



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Leachables from food contact materials & products in contact with drinking water

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Food contact materials

- › Packagings
- › Kitchen utensils
- › Industry equipment
- › All types of materials
- › All types of substances
- › Virgin or recycled
- › Single use or reusable
- › Multilayer materials



	Packaging	Utensils	Industrial uses
Plastic	PET-bottles; trays, bags	Cup, storage container	Flexible hoses
Metals & Alloys	Cans, foil covers	Pans, foil, bottle	Cutting machines; Vessels
Glass	Jars, bottles	glasses, bowls	Control windows
Paper & board	Boxes for frozen vegetables or cereals, bags of chips	Plates, straws	
Wood / cork	Corks, crates,	Cutting boards	Cutting block, wine barrel
Coatings	Cans	Non-stick frying pans	Vessels
Rubber /silicone	Sealing rings	baby bottle spouts, ice cube trays, molds	Conveyor belt, mold
Enamel /Ceramic		Plates, mugs, tajines	Inside of oven
Colorants	Inks on packaging	Colored items	
Ion exchange resin			Filter media
Textile	Sisal bags		



Safety of Food contact materials (FCM)

- › Substances can migrate into the food > ‘shall not pose a health hazard’
 - › European regulations
 - › Additional National regulations
 - › Mutual recognition, Council of Europe
 - › BeNeLux Resolutions
 - › Mutual agreements between MS
 - › Guidances & Recommendations



European Regulation

› Framework legislation

› GMP Regulation

› Material specific legislation

- Positive lists of starting substances & restrictions
- Restrictions
- Positive list of processes (recycling of plastic)

› Substance specific legislation

- Bisphenols BPA & BPS
- N-nitrosamines and N-nitrosatables
- Epoxy derivatives
- Vinyl chloride monomers

[Legislation - European Commission](#)



European Regulation - Gaps

- › Non – Intentionally Added Substances (NIAS)
 - Responsibility of the chain of producers / packagers
- › Harmonised rules for most specific materials
- › Mixture toxicity
- › Enforcement capacity



Dutch Regulations

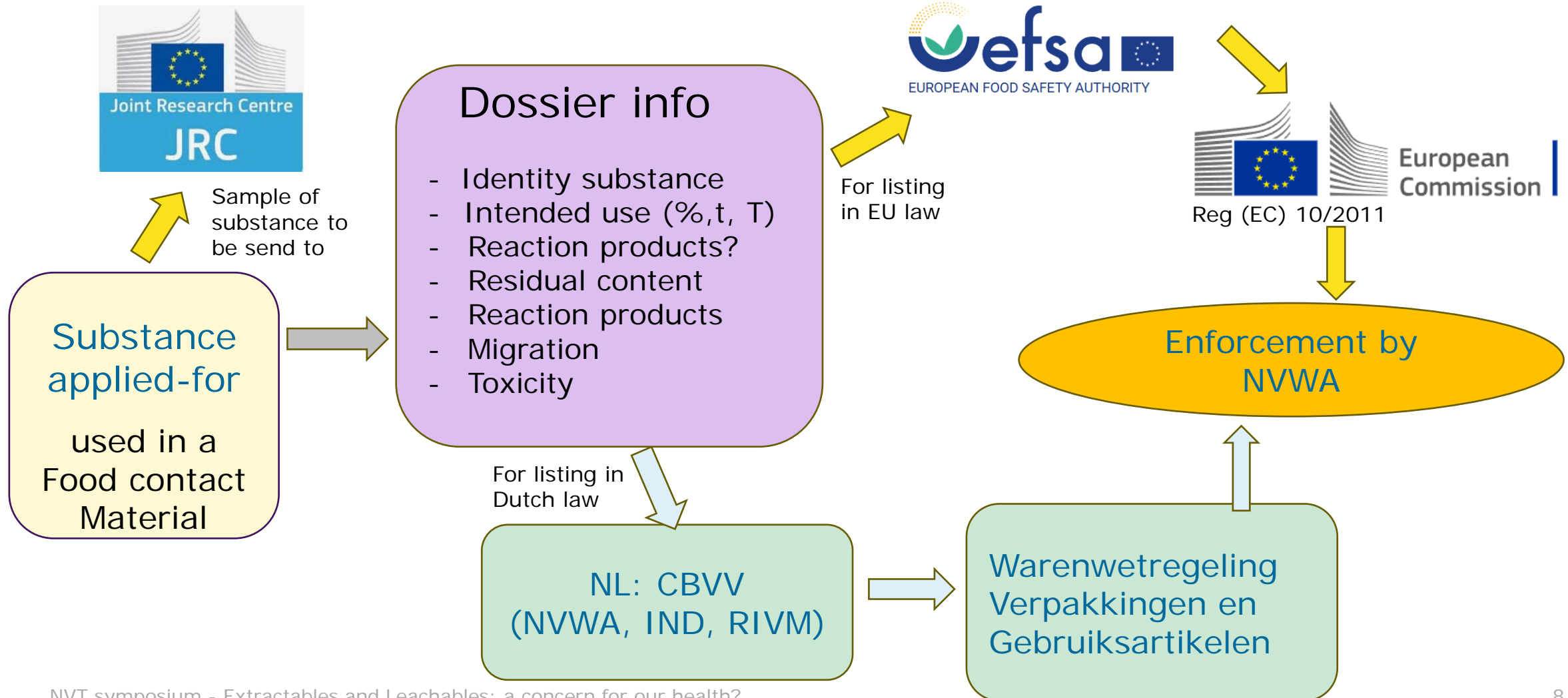
Plastics	PL (for PPA & APs) &	reference to →
Paper and board	PL	
Rubber	PL	
Metals	PL	
Glass & –ceramics	SMLs	
Ceramics and enamel	SMLs	
Textile	SMLs	
Regenerated Cellulose		reference to →
Wood and cork	PL / SMLs	
Coatings	PL	
Colorants & pigments	SMLs	
Epoxy polymers	PL	

