POST-CONSUMER RECYCLED PLASTICS IN FOOD CONTACT: SUSTAINABILITY & SAFETY CONCERN

Industrial Practices to Ensure Consumer Safety with recycled plastics

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- What are the food safety and quality **risks** identified with the mechanical recycling systems for polymers?
- How are these **risks** managed through legislative mechanisms
- What are the differences between the EU and US standards and protocols?
- How are recycling systems validated through these systems?

Circular economy has become ***the predominant*** business development model

Circular Economy consists in an economy model that is
"lowing, closing, and narrowing resource loops"

- Developed Countries have adopted Circular Economy principles as part of their growth strategies
  - Europe: *European Commission, Moving towards a circular economy.* *http://ec.europa.eu/environment/circular-economy/*
  - China: *Su, B. W., A. Heshmati, Y. Geng and X. M. Yu, "A review of the circular economy in China," Journal of Cleaner Production, 42, 215–227 (2013)*
- Many advantages
  - boosting recycling and preventing loss of valuable materials
  - creating jobs and economic growth
  - showing how new business models work
  - eco-design and industrial symbiosis

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Policies fostering circularity of plastics

The Packaging & Packaging Waste Directive (EU) 2018/853: recycling targets for plastic packaging

- *50% by 2025*
- *55% by 2030*

Single Use Plastics Directive (EU) 2019/904: incorporation of recycled PET in beverage bottles

- *25% by 2025*
- *30% by 2030*

Single Use Plastics Directive (EU) 2019/904: collection rate of PET bottles

- *77% by 2025*
- *90% by 2029*

Mostly managed at States level

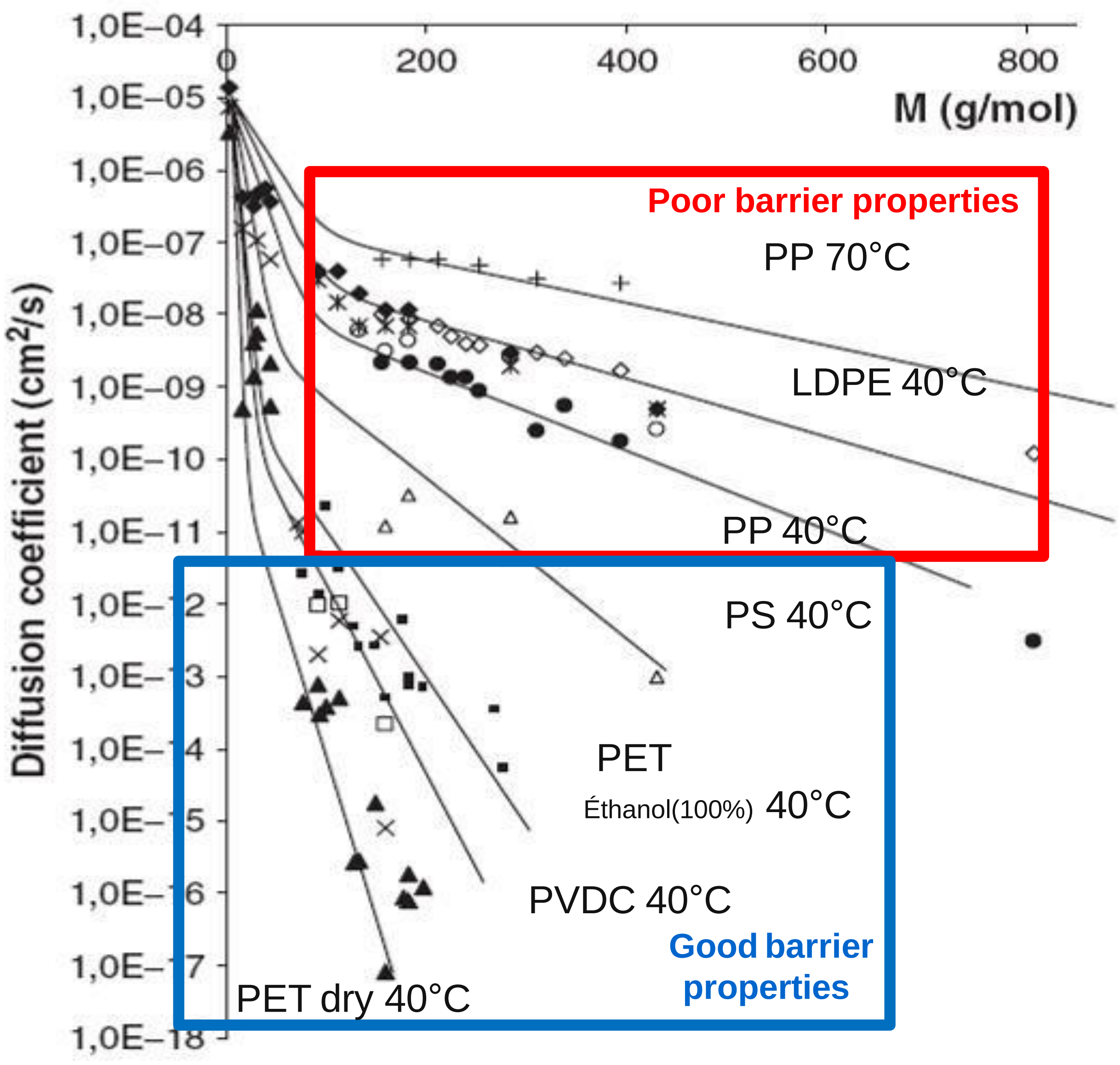
- CA: min. recycled content in plastic beverage containers: 15% in 2022, 35% by 2025 and 50% by 2030.
- NJ recycled content bill (SB 2515) will follow
- EPR bills in NY, WA and more
- Many states and cities have implemented material bans (straws, foam) or plastic bag charges

