FOOD CONTACT REPEATED USE APPLICATIONS

Guidance REV 3

Proposals for exposure assessments for plastic intermediate materials and articles in the frame of article 19 of Plastic Regulation (EU) No 10/2011[1]

[1] **Disclaimer Confidential**

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DISCLAIMER
This guidance is to be considered as a living document.
It will be regularly updated according to the evolution of the legislation and science.

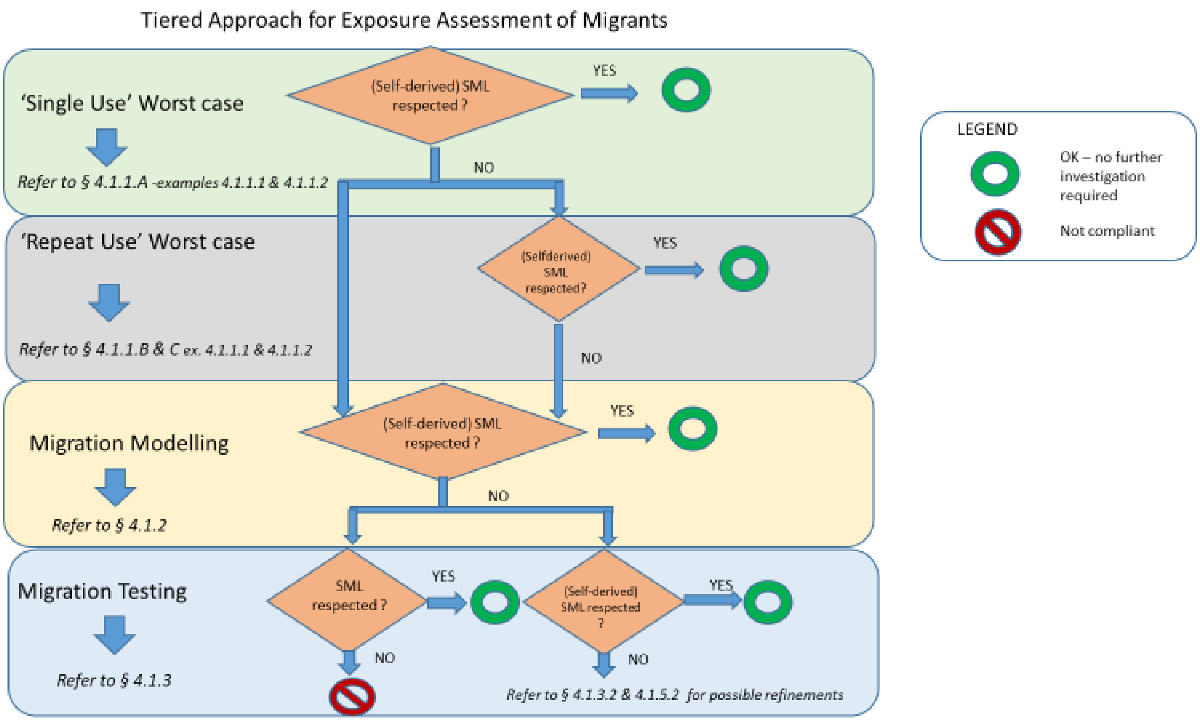
This document is representing the work of the Repeated use task force on the basis of the current knowledge.
It needs to be reviewed and amended by the Food Contact Committee of plastics Europe.

At this stage is it is only for internal review and use within PlasticsEurope and selected members of other associations and not to be further distributed.

THANKS TO NOT DISTRIBUTE FURTHER AT THIS STAGE.
Please revert with all your comments/corrections to Plastics Europe Manager (Michel.cassart@plasticseurope.org).

Executive summary

This guidance proposes a tiered approach for exposure assessments of migrants, one of the two pillars needed for risk assessments. In first instance this guidance document has been developed for Non-Listed Substances (NLS) and Non-Intentionally Added Substances (NIAS) subject to self-derived SML. Same principles are already applied or might be applied in future to Listed substance subject to SML. The outcome of the different exposure routes is leading to the decision tree for the risk assessment following article 19 of the Plastic regulation (EU) No 10/2011 as shown hereunder.



1. ABBREVIATIONS USED

Table 0: Abbreviations used

Abbreviations	Explanations
A_R	A_R relative contact area of rubber product per kg food
BfR	BundesInstitut für Risikoberwertung
DoC	Declaration of Compliance
EDI	Estimated Daily Intake
EDQM	European Directorate for the Quality of Medicine & Healthcare
EFSA	European Food Safety Authority
FCN	Food Contact Notification
JRC	Joint Research Center
LOI	Level of Interest
MoE	Margin of Exposure
NIAS	Non Intentionally added substances
NLS	Non listed substances
NP	Nanoparticles
OML	Overall Migration Limit
PAA	Primary Aromatic Amines
PIM	Plastic Implementation Measure
SML	Specific Migration Limit
TNO	The Netherlands Organization for Applied Scientific Research
ToR	Threshold of Regulation
TDI	Tolerable Daily Intake
TEL	Tolerable Exposure Level
TPE	Thermoplastic elastomers (see definition - paragraph 3)
TTC	Threshold of Toxicological Concern

(Remark: TNO Triskelion, which is a wholly-owned subsidiary of TNO, is the part of TNO we are referring too)

2. SCOPE OF THE GUIDANCE DOCUMENT

The aim of this Guidance is to give support for companies which are in the process of risk assessing their products intended for repeated use food contact applications, since there is currently no pragmatic methodology or rules covering these materials, even though they need to fulfil their obligation of safety. In particular NLS and NIAS need to be risk assessed, according to Article 19 of PIM Regulation.

For this purpose, different exposure scenarios have been investigated, starting with a very conservative scenario (worst case single use) up to more realistic exposure scenario (probabilistic exposure assessment).

This guidance aims to provide different tools adapted to plastics to evaluate their risks to consumers.

The scope of this document is to review the different available approaches and adapt them to risk assess plastic materials and articles intended for repeated use applications. These approaches are developed/proposed based on available information from the supply chain and on the possible options for generic approaches to risk assessment for repeated use applications.

This guidance specifically addresses plastic materials. Reference to rubber articles is only made to explore the exposure assessment approach applied in rubber legislation with considerations on how this could be applied to plastics (section 4.1.5.4).

Although some repeated use articles are multi component articles, we are looking in this guidance document to individual parts and their risk assessments.

Producers of plastics are required to risk assess their products as defined in article 19 of Regulation (EU) No 10/2011. In addition to single use packaging, plastics are used in many other applications, including the food industry and/or appliances used at home.

Please find here a non-exhaustive list of examples:

- Food industry: pipes, filters, membranes, food industry machinery, containers, crates …
- At home: food boxes, kitchenware, dishes, small electric appliances, baby bottles, camping equipment…

(See **Annex 8.1** list of typical repeated use articles and materials covered by the guidance and **Annex 8.2** which lists the typical polymers used for their manufacture).

Although the regulation (EU) No 10/2011, referred to as the PIM (Plastics Implementation measure), covers all the above areas, up to now, the current available exposure tools (Matrix and Facet, see section 4.1.4) have only been developed to cover packaging material.

Within the scope of this guidance, we will use intentionally added substances to demonstrate the validity of the approaches developed, although the methodology developed are meant to take care of non-listed (NLS) substances and particularly the Non Intentionally Added Substances (NIAS).

Examples of Non-Listed Substances (NLS) are e.g. polymer production aids (PPA's), aids to polymerization (AP's), solvents, colorants as defined in the PIM.

The plastics industry requires guidelines and generic methodologies to address the legislative requirements regarding their position in the supply chain and to support their customers in their exercise to place compliant finished products on the market.

Over its life, food can be in contact with plastic materials through 4 steps:

- Contact within the food supply chain
- Contact in the food processing Industry
- Contact with Packaging - covered by existing exposure tools
- Contact with appliance and utensils in the kitchen: kitchenware, miscellaneous applications such as camping equipment

Up until now, PlasticsEurope's work on generic risk assessment has focused on food packaging [1] with limited rules applicable to repeated use materials. Processing conditions in the food industry and conditions of use of kitchen equipment are very different from those of food packaging and have not been well studied.

Specific processing conditions applying to both, food industry machinery as well as to kitchenware are as follows:

- Multiple contact conditions :
    - Repeated uses with dynamic regimes with different flow rates,
    - Contact time with different categories of food ranging from a few seconds to several hours with phases without food contact,
    - High temperature conditions often coupled with pressure and mechanical constraints,
    - cleaning phases,
    - Long life time of these materials and articles (more than 5 years).

- Surface contact exposure:
    - Currently, there is very little knowledge available for repeated use applications,
    - Especially for the range of different consumer use profiles.

3. DEFINITIONS

« Estimated daily Intake » amount of a substance that is absorbed daily through the oral route by the consumer through plastics food contact articles.

« Repeated use article » means an article intended to be used several times that comes into contact with different portions of foods during its lifetime.

Regulation (EU) No 10/2011

« Rubber » means low shear modulus materials, either natural (For example, caoutchoucs which are naturally derived rubber from latex originating from the sap of trees) or synthetic, made up of carbonaceous macromolecules, and characterized by long polymer chains arranged in a three-dimensional flexible network held by chemical covalent cross-links. They present, at service temperature and until their decomposition, elastic physical properties which allow the material to be substantially deformed under stress and recover almost its original shape when the stress is removed. **The definition does not cover thermoplastic elastomers.**

Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf)

« Thermoplastic elastomer » means polymer or blend of polymers that does not require vulcanisation or cross-linking during processing, yet has properties, at its service temperature, similar to those of vulcanised rubber. These properties disappear at processing temperature, so that further processing is possible, but return when the material is returned to its service temperature. They are covered under the definition of plastics.

Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf)

« Specific migration Limit » (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants.

Regulation (EU) No 10/2011

« Overall migration limit » (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants.

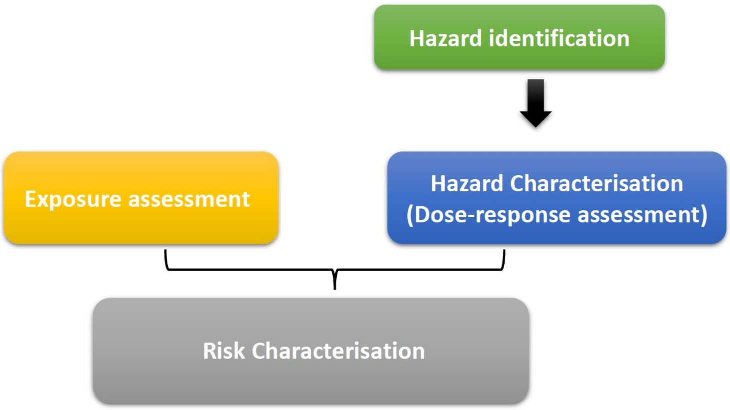
Regulation (EU) No 10/2011

4. Risk assessment principles

NLS and NIAS contained in single as well as in repeated articles, are required to be risk assessed under Article 19 of the European Commission Regulation (EU) No 10/2011.

The risk assessment process, shown in the following figure, consists in:

- Exposure assessment
- Toxicological assessment including hazard Identification and hazard characterisation



In the final risk characterisation step, the typical exposure level to the substance in the daily diet (the Estimated Daily Intake, EDI) is compared to the maximum tolerable exposure level (the Tolerable Daily Intake, TDI). Alternatively, the migration level into the food is compared to a self-derived Specific Migration Limit (SML).

As long as the Estimated Daily Intake is below the Tolerable Daily Intake or the migration level under the typical condition of use is below the self-derived SML, the use of the substance is considered safe.

Exposure (EDI) < exposure threshold (TDI or TTC) or Specific migration < self-derived SML

This guidance details the different possible routes to assess exposure, starting with very conservative scenario (single use worst case migration), up to more realistic exposure scenario, that might be used if necessary (See Section 4.1).

The document also provides guidance for the toxicological assessment (See section 4.2).

Recommendations for risk assessments concerning repeated use articles are given in Section 4.3

4.1. EXPOSURE ASSESSMENT FROM SINGLE TO REPEATED USE

4.1.1. WORST CASE

In this chapter we will investigate 3 different generic worst-case exposure scenarios based on:

- the traditional worst case European consumer's exposure for single use food contact materials and articles (**Case A**)
- exposure to migrants after 3 uses (**Case B**)
- Exposure to migrants over the lifetime of the article (**Case C**).

Case A- Worst case exposure using the conventional European Food Consumption

The default exposure assumption in Europe is that an adult person consumes 1 kg of food, packed in a cube of 1 dm^3 having 6 faces of each 1 dm^2. [2] Article 17 of the Regulation (EU) No 10/2011 refers nevertheless to real surface to volume ratio to be used for verification of compliance. Note that according to the Scientific Opinion of EFSA on the Recent Developments in the risk assessment of chemicals in food and their potential impact on the Safety Assessment of Substances used in Food Contact Materials [2], the panel confirmed that the total food consumption for infants and toddlers are in the same range than the current model for adults. The EFSA opinion considers the following figures:

- For infants a dietary intake of 200 g/kg body weight /day and a body weight of 5 kg
- For toddlers, a dietary intake of 83 g/kg body weight / day and a body weight of 12 kg

Following assumptions are made:

- 100% migration of substance at any one time from 6 dm^2 contact surface into one kg food
- The food contact material cube is in contact with a single type of the same food and the food is the most aggressive extractor of substance
- The substances are distributed homogeneously in both phases, the polymer and the food
- The individual consumer has the same exposure every day throughout its life.

Therefore, the default food contact surface is determined to be 6 dm^2/adult person/day.

[2] This part might be subject to revision after the adoption by EFSA on a new exposure approach [EFSA Journal 2016; 14(1):4357] [2]

The Worst Case Estimated Daily Intake corresponding to a single use may be calculated from the following generic formula:

$$\mathbf{EDI_{worst\ case\ single\ use}\ (mg/person/day) = food\ consumption\ (kg/person/day) * C_{food}\ (mg/kg)}$$

Considering the default exposure assumption in Europe for an adult:

$$\mathbf{EDI_{worst\ case\ single\ use}\ (mg/person/day) = 1\ kg\ food/\ adult\ person/day * C_{food}\ (mg/kg)}$$

C_{food} is the concentration of the substance into food (mg/kg), assuming 100% migration of the substance, at any one time, from a surface contact of 6 dm^2 with 1 kg food.

C_{food}, may be calculated using the following formula:

$$\mathbf{C_{food} = C_{pol} \times (d_{pol} / d_{food}) \times (S_{FCM} / V_{food}) \times e_{FCM}}$$

Where :

- C_{food} = concentration of the substance into food (mg/kg)
- C_{pol} = concentration of the substance into polymer (mg/kg)
- d_{pol} = density of the polymer (g/cm^3)
- d_{food} = density of the food (g/cm^3)
- S_{FCM} = contact area of the food contact material (cm^2)
- e_{FCM} = thickness of the food contact material ($cm = 10^4$ (µm))
- V_{food} = volume of food (cm^3)

using the EU cube assumption $S_{pol} = 600\ cm^2$, $V_{food} = 1000\ cm^3$ and $d_{food} = 1 g/cm^3$

$$C_{food} = \frac{C_{pol} \times d_{pol} \times 600 \times e_{FCM}}{1000}$$

Where: C_{food}, C_{pol}, d_{pol} and e_{FCM} have the same meaning as mentioned above.

