ILSI EUROPE

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Risks of new trends related to food contact materials

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[1]Organic Contaminants and Additives Service, Sciensano

Declaration of Interests

Affiliation / Financial interests	Organisation
Employment	Sciensano
Grants / Research support	Federal Public Service – Human Health
Scientific Advisory Board / Consultant	none
Government	Institute
Other	none

Introduction

New materials/applications are appearing on the market due to….

SUP Directive (EU) 2019/904

Royal Decree of 25/05/2024

Ban on certain single use plastic in Europe

Fevia

FEVIA (Federation of Belgian Food Industry)

-

100% of reusable, recyclable or biodegradable packaging by 2025

Introduction

What are the
potential risks
related to these new trends?

Sampling

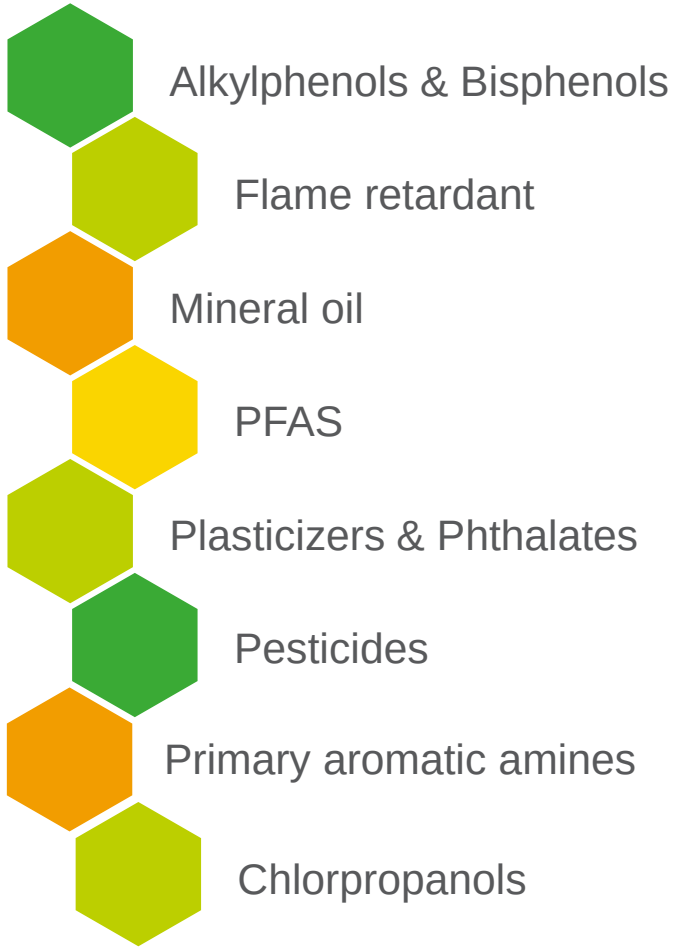


78 samples made of **paper and board**
(pizza box, hamburger box, straw, cup, bowl etc.)




99 samples made of **bagasse, palm leaves, coconut, textiles, bioplastic, recycled plastic, silicones**

Targeted substances



- Alkylphenols & Bisphenols
- Flame retardant
- Mineral oil
- PFAS
- Plasticizers & Phthalates
- Pesticides
- Primary aromatic amines
- Chlorpropanols

- Formaldehyde
- Photoinitiators
- Trace elements

513

substances

FCM legislation & resolutions

Framework Regulation
Regulation No. 1935/2004

Good Manufacturing Practice
Regulation No. 2023/2006

Specific materials

Plastics *Regulation No. 10/2011*	Recycled Plastics *Regulation No. 282/2008*
Ceramics *Directive No. 84/500/EC – RD 1/5/2006*	Regenerated cellulose *Directive 2007/42/EC – RD 23/11/2004*
Active and intelligent materials *Regulation No. 450/2009*	

Specific substances

Nitrosamines *Directive 93/11*	BADGE/NOGE/BDFGE *Regulation 1895/2005*
Bisphenol A *Regulation 2018/213*	

Coatings *RD 25/9/2016*	Metals and alloys *RD 17/2/2021*
Bisphenol A (0-3 years) *RD 17/2/2021*	
DoC, glass, paper and board *RD 11/5/1992*	

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Coatings	Silicone	Printing ink
Rubber	Ion exchange resin	
Paper and board	Metals and alloys	
Resolutions & Technical documents		

→ National recommandations

Targeted populations

Children
(3-10 years old, 23 kg)

Teenagers
(14-18 years old, 61 kg)

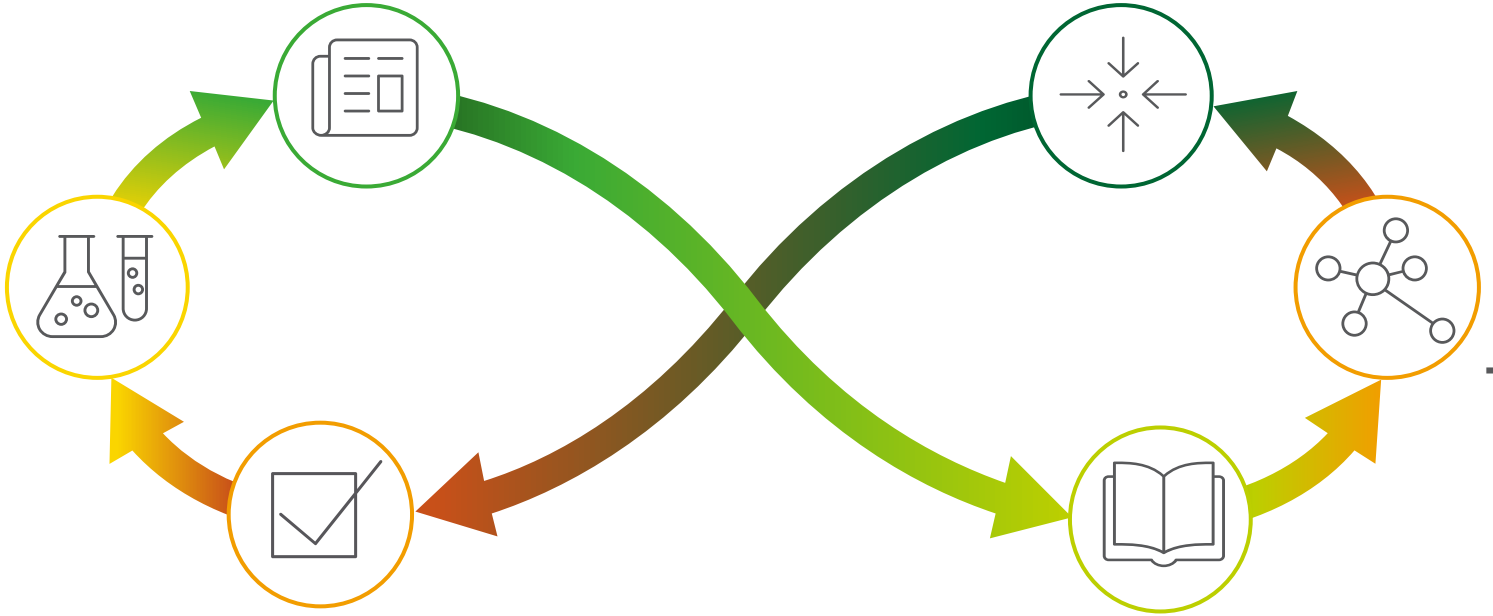
Adults
(18-64 years old, 70 kg)

Workflow of the risk assessment

Determination of the hypotheses of consumption per population category

If no reference point was available:
➔ TTC was used

Determination of the amount of substance that could potentially migrate from the FCM



If no toxicological information available :
➔ Reference point (NOAEL, BMDL)

Combinaison of:
- Quantity of substance
- Weight of the population
- Hypothesis of consumption

➔ **Exposure in mg/kg bw/day**

➔ **Evaluation according to the RACE tool**

Literature search of toxicological information (e.g., TDI)

Risk assessment of the quantified migrants

RACE tool

Rapid Assessment of Contaminant Exposure tool developed by EFSA for FAST risk evaluation of food contaminants, including FCM substances

