SCIENTIFIC GUIDANCE: EVALUATION CRITERIA

#OpenEFSA

SCIENTIFIC GUIDANCE

- Main sections:
  - Evaluation criteria
  - Requirements for the technical dossier

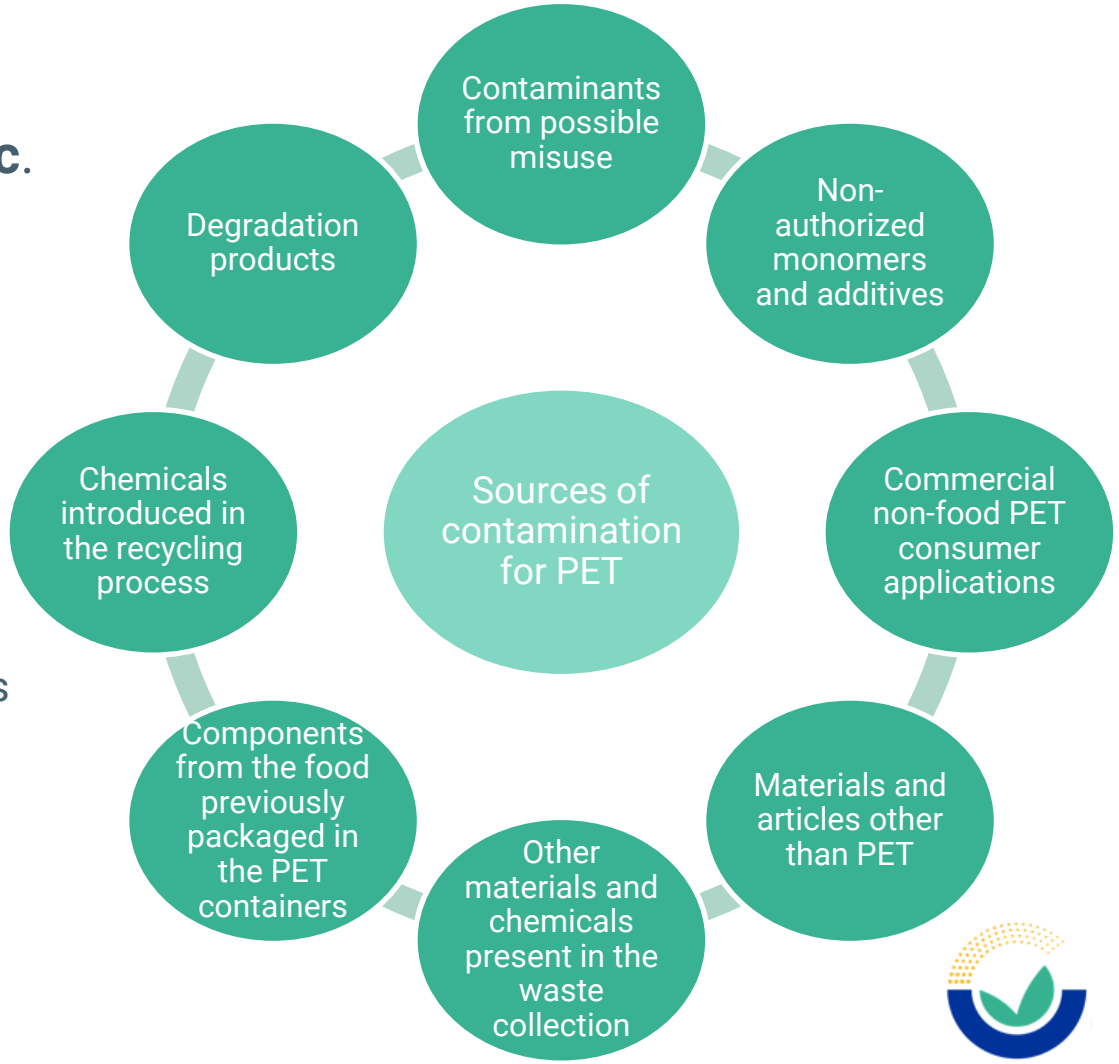
GENERAL PRINCIPLES FOR SAFETY ASSESSMENT OF RECYCLED PLASTICS FOR FOOD CONTACT

- Health risks associated with use of recycled plastic FCMs due to **possible migration into the packaged food of contaminants present in the recycled plastic**.

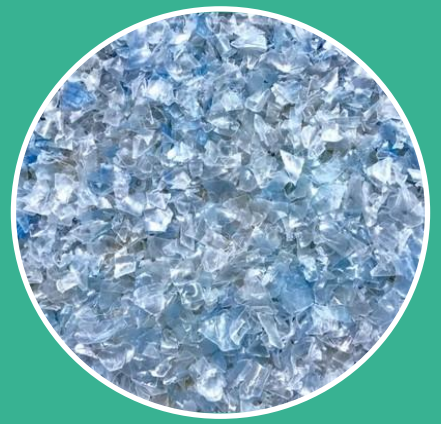
- The recycling process must be **capable of applying the suitable technology** for PET so that **plastic materials and articles manufactured with it,**