As already mentioned in the PlasticsEurope Document on 'Risk assessment of non-listed substances (NLS) and not-intentionally added substances (NIAS) under Article 19, it is assumed (by convention and as documented in the EFSA Note for Guidance (page 90-91 of the version of July 2008) [3] that for most plastics, migration under typical conditions of use primarily takes place from the first 250 µm of the plastic layer in contact with the food. Exceptions are plasticized polymers and the migration of components with low diffusion coefficients (volatile components).

This approach might be subject to revision, following the adoption of the JRC Technical Guidance for migration testing (Draft for consultation, 2016)[4].

For information, see the following table coming from the last draft of the JRC Guidance dated 2016.

Table 1: Layer thickness L (in µm) for which total mass transfer assumption can be made at different contact conditions for four different molecular mass ranges

Polymer type	time/Temp	layer thickness L in [µm] for			
molecular mass of migrant (g/mol)		100-250	251-500	501-750	751-1000*
LDPE, PP rubbery[9]	10 days at 60°C	Full L	Full L	2400	960
	10 days at 40°C	Full L	3000	920	360
	10 days at 20°C	2500	880	300	120
	2h at 100°C	Full L	4000	1220	480
HDPE	10 days at 60°C	Full L	3425	1050	420
	10 days at 40°C	2950	1100	330	135
	10 days at 20°C	800	300	100	42
	2h at 100°C	Full L	2150	660	260
PP isotactic/homo PP random	10 days at 60°C	5000	1700	520	210
	10 days at 40°C	1460	550	170	72
	10 days at 20°C	400	155	55	20
	2h at 100°C	2925	1080	330	135
PET, PBT, PEN	10 days at 60°C	40	15	5	2
	10 days at 40°C	13	5	2	1
	10 days at 20°C	4	2	1	0.5
	2h at 100°C	25	10	3	2
PS	10 days at 60°C	55	21	7	3
	10 days at 40°C	20	10	5	2
	10 days at 20°C	7	3	2	1
	2h at 100°C	27	10	5	3
SBS	10 days at 60°C	Full L	Full L	1900	750
	10 days at 40°C	Full L	2300	700	285
	10 days at 20°C	2100	750	235	100
	2h at 100°C	Full L	3100	950	375
PA 6 (not swollen: e.g. direct contact with food simulant D2 and iso-octane)	10 days at 60°C	91	33	10	4
	10 days at 40°C	34	13	4	2
	10 days at 20°C	11	5	2	1
	2h at 100°C	44	17	6	3

* In case of perfluorinated substances the maximum molecular mass should be 1500 g/mol due to the comparable lower molecular volume.

The 250µm thickness has been retained for the different examples described in chapters 4.1.1.1 and 4.1.1.2. Calculations might be revised using other thickness layers there were needed.

Further refinements may be applied by using the real S/V ratio and replacing the ratio (600/1000) in the above-mentioned formula by the real S/V values, expressed as cm^2/cm^3.

When using for some repeated use articles the real S/V ratio, it is expected to lead to a concentration of substance in food lower than when using the conventional S/V ratio of 6 dm^{-1}. Some of the repeated use articles listed in **Annex 8.1**, are characterized by very low S/V ratios.

Example: 100 ppm of a migrant leads to a worst case migration of 0.6 ppm from a 100 µm thick and 6 dm^2 polymer having a density of 1 g/cm^3.

Case B - EDI based on 100% migration after 3 times use (repeated use under 10/2011)

The EDI is calculated on the basis of the total release of the substances contained in the repeated use materials after 3 times of contact.

In this case, the EDI is calculated to be the product of the daily food consumption by the average quantity of the substance released per kg food during the 3 contacts.

$$\boxed{EDI_{\text{worst case 3 contact times}} = \text{Food consumption} * C_{food} / 3}$$

For an adult default exposure assumption:

$$\boxed{EDI_{\text{worst case 3 contact times}}\ (\text{mg/person/day}) = 1\ \text{kg food/person/day} * C_{food} / 3\ (\text{mg/kg food})}$$

C_{food} /3 is the average concentration of the substance into food (mg/kg), assuming 100% migration of the substance, during 3 contact times from a surface contact of 6 dm^2 with 1 kg food.

Case C- Worst case migration scenario for repeated uses may be based on the release of 100% of substances contained in the repeated food contact material or article over its life time, in the real conditions of use.

This approach is based on the FDA approach detailed in the Guidance for Industry: preparation of Premarket Submissions for food contact substances: chemistry recommendation- April 2002 - December 2007 – Appendix II - point 4 [5] which strongly recommends an initial calculation of a worst case level assuming 100% migration of the substance over the service life.

This approach may be used for food industry machinery and in home food appliances (blenders, mixers) based on the maximum quantity the machine may contain and on a daily use of the appliance over its life time.

It may be difficult to know the ***real lifetime for kitchenware used at home***. In this case, even if the FDA does not have a set of default assumptions published for food processing equipment uses [5], we will consider as a worst-case exposure scenario:

Instead of the conventional 1000 grams contacting 6 dm^2, we consider 1000 grams of food contacting 1 $inch^2$ (corresponding to 6,452 cm^2) of material over the product lifetime, which is equivalent to using the end product only 100 times. For the details of this assumption, please see section 4.1.5.1 of this Guidance.

From a precautionary point of view, we might limit the number of events to 100. If, based on sound arguments, we can go for a higher number of events, we need to document this properly.

Calculation is based on:

- The weight of material and article in contact with food and,
- The total sum of quantity of the food contacting this known weight of repeated use material/article during the whole life time of the article.

We can therefore calculate the concentration of migrants released in the total food during the whole life time of the material or article assuming 100% migration into the food from which we derive the Estimated Daily Intake, $EDI_{worst\ case}$ on the basis:

- The conversion of the quantity of migrants in food during the whole process to the average quantity of migrants released per kg food, assuming the constant release over time of migrants in food,
- The default assumption in Europe of 1 kg food ingested daily during a lifetime (always contacting the same material or article in a repeated process).

The $EDI_{worst\text{-}case}$ is the average amount of migrant transferring into the food in contact with the plastic material during the whole life time. Keep in mind that from a mechanistic point of view, the real migration is a decreasing process and for the first contacts the migration could be higher than the average value and potentially the SML.

$$\mathbf{EDI = Food\ consumption * C_{Average}}$$

$$\mathbf{EDI_{worst\ case\ repeat\ use}\ (mg/person/day) = 1\ kg\ food/person/day * C_{Average}\ (mg/kg)}$$

In the examples developed hereunder, our proposal is to start with the calculations for 3 uses (n=3). If we can already conclude with 3 events that the risk assessment is giving us a "safe use" answer, then we can stop the exercise here. If this is not the case, we go for 100 uses (n=100).

If appropriate and properly documented, a higher number of uses based on the whole foreseeable service life of the article can be used in the assessment.

In the examples of industrial applications as well as kitchen appliances developed further down in sections 4.1.1.1 and 4.1.1.2 respectively,, the figure for 100 uses has been included. Nevertheless, the number of use events is expected to be far above 100.

4.1.1.1. EXAMPLES OF INDUSTRIAL APPLICATIONS AND REPEATED USE EXPOSURE DETERMINATION

Industrial applications are those used in an industrial environment, like processing equipment's and their individual parts, flexible and rigid pipes, pumps and valves and so on.

In the text here beneath, examples of exposure's calculations are proposed for some typical industrial applications.

4.1.1.1.1. PIPES

An example is given of a worst-case migration scenario for a pipe manufactured with PVDF and intended to be used in the food industry to transport liquid food.

Using parameters provided in the tables below, the quantity of food processed over the life of the pipe and the total exposed surface area could be determined.

Table 2: Used parameters versus typical value

Parameter Estimation	Value Modelled	Typical Value
Pipe length (m)	100	< 100
Pipe inside radius (mm)	8	> 15
Residual level of migrant (Substance X) in pipe (ppm)	100	< 50
Fluid Flow rate (cm^3/minute)	4 000	> 40 000
Hours Run per day	8	> 8
Days run per year	210	> 300

Total Years of service	5	>10
Thickness of the pipe (cm)	0,025	0,30
Specific gravity of pipe (g/ cm^3)	1,78	-
Specific gravity of food (g/ cm3)	1	

From these data, the following parameters are calculated:

Table 3: parameters estimation

Parameter Estimation	Value Modelled
Fluid Flow rate (dm^3/h)	240
Total hours of service	8400 hours
Total volume of fluid during life service (dm^3)	2 016 000
Total quantity of food during life service, (kg)	2 016 000
Pipe inside surface area (cm2)	50 560
Pipe inside volume (dm3)	20,096

For estimating the worst case dietary exposure of the chemical, assumptions for low flow rate, high surface area to food, log in-service life, limited run time and high residual level of migrant were used.

It has been established that migration occurs in the first 250 µm of a food contact surface. Consequently the thickness of the article was set at 250 µm for the estimation of the worst-case migration of the chemical.

It is also assumed that there is 100% migration of the migrant over the service life of the pipe.

The concentration of migrant in the foodstuff during the service life of the pipe could be calculated using the following relationship corresponding to the division of the total residual quantity of migrant in the pipe (100 % migration) by the total quantity of food processed:

$$C_{Food}(mg/kg) = \frac{\mathrm{M_{migrant}}(mg/kg) x \rho_{polymer}(g/cm^3) x S_{pipe}(cm^2) x e_{pipe}(cm)}{M_{food}(g)}$$

and

$$M_{food}(g) = \text{ Volume of Food x Specific Gravity of food}$$

Where :

- $M_{migrant}$: Residual concentration of the migrant (Substance X) in the PVDF pipe
- $\rho_{polymer}$: The specific gravity of the pipe
- S_{pipe} : The internal surface of the pipe
- e_{pipe} : The thickness of the pipe = 250 µm
- M_{food} : The total quantity of food processed during the service live of the pipe

Based on the conditions provided by the above tables (100 ppm of Substance X into PVDF), the estimated worst-case concentration of migrant into the food processed is around **0,11 µg/kg**, corresponding, by applying the following formula over **the life time** of the pipe, to an EDI of 0,11 µg / person/day:

Having the same reasoning, but with n = number of service days of the pipe: 1, 3, 100 and lifetime

$$\boxed{\mathbf{EDI_{worst\ case,\ n\ days}\ (\mu g/person/d) = 1\ kg\ food\ /person/day * C_{food}\ (\mu g/kg\ food)\ /n}}$$

By using the abovementioned formula and considering 2 concentrations of Substance X (0,1% and 0,01%) in PVDF for n = 1,3, 100 and lifetime, the following results are obtained:

Table 4: Estimated daily intake calculated for pipes

		EDI of Substance X (µg/person/day)		
N, number of service days	S/V dm^{-1}	For 0,1% (1000 ppm) Substance X in the pipe	For 0,01% (100 ppm) Substance X in the pipe	Ratio EDI static / EDI dynamic
1	0,26	1 172	117	96
3	0,09	391	39	287
100	**0,003**	**11,7**	**1,17**	9 554
life time n=1 050 days	0,0003	1,1	0,11	100 318
Static	25,16 (surface pipe/volume pipe)	111 959	11 196	

See details on calculations provided in the **Annex 8.3 and 8.4** Excel sheets for static and dynamic conditions respectively.

If we change the conditions, and especially, by using real parameters for a typical processing plant, the estimated concentration will decrease because an increase of the flow rate, the service life, or the number of hours run per year, induces an increase of the total quantity of food processed during the service live of the pipe.

Under dynamic conditions, the total quantity of food that comes into contact with the pipe's surface its life service is calculated to be: 2 016 000 dm3, whereas the quantity of food that contact the surface in static conditions is equivalent to the quantity of food contained in the pipe inside volume. is calculated to be 20,096 dm3.

By applying worst case calculations detailed under section 4.1.1. for dynamic conditions and replacing the total quantity of food of 2 016 000 dm3 by the one corresponding to static conditions, we calculate the ratio of Estimated Daily Intake under static conditions and dynamic conditions as being at least 100 000.

Furthermore, for comparison purposes, the ratio between the EDI calculated over the whole service life of the pipe and the that obtained by assuming the release of 100 ppm of substance X from the pipe into the food volume contained in the pipe, under static conditions, is calculated to be around 100 000. Detailed calculations are given in Annex 8.4.1 EDI calculations comparison between dynamic and static conditions

The above calculations show that dynamic conditions allow to considerably increase the total mass of the food that contacts the pipe surface compared to static conditions, which limits the quantity of food that may be contained in the inside pipe volume. Consequently, in the above conditions, dynamic food contact conditions significantly decrease the concentration of migrants into food, thus leading to very a small EDI, i.e. very low exposures compared to static conditions.

4.1.1.1.2. MILKING SESSION

Example is given on the tubing in a milking machine. See **Annex 8.9** 'Comparison on Testing conditions on selected repeated use articles according to different approaches_ JRC_AP(2004)4_M&A Guidance'

The tubing has an inside diameter of 15 mm and a wall thickness of 1.5 mm. The length may vary from 1 to 2,5 m. Each cow is connected to the machine for 15 minutes and delivers 10 l of milk on each occasion, twice a day. Life time of the tubing is guaranteed for 1 year but will be replaced only after 2 years. The unit has a maximum capacity of 10 cows / milking session. Tubing is cleaned with hot water before first use and in between two milking sessions.

From this data, the weight of the tubing is calculated assuming

- A density of the tubing of 1 g/cm^3,

- A contact area which may be calculated from the diameter and the length of the tubing $S = 2\pi (D/2) * L$, → $S = 2*\pi*(1{,}5/2)*250 = 1\ 178\ cm^2$

Considering that 10 cows are delivering 10 l milk per session and 2 sessions are made per day, the total volume of milk passing through one machine each day is 200 liters = 200 000 cm^3.

For comparison purposes, we will consider different scenarios, where:

- Concentration of migrant in milk is calculated after the use of the milking session for 1 day, 3 days, 100 days, 1 year and 2 years (365 days/year)
- The Substance X is present at different levels (100 and 1000 ppm) in the tubing

Assuming a constant rate of release of the substance over time into food, 1 liter milk (with a density of 1 g/cm^3) ingested daily in contact with the same tubing , EDIs may be calculated as follows:

$$EDI_{worst\ case,\ n\ uses}\ (\mu g/person/d) = 1\ kg\ food/person/day * C_{food}\ (\mu g/kg\ food) / n$$

With n= 1, 3, 100, 365 and 730.

