



Migration Testing in the U.S., MERCOSUR, and China

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PIRA – Plastics & Paper

Step toe

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Migration Testing in the U.S.A.



Fundamentals

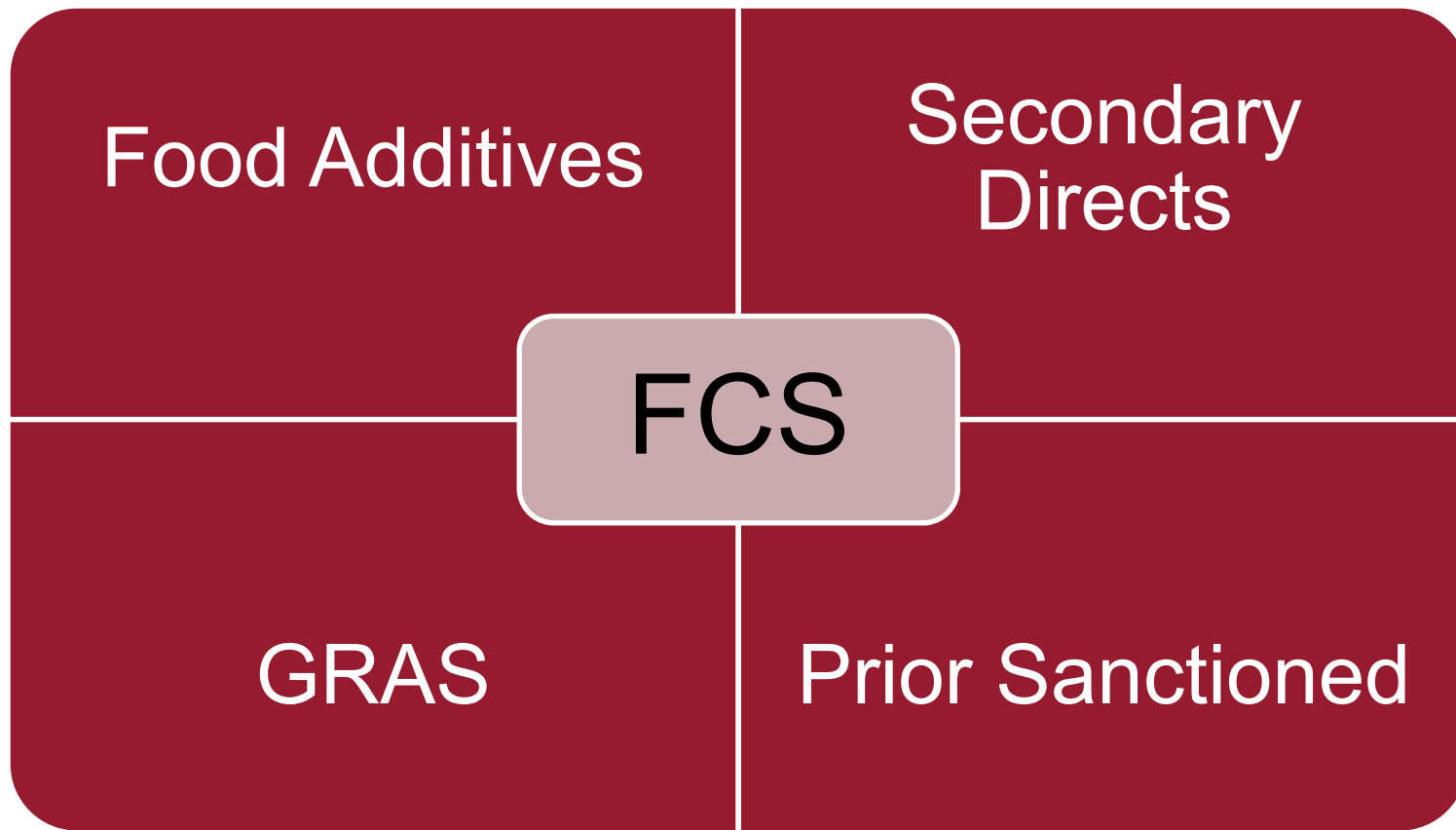
In the U.S., food-contact materials (i.e., food packaging) regulated as “food additives”

“Food additives” must have FDA pre-market clearance, since 1958 (§ 409)

An uncleared food additive that has not been the subject of FDA review is adulterated and in violation of the law *per se*

Not all food-contact materials are “food additives” and some food additives are exempt from premarket review

Food Contact Substance



What's Regulated in the U.S.?

Indirect
additives

Adhesives, Coatings, Paper, **Plastics**

Polymers and Starting Substances

Adjuvants and Processing Aids

Radiation

Secondary
directs

Boiler Water Additives

Ion Exchange Resins

Other: not
“food
additives”

GRAS Substances

Antimicrobials

Is there an
ongoing
technical effect
in the food?



What's Needed to Establish Compliance?



Chemistry Information

- Chemical identity and composition of FCS
- Properties and specifications
- Manufacturing process
- Impurities and breakdown products



Intended Conditions of Use

- Use level
- Single/repeat use
- Food types
- Conditions of use



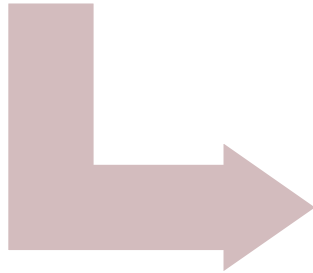
Migration and Exposure

- Level of migration, as determined by calculations, modeling, or testing
- Estimation of dietary exposure, including cumulative exposure

Calculating Migration

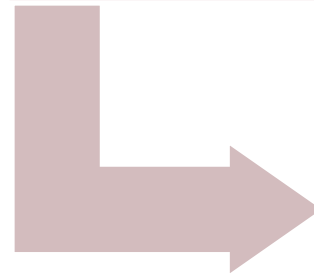
May be able to assume 100% migration of the FCS

- Formulation information
- Analysis for concentration of residual migrant in the FCS



