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Recycled Plastic in Food Packaging: Perspectives in China, the United States, and the European Union

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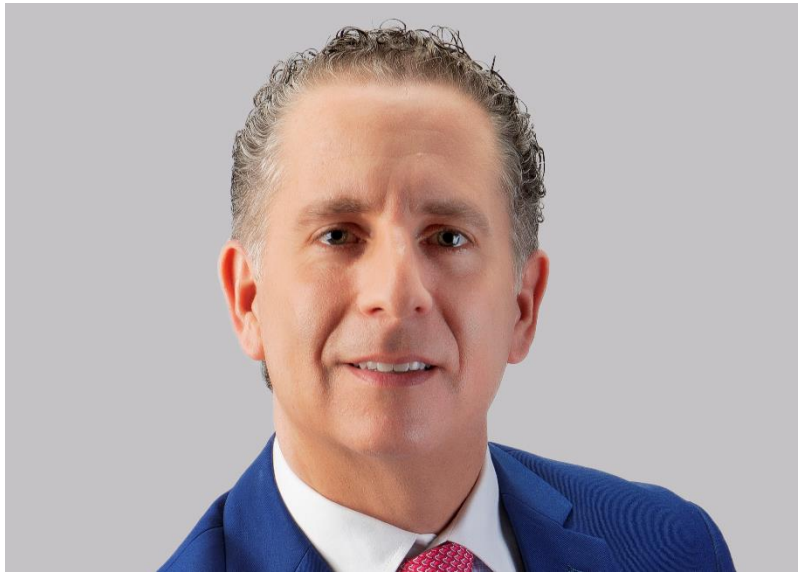


David Ettinger counsels multinational companies on food and food-related products, as well as consumer and tobacco and tobacco-related products. He assists clients in navigating the import and export of goods to ensure compliance with regulations in the U.S., Europe, and Asia. David counsels companies in China and throughout Asia on matters ranging from ingredient and labeling, to product seizure and detention, to food and consumer product recalls and consumer complaints.

David is the chief representative in Keller and Heckman's Shanghai, China office and previously worked in the firm's Washington, DC and Brussels offices. His global experience uniquely positions him to counsel foreign companies who need to navigate the regulatory landscape in Asia. David is Chair of Mackrell International, a global network of over 90 international law firms. He is on the leadership committee of the American Chamber of Commerce Shanghai's Food, Agriculture & Beverage Committee, and a frequent lecturer and author on international food safety matters. Mr. Ettinger is a Chambers and Partners ranked attorney in the area of Life Sciences (International Firms) China and since 2016 he is a Best Lawyers in America® ranked attorney for FDA Law.

Hazel O'Keeffe
Partner, Brussels Office

Hazel O'Keeffe counsels clients on the regulation of food-contact materials, notably in the European Union (EU), Switzerland, and the United Kingdom, focusing on establishing a suitable status for all types of food-contact materials at both the EU and national level.

Hazel helps clients navigate the complexities of applying the principle of mutual recognition to facilitate the free movement of non-harmonized products throughout the EU, the European Economic Area (EEA), and the European Free Trade Association (EFTA) countries. She advises on inter alia, EU requirements for biocides, materials in contact with drinking water, personal protective equipment, packaging waste and single-use plastics, medicinal products/European Pharmacopoeia, medical devices, cosmetics, fluorinated greenhouse gases, ozone depleting substances and recycling and green claims.

She completed an internship at the European Commission during which she specialized in relations with the European Parliament and gained first-hand experience of the workings of the EU institutions.

Hazel is a contributing author to packaginglaw.com, as well as related industry publications, and is frequently invited to speak at international food-contact conferences.

Natalie E. Rainer
Partner, San Francisco Office

Natalie Rainer practices food and drug law, advising clients on regulatory requirements for foods, dietary supplements, cosmetics, and food and drug packaging in jurisdictions around the world, including North America, Latin America, Europe, Asia, and the Middle East.

Natalie specializes in evaluating the regulatory status of food-contact materials, food additives, and color additives. She counsels companies on advertising and labeling requirements, including claim substantiation, nutrition labeling, menu labeling, and environmental claims. She also provides guidance regarding compliance with U.S. Department of Agriculture regulations, including the Bioengineered Labeling rules, organic rules, and regulations related to additives in meat and poultry products. She is proficient on the practical application of Proposition 65 and assists in defending against Proposition 65 enforcement actions.

Natalie helps clients bring new food additive, color additive, food-contact material, and feed additives to market. She excels in working with color additives and successfully filed four color additive petitions. She regularly prepares Generally Recognized as Safe (GRAS) Notices, Food Contact Notifications, and U.S. Department of Agriculture (USDA) safety and suitability determinations. Natalie's experience working in bioethics during law school and attending cooking school gives her a unique perspective to her work, a perspective that benefits her clients.