From the above assumptions taken, C_{food} the concentration of migrant X assuming 100% into food at any one time is calculated, as follows:

C_{food} = 1000 (mg/kg) x (0,15 cm) x (1 g/cm^3/ 1g/cm^3) x (1 178 cm^2 / 200 000 cm^3) = 0,88 ppm

C_{food} = 100 (ppm) x (0,15 cm) x (1,0 g/cm^3) x (1 178 cm^2 / 200 000 cm^3) = 0,09 ppm,

Obtained EDI's results, expressed as µg/person/day, are summarized in the following table:

Table 5: Estimated daily intake calculated for tubing

		EDI of Substance X (µg/person/day)	
N, number of uses	S/V dm-1	0,1% (1000 ppm) Substance X in tubing	0,01% (100 ppm) substance X in tubing

1	0,0589	883	88
3	0,0196	294	29
100	**0,0006**	**8,8**	**0,9**
365	0,0002	2,4	0,2
730	0,0001	1,2	0,1

See details on calculations provided in the **Annex 8.4** Excel sheet.

4.1.1.1.3. CONVEYOR BELTS

Another example is taken of a conveyor belt used for bakery products.

The belt has a length of 60 meters with a width of 0.6 m. The life time of the belt is 3 years. The belt is intended to be used to transport cakes from the oven to the packing department. Initially, the cakes have a temperature of 90°C and at the end they will be cooled down to 20°C. The cakes have a size of 8 cm diameter and a weight of 100 g each.

The average production is 10 000 cakes per hour. The Bakery is producing for 8 hours a day during 220 days a year.

1,1 g/cm3 represents the density of plasticized PVC,

0,025 cm (=250 µm) the maximum worst case thickness (see § 4.1.1)

From these data, the contact surface of the conveyor belt is calculated to be = 60 * 0,6 = 36 m^2.

The weight of cakes, in contact every working day with the conveyor belt is 1000 kg/ day

For comparison purposes, we will consider different scenarios, where:

- Concentration of migrant in cakes is calculated after the use of the conveyor belt for 1 day, 3 days, 100 days and 3 years (220 working days)
- The Substance X is present at different levels (100 and 1000 ppm) in the plasticized PVC

Assuming a constant rate of release of the substance over time into food, 1 kg food ingested daily in contact with the same conveyor belt, EDIs may be calculated as follows:

$$EDI_{\text{worst case, n uses}}\ (\mu g/person/d) = 1\ kg\ food/person/day * C_{food}\ (\mu g/kg\ food) / n$$

With n= 1, 3, 100 and 660.

From the above assumptions taken, Cfood the concentration of migrant X assuming 100% into food at any one time is calculated, as follows:

C_{food} = 1000 (mg/kg) x (0,0250 cm) x (1,1 g/cm^3/ 1g/cm^3) x (360 000 cm^2 / 1 000 000 cm^3) = 9,9 ppm

C_{food} = 100 (ppm) x (0,0250 cm) x (1,1 g/cm^3) x (360 000 cm^2 / 1 000 kg) = 0,99 ppm,

Obtained EDI's results, expressed as µg/person/day, are summarized in the following table:

Table 6: Estimated daily intake calculated for conveyor belts

		EDI of Substance X (µg/person/day)	
N, number of uses	S/V dm^{-1}	0,1% (1000 ppm) Substance X in conveyor belt	0,01% (100 ppm) Substance X in conveyor belt
1	3,6	9 900	990
3	1,2	3 300	330
100	**0,036**	**99**	**9,9**
660	0,005	19	1,9

See details on calculations provided in the **Annex 8.4** Excel sheet.

4.1.1.1.4. RETURNABLE HDPE CRATES FOR THE TRANSPORT AND STORAGE OF MEAT

600 (L) x 400 (B) x 200 (H) mm HDPE crates are used to store and transport meat under the following conditions :

- 20 kg of meat per HDPE crate, having a density of 0.97 g/cm3
- Use: 1 day up to 1 week (52 times a year as a minimum)

- Assumption is made: Minimum Service time: 10 years

With :

0,97g/cm^3 for the density of HDPE material,

0,025 cm (=250 µm) for the maximum worst case thickness (see § 4.1.1)

And a food contact surface of 6400 cm^2 = (60*40) +2*(60*20) +2*(40*20)

We will consider different scenarios, where:

- The food HDPE crate is used for 1, 3, 100 and 520 days (corresponding to the use of HDPE crates once a week over 10 years),
- The substance X is present at different levels (100 and 1000 ppm) in the HDPE crate

Assuming a constant rate of release of the substance over time into food, 1 kg food ingested daily in contact with the same HDPE crate, EDIs may be calculated as follows:

$$\mathbf{EDI_{worst\ case\ ,\ n\ uses}\ (\mu g/person/d) = 1\ kg\ food/person/day * C_{food}\ (\mu g/kg\ food)\ /\ n}$$

With n= 1, 3, 100 and 520.

From the above assumptions taken, C_{food} the concentration of migrant X assuming 100% into food at any one time is calculated, as follows:

C_{food} = 1000 (ppm) x (0,0250 cm) x (0,97 g/cm^3) x (6400 cm^2 / 20 000 g) = 7,76 ppm

C_{food} = 100 (ppm) x (0,0250 cm) x (0,97 g/cm^3) x (1336 cm^2 / 20 000 g) = 0,776 ppm,

Obtained EDI's results, expressed as µg/person/day, are summarized in the following table:

Table 7: Estimated daily intake calculated for HDPE crates

	EDI of Substance X (µg/person/day)

N, number of uses	S/V dm-1	0,1% (1000 ppm) Substance X in HDPE crates	0,01% (100 ppm) Substance X in HDPE crates
1	3,2	7 760	776
3	1,1	2 587	259
100	**0,032**	78	7,8
520	0,006	15	1,5

See details on calculations provided in the **Annex 8.4** Excel sheet

4.1.1.2. Examples of kitchen equipment & appliances and repeated use exposure determination

Examples of exposure's calculations are proposed below for selected typical kitchen equipment and appliances

4.1.1.2.1. Water bottle

An example is given of a PP bottle with an internal diameter of 80 mm, height = 200 mm, volume of 1005 cm3, contact area of 553 cm2, wall thickness of 1,5 mm, PP density of 0,9 g/cm3, and 0,025 cm (= 250 µm) the maximum worst case thickness (see § 4.1.1)

Contact time between the bottle and tap is 10 hours at 10°C.

Service life time of the bottle is 10 years.

Adult consumption = 2 litres of water per day. The bottle is filled twice a day.

For comparison purposes, we will consider different scenarios, where:

- The water bottle is used for 1, 3, 100 and 3650 days (corresponding to a usage of once a day over 10 years,
- The substance X is present at different levels (100 and 1000 ppm) in the PP bottle.

Assuming a constant rate of release of the substance over time into food, 2 litres water in contact with the water bottle, ingested daily, and the bottle is filled twice a day, EDIs may be calculated as follows:

$$\mathbf{EDI_{worst\ case\ ,\ n\ days\ of\ use}\ (\mu g/person/d) = 2\ liters\ water/person/day * C_{food}\ (\mu g/kg\ food) / n}$$

With n = 1, 3, 100 and 3650 which corresponds to the number of days of use.

From the above assumptions taken, C_{food} the concentration of migrant X assuming 100% migration into food per day, is calculated, as follows:

C_{food} = 1000 (ppm) x (0,0250 cm) x (0,9 g/cm^3 / 1 g/cm^3) x (553 cm^2 / (2010 cm^3) = 6,19 ppm

C_{food} = 100 (ppm) x (0,0250 cm) x (0,9 g/cm^3 / 1 g/cm^3) x (553 cm^2 / (2010 cm^3) = 0,62 ppm,

Remark: If the total thickness of the plastic material is used, the worst case concentration of the migrant into food is C_{food} = 1000 (ppm) x (0,15 cm) x (0,9 g/cm^3 / 1 g/cm^3) x (553 cm^2 / (1005 cm^3) = 74,3 ppm.

Obtained EDI results, expressed as µg/person/day, are summarized in the following table:

Table 8: Estimated daily intake calculated for water bottles

		EDI of Substance X (µg/person/day)	
N, number of uses	S/V dm^{-1}	0,1% (1000 ppm) Substance X in the PP bottle	0,01% (100 ppm) Substance X in the PP bottle
1	2,8	12 381	1 238
3	0,92	4 127	413
100	**0,03**	**124**	**12,4**
3650	0,001	3,4	0,34

See details on calculations provided in the **Annex 8.4** Excel sheet

4.1.1.2.2. Food contact boxes

An example is given for a PP food contact box (density 0,9 g/cm3) having the following dimensions:

Inside Volume: L x l x h = 26 x 16 x 6 cm3 = 2496 cm3.

Surface of the box: 1336 cm2 = 2*(26*16) +2*(6*16) +2*(6*26), assuming the box cover made with the same PP materials

Thickness: 2-3 mm. For calculations: 0,025 cm (=250 µm) the maximum worst case thickness (see § 4.1.1) is taken.

All types of food may be stored in the container, first in the fridge and then in the microwave up to 100°C for several minutes.

Contact time: several hours to 24 hours.

Use: Once a week (52 times a year) as a minimum

Minimum Service time: 10 years

For comparison purposes, we will consider different scenarios, where:

- The food contact box is used for 1, 3, 100 and 520 days

  (corresponding to the usage of once a week over 10 years),
- The Substance X is present at different levels (100 and 1000 ppm) in the PP box

Assuming a constant rate of release of the substance over time into food, 1 kg food ingested daily in contact with the same box, EDIs may be calculated as follows:

$$\mathbf{EDI_{worst\ case\ ,\ n\ uses}\ (\mu g/person/d) = 1\ kg\ food/person/day * C_{food}\ (\mu g/kg\ food) / n}$$

With n= 1, 3, 100 and 520.

From the above assumptions taken, C_{food} the concentration of migrant X assuming 100% into food at any one time is calculated, as follows:

C_{food} = 1000 (ppm) x (0,0250 cm) x (0,9 g/cm^3 / 1 g/cm^3) x (1336 cm^2 / 2496 cm^3) = 12,0 ppm

C_{food} = 100 (ppm) x (0,0250 cm) x (0,9 g/cm^3 / 1 g/cm^3) x (1336 cm^2 / 2496 cm^3) = 1,2 ppm,

Obtained EDIs results, expressed as µg/person/day, are summarized in the following table:

Table 9: Estimated daily intake calculated for food contact boxes

		EDI of Substance X (µg/person/day)	
N, number of uses	S/V dm^{-1}	0,1% (1000 ppm) Substance X in the PP box	0,01% (100 ppm) Substance X in the PP box
1	5,4	12 043	1 204
3	1,78	4 014	401,4
100	**0,05**	**120**	**12,04**
520	0,01	23	2,32

See details on calculations provided in the **Annex 8.4** Excel sheet

4.1.1.2.3. BAKING FORMS

An example is given of baking forms (moulds) made with steel coated with a non-stick PTFE layer (density 2,18 g/cm3) with a thickness of 5 µm.

Temperature of use in oven is usually more than 150°C up to 225°C and contact with food is between 0.5 hour
and 1 hour.

Mainly contact with cakes having fatty substances on the surface.

An example is given for small rectangular cake mould ('financier' type) which exhibit high S/V ratio (L x l x w = 9 cm x 4.5 cm x 1 cm)

Calculated Contact Surface = 63 cm^2

Food volume (assuming d food = 1 g/cm3) = 40.5 cm^3

Use: Two cooking batches a week (52 times a year)

Minimum Service time: 10 years

Assuming a constant rate of release of the substance over time into food, 1 kg food ingested daily, in contact with the same box EDIs may be calculated as follows:

$EDI_{worst\ case,\ n\ uses}$ (µg/person/d) = 1 kg food/person/day * C_{food} (µg/kg food) / n

With n= 1, 3, 100 and 1040 (corresponding to 2 uses per week over 10 years).

From the above assumptions taken, C_{food} the concentration of migrant X assuming 100% into food at any one time is calculated, as follows:

C_{food} = 1000 (ppm) x (0,0005 cm) x (2,18 g/cm^3 / 1 g/cm^3) x (63 cm^2 / 40,5 cm^3) = 1,7 ppm

C_{food} = 100 (ppm) x (0,0005 cm) x (2,18 g/cm^3 / 1 g/cm^3) x (63 cm^2 / 40,5 cm^3) = 0,17 ppm

Obtained EDI results, expressed as µg/person/day, are summarized in the following table:

Table 10: Estimated daily intake calculated for food baking form

		EDI of Substance X (µg/person/day)	
N, number of uses	S/V dm^{-1}	0,1% (1000 ppm) Substance X in the baking form	0,01% (100 ppm) Substance X in the baking form
1	15,6	1 700	170
3	5,2	570	57
100	**0,16**	**17**	**1,7**
1040	0,01	1,6	0,16

See details on calculations provided in the **Annex 8.4** Excel sheet

4.1.1.2.4. BLENDER BOWLS

An example is given of a blender bowl made with SAN (density 1,08 g/cm^3)

Food Volume: 0,5 to 2 litres (dm^3),

Maximum Contact Surface: 16 dm^2 (diameter 18 cm - height: 25 cm);

Thickness: 2-3 mm. For calculations: 0,025 cm (=250 µm) the maximum worst case thickness (see § 4.1.1) is taken.

All types of food- hot (up to 100°C) to refrigerated food,

Contact time: 10 - 30 minutes,

Use: 2 times a week (as a minimum),

Minimum Service time: 5 years.

Again, different scenarios, have been investigated:

- The blender is used for 1, 3, 100 and 520 days (corresponding to the usage of twice of week over 5 years),
- The Substance X is present at different levels (100 and 1000 ppm) in the SAN blender bowl.

Assuming a constant rate of release of the substance over time into food, 1 kg food in contact with the same blender bowl, ingested daily, EDIs may be calculated as follows:

$$\mathbf{EDI_{worst\ case\ ,\ n\ \ uses}\ (\mu g/person/d) = 1\ kg\ food/person/day * C_{food}\ (\mu g/kg\ food)\ /\ n}$$

With n= 1, 3, 100 and 520

From the above assumptions taken, C_{food} the concentration of migrant X assuming 100% into food at any one time is calculated, as follows:

C_{food} = 1000 (ppm) x (0,0250 cm) x (1,08 g/cm^3 / 1 g/cm^3) x (1600 cm^2 / 500 cm^3) = 86,4 ppm

C_{food} = 100 (ppm) x (0,0250 cm) x (1,08 g/cm^3 / 1 g/cm^3) x (1600 cm^2 / 500 cm^3) = 8,6 ppm,

Where:

It is assumed that the whole surface of the bowl is in contact with the lowest quantity of food contained in the bowl, when the blender is switched on.

Obtained EDI results, expressed as µg/person/day, are summarized in the following table:

Table 11: Estimated daily intake calculated for blender bowls

	EDI substance X (µg/person/day)

N, number of uses	S/V dm-1	For 0,1% (1000 ppm) Substance X in the blender bowl	For 0,01% (100 ppm) Substance X in the blender bowl
1	32	86 400	8 640
3	10,7	28 800	2 880
100	**0,32**	**864**	**86,4**
520	0,06	166	16,6

See details on calculations provided in the **Annex 8.4** Excel sheet

4.1.1.2.5. DISHES

An example is given of plastic 'baby dishes', which mainly concern toddlers (young children aged from 12 months up to and including 36 months).

