

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

RAFA 2024

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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

”

Introduction



What are the potential risks related to these FCM?



Objectives



WP1
Market study



WP2
Selection of compounds



WP3
Selection of the samples



WP5
Risk assessment of migrants



WP4
Identification of (potential) migrants

Market study



WEB SCRAPING

59 Websites consulted



KEY WORDS

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

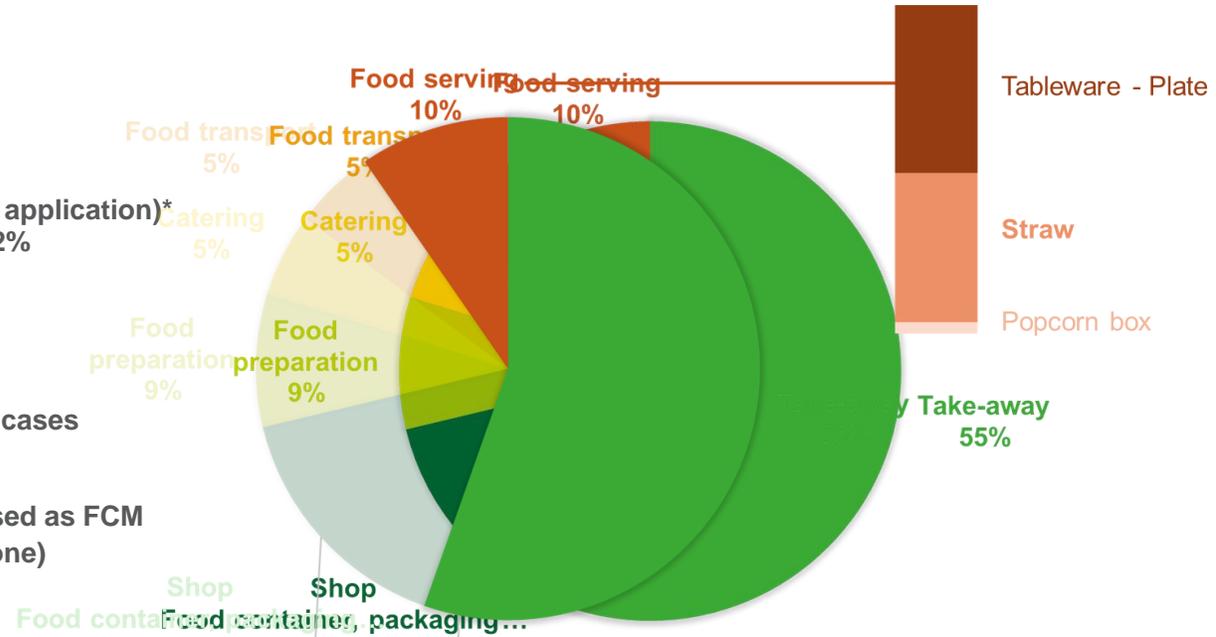
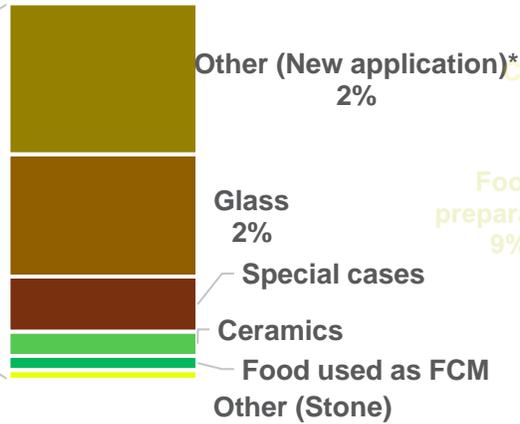
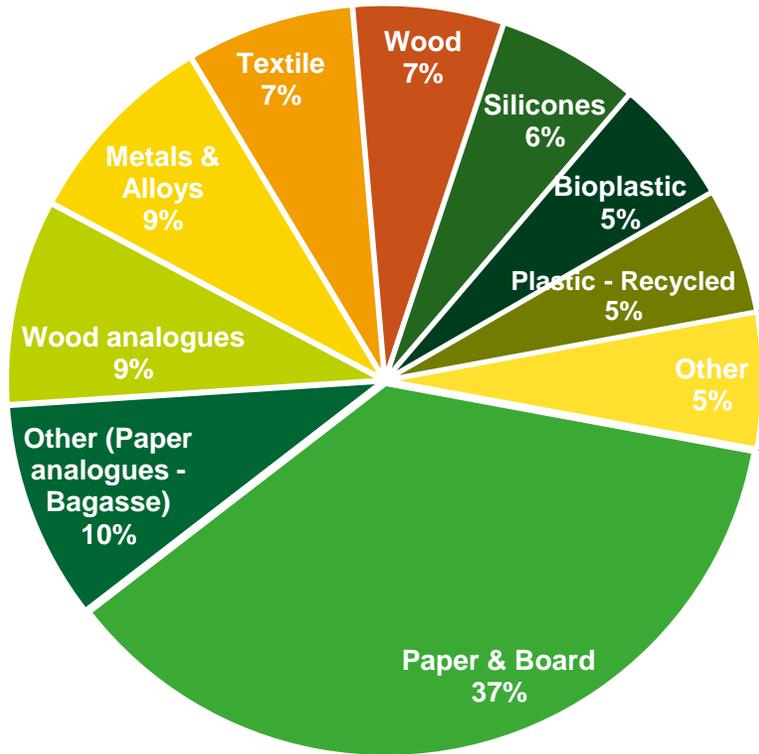
DATA CLEANING & HARMONIZATION



