Criteria for safety evaluation of PET recycling processes

Dr. Eric Barthélémy

Scientific Officer for FCM, Food Ingredients & Packaging Unit

ILSI Symposium on FCM, Berlin, November 2012
The content of this presentation does not necessarily represent the position of EFSA and of CEF Panel
To consult the opinions of EFSA, see www.efsa.europa.eu
Outline

- Background
- EFSA Criteria
- Example & Conclusion
Risk = migration out of recycled PET of contaminants introduced through misuse by the previous consumer

Reg. (EC) 282/2008

• Mechanical processes have to be authorised by Commission after EFSA evaluation of dossiers prepared following EFSA Guidelines (EFSA, 2008)

• Input = food contact material (FCM)

• (Input + Output) controlled; Uses defined

• Process able to reduce any contamination of plastic input to a concentration that does not pose a risk
Scientific opinion on the criteria to be used for safety evaluation of a mechanical process to produce recycled PET (EFSA CEF Panel, 2011)

✓ Setting criteria for assessment of the decontamination efficiency of the process

✓ Identifying the level of contaminant in cleaned recycled PET (output) which could lead to a potential migration below a level of negligible health concern
Reference contamination level of flakes 3 mg/kg PET

Decontamination efficiency challenge test $\text{Eff} (%)$

Residual contamination in the recycled PET
$\text{Cres} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff})$

Maximum potential intake of
$0.0025 \mu\text{g/kg bw/day}$
Migration $0.1 \mu\text{g/kg food}$*

$C_{\text{mod}}$ modelled residual contamination in the recycled PET

If $\text{Cres} < C_{\text{mod}}$
No safety concern

*: Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 $\mu\text{g/kg food}$ respectively.
Reference contamination level of flakes *3 mg/kg PET*

Decontamination efficiency challenge test \( \text{Eff} (\%) \)

Residual contamination in the recycled PET
\[ \text{Cres} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff}) \]

Maximum potential intake of 0.0025 \( \mu \text{g/kg bw/day} \)
Migration 0.1 \( \mu \text{g/kg food} \)*

\( \text{Cmod} \) modelled residual contamination in the recycled PET

If \( \text{Cres} < \text{Cmod} \)
No safety concern

*: Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 \( \mu \text{g/kg food} \) respectively
FAIR-CT98-4318 project

- EU survey on contamination of post-consumer PET (thousands soft-drink bottles collected from 12 MS)
- Recurrent contamination is food borne (e.g. Limonene max 20 ppm)
- Miscellaneous plastic substances (additives < 0.5 ppm)
- Misuse by household, fuel (toluene estimated up to 6750 mg/kg PET) + rare case (3-4/10000 bottles) \(\Leftrightarrow\) after dilution over whole batch = 2.7 mg/kg PET

Reference contamination of 3 mg/kg washed & dried PET
Reference contamination level of flakes \( 3 \text{ mg/kg PET} \)

Decontamination efficiency challenge test \( \text{Eff} \) (%)

Residual contamination in the recycled PET
\[
\text{Cres} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff})
\]

Maximum potential intake of 0.0025 \( \mu \text{g/kg bw/day} \)
Migration 0.1 \( \mu \text{g/kg food} \)

\( \text{Cmod} \) modelled residual contamination in the recycled PET

If \( \text{Cres} < \text{Cmod} \)
No safety concern

*: Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 \( \mu \text{g/kg food} \) respectively.
Decontamination efficiency

✔ Determined by “Challenge test”

• PET flakes/pellets artificially highly contaminated with surrogate contaminants
• Contaminated PET flakes/pellets must be washed & dried to eliminate surface contamination
• Contaminated PET is submitted to the decontamination process
• Test at full or reduced scale but representative of conditions of processing in real plant
Decontamination efficiency

- **Recycled articles**: bottles, sheets
- **Post-consumer articles**: mainly bottles
- **Sorted, washed & dried flakes**
- **Decontamination technology**: reactors, extrusion, SSP, etc.

- **Efficiency (%)** calculated based on residual concentration of surrogate contaminants measured **before** and **after** decontamination technology of the process challenged
Reference contamination level of flakes **3 mg/kg PET**

Decontamination efficiency challenge test **Eff (%)**

Residual contamination in the recycled PET

\[ \text{Cres} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff}) \]

Maximum potential intake of 0.0025 µg/kg bw/day
Migration 0.1 µg/kg food*

Cmod modelled residual contamination in the recycled PET

If Cres < Cmod
No safety concern

*: Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food respectively.
Reference contamination level of flakes: 3 mg/kg PET

Decontamination efficiency challenge test: Eff (%)

Residual contamination in the recycled PET: 
\[ C_{\text{res}} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff}) \]

Maximum potential intake of: 0.0025 \( \mu \text{g/kg bw/day} \)
Migration: 0.1 \( \mu \text{g/kg food}^* \)

\[ C_{\text{mod}} \text{ modelled residual contamination in the recycled PET} \]

If \( C_{\text{res}} < C_{\text{mod}} \)
No safety concern

*: Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 \( \mu \text{g/kg food} \) respectively.
Set a dietary exposure level that does not pose a risk to human