Dishes are used once a day and may contain all type of solid food including: ready to eat and home-made meals, based on different ingredients: vegetable, cereal, meat or fish.

The dish may be used to serve refrigerated and hot food as well as to heat food in the microwave oven for several minutes.

According to the scientific opinion of EFSA on 'Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials' [2] the highest 95th percentiles of consumption of toddler for ready-to-eat meals is 48.3 g/kg bw/d.

Toddlers body weight is taken at 12 kg.

Consumption = 0,5796 kg/day

The surface in contact with food is considered to be 314 cm^2 (dish diameter of 20 cm)

And the minimum service time is taken at 2 years

Where:

1,57 g/cm^3 represents the density of plastic material, 0,025 cm (=250 µm) the maximum worst case thickness (see § 4.1.1)

It is assumed that the whole surface of the dish is in contact with the total amount of daily food.

The different scenarios are:

- The baby dish is used for 1, 3, 100 and 730 days (corresponding to the usage of every day, over 2 years),
- The Substance X is present at different levels (100 and 1000 ppm) into the plastic dish.

Assuming a constant rate of release of the substance over time into food, 0.5796 kg food ingested daily and in contact with the dish, EDIs may be calculated as follows:

$$\mathbf{EDI_{worst\ case\ ,\ n\ uses}\ (\mu g/person/d) = 0{,}5796\ kg\ food/toddler/day * C_{food}\ (\mu g/kg\ food)\ /\ n}$$

With n= 1, 3, 100 and 730,

and maximum food ingested per day and per toddler = (48,3)*12/1000 = 0,5796 kg/toddler/day

From the above assumptions taken, C_{food} the concentration of migrant X assuming 100% into food at any one time is calculated, as follows:

C_{food} = 1000 (ppm) x (0,0250 cm) x (1,57 g/cm^3 / 1 g/cm^3) x (314 cm^2 / 579,6 cm^3) = 21,26 ppm

C_{food} = 100 (ppm) x (0,0250 cm) x (1,57 g/cm^3 / 1 g/cm^3) x (314 cm^2 / 579,6 cm^3) = 2,13 ppm,

Obtained EDI results, expressed as µg/person/day, are summarized in the following table:

Table 12: Estimated daily intake calculated for plastic dishes

		EDI substance X (µg/person/day)	
N, number of uses	S/V dm-1	For 0,1% (1000 ppm) Substance X in the dish	For 0,01% (100 ppm) Substance X in the dish
1	5,4	12 325	1 232
3	1,8	4 108	411
100	**0,05**	**123**	**12**
730	0,01	17	1.7

See details on calculations provided in the **Annex 8.4** Excel sheet

4.1.1.2.6. KITCHEN COUNTERTOPS

An example is given of kitchen countertops coated with PVDF (thickness may go up to several mm) in contact with all type of foods (simulant E and D2), with S/V ratios of 1/3 dm^1 , contact time of 1800 seconds (30 min), 3 cycles a day, contact temperature of 20°C, contact time for 1 cycle, when not used is 360 min (6 hours).

1,78 g/cm3 represents the density of amorphous PVDF and 250 µm the maximum worst case thickness (see § 4.1.1).

Assuming a level of substance X of 1000 ppm and 100 ppm in the PVDF, the concentration of substance X assuming 100% migration into food at any one time is calculated, as follows:

C_{food} = 1000 (ppm) x (0,0250 cm) x (1,78 g/cm^3 / 1 g/cm^3) x (100 cm^2 / 3000 cm^3) = 1.48 ppm

C_{food} = 100 (ppm) x (0,0250 cm) x (1,78 g/cm^3 / 1 g/cm^3) x (100 cm^2 / 3000 cm^3) = 0.148 ppm, The countertop is intended to be used every day, 3 times of day over 20 years corresponding to (3 x 7300) times over its lifetime.

For comparison purpose, we will consider different scenarios, where:

- The kitchen countertop is used for 1, 3, 100 and 7300 days,
- The Substance X is present at different levels (100 and 1000 ppm) into the PVDF layer.

Assuming a constant rate of release of the substance over time in food, 1 kg food in contact with the same countertop, ingested daily, EDIs may be calculated as follows:

$EDI_{worst\ case,\ n\ uses}$ (µg/person/d) = 1 kg food/person/day * C_{food} (µg/kg food) / n

With n= 1, 3, 100 and 7 300, 21 900.

Obtained EDI results, expressed as µg/person/day, are summarized in the following table:

Table 13: Estimated daily intake calculated for kitchen countertops

		EDI substance X (µg/person/day)	
N, number of uses	S/V dm-1	For 0,1% (1000 ppm) Substance X in the countertops	For 0,01% (100 ppm) Substance X in the countertops
1	0,3	1 483	148
3	0,11	494	49.4
100	**0,003**	**14.8**	**1.48**
7300	0,001	0.2	0.02
21 900	0,00002	0.07	0.007

4.1.2. Migration Modeling

Migration modeling was implemented in the EU food contact materials legislation in 2001 (sixth amendment of EU Plastics Directive 90/128/EEC) as a tool to estimate specific migration of substances from plastic food contact materials into food simulants as an alternative to experimental testing. Today migration modeling is a so-called screening approach as per Annex V to Regulation (EU) No 10/2011.

Migration modeling is able to estimate the migration from monolayer and multilayer materials into foods or food simulants, or other contact media under single or repeated use conditions under consideration of material ageing and set-off.

For readers that are not familiar with the modelling approach, see **Annex 8.5 - 1** Simplified approach of migration modelling concept.

Estimation / calculation of migration by migration modeling is associated with uncertainty which is mainly caused by the uncertainty of the parameters used. The problem of uncertainty can be solved for migration modeling under single use conditions by introduction of the upper limit concept, i.e. use of upper limit polymer specific constants respectively upper limit diffusion coefficients and lower limit partition coefficients. Based on upper limit diffusion coefficients and lower limit partition coefficients an overestimated migration with a given confidence results (typically 95%). The confidence of overestimation is associated to the parameters used.

Migration modeling under repeated use conditions faces the problem that if the overestimation in the time periods at the beginning is high, underestimation in the following time periods may occur.

One possibility to reduce the risk of underestimation can be to develop more precise estimation procedures for diffusion- and partition coefficients, however this is associated with significant work and costs. Another possibility is to shift from deterministic to probabilistic migration modeling under consideration of input related uncertainty. As a consequence, the modeling result is a distribution (as the inputs) and, in case the lowest diffusion coefficient gives the highest migration result after several repeated use cycles, this result will be part of the output distribution. In other words no systematic underestimation compared to the "real" migration can occur.

4.1.2.1. Diffusion Coefficient

The diffusion behavior of a substance in a material, e.g. a polymer, depends on the substance and material properties and temperature as expressed by the Arrhenius relationship [6]. The Arrhenius equation may be used to describe either the temperature dependence of the reaction rate constant in a chemical reaction or the temperature dependence of the diffusion coefficient in a diffusion process. The latter is of interest to us in this context. The equation was first proposed by J. H. van't Hoff in 1884 and five years later Svante Arrhenius provided a physical justification and interpretation for it. Nowadays is should be better understood as an empirical relationship.

The diffusion coefficient depends on (a) the activation energy (E_A) required to facilitate the cooperative motion of molecule and polymer and substance mass transfer through the matrix under influence of the gradient in the chemical potential between materials and contact media, (b) the intrinsic mobility of the matrix, and (c) on the temperature due to intensification of the Brownian motion of the molecule and the matrix with increasing temperature.

The activation energy required to facilitate the motion of a molecule in solution under the influence of a gradient in the chemical potential depends on the mobility of the molecule and the intrinsic mobility of the matrix. To change a dissolved molecule's place in a matrix requires the cooperative movement of both, the polymer chain and the molecule. Movement ability of the polymer chain is related to its intrinsic mobility and free volume. The mobility of the molecule is related to its size and is high for small molecules like gases, solvents, monomers, etc. and low for big molecules like polymers. Mobility may be even lower for macromolecules, molecule clusters or nanoparticles.

In the last two decades several practicable estimation procedures for diffusion coefficients of substances in polymers were developed due to the lack of data in the scientific literature for the many combinations of polymers and substances encountered in practice. The most popular estimation procedure was developed by Piringer [7], the latest ones by Welle [8] and Brandsch [9]. The estimation procedures referenced can be lead back to the Arrhenius relationship. The estimation procedures referenced can be led back to the Arrhenius relationship, but as shown by Fang *et al.* [10], temperature effects are related to free-volume effects in the polymer. Geometric models have been shown to be particularly predictive and implementable in simple decision trees [11]. Direct calculations by molecular dynamics have been proposed by Durand *et al.* [12]. The performances and reliability of mechanistic models and those used for compliance testing have recently been reviewed by Fang and Vitrac [13].

For more details, please refer to **Annex 8.5- 2** Estimation of Polymer Diffusion properties to be used for migration modelling in support of exposure and material safety assessment.

4.1.2.2. PARTITION COEFFICIENT

In case of two non-miscible media in contact with each other, e.g. octanol in contact with water, a substance added to the system will partition between the two media such that at equilibrium the substance exhibits the same chemical potential in each phase, resulting in two distinct equilibrium concentrations. The ratio of the two equilibrium concentrations is the partition coefficient and expresses the relative chemical affinity for each phase. When the substance concentration in each phase is not too high (i.e. infinite dilution) and when the substance is perfectly dispersed, the ratio is independent of concentrations, of the phase volume ratio and of the contact surface area between the two phases. As the effect of temperature is controlled by the difference in heat of sorption between the two phases, the effect of temperature on partitioning is usually low and could be considered negligible, except for polar substances distributed between a polar phase and a non-polar one. In this case, the substance dissolves exothermically in the first and endothermically in the second; the chemical affinity for the non-polar phase will be higher when the temperature will be increased. The relevance of the use of simple equilibrium descriptions in polymers above and below their glass transition temperatures has been discussed by Kadam [14].

Substances in food contact materials redistribute not only between the food contact layer and the food (or food simulant) but also between all adjacent layers and materials with or without direct contact. The only condition to observe this redistribution is that some mass transfer can occur between the two phases. Such a transfer can occur across a gas without contact (see modeling in [15]), via set-off for materials stored on the role or in reels (see their modeling in [16]).

Direct estimation procedures for partition coefficients between liquids and polymers have been recently devised as discussed in a review [17] . These methods using molecular modeling and the Flory approximation replace advantageously group contribution methods, such as the UNIFAC one [18] and Polyparameter Linear Free Energy Relationships [19], which require a large set of reference data. Based on an exhaustive comparison between pure predictions (without fitting) and experimental partitioning (n-alkanes, n-alcohols, volatile compounds additives; homo and random polymers, simple and complex food simulants)[20-23], it has been shown that the number of hydrogen bonds, which can be created, the differences in size between the migrating substances (e.g. oligomers, additives) and the molecules of food simulants (e.g. water, ethanol, etc.) are the most driving parameters.

Several practical and predictive relationships using solubility parameters in the polymer (see [21]) or limits of solubility (see [23]) have been proposed. For a solute, denoted *I*, the partitioning between an hydrophobic polymer and water can be estimated robustly from the following relationship:

$$K_{i,P/F}^{(T)} = \frac{C_{i,P}^{eq}}{C_{i,F}^{eq}} \approx (1-c)\left(-ln\phi_{i,w}^{sat(T)} - \chi_{i,P} - 1\right)$$

where c is the polymer crystallinity, $\phi_{i,w}^{sat(T)}$ is the solubility limit in water expressed in volume fraction, $\chi_{i,P}$ is the Flory-Huggins interaction coefficient (dimensionless excess energy of mixing) calculated from molecular simulations or solubility parameters (see procedure in [20]).

Empirical approaches have also been proposed for main food simulants (e.g., ethanol 10%, ethanol 50%, ethanol 95% and vegetable oil) based on log-log relationships between octanol partition coefficients and plastic ones [24]. More refined log-log relationships, including allocation to individual food groups were developed in the FACET project [25].

The estimation of these partition coefficient remains complex, and no practical prediction models exist in the scientific literature, so that the current migration models apply today over-estimated partition coefficients. The JRC technical guidance on the application of migration modeling for the estimation of specific migration [26] recommends to use in the absence of specific data, as a worst case scenario, a partition coefficient $K_{P/F} = 1$, which means that the migrant is well soluble in food (F). This option leads to the highest migration value, i.e. complete transfer of the migrant into food at equilibrium. A $K_{P/F} = 1\ 000$ is proposed for use for migrants sparingly soluble in food.

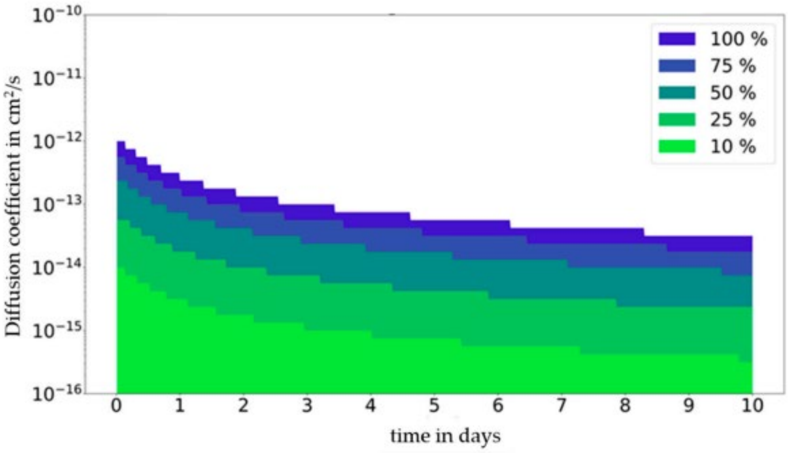
From these above considerations, it is of particular interest to determine under which circumstances the knowledge of partition coefficient is of minor importance, in order to simplify the assessment of food contact materials and the application of migration modelling, by predicting realistic migration levels based only on realistic diffusion coefficient without considering the partition coefficients.

In a recent study, Brandsch et al. [27], identified the conditions of use under which no equilibrium can be developed and in which partitioning can therefore only have a negligible influence on the migration process for single use as well as repeated use articles.

From a general point of view, the contribution of the partition coefficient to the migration is expected to only play a minor role for short term contact conditions and moderate use temperatures, for which no steady -state conditions are reached. That seems to be of interest for repeated use articles, characterized by short contact time.

The authors defined a quantitative criterion set at 10% migration level deviation by considering the partition coefficients in migration modelling, below which they consider a negligeable impact of partitioning on the migration results. This 10% threshold is supported by the fact that migration testing is typically associated with 10% uncertainty on the obtained results.