Market study



Market study



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

Identification of potential migrants

Analytical strategy



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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



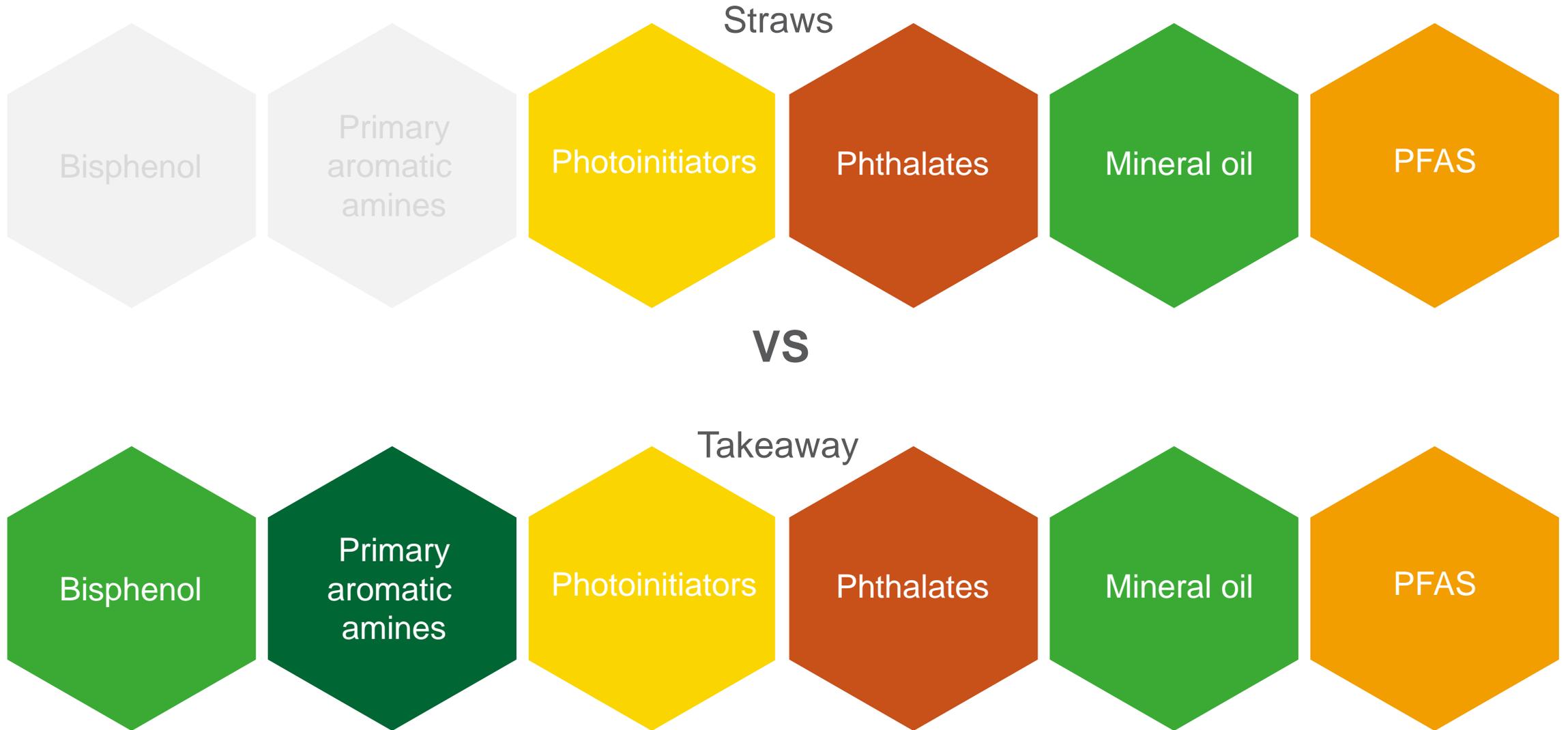
Primary aromatic amines



