

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

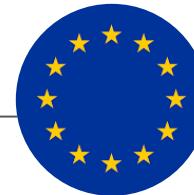
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“

Royal Decree
of
25/05/2024

”



“

Ban on certain single
use plastic in Europe

”

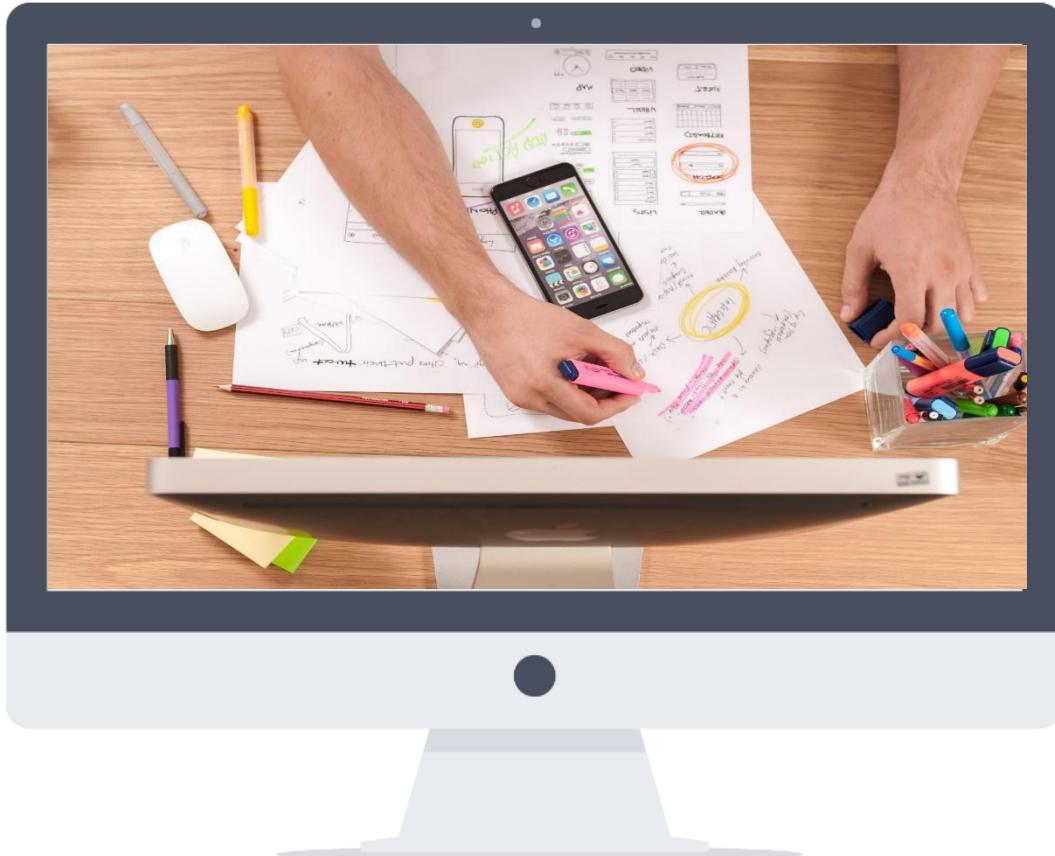


“

FEVIA (Federation of
Belgian Food Industry)
-
100% of reusable,
recyclable or
biodegradable
packaging by 2025

”

Market study



WEB SCRAPING

59 Websites consulted

DATA CLEANING & HARMONIZATION

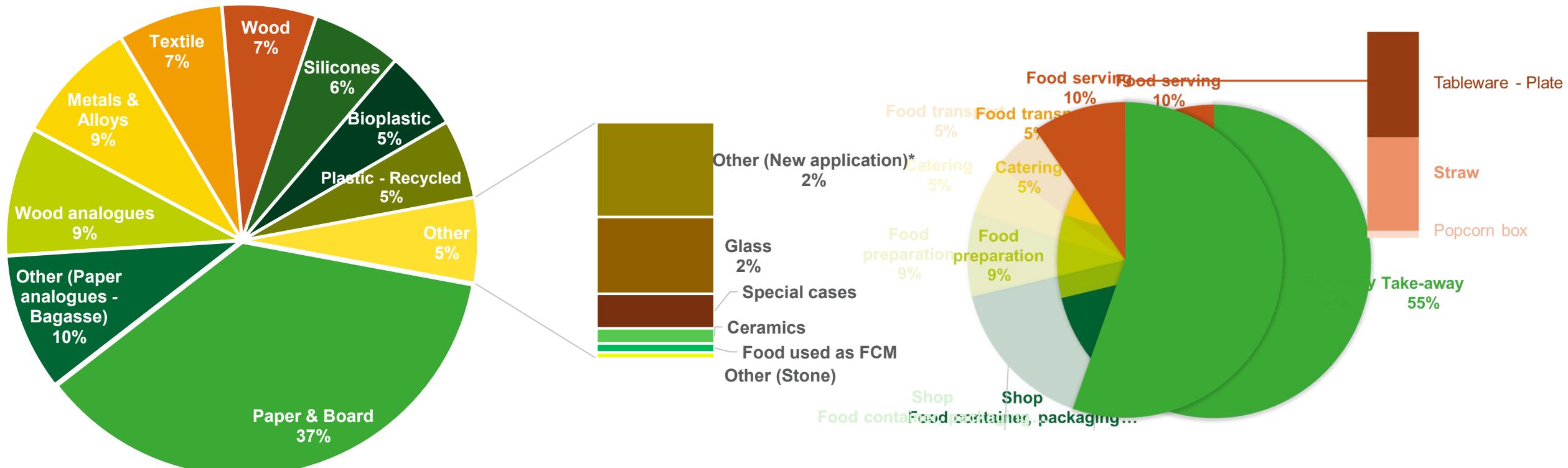


KEY WORDS

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



Market study



Introduction



What are the potential risks related to these FCMs?



Sampling

58 Takeaway articles

20 Straws



Identification of potential migrants

Analytical strategy



Migration experiments

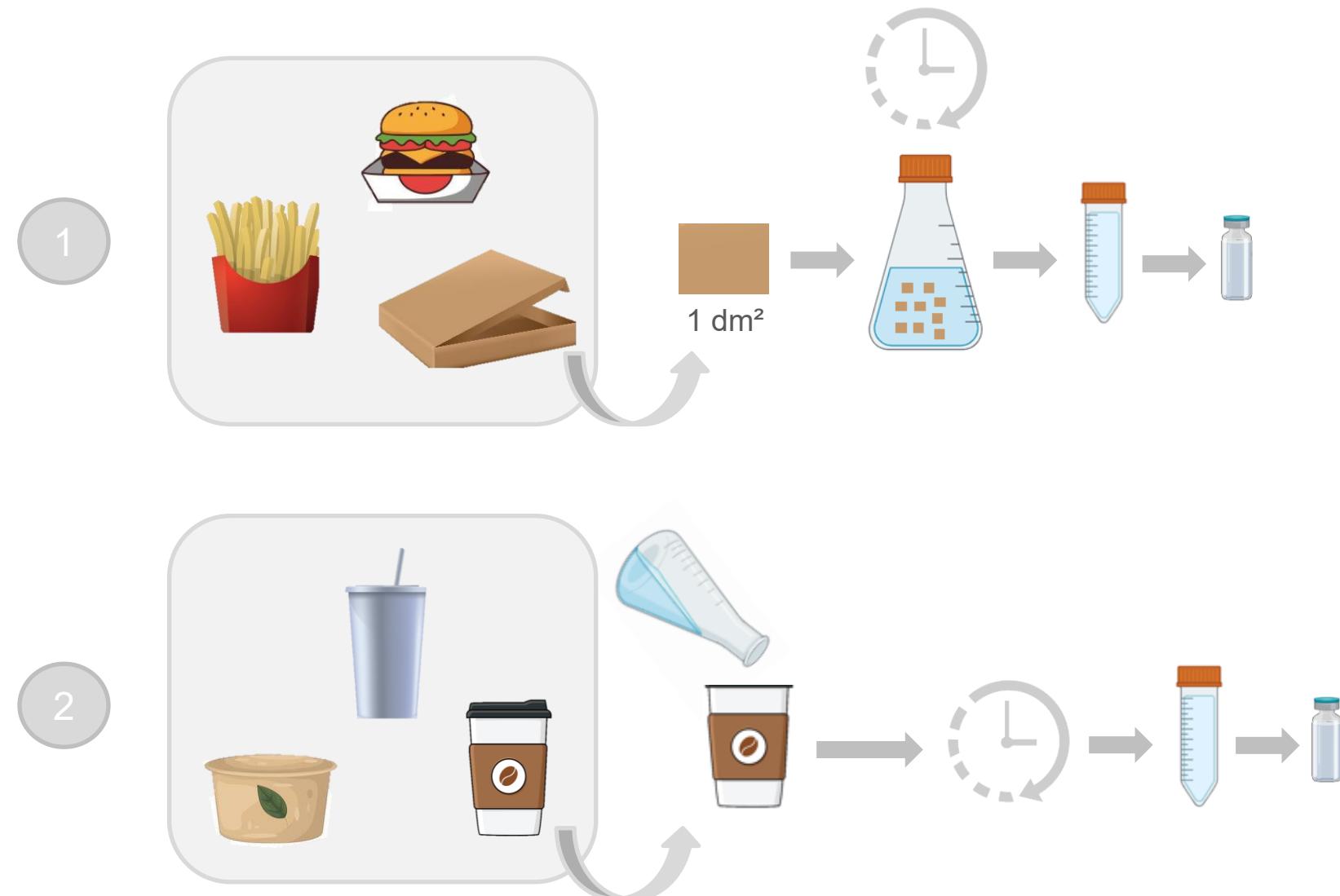
According to the EURL
kitchenware guidelines



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 ?