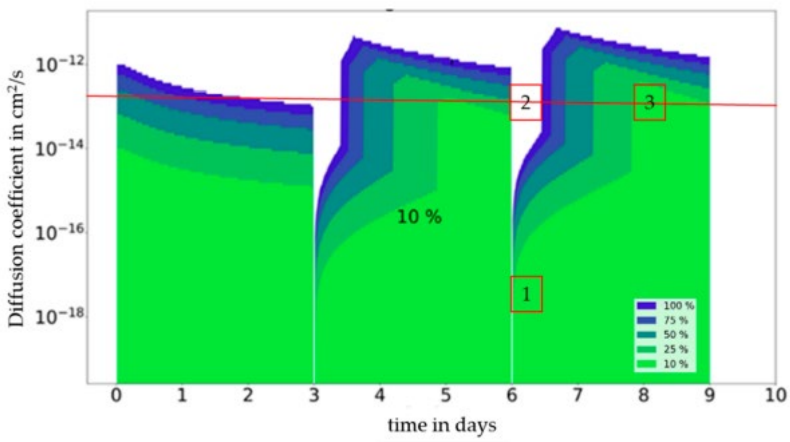
The impact of partition coefficient on migration may be visualized on the following migration map plotting diffusion coefficient as function of contact time, for a material thickness of 2 000 µm, migrant initial concentration of 1 000 and a S/V ratio of 6 dm^2 per kg food, by the color's changes:



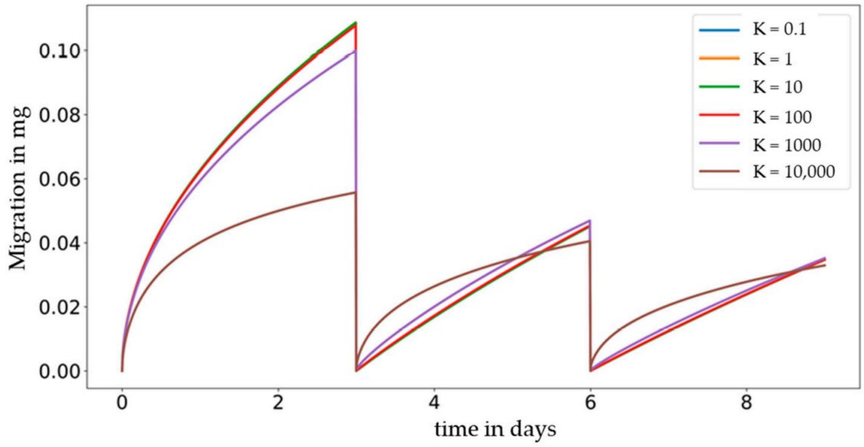
The map gives the possibility to decide whether the partition coefficient of a given migrant needs to be considered or not, at a given diffusion coefficient and at a given contact time.

For example, the impact of the coefficient partition is of low significance (< 10%) at a diffusion parameter of 10^{-15} cm^2/s and a contact time of 2 days.

Considering repeated use applications, it may be visualized on the following map, corresponding to 3 consecutive 3 days repeated use, that the impact of the partition coefficient during the first contact period is the same than the one observed during single use applications.



However, at the beginning of the second and following cycles, when fresh food is brought into contact with the material, the impact of the partitioning is high at the beginning of the contact time and lowers with time until the next repeated use occurs. This is explained by the fact that the diffusion controlled part of the migration curve is proportional to the migrant's concentration , which is high at the interface when the partition coefficient is high and low at the interface when the partition coefficient is low, as below described by the figure using the following parameters : Repeated use 3 x 72 hours (= 3 x 3 days) with a diffusion coefficient of 10^{-13} cm^2/s and partition coefficient $K_{P/F}$ = 0.1 to 10 000.

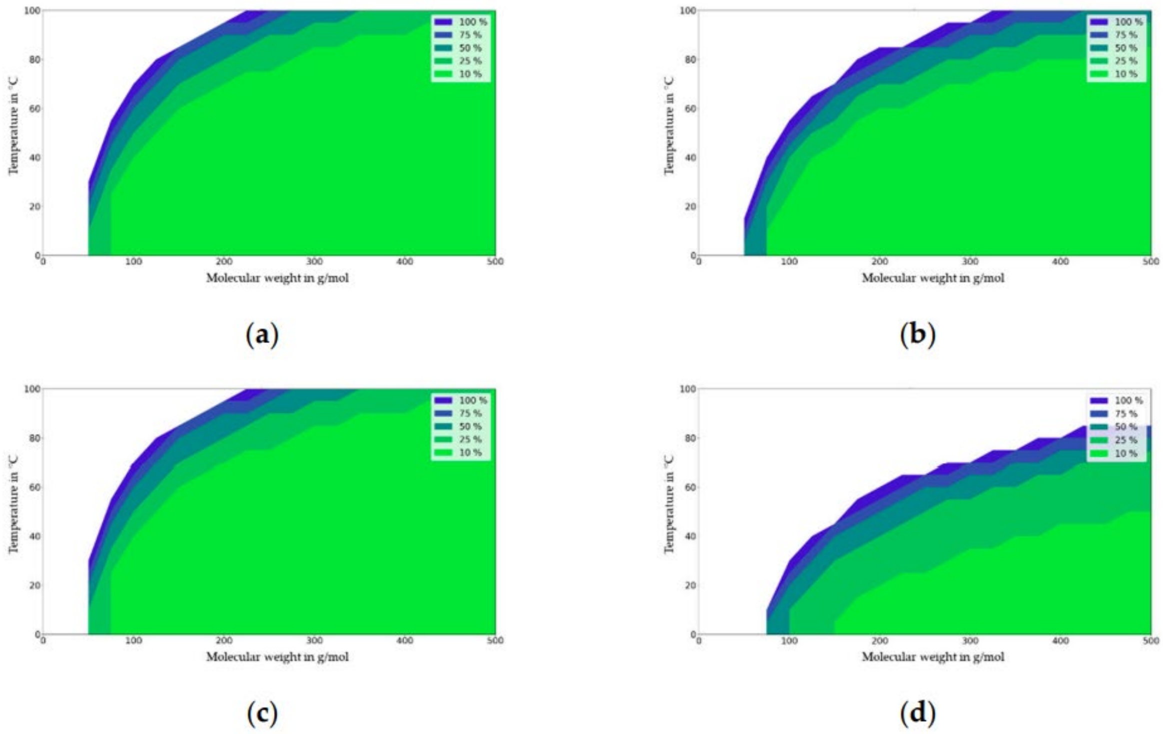


The conversion of these maps in more practical maps, taking into account the % deviation in migration independent of the partition coefficient , as function of temperature and migrant molecular weight for different materials, allows the authors to conclude that for short term single use applications based on a given initial concentration (1000 mg/kg), material thickness (2000 µm), and area to volume ratio (6 dm^2 per kg food), the partitioning is considered to be negligeable in cases of:

➢ low diffusivity polymers (polymers with a Tg of at least 70°C) such as styrene based polymers (PS, ABS, SAN, etc.) or polyesters (PET or other aromatic polyesters) at temperature below 40°C for almost all migrants (with Molecular weight (Mw) > 50 and 100 g/mole for PET and ABS respectively) and contact time less than 1 day duration.

In contrast, High diffusivity polymers corresponding to polymers with a Tg below room temperature (such as PP, LDPE, HDPE etc.), the impact of partition coefficient on migration at refrigerated temperature (< 20°C) is relevant for all migrants with Mw below 1 000 g/mole, for 1 hour of duration.

A map example of single and repeated-use migration is given below for PET in single-use migration for contact of 1 day (a) and 10 days (b) in repeated-use migration for contact times of 3 × 1 day (c) and 3 × 3 days = 9 days (d):



The main difference compared to single-use contact is that under repeated-use conditions (3 consecutive 3 days testing: curve d), the partition coefficient is significant for the whole range of migrants at temperatures above 50°C, whereas for 10 days single use contact (curve b), the impact on partitioning becomes negligible (<10%) at temperatures of 50°C for migrant's molecular weights of around 180 g/mole.

To conclude, repeated use food contact applications are characterized by short contact time, under which steady-state conditions are not likely to be reached: these conditions would have favoured a minor contribution of the partition coefficient $K_{P/F}$ to the migration process. However the 'repeated-use' nature of the contact, where the food is periodically removed from the material and brought in contact with fresh portion, makes the impact of partition coefficient on migration higher than for single-use applications.

This study also highlights the importance of the duration between two migration testing (called as 'empty migration time') on the migration results. In particular, occasional use (once per week) leads to migration observed migration amounts close to the migration amount seen for single-use applications.

4.1.2.3. TOOLS

Today, to the best of our knowledge, there are three validated software systems using application of Finite Element Analysis available. They are designed to overestimate migration.

The systems are:

- SML from AKTS (http://www.akts.com/sml-diffusion-migration-multilayer-packaging/download-diffusion-prediction-software.html)

- Migratest/migrapipe from Fabes (https://www.fabes-online.de/en/welcome/)
- SFPP3 from INRA (http://sfpp3.agroparistech.fr/)

4.1.3. Migration testing

4.1.3.1. Plastic Implementation Measure - Regulation (EU) No 10/2011

Regulation (EU) No 2020/1245, also known as the 15th amendment of Commission Regulation (EU) No 10/2011 has introduced new clauses concerning both specific and overall migration testing for repeated use materials and articles, that are below briefly described separately.

For full details see **Annex 8.8** of the Guidance that introduces the presentation entitled 'Migration tests on repeated use materials and articles' done by Marcel Bosma on 14-16th December 2021.

Specific migration (SM) testing

According to the revised Annex V chapter 2 point 2.1.6. of amended Regulation (EU) No 10/2011, specific migration tests for repeated use articles/materials shall be carried out three times on the same test sample, with fresh simulant each time. The compliance of the material is then checked on the basis of the level of the migration found in the third test, provided the stability of the material is considered as sufficient, meaning that:

- migration found in the subsequent tests are in a downwards trend,
- migration above the ND level shall not be observed in any of the three migration tests.

This is necessary to show that there is no polymer degradation during the test, leading to insufficient stability and then to the impossibility to establish SM compliance, even if it is demonstrated that the SML is not exceeded in any of the three tests.

However, if there is scientific evidence that the level of specific migration, does not increase in the second and third tests and if the migration limit is not exceeded on the first test, no further test is necessary besides the first test.

Highlight is made in Annex V chapter 2 point 2.1.6 that substances prohibited from migration or from being released in detectable quantities under Article 11(4), shall never be considered to comply with Regulation (EU) No 10/2011, if they are detected in the first migration test.

Overall migration (OM) testing

According to the revised Annex V chapter 2 point 3.3.2 of amended Regulation (EU) No 10/2011, and like for specific migration testing, overall migration tests for repeated use articles/materials shall be carried out three times on the same test sample, with fresh simulant each time.

The OM compliance of the material is then checked on the basis of the level of the migration found in the third test, provided:

- migration found in the subsequent tests are in a downwards trend, reflecting the stability of the material.

However if it is not technically feasible to test the same sample three times, such as when testing in vegetable oil, the OM test can be carried out by testing different samples for three different periods of time, lasting, one, two and three times the applicable contact time, at the testing temperature T.

Example: For a contact time of 10 days, the periods of time to consider are: 10 days, 20 days and 30 days.

The difference between the third test, noted OM^{T}_{3xt} and the second test, noted OM^{T}_{2xt}, is considered to be the Overall Migration Limit OML.

The OM compliance of the material is then checked on the basis of the difference between the third and the second test results, that shall not exceed the OML (Equ.1):

$$OM^{T}_{3xt} - OM^{T}_{2xt} < OML \qquad \text{(Equ.1)}$$

Provided that:

- the difference between the second and the first test, noted OM^{T}_{t}, results is lower than the first test results (Equ.2):

$$OM^{T}_{2xt} - OM^{T}_{t} < OM^{T}_{t} \qquad \text{(Equ.2)}$$

and

- the difference between the third and the second test results is lower than the difference between the second and the first test results (Equ.3):

$$OM^{T}_{3xt} - OM^{T}_{2xt} < OM^{T}_{2xt} - OM^{T}_{t} \qquad \text{(Equ.3)}$$

Like for SM testing, if there is scientific evidence that the level of overall migration, does not increase in the second and third tests and if the OML is not exceeded on the first test, no further test is necessary besides the first test.

Verification of SM and OM compliance

To verify compliance with the relevant restrictions, migration testing should be performed by taking into account the most severe contact conditions of use (time and temperature) and the appropriate food simulants. The representative conditions shall be taken from Annex III (selection of the appropriate food simulant) and Annex V of Regulation (EU) No 10/2011, for the selection and time/temperature conditions. Combinations of different conditions may be used, for specific uses.

Recommendations are made for migration testing to:

- Consider for OM, the allowed analytical tolerances, as introduced by the CEN Standard series 1186 (lastly updated in 2002) or by the *JRC Guidelines on testing conditions for articles in contact with foodstuffs (1rst Edition EUR 23814 EN 2009)* [28]
  - *12 mg/kg food or 2 mg/dm² for all aqueous food simulants (including food simulant D1)*
  - *20 mg/kg food or 3 mg/dm² for all fatty food simulants and substitute test media*
- Conduct OM testing (in particular in food simulant D2) in experienced laboratories,
- Conduct migration testing in triplicates, when necessary,
- Apply a duration of 24 hours between 2 subsequent migration trials in order to establish the equilibrium within the test sample. These conditions are also known to be more representative of the use of a repeated use article.

Note that the new above-detailed testing conditions as introduced by Annex V points 2.1.6 and 3.3.2 would require further clarifications and alignments with the other paragraphs of Annex V, in particular those introducing simulant substitutes, that can be used when testing is not technically feasible, such as 'Substitute overall migration tests for tests with food simulants D2' (point 3.2), 'Food simulant substitute' (point 3.4.2) 'Conditions of contact when using food simulants (point 2.1.3) and 'Food simulant substitute' (point 2.2.4).

Furthermore, for some repeat use articles, the amount of food in contact with the article cannot easily be established.

This is the case of food preparation utensils, food serving implements, dishes, etc which fall under Article 17.2 (b) specifying the surface to volume ratio to be taken into consideration is 6 dm^2 / kg food, unless the approach detailed in **Annex 8.11** may be developed to determine consumer's exposure.

Metals and alloys used in food contact materials and articles, a practical guide for manufacturers and regulators, 2013, 1st edition, published under the aegis of the EDQM, a Directorate of the Council of Europe [29] , introduces in its Annex II, a direct and simple calculation in mg/kg and relates it to consumer's exposure for materials for which it is impossible to estimate the ratio surface area to the amount of foodstuffs in contact with it. It is typically the case of utensils. This procedure allows the determination of consumer's exposure for articles for which the surface area is not linked to consumer's exposure. This may be used for listed substances as well as NLS and NIAS.

The method which is based on the calculation of the envelope volume of the utensil is further detailed in **Annex 8.11**.

An important part of migration testing is to select testing conditions and establish the S/V ratio, to recalculate the SM values into mg/kg for compliance assessment with SML.