EU Regulations

PL for monomers & additives	"shall be safe"
Nitrosamines & nitrosables	"shall be safe"
	"shall be safe"
SMLs (only Pb & Cd)	"shall be safe"
PL for monomers & additives	"shall be safe"
	"shall be safe"
	"shall be safe"
Some epoxy-derivates	



Evaluation of substances





Migration of substances

Parameters of influence:

- › Quality of product: processing conditions
- › Surface/volume ratio (6 dm² / kg food)
- › Contact time (1h, 24h, 10 days,)
- › Contact temperature (frozen to sterilizing, baking)
- › Type of food => simulants (fatty, acidic, alcoholic, dry, aqueous food)

Worst case use scenario: migration in food = applied-for SML

SML = Specific Migration limit



Toxicity data requirements: migration tiers

Migration into food	Toxicological data
<0,05 mg/kg	<ul style="list-style-type: none">- Genotoxicity<ul style="list-style-type: none">i) AMES testii) in vitro micronucleus test (MNT)
0.05 to 5 mg/kg	<ul style="list-style-type: none">- Genotoxicity (AMES & in vitro MNT)- A 90-day tox study- Absence of accumulation in man
> 5 mg/kg	<ul style="list-style-type: none">- 90-day oral toxicity study (2 tests)- ADME- Reproduction and Development- Long-term toxicity/carcinogenicity



Risk assessment (one safe use):

For all 'relevant' substances

- e.g. Antioxidant > also the degradation products

Exposure Food intake => 1 kg per person per day

For lipophilic substances => 0,2 kg fat per person per day (FRF)

Applied-for-SML x 1 kg < ADI x 60 (kg bw)?