Migration modeling

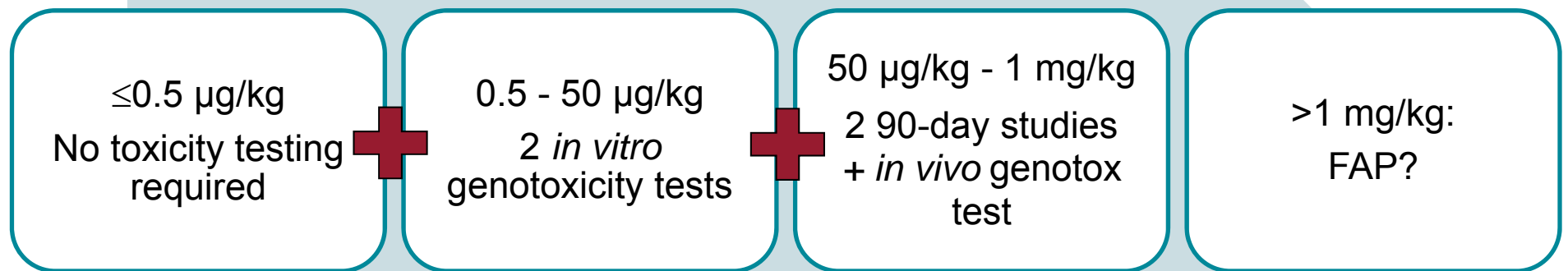
- Fickian diffusion
- Polymer constants



Migration testing

Showing Safety in the U.S.: Toxicity Data

- Migration converted to exposure through consumption factors and food type factors
 - See FDA Chemistry Guidance
- Cumulative exposure values are compared to available toxicity data on the FCS
- Toxicity data recommendations (based on exposure):



Migration Testing

- Testing conditions determined by the intended use of the product
 - Food types
 - Times and temperature of use
 - Special uses (infants?)
- Limits of detection should consider the intended use and the toxicity of the substance
- Start with FDA's *Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations*

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081818.htm>

What Foods Will Be Contacted?

- Food Types

- First defined in 21 C.F.R. § 176.170 (paper regulation)
- Updated version available online:

<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsOfUse/ucm109358.htm>

- Food Type Factors

- In FDA's Chemistry Guidance
- More simplified than the food types
- Aqueous, acidic, fatty, alcoholic

Table 1-Types of Raw and Processed Foods

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0)
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content
- IV. Dairy products and modifications:
 - A. Water-in-oil emulsions, high- or low-fat
 - B. Oil-in-water emulsions, high- or low-fat
- V. Low-moisture fats and oil
- VI. Beverages:
 - A. Containing up to 8 percent of alcohol
 - B. Nonalcoholic
 - C. Containing more than 8 percent alcohol
- VII. Bakery products other than those included under Types VIII or IX of this table:
 - A. Moist bakery products with surface containing free fat or oil
 - B. Moist bakery products with surface containing no free fat or oil
- VIII. Dry solids with the surface containing no free fat or oil (no end test required)
- IX. Dry solids with the surface containing free fat or oil

What Simulants?

- Aqueous, acidic and low alcohol foods – 10% Ethanol
 - Food types I, II, IV.B, VI.A, VI.B, and VII.B
- High-alcohol foods – 50% Ethanol
 - Food type VI.C (spirits)
- Fatty foods – food oil or synthetic fat (Miglyol 812, HB307)
 - Food types III, IVA, V, VIIA and IX
 - Cooking at temperatures >121 deg. C
 - Polyolefins – 95% ethanol
 - Rigid PVC, PS, rubber modified PS, PET – 50% Ethanol
- Currently no dry food simulant

Special Case Simulants

- Infant formula or breast milk – 50% ethanol
- High acid foods/acid-sensitive substances/transesterification
 - Water
 - 3% Acetic Acid
 - No 10% ethanol
- Wine and beer (up to 15% ethanol) – 10% ethanol
- Biopolymers – water?

Conditions of Use – Table 2

- A. High temperature heat-sterilized (e.g., over 212 deg.F)
- B. Boiling water sterilized
- C. Hot filled or pasteurized above 150 deg.F
- D. Hot filled or pasteurized below 150 deg.F
- E. Room temperature filled and stored (no thermal treatment in the container)
- F. Refrigerated storage (no thermal treatment in the container)
- G. Frozen storage (no thermal treatment in the container)
- H. Frozen or refrigerated storage: ready-prepared foods intended to be reheated in container at time of use:
 - A. Aqueous or oil-in-water emulsion of high- or low-fat
 - B. Aqueous, high- or low-free oil or fat
- I. Irradiation
- J. Cooking at temperatures exceeding 250 deg.F

FDA's Testing Protocols

- General single service testing protocols
 - A, 121 deg. C for 2 h, then 40 deg. C for 238 h
 - B, 111 deg. C for 2 h, then 40 deg. C for 238 h
 - C, 100 deg. C for 0.5 h, then 40 deg. C for 238 h
 - D, 66 deg. C for 0.5 h, then 40 deg. C for 238 h
 - E, 40 deg. C for 240 h
 - F, 20 deg. C for 240 h
 - G, 20 deg. C for 120 h
 - H, 100 deg. C for 2 h
 - I, Discuss with FDA
 - J, Maximum intended cooking time, for longest cooking time
- Repeated use
 - 10% ETOH, 50% ETOH, and fatty food simulant, at highest temperature of use

Special Cooking Applications

- Microwave-only containers
 - Testing under COU H may be sufficient
 - Fatty food simulant, at 130 deg. C for 15 mins
 - Aqueous food simulant, 100 deg. C for 15 mins
- Dual-Ovenable Trays – use COU J testing
- Microwave Susceptor – see FDA guidance

Migration Test ≠ End Test

- Several FDA regulations contain end-tests
 - E.g. 21 C.F.R. Sections 175.300, 176.170
- These are quality control test methods, NOT migration protocols
 - Gross measure of compliance with regulation
 - Different simulants, times/temperatures for tests

Validation

- Requires spiking and recovery studies
 - Spike test solutions at one-half (1/2), one (1), and two (2) times the measured concentration of the analyte in the food simulant
 - Spike in triplicate