  - **meet Article 3 of Regulation (EC) No 1935/2004**,
    - i.e. they do not transfer their constituents to food in quantities which could a) endanger human health, b) bring about an unacceptable change in the composition of the food, and c) bring about a deterioration in the organoleptic characteristics thereof,

  - **and are also microbiologically safe.**



GENERAL PRINCIPLES FOR SAFETY ASSESSMENT OF RECYCLED PLASTICS FOR FOOD CONTACT



Input

- Considering the potential sources of contaminants: high importance of **quality of input**
- Need for pre-established **specifications**

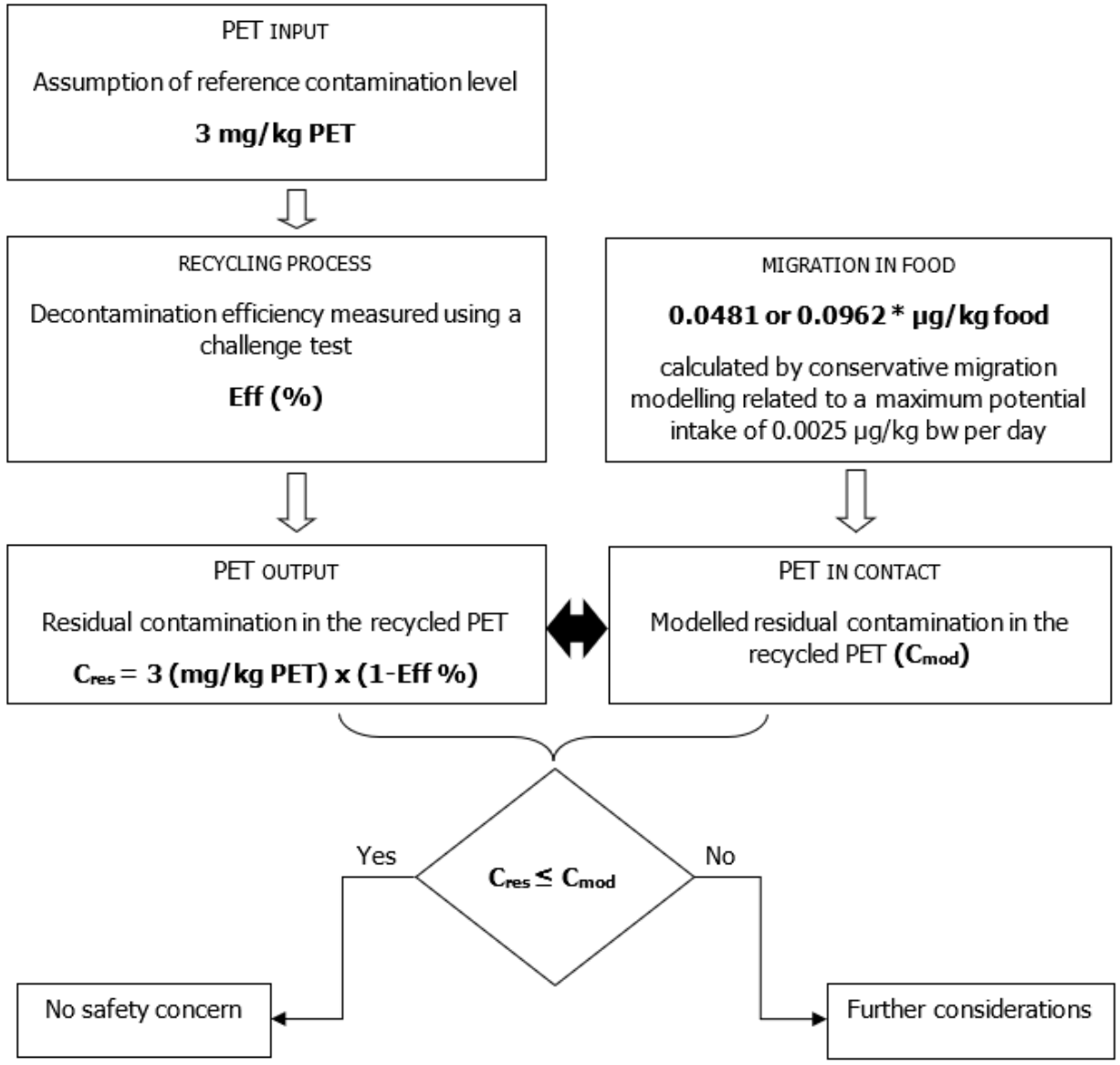
Recycling process

- **Efficiency** of the recycling process to **remove contaminants (decontamination efficiency)** → to be determined experimentally by **challenge test**

Safety assessment

- Decontamination efficiency to be assessed against a **reference input contamination** and potential migration of **residual contaminants from the recycled articles**

EVALUATION SCHEME



- Reference contamination
- Decontamination efficiency
- Migration criteria
- Actual and modelled residual contamination
- Comparison of Cres vs Cmod

Cres ≤ Cmod

→potential migration of contaminants does **not give rise to a dietary exposure exceeding the threshold of toxicological concern** for substances with a structural alert for **genotoxicity** (0.0025 µg/kg bw per day)