U.S. Regulatory Requirements

FDA Regulatory Framework

- Recycled plastics must meet the same regulatory requirements that apply to virgin materials
- FDA's regulatory scheme is based on the *composition* of the plastic – not a specific manufacturing process
- Self-determination of compliance is legal, but FDA will consider recycling *process* submissions on voluntary basis

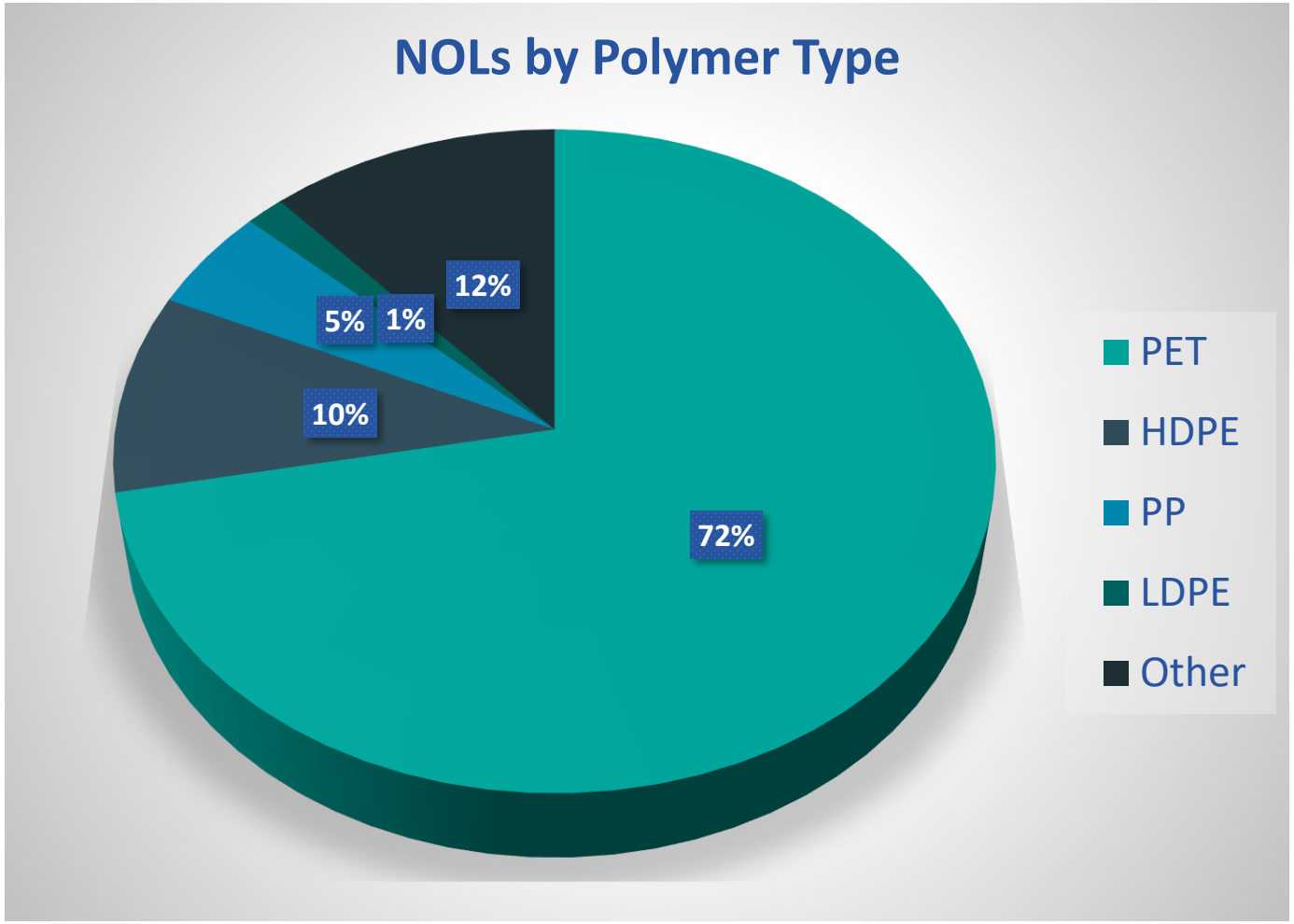
FDA "No Objection" Letter (1)

- Voluntary process, but may be required by customers or advantageous for marketing
- Agency concurrence that recycling *process* can effectively reduce potential contaminants in PCR to level that constitutes negligible safety risk
- NOT a regulatory clearance – still must comply with applicable food additive authorizations

FDA "No Objection" Letter (2)

- FDA's Recycled Plastics Database:

  https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=RecycledPlastics
- 266 NOLs currently on FDA's Inventory (some cover multiple polymer types)



FDA U.S. FOOD & DRUG ADMINISTRATION

Submissions on Post-Consumer Recycled (PCR) Plastics for Food-Contact Articles

FDA Home › Food Ingredient & Packaging Inventories › Recycled Plastics in Food Packaging
› Submissions on Post-Consumer Recycled (PCR) Plastics for Food-Contact Articles

This is a list of submissions for which FDA issued a favorable opinion on the suitability of a specific process for producing post-consumer recycled (PCR) plastic to be used in the manufacturing of food-contact articles. The list includes the date of our **no objection letter** (NOL), the company that made the request, the subject plastic, whether the recycling process is physical or chemical, and limitations on the conditions of use for the recycled plastic.

