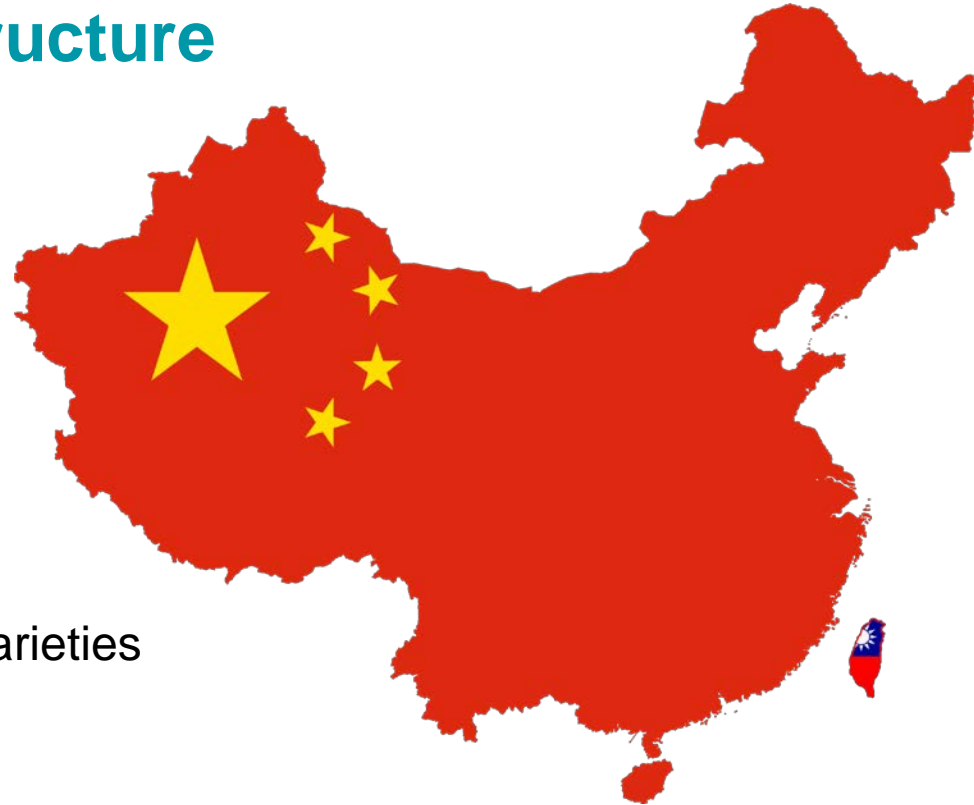
\*For harmonized substances

# What is the Basis for Food Contact Status?

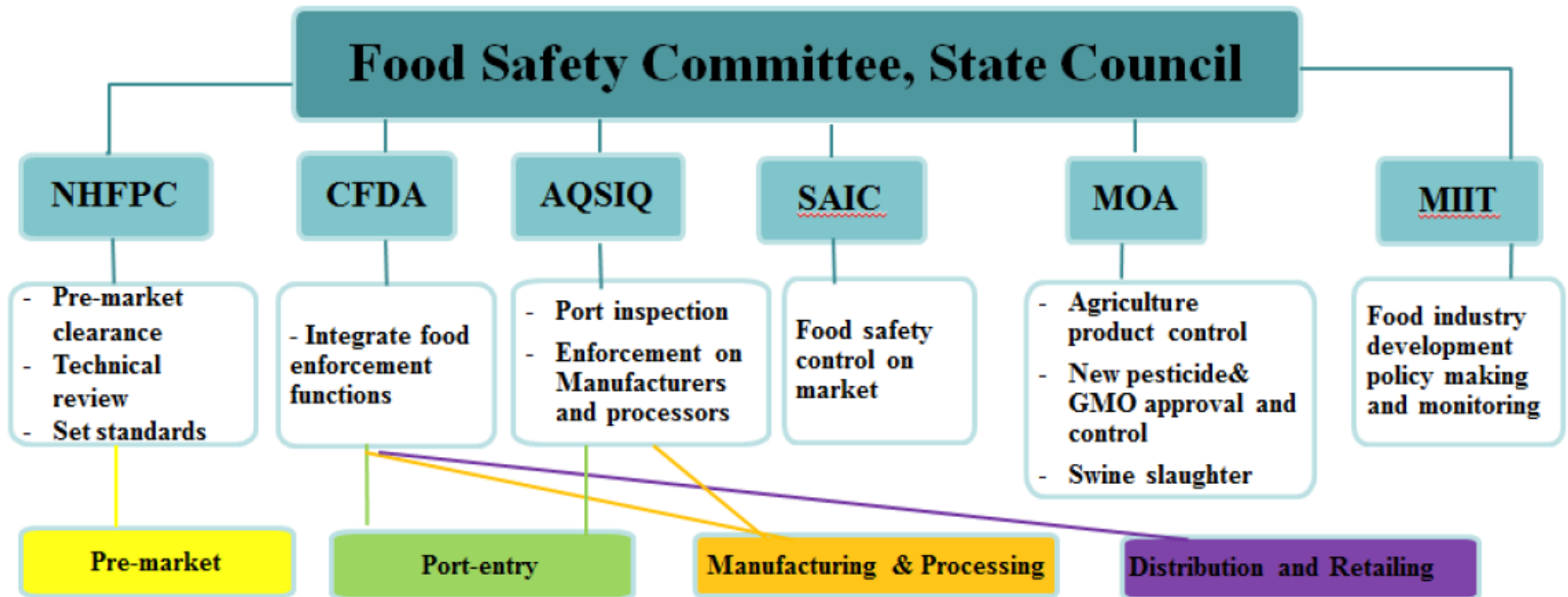
- Explicit FDA Clearance
  - Regulation, TOR exemption, FCN, prior sanction letter
  - Provides reference tool for any questions, easy to understand
- Explicit EU Clearance
  - Plastics Regulation
  - BfR?
- Self-determination/third-party opinion
  - Based on scientific principles
  - GRAS concept uniquely American

# Chinese Regulatory Structure

- Laws
  - Food Safety Law
  - Product Quality Law
- Regulations and Rules
  - Management Rules for the Administrative Approval of New Varieties of Food-Related Products
- Standards
  - GB 2760, GB 4806, GB 9685
  - “Commodity” Standards (i.e., coatings, paper, resin standards)
  - Finished Article Standards