REFERENCE CONTAMINATION LEVEL OF THE INPUT

- Non recent relevant studies on the contamination levels of post-consumer PET bottles for the European market

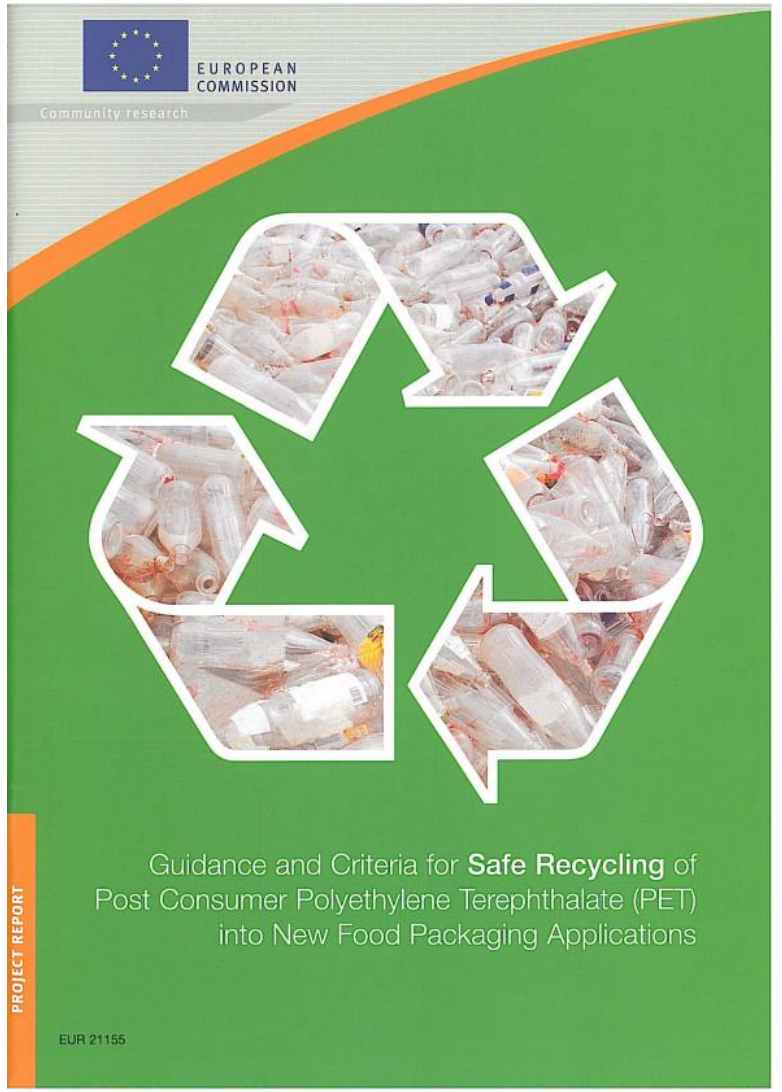
- Main source of data/information:

EU project FAIR-CT98-4318 'Recyclability'

- **washed and dried post-consumer PET flakes** obtained from thousands (7,000-10,000) of soft drink bottles collected in 12 European countries
- most typical post-consumer contaminant: limonene at an average concentration of 2.9 mg/kg and at a maximum of about 20 mg/kg
- **Misuse** contamination in **three cases** of washed and dried PET flakes:
  - Xylene: 2,000-3,000 mg/kg, Toluene: 2,000-3,000 mg/kg and 4,500-6,750 mg/kg

- **Incidence of misuse**: 0.03-0.04% → highest concentration of toluene: 1.4 to 2.7 mg/kg PET

Reference contamination level: 3 mg/kg PET



NON-FOOD CONTACT APPLICATIONS

- Possible presence of containers for **non-food applications in the input stream**, e.g. mouthwash, detergents, shampoos, household cleaning products
- Contained chemicals can be absorbed into the PET → introduction of non-food substances
- Requirements regarding collection and input (Regulation (EU) 2022/1616):

	Specification of plastic input
1. Waste management operators that participate in the supply chain of plastic input shall ensure that the collected plastic waste meets the following requirements:	
(a) the plastic waste originates only from municipal waste, or from food retail or other food businesses if it was only intended and used for contact with food, including waste discarded from a recycling scheme in accordance with Article 9(6);	
(b) the plastic waste originates only from plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011 or recycled plastic materials and articles manufactured in accordance with this Regulation;	Only PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances.
(c) the plastic waste is subject to separate collection;	
(d) the presence of plastic materials and articles that are different from the plastic for which the decontamination process is intended, including caps, labels and adhesives, other materials and substances, and remaining food is reduced to a level specified in the requirements for the plastic input provided by the recycler and which shall not compromise the achieved level of decontamination.	

NON-FOOD CONTACT APPLICATIONS

- If it is demonstrated (by the challenge test) that the recycling process is able to remove surrogate contaminants, this applies to all possible contaminants represented by the surrogates, irrespectively of their origin.