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



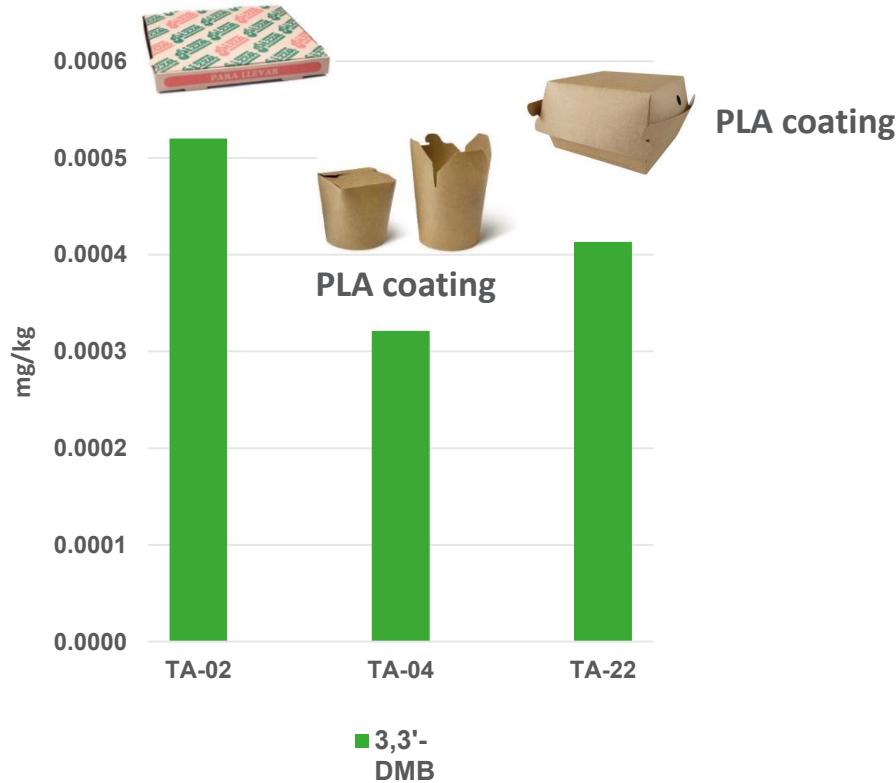
Primary aromatic amines



Photoinitiators



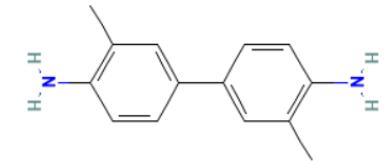
PAA in takeaway articles



PLA coating

PLA coating

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



3,3-DMB is carcinogenic

Can be used 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

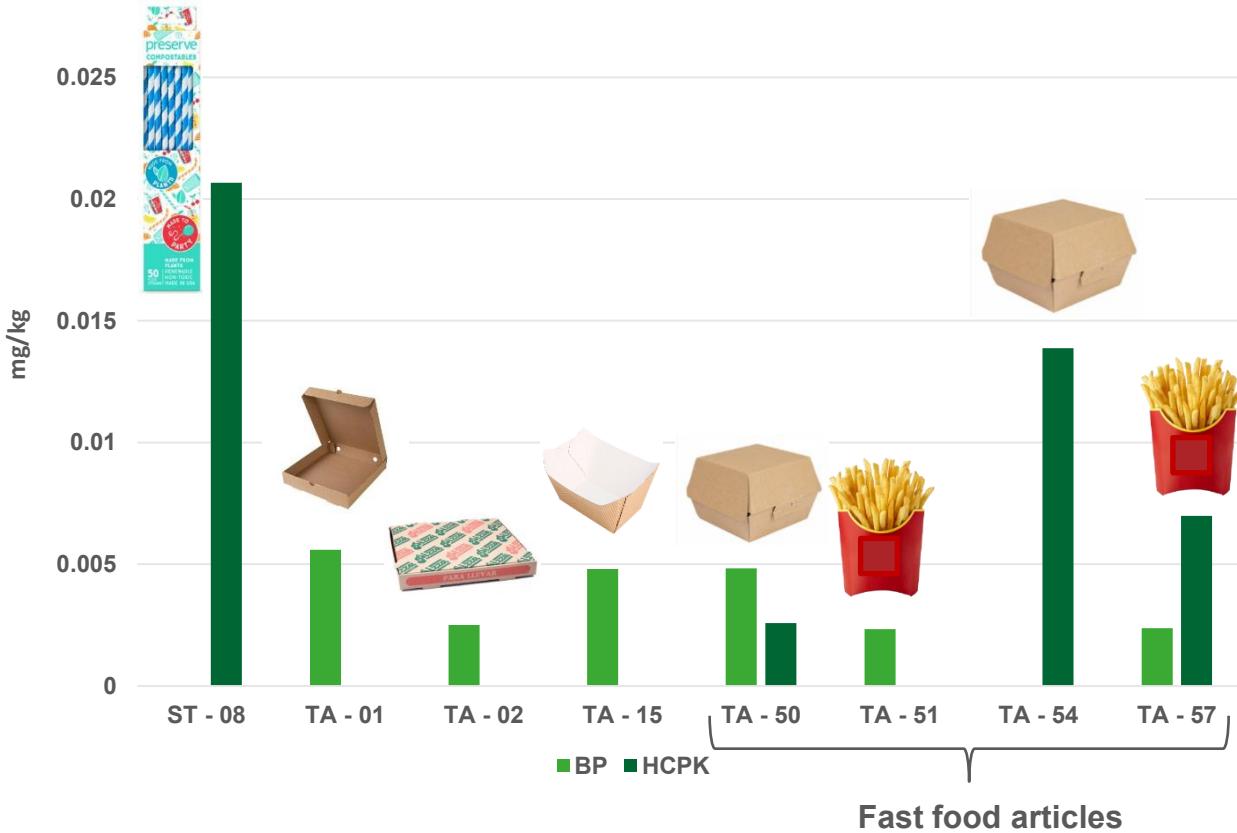


2 bisphenols found out of 5
11 samples out of 58 (19,0%)



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%)