Levels in food or food simulants ^(a)	Acceptable average recovery	Acceptable relative standard deviation
<0.1 mg/kg	60-110%	<20%
>0.1 mg/kg	80-110%	<10%

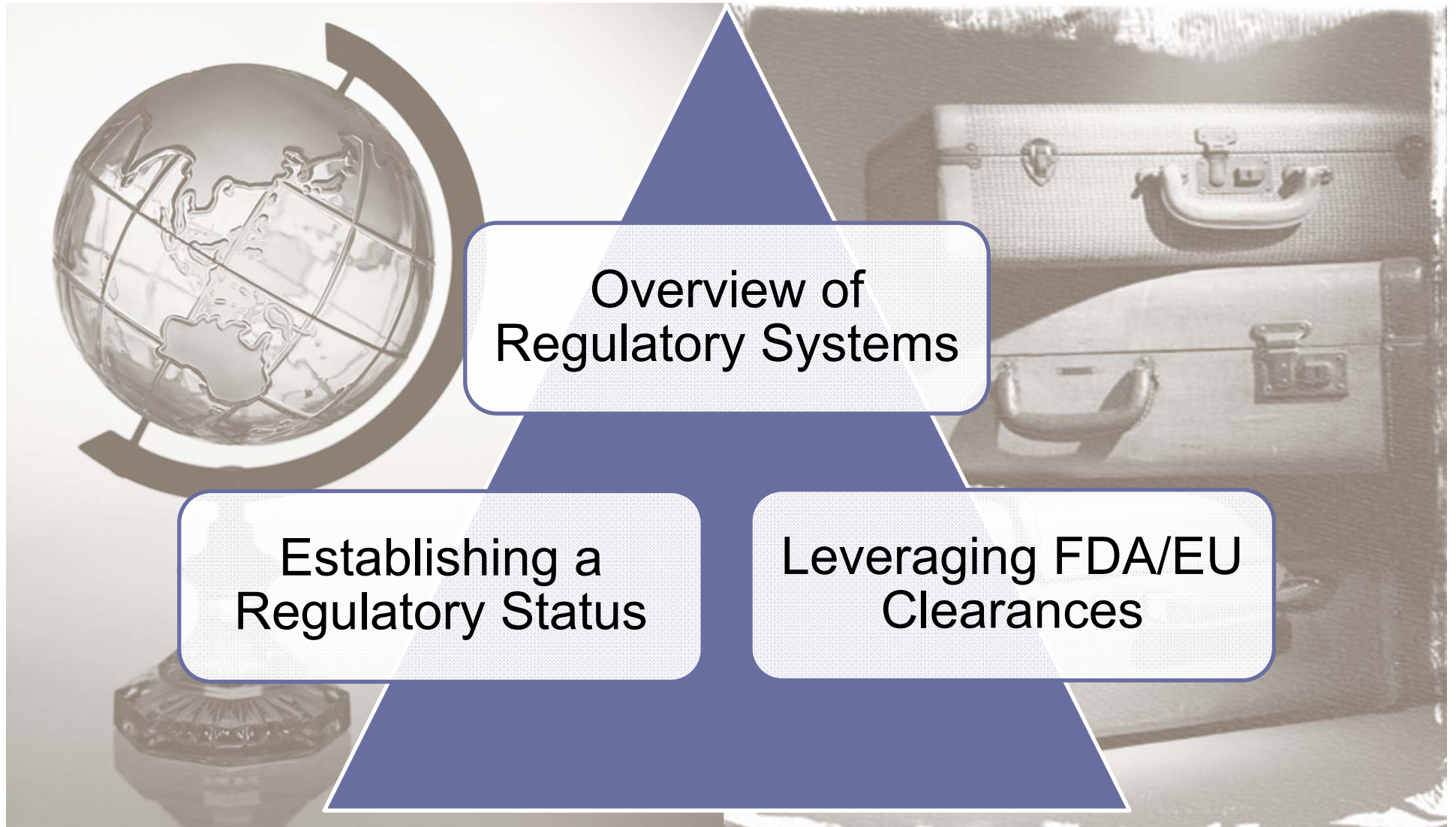
^(a)If 0.001 mg of a substance is extracted from one square inch of packaging material into 10 grams of food or food simulant, the estimated concentration in food is 0.1 mg/kg.

- If FCS was not detected, must determine the LOD for the method
- Alternatively, can validate using two independent methods