Additional information on the safety of recycled plastics in Food Packaging is found at Recycled Plastics in Food Packaging.

If a listed process is sublicensed to be used by another manufacturer, there is no need for the sublicensing company to obtain a new favorable opinion letter issued to their name, as long as the recycling process and intended use conditions of recycled plastic are exactly the same as described in the original favorable letter listed on this website. The original favorable opinion letter is applicable to the recycling process that FDA reviewed, regardless of which manufacturer uses it.

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Basic Search | Advanced Search | Field Search

Search: Show Items Clear

Records Found: 266 Show All Page 1 of 6

Recycle Number (sorted Z-A)	Date of NOL	Company	Polymer	Use Limitations	Recycling Process
266	Mar 25, 2022	Dalmia Polypro Industries Private Limited	Polyethylene terephthalate (PET)	Fabrication of single layer clamshells and containers that contact raw fruits, vegetables, and shell eggs under Conditions of Use E through G, provided the PCR-PET comes from food containers and complies with all applicable authorizations.	Physical
265	Mar 17, 2022	TSAAKIK MEXICO	High density polyethylene (HDPE)	Articles that contact raw fruits, vegetables, and shell eggs under Conditions of Use E through G, provided the PCR-HDPE material comes from food containers and complies with all applicable authorizations.	Physical

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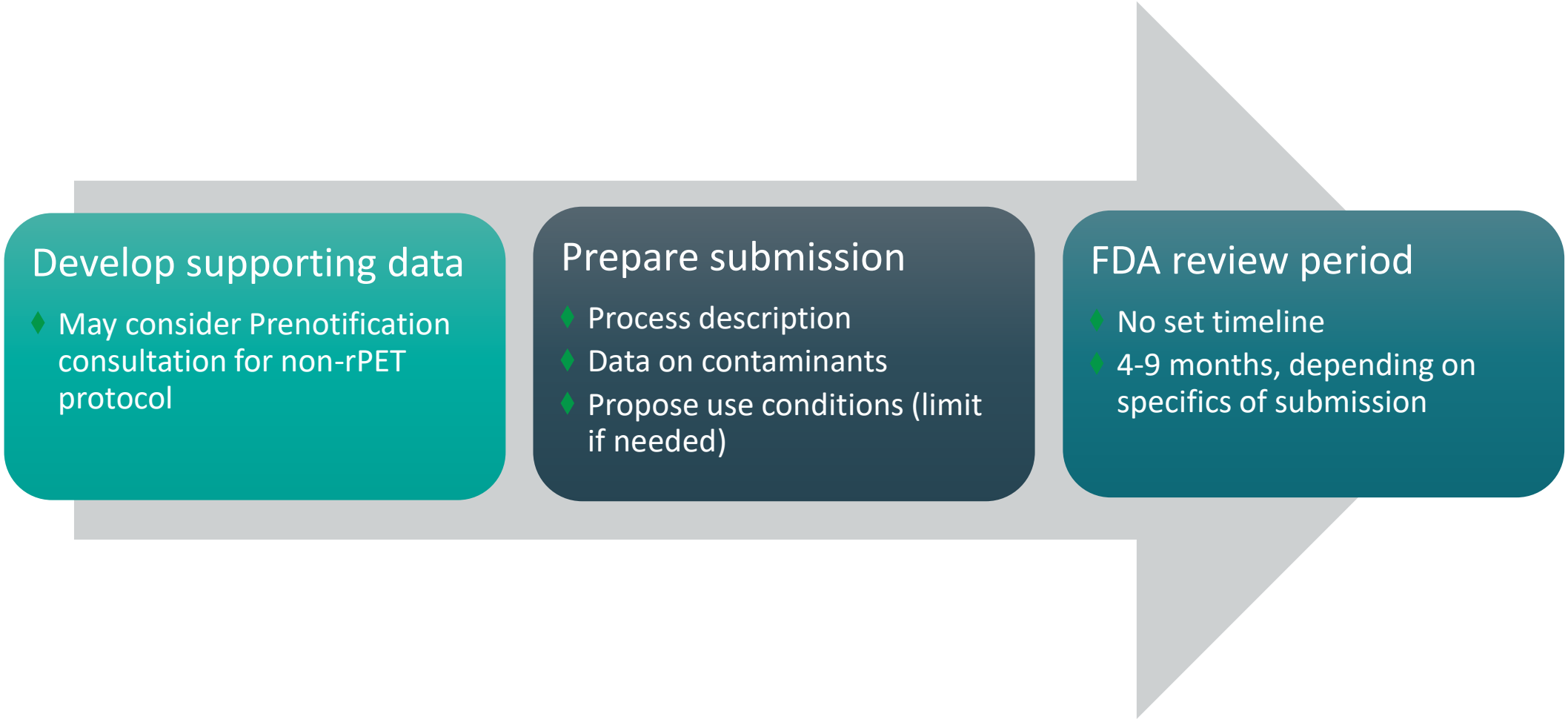
“No Objection” Letter Process