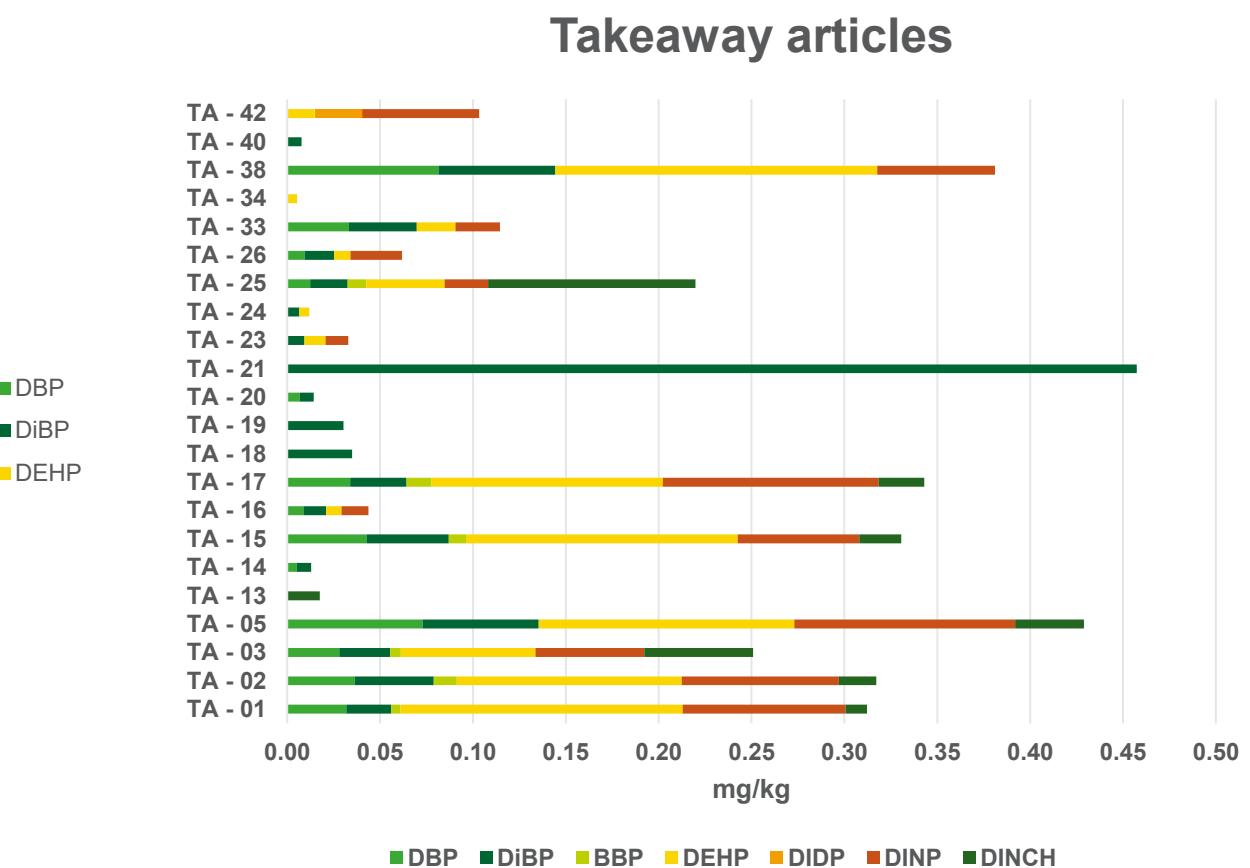
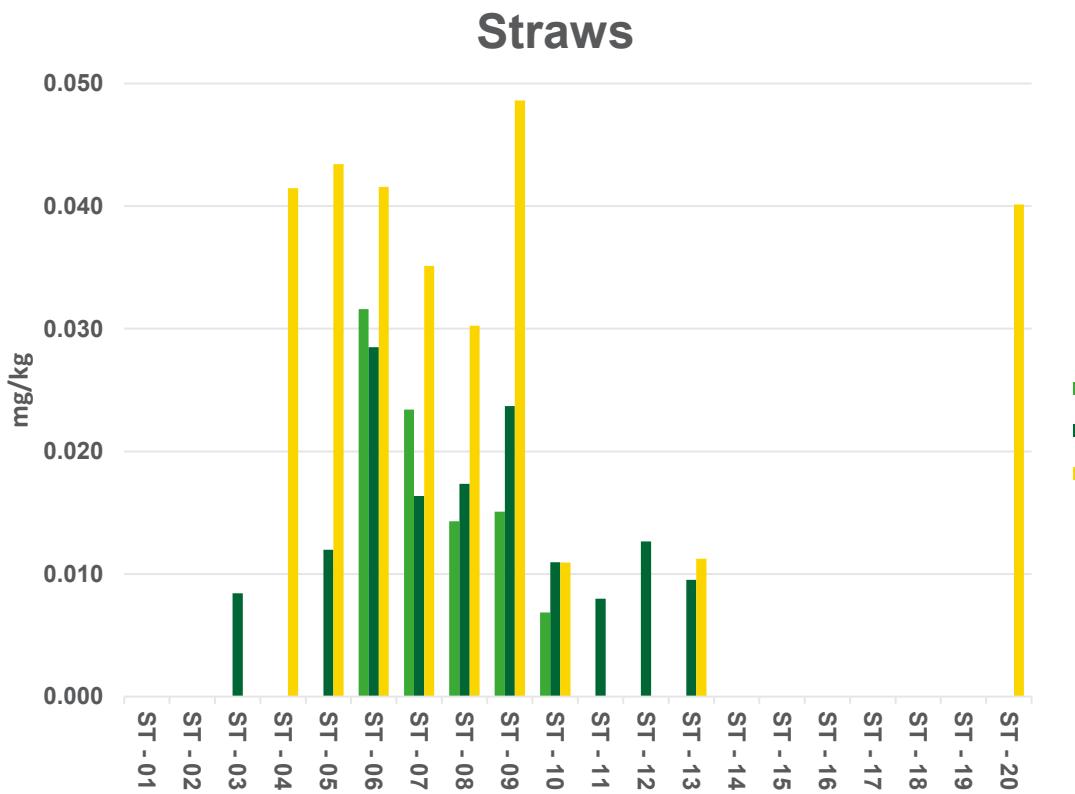


Benzophenone ranging from 0.0023 up to 0.005 mg/kg
HCPK ranging from 0.003 up to 0.02 mg/kg



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

Phthalates

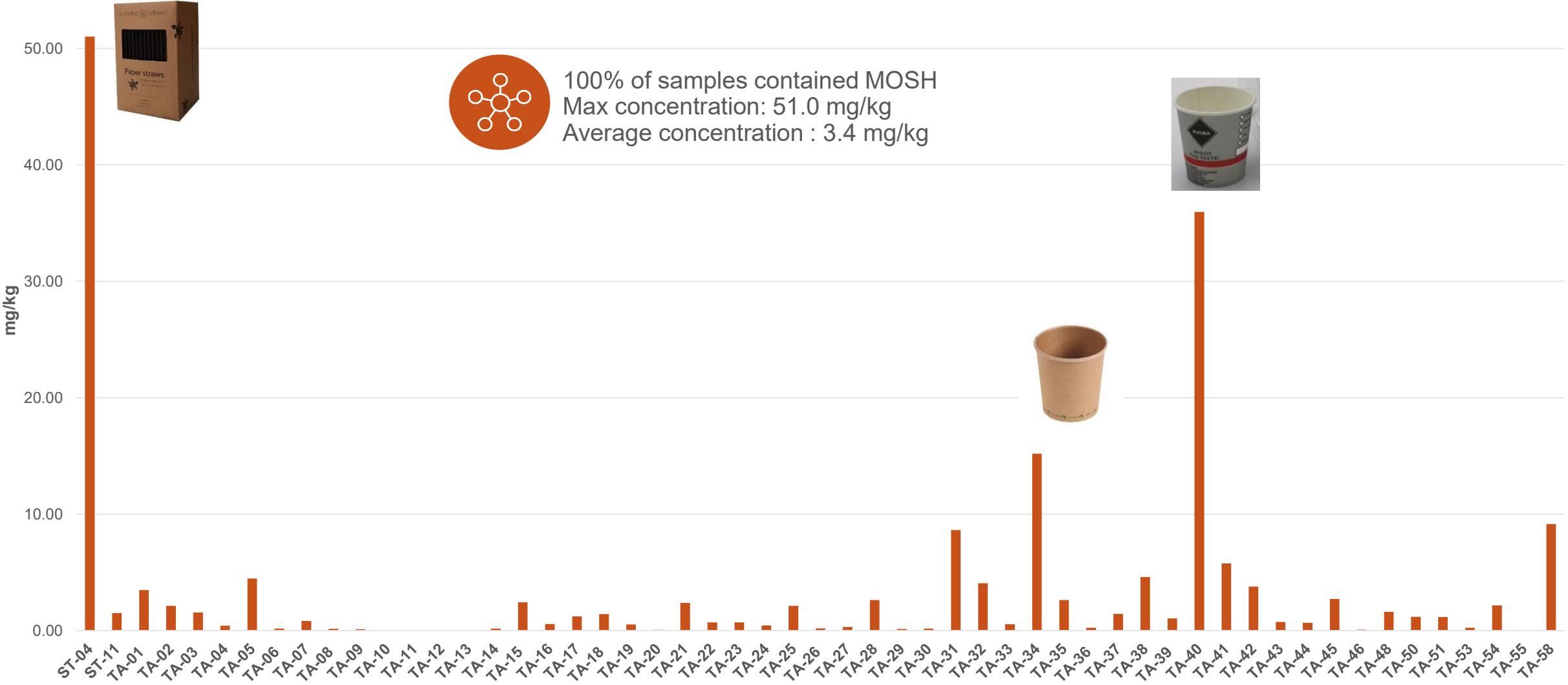


3 phthalates found out of 14
12 samples out of 20 (60%)