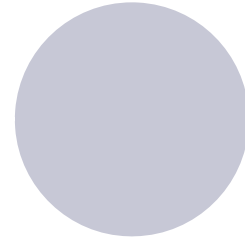
Testing in MERCOSUR



MERCOSUR+



Mercado Común del Sur



Treaty of Asunción del Paraguay: March 26, 1991



Brazil, Argentina, Paraguay, Uruguay, and Venezuela



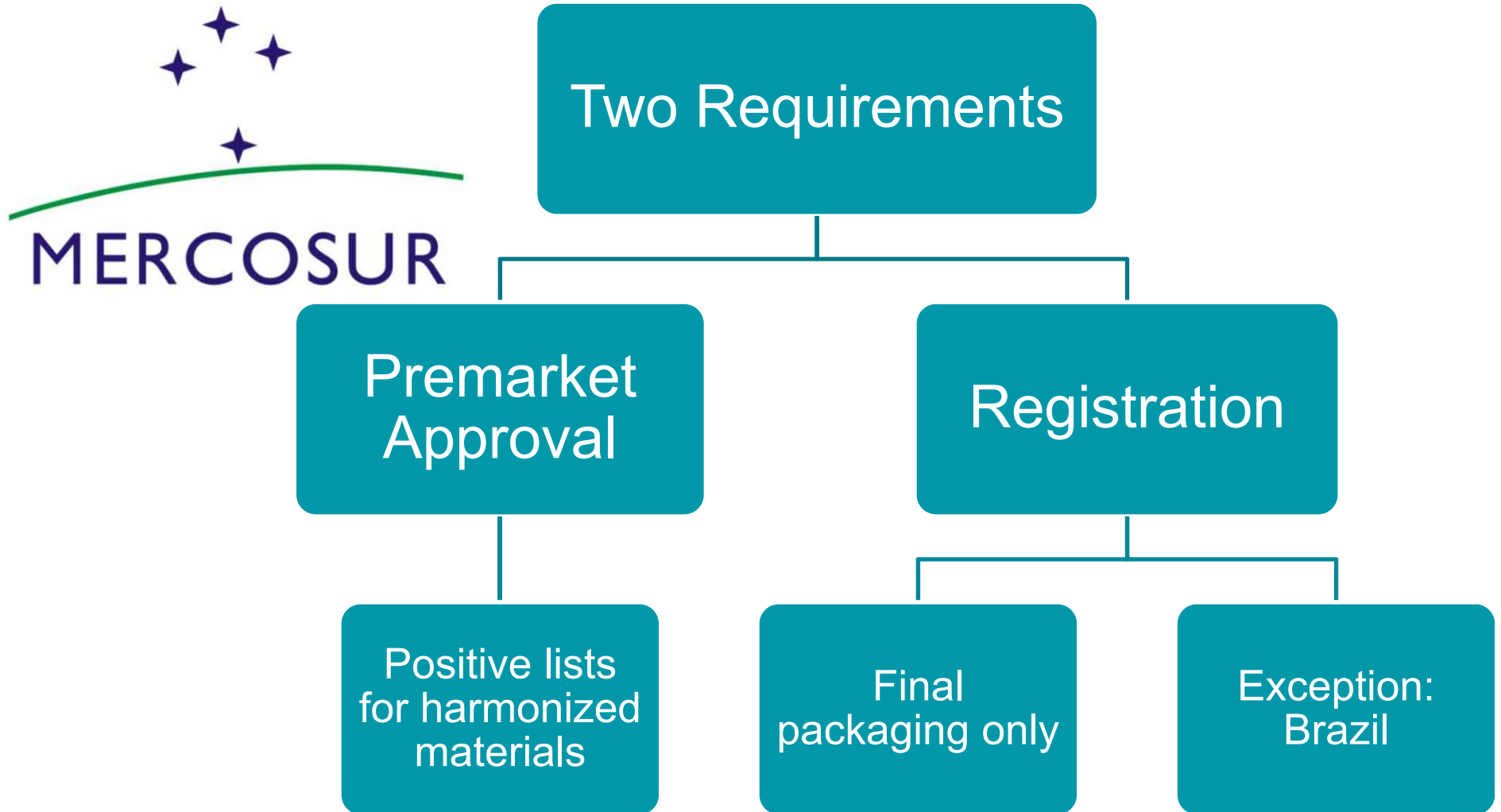
Grupo Mercado Común (GMC)



Member State Sovereignty

- GMC Resolutions must be transposed into national law

Regulatory Structure



Framework Regulation

GMC Res. 3/92



Manufactured using GMP



Suitably pure



Transfer harmful or toxic compounds



Alter organoleptic properties

General Requirements for Plastics

GMC Res. 56/92, General Provisions for Plastic Containers and Equipment in Contact with Food

- Includes multi-layer and multi-material products with plastic food contact layer
- Must be safe and suitable
- Establishes OML and limits on heavy metals and primary aromatic amines in colorants
- Generally prohibits recycled plastic
 - Regrind is permitted
 - Returnable containers are permitted

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

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

MERCOSUR GMC Res.	Brazil RDC Res.	Argentina Food Code Chapter IV
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 [^]
46/06-Metals*	20/07	SPRyRS 85/08 / SAGPyA 338/08
54/97-Elastomers	123/01	Articulo 219 bis [^]
27/99-Adhesives	91/01	Articulo 186 cuater [^]

Clearance Limitations



- Overall migration limit(s)
 - 50 mg/kg simulant, when volume >250 ml
 - Surface area cannot be determined
 - Closures with small surface area
 - 8 mg residue/dm², when volume <250 ml
- Specific migration limit(s) (LME)
- Concentration/residual limits (QM) (LC)
- Food type or condition of use

Testing: FDA vs. EU vs. MERCOSUR

- Testing for MERCOSUR is similar to the testing that was required under EU Directive 82/711
 - Directive 82/711 replaced by new EU Regulation 10/2011
 - Testing under Plastics Regulation more severe
- Testing under FDA conditions of use may be acceptable, depending on specific facts

Resolution GMC 32/99

- List of analytical methods for certain substances:
 - Vinyl acetate
 - Maleic acid / maleic anhydride
 - Methacrylic acid
 - Terephthalic acid
 - Acrylonitrile Unsulfonated primary aromatic amines in pigments and solvent soluble dye
 - Bisphenol A
 - 2,2-bis (4-hydroxyphenyl) propane-bis-2,3-epoxypropyl) ether (BADGE) (2 methods)
 - Caprolactam
 - Migration of vinylidene chloride monomer (CVDM) of objects based on poly vinylidene chloride and copolymers
 - Formaldehyde
 - 1-octene
 - 1,1,1-trimethylolpropane

Simulants (GMC 32/10)

- A (non-acidic aqueous foods (pH > 4.5)): distilled or deionized water
- B (aqueous food simulant acid (pH < 4.5)): 3% acetic acid
- C (alcoholic): 10% ethanol
 - Increase ETOH concentration to actual content if > 10%
- D (fatty food): 95% ethanol, isooctane, or MPPO (modified polyphenylene oxide)
- D': edible oils (olive oil, sunflower oil, corn oil) or synthetic triglyceride mixtures
- 50% ethanol for oil-in-water emulsions
- For colorants in plastic: coconut oil
- No dry food simulant

Times for Testing

More predictable conditions contact Severe	Conditions equivalent test (For simulant A, B, C and D, for simulant D, see Table 4)
Contact time (t)	Test time
$t \leq 5 \text{ min}$	(1)
$5 \text{ min} < t \leq 30 \text{ min}$	30 min
$30 \text{ min} < t \leq 1 \text{ h}$	1h
$1 \text{ h} < t \leq 2 \text{ h}$	2h
$2 \text{ h} < t \leq 4 \text{ h}$	4h
$4 \text{ h} < t \leq 24 \text{ h}$	24 h
$t > 24 \text{ h}$	10 days

