

# Investigation of potential migratables from paper and board food contact materials intended for takeaway

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# Introduction

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



“

SUP Directive (EU)  
2019/904

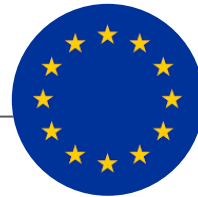
”



“

Royal Decree  
of  
25/05/2024

”



“

Ban on certain single  
use plastic in Europe

”



“

FEVIA (Federation of  
Belgian Food Industry)

100% of reusable,  
recyclable or  
biodegradable  
packaging by 2025

”

# Market study



## WEB SCRAPING

59 Websites consulted



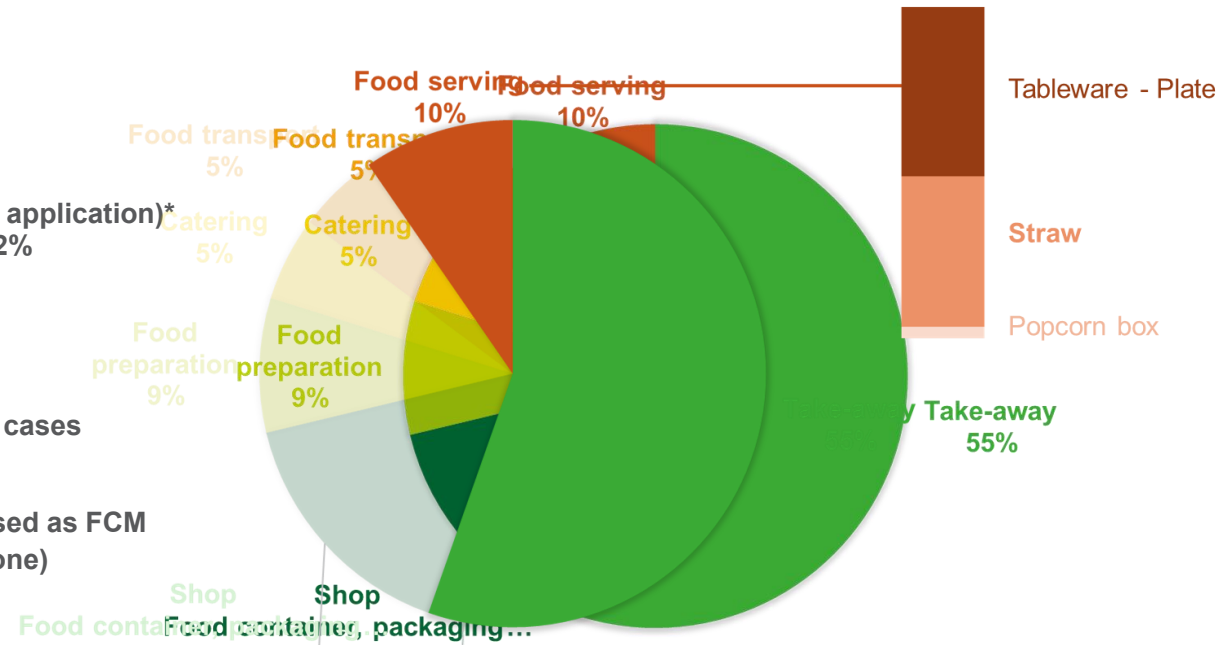
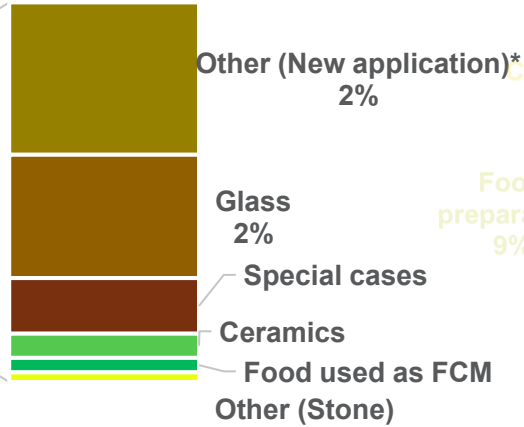
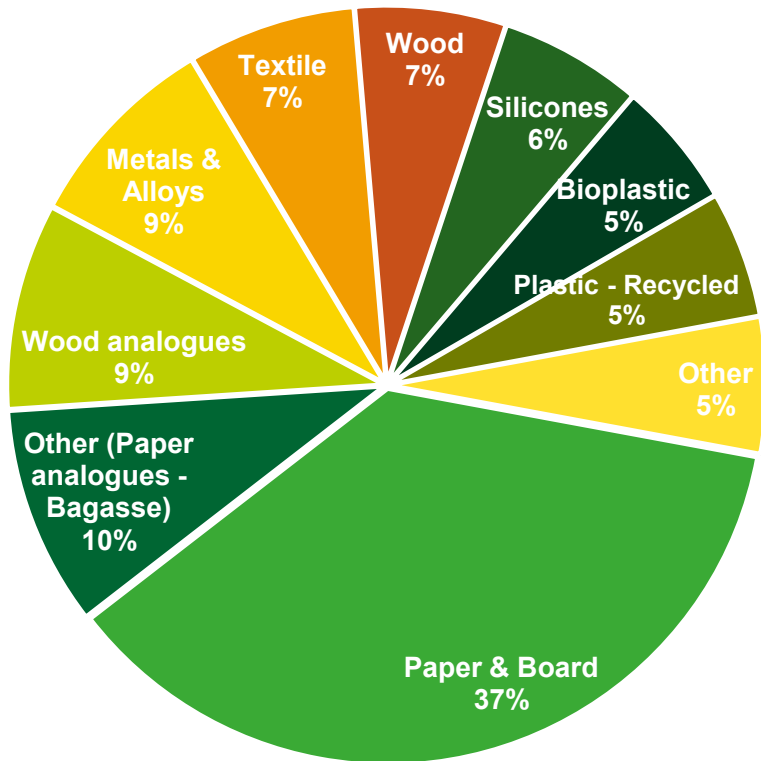
## KEY WORDS

Green, Sustainable, eco friendly,  
green, recycled, compostable,  
natural, zero waste, reusable etc...

## DATA CLEANING & HARMONIZATION



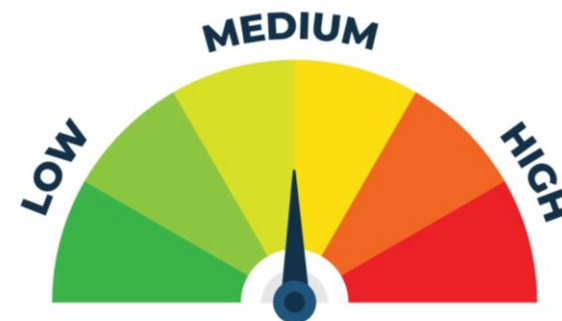
## Market study



# Introduction



What are the  
**potential risks**  
related to these FCM?





# Sampling



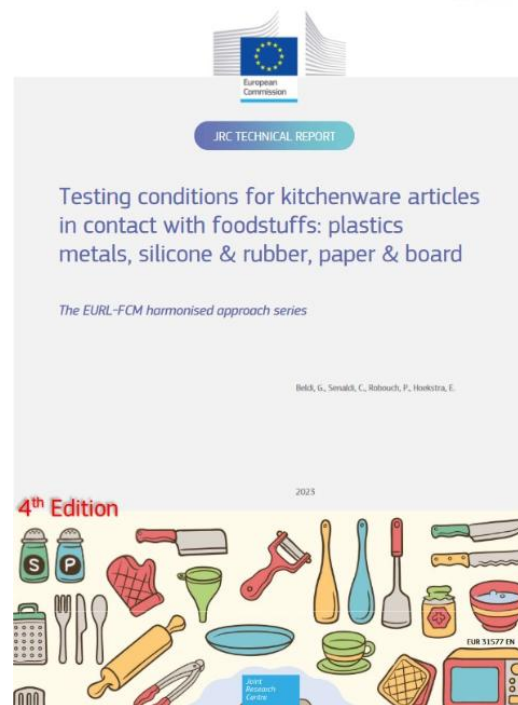
# Identification of potential migrants

## Analytical strategy



## Migration experiments

According to the EURL kitchenware guidelines



**Table 5A** presents the relevant test conditions for migration from coated/treated paper and board articles. If the paper and board item includes a barrier layer against fat/grease/water (e.g. a plastic layer) and does not absorb moist and/or oil, and if no loss of physical structure occurs, the test conditions prescribed by Regulation (EU) No 10/2011 for plastic can be applied. When the structural integrity of the paper regarding to the testing conditions prescribed for plastics is unknown, migration conditions as set in Table 5A should be followed in first instance. However, when an alteration of the material is evidenced after the contact phase, the testing conditions of Table 5B should be applied. A case-by-case analysis is necessary.

**Table 5B** presents "extraction" conditions for coated, uncoated and treated/impregnated paper and board articles that do not withstand migration test conditions and food simulants prescribed by Regulation (EU) No 10/2011 and that lose their physical structure. These methods are selected taking into account the currently available CEN standards and the practical guideline for manufacturers and regulators on "*Paper and Board used in food contact materials and articles*" published by the Council of Europe.