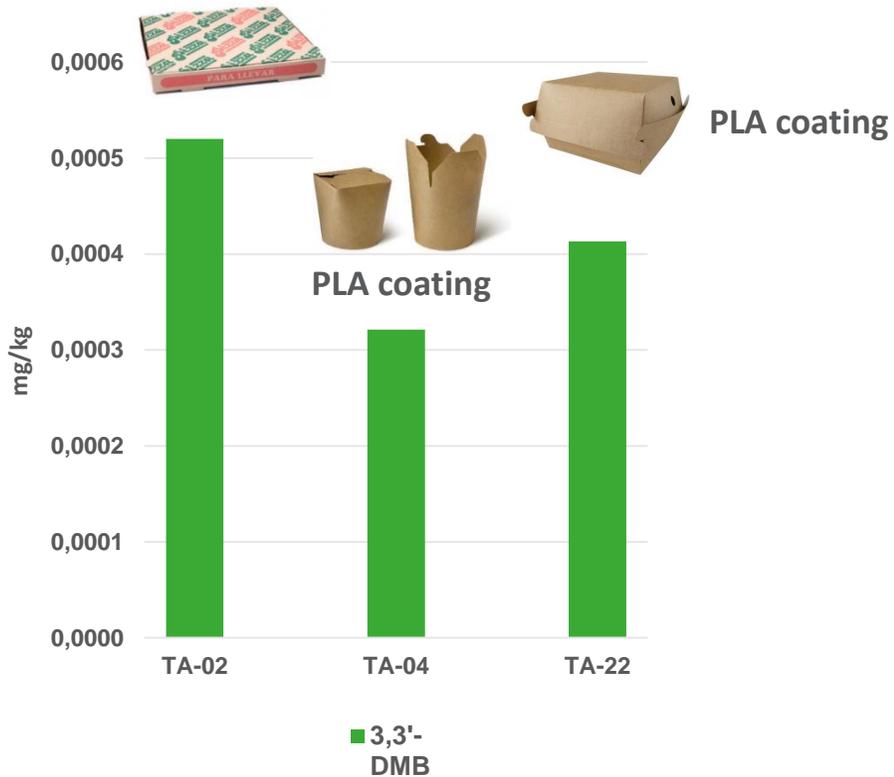
Photoinitiators



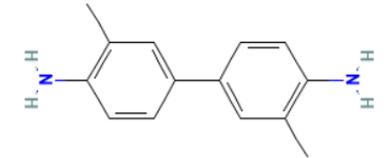
Results overview



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

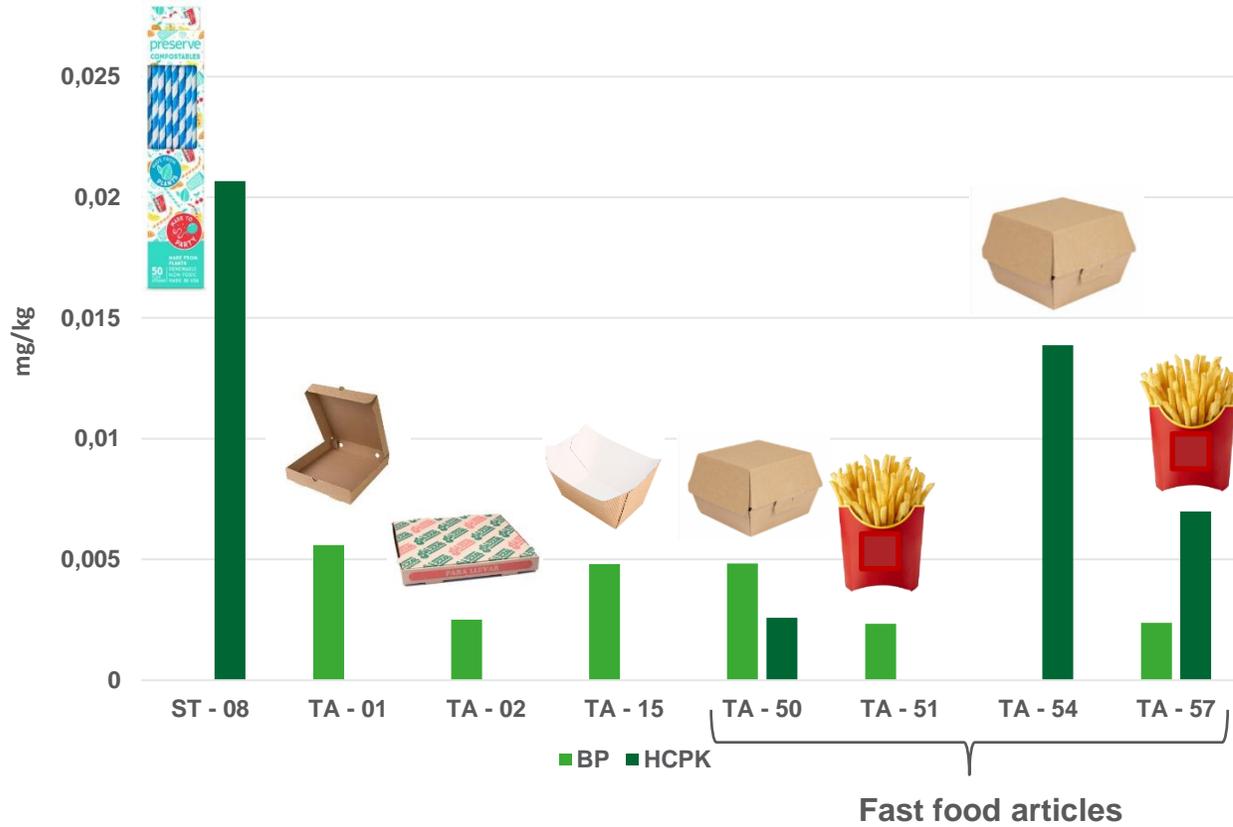


2 bisphenols found out of 5
11 samples out of 58 (19,0%)



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%)



