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Table of Appendixes

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Annex 8.1. List of plastic : typical repeated use articles and materials

Repeated use articles made with (or containing part of) plastic cover different areas which are described below:

- **Food Processing Industry:**
  - Food processing machinery,
  - Pipes,
  - Conveyor belts
  - Filters
  - Membranes
  - Containers
  - Crates....

- At home
  - Food packing: food boxes
  - Food preparation utensils (spatulas…)
  - Tableware, plates, dishes, glasses…
  - Bakeware for oven
  - Microwave materials
  - Roast strings
  - Mixing bowls
  - Apron for home use
  - Cutting boards
  - Coffee maker
  - Kettle/teapot
  - Baby bottles
  - Flask and jugs
  - Food trays
  - Thermos
  - Kitchen small appliance: mixers, blenders, ice cream machine
  - Machinery to prepare and distribute Soda or beer ....
- Miscellaneous applications:
  - Camping equipment (plastic spoons, forks, glasses, dishes, gourds…)
  - Vending machines
  - Tubing in milking machine

Annex 8.2. List of polymers used

This list only refers to polymers covered by regulation (EU) No 10/2011 and further amendments

Name	Polymer Category
ABS = Acrylonitrile butadiene styrene	Thermoplastic Elastomer
ACM = Acrylic rubber	Rubber
AMMA = Acrylonitrile methyl methacrylate	Thermoplastic
ASA = Acrylonitrile styrene acrylic ester	Thermoplastic
CA = Cellulose acetate	Thermoplastic
CAB = Cellulose acetate butyrate	Thermoplastic
CAP = Cellulose acetate propionate	Thermoplastic
EAM = Ethylene-acrylate copolymer	Thermoplastic
EP = Epoxy	Thermosetting resins
EPS = Expandable polystyrene	Thermoplastic
ETFE = Ethylene tetrafluoroethylene	Thermoplastic
EVA = Ethylene-vinyl acetate	Thermoplastic / Rubber
EVAL, EVOH = Ethylene-vinyl alcohol	Thermoplastic
FEP = Fluorinated ethylene propylene	Thermoplastic
LCP = liquid crystal Polymers	Thermoplastic
MBS = Methyl methacrylate-butadiene-styrene	Thermoplastic
MC = Methyl cellulose	Thermoplastic
MF = Melamine formaldehyde	Thermosetting resins
MP = Melamine phenolic	Thermosetting resins
PA = Polyamide	Thermoplastic
PAI = Polyamide-imide	Thermoplastic
PAN = Polyacrylonitrile	Thermoplastic
PAR = Polyarylate	Thermoplastic
PB-1 = Polybutene-1	Thermoplastic
PBT = Polybutylene terephthalate	Thermoplastic
PC = Polycarbonate	Thermoplastic
PCT = Polycyclohexyl dimethylterephthalate	Thermoplastic
PCTFE = Polychlorotrifluoroethylene	Thermoplastic

PE = Polyethylene	Thermoplastic
PE-HD = High-density polyethylene	Thermoplastic
PE-LD = Low-density polyethylene	Thermoplastic
PE-LLD = Linear low-density polyethylene	Thermoplastic
PE-UHMW = Ultra-high-molecular-weight polyethylene	Thermoplastic
PEBA = Polyether block amide	Thermoplastic Elastomer
PEC = Polyestercarbonate	Thermoplastic
PEEK = Polyetheretherketone	Thermoplastic
PEI = Polyetherimide	Thermoplastic
PEK = Polyetherketone	Thermoplastic
PEN = Polyethylene naphthalate	Thermoplastic
PESU or PES = Polyethersulfone,	Thermoplastic
PET = Polyethylene terephthalate	Thermoplastic
PF = Phenol formaldehyde resin	Thermosetting resins
PFA = Perfluoroalcoxy	Thermoplastic
PI = Polyimide	Thermoplastic or Thermosetting resins
PK = Polyketone	Thermoplastic
PMMA = Polymethyl methacrylate	Thermoplastic
PMP = Polymethylpentene	Thermoplastic
POM = Polyoxymethylene polyacetal	Thermoplastic
PP = Polypropylene	Thermoplastic
PPE = Polyphenyl ether	Thermoplastic
PPO ou PPE = Polyp-phenylene oxide ou polyp-phenylene ether	Thermoplastic
PPOx = Polypropylene glycol ou polypropylene oxide	Thermoplastic
PPS = Polyp-phenylene sulfide	Thermoplastic thermostable
PS = Polystyrene	Thermoplastic
PSU = Polysulfone	Thermoplastic thermostable
PTFE = Polytetrafluoroethylene	Thermoplastic thermostable
PUR = Polyurethane	Thermoplastic
PVAC = Polyvinyl acetate	Thermoplastic
PVAL = Polyvinyl alcohol	Thermoplastic
PVC = Polyvinyl chloride	Thermoplastic