- However, in any case, containers coming from non-food uses should not intentionally be included as input for the recycling stream

→Mechanical recycling of PET: no more that 5% non-food contact input

NON-FOOD CONTACT APPLICATIONS

- According to data from literature, substances found in non-food PET containers:
  - **Methyl salicylate**: 15 mg/kg non-food PET containers (Bayer, 2002)
  - **2-Butanone**: 20 mg/kg non-food PET containers (Franz and Welle, 2020)
  - **Ethanol**: 440, 940, 1100 mg/kg non-food PET containers (Franz and Welle, 2020)

Detection frequency / 5% non-food containers in the input

Concentration of non-food contact substances in the input in the range or below the reference contamination (3 mg/kg PET)

DIETARY EXPOSURE

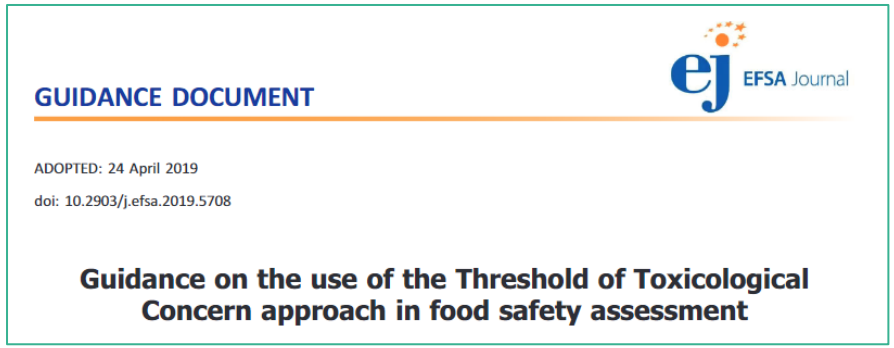
- **Dietary exposure via migration** into food of a potential unknown contaminant shall not exceed a level of dietary exposure below which the risk to human health would be negligible.
- It is **impossible to predict the identity of contaminants** potentially present in post-consumer PET used as input of a recycling process and to ensure that they are not genotoxic.

→Therefore, a level of **dietary exposure** that can be **considered of negligible risk to human health** must take this possibility into account.

DIETARY EXPOSURE – NEGLIGIBLE RISK TO HUMAN HEALTH

- Exposure level for chemicals with structural alerts that raise concern for **potential genotoxicity** based on **human exposure threshold value below which the probability for adverse effect for human health is negligible**

0.15 µg/person/day for a person of 60 kg body weight (bw), corresponding to **0.0025 µg/kg bw per day**



→Generally considered low enough to address concern over all toxicological effects

→Low probability of contamination of post-consumer PET by misuse with substances classified as genotoxic

→Reactivity of functional groups associated with genotoxicity → reaction during recycling process at high temperatures → decrease of concentration/migration

EXPOSURE SCENARIOS

Previous evaluation criteria

Infants scenario: 150 g/kg bw per day

Scenario A

- **Water and baby bottle contents** such as reconstituted milk formula
- Consumption: **260 mL/kg bw per day** (EFSA Scientific Committee, 2017)

Toddlers scenario: 90 g/kg bw per day

Scenario B

- **Milk, liquid milk products** and other **non-alcoholic drinks** (e.g. fruit and vegetable juices); **Solid foods specifically intended for infant and toddlers**
- Consumption: **80 g/kg bw per day** (EFSA CEF Panel, 2016)

Adults scenario: 16.7 g/kg bw per day

Scenario C

- **All other foods** not covered by the previous scenarios
- Consumption: **20 g/kg bw per day** (EFSA CEF Panel, 2016)