This point is fully detailed in many examples in the draft guidance of the JRC on migration testing from 2014 (see chapter **4.1.3.3** and **Annex 8.9** of this Guidance).

Examples are however given below for gloves used in the chocolate industry.

The case of gloves used in the chocolate industry is an interesting example for which two different approaches (repeated use or single use approaches) may be used. It is detailed below:

The parameters are:

o Contact time of gloves with chocolates: 1 dm^2,
o Contact conditions: 0, 5 min. to take 10 chocolates with a weight of 100 g,
o Use period: 2 hours then gloves are changed.

**<u>Approach based on repeated use:</u>

Ratio food/contact area = 0.1kg / 1 dm^2

Migration test: 3 subsequent tests with fresh simulant each time for 5 min. at 40°C in simulant D2. The result of the third migration should be divided by a factor of 3 prior comparison with SML, except for substances with SML = Non Detectable (Detection Limit = 10 ppb unless specified differently), which should not migrate in detectable amounts after the first migration.

**<u>Batch approach</u> (exposure assessment taking into account the whole service lifetime of the gloves = may be assimilated to single use conditions applied during the whole service lifetime of the gloves):

Ratio food/contact area = 24 kg / 1 dm^2

Migration test: 1 test for 2 hours at 40°C in simulant D2 – the result of the migration should be divided by a factor of 3, except for substances with SML = Non Detectable (Detection Limit = 10 ppb or unless specified differently), which should not migrate in detectable amounts.

4.1.3.2. How to manage the case where the migration is above the SML during first cycles of use?

The third successive migration level may, in some cases exceed the established SML for monomers and additives, whereas the asymptotic value has not been reached: in this case the material is considered to be non-compliant with the legislation.

However in the case of NLS and NIAS, which require risk assessment during the expected lifetime of the repeat use article, it may be proposed, if necessary, to carry out an additional specific risk assessment taking into account the first uses, leading to migration above the SML or self-derived SML.

Successive migration cycles measurements, will allow to determine the decrease of migration over the lifetime and to assess the chronic exposure to migrants, based on the migration asymptotic value. For this reason, it may be recommended to perform migration cycles until the asymptotic value is reached, if necessary, i.e. if migration levels obtained during the first cycles do not allow to ensure the safety of the finished food contact material or article.

See chapter 4.3 of this Guidance.

4.1.3.3. JRC Guidelines (2009 & Draft 2014)

The documents are:

- JRC Guidelines on testing conditions for articles in contact with foodstuffs (1rst Edition EUR 23814 EN 2009) [29] and,
- JRC Technical Guidelines for compliance testing with regards to Regulation (EU) No 10/2011 (draft for consultation_2014) [30].

These guidelines confirm the rules established by PIM (See chapter 4.1.5.1) and provide more details on the testing conditions for different typical repeat use articles based on their intended and foreseeable worst case specific uses.

Some typical examples are examined below. Not the examples themselves, but the principles used to arrive to the conclusion, should be considered and used to extrapolate to other repeated use articles.

The typical repeat use examples are summarized below and further described in **Annex 8.9** on 'Comparison on testing conditions on selected repeat use articles according to different approaches which are JRC approach, AP(2004)4 on rubbers and Metals and Alloys Guidance.

**** Food contact boxes may be used for different purposes: for transporting meat (crate: The dimensions are 600x400x200 mm, the maximum load is 20 kg), food preparation, food cooking using a microwave oven, and for food storage in the fridge for 2-3 days or in the freezer up to several months.

The JRC guidelines from 2009 and 2014 describes only for the use of boxes for food preparation and cooking, test conditions principles to be followed. They are summarized in **Annex 8.9.**

**** Baking forms have not been described in the JRC Guidelines. No direct comparison with the other different approaches may be done.

**** Dishes/plates are defined to be mainly flat vessels on which food is served.

Their usage corresponds to hot fill migration testing conditions, described in **Annex 8.9.**

Example is given in **Annex 8.9** on testing conditions that apply when a dish is subject to two or more successive time temperature conditions. In this case the article should undergo the same sequence of time-temperature conditions using the same portion of food simulant. As an alternative, a single migration test contact time and temperature may be calculated using the Arrhenius equation as provided in Section 2.1.4 of Annex V of Regulation (EU) No 10/2011.

**** Utensils are used at a broad range of conditions of contact time, temperature with all type of foods. They may be used during baking and frying, which are considered as worst case conditions.

Temperature at the interface may easily reach 175°C, whereas the contact time remains less than 30 minutes.

Conditions testing are described in **Annex** 8.9.

**** Pipes: An example is given on tubing of a milking machine (JRC document draft 2014) which may simulate the dynamic regime of pipes in the food industry.

It is fully described in **Annex 8.9.**

**** Conveyor belts; Example is given (JRC document draft 2014) on a conveyor belt for bakery products, which is fully described in **Annex 8.9.**

4.1.3.4. RUBBER INDUSTRY

The Dutch Packaging and Consumer Articles Regulation in its chapter III [31] (Warenwet), as well as the Resolution of the Council of Europe AP (2004)4 on rubber products intended to come into contact with foodstuffs (version 1 _ 10.06.2004) [32] cover rubbers as well as thermoplastic elastomers, the latter also being covered by PIM.

The below described legal approach for rubbers in the Netherlands, if used for plastics other than thermoplastic elastomers, would require defining the appropriate criteria adopted for plastics, prior to be used.

NB : the German BfR uses a similar categorisation approach for rubbers (Recommendation XXI - commodities based on natural and synthetic rubber); This German approach, which is only based on contact time and temperature, has not been retained for further extrapolation to plastics repeat use materials.

The Dutch approach is based on three types of use category, each of which considers four contact criteria defined to be:

- R_1 the relative surface area,
- R_2 the contact temperature,
- R_3 the contact time,
- R_4 number of times the rubber contact the food.

R_1, R_2, R_3 and R_4 have been conventionally quantified and used to classify rubbers into three categories 1, 2 and 3 in accordance with their intended use (Cat 1) and their potential migration (Cat 2 & 3), in order to avoid unnecessary migration testing for insignificant exposure.

The specific formulae proposed to calculate the R factors are detailed below:

- $R_1 = A_R / 100$, where A_R represents the relative contact area of rubber product per kg food, expressed in cm^2/kg; For relative surface greater than 100 cm^2/kg, R_1 always has the value of 1.
- R2 = 0.05 e0.023T, where T is the temperature, in °C (R2 = 0 near 0°C and R2 = 1 near 130°C)
- $R_3 = t/10$, where t is contact time in hours (R_3 = 1 for t = 10 hours)
- $^{10}\log R_4 = 6 - 2\ ^{10}\log N$, where N is number of contact time (below 1000 contacts, R_4=1)

All of these factors do not exceed the value of 1.

The multiplication of these four R factors gives a factor called R_{total}, which is directly proportional to the expected migration. The higher R_{total} is, the greater is the potential of migration.

The proposed categories of use are as follows:

Category 1: concerns rubber products requiring special attention because of their intended use (baby bottle, and materials that will come into contact with baby food and very young children)

Category 2: comprises rubber products for which the product of the 4 factors R_1, R_2, R_3 and R_4 is greater than the conventional value of 0,001, meaning that migration testing must be carried out.

Category 3: comprises rubber products where the product of the 4 factors R_1, R_2, R_3 and R_4 is lower than 0,001, meaning that migration tests are not required.

This approach is based:

-on the positive list principle for monomers, others base substances and auxiliaries,

-the base materials must be of high technical quality,

-any auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product

The Resolution of the Council of Europe AP(2004)4 proposes examples of classification rubber products used in static conditions and in dynamic conditions.

It is interesting to compare the approach introduced by the Dutch legislation on rubbers / Resolution of the Council of Europe on rubbers AP(2004)4 for the same examples of dynamic contact, than those described by JRC for tubing in a milking machine and conveyor belts for bakery products. Both of the approaches are detailed in Annex 8.9 The approaches coming from the Dutch Warenwet do not require migration testing for the 2 cases investigated in Annex 8.9, whereas the JRC approach requires migration testing to be done.

Indeed, in these two cases, the high number of recurrent uses (R_4) contributes to lower the R_{total} below the 0.001 level, below which no migration testing is required. In other words, the total quantity of food that is in contact with the surface material or article during its whole service life is very high such that the average exposure to migrants is expected to be very low. This approach is comparable to the FDA approach which considers the chronic nature of exposure through repeated use materials and articles.

4.1.4. NIAS Approach derived from the Matrix methodology

4.1.4.1. Definition of the Level Of Interest LOI and rationale for a Tolerable Exposure Level (for unkown NIAS)

The Exposure Matrix project developed by industry collected information on the composition and amount of food packaging in five EU countries (DE, UK, IT, FR, ES) over a 3-years- period from 2003 - 2006. The scope of the project was direct food contact packaging for pre-packed food sold to consumers in retail channels. The packaging use data is a combination of data obtained from third party market survey, organisations and information collected from member companies of the participating associations. Background information can be found here (registration and log-in required, but free of charge): https://matrixcalculation.eu/matrix/matrix.nsf/mv-exposure-matrix-14-01-2008.pdf. The data collected for packaging use has been combined with official dietary surveys from the five countries using methods of stochastic modelling to generate a value for the average daily consumer exposure expressed as an average area (i.e. the 50th percentile of the distribution) of food packaging, split up per food type and per packaging type. The calculated values are an average because the intention was to look at results over the entire diet or at least large parts of it.

The Guidance Document on Exposure Matrix_edition dated 26.01.2011 [33] introduces a level of migration, called Level of Interest (LOI), above which every migrant from the surface of packaging materials and especially NIAS should be known and assessed but below which the corresponding exposure is admitted trivial enough to avoid further assessment. This level linked to each packaging material, will be a function of the exposure of consumers to this material. If the surface of a given material to which one consumer is exposed through his daily diet is known, exposure to any substance migrating from this surface is:

Exposure [µg/person/day] = Migration [µg/dm²] x S [dm²/person/day]

With Migration [µg/dm²] obtained by worst-case calculations or migration modelling or migration testing (based on single use migration values for materials used also in packaging and based on repeated use migration values for materials only used for repeated use materials).

According to the regulation (EU) No 10/2011 any non-listed substances which are neither classified as CMR substances, nor are nanoforms, shall not be detectable when measured with statistical certainty by a method of analysis set out in Article 11 of Regulation (EC) No 882/2004[3] with a limit of detection of 0.01 mg/kg.

Per default this 10 ppb level is used as the Tolerable Exposure Level (TEL). When toxicity data is available, the TEL might be defined at a specific level derived from this data (example: toxicity data exclude genotoxicity and substances do not belong to any exclusion class of the TTC approach, TEL = 90µg/person/day).

Consequently the LOI is calculated by dividing the value of the Tolerable Exposure Level (TEL), by the corresponding average surface exposure S, which corresponds to the average surface of packaging in contact with the daily diet according to the following formula:

$$\boxed{\frac{\text{TEL (NIAS/NLS)}\ (\mu g/person/day)}{S\ (dm^2/person/day)} = \text{LOI}\ (\mu g/dm^2)}$$

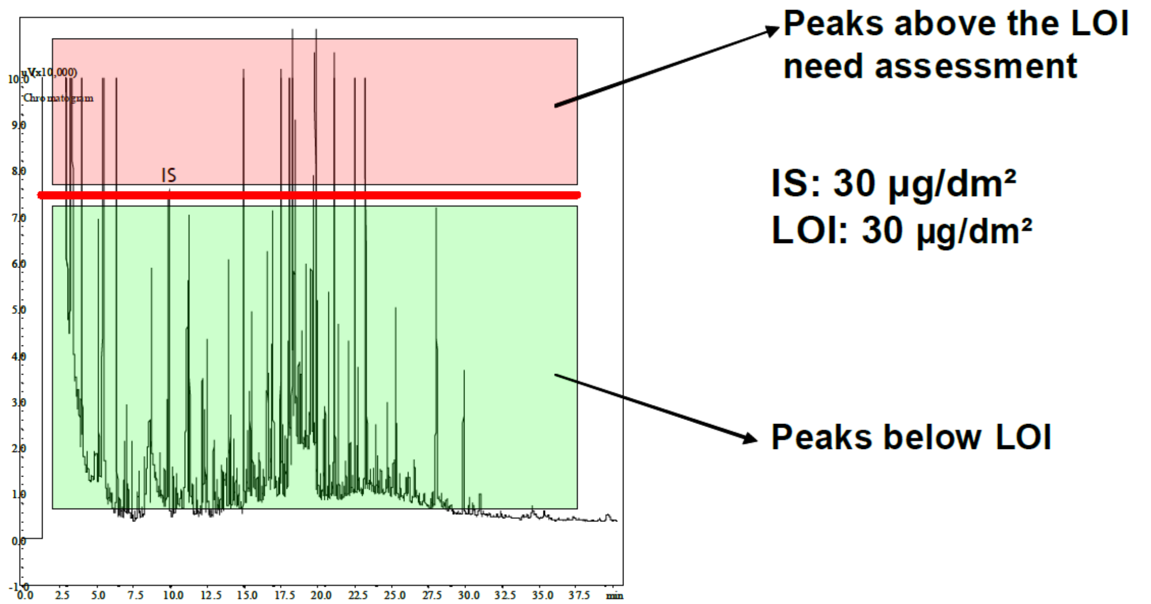
Thus, the LOI corresponds to the maximum migration tolerable for this material and this consumer:

- Migration below the LOI may be considered as negligible so that no further risk assessment is required

[3] Regulation (EC) No 882/2004 of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

○ Above the LOI, every migrant should be identified and risk assessed.

This is illustrated by the following figure
(Source [33]: Fig.7 of the Guidance Document on Exposure Matrix_ edition of the 26.01.2011)



For specific packaging not often used in one country and packing specific food not often consumed, the average real surface exposure can be very low compared to the standard 600 cm^2 (i.e. for Aluminium foil the surface exposure is 0.06 dm^2/person/day) which can lead to a high Limit of Interest. However, it was agreed by industry that even if the calculated LOI was above 100 µg/dm^2, in case of negligible or low surface exposure (Surface < 0.1 dm^2/person/day), then by precaution a default value of LOI of 100 µg/dm^2 would apply.

This approach addresses packed food and does not specifically address repeated use materials.

We currently have very little knowledge on real surface exposures available for repeated use applications compared with the packaging application, where we can use the conventional 6 dm^2 surface in contact with 1 kg food ingested daily (S = 6 dm^2/person/day that leads up to the LOI of 1.67 µg/dm^2).