# How were analysed the samples ?



JRC TECHNICAL REPORT

Testing conditions for kitchenware articles  
in contact with foodstuffs: plastics  
metals, silicone & rubber, paper & board

The EURL-FCM harmonised approach series

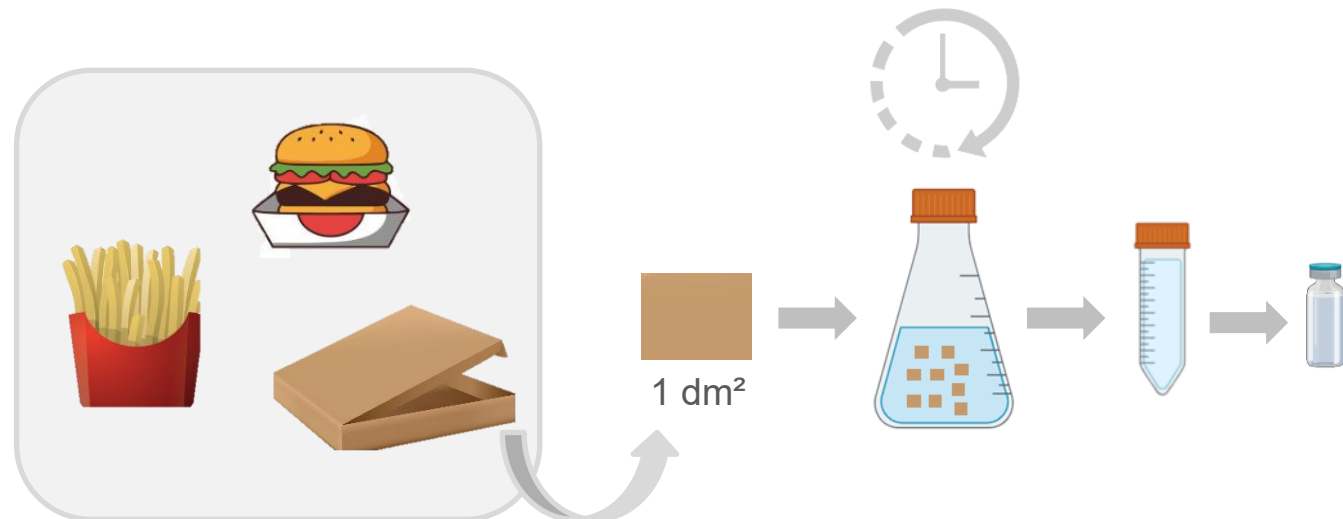
Beldk, G., Senadik, C., Robouch, P., Hoekstra, E.

2023

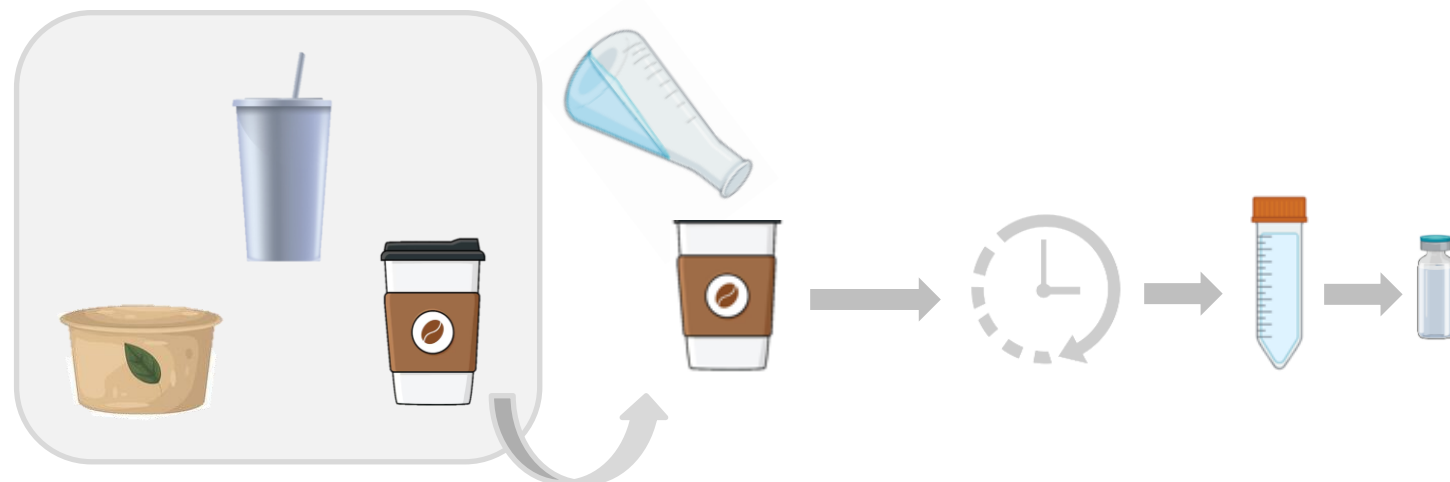
4<sup>th</sup> Edition



1



2





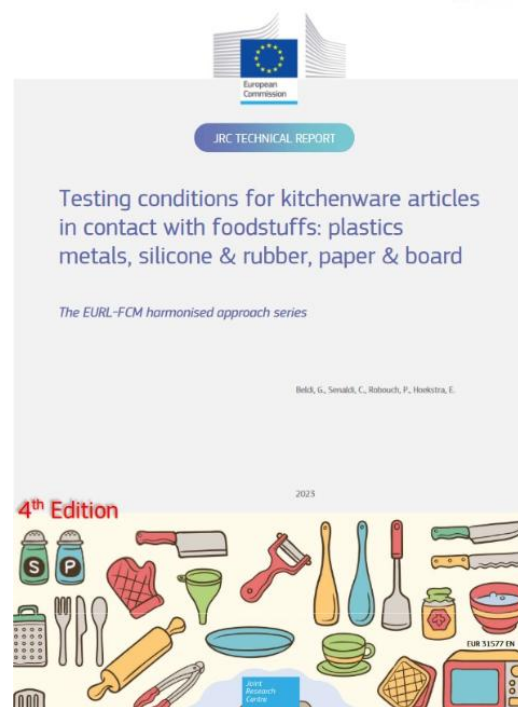
# Identification of potential migrants

## Analytical strategy



### Migration experiments

According to the EURL kitchenware guidelines



### Quantitative analysis of organic substances

using GC-MS/MS, LC-GC-FID, LC-MS/MS



### Targeted screening of substances included in Annex I of Regulation (EU)

No. 10/2011

using LC-HRMS



### Untargeted screening

using GC(xGC)-TOF/MS

# Targeted analyses



Bisphenols



MOSH/MOAH



Plasticizers & Phthalates



PFAS



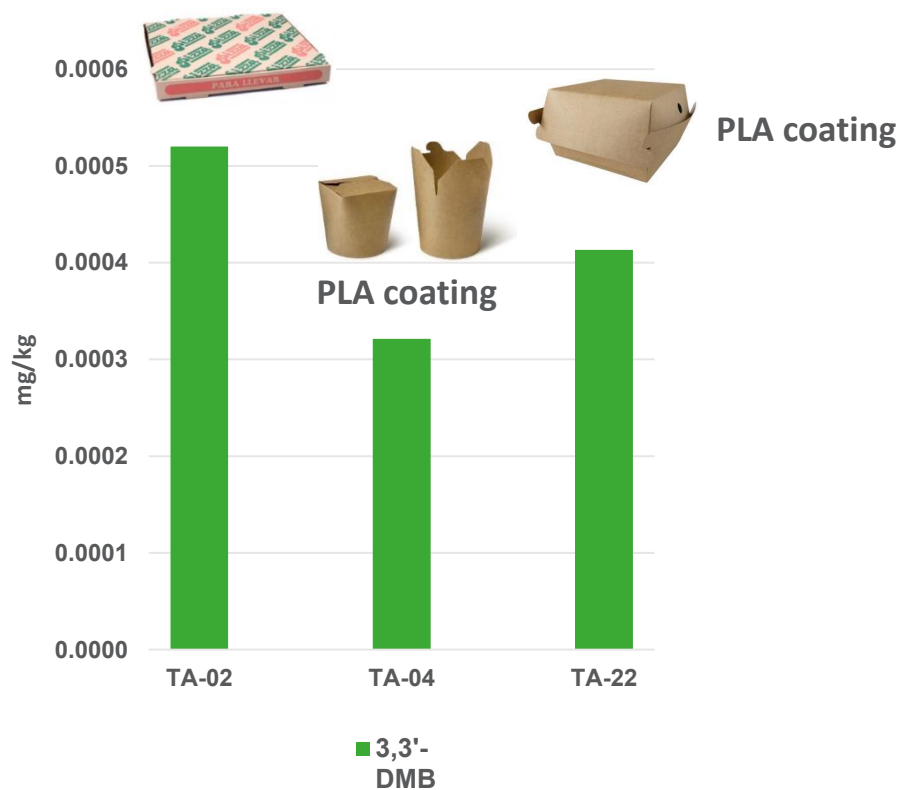
Primary aromatic amines



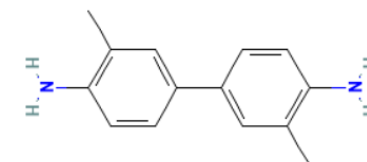
Photoinitiators

91  
Compounds

# PAA in takeaway articles



1 amine found out of 25 in  
3 samples out of 58 (5,2%)



3,3'-DMB is carcinogenic



Can be use in the production of azo dyes and  
insoluble pigments in the paper industries