TECHNICAL REPORT

efsa European Food Safety Authority Supporting Publications

APPROVED:16 April 2019

doi:10.2903/sp.efsa.2019.EN-1625

Risk evaluation of chemical contaminants in food in the context of RASFF notifications:

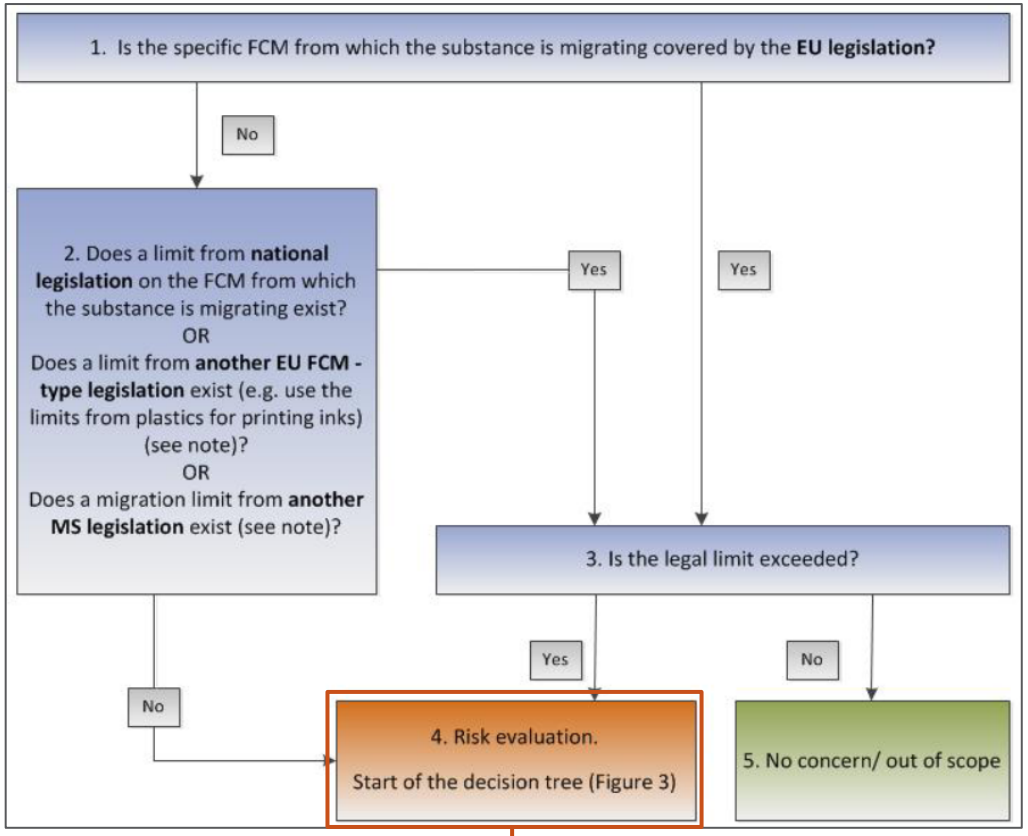
Rapid Assessment of Contaminant Exposure tool (RACE)

European Food Safety Authority (EFSA), Peter Fürst, Maria Rosaria Milana, Karla Pfaff, Christina Tlustos, Christiane Vleminckx, Davide Arcella, Eric Barthélémy, Paolo Colombo, Tilemachos Goumperis, Luca Pasinato, Ruth Roldán Torres and Ana Afonso

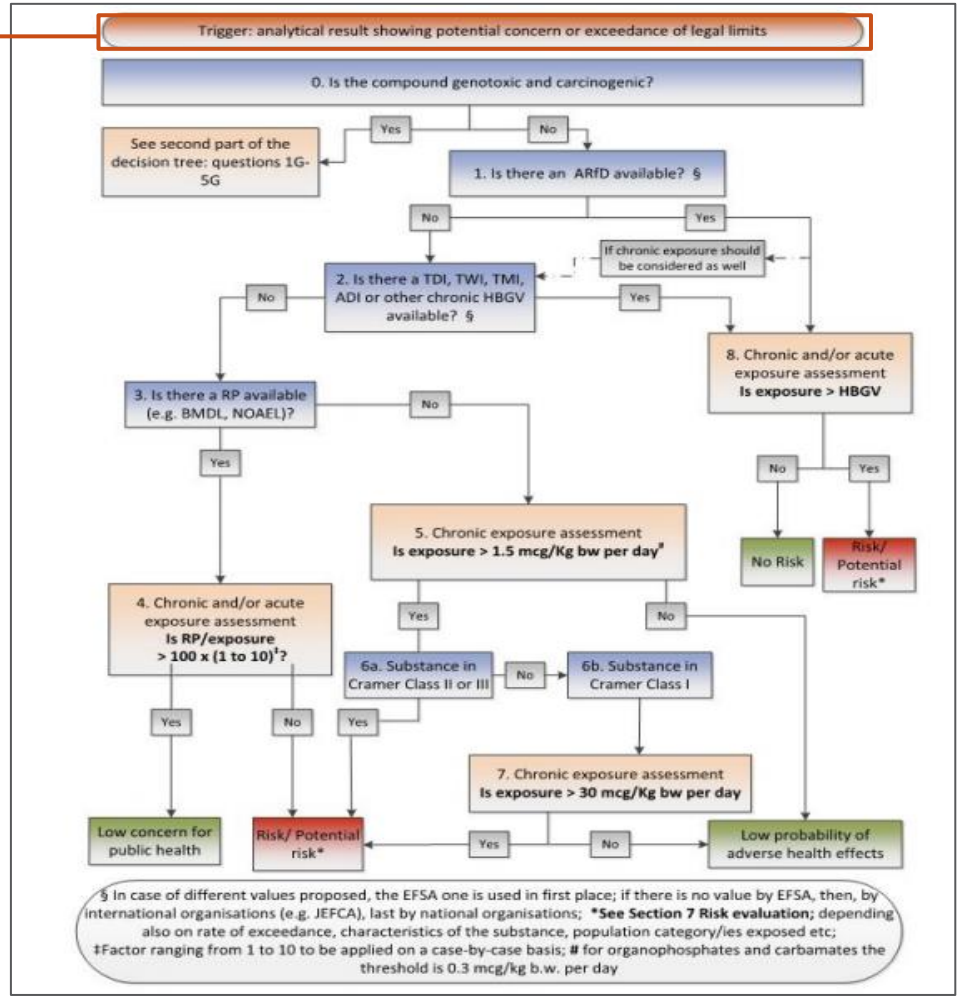
EFSA suporting publication (10.2903/sp.efsa.2019.EN-1625)

EFSA RACE tool

Pre-decision tree for food contact materials



Decision tree for food contact materials



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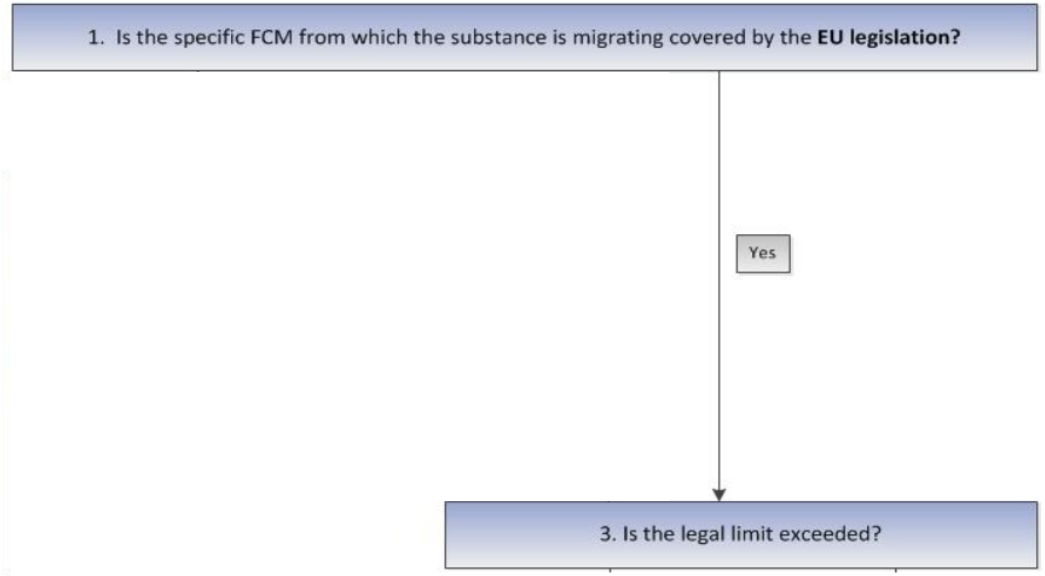
EFSA RACE tool