Congress to establish nationwide container deposit system and EPR for packaging.

- Ban of single-use plastic bags, EPS containers, utensils and straws
- Mandatory post-consumer recycled content min. would increase from 25% by 2025 to 80% in 2040

Challenge of contaminants in post-consumer plastic waste stream

- The main contaminants originate from the packaged food itself, e.g. limonene from beverages, oils, fats and aromas adsorbed in the plastic
- Incidental contamination from misuse, e.g. storage of fuel or solvents in bottles
- Non food contact containers: lindane from shampoos, methyl salicylate from cosmetics, acetone or other solvents
- degradation products and additives (acetaldehyde from PET, oligomers etc)
- Residues from process chemicals (alkali from washing and labels removal)
- Other plastics, such as PVC PO’s caps, and other components such as adhesives



PET best suited for recycling to create a circular economy

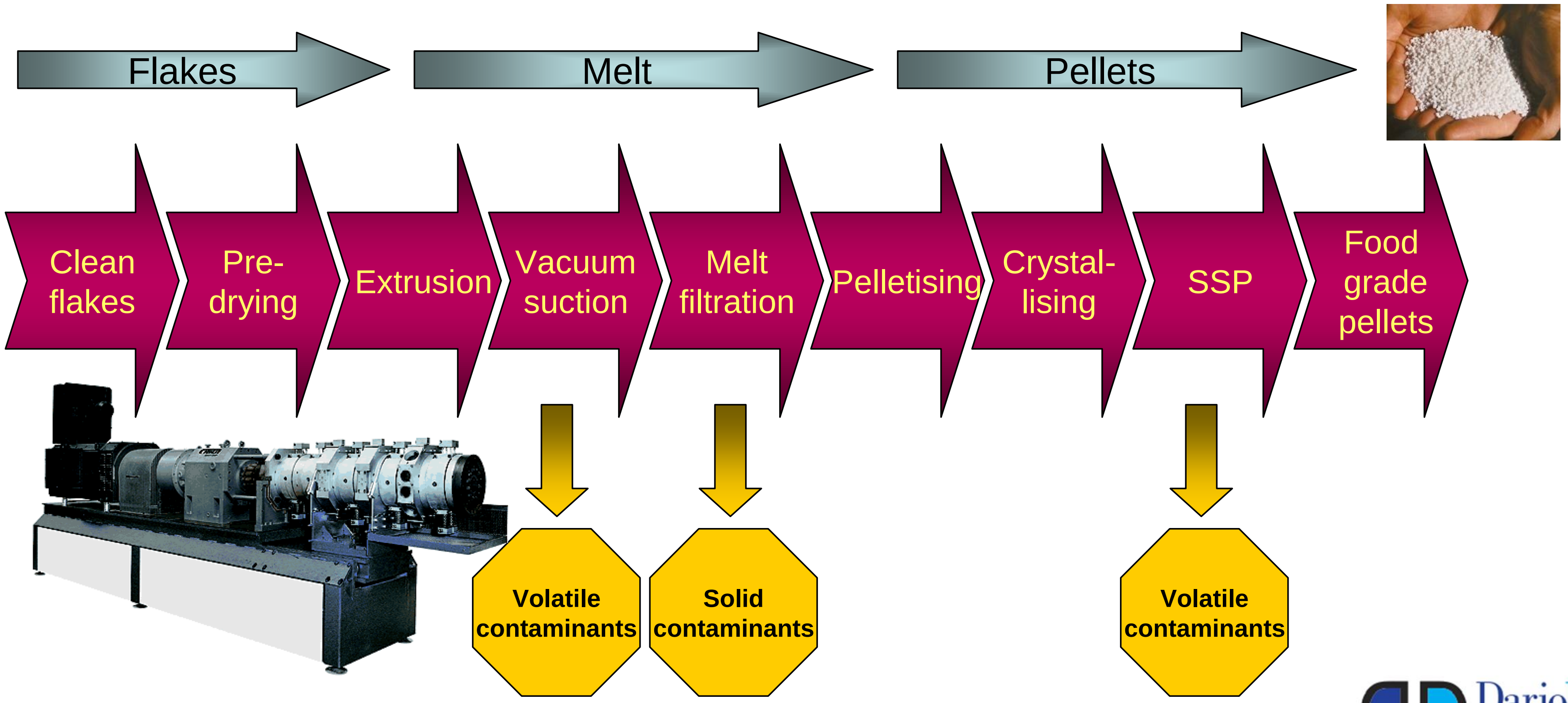
- High melting temperature (256°C)
  - Pro: volatiles are easily stripped and can't be found in the rPET
  - Cons: impurities and contaminants decompose and cause spots/colours problems.
  - Consequences: High purity is needed in the input stream
- It is produced via polycondensation (unlike polyolefins)➔ can be depolymerized by temperature and solvents (e.g. alkali or glycols), and subsequently re-polymerized
- The molecular weight (MW) can be modulated giving enough time to the polymerization to proceed (Solid Phase Polymerization- SPP)
- MW is key for processability: MW for production of preforms/bottles much higher than other processes, such as fabrics