Is used in the production of plastics for  
coating

# Bisphenols in takeaway articles

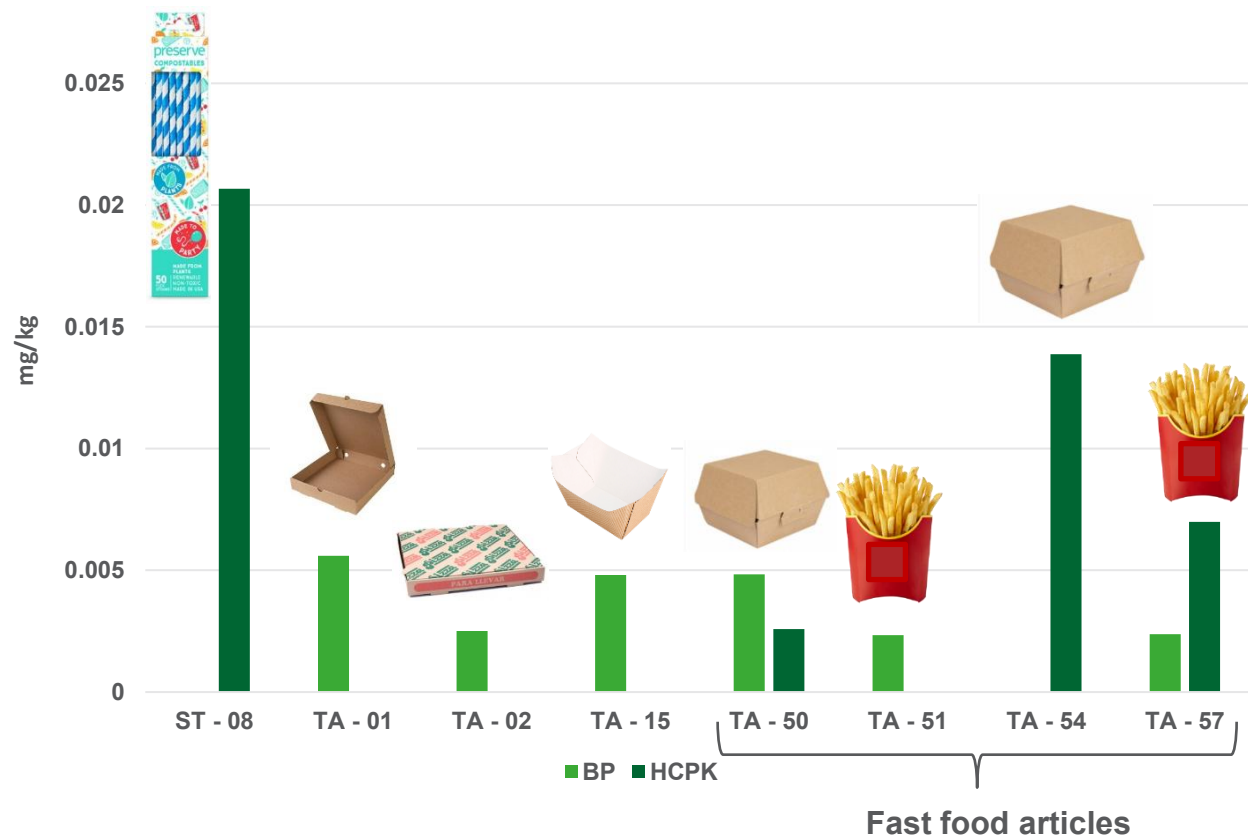


2 bisphenols found out of 5  
11 samples out of 58 (19,0%)



BPS ranging from 0.008 up to 0.017 mg/kg  
BPA ranging from 0.004 up to 0.026 mg/kg

# Photoinitiators



2 photoinitiators found out of 20  
8 samples out of 78 (10.2%)



Benzophenone ranging from 0.0023 up to 0.005 mg/kg  
HCPK ranging from 0.003 up to 0.02 mg/kg

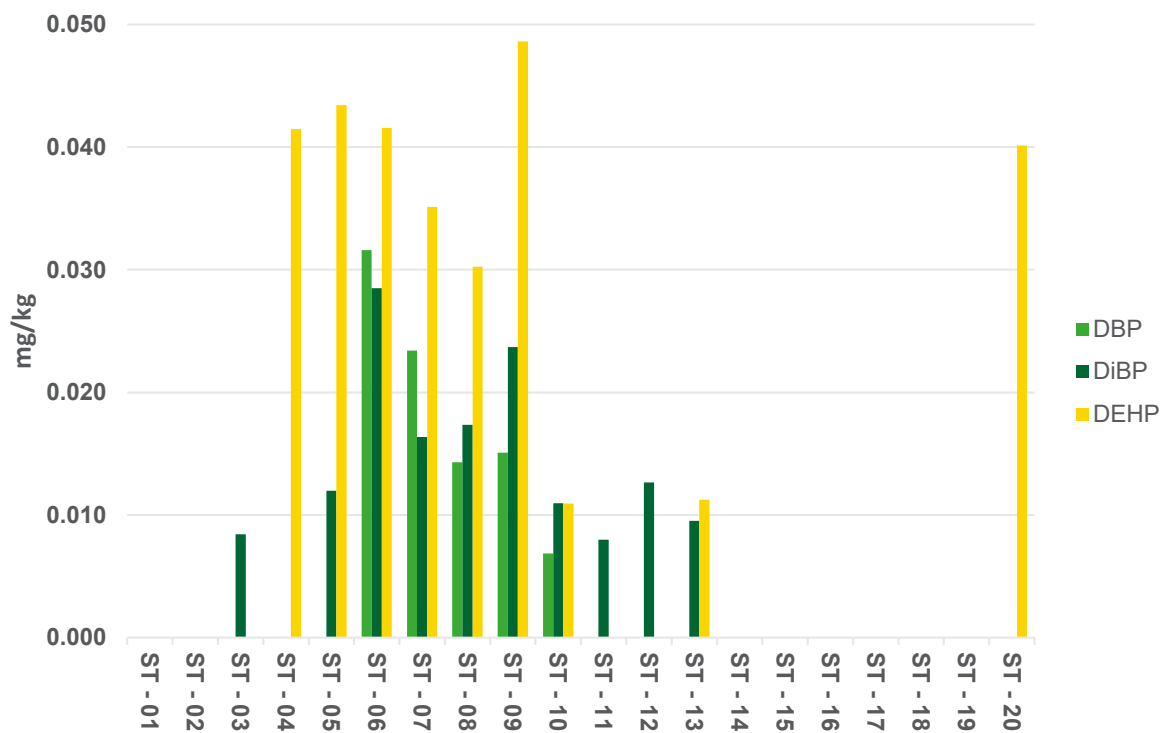


Photoinitiators are used in the UV curing processes  
of inks and lacquers applied to the packaging  
surface, mainly cardboard boxes