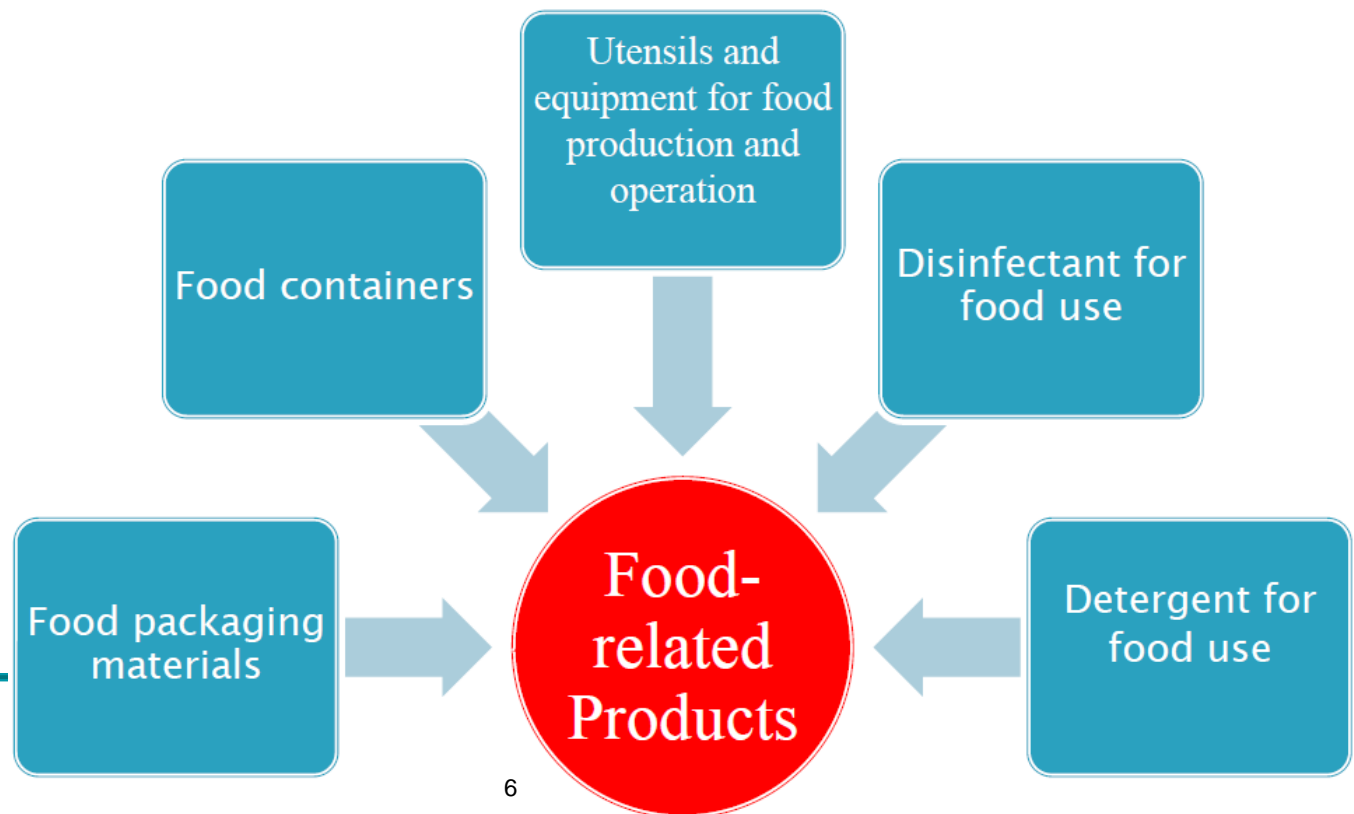
# Governmental Structure



- **NHFPC**: National Health and Family Planning Commission
- **CFDA**: China Food and Drug Administration
- **AQSIQ**: Administration of Quality Supervision, Inspection and Quarantine
- **SAIC**: State Administration of Industry and Commerce
- **MOA**: Ministry of Agriculture
- **MIIT**: Ministry of Industry and Information Technology

# Food Safety Law

- Entered into force on October 1, 2015
- Resulted from many food safety scandals, both foreign and domestic
- Focus on traceability, responsibility, and liability
- Article 50: food producers must check for compliance of “food-related products”



# Article and Standards Clean Up

Article Std.	Scope	Resin Std.	Scope
GB 9681	PVC	GB 9691	Polyethylene
GB 9687	Polyethylene	GB 9692	Polystyrene
GB 9688	Polypropylene	GB 9693	Polypropylene
GB 9689	Polystyrene	GB 16331	Nylon 6 (PA6/PA66)
GB 9690	Melamine-formaldehyde	GB 4803	PVC
GB 13113	Polyethylene terephthlate	GB 15204	PVdC
GB 14942	Polycarbonate	GB 13114	PET
GB 14944	Bottle sheet and granular PVC	GB 13115	Unsaturated polyester and glass fiber
GB 16332	Polyamide nylon	GB 13116	Polycarbonate
GB 17326	Robber-modified ABS		107 Resins (“Clean up”)
GB 17327	Acrylonitrile-styrene		

# GB 4806, General Safety Requirements

- Requires all food packaging materials to be safe and suitable
- Important definitions
  - “Non-intentionally added substances” (NIAS)
    - Requires safety assessments
    - Does not require explicit approvals
  - Functional barrier: permits the use of unlisted substances when:
    - Used behind a barrier
    - The substance migrates at less than 0.01 mg/kg,
    - The substance is not a carcinogen, mutagen, reproductive toxin (CMR) or nano substance



# GB 9685, Standard on the Uses of Additives

- Recently and significantly revised
  - Scope expanded – covers monomers and starting substances
  - Updated definitions – revise “food contact materials,” add SML(T)
  - Revised positive list (Appendix A)
    - New tables of approved substances by application (plastic, coatings, rubber, printing inks, adhesives, paper, silicone rubber)
    - Many substances added – “Clean Up” process and new approvals
  - New and Revised Appendices
    - Appendix B – lists SML(T)s
    - Appendix C – restrictions for metal ions
    - Appendix D – abbreviations for resins
    - Appendix E – catalogue for Appendix A, sorted by CASRN
  - Permits use of direct food additives (GB 2760), provided no technical effect in food