GENERAL SAFETY REQUIREMENTS

1. Packaging **shall not endanger the consumer** through product adulteration due to chemical migration from packaging

2. Packaging **shall not impact the taste/smell** of the product contained within

All regulatory systems aim at qualifying the suitability of processes to clean-up the flakes and obtain food-grade PET pellets



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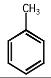
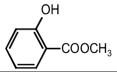
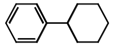
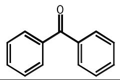
Challenge Test demonstrates the cleaning ability of a recycling process

1. Spike clean virgin material with known amounts of specific substances
2. Process the spiked materials and analyse levels of spiked substances in output material
3. Levels of spiked substances shows the ability of process to reduce contamination

Chemical name, formula	M_W[a]	Structure	Functional Group	Physical properties
Toluene	92.1		aromatic hydrocarbon	volatile, non-polar
Chlorobenzene	112.6	C_6H_5Cl	halogenated aromatic hydrocarbon	volatile, medium-polar, aggressive to PET
Chloroform	119.4	$CHCl_3$	halogenated hydrocarbon	volatile, polar, aggressive towards PET
Methyl salicylate	152.2		aromatic ester	non-volatile, polar
Phenyl cyclo-hexane	160.3		aromatic hydrocarbon	non-volatile, non-polar
Benzophenone	182.2		aromatic ketone	non-volatile, polar
Methyl stearate	298.5	$CH_3(CH_2)_{16}COOCH_3$	aliphatic ester	non-volatile, polar

[a]Molecular weight in g mol^{-1}

This determines the residue concentration, that is a function of the molecular weight