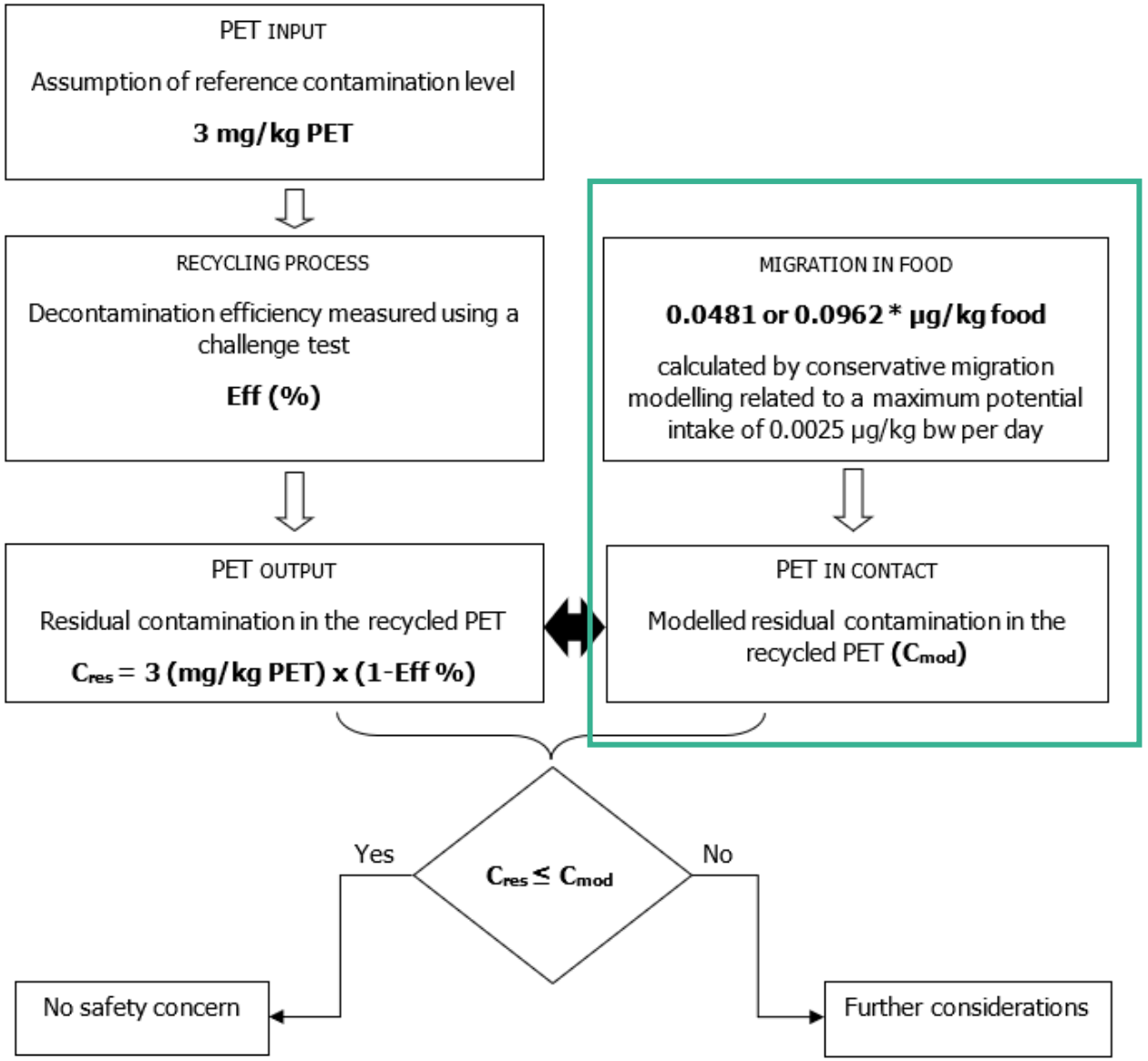
Predefined exposure scenarios to be selected by applicants

EXPOSURE SCENARIOS AND MIGRATION CRITERIA

			Maximum migration
Scenario A	• Consumption: **260 mL/kg bw per day**	Human **exposure threshold** value: 0.0025 µg/kg bw per day	**0.00962** µg/kg food
Scenario B	• Consumption: **80 g/kg bw per day**		**0.0312** µg/kg food
Scenario C	• Consumption: **20 g/kg bw per day**		**0.125** µg/kg food

These migration values are related by **migration modelling** to **maximum residual concentrations in PET** after decontamination *(Cmod)*