Set a corresponding contamination level in food using food consumption data

Set corresponding contamination level in PET using migration modelling (Cmod) which can be compared with the residual concentration of surrogate contaminants calculated (Cres)
✓ Exposure level that does not pose a risk to human
  = Exposure for chemicals with structural alerts that raises concern for potential genotoxicity & below which probability for adverse effect in human is negligible
  = 0.0025 µg/kg bw/day

✓ Default (highest) consumption: Infant (0-12 months)
  =150 g water/kg bw/day (5 kg bw bw/0.75l water)

→ Concentration of contaminant in food that does not pose a risk to human = 0.017 µg/kg food
Concentration in food (0.017 µg/kg food)

Modelled concentration in PET (Cmod)

Migration modelling
Over-estimation x 5-100

✔ Instead of calculated concentration of contaminant in food (0.017 µg/kg food) => Concentration in food used to set concentration in PET (Cmod) which should not be exceeded = 0.1 µg/kg food (~ 5*0.017)
✓ Set concentration of contaminant in PET that leads to 0.1 µg/kg food using migration modelling

<table>
<thead>
<tr>
<th>Surrogate</th>
<th>MW (Da)</th>
<th>Cmod (mg/kg PET)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toluene</td>
<td>92</td>
<td>0.09</td>
</tr>
<tr>
<td>Chlorobenzene</td>
<td>113</td>
<td>0.09</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>152</td>
<td>0.13</td>
</tr>
<tr>
<td>Phenylcyclohexane</td>
<td>160</td>
<td>0.14</td>
</tr>
<tr>
<td>Benzophenone</td>
<td>182</td>
<td>0.16</td>
</tr>
<tr>
<td>Lindane</td>
<td>291</td>
<td>0.31</td>
</tr>
<tr>
<td>Methyl stearate</td>
<td>298</td>
<td>0.32</td>
</tr>
</tbody>
</table>

Parameters: 1 year at 25°C, Kp,F=1 (good solubility), 6dm²/1kg food, 300µm thickness, Ap’=3.1 & tau=1577 for tau <=70°C (EC, 2010)
EFSA criteria scheme

Reference contamination level of flakes 3 mg/kg PET

Decontamination efficiency challenge test $\text{Eff} (\%)$

Residual contamination in the recycled PET
$C_{\text{res}} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff})$

Maximum potential intake of 0.0025 µg/kg bw/day
Migration 0.1 µg/kg food*

$C_{\text{mod}}$ modelled residual contamination in the recycled PET

If $C_{\text{res}} < C_{\text{mod}}$
No safety concern

*: Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food respectively

<table>
<thead>
<tr>
<th>Surrogates</th>
<th>Concentration before drying and crystallisation (step 2) (mg/kg PET)</th>
<th>Concentration after SSP (step 4) (mg/kg PET)</th>
<th>Decontamination Efficiency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toluene</td>
<td>563</td>
<td>&lt;0.8*</td>
<td>&gt;99.9</td>
</tr>
<tr>
<td>Chloroform</td>
<td>1900</td>
<td>&lt;0.5*</td>
<td>&gt;99.9</td>
</tr>
<tr>
<td>Phenylcyclohexane</td>
<td>538</td>
<td>&lt;0.3*</td>
<td>&gt;99.9</td>
</tr>
<tr>
<td>Benzophenone</td>
<td>694</td>
<td>10.8</td>
<td>98.4</td>
</tr>
<tr>
<td>Lindane</td>
<td>373</td>
<td>33.9</td>
<td>90.9</td>
</tr>
</tbody>
</table>

* Not detected at the limits of detection of 0.8 mg/kg PET, 0.5 mg/kg PET and 0.3 mg/kg PET respectively

<table>
<thead>
<tr>
<th>Surrogates</th>
<th>Decontamination efficiency (%)</th>
<th>Cres (mg/kg PET)</th>
<th>Cmod (mg/kg PET)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toluene</td>
<td>99.9</td>
<td>0.003</td>
<td>0.09</td>
</tr>
<tr>
<td>Chloroform</td>
<td>99.9</td>
<td>0.003</td>
<td>0.10</td>
</tr>
<tr>
<td>Phenylcyclohexane</td>
<td>99.9</td>
<td>0.003</td>
<td>0.14</td>
</tr>
<tr>
<td>Benzophenone</td>
<td>98.4</td>
<td>0.048</td>
<td>0.16</td>
</tr>
<tr>
<td>Lindane</td>
<td>90.9</td>
<td>0.273</td>
<td>0.31</td>
</tr>
</tbody>
</table>
• Input= (All food grade, ≤5% non-food use articles)
• Reference contamination of 3 mg/kg PET = worst case from experimental data (FAIR project)
• Dietary exposure is low enough to cover all toxicological effects including genotoxicity: contaminants were treated as they were genotoxic
• Most conservative food consumption scenario (i.e. infants)
• Modelling is over-estimating (5 to 100) and parameters selected conservative for PET (1 year at 25°C)

➡️ Under these conditions, EFSA has considered that PET recycled articles are safe and consumers protected
Thank you for your attention

*let us contribute together to a safe food*

My e-mail: Eric.barthelemy@efsa.europa.eu

EFSA: http://www.efsa.europa.eu/


Migration testing: http://crl-fcm.jrc.it