PVDF = Polyvinylidene fluoride	Thermoplastic
PVF = Polyvinyl fluoride	Thermoplastic
SAN = Styrene-acrylonitrile	Thermoplastic
SMA, SMAnh = Styrene maleic anhydride	Thermoplastic
TPE = Thermoplastic elastomer	Thermoplastic Elastomer
TPE-A = Thermoplastic elastomer on polyamide basis	Thermoplastic Elastomer
TPE-E = Thermoplastic elastomer on polyester basis	Thermoplastic Elastomer
TPE-O = Thermoplastic elastomer on polyolefine basis	Thermoplastic Elastomer
TPE-S = Thermoplastic elastomer on styrene basis	Thermoplastic Elastomer
TPU = Thermoplastic elastomer on polyurethane basis	Thermoplastic Elastomer
UF = Urea-formaldehyde	Thermosetting resins
UP = Unsaturated polyester	Thermosetting resins

For information, is given the list of polymers falling under definition of rubbers, according to chapter 3. Definitions of this Guidance

Rubbers are out of the scope of this Guidance.

Name	Category
ACM = Acrylic rubber	Rubber
AU = Polyesterurethane,	Rubber
BR = Butadiene rubber	Rubber
CM = Chlorinated polyethylene rubber	Rubber
CO = Epichlorohydrin rubber	Rubber
CR = Chloroprene rubber	Rubber
CSM = Chlorosulphonated polyethylene rubber	Rubber
DAP = Diallyl phthalate	Rubber
ECO = Epichlorohydrin copolymer rubber	Rubber
EPDM = Ethylene-propylene-diene monomer rubber	Rubber
EPM = Ethylene-propylene copolymer	Rubber
EU = Polyetherurethane,	Rubber

EVA = Ethylene-vinyl acetate	Thermoplastic / Rubber
FKM, FPM = Fluorinated rubber	Rubber
HNBR = Hydrogenated nitrile butadiene rubber	Rubber
IIR = copolymer isobutylene-isoprene: Butyl rubber	Rubber
IR = Isoprene rubber	Rubber
NBR = Nitrile butadiene rubber	Rubber
NR = Natural rubber	Rubber
PBR = Polybutadiene-vinylpyridine rubber	Rubber
PIB = Polyisobutylene	Rubber
SBR = Styrene-butadiene	Rubber
SI = Silicone	Rubber
VMQ = Vinylmethyl silicone	Rubber

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Annex 8.3 EDI's calculations comparison between dynamic and static conditions

Example is given of a worst case migration scenario for a pipe intended to be used in the food industry to transport liquid food. See section 4.1.1.1.1.

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

Used parameters versus typical value

Parameters	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/ cm^3)	1	

From this data, the following parameters are calculated:

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 (cm^2)	50 560
Pipe inside volume (dm^3)	*20,096*

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 dm^3, 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 dm^3.

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 dm^3 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.