Temperatures for Testing

<u>Contact temperature (T)</u>	<u>Test temperature</u>
$T \leq 5 \text{ } ^\circ\text{C}$	5 ° C
$5 \text{ } ^\circ\text{C} < T \leq 20 \text{ } ^\circ\text{C}$	20 °C
$20 \text{ } ^\circ\text{C} < T \leq 40 \text{ } ^\circ\text{C}$	40°C
$40 \text{ } ^\circ\text{C} < T \leq 70 \text{ } ^\circ\text{C}$	70°C
$70 \text{ } ^\circ\text{C} < T \leq 100 \text{ } ^\circ\text{C}$	100 ° C
$100 \text{ } ^\circ\text{C} < T \leq 121 \text{ } ^\circ\text{C}$	121 ° C (2)
$121 \text{ } ^\circ\text{C} < T \leq 130 \text{ } ^\circ\text{C}$	130 ° C (2)
$130 \text{ } ^\circ\text{C} < T \leq 150 \text{ } ^\circ\text{C}$	150 ° C (2)
$T > 150 \text{ } ^\circ\text{C}$	175 ° C (1) (2)

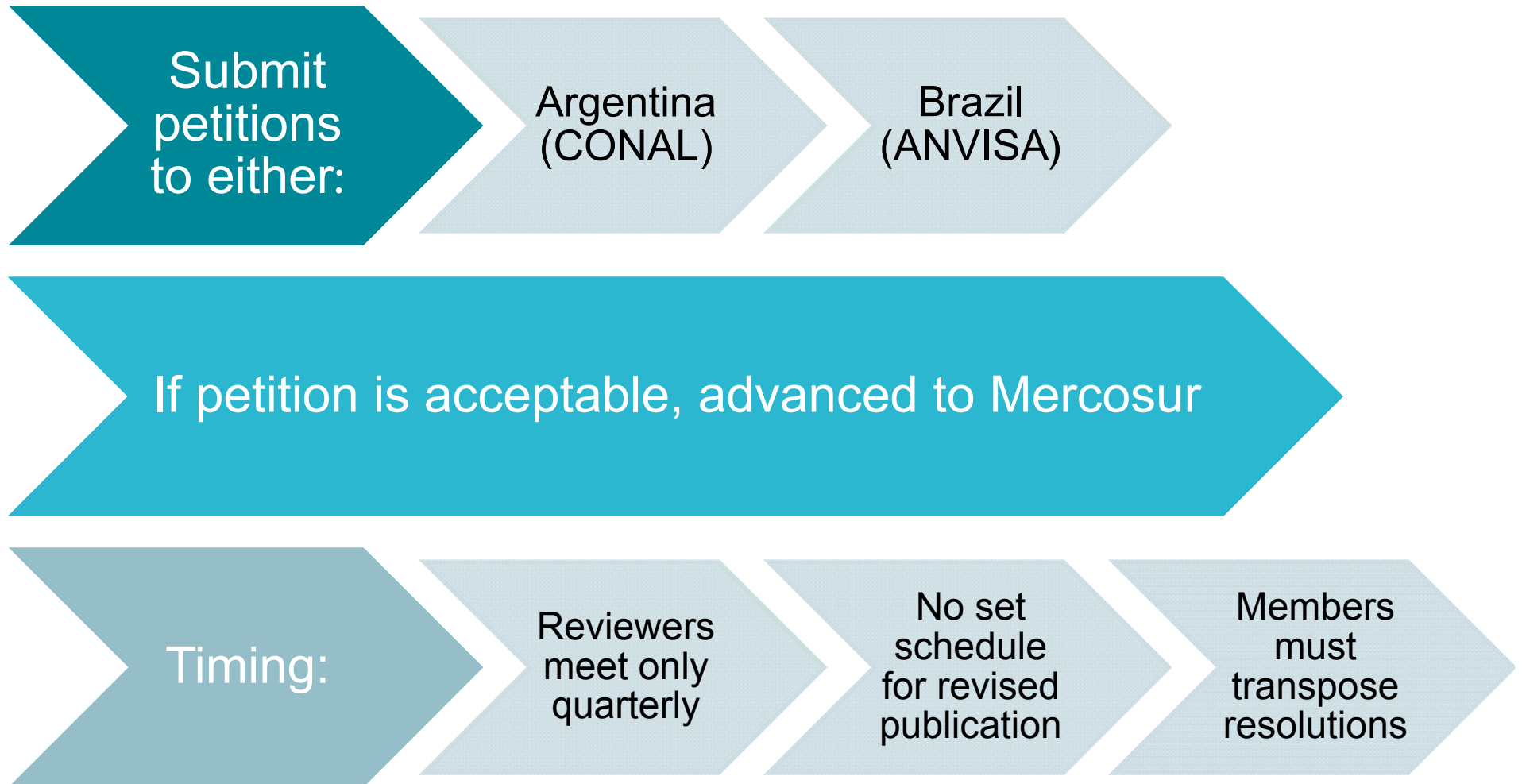
- (1): in cases where the actual conditions of contact of the plastic material and the food are not adequately covered by the test conditions of this table (for example, contact times less than 5 minutes or temperatures greater than 175° C), you can use more appropriate conditions, provided they represent the most severe conditions expected
- (2): this temperature corresponds only in the case of using D' simulant