Pre-decision tree for food contact materials



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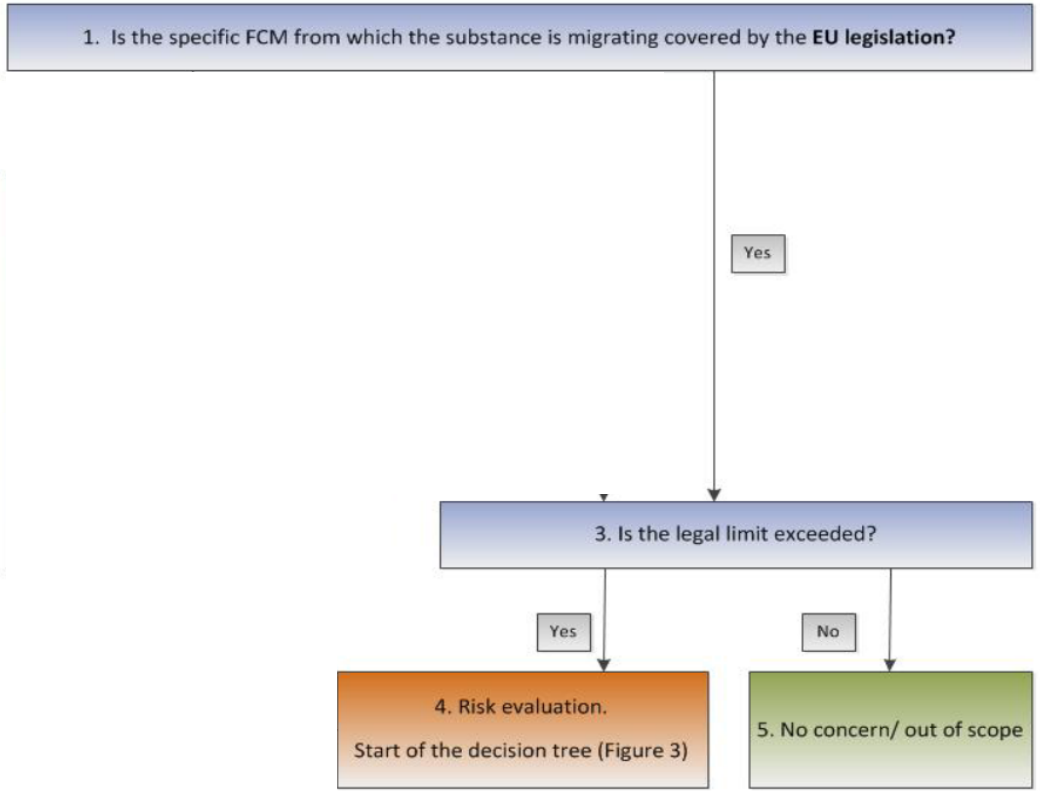
Pre-decision tree for food contact materials



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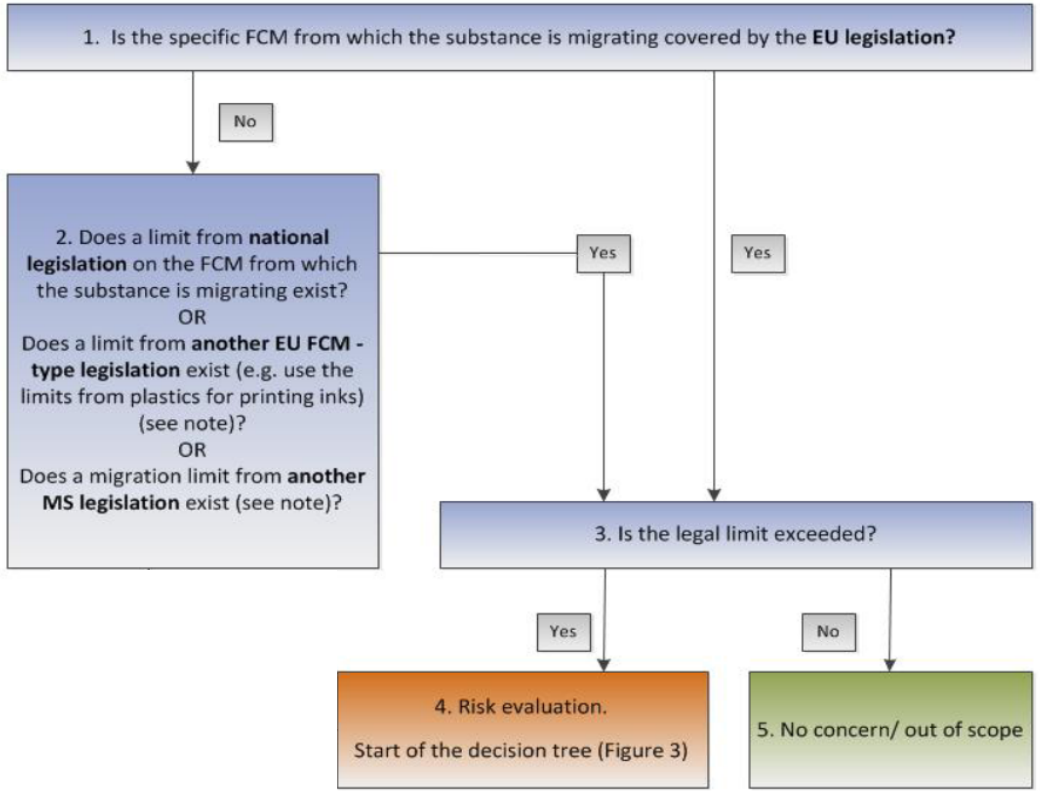
EFSA RACE tool