Use conditions	Dynamic conditions during the life service of the pipe	Static conditions
Cfood µg/kg	0,11	11 196
EDI µg/person/day	0,11	11 196
Ratio $EDI_{static}/EDI_{dynamic}$	100 318	

Annex 8.4 Excel sheet on Worst case calculations according to chapter 4.1.1

Annex 8-4_Worst case calculations.xlsx

Annex 8.5 Migration modelling

Annex 8.5. 1- Simplified approach of migration modelling concept

ANNEX%208.5%20-1
%20Simplified%20app

Annex 8.5. 2- Estimation of Polymer Diffusion properties to be used for migration modelling in support of exposure and material safety assessment in support of exposure and material safety assessment

Annex%208.5-2%20E
stimation%20of%20pc

Annex 8.6. Detailed background on Dietary Exposure Assessment

Annex%208.6%20Gui
dance%20Document%

Annex 8.7 Migration modelling reports

Annex 8.7.1 Report KinetikTEST – MDCTec Services 10.03.2017

Annex 8.7.1 MDCTEc
Migration studies.pdf

Annex 8.7.2 Investigation Report – Fabes – 15.12.2006

Annex 8.7.2 Fabes
Migration studies - ex

Annex 8.8. Presentation from M. Bosma entitled ‘ Migration tests on repeated use materials and articles’_ P&P_14th-16th December 2021

PDF

Migration tests on
repeated use materia

Annex 8.9. Comparison on testing conditions on selected repeated use articles according to different approaches: JRC, Dutch Warenwet / Res. of Council of Europe AP(2004)4 on rubbers and Metals & Alloys Guidance

Annex 8.8_ Testing conditions according

Annex 8.10. Exposure assessment scenarios: input data, advantages/disadvantages

Annexe 8.9 exposure assessment scenarios

Annex 8.11. Calculation of worst case exposure for utensils (Corresponding to Annex II of the Metals and Alloys Guidance, edition 2013)

The Guidance for metals and alloys[28] provides a procedure to risk assess, articles that cannot be filled and for which it is impractical to estimate the ratio of surface area to the amount of foodstuffs in contact with it. This approach typically addresses utensils, whose surface area is not correlated with consumer exposure.

The method is based on the following steps:

1- Determination of the calculation of the envelope volume of the utensil
2- Determination of the reference weight of the food in contact
3- Determination of the released mass of a specific substance
4- Determination of the specific release

1- Determination of the calculation of the envelope volume of the utensil

Utensils are tree-dimensional objects, characterized by:

a. X depth
b. Y width
c. Z height

From which is calculated a parallelepiped using the following conventions for the choice of the values of X, Y and Z, ranging from 5 to more than 25 cm:

Measurements (cm)	Value to be assigned
X, Y or Z < 5 cm	5 cm
5 cm< X, Y or Z < 10 cm	10 cm
10 cm< X, Y or Z < 15 cm	15 cm
15 cm< X, Y or Z < 20 cm	20 cm
20 cm< X, Y or Z < 25 cm	25 cm
X, Y or Z > 25 cm	30 cm

Measures of the value X, Y and Z exclude the handle and is achieved by using a gauge

(e.g. Vernier calipers).

Measurement of Z:

For articles whose functional part HN (corresponding to the part in contact with the foodstuffs) is somewhat distant from the handle, a value of 2/3 of the height excluding the handle, is assigned for the total height.

If the handle is made of plastic and is not clearly separated from the rest of the article, it is assigned a default length of 1/3 of the total height.

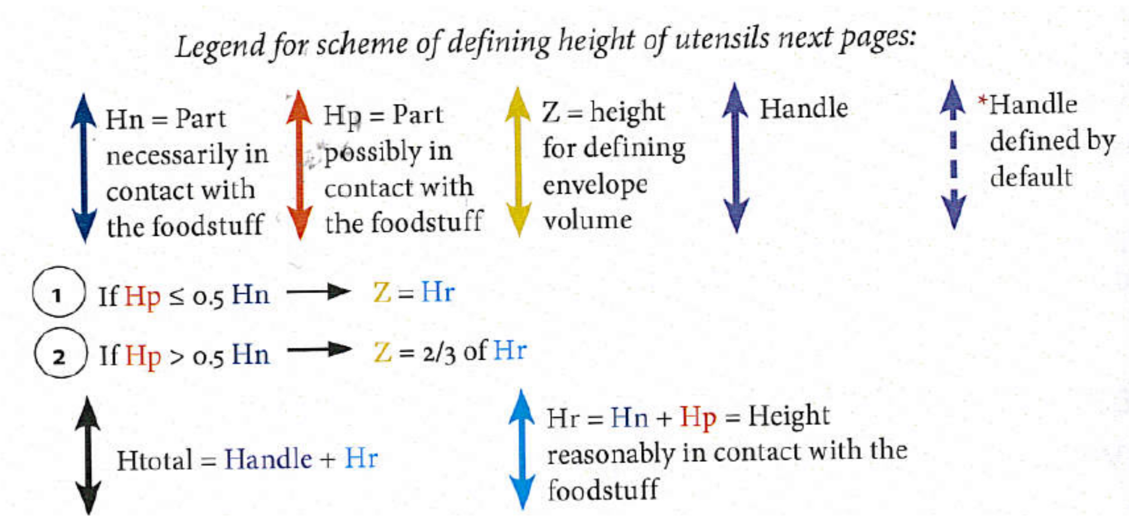
Hp is the part of the utensil possibly in contact with the foodstuffs and Hr is the sum of Hn and Hp