# Update to Material Standards

- NHFPC released on November 18, 2016 6 food contact standards:
  - GB 4806.6-2016 Plastic Resins
  - GB 4806.7-2016 Plastic Materials and Products
  - GB 4806.8-2016 Paper, Paperboard and Paper Products
  - GB 4806.9-2016 Metal Materials and Products
  - GB 4806.10-2016 Coatings and Coating Layers
  - GB 4806.11-2016 Rubber Materials and Products
- Include requirements on raw materials, sensory parameters, physical and chemical specifications, additives and migration specifications, etc.
- Some include positive lists of permitted materials
- Effective April 19, 2017

# Plastic Materials and Products for Food Contact Use

- Covers plastic materials/articles, multi-layer plastics, and plastic layers in multi-layer, multi-material articles
- Sensory Requirements
  - Organoleptic
  - Soaking solution: the soaking solution obtained from migration test should not yield color, turbidity, precipitation, smell and other sensory deteriorations
- Physical and Chemical Indicators
  - OML: General =  $\leq 10$  mg/dm<sup>2</sup>, Infants =  $\leq 60$  mg/kg
  - Consumption of potassium permanganate:  $\leq 12$  mg/kg (water, @ 60C, 2H)
  - Heavy metals:  $\leq 1.2$  mg/kg (as lead, 4% AA, @60C, 2H)
  - Decolorization: must be negative (only if colorants are added)
- Must meet applicable SMLs
- Labeling requirements

# Plastic Resins for Food Contact Use

- Raw materials must be safe for their intended use
- Same sensory requirements and physical/chemical indicators as articles
- Appendix A – Covers 103 resins and groups of resins
  - SML
  - Residue limits
  - SML(T)
  - Other limitations

No.	CAS Number	Chinese name	Common Category name	Specific migration limit (mg / kg)	Maximum residue levels (mg / kg)	SML (T) (mg / kg)	SML (T) group number	Remark
4	26221-27-2	Ethylene - vinyl alcohol copolymer	EVOH	12 (vinyl acetate)				Not available for contact with an ethanol content of more than 8% of the food.
5		Polypropylene (propylene homopolymer)	PP					
6	25722-45-6, 107001-49-0, 25895-47-0, 29160-13-2, 9010-79-1	Polymers of propylene and one or more of the following monomers: maleic anhydride, ethylene, 1-butene, other $\alpha$ -olefins, which may contain 5-ethylidene-2-norbornene as modifying monomers, which accounted for the largest mass fraction of propylene	PP		0.05 mg / 6 dm <sup>2</sup> (5- ethylidene-2-norbornene)	30	3	The residual amount, the weight ratio of the area of contact with the food less than 2 dm <sup>2</sup> / kg

# GB 31604.1-2015 Migration Testing

- Published October 30, 2015
- Provides simulants and testing conditions
  - Compliance testing for SMLs and OML
  - Testing for new clearances
- Similar to Plastics Regulation, with some modifications

# Petitions for New Materials

- Application form (Online)
- Physicochemical properties
- Technical necessity, intended use, and conditions of use
- Manufacturing process details
- Quality specifications, test methods and test report
- Toxicological safety assessment materials
- Migration and/or residual level, estimated dietary exposure and method used for estimation
- Domestic and international clearance status
- Other relevant materials

Copies: one original and four copies

# Conclusions

- Hybrid system
  - Relies heavily on EU system
  - Aspects of FDA and Japanese systems
- Clearances will be hybrid of international listings
- System very much in development

# MERCOSUR



Treaty of Asunción del Paraguay: March 26, 1991

Brazil, Argentina, Paraguay, Uruguay, and Venezuela

Grupo Mercado Común (GMC)

