



# Regulation of Plastic Additives Used in Contact with Food

June 14, 2023

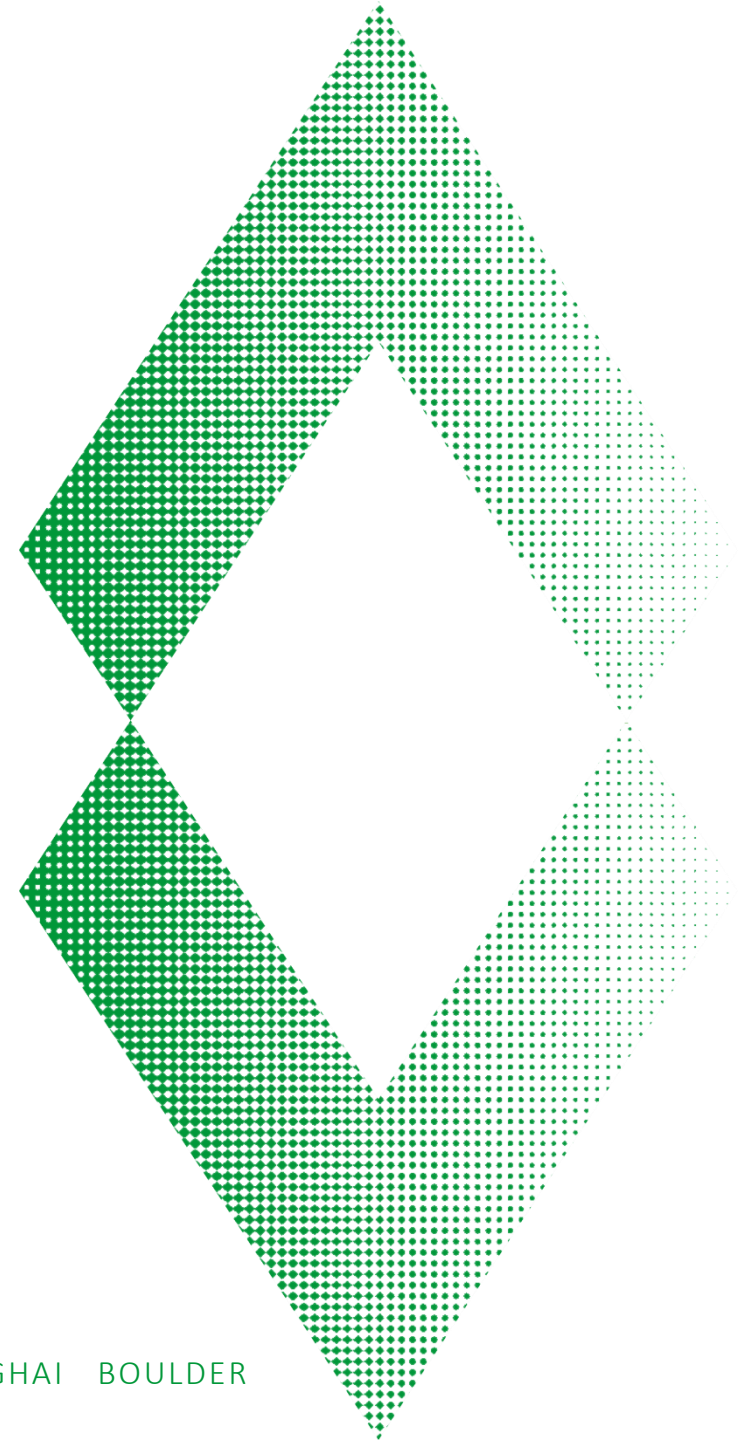
Kathryn C. Skaggs

Partner

Washington, DC

202.434.4247

skaggs@khlaw.com



# Agenda

- ◆ **Overview of regulation of additives for food-contact plastics**
  - ◆ United States
  - ◆ European Union
  - ◆ China
- ◆ **Discussion of emerging issues**
  - ◆ Chemical-specific regulations
  - ◆ Risk-assessment challenges
- ◆ **Summary and conclusions**



# U.S. Food Contact Regulations



- ◆ Federal Food, Drug, and Cosmetic Act prohibits adulteration of food
  
- ◆ Food packaging may adulterate food if it:
  - ◆ Makes food unsafe
  - ◆ Makes the food unfit for consumption (e.g., imparts off-taste or odor)
  - ◆ **Meets the *food additive* definition, and is not the subject of an FDA premarket clearance**

- ◆ Definition of *food additive*:
  - ◇ “...any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food...”
  