Basic Requirements

Must Comply with Federal Food, Drug, and Cosmetic Act (FFDCA)

- ✓Base resin and additives must comply with applicable regulations (or be exempt from premarket clearance)

Suitable Purity Requirements Apply (21 C.F.R. § 174.5)

- ✓Must not adulterate or contaminate food
- ✓Must not impart adverse taste or odor to food

Suitable Purity Concerns – Recycled Plastic

- Recycled post-consumer material may be composed of non-FDA-compliant virgin material
  - e.g., PET doesn't fully comply with 21 C.F.R. § 177.1630
- Adjuvants in the recycled plastic may not comply with relevant regulations for food use
  - e.g., Uncleared additive or an additive that is subject to end-use restrictions, such as food type, temperature, etc.
- Consumer abuse and storage of non-foods during first-use
  - Contaminants from post-consumer material may appear in the final food-contact product made from the recycled material

Suitable Purity Concerns – Recycled Plastic

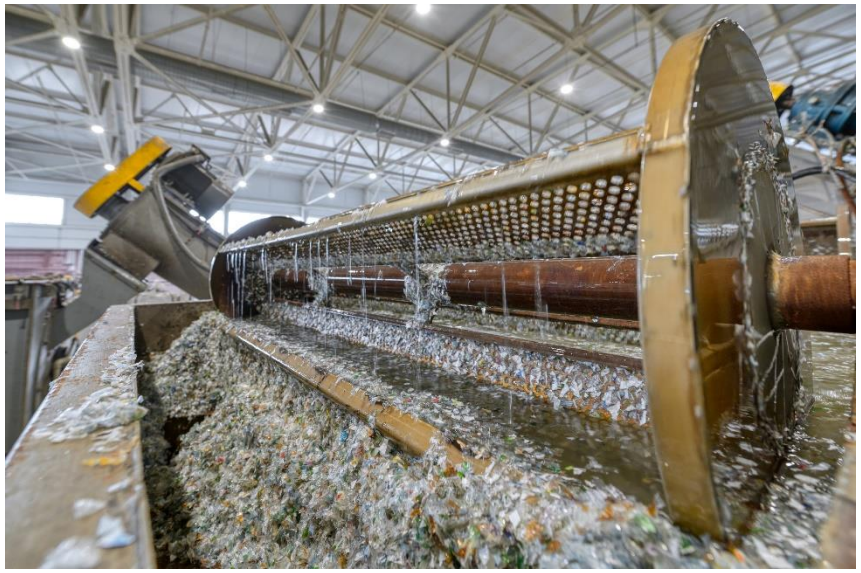
- Suitable purity concerns depend in large part on end uses.
- Compare
  - Berry baskets, shell egg containers, trays for fresh whole produce
  - Use of recycled plastic in combination with virgin food-contact layer
  - Direct contact with all types of food under Conditions of Use C-G

Surrogate Testing

- Purpose: Demonstrate clean-up and reprocessing steps effective in removing potential contaminants
- Process:
  - Flake contaminated with known surrogates and processed through recycling process
    - Surrogates intended to simulate range of potential contaminants, including volatile and non-volatile, as well as polar and non-polar compounds
  - Recycled plastic analyzed to determine maximum residual level of surrogate contaminants

Surrogate Testing

- Flake or bottles are rinsed following contamination step
- Plastic is subjected to standard cleaning and recycling processes
  - Commercial process or bench top simulation
- Residual contaminant levels determined



Other Options

- If residual levels for any surrogate contaminant above maximum limits, consider:
  - Limit use of recycle to blends with virgin resin
  - Limited or specialized uses:
    - Specific type of package (lower CF)
    - Use diffusion modeling or migration testing to consider specific conditions of use or use with barrier layers

FDA Guidance on Recycled Plastics

- Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations); (August 2006, updated July 2021)
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations
- Addresses different categories of recycling:
  - Primary (recycling of pre-consumer scrap)
  - Secondary (physical reprocessing)
  - Tertiary (regeneration of purified starting materials)
- Recommendations on contaminant testing to demonstrate decontamination efficiency of secondary and tertiary recycling processes

EU Regulatory Requirements

The European Union

- Focus on the draft Recycled Plastics Regulation
  - Timing for Adoption
  - General Overview of Objectives, New Terminology and Main Requirements
  - Requirements for “Suitable Technologies” vs. “Novel Technologies”
  - Some Outstanding Issues and Transitional Provisions