Testing with Simulant D

Conditions of time and temperature to simulate and D't	Time and temperature conditions with simulant D		
	isooctane	aqueous solution 95% ethanol (v / v)	MPPO (oxide polyphenylene modified)
10 gives 5 ° C	12 hours at 5 ° C	10 d at 5 ° C	-
10 gives 20 ° C	1 provides 20 ° C	10 gives 20 ° C	-
10 gives 40 ° C	2 nd 20 ° C	10 gives 40 ° C	-
2 ha 70 ° C	30 min at 40 ° C	2 h at 60 ° C (1)	-
30 min at 100 ° C	30 min at 60 ° C (1)	2.5 h at 60 ° C (1)	30 min at 100 ° C
1 ha 100 ° C	1 at 60 ° C (1)	3 hours at 60 ° C (1)	1 ha 100 ° C
2 h at 100 ° C	1.5 at 60 ° C (1)	3.5 h at 60 ° C (1)	2 h at 100 ° C
30 min at 121 ° C	1.5 at 60 ° C (1)	3.5 h at 60 ° C (1)	30 min at 121 ° C
1 ha 121 ° C	2 h at 60 ° C (1)	4 h at 60 ° C (1)	1 at 121 ° C
2 h at 121 ° C	2.5 h at 60 ° C (1)	4.5 h at 60 ° C (1)	2 h at 121 ° C
30 min at 130 ° C	2 h at 60 ° C (1)	4 h at 60 ° C (1)	30 min at 130 ° C
1 ha 130 ° C	2.5 h at 60 ° C (1)	4.5 h at 60 ° C (1)	1 ha 130 ° C
2 h at 150 ° C	3 h at 60 ° C (1)	5 h at 60 ° C (1)	2 h at 150 ° C
2 h at 175 ° C	4 h at 60 ° C (1)	6 h at 60 ° C (1)	2 h at 175 ° C

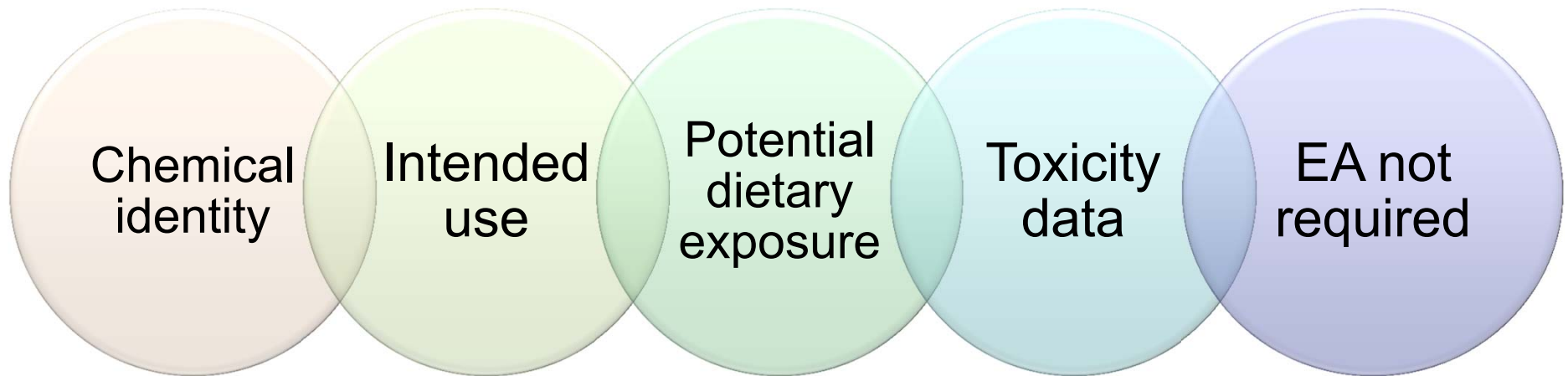
- (1): volatile simulants are used to a temperature of 60° C. Use simulant D' if does not adversely impact the physical properties of the test sample

Getting Premarket Clearance



What Goes Into the Petition

- No set requirements
 - Model after either EU dossier or FCN
 - Include final decision: EFSA opinion and FDA “effective” letter
- Petition should include:



New Clearances

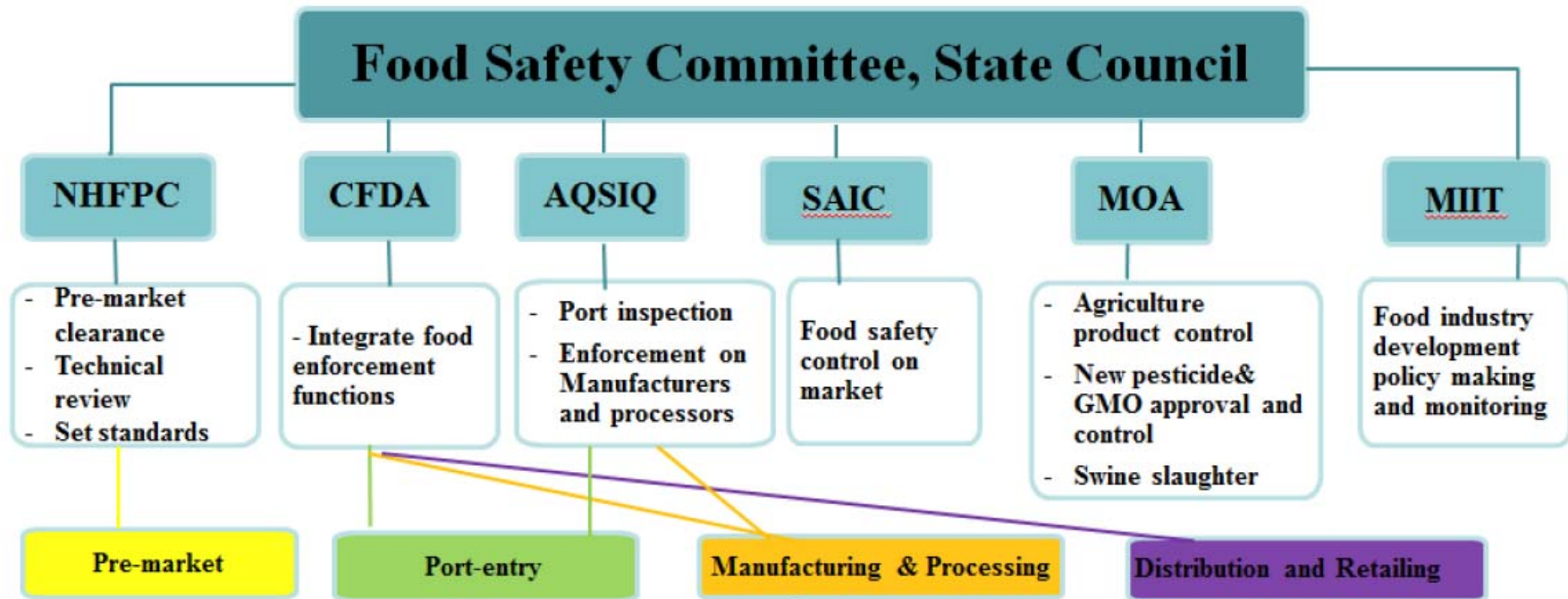
- Either EU or U.S. clearance required
 - EU: Listing on Plastics Regulation
 - U.S: Food additive regulation, FCN, TOR
 - No GRAS, but principles of low dietary exposure possible
- Full petition still required
 - Likely to be adopted with similar limitations
 - EU limits prevail
 - FCN clearances not proprietary