- ◆ Exemptions from the definition include:
  - Generally Recognized as Safe (GRAS) substances
  - Prior sanctioned substances
  - Pesticide residues on raw agricultural commodities and processed food
  - Pesticide chemicals
  - Color additives
  - New animal drugs
  - Dietary supplements

# Types of Food Additives



**Direct**

Food ingredients



**Secondary direct**

Added to food during processing  
but removed



**Indirect**

# Food Contact Substance Definition



- ◆ Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in food
- ◆ Not all food contact substances meet the food additive definition
- ◆ A food contact substance requires FDA premarket clearance only if it meets the food additive definition (*i.e.*, it is reasonably expected to become a component of food)

# Evaluating U.S. Status of FCS (1)

- ◆ Is the product already cleared by FDA?
  - ◇ Food additive regulation (21 C.F.R. § 170-199)
  - ◇ Threshold of Regulation exemption
  - ◇ Food Contact Notification
- ◆ Is an exemption from clearance available?
  - ◇ Prior Sanction
  - ◇ GRAS
  - ◇ No Migration
  - ◇ Other
- ◆ If FDA premarket review is needed, what mechanism should be used?
  - ◇ Food Contact Notification
  - ◇ Threshold of Regulation
  - ◇ Food Additive Petition



# FDA Food Additive Regulations

- ◆ Housed at 21 C.F.R. § 170-199
  - ◆ Title 21 CFR Part 175 — Adhesives and Coatings
  - ◆ Part 176 — Paper and Paperboard
  - ◆ Part 177 — Polymers
  - ◆ **Part 178 — Adjuvants, Production Aids, Sanitizers**
  - ◆ Part 181 — Prior Sanctions
  - ◆ Part 182 — GRAS Substances
  - ◆ Part 184 — Direct Additives Affirmed as GRAS
  - ◆ Part 186 — Indirect Additives Affirmed as GRAS



CODE OF FEDERAL  
REGULATIONS

## Title 21 Food and Drugs

Parts 170 to 199

Revised as of April 1, 2018

Containing a codification of documents  
of general applicability and future effect

As of April 1, 2018

Published by the Office of the Federal Register  
National Archives and Records Administration  
as a Special Edition of the Federal Register

<http://www.federalregister.gov>

# Food Additive Regulation Compliance

- ◆ Is the clearance applicable to the intended use of the FCS?
  - ◆ Limitations on type of use
  - ◆ Limitations on use level
  - ◆ Limitations on food type
  - ◆ Limitations of temperature of use
  - ◆ End-test specifications

# Basic Resin Doctrine

- ◆ In clearing resins/polymers, FDA does not generally dictate the manufacturing process
- ◆ Clearance of basic resin/polymer subsumes clearance of the reaction control agents (catalysts, initiators, chain terminating agents)
- ◆ Four criteria are relevant:
  - ◇ Integral to the polymerization process
  - ◇ Used in small quantities
  - ◇ Washed out or becomes part of the polymer backbone
  - ◇ Does not adversely impact suitable purity of the polymer

# No Migration Exemption

- ◆ What does “no migration” mean?
  - ◇ Default of 50 ppb
  - ◇ 10 ppb or less in some cases
    - Toxicity concerns
    - High levels of use
- ◆ No migration conclusion can be supported by the following:
  - ◇ 100% migration calculations
  - ◇ Diffusion modeling under relevant conditions of use
  - ◇ Analytical data
- ◆ No migration exemption is a self-determination
  - ◇ Made on an independent basis without FDA review

# Generally Recognized as Safe (GRAS)

- ◆ GRAS Substances
  - ◇ Substance generally recognized, among qualified experts, as having been adequately shown to be safe under its intended conditions of use are exempt from the food additive definition
- ◆ Multiple pathways to GRAS
  - ◇ Listed in 21 C.F.R. Parts 182, 184, 186
  - ◇ Listed on FDA's Inventory of GRAS Notices
  - ◇ Self-determination
- ◆ Not a permanent determination
  - ◇ Must consider evolving toxicity data
  - ◇ Must consider evolving dietary exposure
- ◆ GRAS under attack
  - ◇ Consumer/public advocacy groups disfavor GRAS determinations