Timing for Adoption

Timing for Adoption

- Draft Recycled Plastics Regulation will repeal Regulation 282/2008
- Draft Regulation was open for public consultation until 18 January 2022
- Adopted by Standing Committee on Plants, Animals, Food and Feed ('SC-PAFF') on 4 April 2022 following written vote of EU Member States
- Currently undergoing 3 month scrutiny of European Parliament and Council
- Thereafter, will be published in Official Journal of the European Union

General Overview of Objectives, New Terminology and Main Requirements

Objectives

- Legal basis for recycling authorizations
- Objectives:
  - Ensure recycled plastic is safe for food contact
  - Require that plastic is decontaminated during recycling
  - Regulate ALL recycling processes
  - Ensure clear terminology
  - Simplicity, including enforcement and evaluation
  - Deal with issues regarding the transitional period in Regulation 282/2008

New Terminology

New Terminology

1. Recycling ***Technology***
   - ◊ Generic concepts, principles, and practices to recycle a defined input to output
   - ◊ E.g., “Mechanically recycled PET” and “closed-loop recycling”
2. Recycling ***Process***
   - ◊ Specific sequential operations using a recycling technology
   - ◊ E.g., “EREMA Basic,” “Starlinger DeCon”
3. Recycling ***Installation***
   - ◊ Equipment operating at least part of a recycling process

New Union Register

- Recycled plastic must be manufactured using a “suitable” technology or a “novel technology” in accordance with applicable rules
- Registration on **new public “Union Register”** to ensure transparency. Details regarding the manufacture of recycled plastic include:
  - Decontamination installation where the recycled plastic is manufactured, address of recycling facility, and identity of recycler operating it
  - Applied authorized recycling process (if the suitable technology requires authorization of recycling process)
  - Name of recycling scheme, identity of entity managing it, applied markings (if the applied recycling technology required the use of a recycling scheme)
  - Name of novel technology, names and addresses of developer(s)

Focus on Decontamination

- Draft regulation splits recycling processes into 3 stages:
  - Pre-processing
  - Decontamination (main focus)
  - Post-processing
- Example from EC's 16-17 December 2021 webinars:

Default General Rules for Plastic Recycling (1)

Note: Default rules could be overridden by technology, authorization and individual recycling scheme requirements

- **Collection and Pre-processing**
  - Plastic waste originates from municipal waste/food retail/food businesses if only intended and used for contact with food
  - Input must originate from FCMs compliant with Plastics Reg or Recycled Plastics Reg
  - Plastic waste is subject to separate collection
  - Other materials and substances and remaining food must be reduced to level specified by recycler

Default General Rules for Plastic Recycling (2)

- **Decontamination**
  - Plastic input and output of decontamination process must meet specifications in Annex to Regulation and, if applicable specific criteria in authorization
  - Must comply with GMP Regulation 2023/2006
  - Several requirements for decontamination installation (e.g. must be located in a single recycling facility and new contamination must be prevented)
- Records on individual batches must be maintained for at least 5 years

Default General Rules for Plastic Recycling (3)

- **Post-processing**
  - Sets requirements that converters, food business operators and retailers must comply with notably regarding the communication and following of relevant instructions in the supply chain

Documentation (1)

- **Compliance Monitoring Summary Sheet ('CMSS')** plays an important role
  - Summary describing the recycling installation, its operation, the relevant procedures and it documents compliance with the Regulation
  - Must be submitted to competent authority within **one month** of start of production at decontamination installation
  - Starting point for any audit/control
  - Template in Annex II of draft Regulation

Documentation (2)

- **Declarations of Compliance** with specified content
  - Templates in Annex III of draft Regulation (for both recyclers and converters)
- **Individual batches** of recycled plastic and of recycled plastic materials and articles subject to a single document/record regarding their quality
  - Labelling requirements also apply to containers of recycled plastic delivered to converters

Requirements for “Suitable Technologies” vs. “Novel Technologies”

"Suitable" Technologies

- When EC decides technology is "suitable," will list in Annex I, along with any limitations

- Initially, two "suitable" technologies:

  1. Mechanically-recycled PET

  2. Closed-loop recycling

Potential Limitations for "Suitable" Technologies

When the EC deems a technology "suitable," it may apply limitations:

- **"Individual authorization"**
  - A requirement that **developer of decontamination process of the recycling "process"** utilizing the suitable technology submit a dossier, and seek approval by EFSA + the EC before marketing
  - At the outset, this applies to processes for mechanically-recycled PET
- **Other limitations**
  - In the Annex I listing, EC may establish other limitations through definitions, descriptions, etc.

