



# Overview of the World Legislation on Adhesives: Part 1

8 November 2018

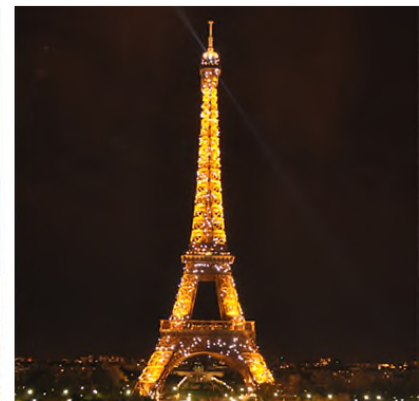
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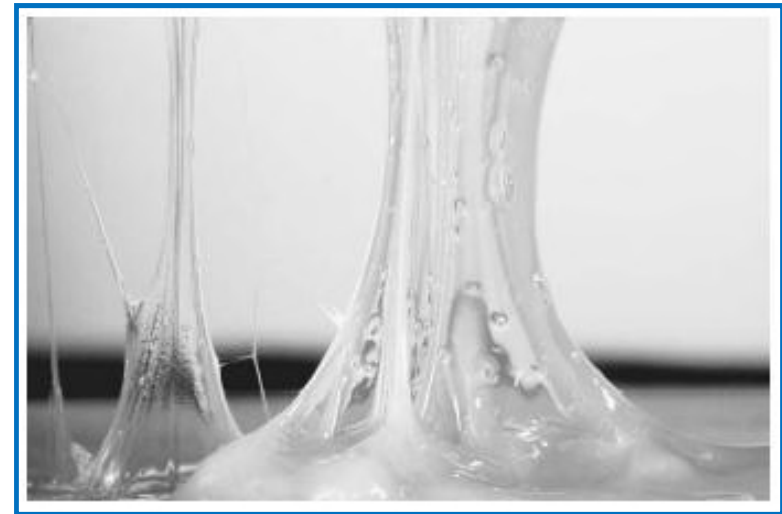


# Agenda: Part 1

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- EU
  - EU legislation
  - Member State legislation
- Mercosur

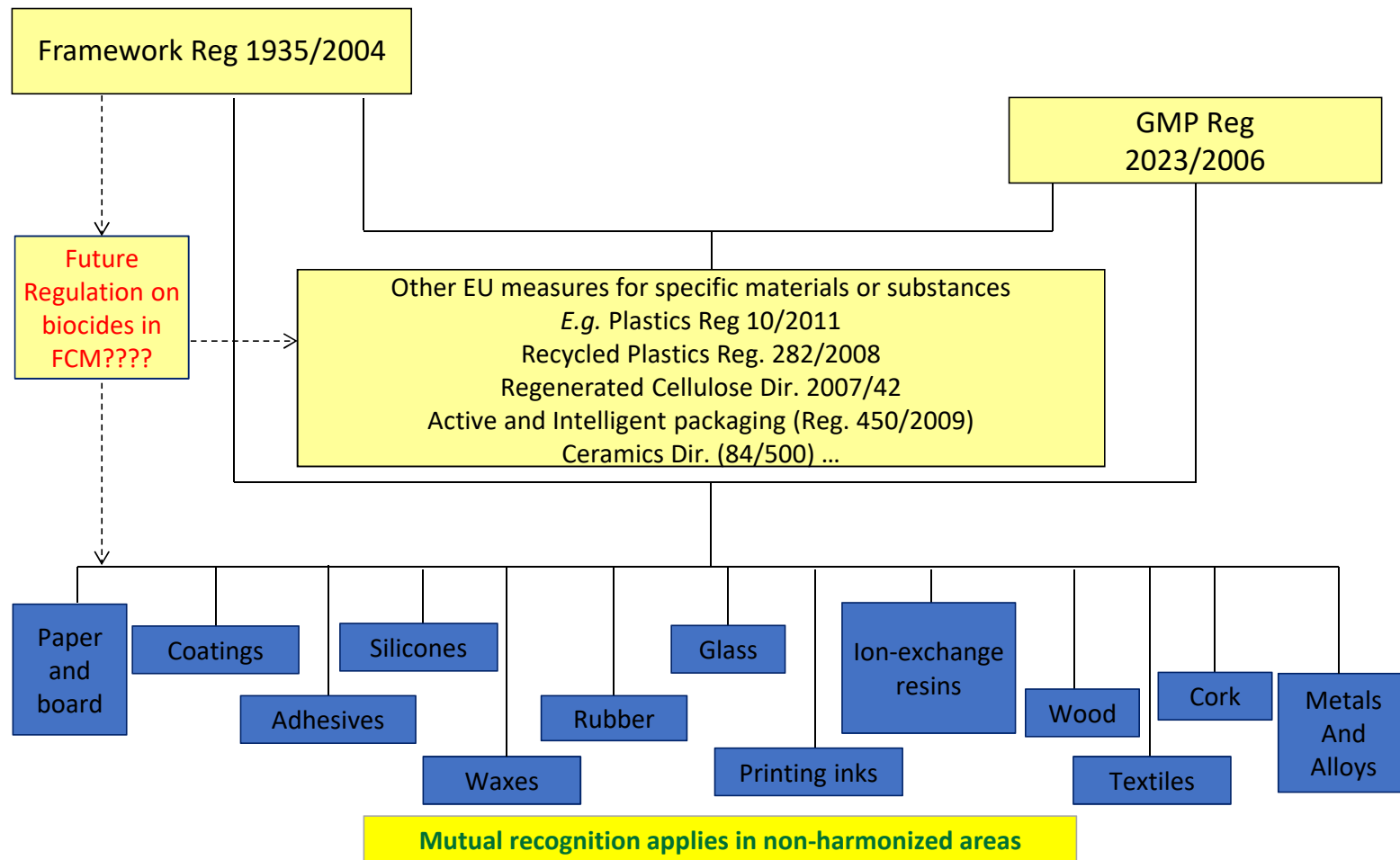


# EU legislation



- EU Harmonized Legislation
  - Framework Regulation (EC) No. 1935/2004
  - Good Manufacturing Practice (GMP) Regulation (EC) No. 2023/2006
  - Plastics Regulation (EC) No. 10/2011
  - Other specific measures under Framework Regulation
- EU MSs Legislation
  - Spain
  - Italy
  - The Netherlands
  - Croatia
  - Germany (BfR Recs)

