EFSA GUIDANCE ON PET RECYCLING AND UPDATE ON NOVEL TECHNOLOGIES

FIP FCM Network, 22-24 October 2024

Katharina Volk (EFSA FIP)

EUROPEAN FOOD SAFETY AUTHORITY

BACKGROUND

- **October 2022:** entry into force of Regulation (EU) 2022/1616 on recycled plastics for food contact, and repealing Regulation (EC) No 282/2008

- New concepts and terminologies
- New procedures (suitable vs novel technologies)
- New requirements for the technical dossier to be submitted by an applicant

Need for updating EFSA's guidance documents for the area of recycling plastics

20.9.2022 EN Official Journal of the European Union L 243/3

COMMISSION REGULATION (EU) 2022/1616

of 15 September 2022

on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008

MANDATE

- Request for EFSA to prepare guidance documents laid down in **Article 20** of Regulation (EU) 2022/1616

Article 20

Guidance published by the Authority

1. The Authority shall publish detailed guidance, following the agreement with the Commission, concerning the preparation and the submission of the application, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.

2. For each suitable recycling technology for which the authorisation of individual recycling processes is required, the Authority shall publish scientific guidance describing the evaluation criteria and the scientific evaluation approach it will use to evaluate the decontamination capability of those recycling processes. The guidance shall specify the information required to be included in an application dossier for the authorisation of a recycling process applying that specific technology.

Administrative guidance

Scientific guidance

BACKGROUND

- Core documents related to EFSA's work on the safety evaluation of recycling processes:
  - **Scientific** guidance:
    - Criteria for safety evaluation of PET recycling processes (2011)
    - Guidelines on recycling plastics (2008; administrative update in 2021 for alignment with the Transparency Regulation)
  - **Administrative** guidance (2021)

OBSOLETE


efsa
European Food Safety Authority
EFSA Journal 2011;9(7):2184

SCIENTIFIC OPINION

Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food[1]

EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)[2,3]

European Food Safety Authority (EFSA), Parma, Italy


efsa
European Food Safety Authority
The EFSA Journal (2008) 717

tific Panel on food additives, flavourings, processing
in contact with food (AFC) on

dossier for safety evaluation by the EFSA of a
uce recycled plastics intended to be used for
and articles in contact with food


efsa
TECHNICAL REP

APPROVED: 9 March 2021
IMPLEMENTATION DATE: **27 March 2021**
doi:10.2903/sp.efsa.2021.EN-6512

Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food

European Food Safety Authority (EFSA)

MANDATE

- → EFSA internal mandate for the preparation of a **scientific guidance** on **post-consumer mechanical PET recycling** processes intended to be used for manufacture of materials and articles in contact with food

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Recycling technology number	Technology name	Polymer type (detailed specification in Table 2)	Short description of the recycling technology (detailed specification in Table 3)	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances.	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	Yes

The development of guidance for other technologies and/or plastics may be considered in the future, in line with the procedures set out for novel technologies in Regulation (EU) 2022/1616

TERMS OF REFERENCE

- Prepare a **scientific guidance on post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food**.
- Starting point: the **previously published scientific outputs** providing the context for the evaluation of recycling processes (i.e. guidelines on recycling plastics (EFSA, 2008) and criteria for safety evaluation of PET recycling processes (EFSA CEF Panel, 2011)) **should be**

1) updated, taking into account the new legislative context of Regulation (EU) 2022/1616 as well as new scientific evidence, if available, and

2) integrated into **one scientific guidance,** presenting

- the evaluation criteria and the scientific evaluation approach that will be used to evaluate the decontamination capability of such recycling processes, and

- the requirements for the content of the technical dossier.