Mechanically Recycled PET: Suitable Technology

- Listed in Annex I of draft Regulation
  - Individual processes must be authorized
  - Each decontamination facility must be registered
- PCR-PET Source material:
  - Plastic must be manufactured in accordance with Reg. No. 10/2011
  - 5% (max) from articles not previously in contact with food
- Specification (Table 2) for content of PET

Closed Loop Recycling: Suitable Technology

- Listed in Annex I of draft Regulation
  - Individual processes need not be authorized
  - Subject to “Recycling Scheme”
  - Each recycling facility must be registered in Union Register and must be managed by a single-legal entity
- Source material:
  - Plastic must be manufactured in accordance with Reg. No. 10/2011
  - Plastic collected from articles in food distribution chain or catering services
- Output material:
  - Remolded into same material and article as those originating plastic input

"Novel" Technologies (1)

- **"Novel"** recycling technology
  - Has **not** been independently verified but is allowed on the market for data development purposes
  - Examples of novel technologies
    - HDPE mechanical recycling
    - Certain chemical recycling
      - Complete depolymerization to monomers *exempt* from draft Regulation (subject to Plastics Regulation 10/2011)
      - If depolymerization is incomplete (e.g., glycolysis) = novel technology
      - EC noted manufacture of BHET (bis (2-hydroxyethyl)terephthalate) may be considered to be a novel technology
    - Recycled plastics behind a functional barrier (specific rules apply)

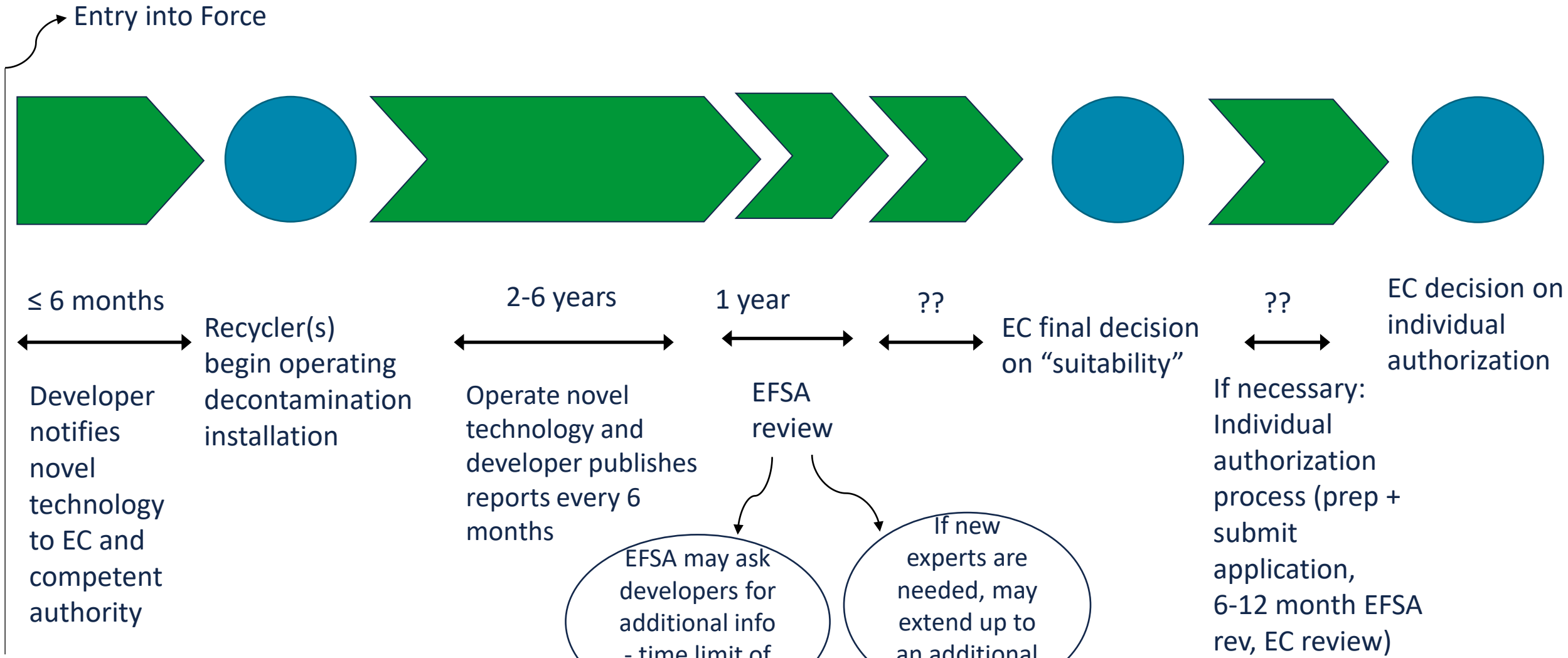
“Novel” Technologies (2)

- Must be notified by developer to competent authority in territory where recycling installation is located and EC at least **6 months** prior to start of operation
- Notification should include:
  - Characterization of novel technology, explanations re deviations, extensive reasoning, scientific evidence, and studies re why plastic from process complies with Art 3 Framework Reg
  - Description of typical recycling process using technology with block diagram of main manufacturing stages
  - Summary proposing evaluation criteria for EFSA in potential future evaluation and explanation as to why technology is different to other technologies
  - Estimate of expected number of decontamination installations