Member State Sovereignty

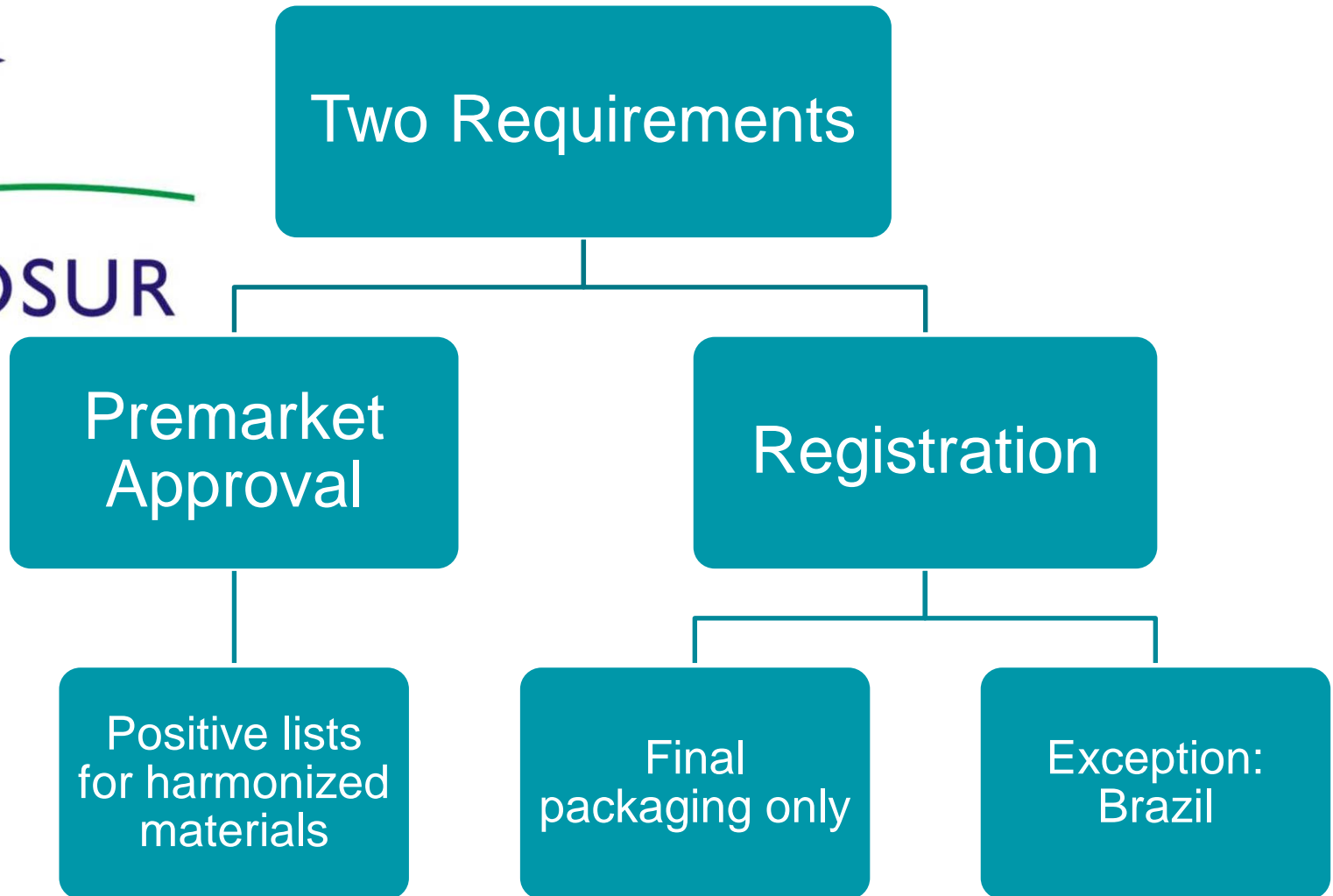
- GMC Resolutions must be transposed into national law



# Regulatory Structure



MERCOSUR



# Framework Regulation

## GMC Res. 3/92



Manufactured using GMP



Suitably pure



Transfer harmful or toxic compounds



Alter organoleptic properties

# Resolutions

Reference analytical methodology for the control of FCM  
(32/99)

## Plastics:

- Positive list of monomers and polymers (02/12)
- Positive list of additives (32/07)
- Migration methods (32/10)
- Colorants and pigments (15/10)
- Fluorinated polyethylene (56/98)
- Polymeric and resinous coatings for foods (55/99)
- Refillable PET packages for carbonated non-alcoholic beverages (16/93)
- Repealed: Methodology for determining residual vinyl chloride monomer content in PVC and residual styrene monomer content in polystyrene