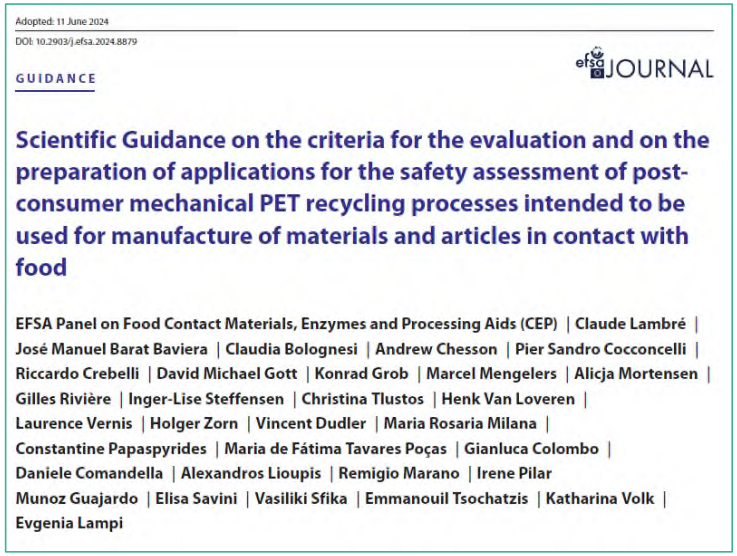
SCIENTIFIC GUIDANCE

44th plenary meeting of the CEP Panel - Open for observers

11 June 2024, 14.00 - 18.00 (CEST);
12 June 2024, 09.00 - 18.00 (CEST);
13 June 2024, 09.00 - 15.30 (CEST)

Parma, Italy

Share:



Adopted: 11 June 2024
DOI: 10.2903/j.efsa.2024.8879

efsa JOURNAL

GUIDANCE

Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) | Claude Lambré | José Manuel Barat Baviera | Claudia Bolognesi | Andrew Chesson | Pier Sandro Cocconcelli | Riccardo Crebelli | David Michael Gott | Konrad Grob | Marcel Mengelers | Alicja Mortensen | Gilles Rivière | Inger-Lise Steffensen | Christina Tlustos | Henk Van Loveren | Laurence Vernis | Holger Zorn | Vincent Dudler | Maria Rosaria Milana | Constantine Papaspyrides | Maria de Fátima Tavares Poças | Gianluca Colombo | Daniele Comandella | Alexandros Lioupis | Remigio Marano | Irene Pilar Munoz Guajardo | Elisa Savini | Vasiliki Sfika | Emmanouil Tsochatzis | Katharina Volk | Evgenia Lampi

- **Adopted** on 11 June 2024

- **Published** on 30 July 2024

https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2024.8879

- **Targeted** consultation
  - 13 December 2023 – 11 January 2024
  - Open only to Member State public institutions
  - 12 comments received
- **Public** consultation
  - 7 February – 20 March 2024
  - Open to the entire public
  - 28 comments received

→ Outcome of the consultations is reported in **Annex B of the guidance**

ADMINISTRATIVE GUIDANCE

Individual recycling processes – Administrative guidance

APPROVED: 17 June 2024, pending agreement from European Commission
doi:10.2903/sp.efsa.2024.EN-8968

Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food[1]

European Food Safety Authority (EFSA)