It allows control and optimization of the process conditions

Risk Assessors use data to define any restrictions on use of the material

Typical concentration 500-1000 ppm

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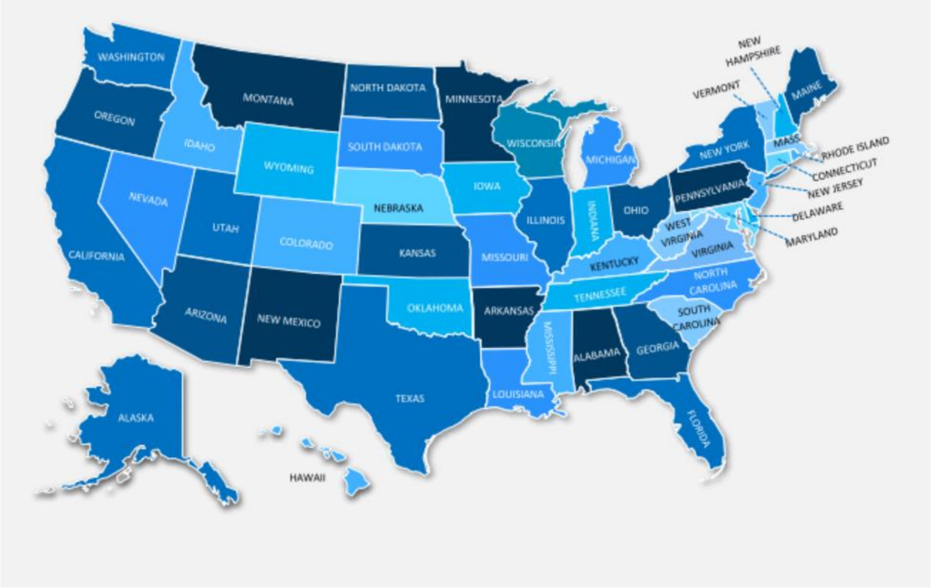
Decontamination technologies have been proven to consistently deliver clean and safe plastics

US FDA approves recycling plants since 1991: 181 grades



EU EFSA started in 2012, and delivered positive opinions for ab. 240 recycling plants

Many other jurisdictions have adopted systems modelled after US or EU for production of food-grade rPET.
Most recent example: Thailand- draft Feb. 2021

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Two main regulatory systems, achieving same safety level

	US FDA	EU EFSA
Regulatory instrument	Guidance for Industry	Regulation (EC) 282/2008
Authorization	Voluntary assessment, open to any operation worldwide. Assessment conducted based on challenge test conducted at the *level of technology licensor*	Mandatory assessment, only open to EU Member States. Assessment conducted based on challenge test conducted at *each recycling operation*
Approval tool	Letters of No Objection are issued and accepted by other regulatory agencies (e.g. MERCOSUR, Japan, etc.)	EU Commission enforcement Decisions, based on EFSA Opinions; this is in progress
Dossier includes	• Process description including characterisation of the input, • Challenge test, • Proposed conditions of use, types of foods.	• Process description including chracterisation of the input, • Challenge test, • Specifications, • Intended application (types of food, conditions of use)
Feedstock requirements	• Food Contact Materials • Recognizes all PET resin to be food grade even those not used in food application • Sets validation rules assuming increase of non-food PET containers in feedstock	• Food Contact Materials only • Requires input to be food-grade and 95% compliant with EU FCM regulation
Max contamination level	No need to establish the maximum level of contamination in PET flakes a priori	Assumes 3-ppm maximum sorption of each contaminant
Evidence of decontamination	Can be established by analytical testing	Relies on mathematical modeling
Declaration of Compliance		As defined in the EU 10/2011 (Plastic) + EC 282/2008 (Recycled plastic)
Quality System		Including quality control plan and monitoring
controls		Recycling plant and converter
labelling		Voluntary, according to ISO 14021:1999

The EU approach to food contact recycling

Recycled Plastics- European Regulation(EC) 282/2008

- Enables direct food contact use of post-consumer recycled plastics, applies to *mechanical recycling of all types of plastics*, other forms of recycling are excluded
- Recycled plastics shall comply with R. (EC) 10/2011 (food contact plastics)
- Recycled plastics in the internal layer of an A/B/A structure are also excluded
- **The process of recycling is subject to EFSA Opinion, and subsequent Commission's authorization with publication of implementing "Decisions" in the OJEC**
- Ab. 200 *EFSA Opinions delivered*, Almost all related to PET; a few "closed loop" systems approved for polyolefins