# Overview of Structure of EU Food-Contact Legislation



# Horizontal Harmonized Legislation

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- The EU Framework Regulation
- The EU GMP Regulation

# Framework Regulation 1935/2004

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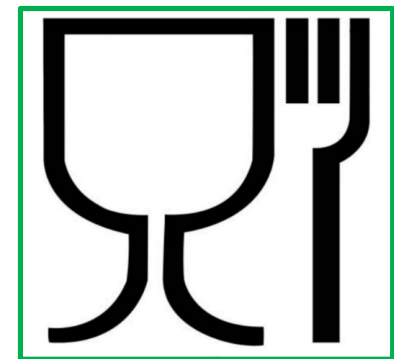
- **ALL** Food Contact Materials & Articles (M&As) intended for **direct** and **indirect contact with food**
- Applies to **M&As** (...) which **in their finished** state:
  - a) are **intended** to be brought into contact with food; or
  - b) are **already in contact** with food and were intended for that purpose; or
  - c) can reasonably be **expected to be brought into contact** with food or to **transfer their constituents** to food under normal or foreseeable conditions of use.

# Framework Regulation

- Article 3.1: M&As must be manufactured in compliance with **GMP** so as to **not transfer their constituents** to food in quantities which could:

SAFETY	a) <b>endanger human health</b> ; or
INERTNESS	b) bring about an <b>unacceptable change</b> in the <b>composition of the food</b> ; or
	c) bring about a <b>deterioration in the organoleptic characteristics</b> thereof.

- Specific labeling and traceability requirements**





# Framework Regulation

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- **Legal basis** for adoption of harmonized legislation
  - 17 groups identified
- Provides **EU authorization procedure** for substances subject to positive listing at EU level
- Requires **Declarations of Compliance (DoC)** in harmonized legislation and allows Member States to set DoC requirements for non-harmonized FCMs (e.g. adhesives)
- Identifies **rights of Member States (MSs)**

# GMP Regulation 2023/2006



- Applies to **all sectors** and to **all stages of manufacture, processing and distribution** of M&A, up to but **excluding** the production of **starting substances**
- Business operators must establish and maintain
  - **Quality assurance** system
  - **Quality control** system
  - **Appropriate (supporting) documentation** in paper or electronic format



# GMP Regulation

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## Specific rules for

- **Printing inks not intended to come into contact with food**
- **Quality assurance system for plastic recycling processes**



# EU Specific Legislation (adhesives-related)

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- Plastics Regulation (EC) No. 10/2011
  - Draft 12th amendment to the Plastics Regulation
- Other specific measures under Framework Regulation
  - Epoxy Derivatives Regulation (EC) No. 1895/2005



# Plastics Regulation



Within



- Printed/coated plastic multilayers with **ADHESIVES**
- Plastic layers/coatings, forming gaskets in caps and closures
- Plastic layers in multi-material multilayers

Outside



- Ion exchange resins
- Rubber
- Silicones

- Does not harmonize composition of inks, **ADHESIVES** and coatings (except coatings forming gaskets in caps and closures)

# Plastics Regulation



- Applies without prejudice to the EU or Member State provisions applicable to adhesives
- The final plastic multi-layer M&As (including components of adhesives) must comply with, *inter alia*,
  - SMLs set out in the Plastics Regulation
  - Provisions on dual-use additives
  - Overall Migration Limit

**Components of adhesives not subject to positive list requirements of Plastic Regulation**

# Plastics Regulation – update on Phthalates



- European Food Safety Authority (EFSA) is re-evaluating:
  - *Di-butylphthalate* (DBP, FCM No 157)
  - *Bis(2-ethylhexyl)phthalate* (DEHP, FCM No 283)
  - *Butyl-benzyl-phthalate* (BBP, FCM No 159)
  - *Phthalic acid, diesters with primary, saturated C<sub>8</sub>-C<sub>10</sub> branched alcohols, more than 60 % C<sub>9</sub>* (DINP, FCM No 728)
  - *Phthalic acid, diesters with primary, saturated C<sub>9</sub>-C<sub>11</sub> alcohols more than 90 % C<sub>10</sub>* (DIDP, FCM No 728)
- Deadline: December 2018
- **FEICA Guidance:**
  - Annex II - Rejection List: Phthalates should not exceed concentrations of 0,1%.

# Epoxy Derivatives Regulation



- Applies to M&As manufactured using BADGE, BFDGE and NOGE
  - M&As = (i) of any types of plastics, (ii) M&As covered by surface coatings and (iii) adhesives
  - Does not apply to containers or storage tanks having a capacity greater than 10,000 litres or to pipelines belonging to or connected with them and covered by heavy-duty coatings
  
- **BADGE** : **SML = 9 mg/kg**
- **BFDGE** : **banned**
- **NOGE** : **banned**
  
- DoC requirement for M&A containing BADGE and its derivatives



# Member States legislation on adhesives

## Non-Harmonized FCMs

- Spain
- Italy
- Netherlands
- Croatia
- Germany (BfR)



# Spain



- Royal Decree 847/2011 regulates non-harmonized polymeric materials
  - Applicable to **ADHESIVES**
  - Monomers, additives and other starting substances authorized for use in polymeric materials must be
    - Listed in Annex I of the Royal Decree; or
    - Listed in the Plastics Regulation; or
    - “Legally authorized” in another EU Member State/EEA/Turkey