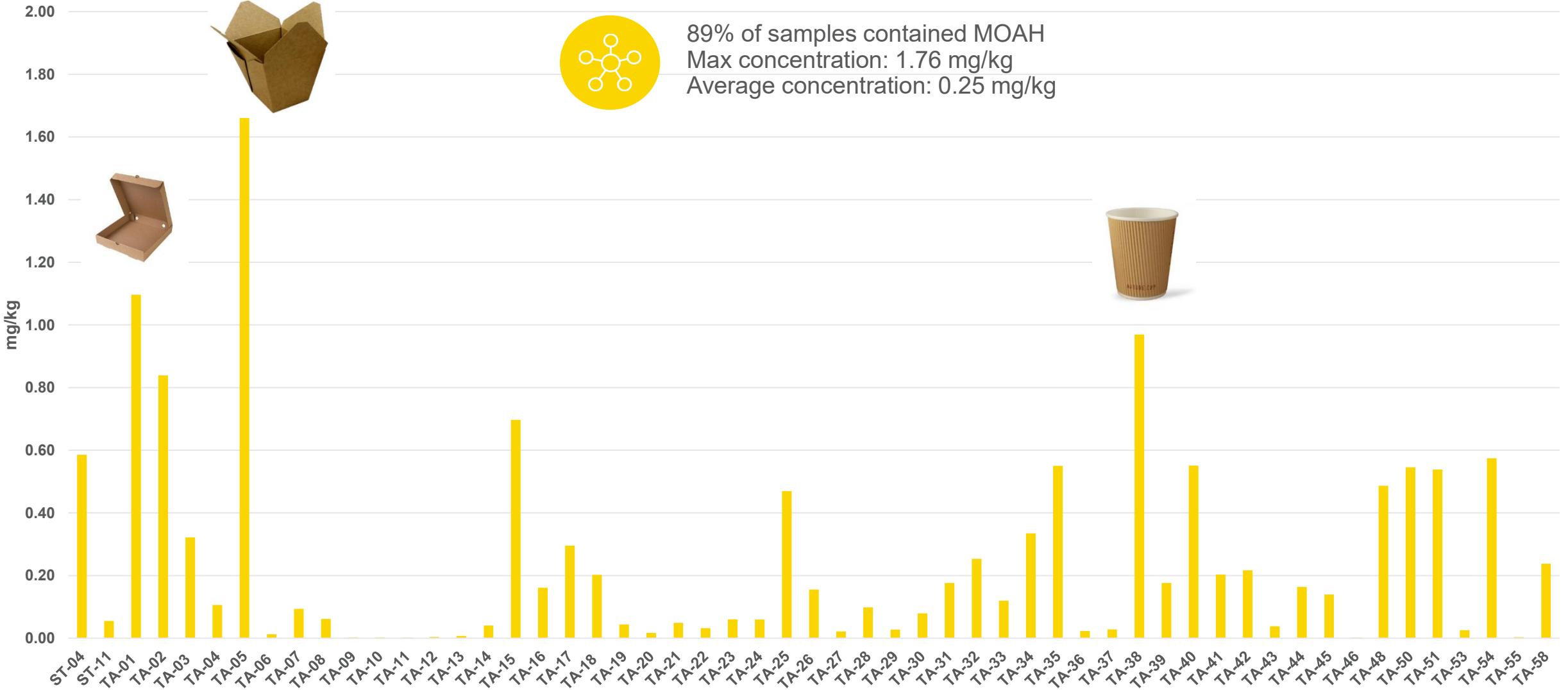


7 phthalates found out of 14
38 samples out of 58 (65,5%)

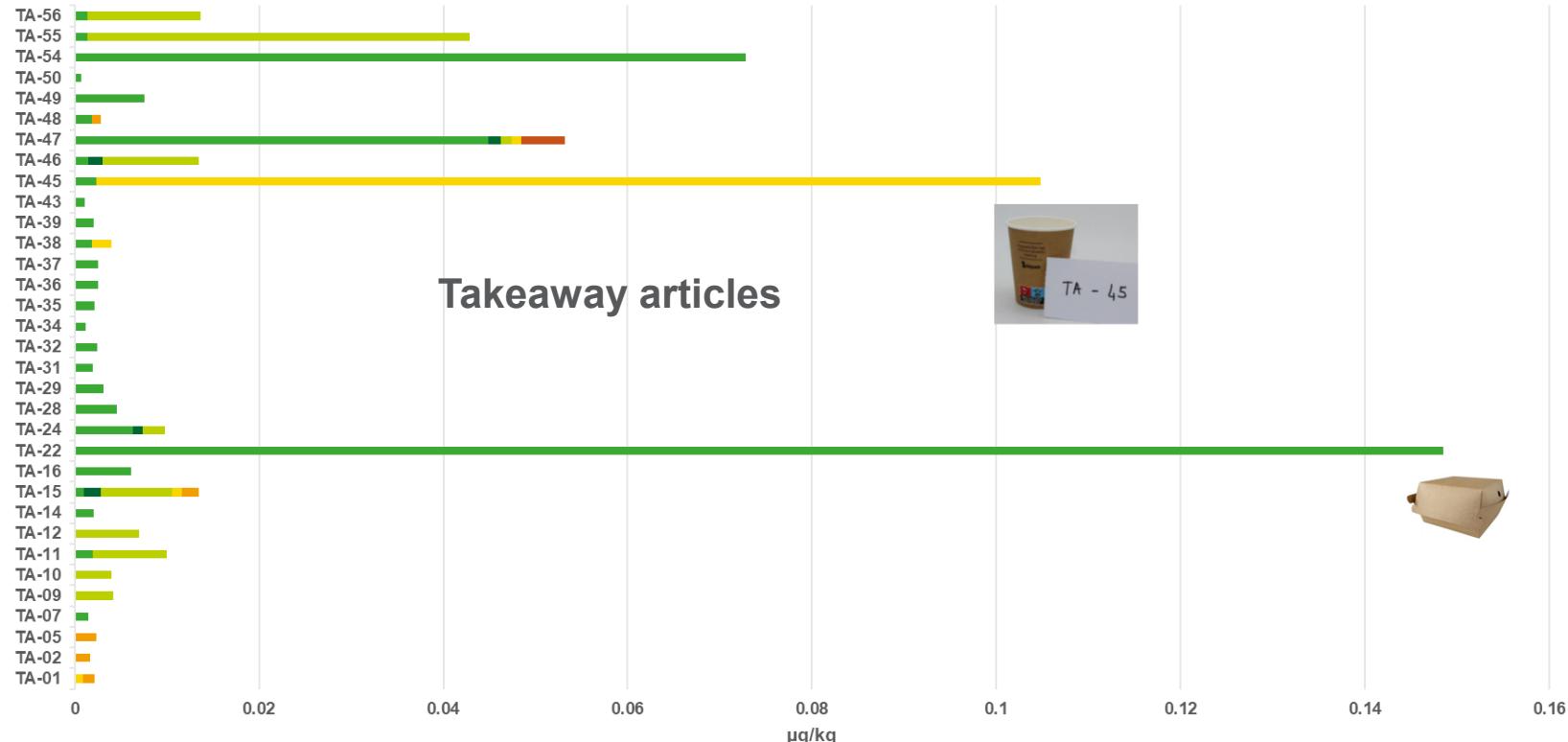
Mineral oil - MOSH



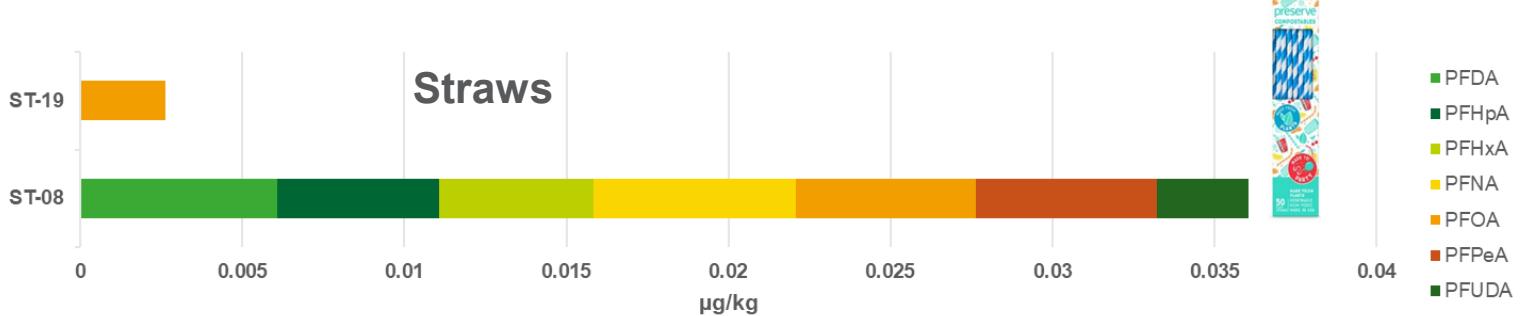
Mineral oil - MOAH



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



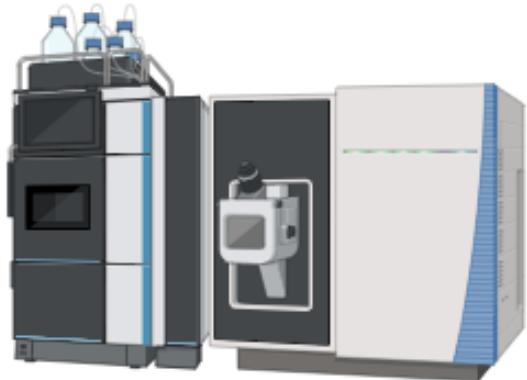
Untargeted screening
using GC(xGC)-TOF/MS