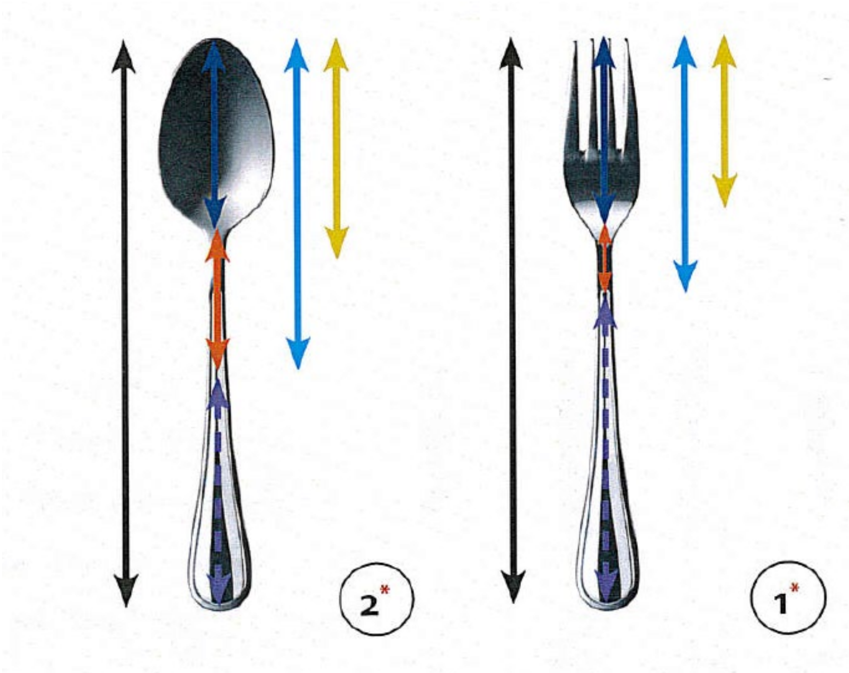
However the following rules should apply:

- If Hp ≤ 0,5 Hn than the value Z defining the height of utensil to be considered is Hr (Case 1)
- If Hp > 0,5 Hn than the value Z defining the height of utensil to be considered is 2/3 of Hr (Case 2)

This is illustrated with the following schemes:

(Source: Annex II of the Metals and Alloys Guidance, edition 2013)





The envelope volume is calculated by the following formula:

Enveloppe Volume (EV) = X Y x Z (in cm^3)

2- Determination of the reference weight of the food in contact

The reference weight with respect to Volume is determined assuming a density a 1 g/ cm^3, using the following formula:

Reference Weight (RW) (kg) = Envelope Volume (cm^3) /1000

3- Determination of the released mass of a specific substance

Conditions of test are determined by Regulation (EU) No 10/2011.