 Substance enters positive list with SML



Issues on FCM

- › Bamboo flour - in 'ecofriendly' melamine
- › PFAS - in cooking pan & paperboard
- › Mineral oils - in Easter bunnies & dry food
- › Leaching metals - ceramics like tagines, crystal glass
- › Bisphenol A – in can coatings & baby bottles
- › benzophenones - printing inks
- › Microplastics - from e.g. friction (water bottles)
- › Misuse of utensils > plastic containers in microwave



Future challenges FCM

- › Ban on several SVHCs, PMTs, ... > Safe alternatives?
- › Mixture toxicology
- › Circular economy
 - Recycling of materials > unknown and newly reacting contaminants
- › Effects on people & planet integrated
 - Ecotoxicology (SUP, PPWR, ban on PMTs,)
 - Worker safety

Published work on the topic



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4-methylbenzophenone

Alternative food contact materials on the Dutch market after implementation of the Single Use Plastic Directive and prioritisation of potential migrating chemical substances

RIVM letter report 2022-0102
A. Zwartsen et al.

[Zwartsen et al. 2023 - Alternative food contact materials | RIVM](#)



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Inventory of reusable food contact materials on the Dutch market as alternatives to single-use plastics and an evaluation of possible safety issues

RIVM letter report 2023-0410
H. McKeon et al.

[McKeon et al. 2024 - Inventory of reusable food contact materials ... | RIVM](#)



Alternative reusable products

Identified materials:

Plastic > Stainless steel > Silicone > Glass >
Bamboo > Ceramic > Unknown > Cardboard >
Wood

Prioritisation criteria chemicals:

- > 2 database entries (FCCmigex) for reusable FCM
- Migration concentrations above SML
- (self-)classified as CMR 1 or 2, STOT-RE 1 or 2 and / or ED

Material	Chemical
Plastic (PP, PE)	Silver Dibutyl phthalate
Plastic (melamine)	Melamine Formaldehyde
Plastic (polycarbonate)	Dibutyl phthalate Bisphenol A
Plastic (polyamide)	4,4'-methylenedianiline 2,4-toluenediamine 2,6-toluenediamine 3,3'-dimethylbenzidine aniline O-anisidine O-toluidine M-phenylenediamine PA 66 & PA 6
Stainless steel	Nickel Cadmium Lead Cobalt
Silicone	Aniline Cyclic siloxanes



Drinking water contact materials

- › Water treatment
 - Water reservoirs
 - Filtermodules water treatment
- › Water distribution network
 - Pipes
 - Tubes
 - Fittings
- › Accessoires
 - Taps
 - Boilers
 - Watermeter



National system (1960 – now)

- › National Certification of DW- Product > KIWA mark
- › System copied from FCM, with differences:
 - Default 10% allocation of ADI
 - Recipes checked by 3rd party
 - Every product tested by 3rd party
 - Regular audits production locations
 - Additional requirement e.g. EMG
 - Exposure mostly known > Risk categories (conversion factors)



Evaluation of Drinking water product

By Committee of experts (CvDMD)
& Subcommittee on toxicological assessment (W4)

Application for approval of products (submitted by manufacturer)

- Formulation check of recipe (KIWA - W4)
- migration evaluation (KIWA)
 - 1st tier: modelling
 - 2nd tier: standardized migration testing
- Enhanced Microbial Growth (KIWA)
- Odour / Flavour / Taste / Turbidity (KIWA)



European system

2003 -2019 > harmonising systems of UK, FR, DE, NL (DK & PT)

- > As of 2027 for new products
- > As of 2033 for products already on the market

Organic materials > Positive lists of starting substances

Metallic materials > Positive lists of compositions

Cementitious materials > Positive lists of organic constituents

Ceramic, Enamel, other inorganic > Positive lists of compositions



EU versus NL

- › New: NIAS screening of each product!
 - GC-MS; identification by library match / Kovats index
 - Substances > 1 microg/L but unidentified or not on Pos List? > **Failure**
- › ECHA is in charge of Positive Lists
 - Expiry dates of all substances (national, EC-FCM list) > **OSOA (?!)**
- › Product certification by 3rd parties (not via CvDMC)



Issues with DWCM

- › Lead in in-house old piping systems in dezincification resistant (DZR) alloys
- › Metals leaching from taps, mainly when imported from China
- › PAHs from bitumen coated cement pipes
- › Aluminium from new cementitious pipes
- › Lead in dezincification resistant (DZR) alloys
- › Microplastics?



Thank you for your attention!

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