Targeted screening

Target screening method by LC-HRMS of

~ 100 substances

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

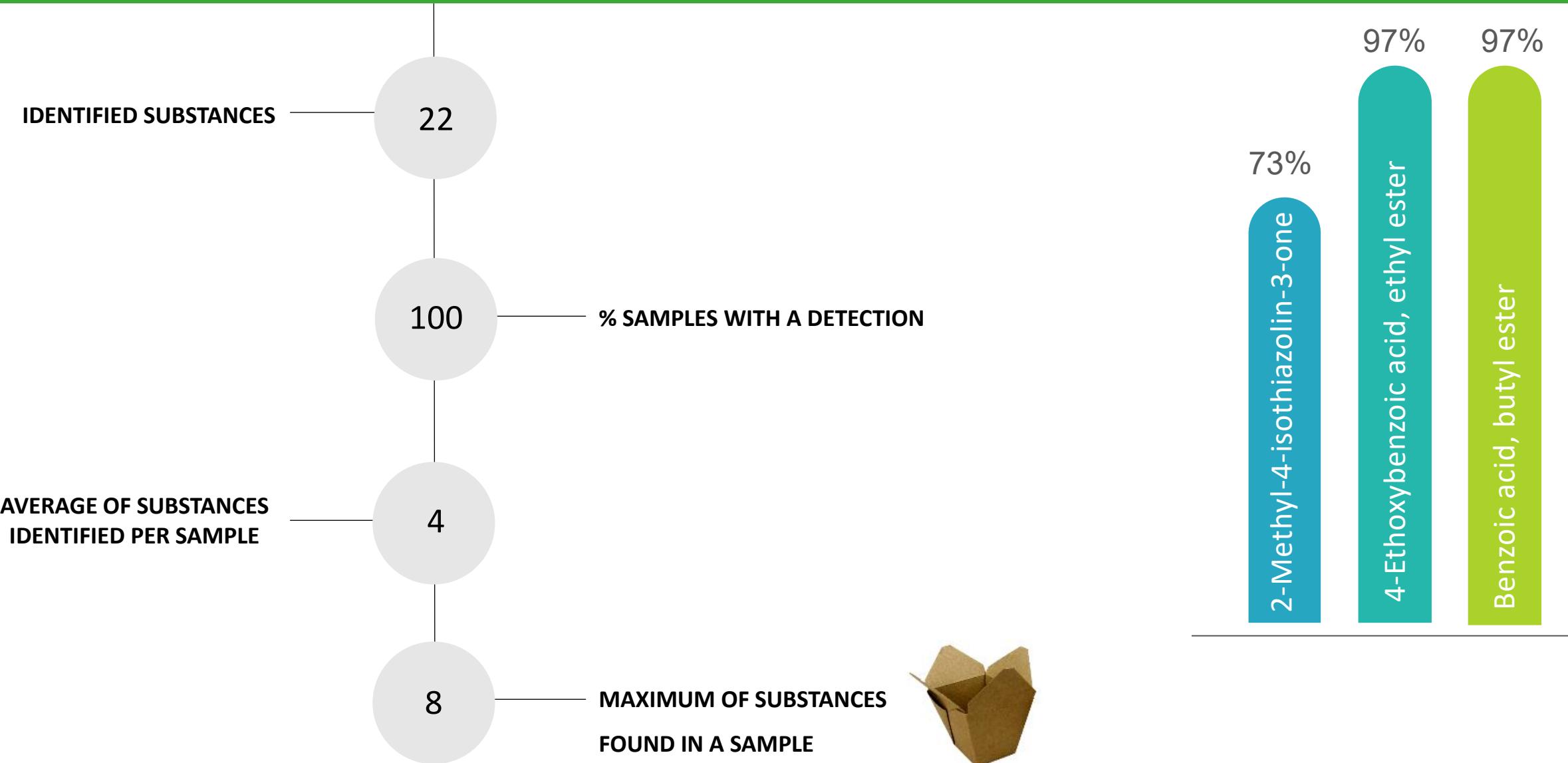


LC-Orbitrap

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

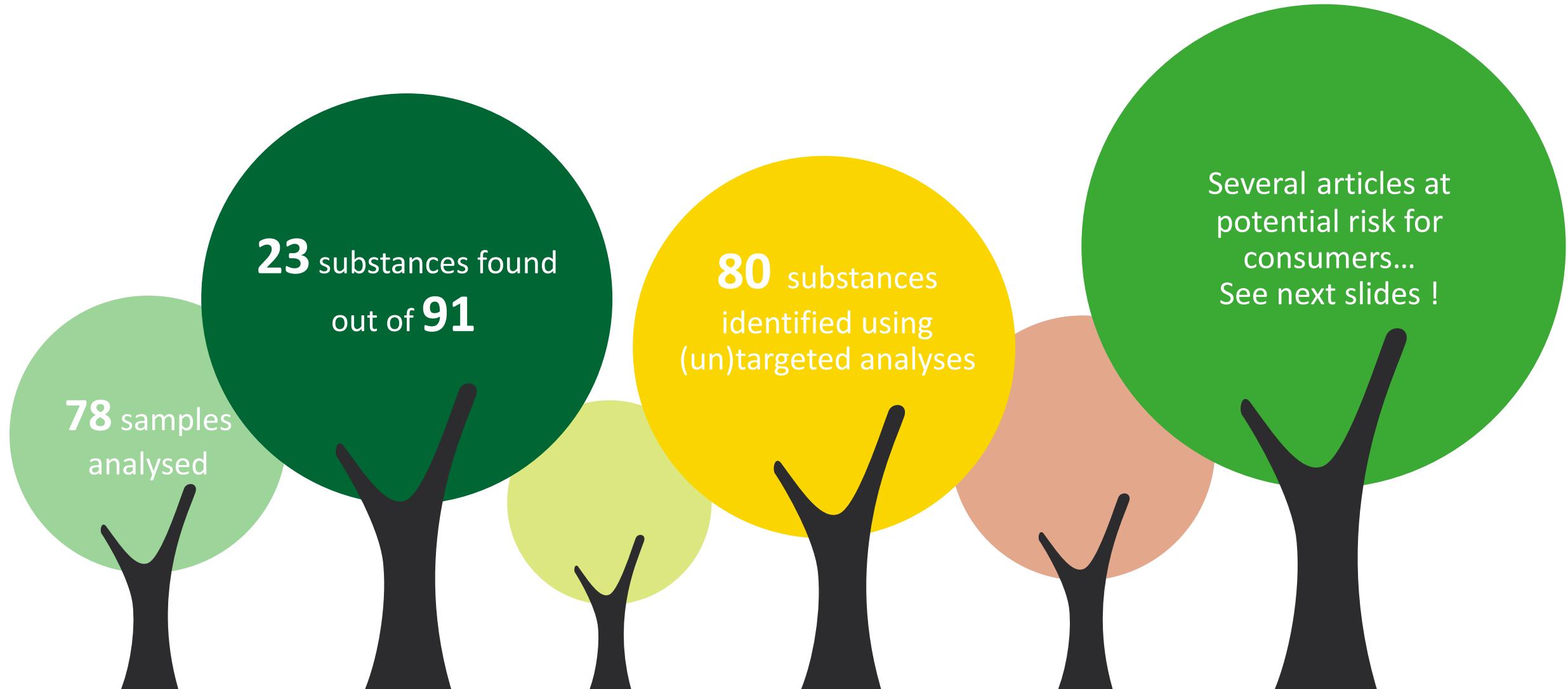
Average of **12** substances per article

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)