"Novel" Technologies (3)

- Extensive information and documentation requirements notably on decontamination
  - Developer must publish monitoring report on novel technology on its website every **6 months** based on information received from all installations using technology
    - Report must include detailed information (e.g., regarding identities of contaminants and their level of migration, analysis of origin of identified contaminants)
  - Goal = after collecting data for 2-6 years, developer of recycling technology submits data to EFSA + EC, becomes a "suitable" technology

Development of Novel Technology Timeline



Some Outstanding Issues and Transitional Provisions

Some Outstanding Issues

- For recycled plastics manufactured outside the EU, the “competent authority” will be a government agency who may be unwilling to certify compliance with Recycled Plastics Reg. requirements
- Most chemical recycling processes will be considered to be novel technologies
- Burdensome data requirements for novel technologies

Transitional Provisions (1)

- PET post-consumer mechanical recycling processes:
  - Application must be submitted to EFSA with **9 months** of entry into force of Regulation
  - Applications under evaluation by EFSA for closed loop technologies or other technologies that are not suitable technologies deemed terminated

- Developers must notify novel technology already in use and publish detailed initial report re the safety of the technology within **6 months** of entry into force of Regulation
  - Exhaustion of stocks clause

Transitional Provisions (2)

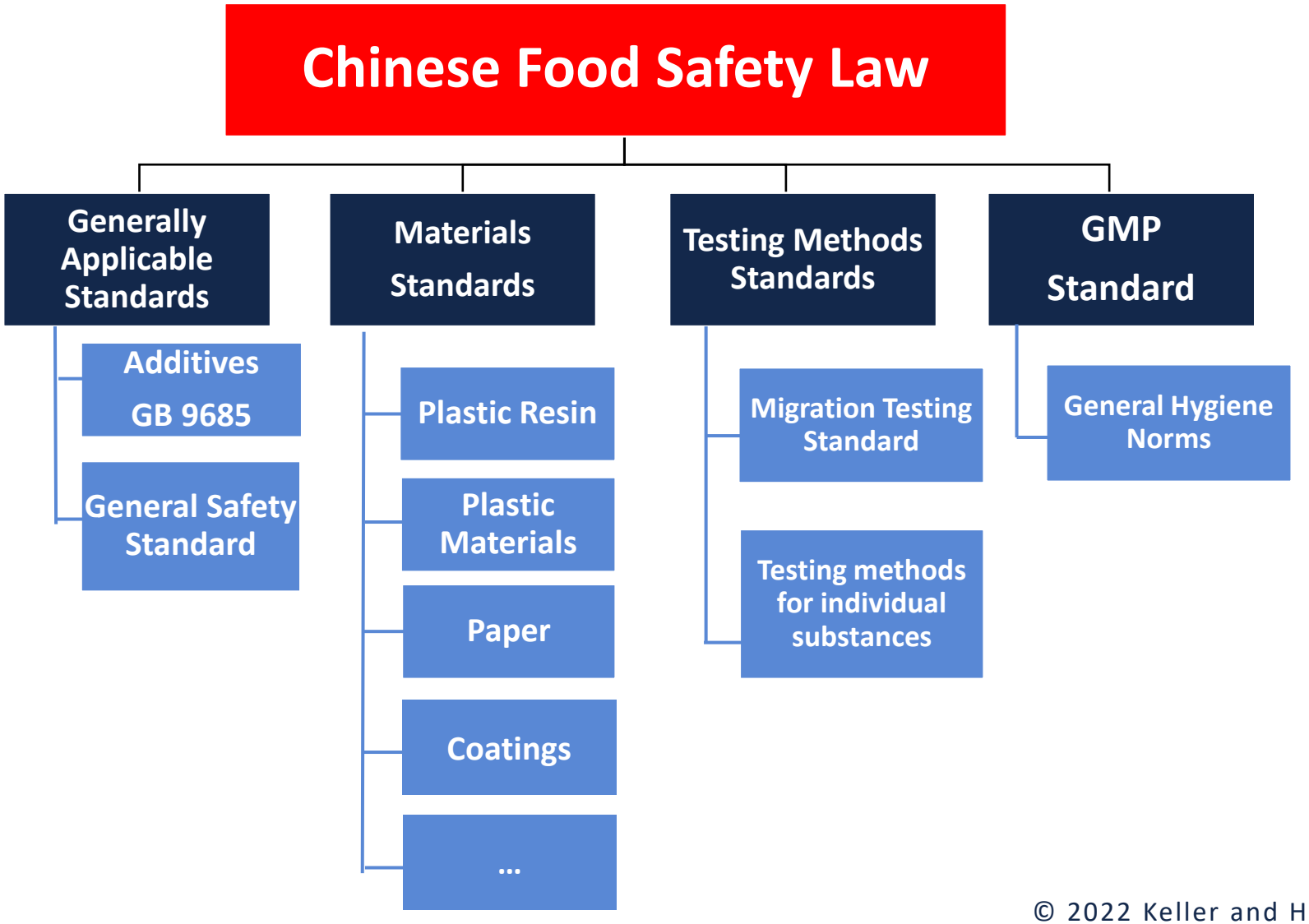
- Insufficient information available on the ability of a **functional barrier** (‘FB’) to prevent migration to food of contaminants contained in the recycled plastic over an extended period of time
  - Not yet a suitable technology
- **Developer of decontamination installation manufacturing recycled plastic** and **post-processing installation** adding FB must submit notification to the EC and competent authority within **6 months** of entry into force of Regulation
- Notification should include results from migration tests or challenge tests or migration modelling demonstrating FB