# General Safety Requirement

- ◆ FDA's Good Manufacturing Practice (GMP) requirements for food-contact substances are found at 21 C.F.R. § 174.5
  - ◆ Must be of a purity suitable for its intended use
  - ◆ Use must not impart unacceptable taste or odor to food
  - ◆ Quantity of substance in application shall be no more than necessary to accomplish intended technical effect

# Latest U.S. Developments

- ◆ Increased focus on “chemicals of concern” in packaging
  - ◇ FDA review of PFAS
  - ◇ NGO petitions to review food packaging chemicals
- ◆ State law initiatives now driving the regulation of chemicals in packaging
  - ◇ PFAS bans in food packaging
  - ◇ “Toxics in packaging” regulatory schemes
- ◆ Growing body of sustainability-related regulation, which is impacting the composition of packaging
  - ◇ Compostability standards
  - ◇ EPR schemes

# Chemical Substance Bans (NY S4008B; S 4246)



## § 27-3425. Prohibition on certain toxic substances and materials.

1. Beginning two years after the promulgation of rules and regulations pursuant to this title, no person or entity shall sell, offer for sale, or distribute into the state any packaging containing any of the following toxic substances:

(a) Ortho-phthalates;

(b) Bisphenols;

(c) Per- and polyfluoroalkyl substances (PFAS);

(d) Heavy metals and compounds, including lead, hexavalent chromium, cadmium, and mercury;

(e) Benzophenone and its derivatives;

(f) Halogenated flame retardants;

(g) Perchlorate;

(h) Formaldehyde;

(i) Toluene;

(j) Antimony and compounds;

(k) Carbon black; and

(l) UV 328 (2-(2H-benzotriazol-2-yl)-4,6-di-tert-pentylphenol).

2. Beginning two years after the promulgation of rules and regulations pursuant to this title, no person or entity shall sell, offer for sale, or distribute for use in this state any packaging containing:

(a) Polyvinyl chloride;

(b) Polystyrene; or

(c) Polycarbonate.