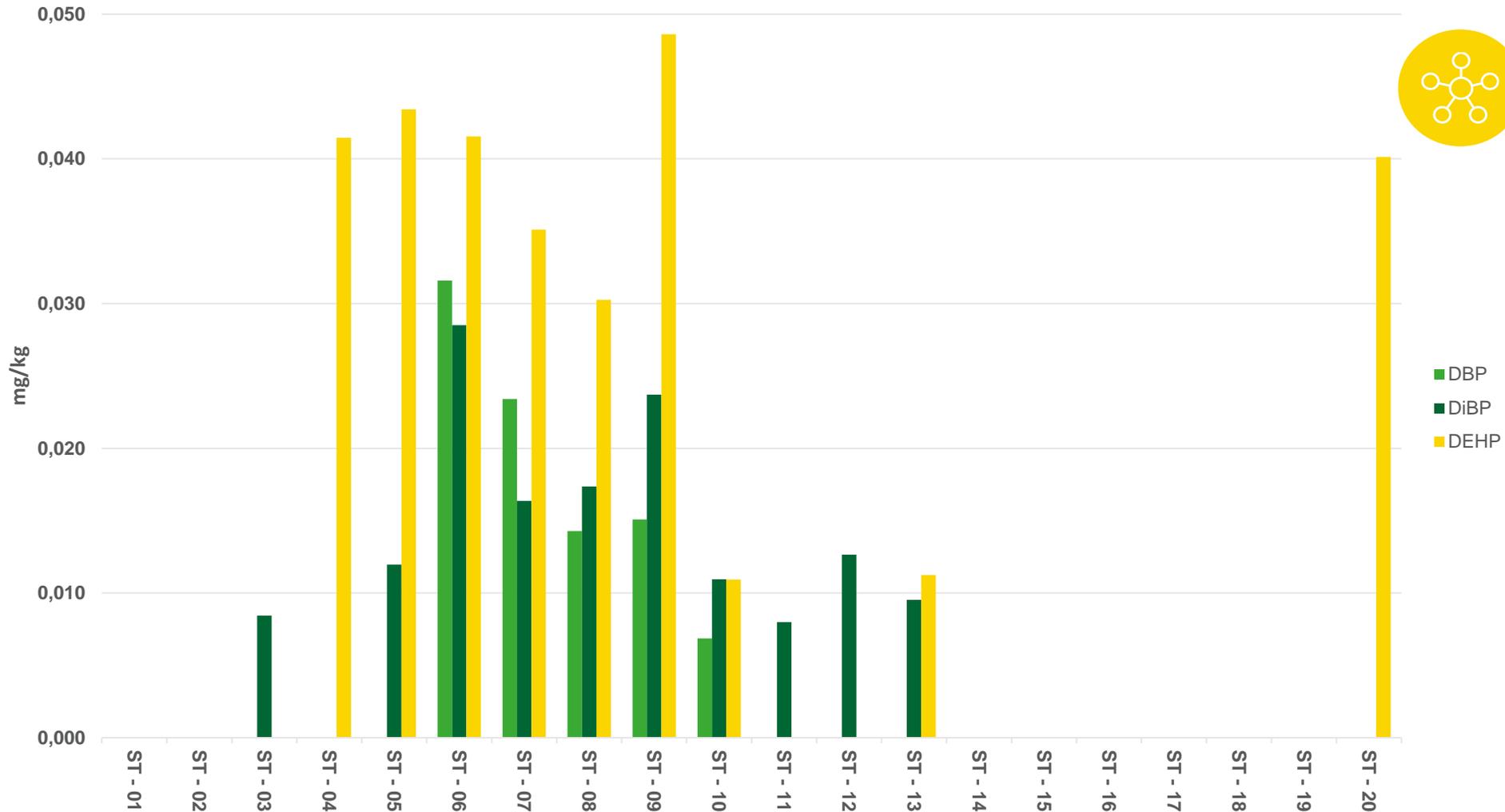
Benzophenone ranging from 0.0023 up to 0.005 mg/kg
HCPK ranging from 0.003 up to 0.02 mg/kg