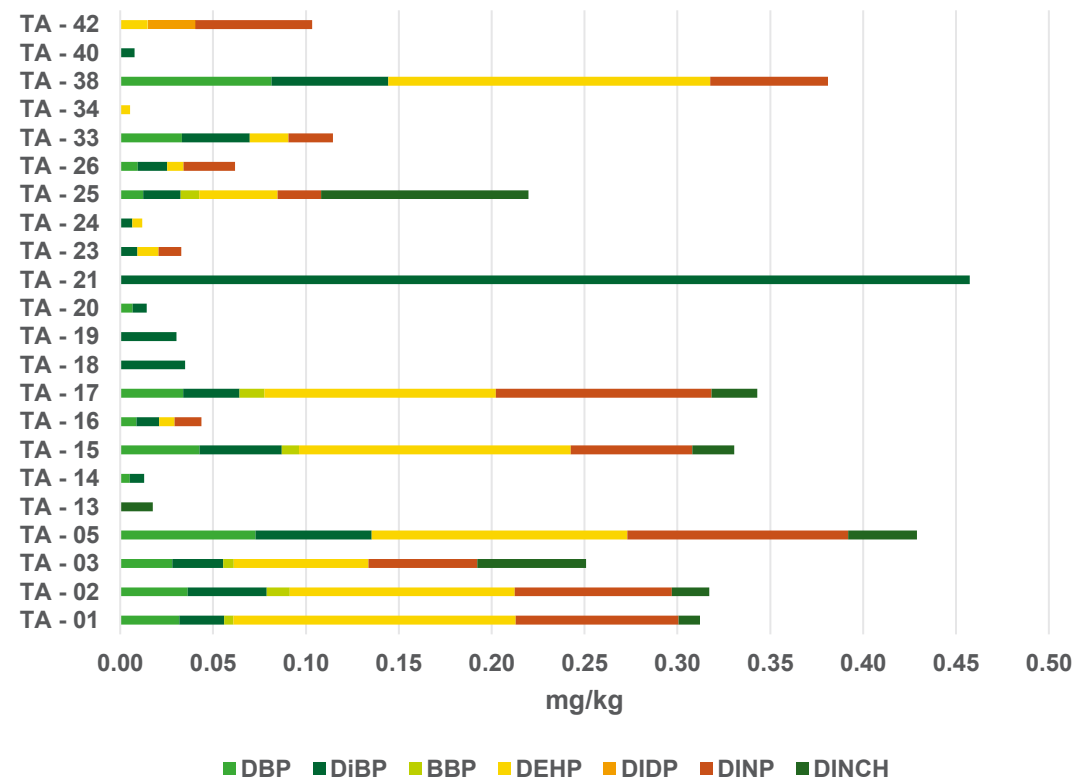


# Phthalates

## Straws



## Takeaway articles

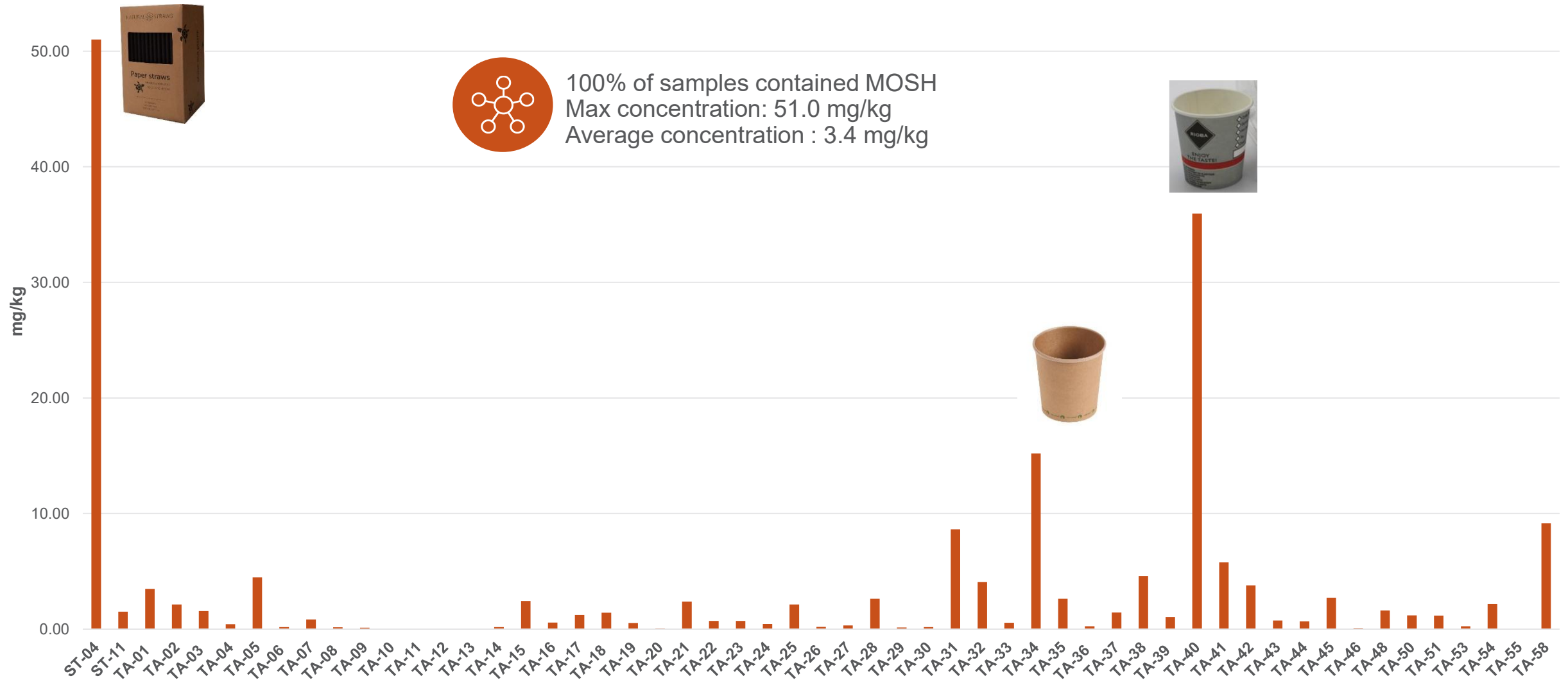


3 phthalates found out of 14  
12 samples out of 20 (60%)

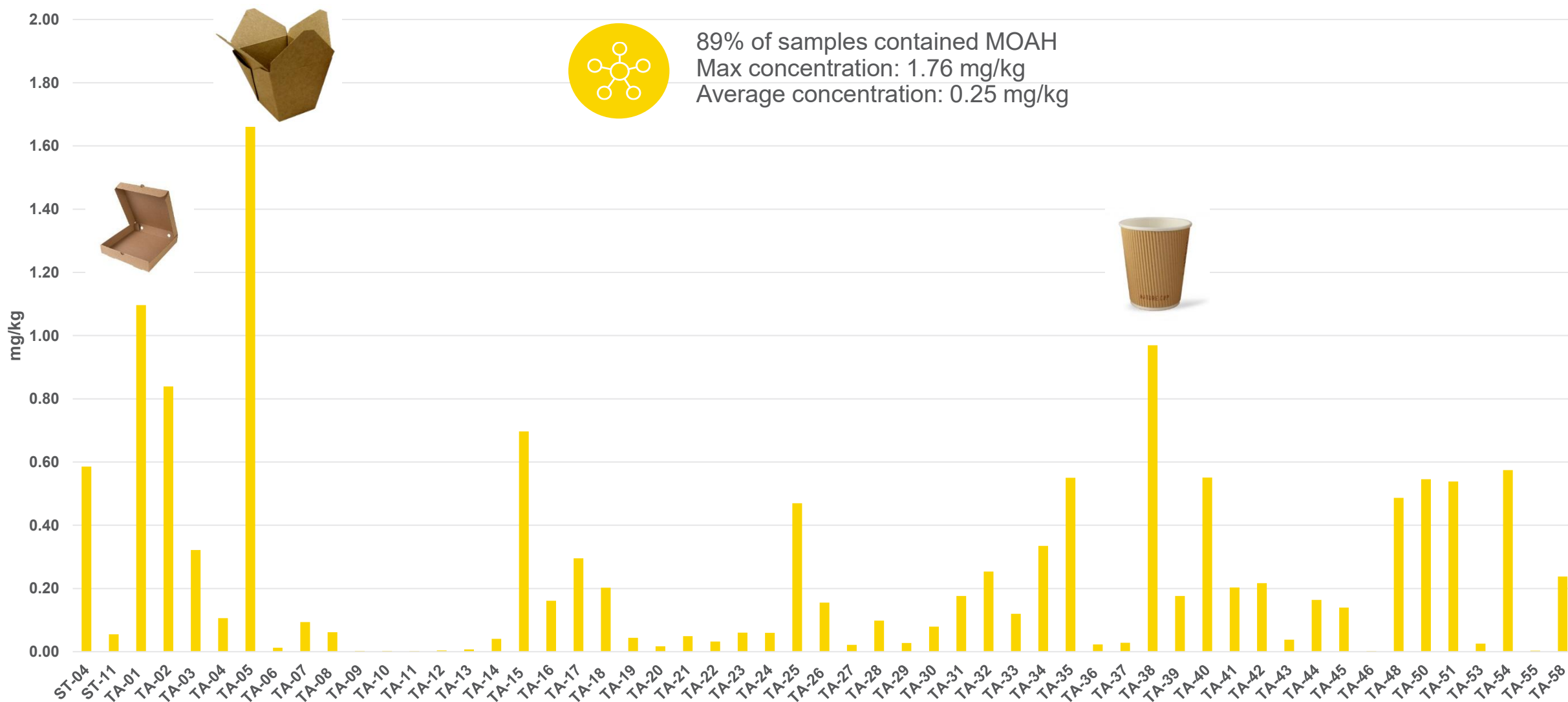


7 phthalates found out of 14  
38 samples out of 58 (65,5%)