The volume of the simulant used is not necessarily the same than the envelope volume. Once the specific substance is released in the food simulant, its concentration in the simulant is measured and the corresponding mass of is calculated on the basis of the following formula

Released mass (M, in mg) = V (cm^3) x C (mg/cm^3)

With V volume of simulant used

C: concentration of the substance to be examined in the simulant

4- Determination of the specific release

As a general rule:

SR (mg/kg) = M (mg) / RW (kg)

If SR < SRL (Substance Release Limit), then the article is compliant

If SR > SRL then the article is non- compliant

Annex 8.12. Nanomaterials

The definition of Engineered nanomaterials has been introduced by Regulation (EU) No 1169/2011 on the provision of food information to consumers, as being:

'any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.'

These substances may be intentionally introduced in the plastic food contact materials. In this case, the nanoform shall be explicitly authorized and mentioned in the specifications of Annex I of Regulation (EU) 10/2011

These substances which may also be present as NIAS and NLS in the food contact materials, require to be risk assessed as regards Article 19 of Regulation (EU) 10/2011.

EFSA's Scientific Committee, in its opinion on nanoscience and nanotechnologies in food and feed safety [The EFSA Journal (2009) 958,1-39], notes that the data currently available are limited, and the lack of test methodologies makes risk assessment of nanotechnology products both difficult and highly uncertain.

Indeed the current risk assessments methodologies, in particular toxicological methods are considered to be not sufficient to address properly all the issues arising from nanoparticles because of their size confers to them specific and unique properties.

However, Migration Studies, (experimental as well as migration modelling studies), performed by the Fraunhofer Institute in recent years suggest:

- there was no experimental evidence NPs would migrate into food simulants from LDPE films, even under severe test conditions.
- Migration modelling indicates that NP larger than 3-4 nm in diameter cannot migrate
- (following Fick's law of diffusion) at all from LDPE and the from any other thermoplastic
- For PET the cut off value would be below 1 nm

These considerations on non-migration, fully justified by analytical and /or modelling experiments, should be sufficient to risk assess the nanoparticles, which may be present in the FCM, as exposure of consumers via ingestion can be excluded.

Annex 8.13. Colorants and Pigments

According to Article 5 of Regulation (EU) No 10/2011, colorants and pigments are excluded from listing in Annex I (Union List). These NLS are however covered by the obligation to meet the general provisions of the framework Regulation (EC) No 1935/2004, and when they exist e.g. in France, the Netherlands, Italy, Belgium, Spain, specific national legislation apply.[1]

A provision on Primary Aromatic Amines (PAAs) which can arise from colorants prepared by diazo-coupling and which are not listed in the Union list (Annex I of Regulation (EU) No 10/2011), has been however adopted: they shall not be detectable in food, with a detection limit of 0,01 mg/kg of food or food simulant.

In the document No 021/2014 of 24 July 2013 on PAA's from printed food contact materials such as napkins or bakery bags, the BfR expressed its opinion that the contact with PAAs classified as carcinogenic (Classes 1A and 1B of the CLP Regulation), should be minimised and proposes the migration of these substances into food or food simulant should not be detectable, as individual substances, with an analytical detection limit of 0,002 mg/kg food (2 ppb), instead of using the aggregate 10 ppb limit.

It has to be reminded that the Committee of Experts of the Council of Europe has adopted on 13 September 1989 a Resolution on this issue: [AP(89)1].

This Resolution has not the status of a national law but may be regarded as a Guidance how to establish the safety of materials for use in food contact applications in European countries having no national provisions.

Resolution [AP(89)1] is based on colorants and pigments purity criteria:

- Heavy metals limits (extractables in 0,1 N HCl)
- Amines: unsulphonated primary aromatic amines soluble in 1N HCl : max 500 ppm & sulphonated primary aromatic amines soluble in 1N HCl : max 500 ppm (expressed as aniline sulphonic acid)
- Benzidine, Beta-naphthylamine and 4-aminobiphenyl, 2-methyl-4-chloroanline single or in total max 10 ppm
- PCBs: polychlorinated biphenyls (PCB) max 25 ppm.

Besides the purity criteria requirements, additional requirements have been introduced in some national legislation:

[1] NB : Two pigments are however covered today by the plastic Regulation (EU) No 10/2011 due to historical reasons. They are :

- Titanium dioxide
- Carbon black with a nano-specification

- In France, the principle of the positive list should apply.
- In the Netherlands, the migration of the components from dyes and pigments in the coloured finished article multiplied by the applicable conversion factor shall not exceed the specified value.