## Metallic FCMs (46/06)

## Glass and ceramic FCMs (55/92)

## Cellulose-based FCMs

- General requisites (19/94, 35/97, 20/00)
- Positive list (56/97)
- Global migration method (12/95)
- Papers for hot filtration and cooking (47/98)
- Papers for cooking in oven (in process)
- Recycled cellulose fibers (52/99)
- Regenerated cellulose FCMs
  - Films (55/97)
  - Casings (68/00)

## Elastomeric FCMs

- General requirements (54/97)
- Positive list of components (28/99)

## Adhesives (27/99)

## Paraffin for food contact (67/00)

# Transposition

<b>MERCOSUR GMC Res.</b>	<b>Brazil RDC Res.</b>	<b>Argentina Food Code Chapter IV</b>
3/92-Framework	91/01	MSyAS 3/95
02/12-Monomers	56/12	SPReI 168/13 / SAGyPA 229/13
32/07-Additives	17/08	SPReI 202/08 / SAGyPA 568/08
32/10-Testing	51/10	SPReI 117/12 / SAGyPA 357/12
15/10-Colorants	52/10	SPReI 27/12 / SAGyPA 21/12
55/99-Coatings	124/01	Articulo 200 bis <sup>^</sup>
46/06-Metals*	20/07	SPRyRS 85/08 / SAGPyA 338/08
54/97-Elastomers	123/01	Articulo 219 bis <sup>^</sup>
27/99-Adhesives	91/01	Articulo 186 cuater <sup>^</sup>

# Positive Lists for Plastics

## GMC Res. 02/12 – Positive List of Monomers and Polymers

- Hybrid of EU and U.S. regulations
- Includes clearance limitations
- Applicable to plastic articles, plastic coatings

## GMC Res. 32/07 – Positive List of Additives

- Under revision (draft available)
- Covers substances intended to have a technical effect or to provide the polymerization medium (e.g., emulsifiers, surfactants, and possibly solvents)
- Excludes: impurities, catalysts

# Getting Premarket Clearance

Submit petitions to either:

Argentina (CONAL)

Brazil (ANVISA)

If petition is acceptable, advanced to Mercosur

Timing:

Reviewers meet only quarterly

No set schedule for revised publication

Members must transpose resolutions

# Analytical Testing

- Migration testing conditions are becoming *less* harmonized, not more
- Consider a “fill in the gaps” approach?
- Jurisdictions have different tolerance levels for flexibility and deviations
- Beware of toxicity requirements!
- Beware of testing more than you need



# Comparison of Food Types

EU	US	MERCOSUR	China
Hydrophilic (aqueous)	Aqueous (pH >5)	Aqueous (pH>4.5)	Aqueous (pH ≥ 5)
Acidic (pH <4.5)	Acidic (pH <5)	Acidic (pH <4.5)	Acidic (pH <5)
Alcoholic (ETOH <20%)	Alcoholic (ETOH <15%)	Alcoholic (ETOH <10%)	Alcoholic (ETOH ≤20%)
--	--	--	Alcoholic (ETOH 20%-50%)
Alcohol (ETOH >20%)	Alcoholic (ETOH >15%)	Alcoholic (ETOH >10%)	Alcoholic (ETOH >50%)
Oil-in-Water Emulsions	Oil-in-Water Emulsions	Oil-in-water emulsions	Oil-in-water emulsions
Surface Fats	Fatty	Fatty	Fatty
Dry	--	--	--

# Comparison of Simulants

Food Type	EU	US	MERCOSUR	China
Aqueous (pH >5/4.5)	10% ETOH	10% ETOH	Water	10% ETOH
Acidic (pH <4.5/5)	3% AA	↓	3% AA	4% AA
Alcoholic (<10% ETOH)	↑		10% ETOH	↑
Alcoholic (>15% ETOH)		20% ETOH	50% ETOH	
Alcoholic (<20% ETOH)	↑	↓	Actual %	50% ETOH
Alcoholic (20-50% ETOH)			50% ETOH	Actual %
Alcoholic (>50% ETOH)	50% ETOH	10% ETOH	50% ETOH	50% ETOH
Oil-in-Water	Veg. Oil	Oil (food or synthetic)	Oil (food or synthetic)	Veg. oil
Fatty	Tenax	--	--	--
Dry				

# Comparison of Times/Temperatures





# Thank You

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For additional information about our food law services, please visit:  
<http://www.steptoe.com/practices-328.html>