Pre-decision tree for food contact materials



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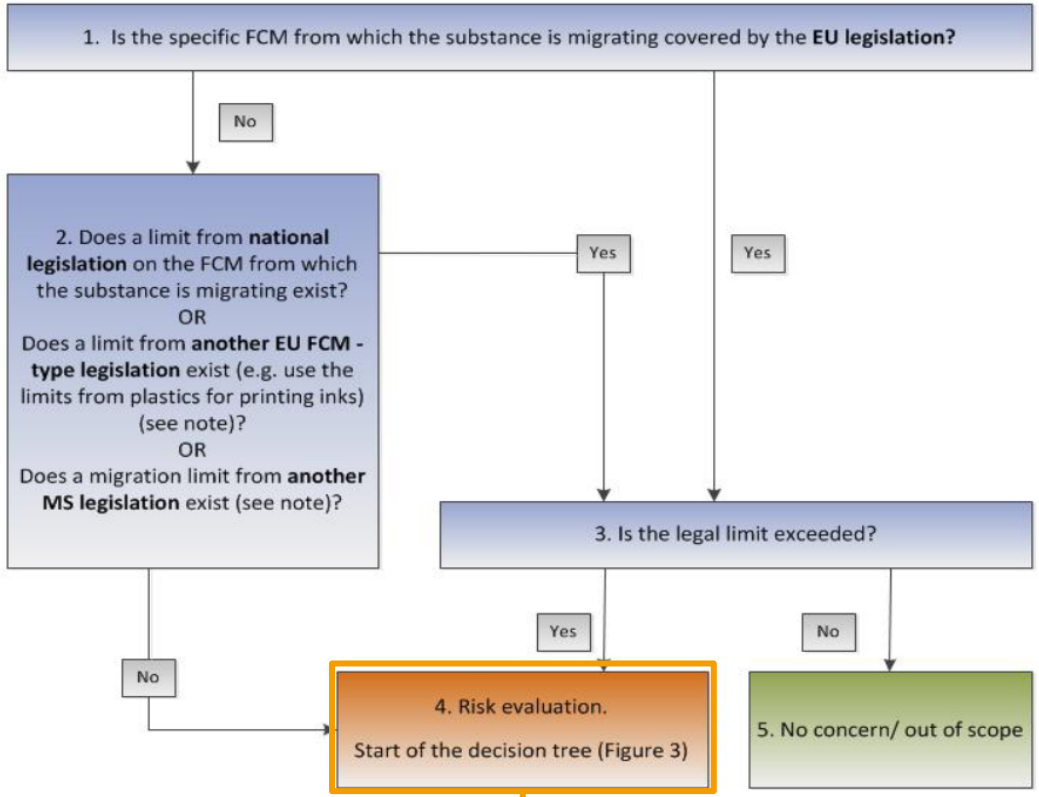
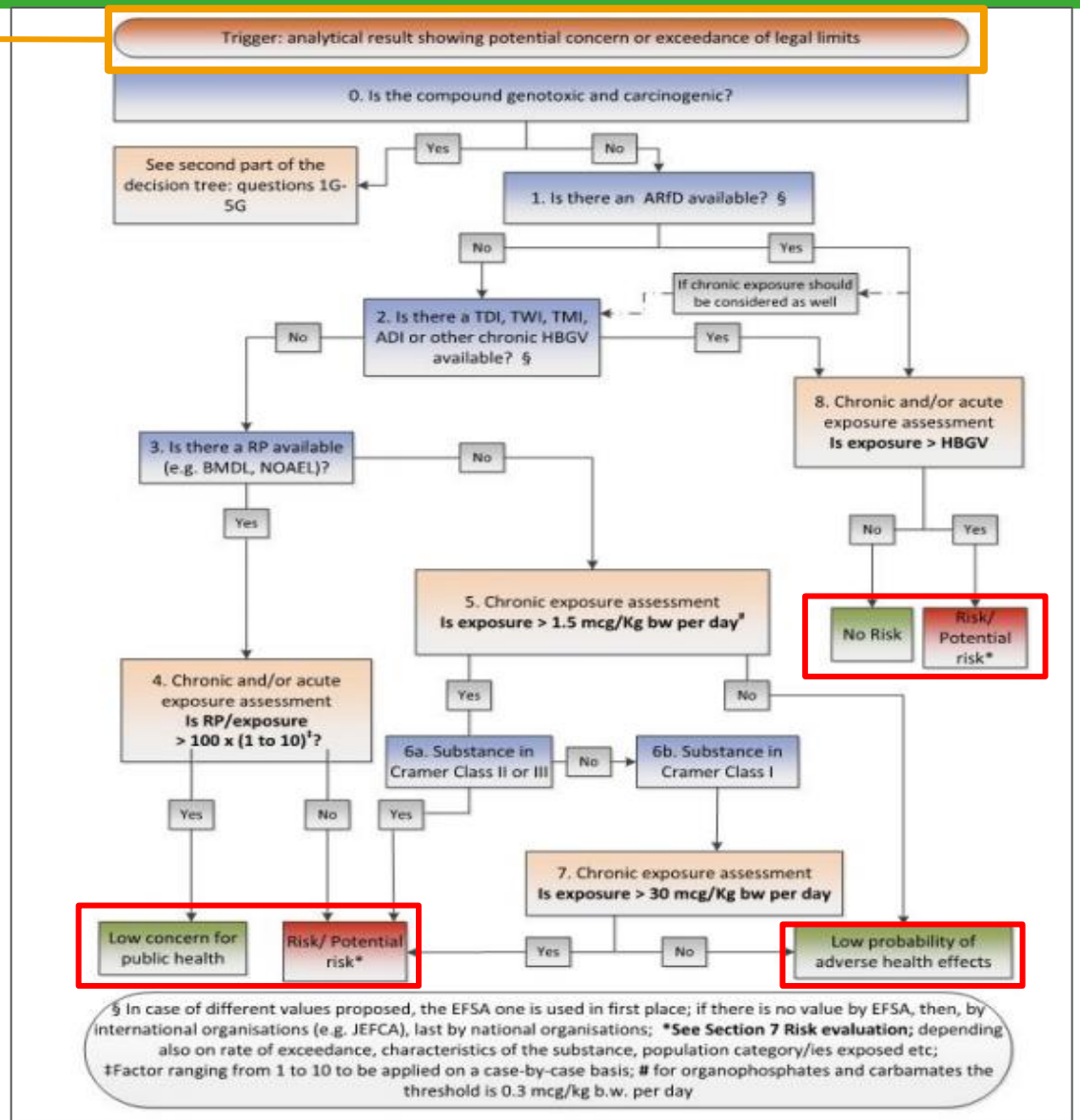
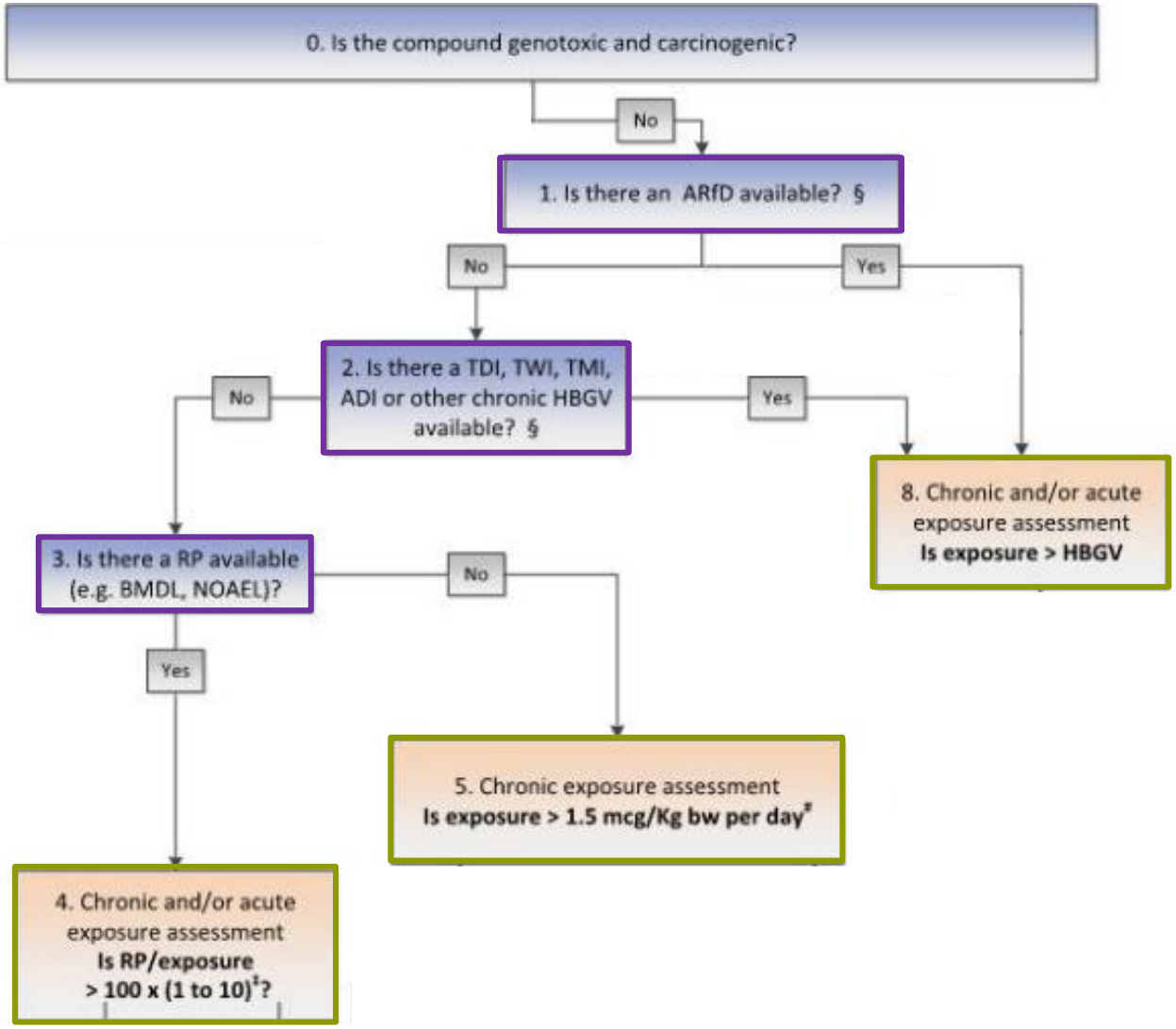
Pre-decision tree for food contact materials