# Spain



- Aids to polymerization and PPAs may be used in the manufacture of polymeric materials provided that they are
  - Listed in Spanish Resolution of 2 November 1982 or
  - “Legally authorized” in another EU Member State
- Generic SML of 60 mg/kg applies to monomers, additives and other starting substances not subject to a SML or other restriction
- OML = 10 mg/dm<sup>2</sup> (60 mg/kg in certain circumstances)
- Cross-reference to testing times, temperatures and simulants in the Plastics Regulation
- Mutual recognition clause for finished materials and articles lawfully manufactured or marketed in another EU Member State



# Italy



- General requirements and positive list for components of adhesives intended for use on plastic or paper
- Positive list in Annex II, Section 3, Part D of the Italian Ministerial Decree of 21 March, 1973
- Adhesives merely used to seal seams of finished paper products not subject to positive list requirements, provided there is no bleeding from the seams to the layer intended to contact the food
- Adhesive may also separated from food by barrier layer

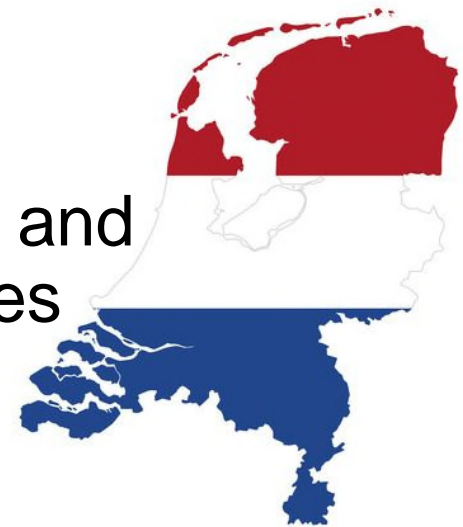


# The Netherlands

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- Dutch Packaging and Consumer Articles Regulation
  - No chapter on adhesives in the Dutch Packaging and Consumer Articles Regulation
    - General requirements of Chapter 0
    - Mutual recognition clause
- Chapters II (Paper and Paperboard), IX (Wood and Cork), and X (Coatings) contain lists of adhesives



- Ordinance on Health Suitability of Materials and Articles Intended to Come into Direct Contact with Food (2009)
  - Specific provisions on adhesives including
    - adhesives connecting pipes
    - adhesives in multi-layer films, notably polyurethane adhesives



# German BfR Recommendations\*



Adhesives:	Positive List
Rec. XXVIII. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials dated 1 January 2010 <a href="https://bfr.ble.de/kse/faces/resources/pdf/280-english.pdf">https://bfr.ble.de/kse/faces/resources/pdf/280-english.pdf</a>	✓
Rec. LII: Fillers dated 1 September 2017 <a href="https://bfr.ble.de/kse/faces/resources/pdf/520-english.pdf">https://bfr.ble.de/kse/faces/resources/pdf/520-english.pdf</a>	✓



**\*Not legally binding**

# Mercosur





# Mercosur

## ■ Treaty of Asunción del Paraguay: March 1991

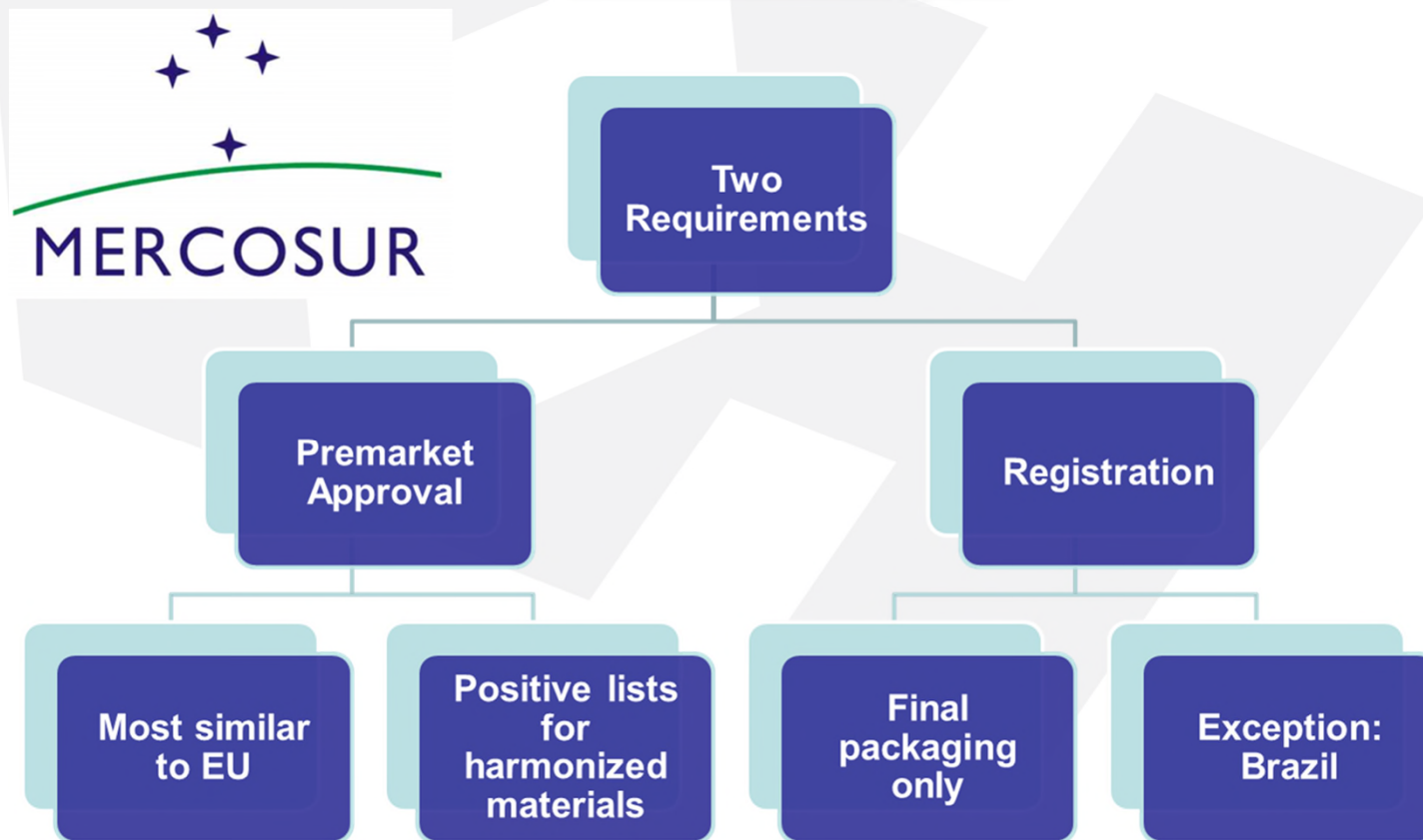
- Trade Group in South America
- Promote free trade
- Harmonize national legislation while maintaining Member State sovereignty