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

Phthalates in straws

Concentrations of phthalates in straws

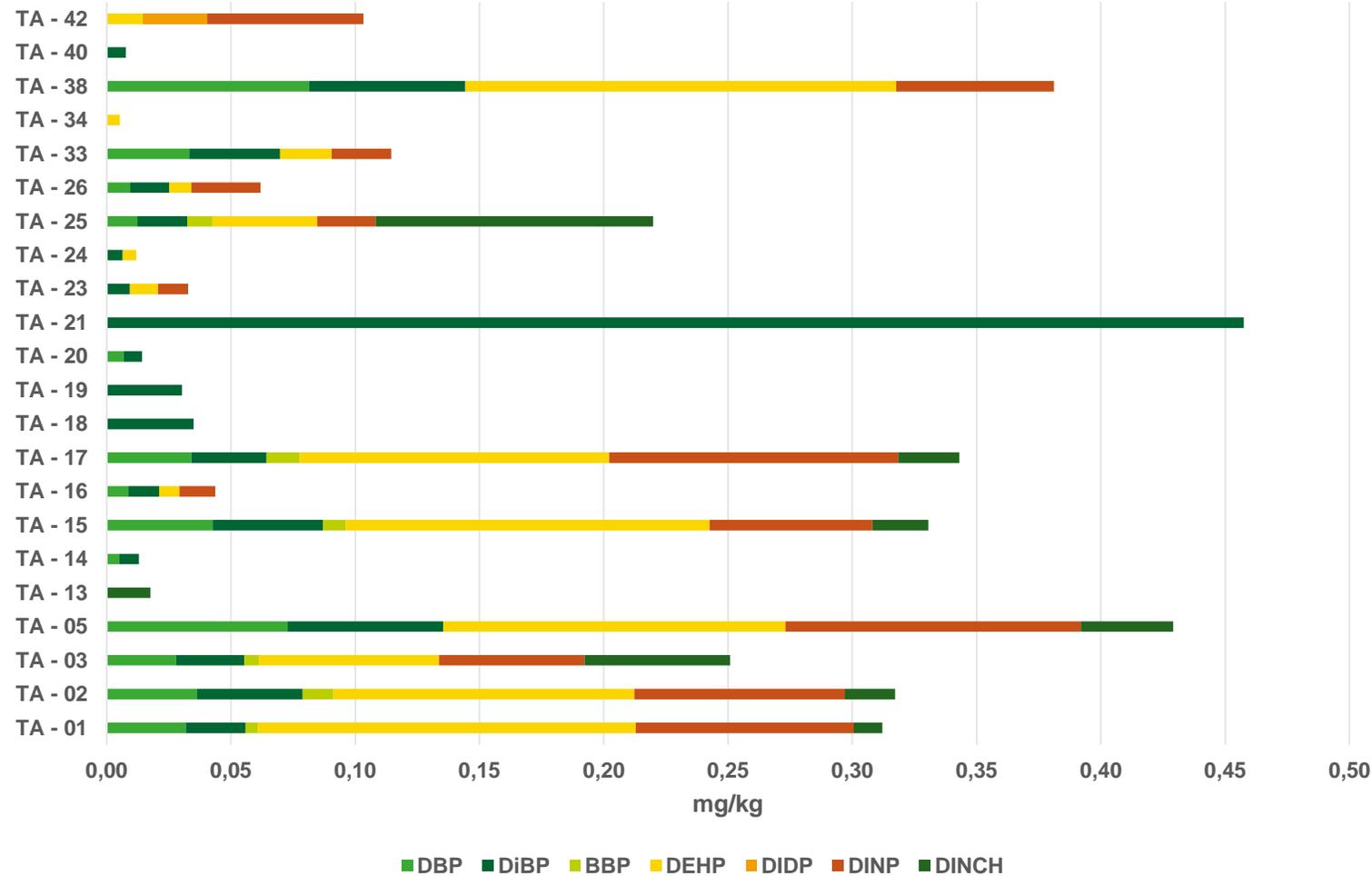


3 phthalates found out of 14
12 samples out of 20 (60%)