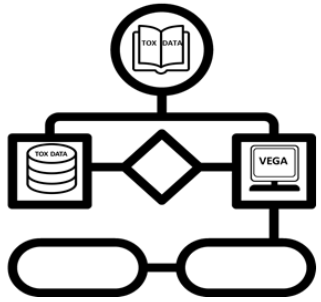
EFSA supporting publication (10.2903/sp.efsa.2019.EN-1625)

Application of the EFSA RACE tool



Next steps:

Collection of/Search for a reference value using the SILIFOOD tool



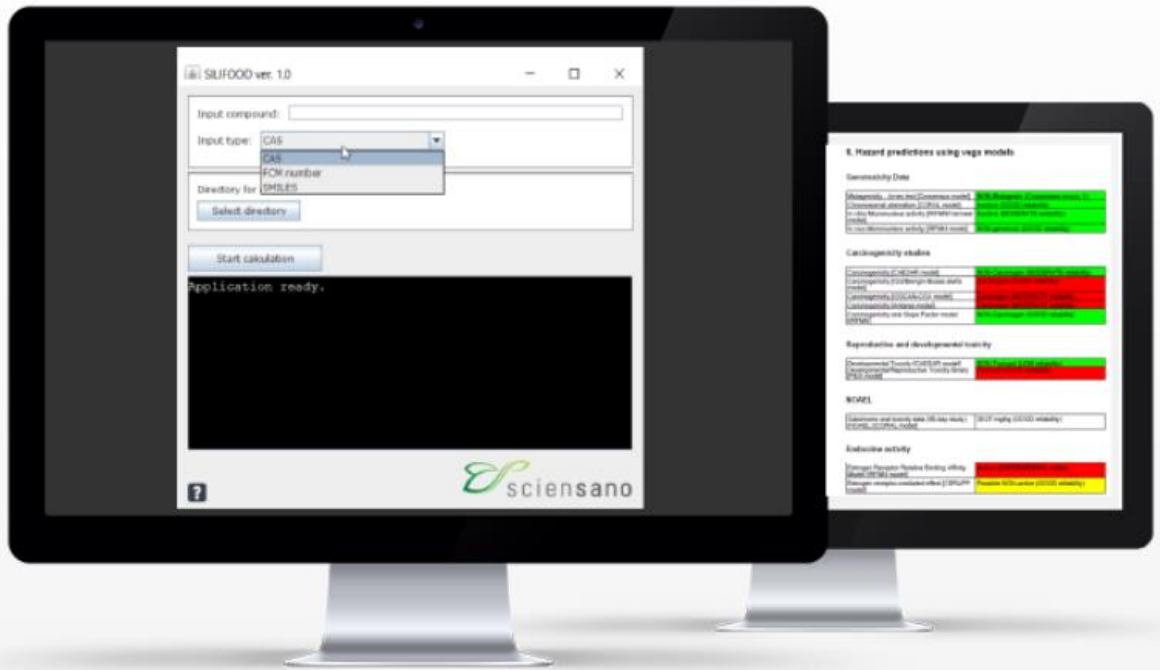
https://www.vegahub.eu/portfolio-item/silifood/

Comparison with the exposure

SILIFOOD Tool

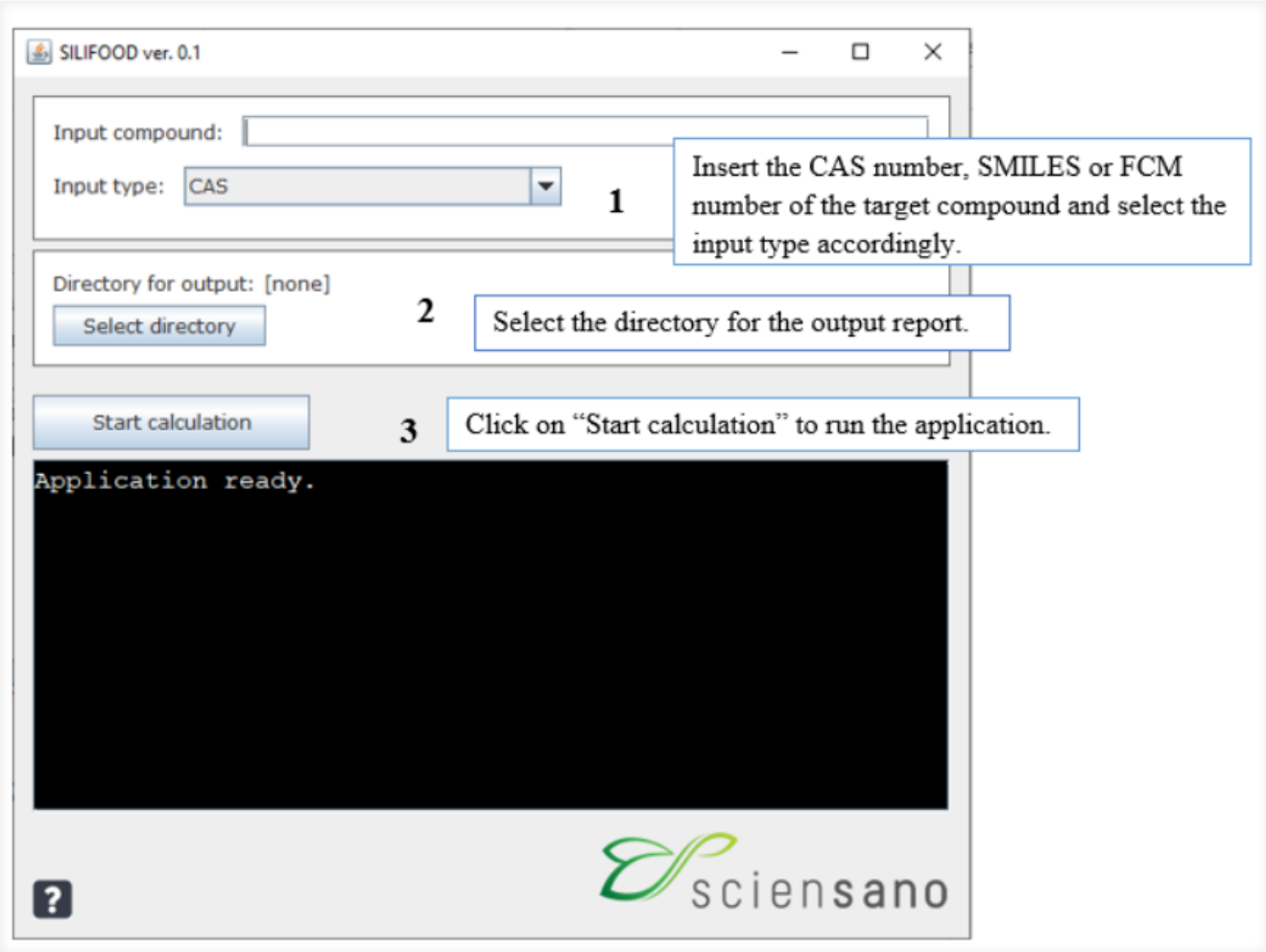
SILIFOOD

SILIFOOD was developed to support a fast risk assessment of non-evaluated Food Contact Material (FCM) substances.



Freely available at: https://www.vegahub.eu/portfolio-item/silifood/

SILIFOOD Tool



Use of the application

The application can be run in just three steps:

1. Insert the 'Input compound' (chemical identifier) and select the 'Input type': The input type can be the CAS number, the SMILES or the FCM number of the target compound.
2. Select the directory for the output on your computer by clicking on 'Select directory': The pdf report generated by the tool will appear in the selected folder.
3. Click on 'Start calculation' to run the workflow, and the report will be generated.

The application will collect information from existing databases and lists and provide VEGA predictions for toxicological endpoints relevant for FCM substances.