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EFSA approach to risk assessment of recycled plastics

Refence contamination level of flakes : 3 mg/kg PET

Max. tolerabe intake:
0.0025 µg/kgbw/day
Migration 0.1 µg(kg food

Decontamination efficiency calculated via challenge test: Eff%

Residual contamination in rPET:
Cres= 3 mg/kg PET x (1-Eff%)

⟷

Modelled residual contamination in rPET: **Cmod**

Cmod < Cres → NO SAFETY CONCERNS

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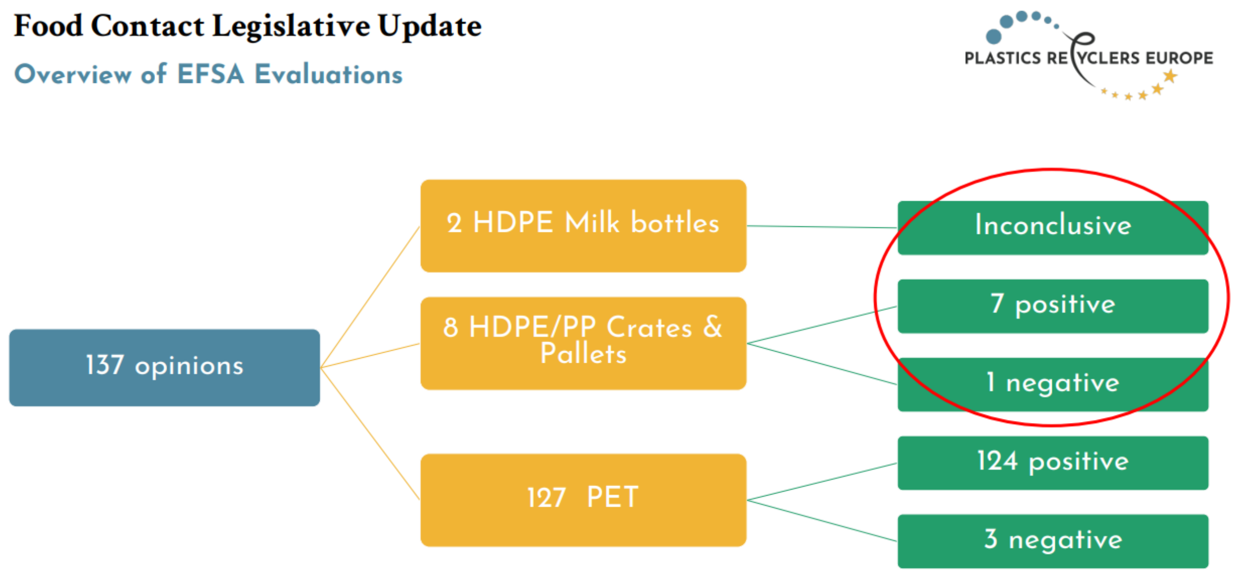
Suits almost entirely to PET

- No max contamination exists for HDPE, PP and other polymers
- Closed loops may trigger EFSA positive opinions as they do not require the challenge test



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HDPE: applications to EFSA

- In 2015 EFSA received 2 applications from UK relative to recycling of HDPE, from CRLrHDPE and Biffa Polymers
  - CLRrHDPE (now Veolia): use in blend up to 50 % with virgin HDPE to manufacture bottles intended to be in contact with pasteurised milk and pasteurised fruit juices or 12-15 days at <5 °C
  - Biffa Polymers: (i) up to 50 % with virgin HDPE for bottles for milk or chilled fruit juice-based drinks for up to 30 days (filtered milk) and for up to 15 days(other milks and fruit juices); (ii) up to 30 % with virgin PP for trays used for fresh meat and fish, cooked proteins (10 -12 days at chill temp.), and for F&V and mushrooms for up to 30 days at r.t.