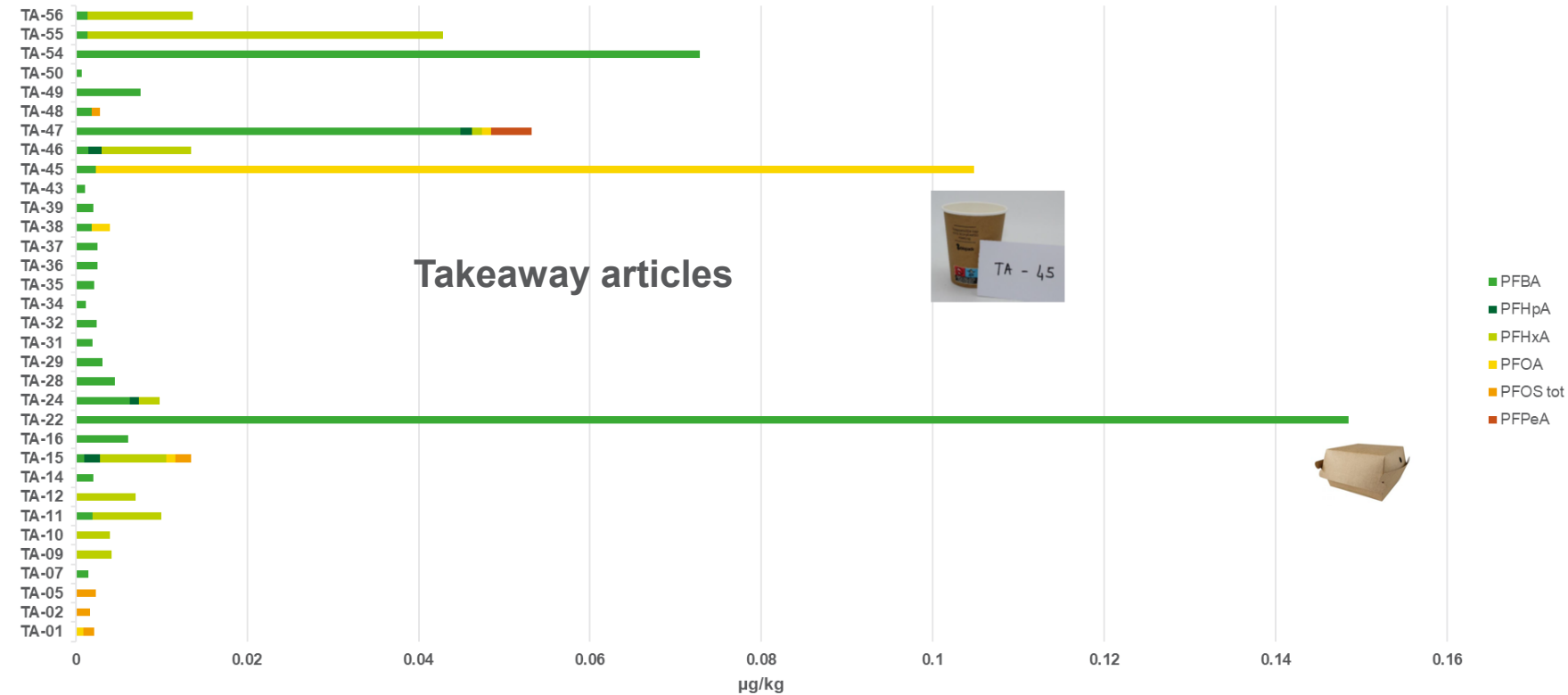
# Mineral oil - MOSH



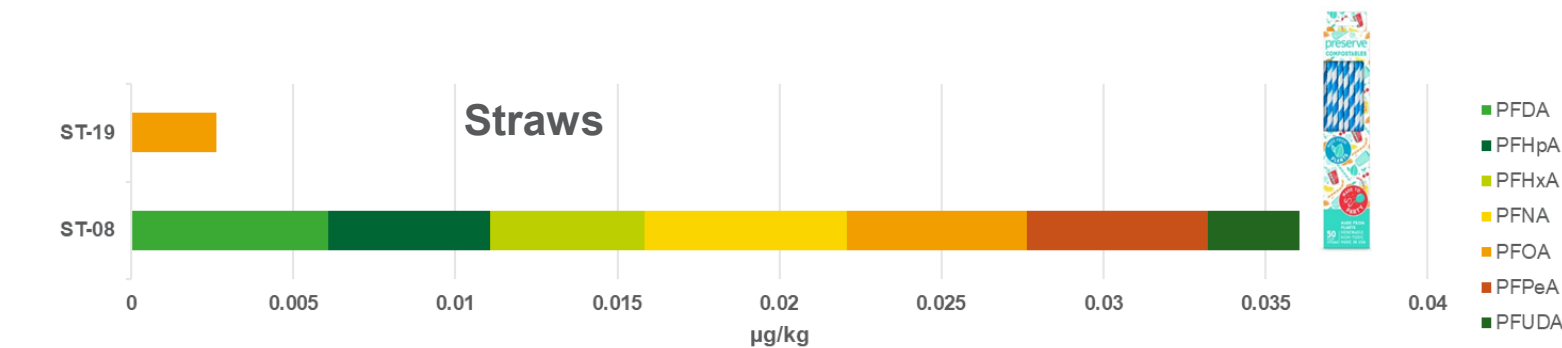
# Mineral oil - MOAH



# PFAS



6 PFAS found out of 25  
33 samples out of 58 (56,9%)



7 PFAS found out of 25  
2 samples out of 20 (10%)



# Identification of potential migrants

## Analytical strategy



### Migration experiments

According to the EURL kitchenware guidelines



Quantitative analysis of  
organic substances  
using GC-MS/MS, LC-GC-FID,  
LC-MS/MS



**Targeted screening of  
substances included in  
Annex I of Regulation (EU)  
No. 10/2011  
using LC-HRMS**



Untargeted screening  
using GC(xGC)-TOF/MS

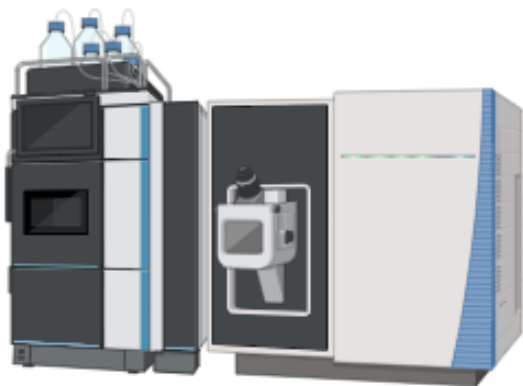


# Targeted screening

Target screening method by LC-HRMS of

**~ 100 substances**

included in Annex I of Regulation (EU) No. 10/2011

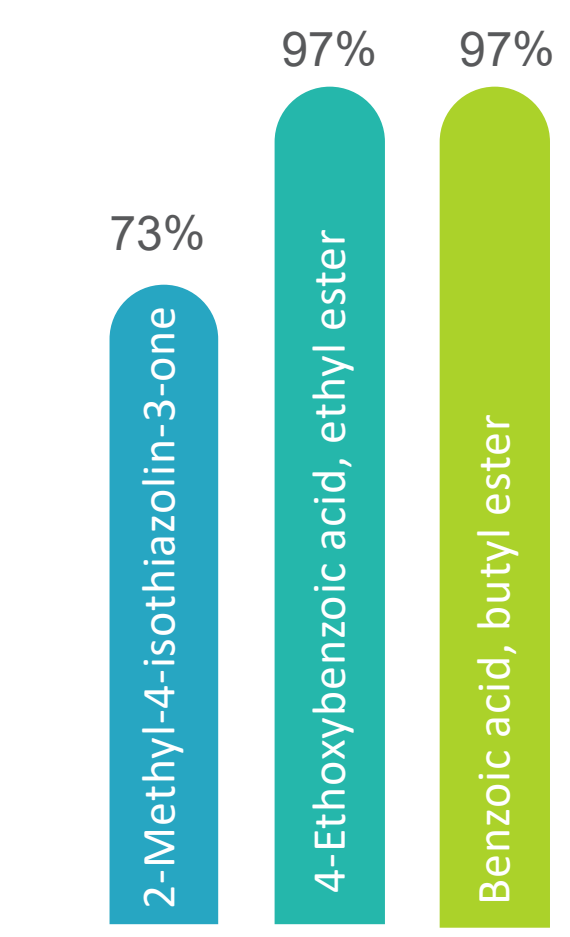
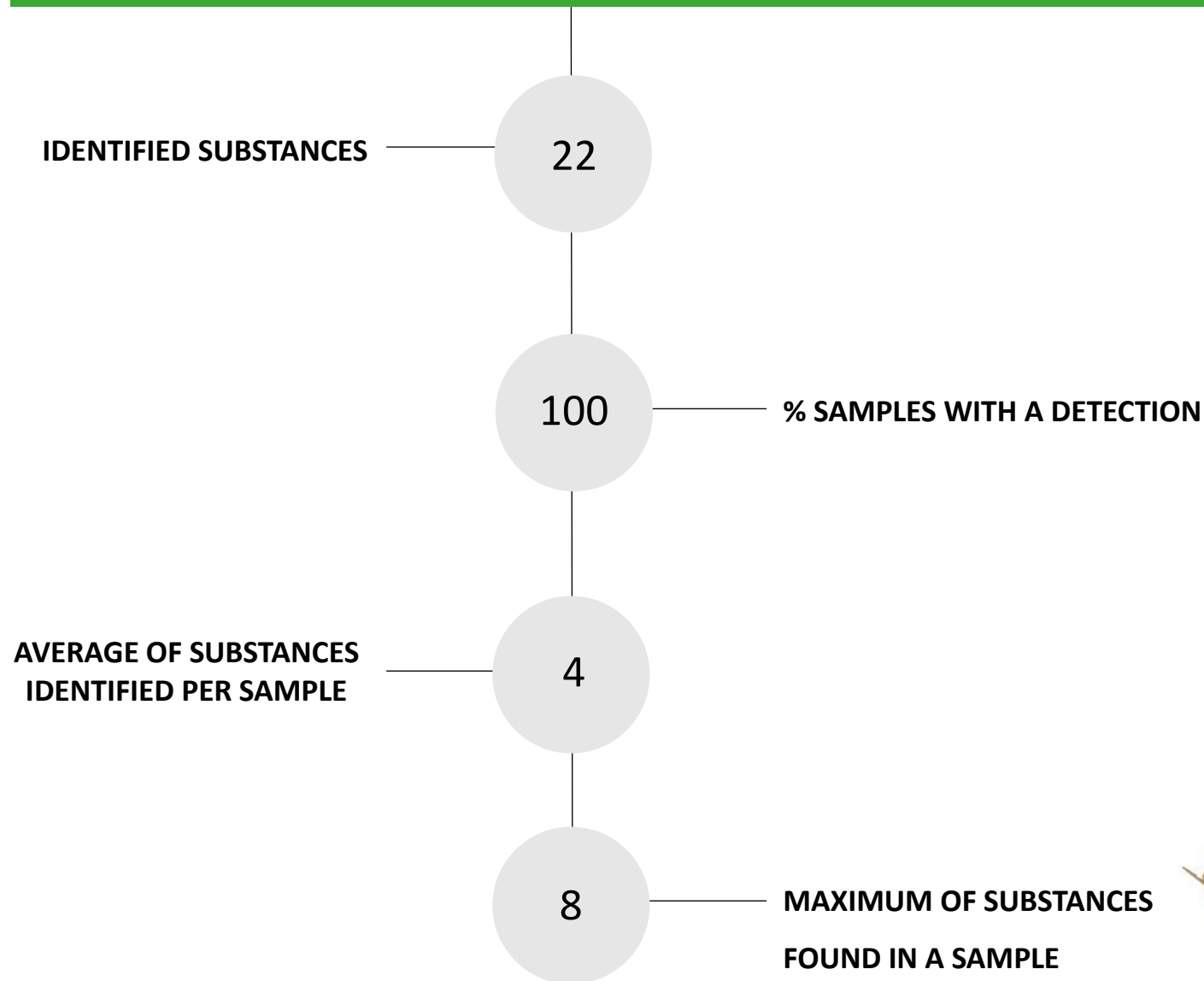


LC-Orbitrap

Paper and board FCM are often coated with plastic



# Targeted screening



# Identification of potential migrants

## Analytical strategy



### Migration experiments

According to the EURL kitchenware guidelines



Quantitative analysis of  
organic substances  
using GC-MS/MS, LC-GC-FID,  
LC-MS/MS



Targeted screening of  
substances included in  
Annex I of Regulation (EU)  
No. 10/2011  
using LC-HRMS