## ■ Members

- **Argentina** (1991)
- **Brazil** (1991)
- **Paraguay** (1991)
- **Uruguay** (1991)
- **Bolivia** (2018)
- **Venezuela** (suspended)



# • What is the Regulatory Framework?



# Mercosur technical regulations/resolutions

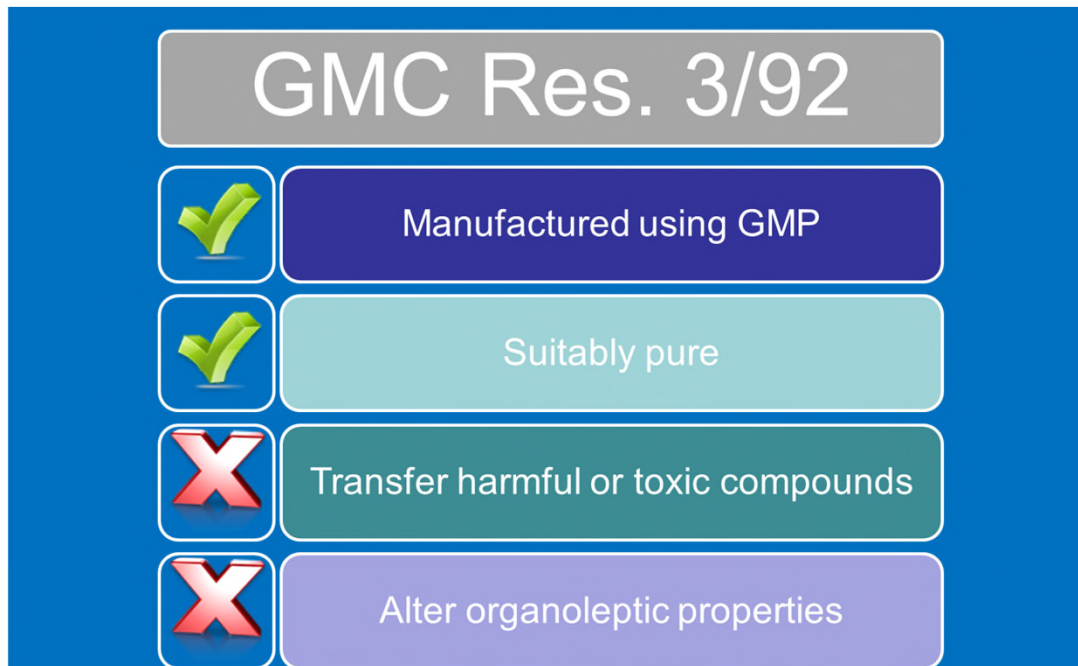
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- Mercosur Resolutions on FCMs used in the manufacture of packaging and equipment intended to enter into contact with foods
  - Must be transposed into Mercosur Member State legislation

# General Safety Standard

- GMC Res. No. 3/92: General Criteria for packaging and articles to come into contact with foodstuff