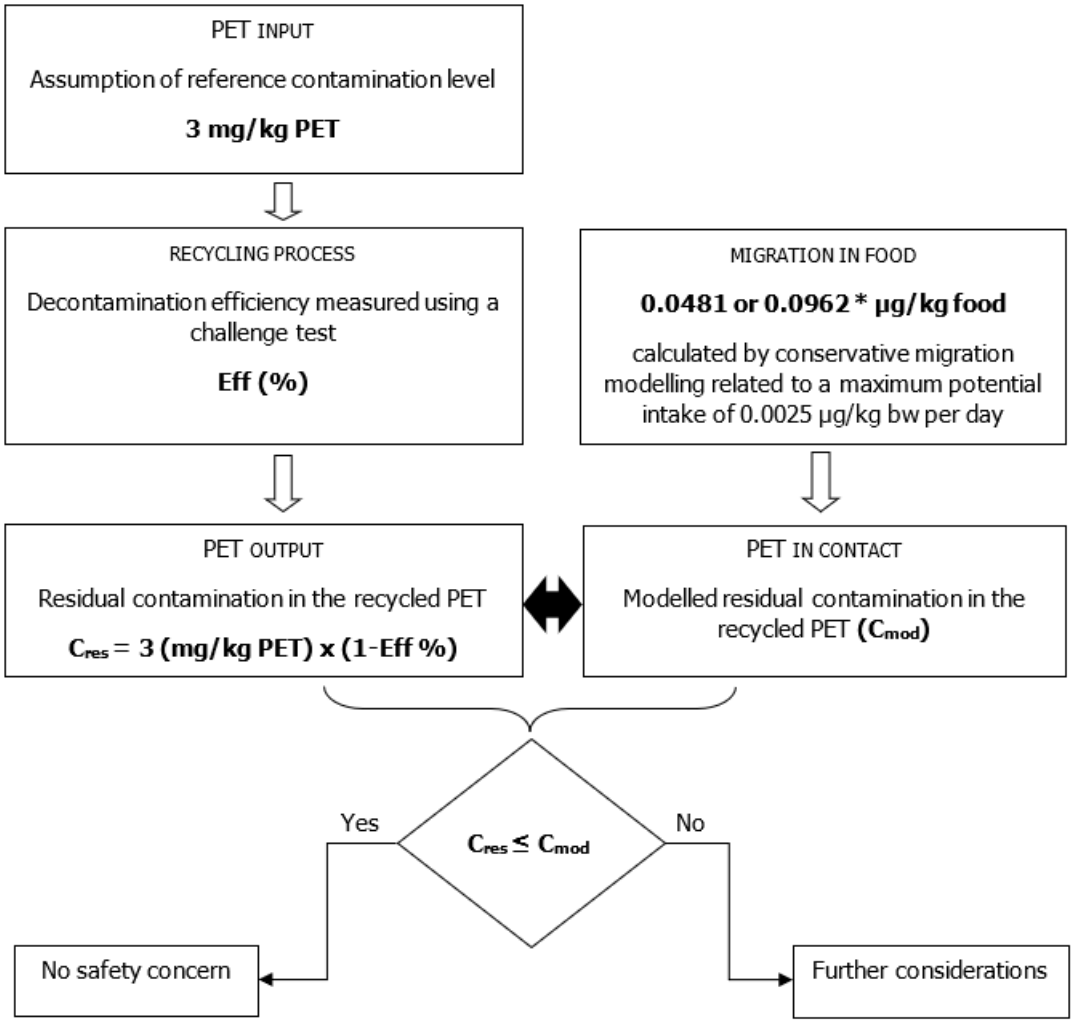
- Update in consideration of
  - the new legislative requirements of Regulation (EU) 2022/1616
  - the requirements laid down in the scientific guidance

- Published on 30 July 2024
  https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2024.EN-8968

SCIENTIFIC GUIDANCE

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

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)

EVALUATION CRITERIA

- Two major changes introduced after the public consultation

Exposure scenarios
for food categories

Overestimation factor for **migration modelling** in relation to molecular weight of the substances