**Untargeted screening**  
using GC(xGC)-TOF/MS

# Untargeted screening

Untargeted analyses on a subset of samples



GC(xGC)-TOFMS  
LECO PEGASUS BTX

**58** substances were identified

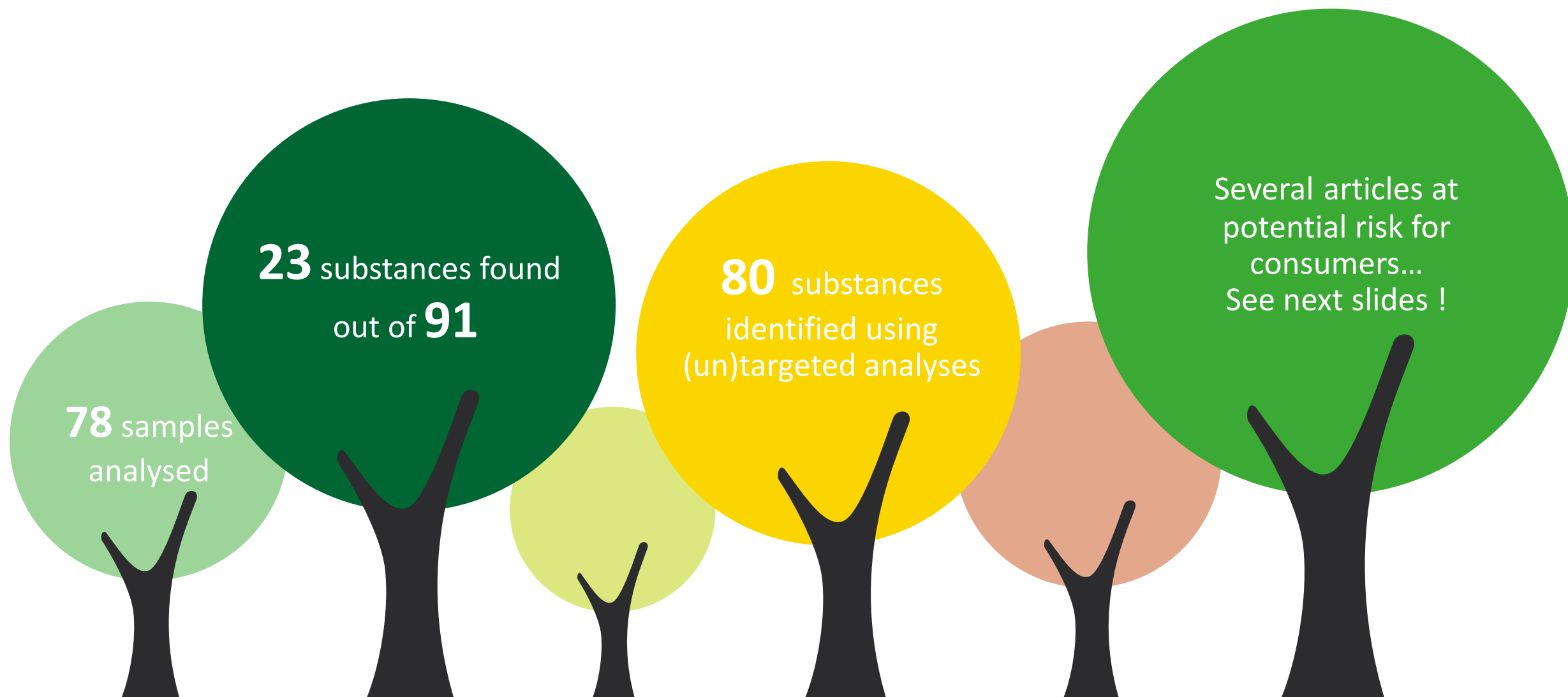
Average of **12** substances per article

Max of **22** substances found in a  
pizza box



Where could come these  
substances from?

## Conclusion – Analytical part





# Targeted populations



Children  
(3-10 years old, 23 kg)

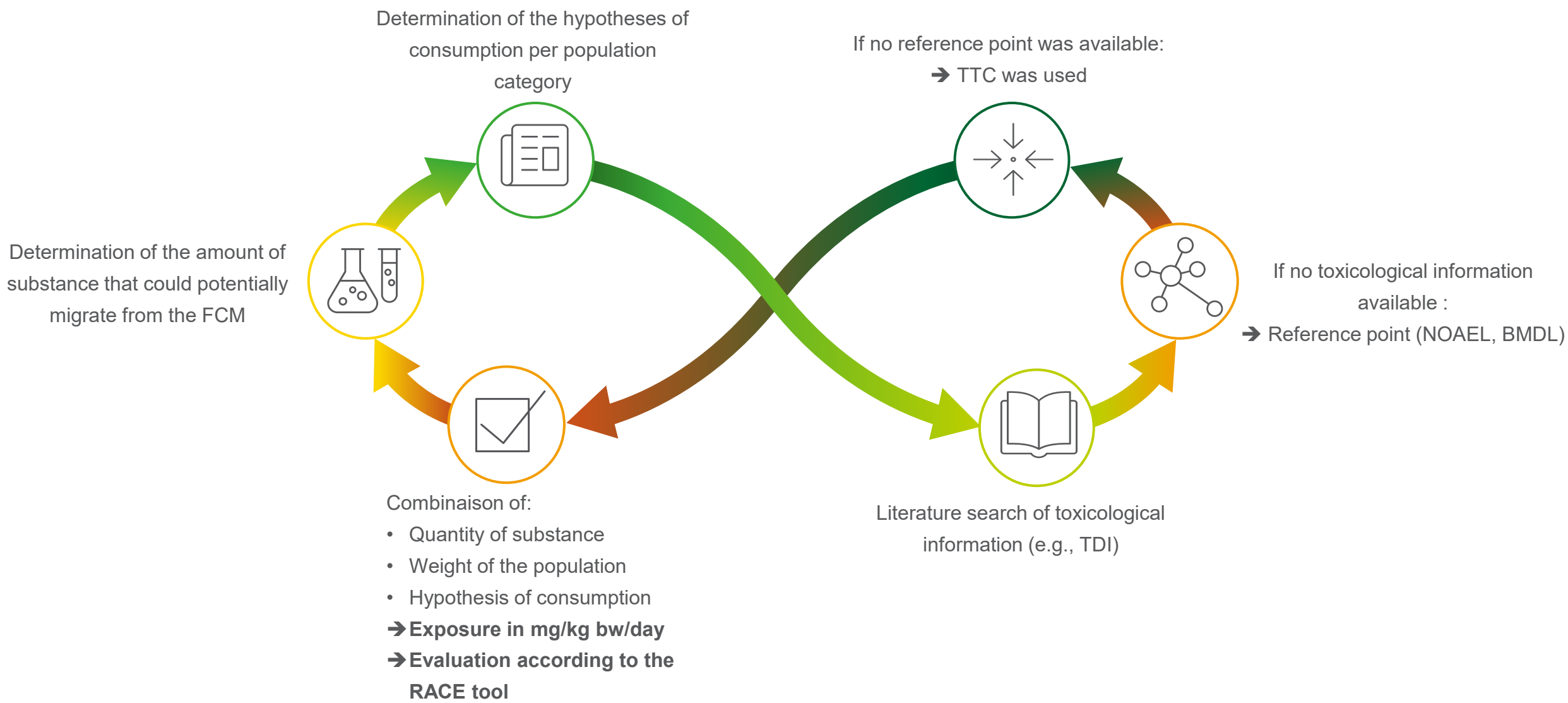


Teenagers  
(14-18 years old, 61 kg)



Adults  
(18-64 years old, 70 kg)