SILIFOOD Tool

	Evaluation status for use in FCM	Legal limit (SML) - Restrictions & specifications	Health based guidance value (e.g. TDI/ADI)	CMR information	ED information
In house FCM database	X	X	X	X	
EFSA OpenFoodTox database	X	X	X	X	X
CoRAP list (ECHA database)	X			X	X
Biocidal active substance list (ECHA database)	X				
CLP regulation Annex 6				X	X
SVHC list				X	X
SIN list				X	X
ED lists					X

ADI: Acceptable Daily Intake, **CLP**: Classification, Labelling and Packaging, **CMR**: Carcinogenic, Mutagenic, toxic for Reproduction, **CoRAP**: Community Rolling Action Plan, **ED**: Endocrine Disrupting/ Endocrine Disruptor, **SML**: Specific Migration Limit, **SIN**: Substitute It Now!, **SVHC**: Substances of Very High Concern, **TDI**: Tolerable Daily Intake

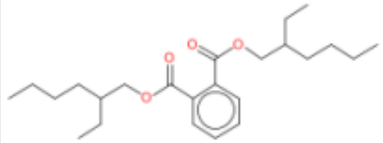
Information sources and type of data

The lists and databases that are searched by the SILIFOOD tool comprise the Sciensano in-house FCM database, the Open Food Tox database (EFSA), the Community Rolling Action Plan (CoRAP) list and the biocidal active substance list (ECHA), Annex 6 of the CLP regulation, the Substances of Very High Concern (SVHC) list, Substitute It Now! (SIN) list and the Endocrine Disruptor (ED) lists.

The type of information retrieved varies by source and comprises regulatory information (Specific Migration Limit (SML), restrictions of use), health based guidance values (Tolerable Daily Intake (TDI)/ Acceptable Daily Intake (ADI)) as well as Carcinogenic, Mutagenic or toxic for Reproduction (CMR) properties and Endocrine Disrupting (ED) activity for the substance.

SILIFOOD Tool

1. Identification of the substance

Molecular Structure	
Substance name	Phthalic acid, bis(2-ethylhexyl) ester (DEHP) (A) Bis(2-ethylhexyl) phthalate (DEHP) (H) bis(2-ethylhexyl) phthalate; di-(2-ethylhexyl) phthalate; DEHP (E) DEHP; Bis(2-ethylhexyl) phthalate (G) Bis (2-ethylhexyl)phthalate (DEHP) (F) Bis(2-ethylhexyl)phthalate (B)
Synonyms	Synonyms not found in data source(s)
CAS number	117-81-7 (A, B, E, F, G, H)
EC List number	204-211-0 (A, E, F, G, H)
Molecular formula	C24H38O4 (A)
Original SMILES	CCCCC(CC)COC(=O)C1=CC=CC=C1C(=O)OCC(CC)CCCC (A, B) CCCCC(CC)COC(=O)c1c(cccc1)C(=O)OCC(CC)CCCC (H) CCCCC(CC)COC(=O)c1ccccc1C(=O)OCC(CC)CCCC (E, F, G)
VEGA SMILES	O=C(OCC(CC)CCCC)c1ccccc1(C(=O)OCC(CC)CCCC) (A, B, E, F, H) CCCCC(CC)COC(=O)c1ccccc1C(=O)OCC(C

2. Information from Food Contact Material Database

(Last review: 17/10/2023)

Results for compound Phthalic acid, bis(2-ethylhexyl) ester (DEHP)

- EU Regulation 10/2011 Annex I

FCM No. : Phthalic acid, bis(2-ethylhexyl) ester (DEHP)
FRF applicable : no
SML [mg/Kg] : 0.6
SML(T) [mg/Kg] : 60 0,6
Group for which SML(T) applies : expressed as the sum of Acetylated mono- and diglycerides of fatty acids, Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C12-C22 fatty acids, Polyesters of 1,2-propanediol and/or 1,3-and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C12-C18 or n-octanol and/or n-decanol, Tri-n-butyl acetyl citrate, Citric acid, triethyl ester, Phthalic acid, dibutyl ester(DBP), Phthalic acid, benzyl butyl ester (BBP), Adipic acid, bis(2-ethylhexyl) ester, Sebacic acid, dibutyl ester, Phthalic acid, bis(2-ethylhexyl) ester (DEHP), Soybean oil, epoxidized, Glycerol monolaurate diacetate, Phthalic acid, diesters with primary saturated C8-C10 branched alcohols, more than 60% C9(DINP), Phthalic acid, diesters with primary, saturatedC9-C11 alcohols more than 90 % C10, 1,2-Cyclohexanedicarboxylic acid, diisononyl ester, Glycerides, castor oil mono-, hydrogenated, acetates, Polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol, Terephthalic acid, bis(2-ethylhexyl) ester, Neopentyl glycol, mixed diesters with benzoic acid and 2-ethylhexanoic acid, Trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethyl hexanoic acid, tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate,
Restrictions : Only to be used as:(a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0.1% in the final product

- Synoptic Document 2005

Restrictions : -
SCF List : 2 - Substances for which a TDI or a t-TDI has been established by this Committee
EFSA/SCF Opinion : Under re-evaluation ---------- TDI: 0.05 mg/kg b.w. (see the individual report, CS/PM/2161 FINAL).

- Swiss Ordinance Annex 10 (previously Annex 6)

Evaluation : Part A - Evaluated substances
SML [mg/Kg] : 1.5
Notice : -
CMR (preposition amendment) : -

- ESCO Reports

The compound is present in the following ESCO reports:

1) Paper & Board (ESCO Reports)

1 entry found
SCF List : -
MS : NL
Safety Evaluation MS : B - Substances used for the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork and evaluated at national level before the publication of SCF Guidelines for Food Contact

6. Hazard predictions using vega models

Genotoxicity Data

Mutagenicity - Ames test [Consensus model]	**NON-Mutagenic (Consensus score: 1)**
Chromosomal aberration [CORAL model]	Inactive (GOOD reliability)
In vitro Micronucleus activity [IRFMN/Vermeer model]	**Inactive (EXPERIMENTAL value)**
In vivo Micronucleus activity [IRFMN model]	NON-genotoxic (GOOD reliability)

Carcinogenicity studies

Carcinogenicity [CAESAR model]	**Carcinogen (EXPERIMENTAL value)**
Carcinogenicity [ISS/Benigni-Bossa alerts model]	**Carcinogen (EXPERIMENTAL value)**
Carcinogenicity [ISSCAN-CGX model]	**Carcinogen (EXPERIMENTAL value)**
Carcinogenicity [Antares model]	**Carcinogen (EXPERIMENTAL value)**
Carcinogenicity oral Slope Factor model [IRFMN]	**Carcinogen (EXPERIMENTAL value)**

Reproductive and developmental toxicity

Developmental Toxicity [CAESAR model]	NON-Toxicant (LOW reliability)
Developmental/Reproductive Toxicity library [P&G model]	**Reproductive and developmental toxicant (EXPERIMENTAL value)**

NOAEL

Subchronic oral toxicity data (90-day study) (NOAEL) [CORAL model]	57.67 mg/kg (MODERATE reliability)

Endocrine activity

Estrogen Receptor Relative Binding Affinity Model [IRFMN model]	**Active (EXPERIMENTAL value)**
Estrogen receptor-mediated effect [CERAPP model]	**NON-active (EXPERIMENTAL value)**