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

MR0

EXPOSURE SCENARIOS AND MIGRATION CRITERIA

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

Maximum migration

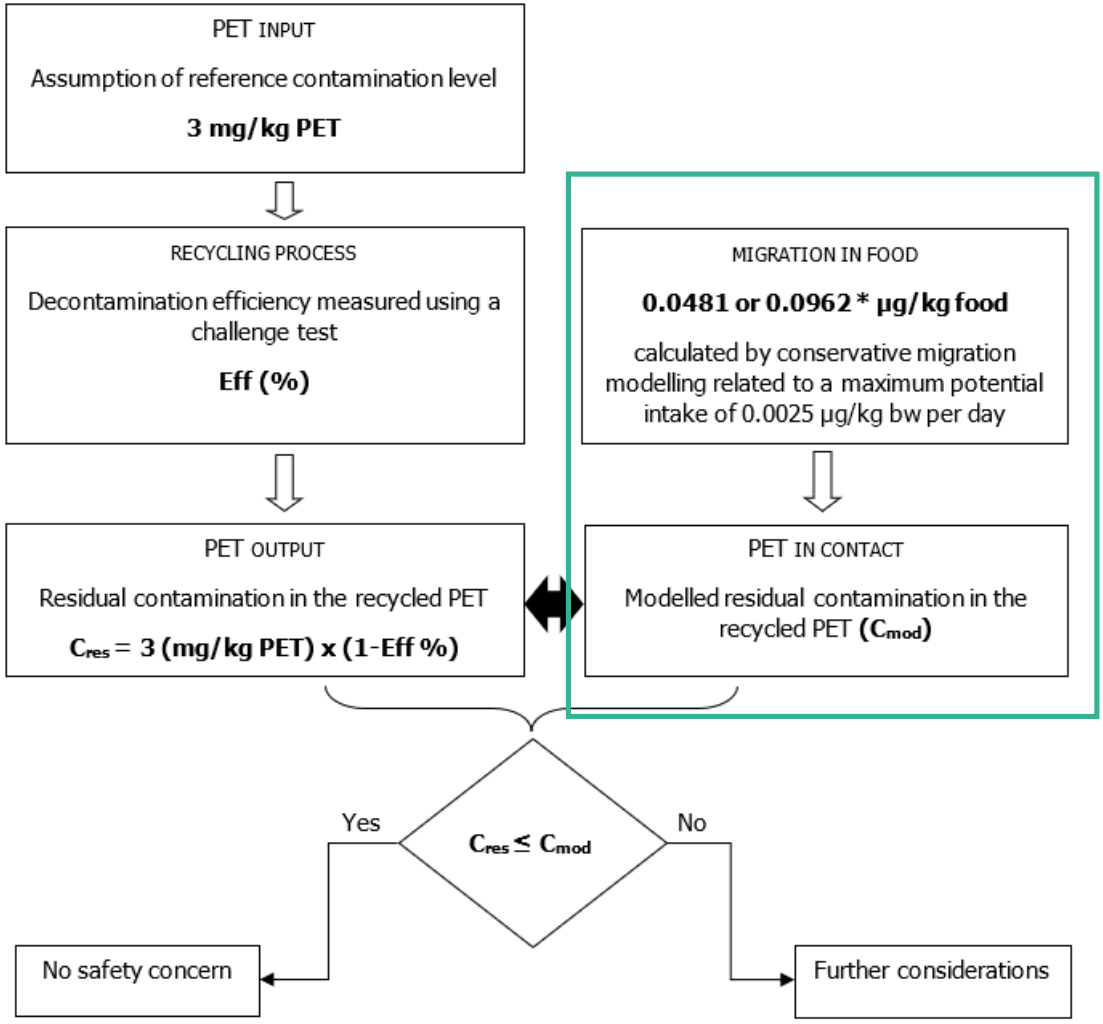
These migration values are related by **migration modelling** to **maximum residual concentrations in PET** after decontamination *(Cmod)*

Slide 13

MR0 I spilitted the slide. From my experience in BTSF It is better not to show all the calculatiosn togheter without an explanation step by step
MILANA Maria Rosaria, 2024-08-08T07:10:05.962

VK0 0 Ok for me, indeed easier for the participants
VOLK Katharina, 2024-08-13T12:43:43.962

FROM MIGRATION TO MODELLED CONTAMINATION IN PET MR0



Slide 14

MR0 I think it is more clear if we add CONTAMINATION IN PET
MILANA Maria Rosaria, 2024-08-08T07:28:59.676