Testing in China



Governmental Structure



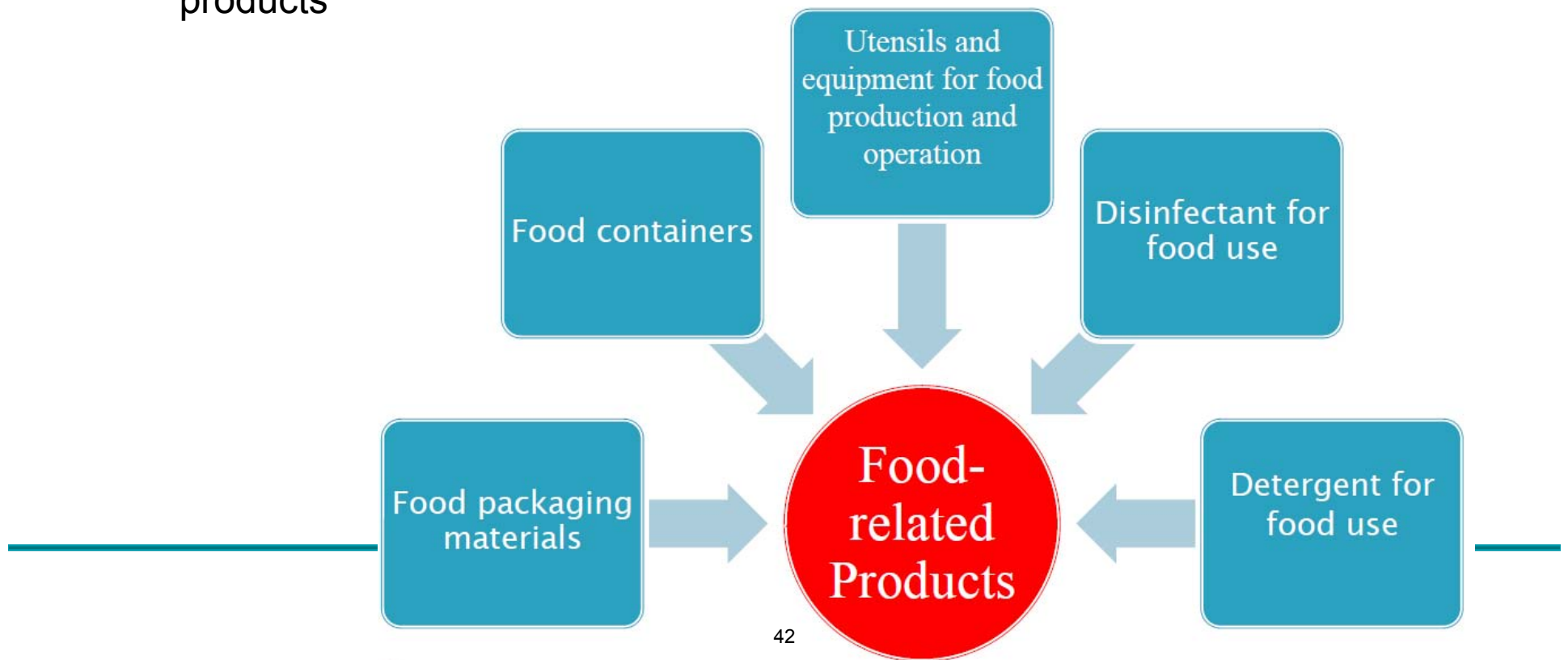
- **NHFPC**: National Health and Family Planning Commission
- **CFDA**: China Food and Drug Administration
- **AQSIQ**: Administration of Quality Supervision, Inspection and Quarantine
- **SAIC**: State Administration of Industry and Commerce
- **MOA**: Ministry of Agriculture
- **MIIT**: Ministry of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

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 9685
 - “Commodity” Standards (i.e., coatings, paper, resin standards)
 - Finished Article Standards

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”



Update to Standards

- Food standards integration
- Standards in the draft
- Standards that will be established in the future

1	Horizontal standard	General safety requirements for FCM
2		Standards for Uses of Additives in Food Contact Materials
3	Commodity standard	Plastic final material
4		Plastic resin
5		Rubber
6		Rubber nipple
7		Coating
8		Paper and paperboard
9		Glass
10		Metal and alloy
11		Ceramics
12		Detergents
13		Disinfectant
14		Disinfection of tableware
15		Adhesive
16		Bamboo and wood
17	Enamel	
18	Multilayer material	
19	Silicone rubber	
20	Lubricant	
21	Printing ink	
22	Textile fiber and textile material	
23	Manufacturing practice	General manufacturing practice for FCM
24	Test method	General principle of the migration test for FCM
25		General principle of pretreatment of the migration test for FCM
	

GB 9685

- 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

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		

Update to Commodity Standards

- NHFPC released on September 29, 2015 70 draft food safety standards, including 6 food contact-related:
 - Paper, Paperboard and Paper Products for Food Contact Use
 - Metal Materials and Products for Food Contact Use
 - Rubber Materials and Products for Food Contact Use
 - Plastic Resins for Food Contact Use
 - Plastic Materials and Products for Food Contact Use
 - Paints and Coating for Food Contact Use
- Include requirements on raw materials, sensory parameters, physical and chemical specifications, additives and migration specifications, etc.