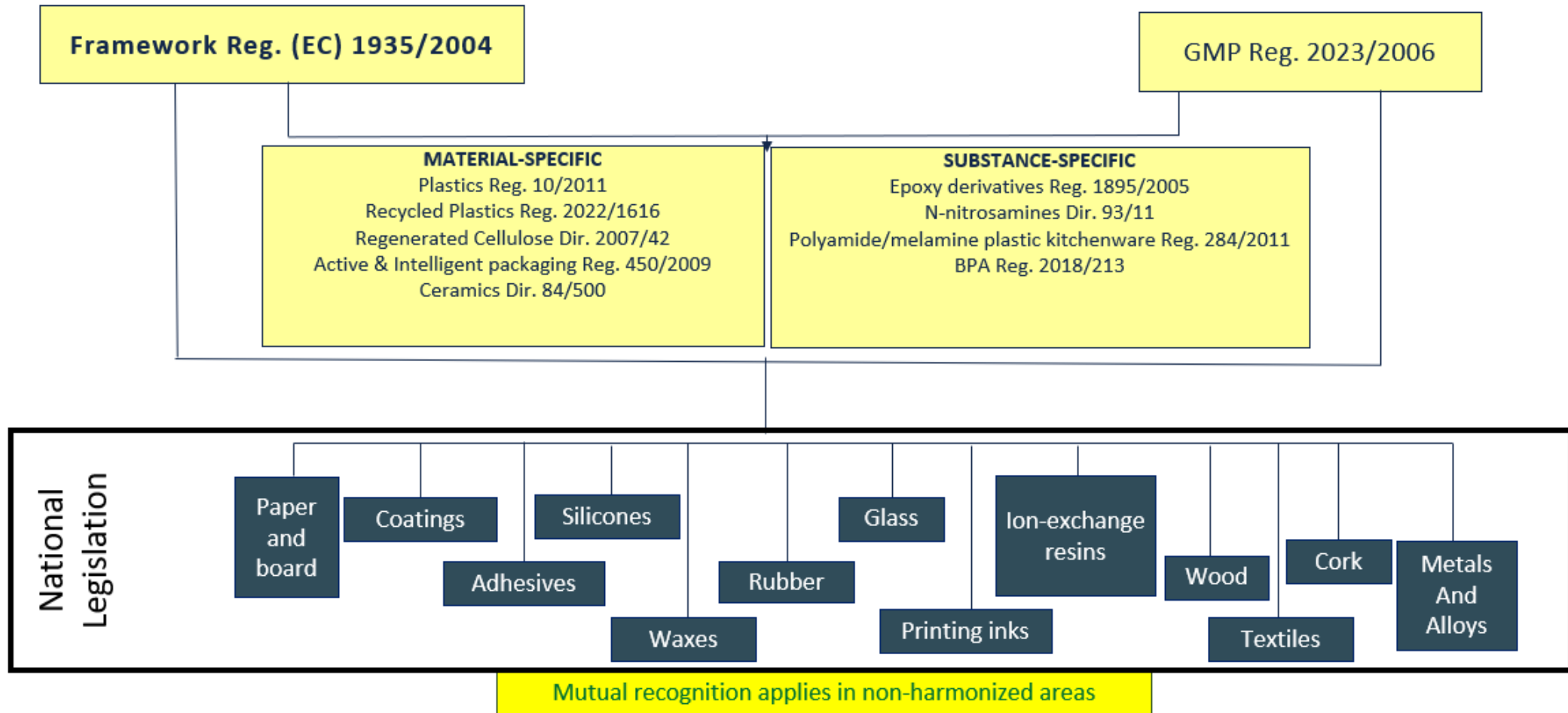




# EU Food Contact Regulations



# Overview of EU Regulation of Food-Contact Substances



# EU Regulation of Additives to Food-Contact Plastics



- ◆ EU Framework Regulation 1935/2004 covers all materials and articles intended for **direct and indirect contact with food** in the EU
  - ◆ Food packaging
  - ◆ Bulk containers
  - ◆ Housewares (*e.g.*, dishes, cutlery)
  - ◆ Food processing machinery
  - ◆ FCMs in contact with water (*e.g.*, bottles) (but does not apply to fixed public or private water supply equipment)
  
- ◆ Applies to materials and articles that, in their finished state:
  - ◆ Are intended to be brought into contact with food; or
  - ◆ Are already in contact with food and were intended for that purpose; or
  - ◆ 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

# General Safety Standard of Framework Regulation

- ◆ Framework Regulation (EC) 1935/2004, Article 3.1
  - ◇ Materials and articles must be manufactured in compliance with Good Manufacturing Process (GMP)
  - ◇ They must 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.