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Challenge test and decontamination efficiency

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- Challenge test executed with conventional method for PET
- Cres > Cmod (C mod is only for PET!)
- The method is unsuitable to determine safety

Biffa Polymers

Surrogates	Total mass of surrogates introduced in the first reactor (step 2) (grams of surrogate)	Total mass of surrogates in the pellets after extrusion (step 4) (grams of surrogate)	Decontamination efficiency (%)
Toluene	23.2	< 0.009	> 99.96
Chlorobenzene	35.4	< 0.004	> 99.99
Butyl salicylate	36.7	20.08	45.28
Benzophenone	36.1	11.22	68.95
Phenylcyclohexane	34.1	9.78	71.34
Methyl palmitate	39.3	26.68	32.23

CLRrHDPE

Surrogates	Total mass of surrogates introduced in first reactor (step 2) (grams of surrogate)	Total mass of surrogates in the pellets after extruder (step 4) (grams of surrogate)	Decontamination efficiency (%)
Phenylcyclohexane	8.5	3	64.7
Benzophenone	9.8	7.4	24.5
Methyl stearate	24.2	24.7	0

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The US approach to food contact recycling

- The system is voluntary: operators may submit their processes to FDA for assessment (FDA does not “approve” recycling processes”)
- Three types of recycling:
  - Pre-Consumer Scrap: Primary Recycling-not expected to pose a hazard to the consumer. GMP to be followed
  - Physical Reprocessing: Secondary Recycling-reprocessing involves grinding, melting, and reforming. Recyclers should be able to demonstrate that contaminant levels in the reformed plastic are reduced to sufficiently low levels to ensure that the resulting packaging is of a purity suitable for its intended use
  - Chemical Reprocessing: Tertiary Recycling-regeneration of purified starting materials

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FDA approves recycling process since 1991

- Over 180 approved, many from non-US applicants
- Process evaluation
  - Recyclers/ licensors submit application describing input material, process of decontamination, results of challenge test, and proposed use of material
  - Must demonstrate that the maximum concentration does not exceed the maximum acceptable level of contaminants
  - FDA issues Letters of No Objection (LONO)
  - Each different technology requires separate approval; new challenge test following any change in process.

Table 1. Examples of Minimum Concentrations of Contaminants in a Surrogate Cocktail

Contaminant	Concentration
Chloroform (volatile polar)	10% v/v[a]
Toluene (volatile non-polar)	10% v/v
Benzophenone (non-volatile polar)	1% v/v
Tetracosane or Lindane (non-volatile non-polar)	1% w/w[b]
Copper(II) 2-ethylhexanoate (heavy metal)	1% w/w
Balance: 2-Propanol (as solvent for Cu(II) 2-ethylhexanoate) Hexane or Heptane (as overall solvent for cocktail)	 10% v/v 68% v/v

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Differences from EU

The max acceptable level of a contaminant in a polymer that corresponds to an EDI equal to 1.5 micrograms/person/day will depend on density, thickness, and CF.

Calculations were done using a CF of 0.05 for each recycled polymer, and container wall thickness of 0.50 mm

- Both food-grade and non-food grade feedstock are allowed; the same standard of purity applies.
- If including non-food in feedstock, the level of contaminants in challenge test should be increased
- Polyolefins are included
- No mandatory quality systems, audits and declaration of compliance
- Based on analytical detection of residue contaminants (no model residue)

Recycled Polymer	Density, g/cm^3	Maximum Residue
PET	1.4	220 µg/kg
Polystyrene	1.05	300 µg/kg
PVC	1.58	200 µg/kg
Polyolefins	0.965	320 µg/kg

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Concluding

Collected post-consumer plastics can be safely recycled into another food contact use

1. ***Food-grade rPET and rPO can be produced from validated decontamination processes; validation is made through a challenge test based on well-established safety principles***

2. ***Criteria adopted by either the US or the EU are protective of the consumers worldwide***

3. ***Recycling process technologies accepted by US FDA or EFSA can be accepted elsewhere***

4. ***Opinions issued by US FDA or EFSA can be regarded as valid for compliance purposes***

5. ***Gap in the EU risk assessment process makes rPO difficult to authorize, while US FDA includes assessment systems valid for both rPET and rPO***

FDA

efsa
European Food Safety Authority