FROM MIGRATION TO MODELLED CONTAMINATION IN PET

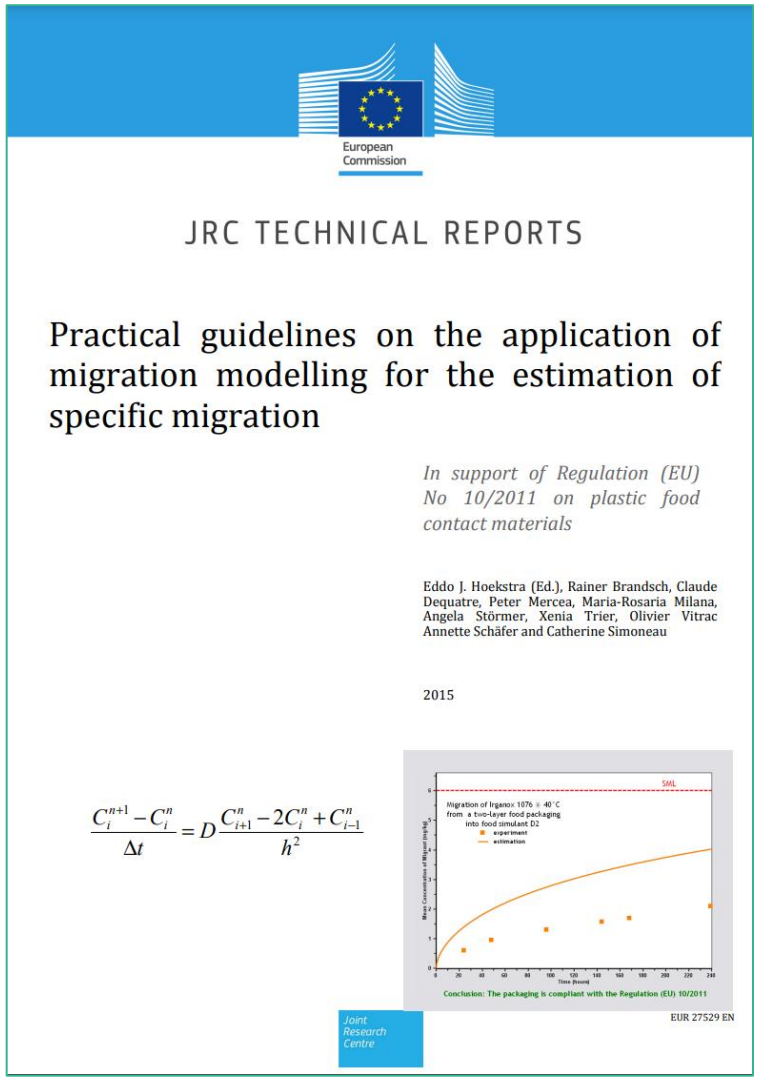


CMOD - MIGRATION MODELLING

- Use of generally recognised migration models in order to estimate the concentration in PET (Cmod), which corresponds to the migration criterion
- These models are settled to be conservative: modelled migration always overestimates the experimental migration
- Overestimation increases with molecular weight of the migrants
- Overestimation factors:
  - **5** for MW ≤ 150 Da and **10** for MW> 150 Da

Previous evaluation criteria: Overestimation factor of 5 independently of the molecular weight

- How to get the modelled concentration IN PET (Cmod)?
  - *a) Calculate the modelled migration in food (i.e the migration criterion)*
  - *b) relate the modelled migration in food (migration criterion) with the modelled concentration **IN PET** (Cmod)*


European Commission

JRC TECHNICAL REPORTS

Practical guidelines on the application of migration modelling for the estimation of specific migration

In support of Regulation (EU) No 10/2011 on plastic food contact materials

Eddo J. Hoekstra (Ed.), Rainer Brandsch, Claude Dequatre, Peter Mercea, Maria-Rosaria Milana, Angela Störmer, Xenia Trier, Olivier Vitrac Annette Schäfer and Catherine Simoneau

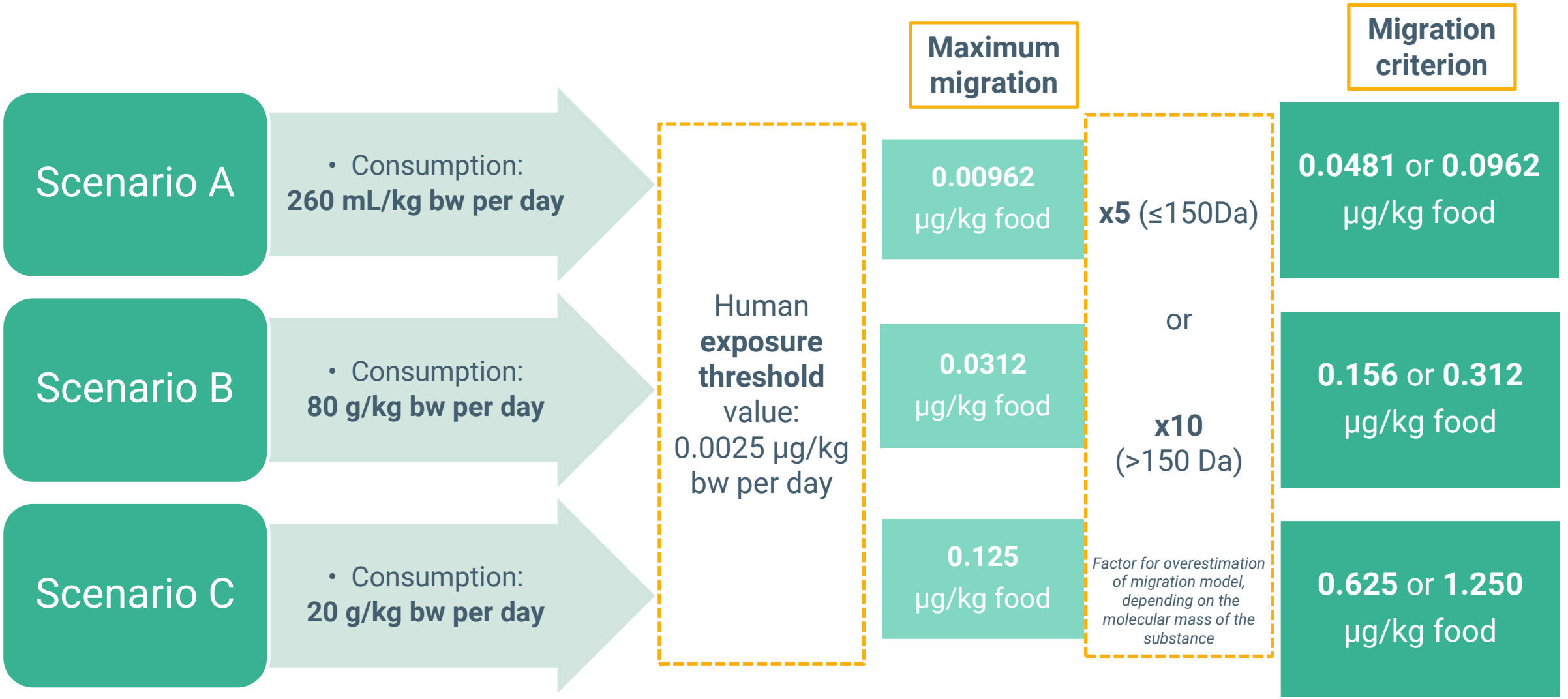
2015

$$\frac{C_i^{n+1} - C_i^n}{\Delta t} = D\frac{C_{i+1}^n - 2C_i^n + C_{i-1}^n}{h^2}$$