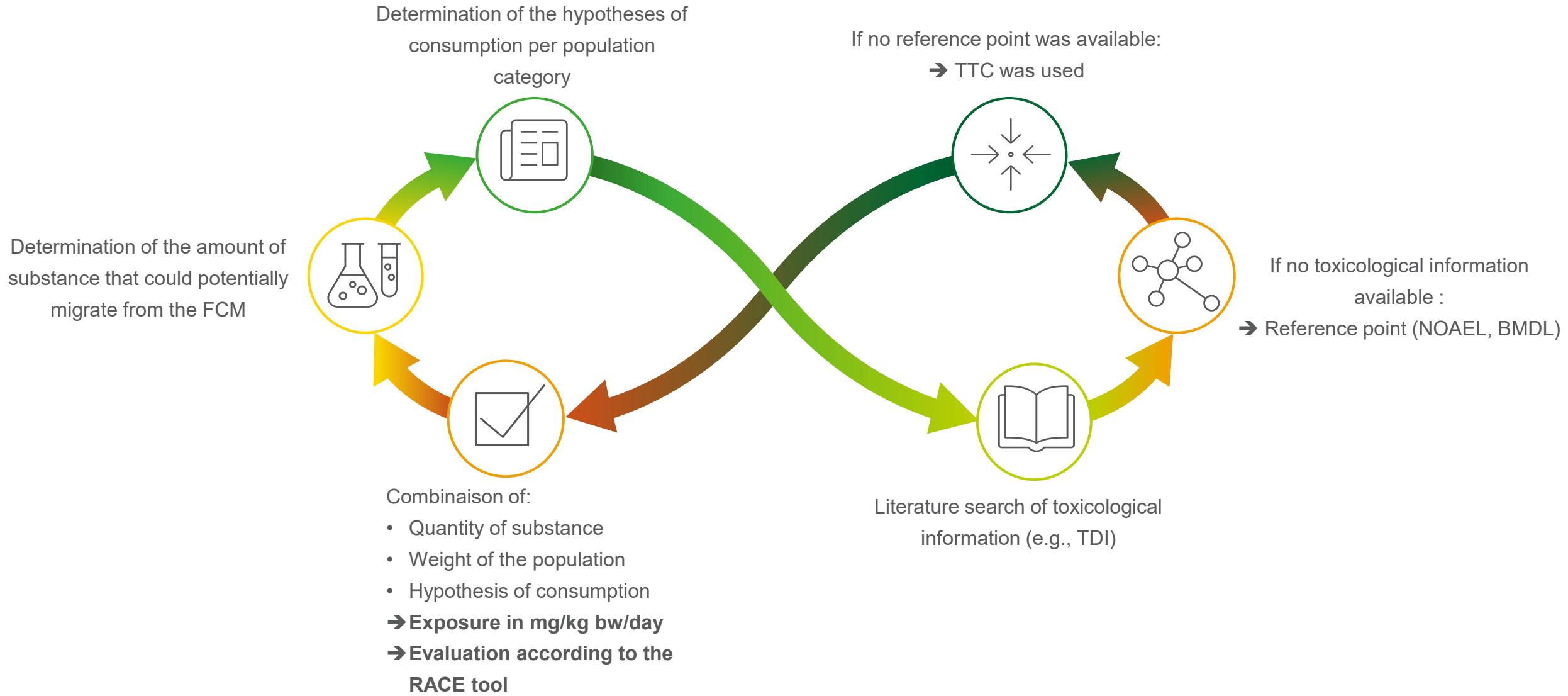


Teenagers
(14-18 years old, 61 kg)



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

TECHNICAL REPORT

APPROVED: 16 April 2019
doi:10.2903/sp.efsa.2019.EN-1625



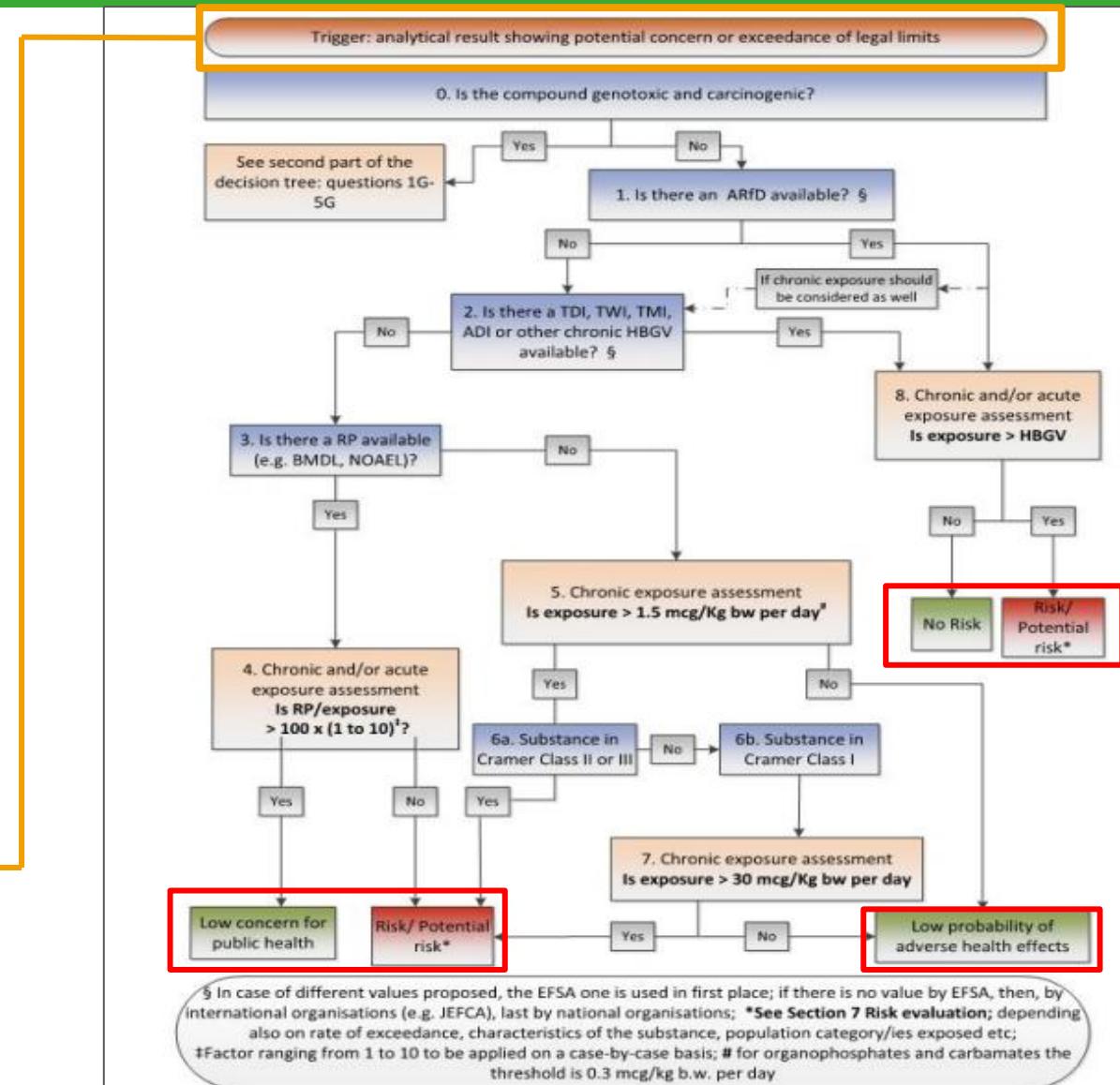
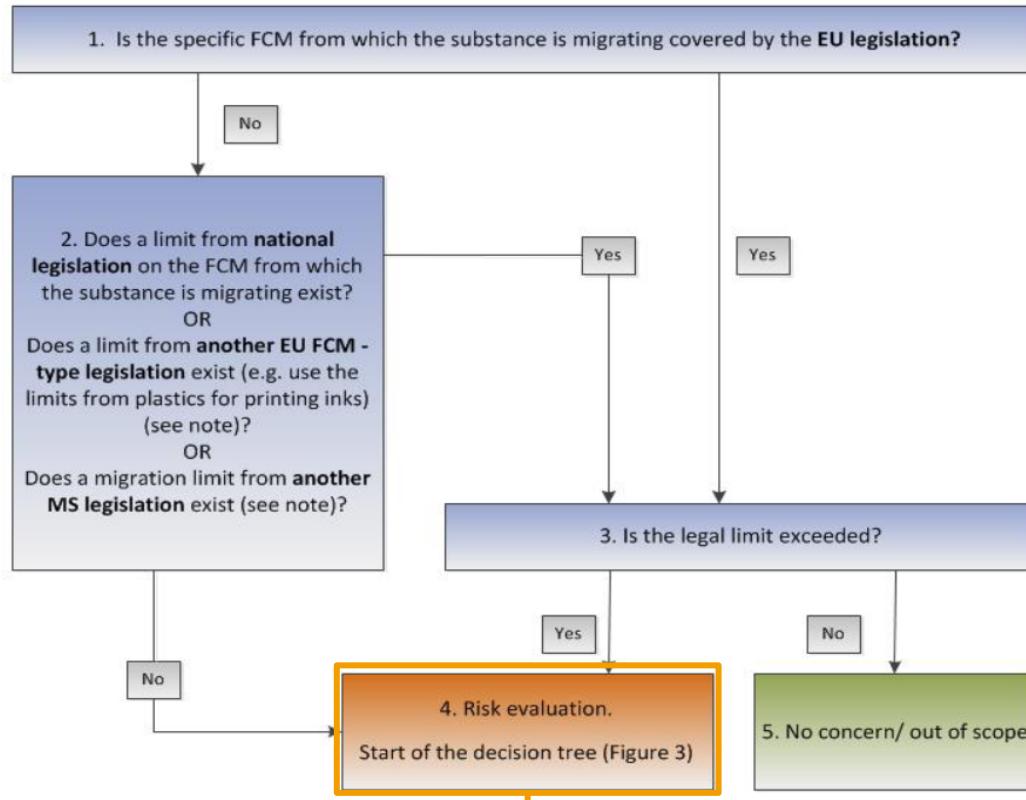
Risk evaluation of chemical contaminants in food in the context of RASFF notifications:

Rapid Assessment of Contaminant Exposure tool (RACE)

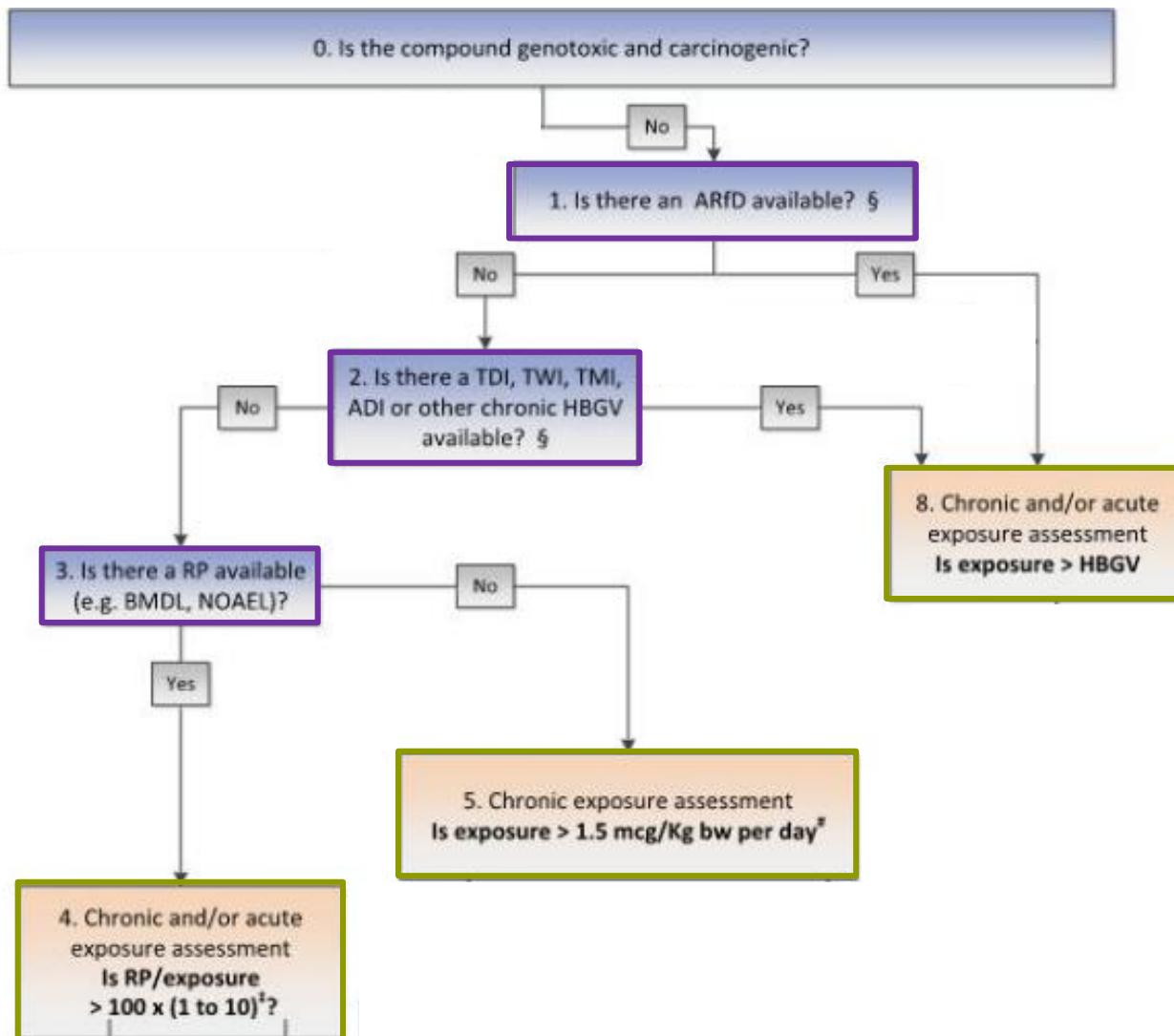
European Food Safety Authority (EFSA), Peter Fürst, Maria Rosaria Milana, Karla Pfaff, Christina Tlustos, Christiane Vleminckx, Davide Arcella, Eric Barthélémy, Paolo Colombo, Tilemachos Goumperis, Luca Pasinato, Ruth Roldán Torres and Ana Afonso

EFSA RACE tool

Pre-decision tree for food contact materials

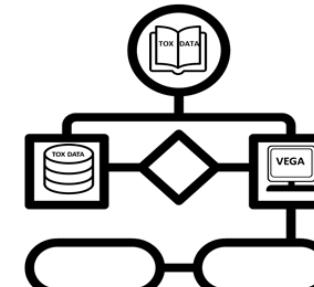


Application of the EFSA RACE tool



Next steps:

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

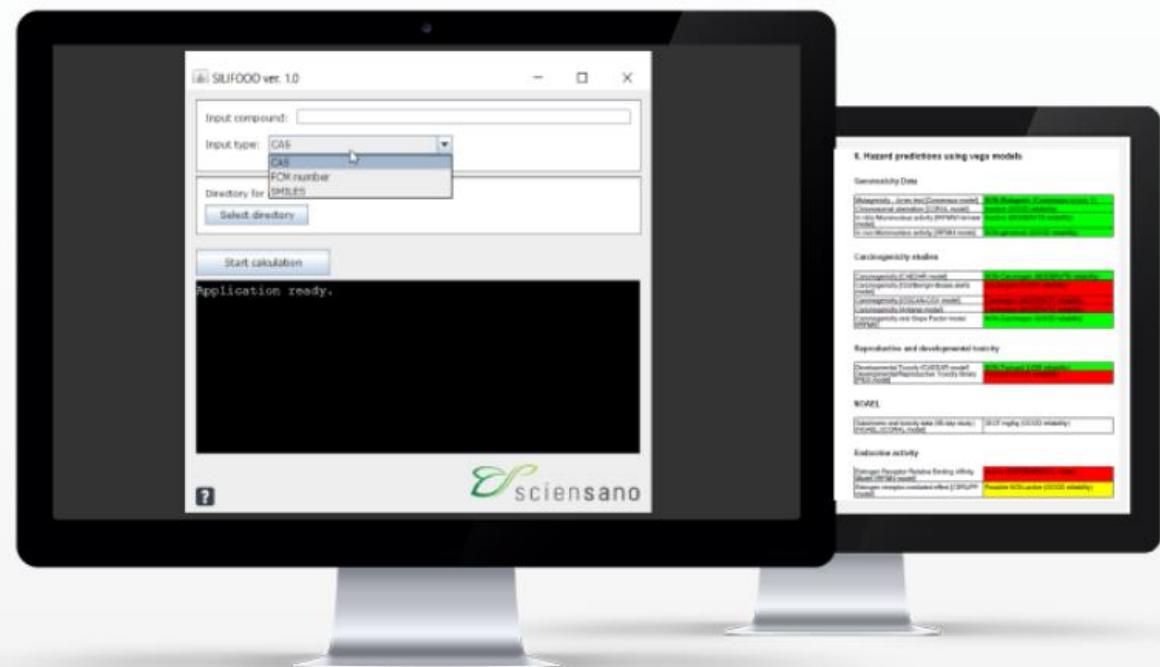


<https://www.vegahub.eu/portfolio-item/silifood/>

SILIFOOD Tool

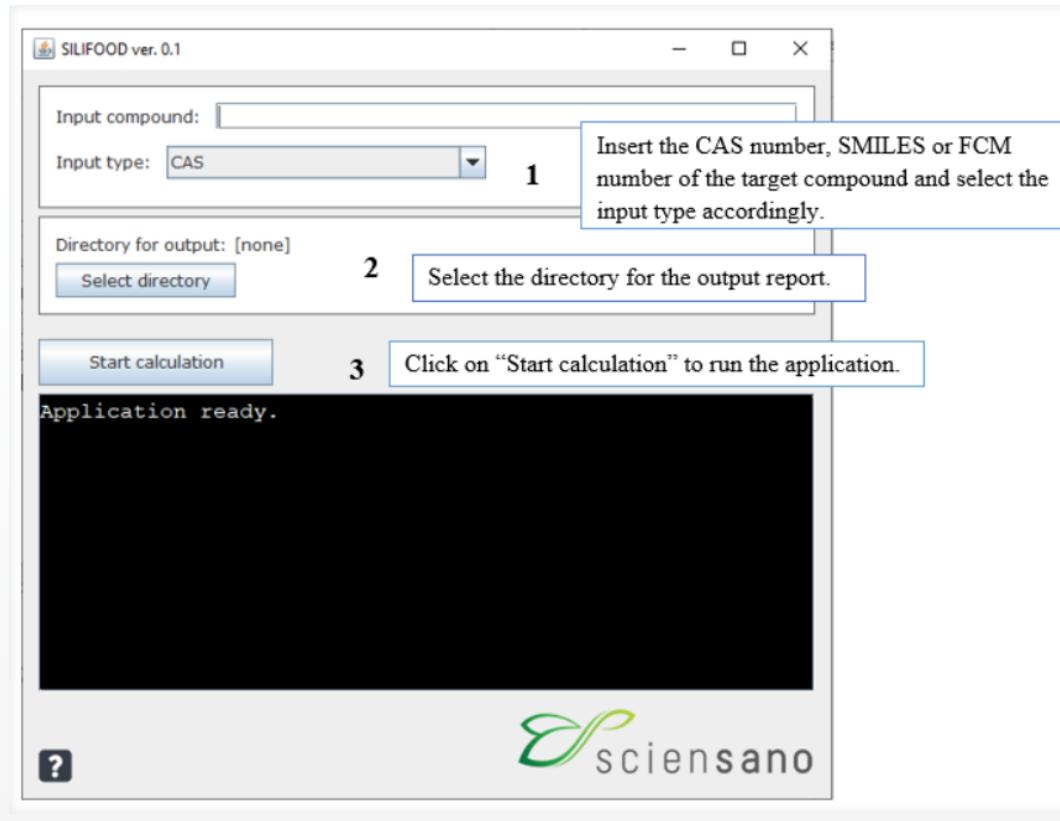
SILIFOOD

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

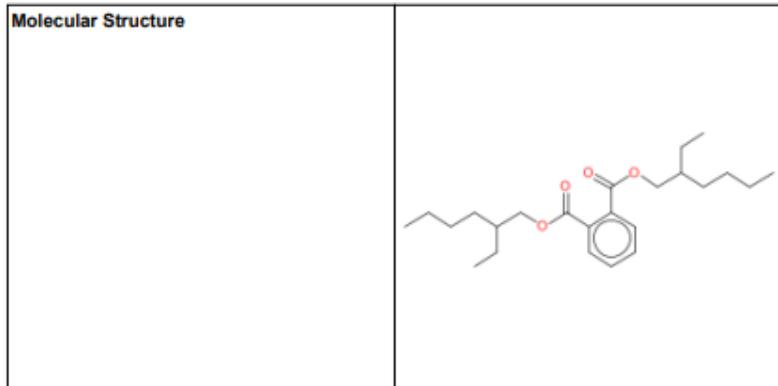


	Evaluation status for use in FCM	Legal limit (SML) - Restrictions & specifications	Health based guidance value (e.g. TDI/ADI)	CMR information	ED information
In house FCM database	X	X	X	X	
EFSA OpenFoodTox database	X	X	X	X	X
CoRAP list (ECHA database)	X			X	X
Biocidal active substance list (ECHA database)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



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)
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Synonyms	Synonyms not found in data source(s)
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CAS number	117-81-7 (A, B, E, F, G, H)
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EC List number	204-211-0 (A, E, F, G, H)
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Molecular formula	C24H38O4 (A)
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Original SMILES	CCCCC(C)COC(=O)C1=CC=CC=C1C(=O) OCC(CC)CCCC (A, B) CCCCC(C)COC(=O)c1cccc1C(=O)OCC(C) CC)CCCC (H) CCCCC(C)COC(=O)c1cccc1C(=O)OCC(C) C)CCCC (E, F, G)
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VEGA SMILES	O=C(OCC(CC)CCCC)c1cccc1(C(=O)OCC(C) C)CCCC (A, B, E, F, H) CCCCC(C)COC(=O)c1cccc1C(=O)OCC(C)
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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 polypropylene glycol 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, Sebamic 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, disiononyl 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/Vermeier 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



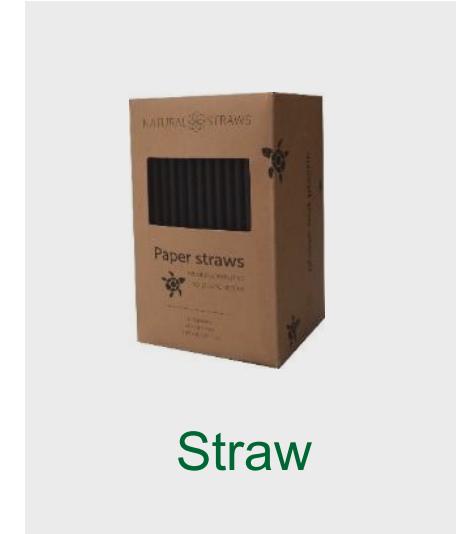
100% of samples contained MOSH !



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



Children Potential risk

Teenagers Potential risk

Adults Potential risk

NOAEL : 236 mg kg⁻¹ 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

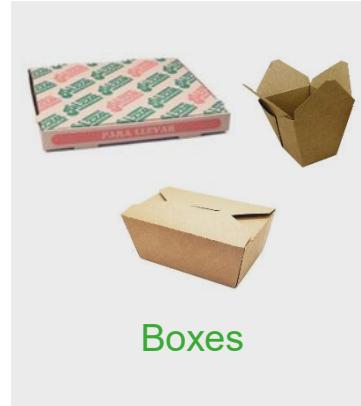
02

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

Risk assessment : MOAH

Scenario 1 : 10%

13/59 samples at potential risk



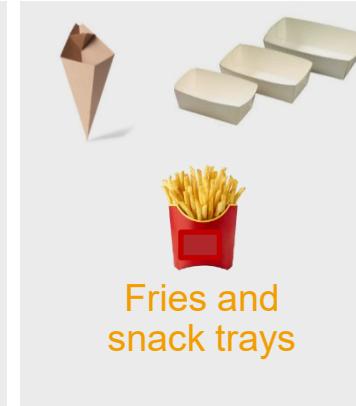
Boxes



Straws



Cups



Fries and
snack trays

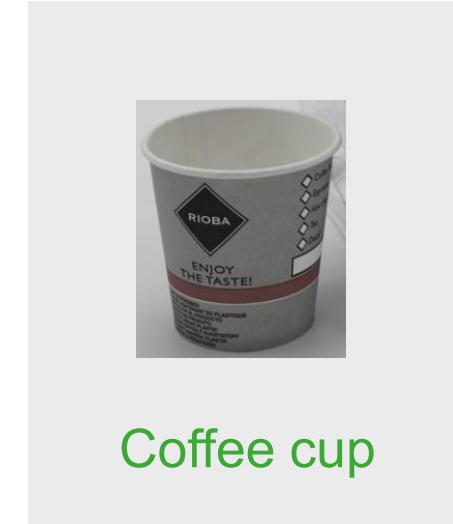
Children	Potential risk	Potential risk	Potential risk	Potential risk
Teenagers	Potential risk	Potential risk	Potential risk	Potential risk
Adults	Potential risk	Low concern	Potential risk	Potential risk

BMDL10 : 0.49 mg kg⁻¹ bw day

Risk assessment : MOAH

2/59
samples at potential risk

Scenario 2 : 1%



Children

Potential risk

Potential risk

Teenagers

Potential risk

Potential risk

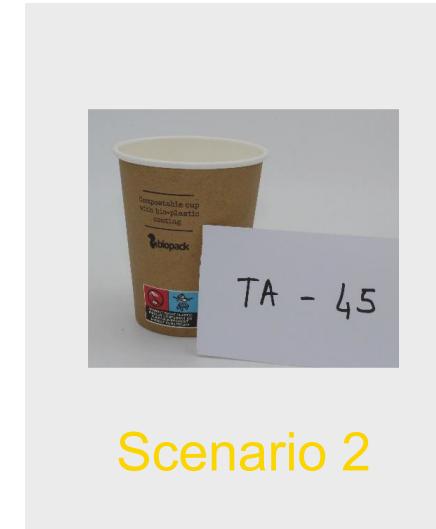
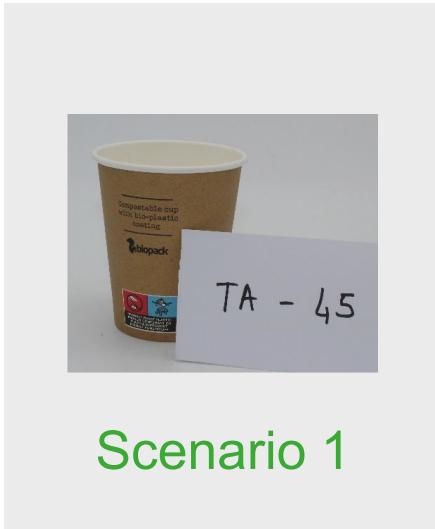
Adults

Potential risk

Potential risk

Risk assessment : PFAS

Scenario 1 :
 Σ EFSA-PFAS



Scenario 2 :
 Σ all detected PFAS

Relative Potency Factor approach

Children

NA

Potential risk

NA

Teenagers

Potential risk

No risk

Potential risk

Adults

Potential risk

No risk

Potential risk

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!