**\*\*Basic requirements  
substantially the same  
as EU Framework  
Regulation**

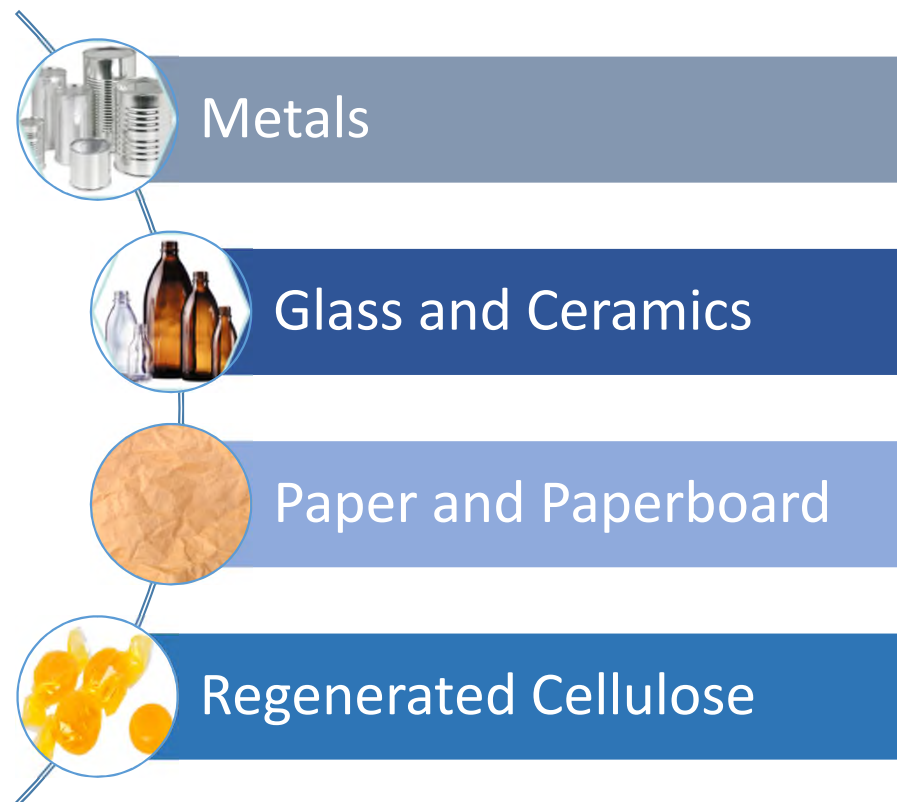
# Food-Contact Materials Covered



- Mercosur/GMC/RES No. 3/92
  - Food packaging and equipment are defined broadly
    - Includes any article used with food during processing, storage, marketing, and consumption of food
    - Examples: packaging, containers, machinery, conveyor belts, pipes, equipment, fittings, valves, utensils and the like



# What Materials are Specifically Regulated?



## Mercosur/GMC/RES No. 27/99 on adhesives

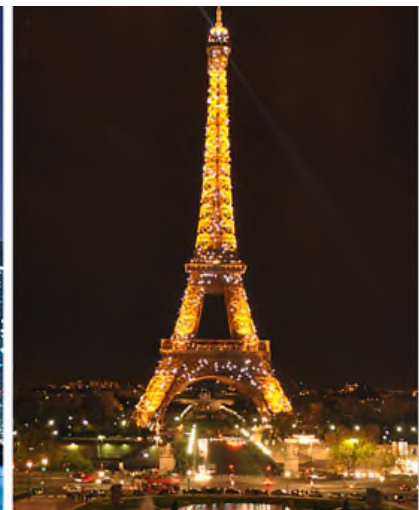
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- Substances permitted in the manufacture of adhesives must be listed in:
  - Positive list of **polymers and resins for containers and plastic equipment** in contact with foods
  - Positive list of **additives for plastic materials intended for the preparation of containers and equipment** in contact with foods
  - Positive list for **containers and cellulose equipment** in contact with foods
  - Positive list for **containers and elastomeric equipment** in contact with foods

- The amount of adhesive in contact with food at joints and edges of laminates should be minimal and at GMP level
- Necessary tests should be performed to verify compliance with GMC Res. No. 3/92
- Labeling requirement:
  - “Adhesive for [material (s) to which it is intended for use] for the manufacture of articles in contact with food”





# THANK YOU

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# Overview of the World Legislation on Adhesives: Part 2

8 November 2018

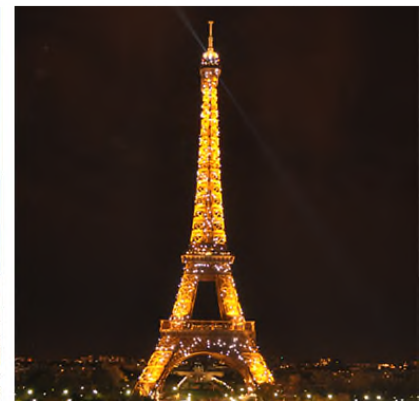
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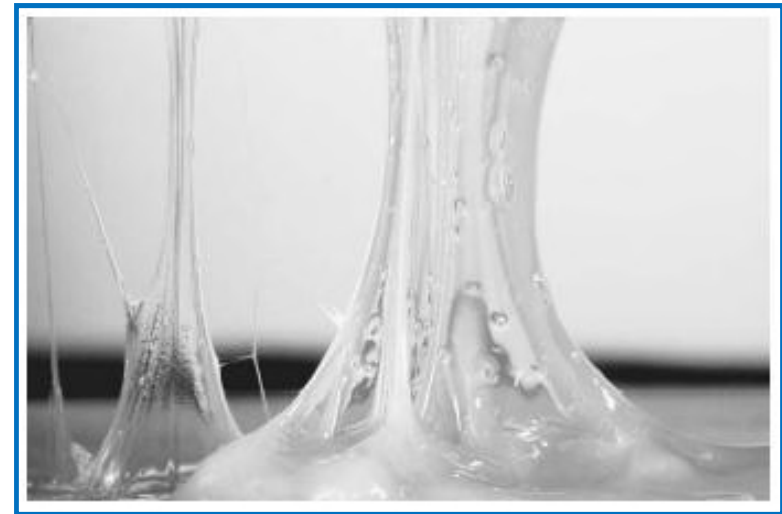


# Agenda: Part 2

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- The United States
- China
- Japan



# The United States



# General Principles

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- The U.S. Food and Drug Administration ('FDA') has authority to require premarket clearance of only those components of adhesives that are “food additives”
- Adhesives may also be used based on available exemptions, e.g., “no migration,” General Recognition of Safety
- Must meet suitable purity standard of 21 CFR 174.5 (FDA's good manufacturing practices regulation for food-contact materials)

# FDA - Adhesives

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- Explicitly Cleared Adhesives
  - 21 C.F.R. 175.105 (“Adhesives”)
  - 21 C.F.R. 175.125 (“Pressure sensitive adhesives”)
  - 21 C.F.R. § 177.1390 (“Laminate structures for use at temperatures of 250 °F and above”)
  - 21 C.F.R. § 177.1395 (“Laminate structures for use at temperatures between 120 °F and 250 °F”)
  - Food Contact Notifications
  - Threshold of Regulation listings