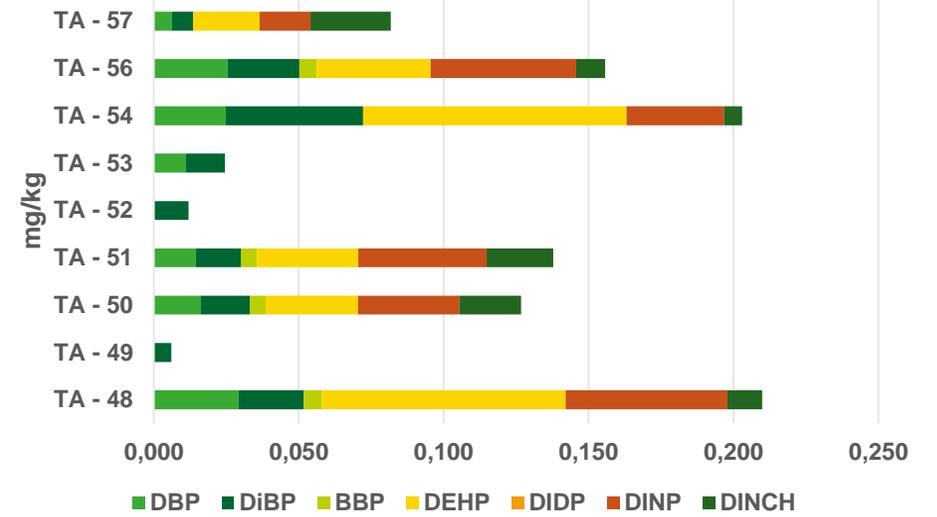
■ DBP
■ DiBP
■ DEHP

Phthalates in takeaway samples

Concentrations of phthalates in takeaway samples