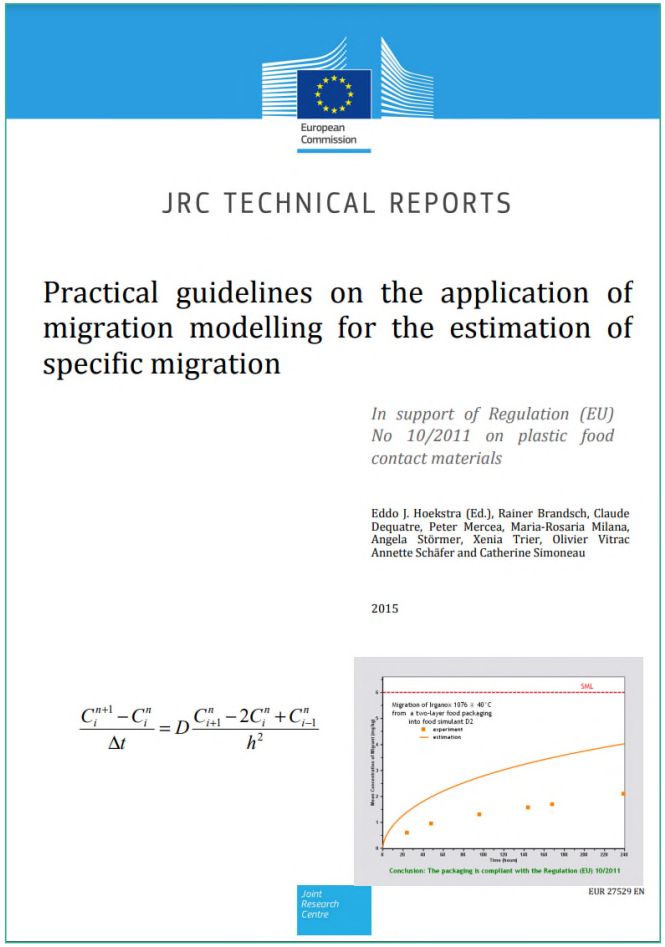
VK0 0 Fine for me, then it is also aligned with the figure
VOLK Katharina, 2024-08-13T12:47:02.453

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 corresponding to the migration criteria*
  - *b) relate the modelled migration in food 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

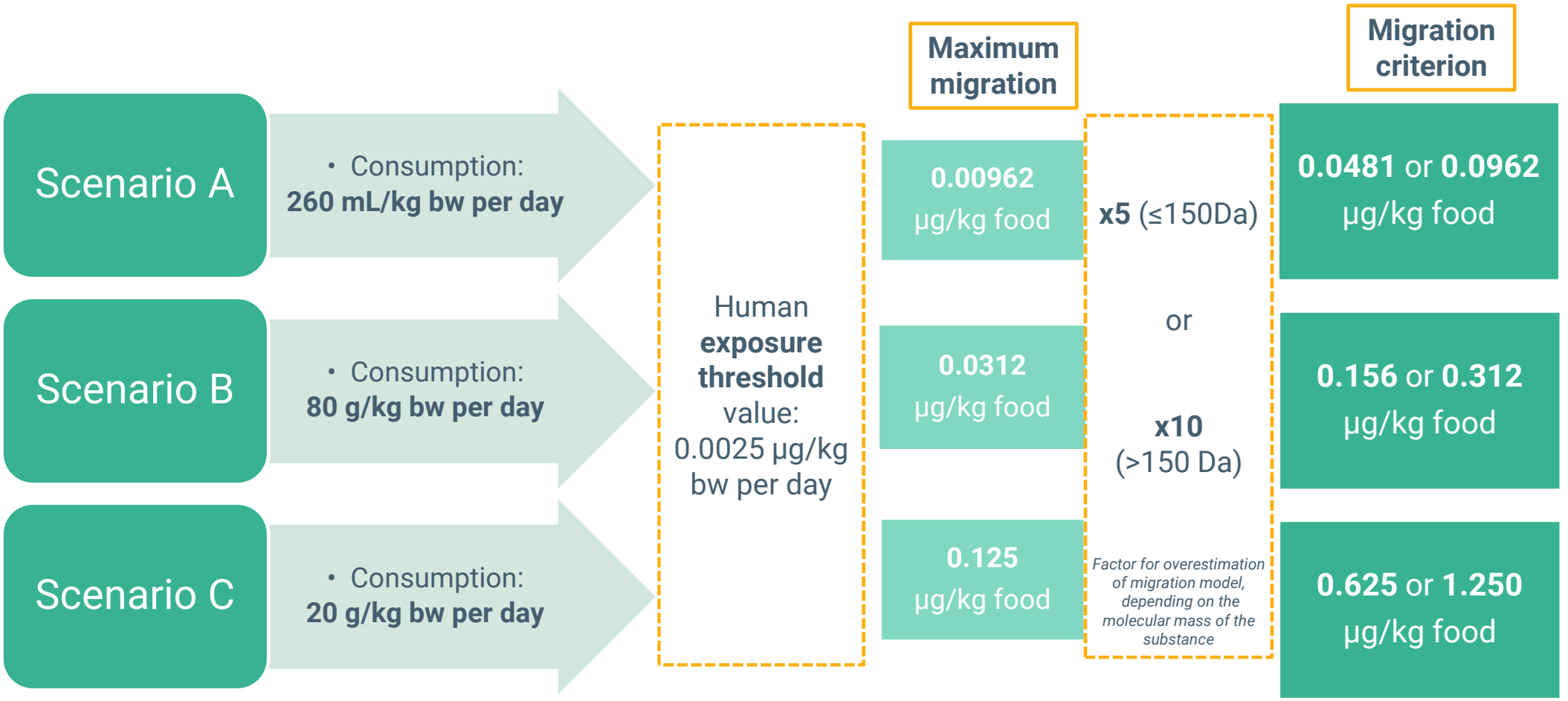
$$\frac{C_i^{n+1} - C_i^n}{\Delta t} = D\frac{C_{i+1}^n - 2C_i^n + C_{i-1}^n}{h^2}$$