# Adhesives Cleared under Section 175.105

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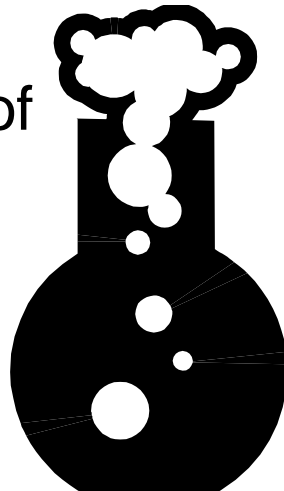


- List of cleared components (175.105(c))
- Generally Recognized As Safe ('GRAS') substances
- Substances prior-sanctioned for use in adhesives
- Flavoring substances permitted for use in food provided that the flavoring substances are volatilized from the adhesive during the packaging fabrication process
- Color additives approved for use in food
- Substances permitted for use in adhesives under other regulations, provided that such substances meet the specifications of the other regulation

## Section 175.105 Permits Reactions



- Under the mixture doctrine, mixtures of cleared materials are also cleared
- Reaction products are not usually covered, but Section 175.105 is one of the exceptions
  - 175.105 anticipates reaction of components in the curing of the adhesive





# Permitted Use Conditions for Adhesives

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- Adhesives cleared under Section 175.105 must be either
  - (a) separated from food by a functional barrier, or
  - (b) used so that quantity of adhesive contacting food does not exceed the limits of good manufacturing practice (GMP).
- For aqueous and fatty foods, GMP requires that the adhesive may contact food only in trace amounts at seams and edges

# Functional Barrier

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- Adhesive used in multilayer film laminate
- Food-contact layer is a 0.5 mil LDPE film
- Adhesive contains 1% low MW oligomers with average MW of ~500 daltons
- Finished package used to hold food at room temperature
- Question: Is food-contact layer a functional barrier to adhesive under intended conditions of use?

# Functional Barrier

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- FDA considers the following to be functional barriers for all possible migrants:
- Aluminum foil
- PET film 1 mil (25  $\mu\text{m}$ ) thick, for room temperature applications
- Polyolefins not considered all-purpose functional barrier

## Section 175.105 Labeling Requirement

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- To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement “food packaging adhesive.”



# China



# Food Safety Law (FSL)



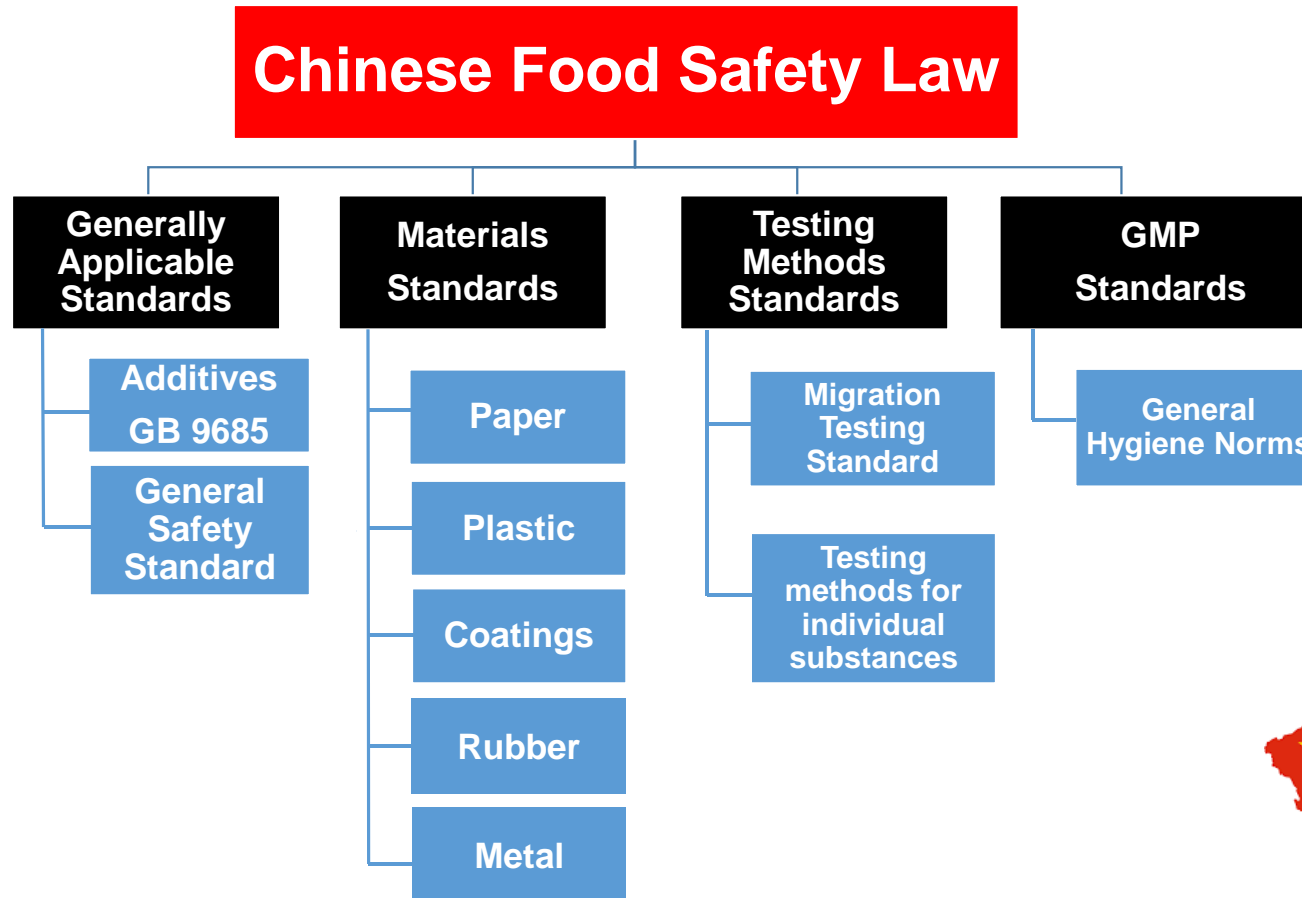
On June 1, 2009, China adopted a new overarching Food Safety Law



- Replaced 1995 Food Hygiene Law
- Amendment: October 1, 2015
- Draft Implementing Regulation (ongoing)
- Mandates regulation of “food-related products” (e.g., food packaging, disinfectants, detergents, etc.)