Furthermore, another undesired effect is that the food contact materials transfers a colour to the food in contact.

Some national legislation, as it is the case for the Netherlands have introduced restrictions to verify the absence of this effect. For instance, the Dutch method is based on the filter paper test with 3% acetic acid or with a fatty food simulant in contact with the article for 5 hours at 40°C: plastics coloured with dyes and/or pigments shall show no difference in colour as compared with the control material.

No specific instruction is given for repeat use articles, as regards the transfer of colour migration testing, which should be compliant at the first contact.

As regards, the issue on aromatic amines expressed here above, it is recommended, in cases the colour pigments contain carcinogenic aromatic amines substances to fully risk assess these substances, in accordance with recommendations given in **chapter 4.3** of this Guidance.

In cases, the pigment is a nanoform, please refer to the considerations mentioned in **Annex 8.12**.

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Annex 8.14. List of References

Will be classified according to their order of apparition in the text

[Nr]	Reference	Authors	Year	Full title	Further details
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[2]	EFSA Journal 2016; 14(1): 4357	EFSA-Q-2011-00107	2016	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'	http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4357.pdf
[3]		EFSA	2008	Note for Guidance for food contact materials- version 30 July 2008	
[4]		Eddo J. Hoekstra	2016	JRC- Technical guidance for migration testing	Draft for consultation (2016)
[5]		FDA	April 2002 & December 2007	Guidance for industry : preparation of premarket submissions for Food contact substances: chemistry recommendations - Appendix II - point 4	http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081818.htm
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[7]	Food Additives and Contaminants (**2005**), 22(1): 73-90, DOI: 10.1002/APP.38885	T. Begley, L. Castle, A. Feigenbaum, R. Franz, K. Hinrichs, T. Lickley, P. Mercea, M. Milana, A. O'Brien, S. Rebre, R. Rijk, O. Piringer;	2005		
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[9]	ILSI Conference 2016, Barcelona	R. Brandsch	2016	to be published in Food Additives and Contaminants	
[10]	*Macromolecules*. 2013;**46**:874-88.	X. Fang, S. Domenek, V. Ducruet, M. Refregiers, O. Vitrac	2013	Diffusion of Aromatic Solutes in Aliphatic Polymers above Glass Transition Temperature.	http://pubs.acs.org/doi/abs/10.1021/ma3022103
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[13]	*Critical Reviews in Food Science and Nutrition*. 2017;**57**:275-312.	X. Fang X, O. Vitrac	2017	Predicting diffusion coefficients of chemicals in and through packaging materials.	http://www.tandfonline.com/doi/full/10.1080/10408398.2013.849654
[14]	*Journal of Polymer Science Part B: Polymer Physics*. 2014;**52**:1252-8.	A. Kadam A, T. Karbowiak, A. Voilley, J.-P. Bellat, O. Vitrac, F. Debeaufort.	2014	Sorption of n-hexane in amorphous polystyrene.	http://onlinelibrary.wiley.com/doi/10.1002/polb.23557/pdf
[15]	*Food Additives and Contaminants*. 2017;**Doi: 10.1080/19440049.2017.1315777**.	P.-M. Nguyen J.-M Julien, C. Breysse, C. Lyathaud, J. Thébault, O. Vitrac	2017	Project SafeFoodPack Design: case study on indirect migration from paper and boards.	http://www.tandfonline.com/doi/full/10.1080/19440049.2017.1315777
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[27]	Molecules, 2022, 27, 121	R. Brandsch, M. Pemberton, D ; Schuster, F. Welle	2022	Impact of partitioning in short-term food contact applications focused on polymers in support of migration modelling and exposure risk assessment	
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[31]	State of 14 March 2014	The Dutch Commodities Act Regulation on Packaging and Consumer Articles in its chapter III		Decree of 1rts October 1979 implemented by the ministerial Regulation of the 25 January 1980 and further supplements Chapter III_ rubbers	
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[41]	DG SANCO	EU - Health and consumers directorate- General (28.11.2013)	2013	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 chain	http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en