Joint Research Centre

EUR 27529 EN

EXPOSURE SCENARIOS AND MIGRATION CRITERIA



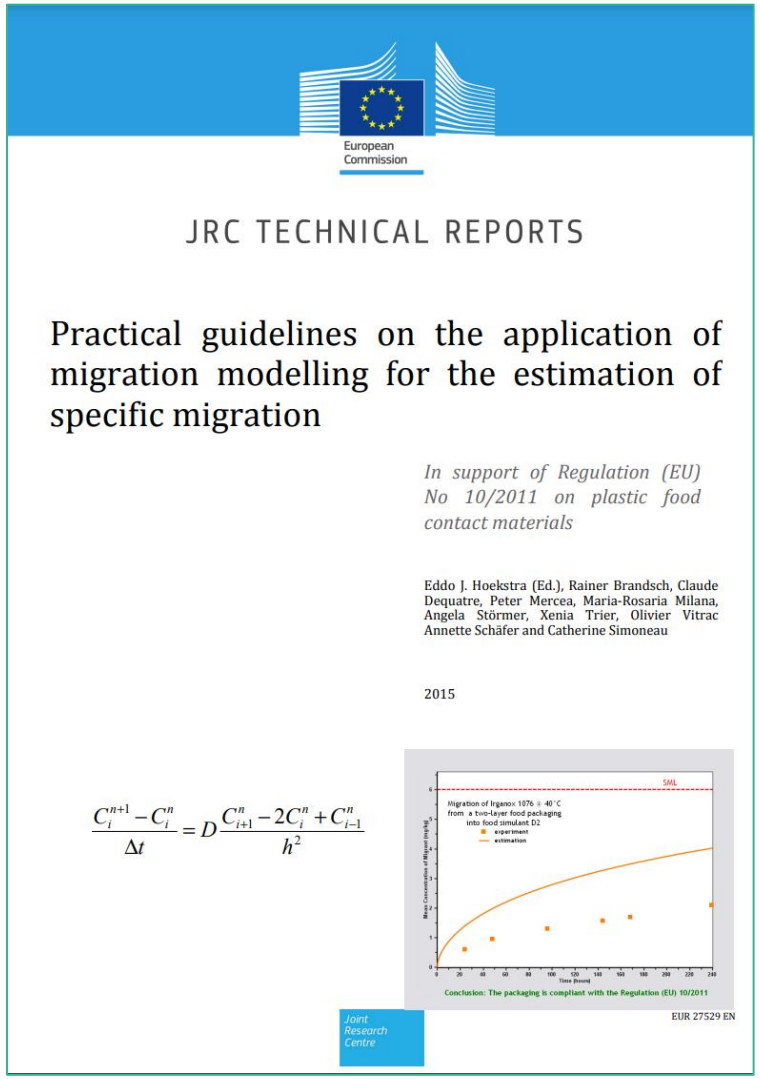
CMOD - MIGRATION MODELLING

- Use of generally recognised migration models in order to estimate the concentration in PET (Cmod), which corresponds to the migration criterion

EXAMPLE FOR SCENARIO A (INFANT/WATER)

Modelling parameters:

- Migration criterion (infants): 0.0481 or 0.0962 µg/kg food
- Long term ambient storage, a shelf life of 1 year at 25°C
- Good solubility of the migrant in food simulant is assumed, (KP/F =1)
- FCM made entirely with 100% recycled PET
- Surface/volume ratio: 6 dm^2 PET to 1 kg food/drink
- Material thickness: 300 µm
- PET density: 1.375 g/cm^3
- Modelling parameters Ap' = 3.1 and τ = 1577 (used to estimate the diffusion coefficient in PET)



CMOD - CALCULATED BY MIGRATION MODELLING

- **Calculated Cmod values for predefined exposure scenarios** available in Appendix D of the scientific guidance

Surrogate	Mr (Da)	Cmod (mg/kg PET) Scenario A	Cmod (mg/kg PET) Scenario B	Cmod (mg/kg PET) Scenario C
Toluene	92.1	0.04	0.13	0.51
Chlorobenzene	112.6	0.05	0.15	0.60
Chloroform	119.4	0.05	0.16	0.63
Methyl salicylate	152.2	0.12	0.40	1.60*
Phenylcyclohexane	160.3	0.13	0.42	1.69*
Benzophenone	182.2	0.15	0.49	1.96
Lindane	290.8	0.28	0.92	3.67*
Methyl stearate	298.5	0.29*	0.95*	3.82*

*Deviation of one unit of the last digit may occur when using different software.