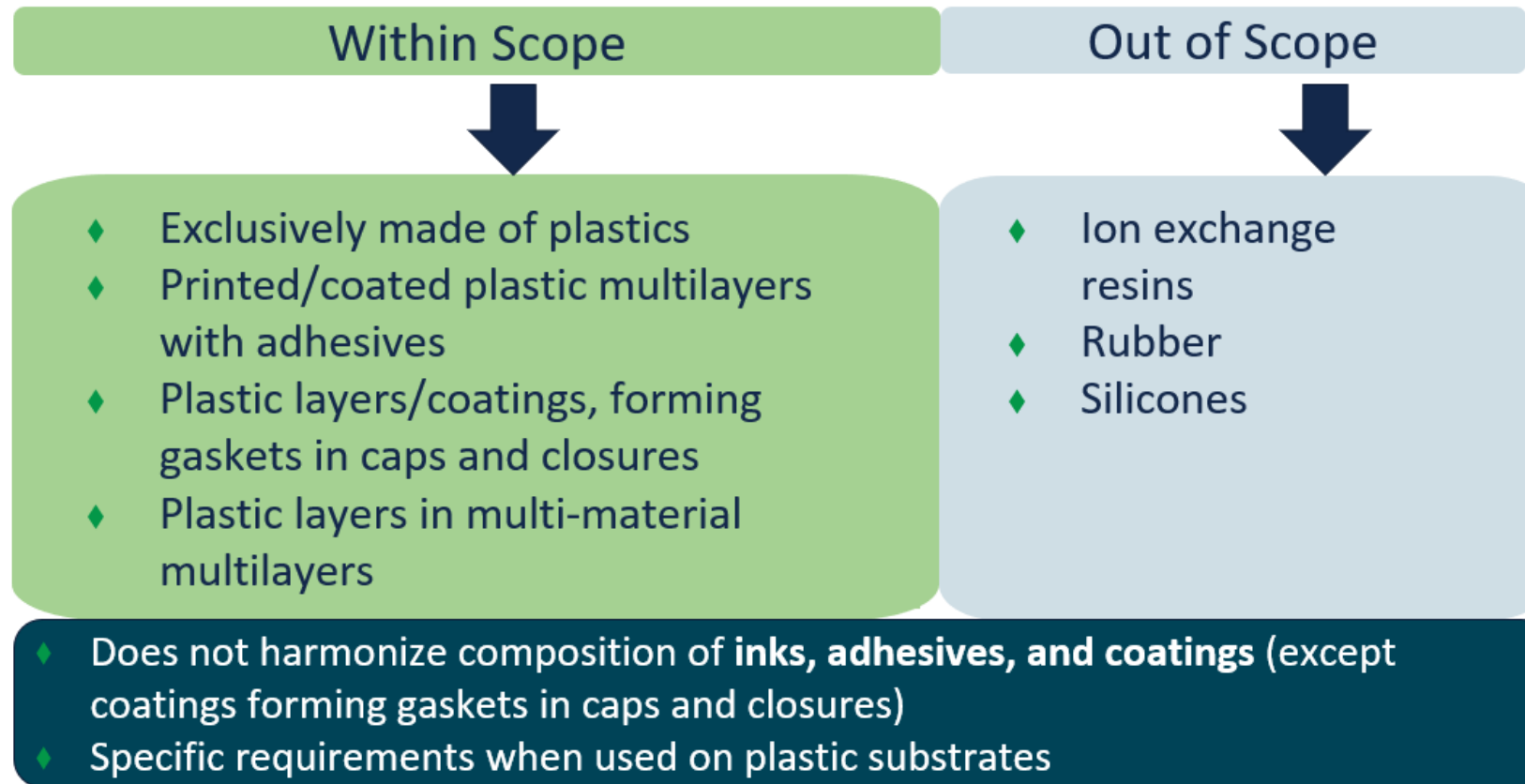
# GMP Regulation 2023/2006

- ◆ Applies to **all sectors** and to **all stages of manufacture, processing, and distribution** of materials and articles, 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



# EU Plastics Regulation (EU) 10/2011

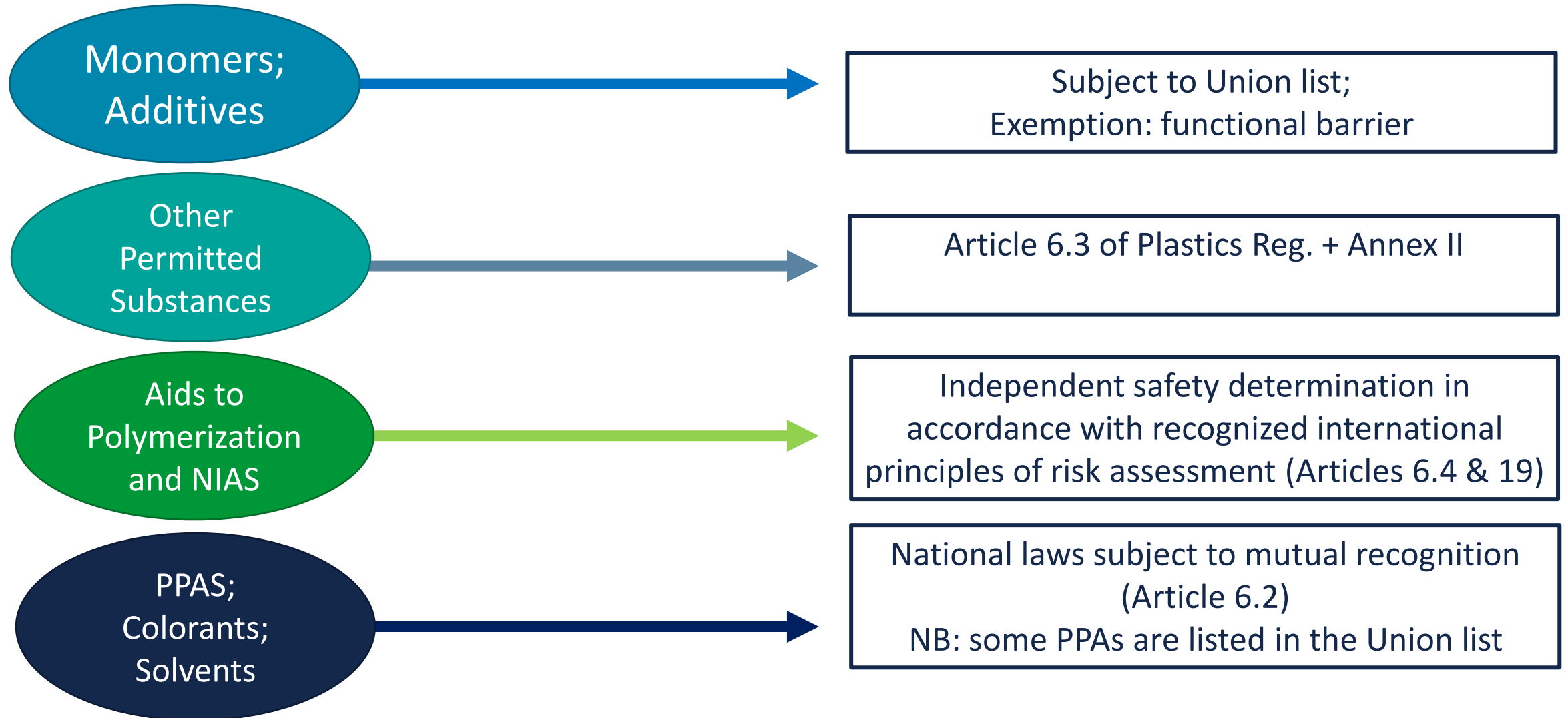
- ◆ Creates a “positive list” system for components of food-contact plastics