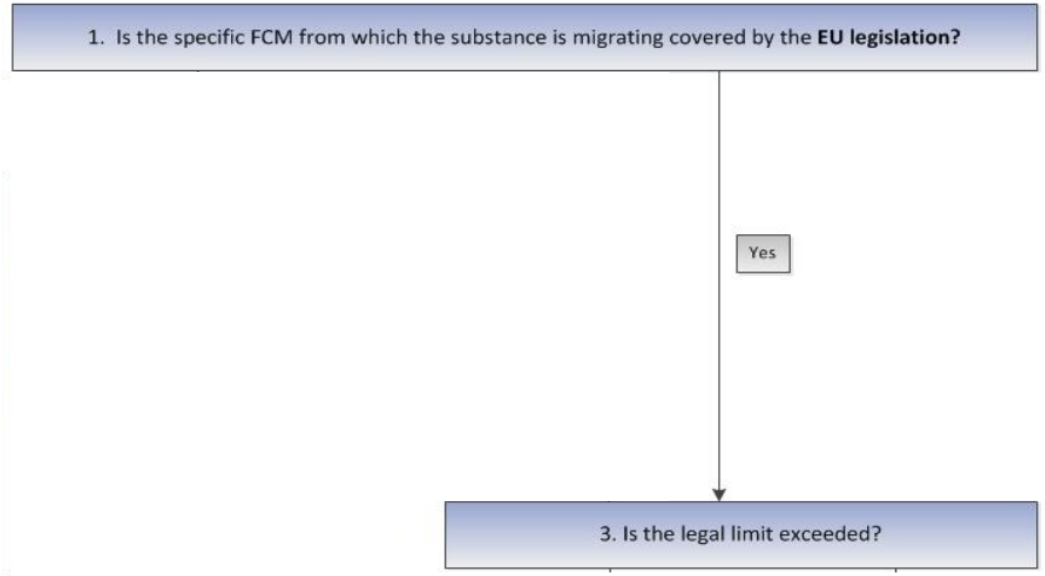
MIGRACARTO project

78 samples made of **paper and board**
(pizza box, hamburger box, straw, cup, bowl etc.)

What are the **potential risks** ?

EFSA RACE tool

Pre-decision tree for food contact materials



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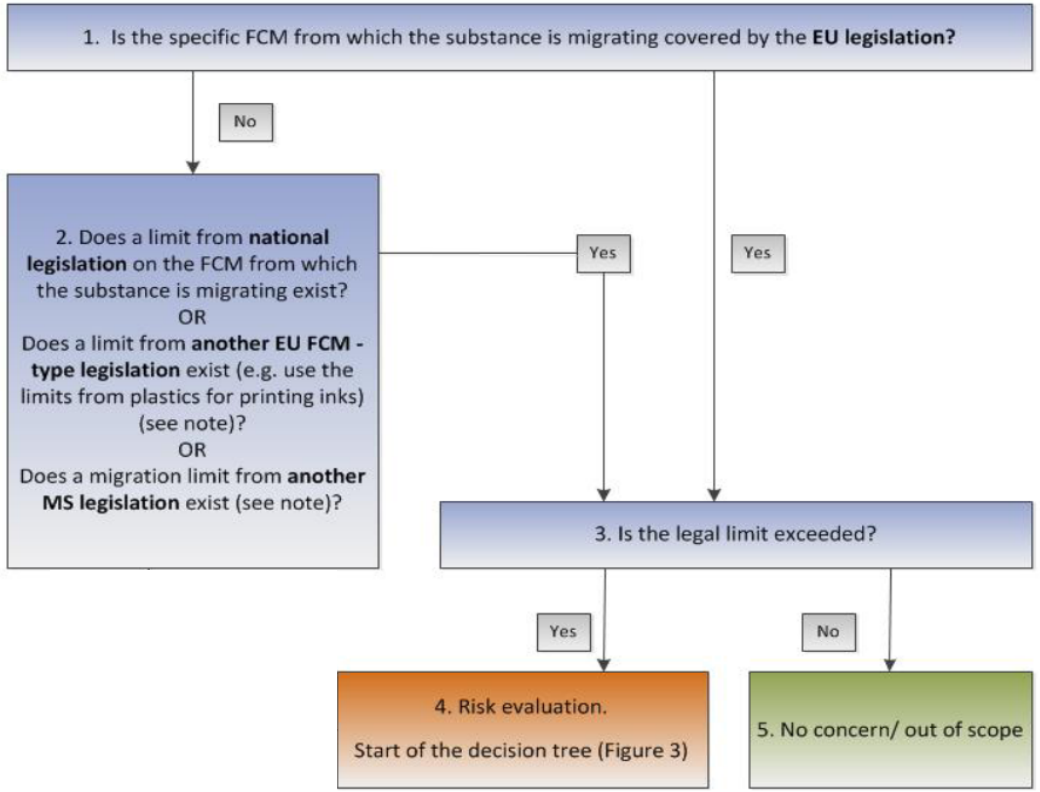

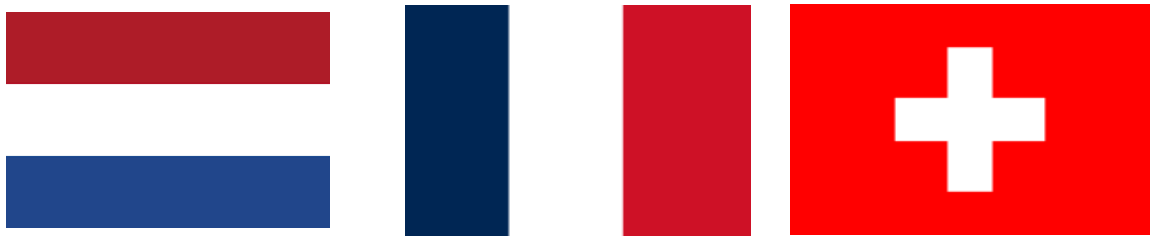

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Primary aromatic amines

3,3-DMB	SML (mg/kg)	Non compliant
CoE	ND (0.002)	3/78
France	ND (0.002)	3/78
Germany	ND (0.002)	3/78
The Netherlands	0.02	0/78
Swiss Ordinance	0.01	0/78
EU Reg 10/2011	ND (0.002)	3/78

3,3-DMB

Pizza box

Children	Potential risk
Teenagers	Potential risk
Adults	No risk

TTC: 0.0025 µg kg^{-1} bw day

Mineral oil - MOSH

100% of samples contained MOSH !

SciCom

COMITÉ SCIENTIFIQUE
de l'Agence fédérale pour
la Sécurité de la Chaîne alimentaire

	MOSH	
	SML (mg/kg)	Non compliant
Scicom – Composite food	10	3/59

Straw

Children	Potential risk
Teenagers	Potential risk
Adults	Potential risk

NOAEL : 236 mg kg^{-1} bw day

Mineral oil – MOAH

89% of samples contained MOAH !

SciCom

COMITÉ SCIENTIFIQUE
de l'Agence fédérale pour
la Sécurité de la Chaîne alimentaire

	MOAH	
	SML (mg/kg)	**Non compliant**
Scicom – Dry food <4% fat	0,5	11/59
Scicom – Food > 4% fat	1,0	2/59
Scicom – Fat or oils	2,0	NA

01 **Scenario 1:** 10% of the amount found is carcinogenic/genotoxic

02 **Scenario 2:** 1% of the amount found is carcinogenic/genotoxic

Risk assessment : MOAH

Scenario 1 : 10%

13/59 samples at potential risk

Boxes

Straws

Cups

Fries and snack trays

	Boxes	Straws	Cups	Fries and snack trays
Children	Potential risk	Potential risk	Potential risk	Potential risk
Teenagers	Potential risk	Potential risk	Potential risk	Potential risk
Adults	Potential risk	Low concern	Potential risk	Potential risk

BMDL10 : 0.49 mg kg^{-1} bw day

Risk assessment : MOAH

Scenario 2 : 1%

2/59
samples at potential risk

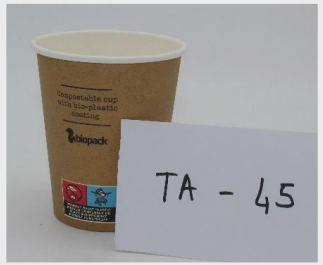
Coffee cup

Straw

	Coffee cup	Straw
Children	Potential risk	Potential risk
Teenagers	Potential risk	Potential risk
Adults	Potential risk	Potential risk

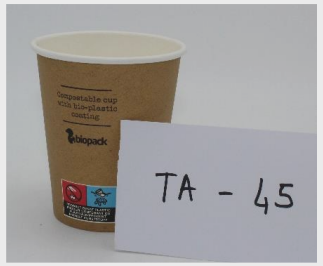
Risk assessment : PFAS

Scenario 1 :
Σ EFSA-PFAS



Scenario 1

Scenario 2



Scenario 2

Scenario 2 :
Σ all detected PFAS

	Scenario 1	Scenario 2	Scenario 2
Children	NA	Potential risk	NA
Teenagers	Potential risk	No risk	Potential risk
Adults	Potential risk	No risk	Potential risk