Joint Research Centre

EUR 27529 EN

MR0

EXPOSURE SCENARIOS AND MIGRATION CRITERIA



Slide 16

MR0 I added Animation for these 2 boxes. easier to explain tghe step
MILANA Maria Rosaria, 2024-08-08T07:58:09.740

VK0 0 Ok, fine with me
VOLK Katharina, 2024-08-13T12:54:25.567

CMOD - MIGRATION MODELLING

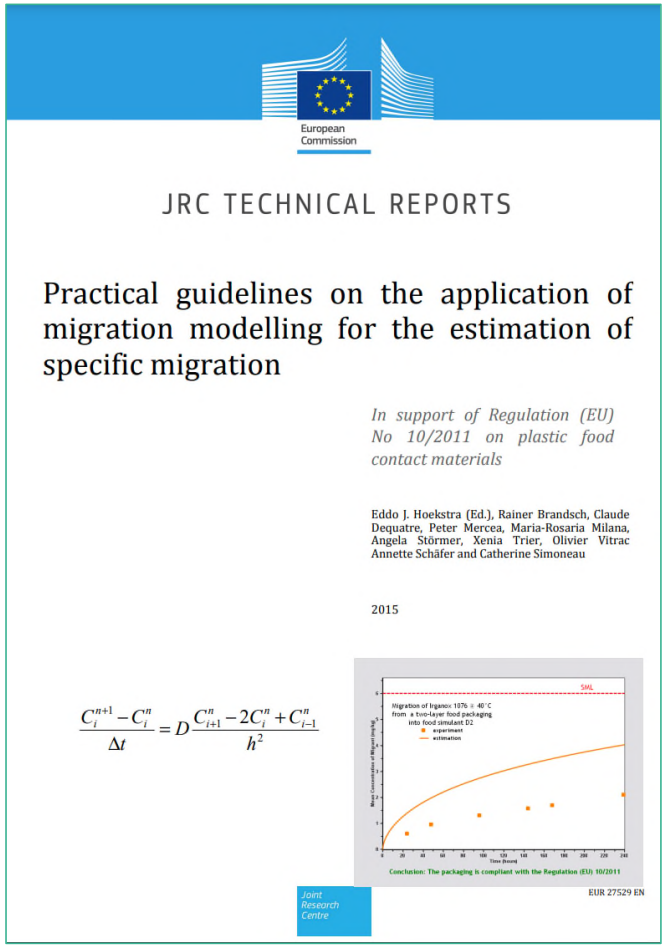
- Use of generally recognised migration models in order to estimate the concentration in PET (Cmod), which corresponds to the migration criterion