# Relevant Plastics Regulation Definitions

- ◆ **Additive:** substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article
- ◆ **Polymer production aid:** means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article
- ◆ **Aid to polymerization:** substance which initiates polymerization and/or controls the formation of the macromolecular structure
- ◆ **NIAS:** impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product

# Plastics Regulation Approach





# Functional Barrier Exemption

- ◆ Substances separated from food by a barrier layer are exempt from positive list
- ◆ Applies to monomers and additives
- ◆ Conditions to rely on exemption:
  - ◆ Non-listed substance must not be carcinogen, mutagen, or reproductive toxin
  - ◆ Substance must not be in nano form
  - ◆ Must be a barrier layer between food and uncleared substance
  - ◆ Must not migrate above 10 ppb

# 15<sup>th</sup> Amendment of Plastics Regulation

- ◆ Changes to Declaration of Compliance requirements
- ◆ Applies to products supplied at intermediate stages
- ◆ Requires that the **identity and concentration** of **substances in intermediate materials** be disclosed in DoC if:
  - ◆ Subject to restrictions under Annex II of the Regulation, or
  - ◆ If genotoxicity cannot be ruled out AND if migration may exceed **0.00015 mg/kg**

# Draft 16<sup>th</sup> Amendment to Plastic Regulation



Addition of new substances to positive list and clarification of existing listings

Delisting of untreated wood flour and fibers; salicylic acid

- ◇ Transitional period will be set to allow the use of these substances provided a petition will be provided within a certain timeline and certain conditions are met

SML (T) = 0.6 mg/kg; sum of DBP, DIBP, BBP, DEHP, expressed as DEHP equivalents using a defined equation