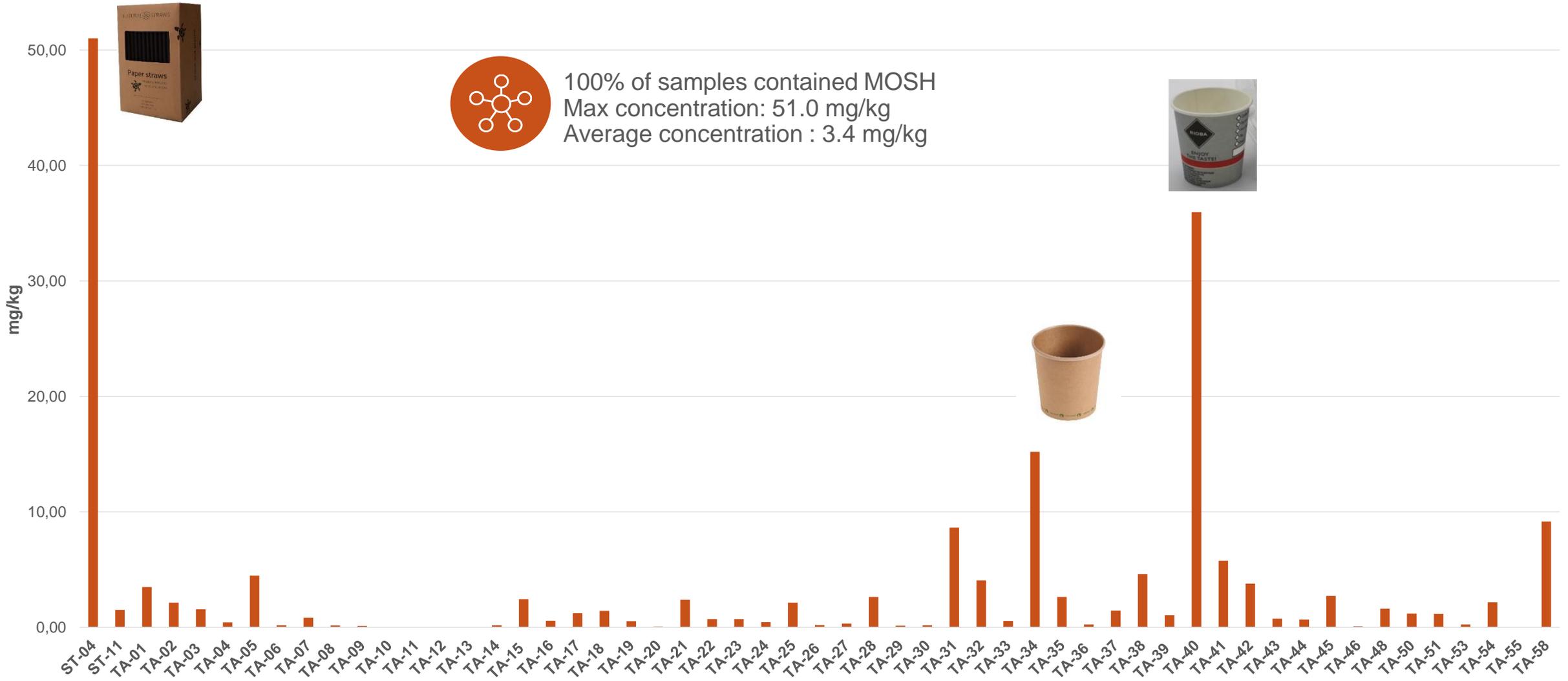


Concentrations of phthalates in fast food samples

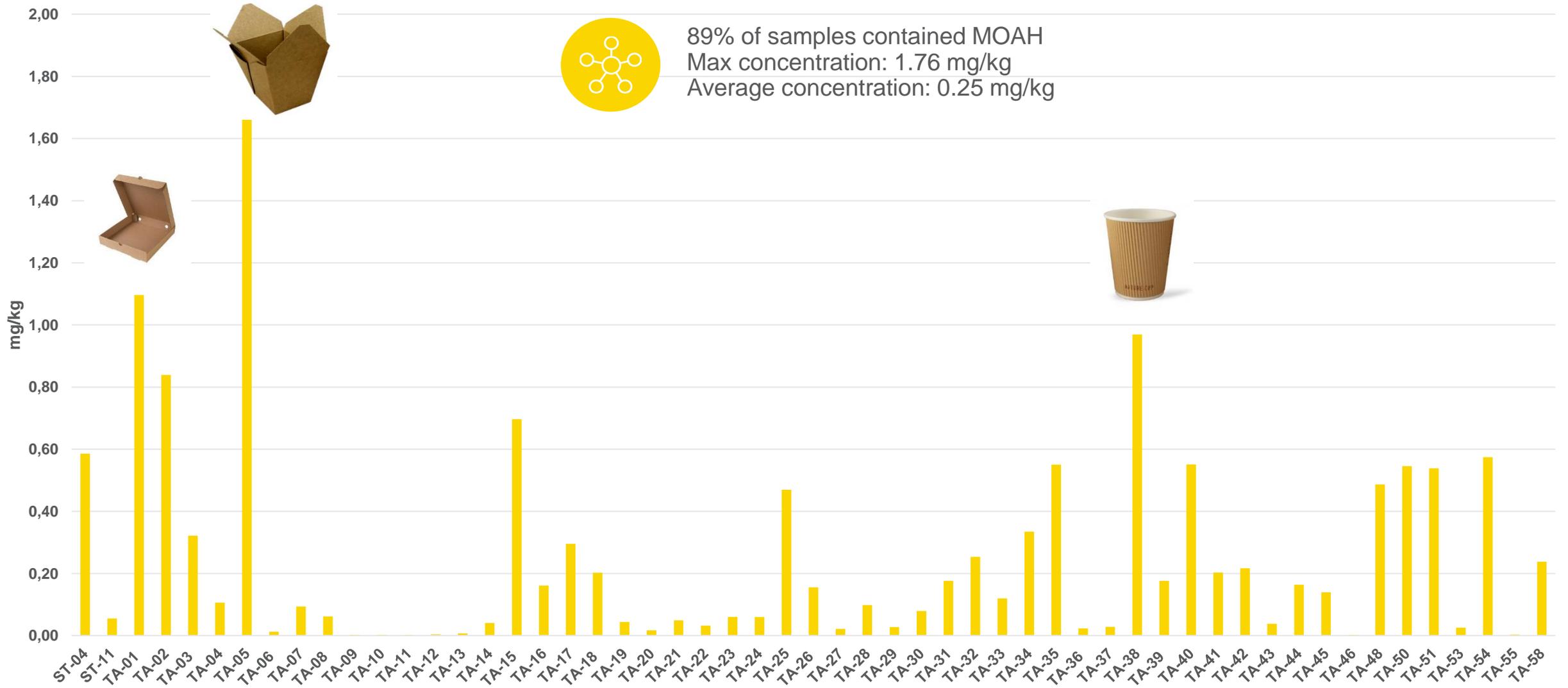