# Food-Contact GB Standards



# GB 4806.1-2016: General Safety Standard



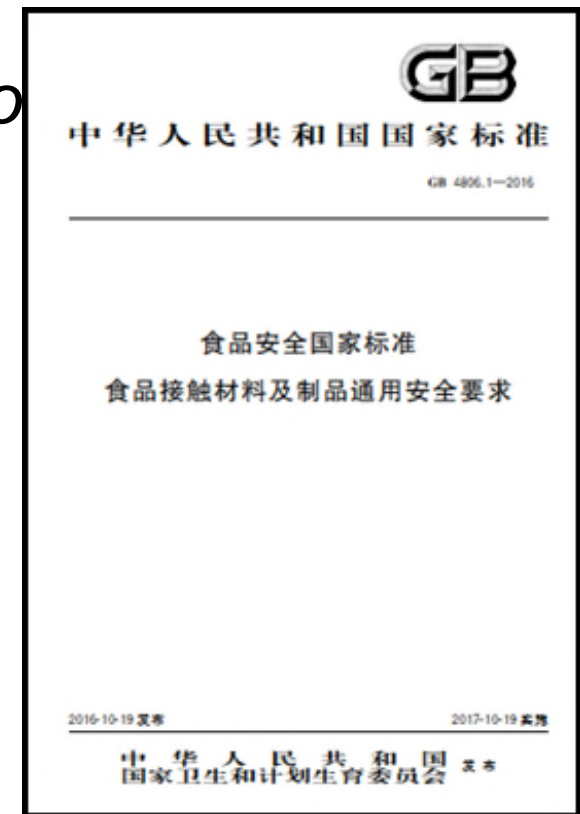
## *General Safety Requirements for Contact Materials and Articles*

- ✓ Applies generally to all food-contact materials and articles
- ✓ Took effect on October 19, 2017

**SAFETY  
FIRST!**



For





# GB 4806.1-2016: General Safety Standard



## Basic requirements relating to FCMs and articles

- ✓ Must not migrate to food at levels that endanger human health
- ✓ Must not impart changes to ingredients, structure, or properties of food (e.g., color, taste, aroma) when in contact with food
- ✓ Must not have any technical effect in food
- ✓ Must be manufactured in keeping with GMP (GB 31603)



# GB 4806.1-2016: General Safety Standard



## Functional barrier:

- 1) A barrier composed of one / more materials used to prevent migration to food of substances behind it
- 2) Migration of unlisted substance must be  $\leq 0.01$  mg/kg (or 10 ppb)

## Requirements

- Manufacturer must perform safety assessment on and control unlisted substances behind the functional barrier to ensure migration  $\leq 0.01$  mg/kg
- Unlisted substance is not a carcinogen, mutagen, or reproductive toxin (CMR) or nanomaterials

➤ *Unlisted substances may be used in food packaging provided that the above criteria are met*



# GB 4806.1-2016: General Safety Standard

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- Other provisions of note:
  - Declaration of Compliance requirement
  - Labelling requirements
  - Non-intentionally added substances not required to be listed

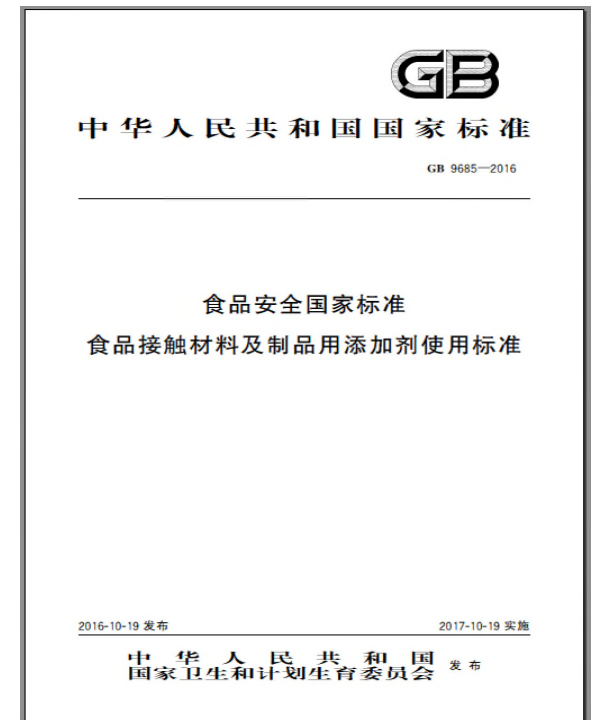


# GB 9685-2016



- Applies to additives used in food-contact materials and articles
- Took effect on 19 October 2017
- “*Additives in food contact materials and articles*”

Substances added during the manufacturing process of food contact materials and articles that assist in improving the quality and properties or aid to improve the quality and properties; also include processing aids added to promote smooth production rather than improve the quality or properties of the final product



# GB 9685-2016: Appendix A



## Positive List of Additives

### ***MANY* new clearances added to the positive list**

- Additives in Appendix A increased from 958 to 1294

### **Permits certain substances that are not explicitly listed**

- ✓ Mixtures of cleared additives, **IF** no chemical reaction occurs
- ✓ Food additives: Only those listed in Table A.2 of GB 2760, **IF** they perform no technical function on food
- ✓ Hydrous forms of permitted substances
- ✓ Salts: *Sodium*, *potassium* and *calcium* salts (including acidic salts and double salts) of listed acids, alcohols, and phenols
- ✓ Polymers: Separately approved food-contact resins having a molecular weight greater than 1,000 Daltons