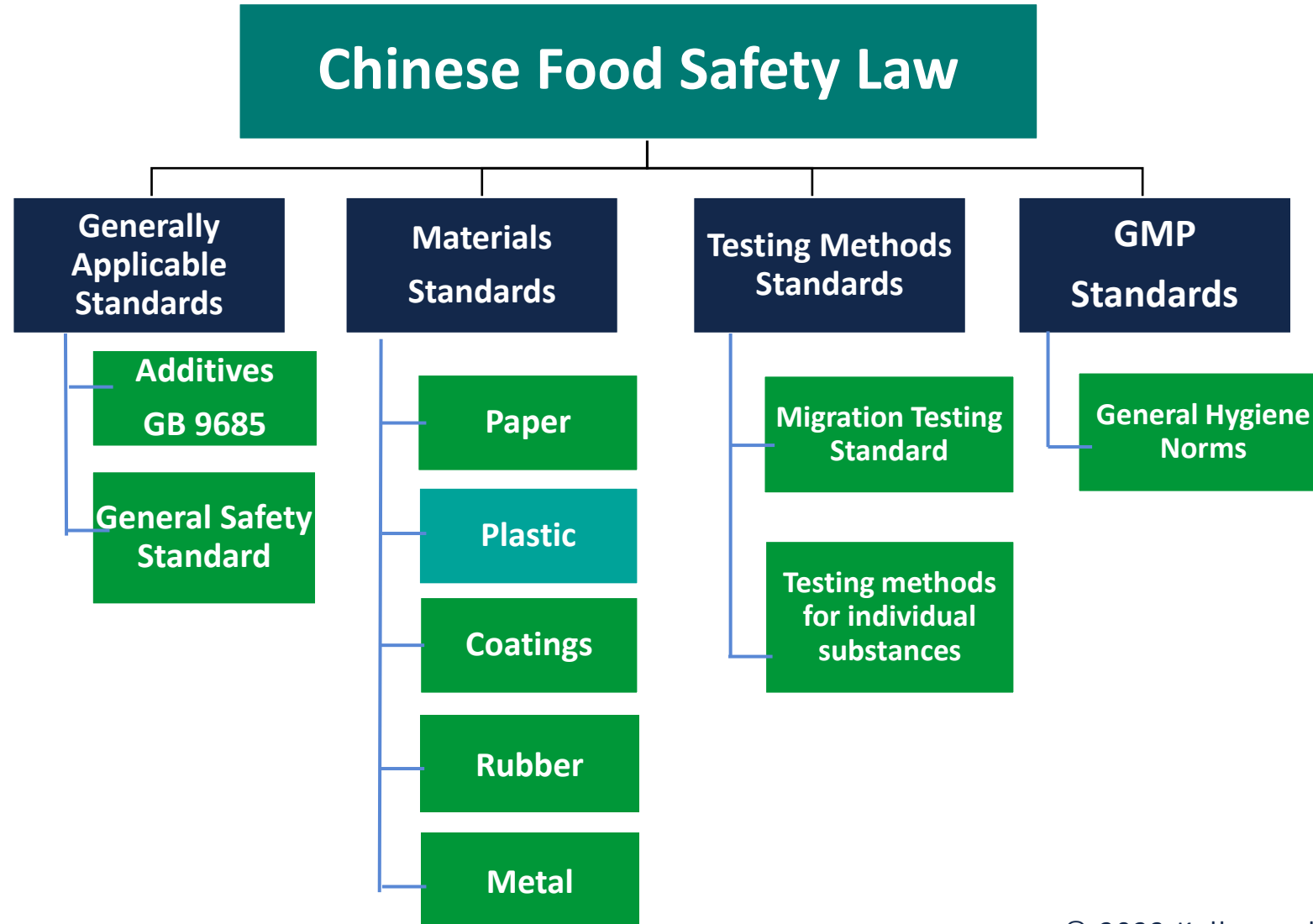
# Other Regulatory Changes

- ◆ ECHA work on PFAS
- ◆ Single-use Plastics Regulation



# China Food Contact Regulations





# China General Safety Standard (1)

- ◆ GB 4806.1-2016 – General safety applies to food-contact materials and articles
- ◆ Basic requirements for food contact substances:
  - ◇ 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
- ◆ NIAS must be safe
  - ◇ Substances that are not intentionally added, including impurities derived from raw and auxiliary materials, decomposition products, contaminants, and residual reaction intermediates resulting from production and use
  - ◇ No positive list requirement; general safety standard only