COMPARISON CRES *vs* CMOD

- **Cmod:**

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- **Cres**: by applying the decontamination efficiency to the reference contamination (3 mg/kg)
  - Example: Phenylcyclohexane (molecular mass 160.3 Da)
    - Decontamination efficiency: 98.5%
    - **Cres** = 3 mg/kg x (1-0.985) = **0.05 mg/kg PET**

- Cres: 0.05 mg/kg
- Cmod scenario A: 0.13 mg/kg

→**Cres < Cmod**

→ **Decontamination efficiency for phenylcyclohexane is sufficient for scenario A**

COMPARISON CRES VS CMOD

- *What happens if Cres > Cmod?*

  - **Cres** phenylcyclohexane: 0.25 mg/kg

→Scenario B and C:

0.25 < 0.42 and 1.69 → passes for 100% rPET for food categories included in Scenarios B and C

→Scenario A:

0.25 > 0.13 → does not pass for 100% rPET, but only for 50% rPET for food categories included in Scenario A

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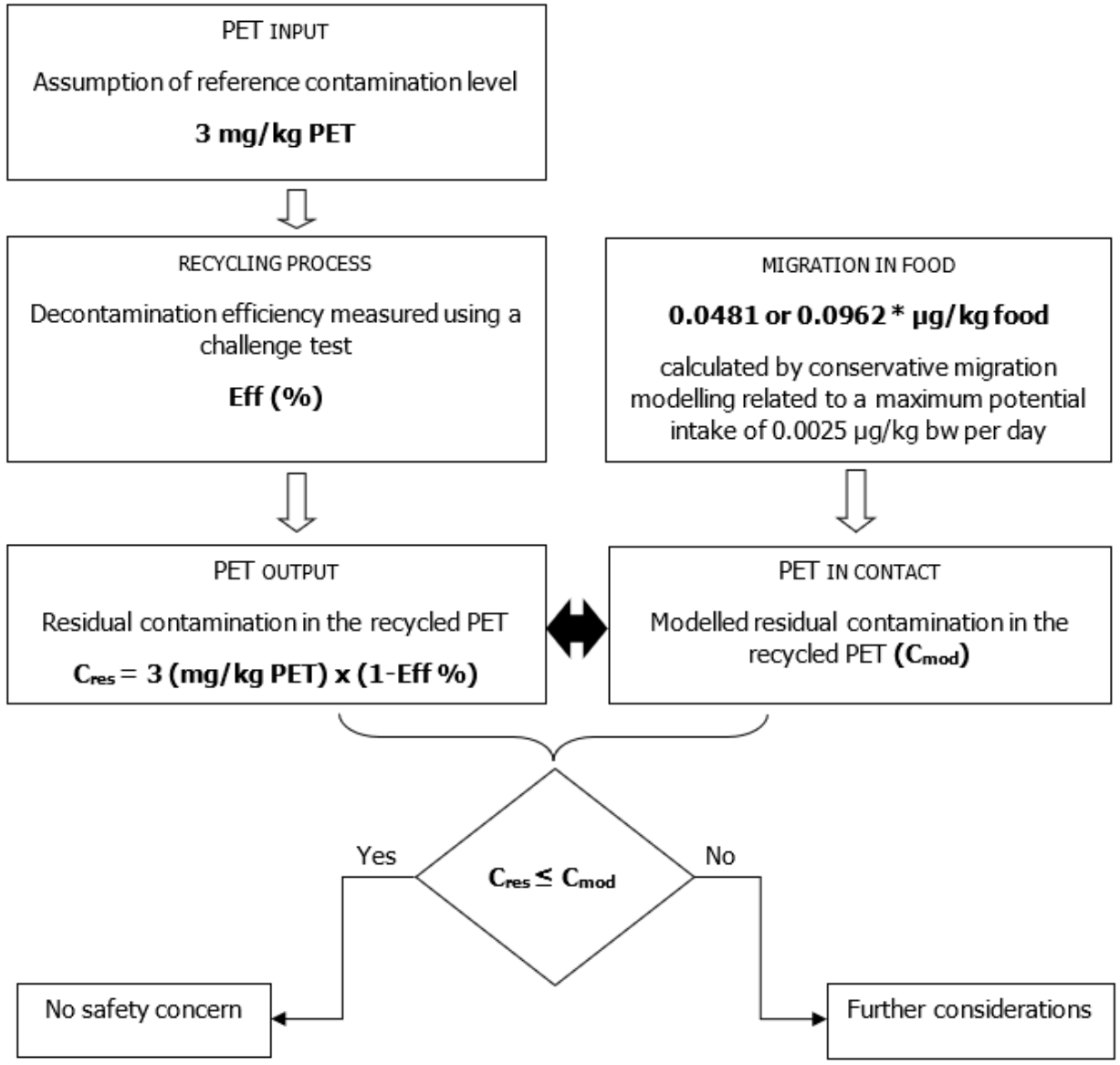
EVALUATION SCHEME



Cres ≤ Cmod

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ASSUMPTIONS AND UNCERTAINTIES IN THE APPROACH

No recent surveys on the frequency and severity of the contamination of post-consumer PET waste streams

(other than the EU FAIR project)

Overestimation of migration from PET by the migration model due to the inbuilt conservative parameters

Migration calculations based on the assumption that all food consumed each day is in contact with 100% rPET and has been in contact for 12 months at 25°C before consumption

Migration model with high uncertainties at the temperatures applied in microwave/oven → such uses are excluded from scope of suitable technology

Sporadic, if any, presence of unknown and possibly genotoxic contaminants in recycled PET (taking into account the collection systems)