# GB 9685-2016: Appendix A

## ■ Table A Includes 7 Tables

- **Table A.1** Additives permitted for use in plastic materials and articles
- **Table A.2** Coatings
- **Table A.3** Rubber
- **Table A.4** Printing inks
- **Table A.5** Adhesives
- **Table A.6** Paper
- **Table A.7** Silicone rubber and others



Substance listings contain the following contents:

FCA No.	Chinese Name	CASRN	Use Scope & Max. Use Level	SML/QM (mg/kg)	SML(T) (mg/kg)	SML(T) No.	Other Requirements

# Permitted Additives and Resins

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- Additives and Resins used in adhesives must currently be either
  - Listed in Table A.5 (Additives) of GB 9685 or
  - Included in the 107 Resin list (list of resins compiled following “clean-up” procedure)OR
  - Approved via the administrative process under the Management Rules
- In all cases applicable restrictions/specifications must be met
- Possible exemption: the functional barrier doctrine

# China – draft Adhesives Standard

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- Chinese draft standard for adhesives:
  - Is currently being prepared by the China National Centre for Food Safety Risk Assessment ('CFSA')
  - Is likely to be released for comments by the end 2018/early 2019
- Proposes to separate adhesives into two categories
  - Direct food contact adhesives
  - Indirect food contact adhesives
    - Separate positive lists for each category





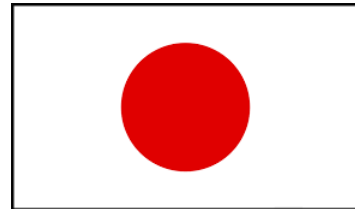
# China – draft Adhesives Standard



- Substances in the positive lists would be mainly from
  - GB 9685,
  - the 107-Resin List and
  - administrative approvals under the Management Rules.
- Specifications would be set for finished food-contact materials and articles that contain adhesives, e.g.,
  - OML
  - potassium permanganate consumption
  - heavy metals
  - Same as other GB standards for various food-contact materials, a cross-reference to the GSS, i.e., GB 4806.1, will be included



# Japan



# Japan – Legislation



- The Ministry of Health, Labour, and Welfare (MHLW) administers the **Food Sanitation Act** (1947)



- The Food Safety Commission (FSC) administers the **Food Safety Basic Law** (2003)

# Japan – Food Sanitation Act



## ■ Food Sanitation Act – **Article 16**

- Prohibits utensils and packaging that
  - Contain substances that are toxic or harmful to human health
  - Contact food or food additives, and have a harmful effect posing a risk to human health



# Japan – Legislation



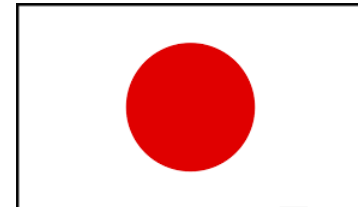
- Under Food Sanitation Act, **Article 18**, Ministry of Health, Labour, and Welfare (MHLW) has authority to specify standards for packaging materials and has done so:
  - General Specifications applicable to all containers/packaging (e.g. limits heavy metals, colorants must be approved unless no migration)
  - Material-Specific Standards (none for adhesives)
  - Specifications that apply to end-uses (performance based)
- These specifications and standards are *mandatory*



# Japan – Voluntary Management Rules



- Lists of raw materials for utensils, containers and packaging
  - Developed by industry-related organizations
  - Positive List (PL) → for acceptable raw materials, e.g.:
    - Japan Hygienic PVC Association
    - Japan Hygienic Olefin and Styrene Plastics Association
    - Japan Hygienic Association of Vinylidene Chloride
    - Japan Thermosetting Plastics Industry Association
    - Society of Rubber Science and Technology, Japan
- Negative List (NL) → unacceptable raw materials, e.g.:
  - **Japan Adhesive Industry Association**
    - Negative list of food packaging adhesives (VI edition)
  - Japan Printing Ink Makers Association



# Japan – Latest Developments

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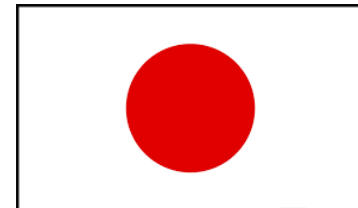


- MHLW moves closer to Positive List System
- In June 2017, MHLW's Committee on the Regulation of Food Utensils, Containers and Packaging published final report detailing steps to develop and implement a positive list system for Utensils, Packaging, Containers:
  - Positive list system will start with *synthetic resins*
    - Will cover monomers, base polymers, additives
  - New system will conduct risk assessments in line with global standards
  - Report notes proprietary system in place in U.S. and suggests consideration of same

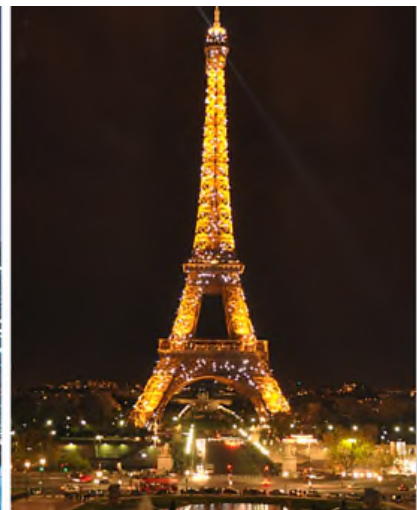
# Japan – Revised Food Sanitation Act



- Transition to a positive list system for regulating food-contact materials on 1 April 2020
- The new scheme seems an extension of the existing private associations' voluntary management practices
- MHLW is examining necessities and priorities for materials other than synthetic resins including adhesives focusing on:
  - The need to launch safety assurance measures based on the type and scale of potential risks for each material
  - The need to identify the current situation in Japan and other countries







# THANK YOU

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