# China General Safety Standard (2)

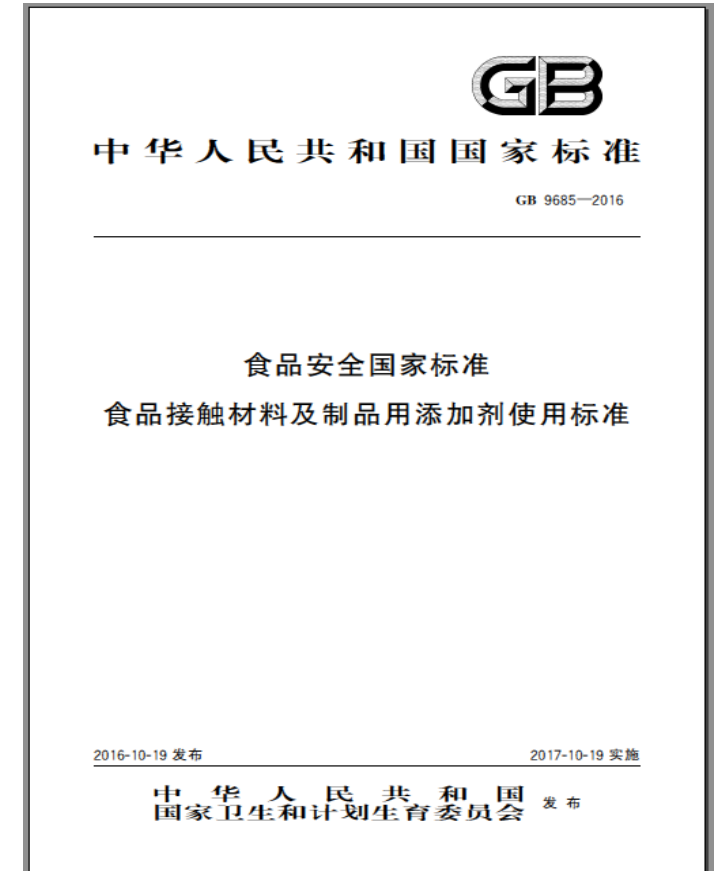
- ◆ For substances not included on an applicable positive list, China recognizes a functional barrier exemption, provided there is:
  - ◆ A barrier composed of one/more materials used to prevent migration to food of substances behind it
  - ◆ Migration of unlisted substance  $\leq 0.01$  mg/kg (10 ppb)
  - ◆ Unlisted substance is not a carcinogen, mutagen, or reproductive toxin or nanomaterial





# GB 9685-2016

- ◆ Applies to additives used in food-contact materials and articles
- ◆ *Additives*: 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 includes processing aids added to promote smooth production rather than improve the quality or properties of the final product



# GB 9685-2016: Appendix A

## ◆ Appendix 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

# Development of New Standards and Revisions



国务院办公厅关于印发  
国务院2020年立法工作计划的通知  
国办发〔2020〕18号

各省、自治区、直辖市人民政府，国务院各部委、各直属机构：  
《国务院2020年立法工作计划》已经党中央、国务院同意，现印发给你们，请认真贯彻  
执行。

国务院办公厅  
2020年6月26日

- ◆ Food Safety Standards Work Plan published annually
- ◆ New Standards developed per government priorities
- ◆ Revisions of existing Chinese Food Safety Standard typically sought every 5 years

# Draft Amendment No.1 to GB 9685-2016



- ◆ Released for public comment on **February 13, 2023**
- ◆ **Amendment proposes to revise only certain content**
  - ◆ Will not serve as a new version of GB 9685
  - ◆ Substances approved by NHC since the issuance of GB 9685 in 2016 have not been added
- ◆ **Annex A**
  - ◆ Additives approved for “rubber” under GB 9685-2008 can be used in production of silicon rubber
  - ◆ Updates to references and errors
- ◆ **Annex B**
  - ◆ The draft incorporates three new group specific migration limits
- ◆ **Annex D**
  - ◆ New abbreviations of “PVA or PVOH” for poly(vinyl alcohol)

# Standards on Fluorine from Packaging

- ◆ February 13, 2023, announcement by NHC that China to Set Standards on Determination of Fluorine in Foods and Fluorine Migration from Packaging
- ◆ References other Food Safety Standards under development by the Chinese authorities, including the following that relate to food packaging:
  - ◆ GB ××××-×××× Determination of Fluorine Migration in FCMs and Articles
  - ◆ GB ××××-×××× Determination of Fluorine in Foods
  - ◆ GB 31604.31-×××× Determination for Residue and Migration of Vinyl Chloride, 1,1-Dichloroethene and 1,1-Dichloroethane in FCMs and Articles
- ◆ Newly developed analytical methods for determining the presence of fluorine in food and the levels migrating from food-contact materials
- ◆ Seemingly related to efforts by the Chinese authorities to assess the prevalence of PFAS in the Chinese market



# Summary and Conclusions



# Summary and Conclusions

- ◆ In the U.S., EU, and China, additives to food-contact plastics require premarket authorization unless subject to an exemption
  - ◇ Competent authorities review the identity, use, migration, and safety of these substances in issuing new clearances
- ◆ Even if subject to an exemption, general safety standard applies
- ◆ New schemes are targeting specific chemicals in contact with food
- ◆ Future compositional changes to comply with new sustainability-focused regulations can be expected



# Thank You

**Any questions?**

Kathryn C. Skaggs

Partner

Washington, DC

202.434.4247

[skaggs@khlaw.com](mailto:skaggs@khlaw.com)