The plastics exposure due to repeated use applications is expected to be lower that the plastics exposure used in packed food. Furthermore the number of different polymers used in repeated use applications is very large. Some of them are common polymers like PP, HDPE, PA and PVC, but a large part of the others are specialty polymers (*e.g*, SAN, PC, Amorphous polyesters….) used for technical reasons in repeated use applications. For common polymers like PP, HDPE that are very often used in packaging applications the surface exposure issued from Matrix project can be used. For technical polymers like PA,

that are not often used in packaging application, the surface exposure is very low compared with the 6 dm^2 standard assumption (0.1 dm^2/person/day for PA in packed food). Therefore it is reasonable to consider that the surface exposure is < 0.1 dm^2/person/day and similar to the packaging approach a LOI of 100 µg/dm^2 for NIAS and NLS originating from repeated use plastic articles can be fixed. This approach is furthermore very conservative because the surface volume ratio could be lower than the standard assumption, the contact time shorter than for packed food and the migration occurs over the whole life of the finished article to the total volume of food in contact with the article.

This approach always requires to use an expert judgement.

A free web-based tool allows one to calculate exposure based on the Matrix consumption tables (https://matrixcalculation.eu/).

4.1.5. OTHER EXPOSURE APPROACHES

4.1.5.1. US FDA

In the memorandum addressed to PlasticsEurope [32], Keller & Heckman fully describes the approach used by the FDA to assess food contact substances used as components of Repeated Use Articles.

Keller & Heckman highlights the fact that when considering the use of a food contact substance in a repeated use application, FDA uses different assumptions than those used in assessing single service packaging applications and fully described in the PlasticsEurope Guidance on risk assessment of NLS and NIAS under Article 19[1].

Indeed, the US guidance for Industry on the preparation of Premarket Submissions for food contact substances [5] recommends extracting substances with the appropriate food simulating solvents at the highest temperature of use for 10 days.

FDA suggests that the migration that occurs during this time period to be divided by the total amount of food that is expected to contact the article over its whole service life.

FDA suggests also to proceed first with an initial calculation of a worst case level in food, assuming 100% migration of the substance over the service life: often migration testing would not be needed since the worst case migration calculations are sufficient to demonstrate safety of a substance in a repeated use article.

Keller and Heckman [34] considers the FDA's approach as rational because the food contact substance exposures are expected to be chronic in nature: dividing the total amount of a potential migrant over the useful life is adequately protective because higher migration that may occur during the first uses of an article are offset by much lower (if any) migration that may occur after the article has been in service.

FDA has not identified the appropriate consumption factors (CF) for repeated use articles in its Chemistry Guidance. Instead, FDA permits petitioners to submit information regarding the foreseeable uses of the substance when conducting migration and exposure estimates of food contact substances to be risk assessed.

However, according to Keller and Heckman, 1000 grams per square inch (1 $inch^2$ = 6.452 cm^2) may be used as a worst case assumption for repeated use articles, as by experience the level of food over the life time in contact with the repeat use article has never been found below the 1000 g/$inch^2$: this is equivalent of using the end product 100 times, the FDA default assumption for single use application being 10 g in contact with 1 $inch^2$. (See section 4.1.1 – Case B of this document).

4.1.5.2. PROBABILISTIC EXPOSURE ASSESSMENT

Dietary exposure assessment is an important step in the risk assessment of substances migrating from repeat use articles in contract with food. Dietary exposure is calculated as the product of food intake multiplied by the concentration of the substance in the food:

$$\boxed{\textbf{Exposure} = \textbf{Amount} \times \textbf{Concentration}}$$

where the amount is the quantity of food consumed and the concentration is the level of the substance in the food.

A number of approaches are possible to estimate the parameters for each of these inputs, ranging from conservative assumptions using worst case estimates, to refined probabilistic approaches. This exposure is then divided by the consumer body weight to express the exposure on a per unit body weight basis, which is then compared with a toxicological reference dose that characterizes the hazard associated with the substance.

Probabilistic exposure assessment refers to the use of statistical distributions as inputs for either the amount of food consumed or the concentration of a substance migrating into foods, in order to capture the variability of these substances. This is with the aim of reflecting the fact that, in reality, food consumption amounts vary

within and between individual consumers, as do their body weights. Additionally, the concentration of a substance migrating from repeat use articles is also variable as it depends on different use conditions such as contact time and temperature, contact area, the lifetime of the article, the type of food, and the concentration of the substance in the repeat use article.

In order to refine an exposure assessment, improved estimates of either food intake or substance concentration (or both) can be sought.

Food Consumption Databases

Food consumption databases are nationally representative surveys of food intake from a population of consumers. They typically contain data on the complete diet for over 1,000 subjects on one or more days, providing additional demographic data such as age, gender and body weight.

Food consumption databases (depending on the country and survey used) contain additional variables at the eating event level that are useful for assigning a likelihood of contact with a repeat use article and the level of migration. Examples include:

- Preparation Method (e.g. Homemade, Industrially Prepared)
- Place of Consumption (Home, Restaurant, Canteen)
- Nutritional Information (Fat Content, Water Content)

The first two examples of variables can be used to exclude consumption events from an exposure assessment (for example, industrially prepared foods will not involve repeat use articles used in the home). Nutritional information can be used to assign more targeted concentration values from migration testing and/or migration modelling, by assigning more appropriate food simulants based on food composition

Chemical Concentration in Food

- For a given food category, article and substance, there are two considerations:

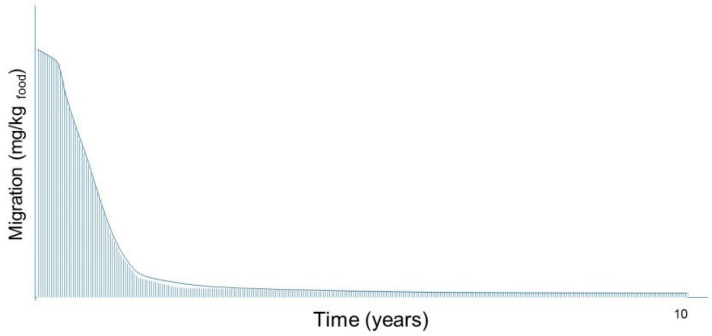
OCCURRENCE and CONCENTRATION

Occurrence

This is the percentage of consumption events that have the potential for exposure, and can be defined as the proportion of foods consumed that are likely to have been in contact with a given repeat use article. As noted above, this can take into account a certain proportion of consumption events, but equally can take into account the proportion of the time certain articles are used over others, the market shares of different materials within different applications, and the composition of these materials.

Concentration

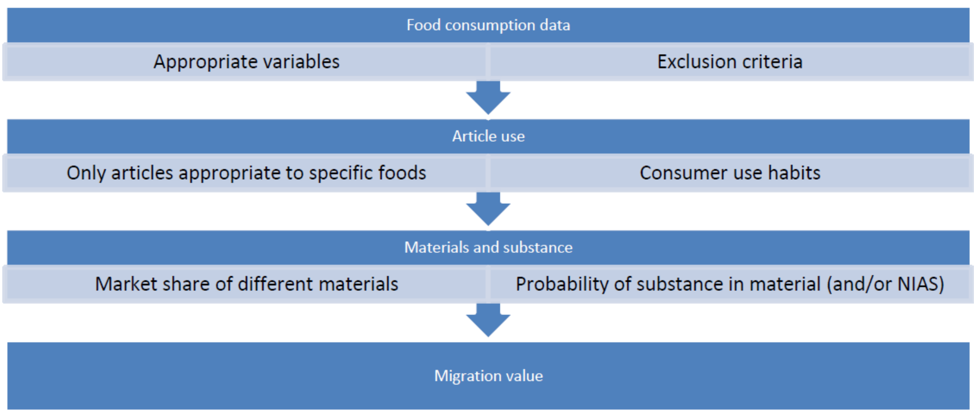
This is defined as the level of migration of a substance, *given that migration occurs*. This can be a point estimate, a statistical distribution, or a set of empirical data points from analytical determinations, coming from either migration testing or migration modelling.



The varying levels of migration over the lifetime of the article may also need to be considered. This can be factored into the assessment by considering the range of migration, and using this range in a probabilistic assessment. This involves random sampling of concentrations from the known range, which if representative of the actual situation, thus incorporates all concentrations the consumer is exposed to.

Linking Food Intake to Migration from Repeat Use Articles

In linking food intake to repeat use article and therefore potential migration, different factors can be considered. These are laid out in the framework and diagram below, and be linked via probabilities and appropriate decision trees. If there is knowledge regarding the simultaneous use of different repeat use articles, then aggregate exposure (multiple sources of the same chemical) can also be addressed. More details on the steps and considerations involved can be found in Annex 8.6.



4.1.6. Comparison of exposure results (worst case, migration modelling and migration testing)

For comparison purpose, migration modelling and experimental migration studies of antioxidants from polypropylene plates into ethanol-water mixtures performed by the two companies MDCTec and Fabes (see the corresponding reports in **Annex 8.7 -1 and 2** respectively) have been performed with a worst case migration calculation scenario using the same parameters.

Migration testing was performed under repeated use conditions by full immersion in food simulants: 50% ethanol and in <u>95% ethanol, which is considered as a worst case as regards the solubility of the lipophilic phenolic antioxidant.</u>

The migrant chosen for the comparison is:

- the phenolic antioxidant (octadecyl-3-(3,5-di-tert.butyl-4-hydroxyphenyl)-propionate), at an initial level of 1200 ppm in PP plaques for MDCTec and up to 850 ppm for Fabes

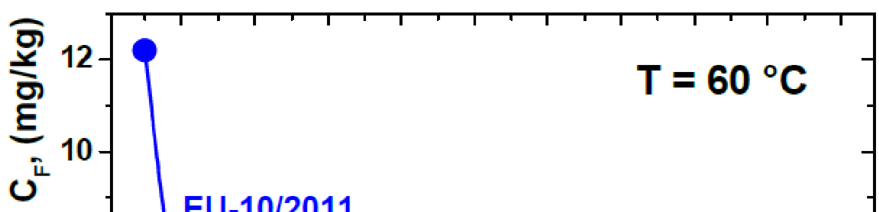
For both migration and modelling estimates, the repeated scenario investigated is the following:

Week	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday		
1		00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 24h00	00h00 - 24h00		08h00 at 60° C
	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00				16h00 at 25° C
	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00				
2	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 24h00	00h00 - 24h00		
	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00				
	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00				
3	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 24h00	00h00 - 24h00		
	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00				
	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00				
4	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 08h00	00h00 - 24h00	00h00 - 24h00		
	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00	08h00 - 16h00				
	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00	16h00 - 24h00				

The experimental migration results obtained by Fabes for the migration of 3-Octadecyl 3-(3,5-di-tertbutyl-4-hydroxyphenyl) propionate in <u>ethanol 95%,</u> (black curve) are compared with migration modelling results using modelling diffusion and partition coefficients estimated according to:

- the Practical Guidance Document of Regulation (EU) No 10/2011 (blue curve)
- Teppfa Fabes for several polyolefin polymers into drinking water (green curve)

The results, [concentration of 3-Octadecyl 3-(3,5-di-tertbutyl-4-hydroxyphenyl) propionate in the food simulant EtOH 95%] as function of the number of cycles, are reported hereafter:



From this data it appears that:

- Migration modelling results obtained with EU parameters developed for single use applications overestimate the migration compared to the experimental results. This is not surprising, as these models are intended to generate results that overestimate the real migration processes.

- The choice of diffusion and partition parameters is of highest importance: the green curve, based on the diffusion and partition coefficients developed by Teppfa Fabes for water, shows a good agreement with the trend of the experimental results. However these results slightly underestimate the real repeated use migration levels.

Comparison of these experimental results is made with the worst case calculation for the PP material, by using the same parameters than those used for this experimental study i.e.

- Sample surface = 120,61 cm2
- Simulant in contact = 60 cm3
- Concentration of the Phenolic antioxidant into the polymer = 850 ppm

And by applying the following:

- Density of the polymer = 0,9 g/dm3
- Density of food = 1 g/dm3
- Retained Thickness = 250 µm
- A constant release of the phenolic antioxidant in food simulant over 1 up to 20 contact cycles

From the above parameters, C_{food} the concentration of the antioxidant assuming 100% migration into food per day, is calculated, as follows:

The concentration of antioxidant in food after one single use is 10,9 times (=38,4/3,52) higher than the experimental result after 1 cycle and around 3 times (=38,4/12,2) higher than for the migration simulation after 1 cycle, and using the EU parameters.

4.2. HAZARD IDENTIFICATION AND CHARACTERIZATION

The PlasticsEurope and the FCA Guidance on the Risk Assessment of NLS and NIAS under Article 19, fully and clearly describes in its chapter 2 how the toxicological assessment of these Non-Listed and Non Intentionally Added substances needs to be performed [1],[35].

Two main cases are identified for dose related substances:

- For threshold toxicological effects, a Reference Dose may be established from available toxicological data. This Dose (often referred as a TDI (Tolerable Daily Intake)) in food contact materials corresponds to the maximum quantity of a given substance in the daily diet below which no risk to human health is expected. The TDI is expressed as an ADI (acceptable daily intake) in cases that the substance has been authorised to be used as a food additive.

In this case, the self-derived SML for a given substance may be calculated based on the assumption that 1 person of 60 kg body weight consumes a kilogram of food per day:

$$\textbf{Self-derived SML}_{\text{mg/kg food}} = \textbf{TDI}_{\text{mg/kg bw/d}} \times \textbf{60}_{\text{kg bw}} \,/\, \textbf{1}_{\text{kg food/d}}$$

As the derivation of the TDI from specific toxicological studies is well described in 'The PlasticsEurope and the FCA Guidances on the Risk Assessment of NLS and NIAS under Article 19' [1],[35] no further information will be given in this Guidance.

It has to be noted that for non-threshold toxicological effects, the establishment of a safe dose is not possible and other concepts need to apply [36].These concepts are based on the scientific principles of low dose extrapolation: the MoE (Margin of Exposure) approach or the Derived Minimal Effect Levels approach.

Examples of non-dose related substances are genotoxic, mutagen and non-threshold carcinogen.

Generally, the aim is to strictly avoid the presence of these substances in food contact materials.

These concepts may not apply for substances with no relevant toxicological studies.

4.2.1. Threshold of Toxicological Concern (TTC)

For those substances with little or no toxicological data, the Concept of the Threshold of Toxicological Concern, has been recognized by EFSA as a useful tool to assess impurities, breakdown and reaction products, metabolites and low-level contaminants in food and feed, when an exposure assessment can be conducted [EFSA Opinion (Journal 2012. 10(7): 2750)] [37].

The TTC is defined to be " the highest nominal oral dose which is **without appreciable risk** to human health **after daily lifetime exposure** " This approach only requires the knowledge of the chemical structure of the substances which need to be assessed.

The TTC thresholds initially developed by Munro et al. (1996) for the Cramer Classes I, II and III, incorporating organophosphates, were calculated including a safety factor of 100 to the 5th percentile of the NOEL.

For organophosphates a separate threshold was elaborated by Kroes et al. in 2004 [38], however without adjustments of the Cramer Class III threshold.

Carbamates were assessed in 2012 by EFSA and included into the same class as organophosphates [37].

Furthermore, in the EFSA Scientific Opinion, 2012, EFSA considered that the TTC approach was not well supported for the Cramer Class II, so that substances belonging to this Class will have to rely on the same exposure threshold than the Cramer Class III substances [37].