China Regulatory Requirements

China: Food Safety Law (FSL)

- **On June 1, 2009, China adopted a new overarching Food Safety Law**
  - Replaced 1995 Food Hygiene Law
  - Amendments: October 2015; December 2018; April 2021
- Mandates regulation of "food-related products" (e.g., food packaging, disinfectants, detergents, etc.)
- Requires development of Food Safety Standards for food-related products

China: GB Food Packaging Standards



China: Plastic Standards

- GB 4806.6: Plastic Resin Standard
  - Positive list of plastic resins
- GB 4806.7: Plastic Materials Standard
  - Adopts specifications for food-contact plastic materials and articles
- A new combined GB 4806.7 is being developed

China: Recycled Plastic in FCM (1)

- *Management Measures on the Hygiene of Food-Use Plastic Articles and Raw Materials* (MOH Order No. 8) prohibited the use of recycled plastic to produce utensils, containers and food packaging materials
  - Published in November 1990
  - **Repealed** in December 2010 without successor

China: Recycled Plastic in FCM (2)

- *Detailed Review Rules for Production Licensing of Food-Use Plastic Packaging, Containers, Tools and Other Articles* by AQSIQ (2006)
  - Prohibited the use of recycled materials to produce plastic food packaging materials
- Replaced in 2018 by new production licensing rules by SAMR
  - Currently effective
  - Removed explicit prohibition on the use of recycled materials

China: Recycled Plastic in FCM (3)

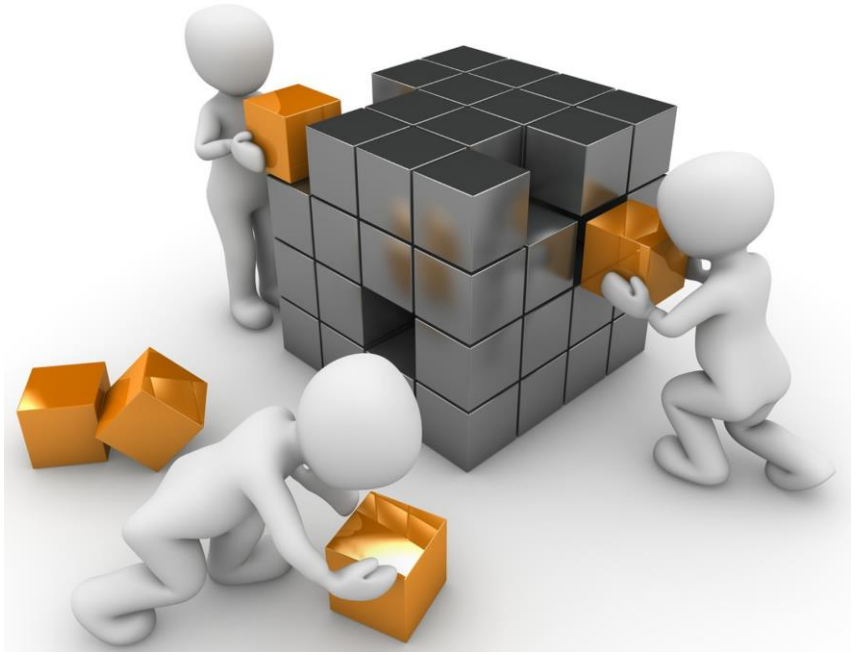
- A “special” approval was granted to a company by MOH and AQSIQ in July 2010
  - For recycled bottle-grade polyester chips
  - The only approval that has ever been issued

China: Recycled Plastic in FCM (4)

- **<u>Currently</u>**, no general authorization or prohibition on use of recycled plastic in FCM
  - Chinese government has been cautious
  - Officials have stated in various occasions that approvals are required
  - But no administrative process is available to obtain approval
  - Considered *de facto* ban

China: Outlook

- New recycled plastics standards
  - Voluntary; for industrial applications; does not explicitly contemplate use of recycled plastic in FCM
- CFSA survey on recycled plastics in 2020
  - To create “risk management” approach
- Work with experts to conduct risk assessment on rPET in FCM



China: Practical Considerations

- Caution is advised
- Import of recycled plastic materials
  - Used in finished packaged food
  - Stand-alone import
  - Proactive claim

Thank You

Any questions?

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