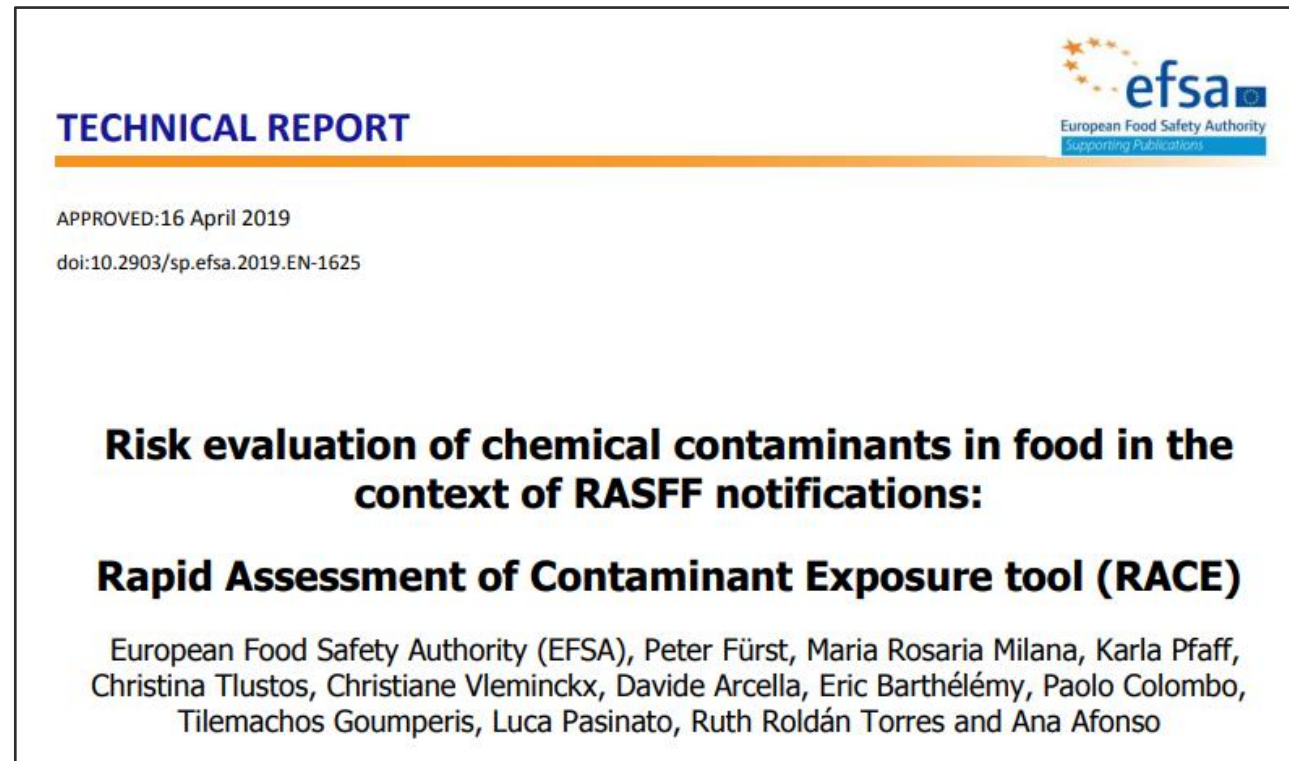
# Workflow of the risk assessment



# Risk assessment of the quantified migrants

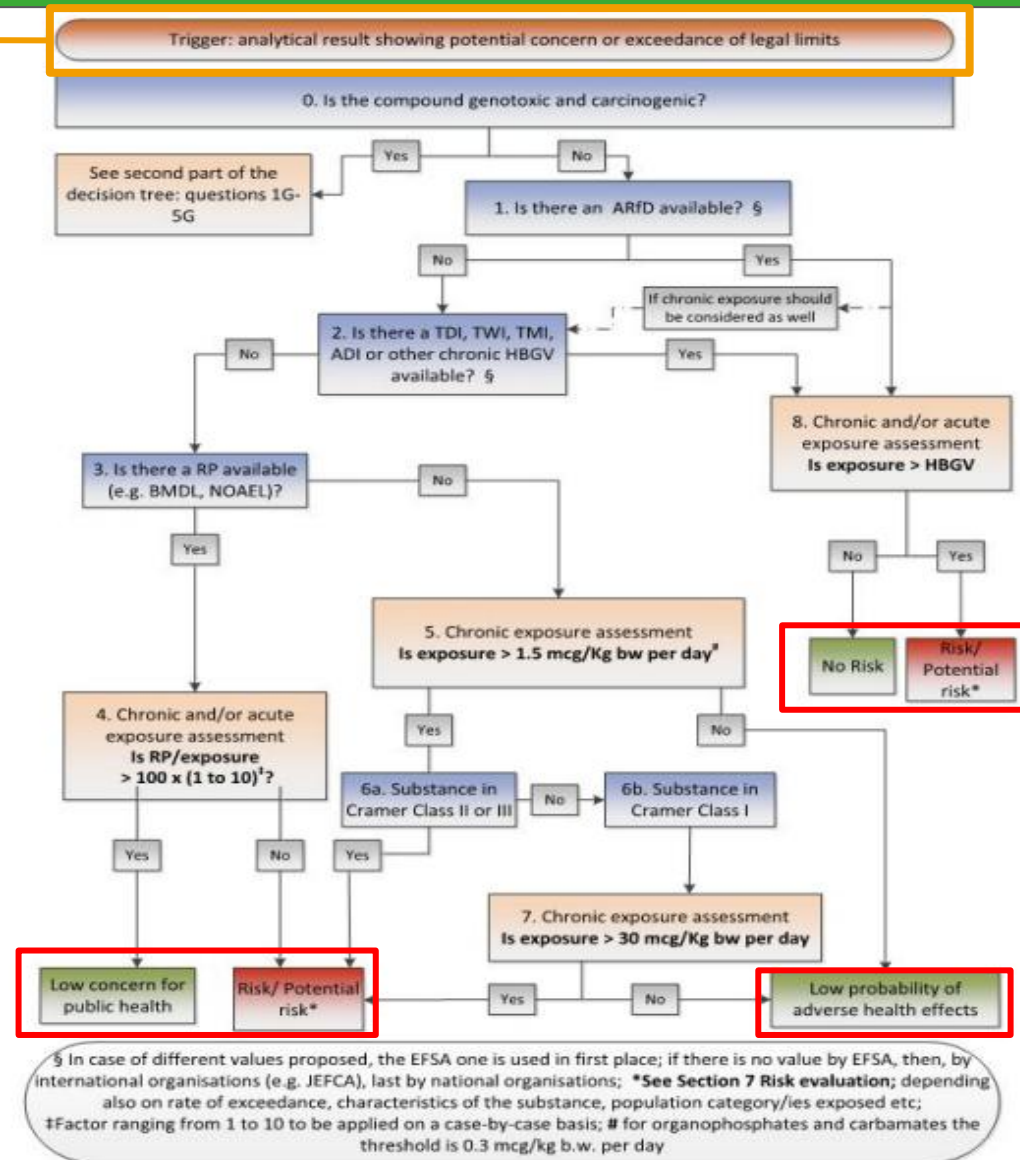
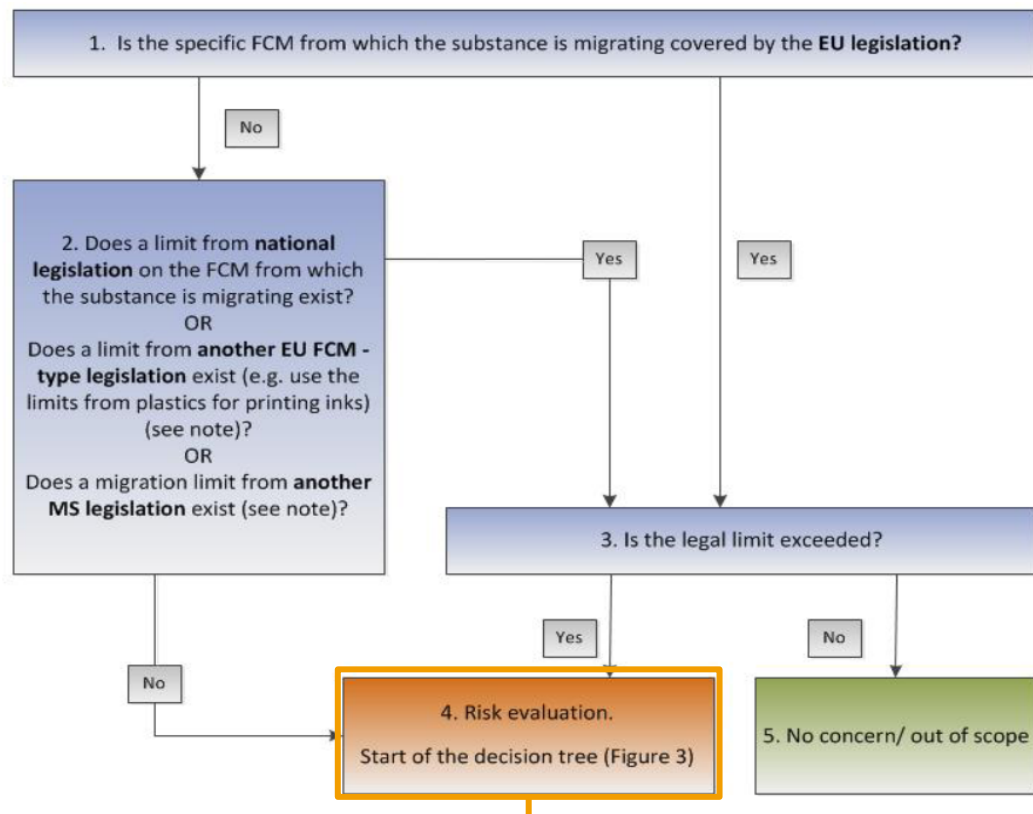
## RACE tool