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 = ≤ 10 mg/dm², Infants = ≤ 60 mg/kg
 - Consumption of potassium permanganate: ≤ 12 mg/kg (water, @ 60C, 2H)
 - Heavy metals: ≤ 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 α -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 ² (5-ethylidene-2-norbornene)	30	3	The residual amount, the weight ratio of the area of contact with the food less than 2 dm ² / kg

GB 31604.1 Draft Migration Testing

- Published October 30, 2015
- Proposed to be effective September 22, 2016
- Provides simulants and testing conditions
 - Compliance testing for SMLs and OML
 - Testing for new clearances
- Similar to Plastics Regulation, with some modifications

Simulants – Table 1

- Non-Acidic (aka aqueous) foods ($\leq 10\%$ ethanol, $\text{pH} \geq 5$): 10% Ethanol
- Acidic foods ($\leq 10\%$ ethanol, $\text{pH} < 5$): 4% Acetic Acid
- Alcoholic foods
 - ETOH content $\leq 20\%$: 20% ethanol
 - ETOH content 20% - 50%: 50% ethanol
 - ETOH content $> 50\%$: Actual concentration or 95% ethanol
- Fatty foods: vegetable oil (refined corn oil or olive oil)
- Oil-in-water emulsions (milk, other dairy): 50% ethanol

Simulants to Cover Multiple Categories of Food

Food Category	Simulants
All foods ^a	4% Acetic Acid Alcoholic food simulants Vegetable Oil
All foods except acidic food	Alcoholic food simulants Vegetable Oil
Non-acidic, alcoholic, milk and dairy products ^b	50% OR 95% Ethanol OR Actual concentration
Non-acidic, acidic, alcoholic, some milk and dairy products ^b	4% Acetic Acid 50% OR 95% Ethanol OR Actual concentration
Non-acidic, alcoholic (ETOH ≤20%)	20% Ethanol
Non-acidic, acidic food, alcoholic (ETOH ≤20%)	4% Acetic Acid 20% Ethanol

^a Selection of food simulants for alcoholic drink shall comply with the provisions in table 1 according to the alcohol content

^b For the specific category, see Appendix A

Times and Temperatures

Extreme Expected Time (t)	Migration test time (t)	Extreme Expected Temperature (T)	Migration Test Temperature (T)
$t \leq 0.5h$	0.5h	$T \leq 5^{\circ}C$	$5^{\circ}C$
		$5 < T \leq 20^{\circ}C$	$20^{\circ}C$
$0.5h < t \leq 1h$	1h	$20 < T \leq 40^{\circ}C$	$40^{\circ}C$
$1h < t \leq 2h$	2h	$40 < T \leq 70^{\circ}C$	$70^{\circ}C$
$2h < t \leq 6h$	6h	$70 < T \leq 100^{\circ}C$	$100^{\circ}C$ or reflux temperature
$6h < t \leq 24h$	24h	$100 < T \leq 121^{\circ}C$	$121^{\circ}C^a$
$1d < t \leq 3d$	3d	$121 < T \leq 130^{\circ}C$	$130^{\circ}C^a$
$3d < t \leq 30d$	10d	$130 < T \leq 150^{\circ}C$	$150^{\circ}C^a$
Above 30d	Comply with 5.1.1.4	$150 < T \leq 175^{\circ}C$	$175^{\circ}C^a$
--	--	$T > 175^{\circ}C$	Actual temperature of use

Microwave Uses and Extended Storage

- Microwave uses
 - Fatty food simulant, at 130 deg. C for 15 mins
 - Water soluble food simulant, 100 deg. C for 15 mins
- Extended storage
 - If multiple conditions of use expected, test as expected for use or most severe conditions

Condition of Use	Test Conditions ^a
Frozen storage > 30d	20°C, 10d
Refrigerated storage > 30d (including test conditions of T≤70°C, t≤2h or T≤100°C, t≤15 min)	40°C, 10d
Room temperature storage >30d, <180d (including test conditions of T≤70°C, t≤2h or T≤100°C, t≤15 min)	50°C, 10d
Room temperature storage >180d (including test conditions of T≤70°C, t≤2h or T≤100°C, t≤15 min)	60°C, 10d

^a The test result under higher temperature can replace the result under lower temperature. Under the same storage or use temperature, the test result under longer time can replace and cover the result under shorter time.

OML Testing

Expected conditions of use	Migration test conditions
Frozen storage and refrigerated storage no heat treatment in vessel heat in vessel before eating	20°C, 10d 100°C, 2h
Room temperature filling and long-term storage (including hot filling and pasteurization under the conditions of $T \leq 70^\circ\text{C}$, $t \leq 2\text{h}$ or $T \leq 100^\circ\text{C}$, $t \leq 15\text{ min}$)	40°C, 10d
Hot filling and pasteurization under the conditions of $T \leq 70^\circ\text{C}$, $t \leq 2\text{h}$ or $T \leq 100^\circ\text{C}$, $t \leq 15\text{ min}$, no long-term storage at or under room temperature	70°C, 2h
Use under the conditions of $T \leq 100^\circ\text{C}$, $t > 15\text{ min}$ (such as cooking or boiling disinfection)	100°C, 1h
Use under the conditions of $T \leq 121^\circ\text{C}$ (high temperature sterilization or distillation)	100°C or reflux temperature, 2h; or 121°C, 1h
Contact with aqueous, acidic, and alcoholic food (ETOH $\leq 20\%$) under the condition of $T > 40^\circ\text{C}$	100°C or reflux temperature, 4h
Use under the conditions of $T > 121^\circ\text{C}$ (such as high bake)	175°C, 2h (only vegetable oil)

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
- GMP Standard forthcoming
- Clearances will be hybrid of international listings
- System very much in development