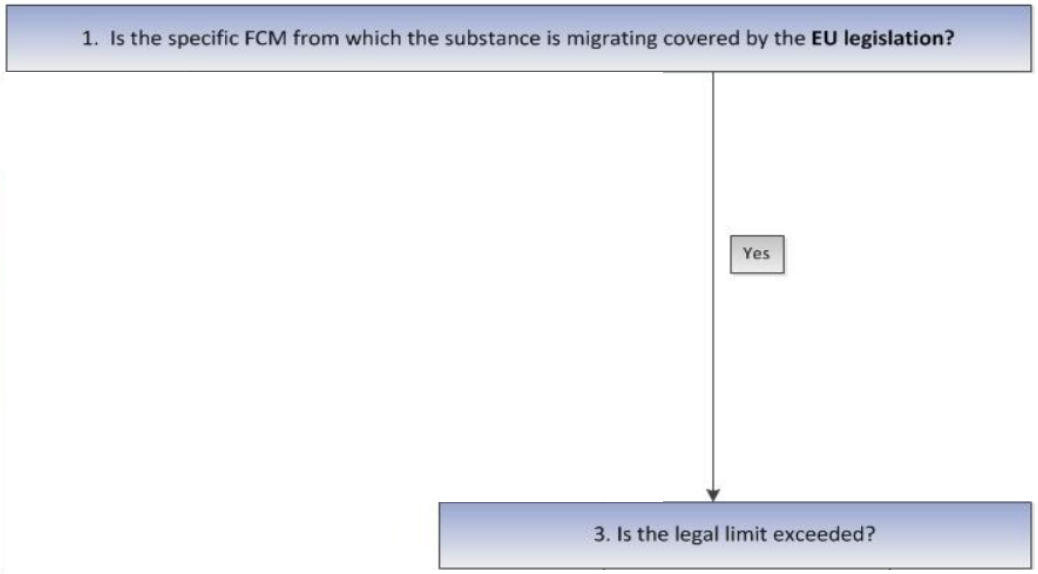
TREFCOM project



99 samples made of **bagasse, palm leaves, coconut, textiles, bioplastic, recycled plastic, silicones**


What are the **potential risks** ?

Is the substance covered by EU legislation?



COMMISSION REGULATION (EU) No 10/2011
of 14 January 2011
on plastic materials and articles intended to come into contact with food

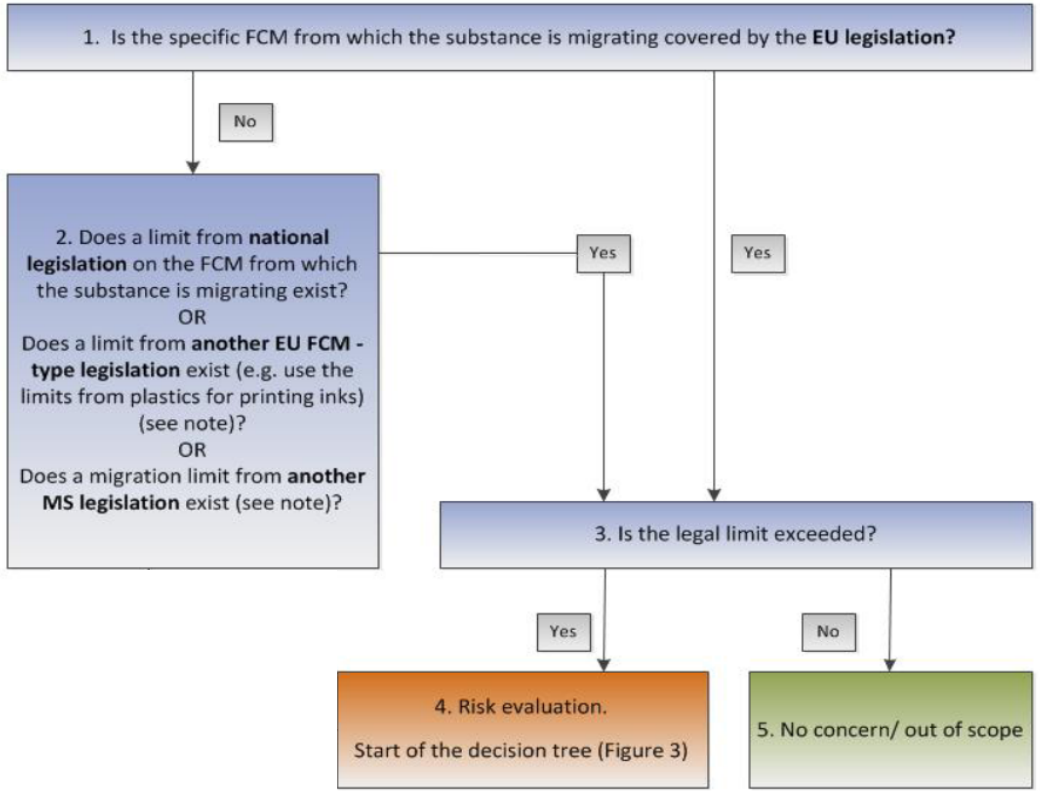
100%

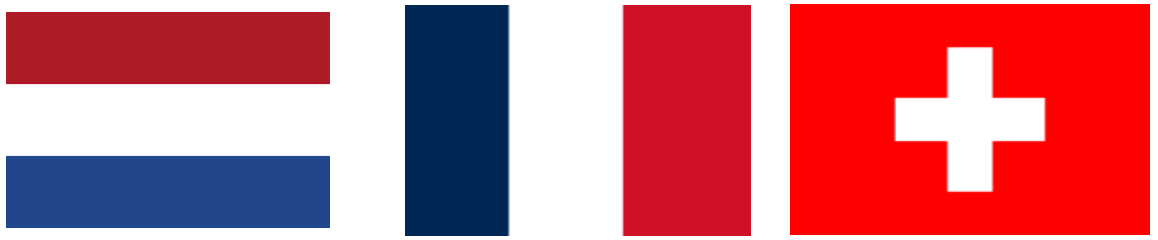
of the samples are compliant

Examples:

EFSA RACE tool

Pre-decision tree for food contact materials





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EFSA supporting publication (10.2903/sp.efsa.2019.EN-1625)

Risk assessment : PFAS

Scenario 1 :
Σ EFSA-PFAS

Scenario 1

Scenario 2

Scenario 2 :
Σ all detected PFAS

	Scenario 1	Scenario 2
Children	Potential risk	Potential risk
Teenagers	Potential risk	Potential risk
Adults	Potential risk	Potential risk

Risk assessment : MOSH

Bowls

Straws

Cutlery

Skewers

	Bowls	Straws	Cutlery	Skewers
Children	Potential risk	Potential risk	Potential risk	Potential risk
Teenagers	Potential risk	Potential risk	Potential risk	Low concern
Adults	Potential risk	Potential risk	Potential risk	Low concern

NOAEL : 236 mg kg^{-1} bw day

Risk assessment : MOAH

Scenario 1: 1% >3-ring MOAH

Plate

Straws

Cutlery

	Plate	Straws	Cutlery
Children	Potential risk	Potential risk	Potential risk
Teenagers	Low concern	Potential risk	Low concern
Adults	Low concern	Potential risk	Low concern

BMDL10 : 0.49 mg kg^{-1} bw day

Scenario 2: 10% >3-ring MOAH

Plate

Straws

Cutlery

	Plate	Straws	Cutlery
Children	Potential risk	Potential risk	Potential risk
Teenagers	Potential risk	Potential risk	Potential risk
Adults	Potential risk	Potential risk	Potential risk

BMDL10 : 0.49 mg kg^{-1} bw day

Conclusion

1. 177 samples were analyses
2. The EFSA RACE tool was successfully applied with the help of the SILIFOOD Tool
3. Several samples were at potential risk for the consumers
4. A more refine exposure scenario is needed
5. Need for hypotheses of consumption linked to FCM
   Need for EU legislation for new materials