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



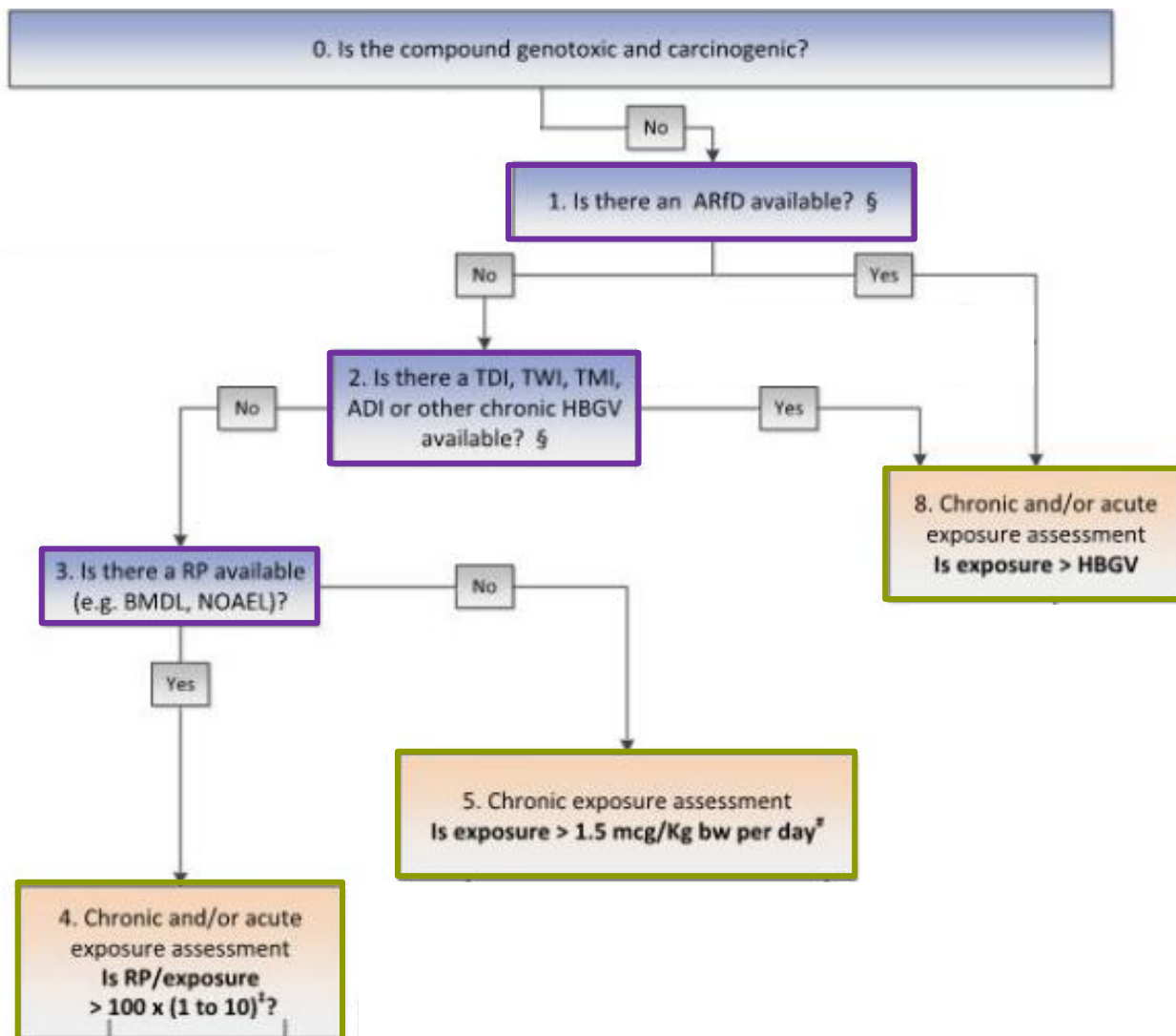
# EFSA RACE tool

## Pre-decision tree for food contact materials



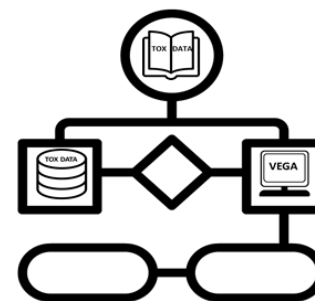


# Application of the EFSA RACE tool



Next steps:

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



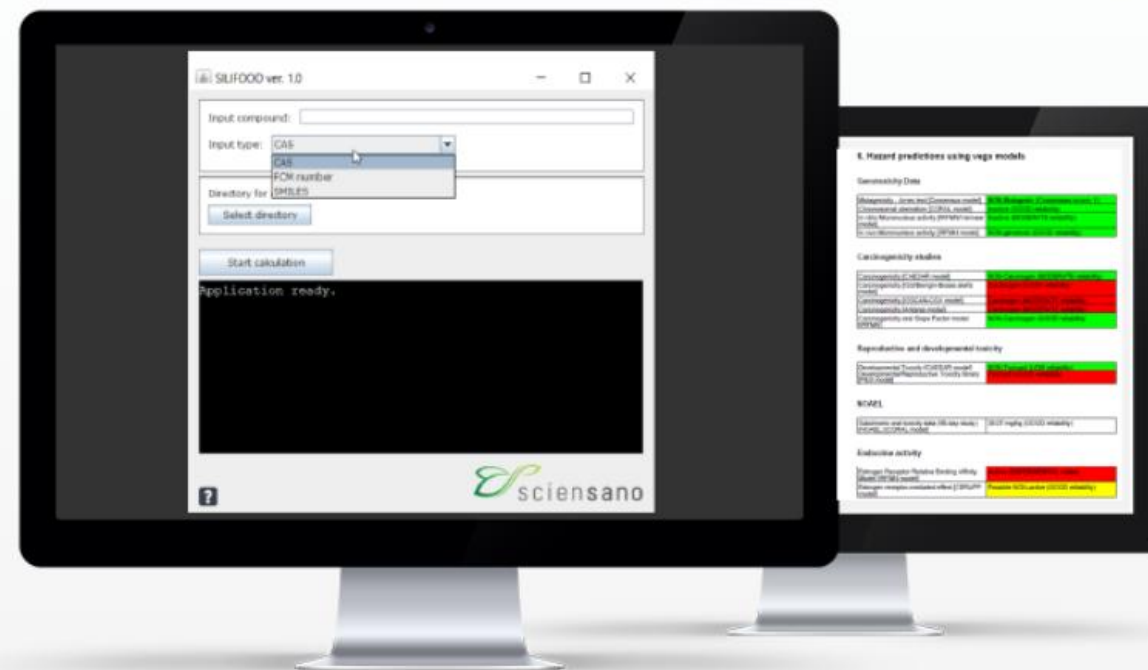
<https://www.vegahub.eu/portfolio-item/silifood/>



# 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

SILIFOOD ver. 0.1

Input compound:


Input type: CAS ▼ **1** Insert the CAS number, SMILES or FCM number of the target compound and select the input type accordingly.

Directory for output: [none] **2** Select the directory for the output report.

Select directory

Start calculation **3** Click on "Start calculation" to run the application.

Application ready.



	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

# 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 (E)
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)c1cccc1C(=O)OCC(C)CCCC (E, F, G)
VEGA SMILES	O=C(OCC(CC)CCCC)c1cccc1C(=O)OCC(C)CCCC (A, B, E, F, H) CCCCC(CC)COC(=O)c1cccc1C(=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, saturated C9-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)
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### Endocrine activity

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

# 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  $\mu\text{g kg}^{-1} \text{ bw day}$*

# Mineral oil - MOSH



100% of samples contained MOSH !



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<sup>-1</sup> bw day

# Mineral oil – MOAH



89% of samples contained MOAH !



**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

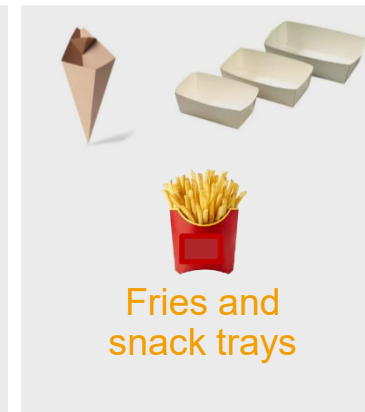
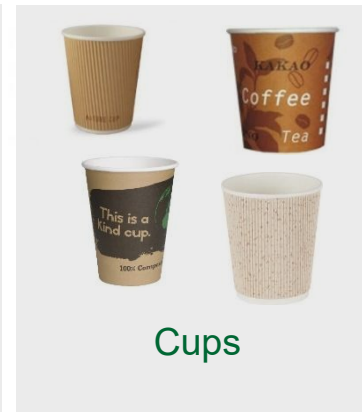
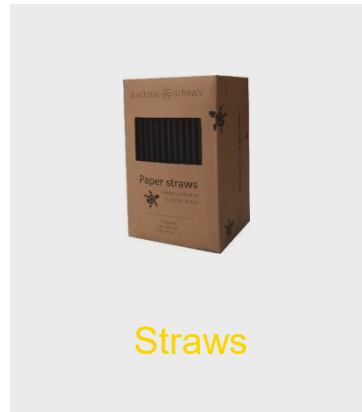
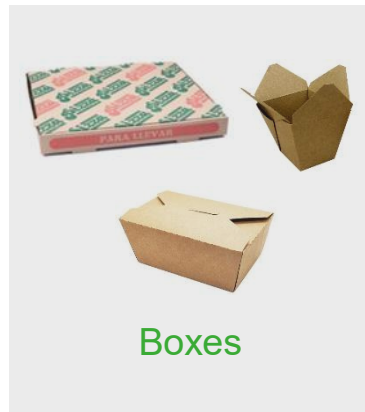
**Scenario 2:** 1% of the amount found is carcinogenic/genotoxic



# Risk assessment : MOAH

## Scenario 1 : 10%

**13/59** samples at potential risk



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<sup>-1</sup> bw day*

# Risk assessment : MOAH

## Scenario 2 : 1%

**2/59**

**samples at potential risk**



Coffee cup



Straw

Children

Potential risk

Potential risk

Teenagers

Potential risk

Potential risk

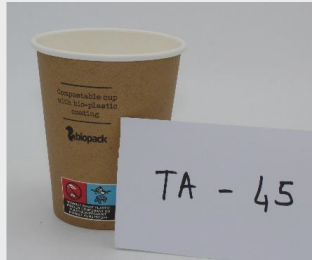
Adults

Potential risk

Potential risk

# Risk assessment : PFAS

## Scenario 1 : $\Sigma$ EFSA-PFAS



Scenario 1

Children

NA

Teenagers

Potential risk

Adults

Potential risk

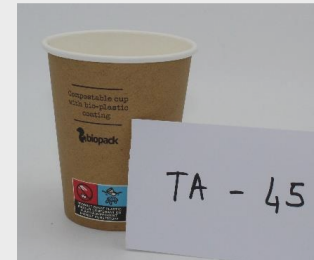


Scenario 2

Potential risk

No risk

No risk



Scenario 2

NA

Potential risk

Potential risk

## Scenario 2 : $\Sigma$ all detected PFAS

Relative Potency  
Factor approach

# Conclusion



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

**Thank you for your attention!**