EXAMPLE FOR SCENARIO A (INFANT/WATER)

MR0

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)



Slide 17

MR0 to be more clear
MILANA Maria Rosaria, 2024-08-08T08:00:27.464

VK0 0 Ok, I added also scenario A&water
VOLK Katharina, 2024-08-13T13:01:21.527

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*

Surrogate	M W (Da)	Cmod (mg/kg PET)
Toluene	92	0.09
Chlorobenzene	113	0.09
Methyl salicylate	152	0.13
Phenylcyclohexane	160	0.14
Benzophenone	182	0.16
Lindane	291	0.31
Methyl stearate	298	0.32

Notes

a) This Table is for the default scenario (Infants). Cmod corresponding to other scenarios (adults, toddlers) can be calculated by using the parameters in point A.

b) Other figures could be considered if appropriate scientific argumentations, when necessary supported by experimental data, is provided to EFSA.

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

MR0

COMPARISON CRES *vs* CMOD

- **Cmod:**

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

- **Cres**: by applying the decontamination efficiency to the reference contamination (3 mg/kg)
  - Phenylcyclohexane - example 1:
    - Decontamination efficiency: 98.5%
    - **Cres** = 3 mg/kg x (1-0.985) = **0.05 mg/kg PET**
    - Cres 0.05 < Cmod (scenario A) 0.13
      - **Decontamination efficiency for phenylcyclohexane is sufficient for scenario A**

- Phenylcyclohexane – example 2:
  - Cres = 0.25 mg/kg PET

→Scenario B and C:

0.25 < 0.42 and 1.69 → passes for 100% rPET for Scenarios B and C

→Scenario A:

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

Slide 19

MR0 I added animation for an easier presentation and to facilitate audience to follow. Better to explain what is on the screen an then add the other boxes, otherwise the audience will watch all the boxes not following the explanation.
MILANA Maria Rosaria, 2024-08-08T08:17:27.126

VK0 0 Surely fine, thanks
VOLK Katharina, 2024-08-13T13:03:01.199

REQUIREMENTS FOR THE CONTENT OF THE TECHNICAL DOSSIER

Article 17

Application for the authorisation of individual recycling processes

5. The technical dossier shall contain the following information:

(a) any information required in the detailed guidance published by the Authority in accordance with Article 20(2);

(b) a description of the pre-processing carried out to produce plastic input suitable for being entered into the decontamination process and of the specific quality control procedures applied during collection and pre-processing, including a detailed specification of the pre-processed plastic input;

(c) a description of any required post-processing of the recycled plastic and of the intended use of the resulting plastic materials and articles and of uses for which it would not be suitable, including relevant instructions and labelling to be provided to convertors and to end-users of the recycled plastic materials and articles;

(d) a simple block diagram of all unit operations used in the decontamination process, that provides a reference to the input, output and quality control procedures applied by each operation;

(e) a piping and instrumentation diagram of the decontamination process in accordance with section 4.4 of ISO 10628-1:2014, showing only the instrumentation relevant for decontamination;

(f) a description of the quality control procedures applied at each unit operation of the decontamination process, including:

(i) the values of monitored parameters such as operating temperatures, pressures, flowrates and concentrations, and acceptable ranges thereof;

(ii) laboratory analysis and its frequency; if any,

(iii) correction and record keeping procedures; and

(iv) any other information the applicant deems relevant to fully describe its quality control procedures.

REQUIREMENTS FOR THE CONTENT OF THE TECHNICAL DOSSIER

- In addition to the requirements laid down in Article 17(5), data requirements for the following topics were elaborated:
  - Description of the **decontamination process** (equipment and operation)
  - **Challenge test** (contamination procedure, challenge test equipment and operation, determination of surrogate levels, derivation of decontamination efficiency)
  - **Self-evaluation** of the recycling process

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EUROPEAN FOOD SAFETY AUTHORITY