The resulting TTC exposure thresholds are summarised in **Table 14**:

Table 14: Combined TTC exposure thresholds as described by Kroes et al. 2004 [38] and EFSA Opinion, 2012 [37]

<table>
<tr><th>Structural Class</th><th>Description</th><th>TTC exposure limit (µg/person/day)</th><th>TTC exposure limit (µg/kg bw/day) (*)</th></tr>
<tr><td>Cramer Class I
(least toxic)</td><td>Substances with simple chemical structure and for which efficient modes of metabolism exist, suggesting a low order of oral toxicity</td><td>1800</td><td>30</td></tr>
<tr><td>Cramer Class II
(intermediate)</td><td>Substances which possess structures that are less innocuous than Class I substances, but do not contain structural features suggestive of toxicity like those in Class III</td><td rowspan="2">90</td><td rowspan="2">1.5</td></tr>
<tr><td>Cramer Class III
(most toxic)</td><td>Substances with chemical structures that permit no strong initial presumption of safety or may even suggest significant toxicity or have reactive functional group</td></tr>
<tr><td>Organophosphates and carbamates</td><td>Organophosphates or carbamates which may have neurotoxic properties</td><td>18</td><td>0.3</td></tr>
<tr><td>Threshold of Regulation (ToR) (**)</td><td>Substances for which there are no structural alerts for genotoxicity</td><td>1.5 (***)</td><td>0.025</td></tr>
<tr><td>Genotoxic alerts</td><td>Substances for which there are structural alerts for genotoxicity but which are not aflatoxin-like ,azoxy- or N-nitroso-compounds and benzidines</td><td>0.15</td><td>0.0025</td></tr>
</table>

(*) with the assumption of 60 kg body weight

(**) Under the US FDA guidance, toxicological data may not be required for substances with an exposure below the Threshold of Regulation (ToR), and no concern of genotoxicity.

(***) based on FDA assumption of 3 kg per person per day of food intake.

In their opinion from 2016, the EFSA and WHO expert group [39] acknowledged that some known categories are excluded from the TTC approach:

- TTC approach should not be used for: inorganic chemicals, metals and organometallics, proteins, steroids, organosilicon compounds, chemicals that are predictive to bio-accumulate, nanomaterials , radio-actives substances
- The TTC value for chemicals with certain structural alerts for genotoxic carcinogenicity may not be sufficiently protective for high potency carcinogens (see in the above table, the line dedicated to ‘genotoxic alerts’.

For additional information on using the TTC concept, the reader should consult the original references, as mentioned in the PlasticsEurope and the FCA Guidance on the Risk Assessment of NLS and NIAS under Article 19 [1], [35].

4.2.2. TNO Approach

In 2014 W.R. Leeman and TNO [40] re-evaluated the Munro dataset to derive more specific TTC thresholds.

Indeed, they confirmed the TTC threshold proposed for organophosphates, and carbamates.

They also proposed a separate class and threshold for organohalogens and a higher threshold for remaining class III substances without organophosphates, carbamates and organohalogens.

Based on this evaluation, the proposed TTC thresholds are below summarized:

Table 15: TTC exposure thresholds as derived by W.R. Leeman, TNO [40]

Structural Class	TTC exposure limit (µg/person/day)	TTC exposure limit (µg/kg bw/day) (*)	Comment
Organophosphates and carbamates	18	0.3	Makes part of this evaluation
Organohalogens	90	1.5	Makes part of this evaluation
Class III without organophosphates, carbamates and organohalogens	240	4	Part of this evaluation
			Does not make part of this evaluation- should be part

Class II	240	4	of Class III according to EFSA Opinion, 2012 (*)

(*) TTC threshold for Class II was initially set by Kroes and all [38] at 9 µg/kg/bw/day but EFSA considered in 2012 [35], it should rather merge with Class III due to the lack of substances supporting the Class II.

Thresholds introduced in chapter 4.2 for Class I and substances with genotoxic alerts, remain unchanged.

4.3. Risk assessment

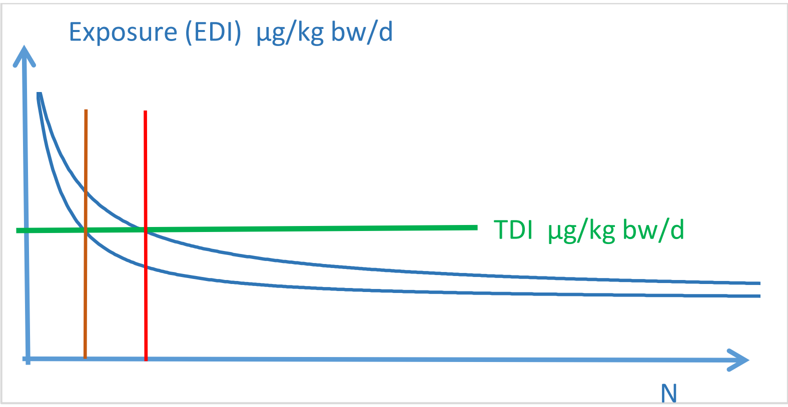
As already introduced in Section 3 of this document, as long as the Estimated Daily Intake is below the Tolerable Daily Intake or the migration level under the typical condition of use is below the self-derived SML, the use of the substance is considered safe.

Exposure (EDI) < exposure threshold (TDI or TTC) or Specific migration < self-derived SML

In the case of repeated use materials, migration is expected to decrease with the number of uses of the food contact materials, down to an asymptotic level. This level may be reached after 3, 5 or 10 uses, depending on a great number of factors such as polymer diffusivity, contact time, temperature…

The estimated daily intake EDI may exceed the tolerable daily intake TDI, during the first uses of the repeat use article, so that an expert judgement may help, if necessary to check about the safe 'acute tolerance' of the article, based on available acute, subacute toxicological data.

This is illustrated by the following figure :



The risk assessment methodology for repeated use articles might require several steps of refinement of the approach used. Indeed, the exposure assessment should follow a tiered approach, starting with a conservative assessment (worst case calculations), then improve the determination of the substance concentration in food through migration modelling and/or migration testing and lastly consider the real the food intake.

See section 6. the decision tree proposed to assess exposure.

Special attention should be given to the risk assessment of non-dose related CMR substances, for which no TDI may be established. In particular, for these substances, the full risk assessment process, including hazard identification and characterization, requires an expert judgment.

For this category of substance, we recommend to consider a single use scenario, because the threshold for which there is no substantial risk shall not be exceeded during any cycle of use, including the first one.
See the decision tree in chapter 6. of this guidance on the tiered approach which may adopted for the exposure assessment of the listed as well as NLS and NIAS.

5. How to deal with the Declaration of Compliance (DoC)?

The Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply [41], introduces the principles for sharing Compliance work throughout the supply chain.

In particular *Point 3. of this Guidance* highlights that a business operator introducing or generating a substance in a product is responsible for compliance of this substance. This includes as well the degradation of a substance linked to its intended use which may be formed at this or at a later manufacturing step under a specific use.

As mentioned in *Point 4*. of this guidance all the aspects of the compliance work linked with the introduction or generation of a substance may not be finalized at the manufacturing stage at which the substance is introduced or generated (due to expected escape of volatile substances during the next conversion step , lack of information on intended conditions of use….).

In this case, the compliance work needs to be delegated to the downstream users: the identity of the substances (chemical name and CAS RN) together with all relevant information for the risk assessment needs to be provided in the DoC. In other cases, when the risk assessment of NLS and NIAS has been carried out in line with the intended conditions of use or under worst case conditions, confirmation that these substances comply with Article 3 of the Framework Regulation and that a risk assessment has been performed in accordance with Article 19 of the Plastic Regulation, should be provided in the DoC.

Information on the conditions covered by the risk assessment and any possible usage restrictions that shall apply for a safe use of the article, should be notified in the DoC.

We would recommend to mention in the DOC, if appropriate, a reference to this guidance document and the approach that has been used so that the customer knows if he can rely on this for his uses or if he needs to perform some additional compliance work.

6. Decision Tree

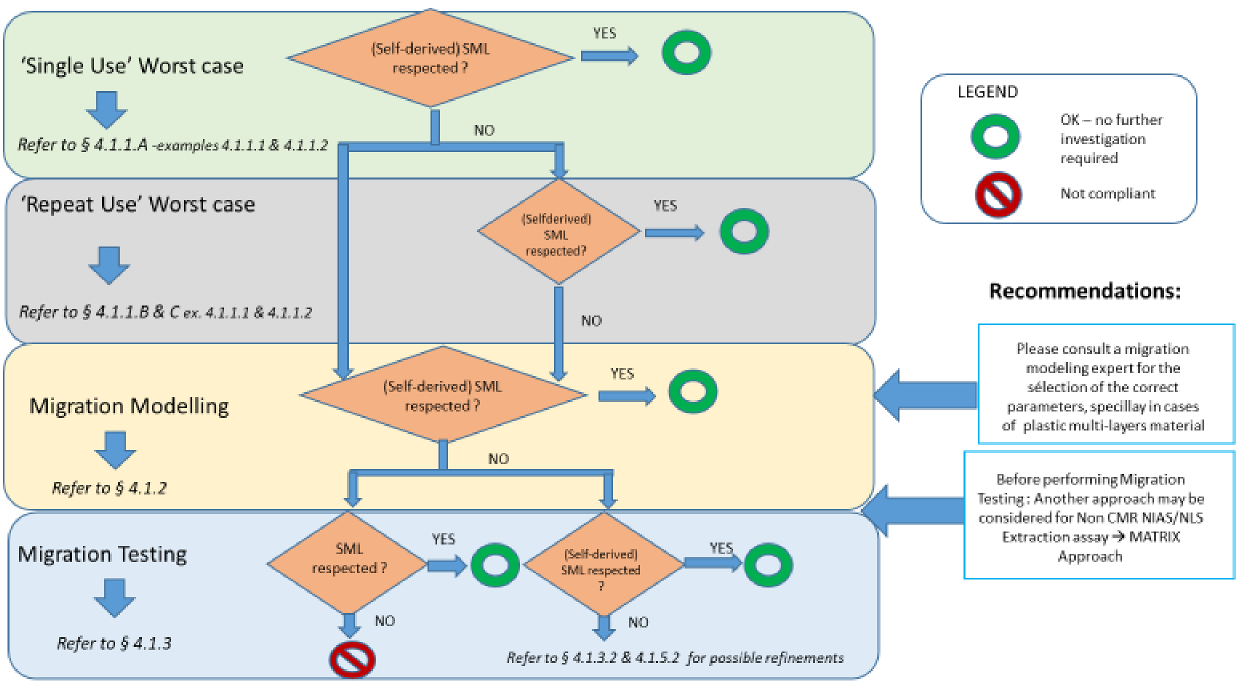
In this Guidance, different ways to risk assess plastic materials and articles intended for repeated uses have been investigated. Possible options for exposure assessment are described in Section 4.1 of the Guidance.

Based on these different options, a tiered exposure approach is proposed for both listed substances referring to substances with SML and for non-listed substances (NLS) and non- intentionally added substances (NIAS) referring to self-derived SML substances.

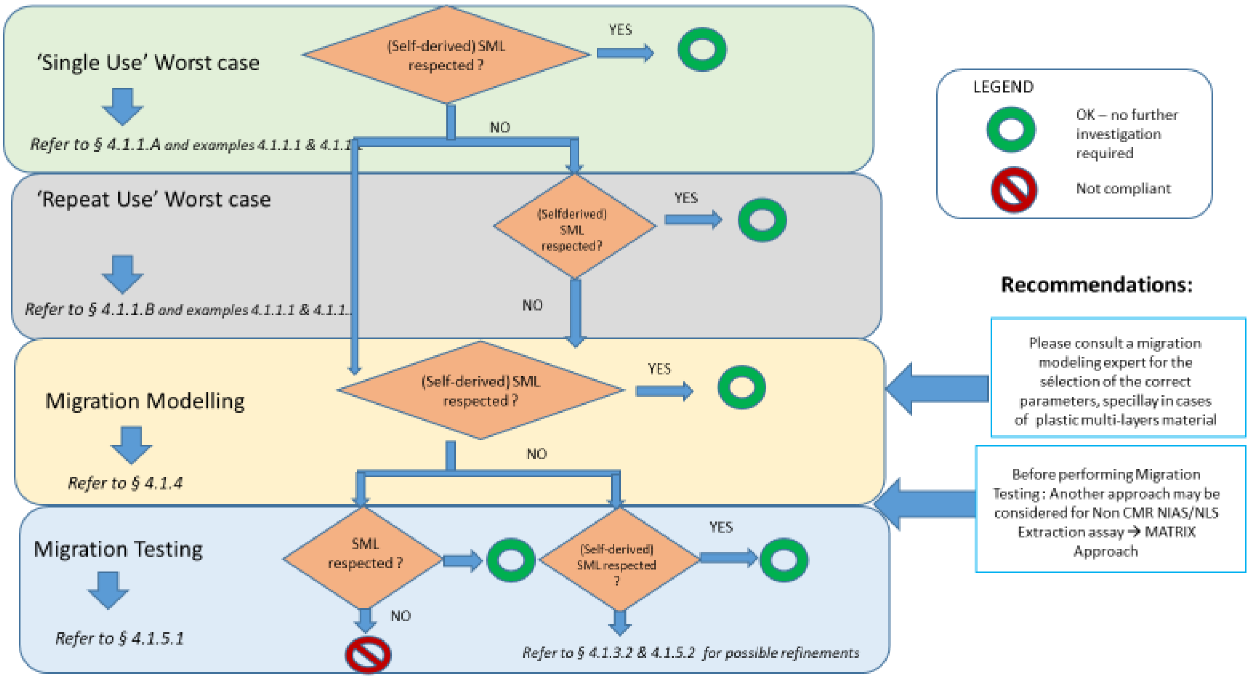
The proposed tiered approach started with very conservative scenario, up to more realistic scenarios, is described in the following decision tree.

Annex 8.10 describes for each exposure scenario, the input data required and its advantages /disadvantages.

Tiered Approach for Exposure Assessment of Migrants



Tiered Approach for Exposure Assessment of Migrants



7. Conclusion

The aim of this Guidance is to give support for companies which are in the process of risk assessing their products intended for repeated use food contact applications, since there is currently no pragmatic methodology or rules covering these materials, even though they need to fulfil their obligation of safety. In particular NLS and NIAS need to be risk assessed, according to Article 19 of PIM Regulation.

For this purpose, different exposure scenarios have been investigated, starting with a very conservative scenario (worst case single use) up to more realistic exposure scenario (probabilistic exposure assessment). Also, different other approaches are discussed: the US approach and the Dutch categorisation approach introduced for rubbers are based on the chronic exposure of consumers to migrants over the whole life service of the repeat use material and articles.

A tiered approach for exposure assessment is laid out by a decision tree introduced in Section 6 of the Guidance, whose purpose is mainly to act as a decision aid tool to risk assess materials intended for repeated uses.