7 phthalates found out of 14
38 samples out of 58 (65,5%)

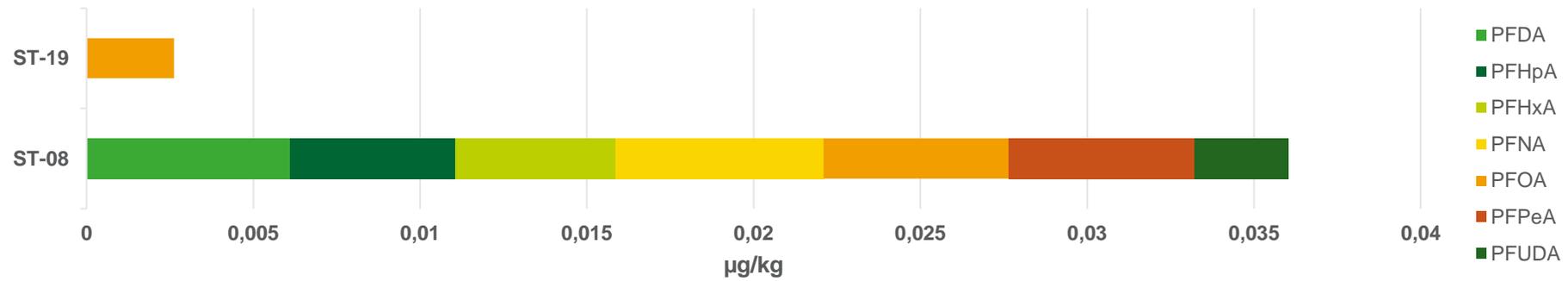
Mineral oil - MOSH



Mineral oil - MOAH

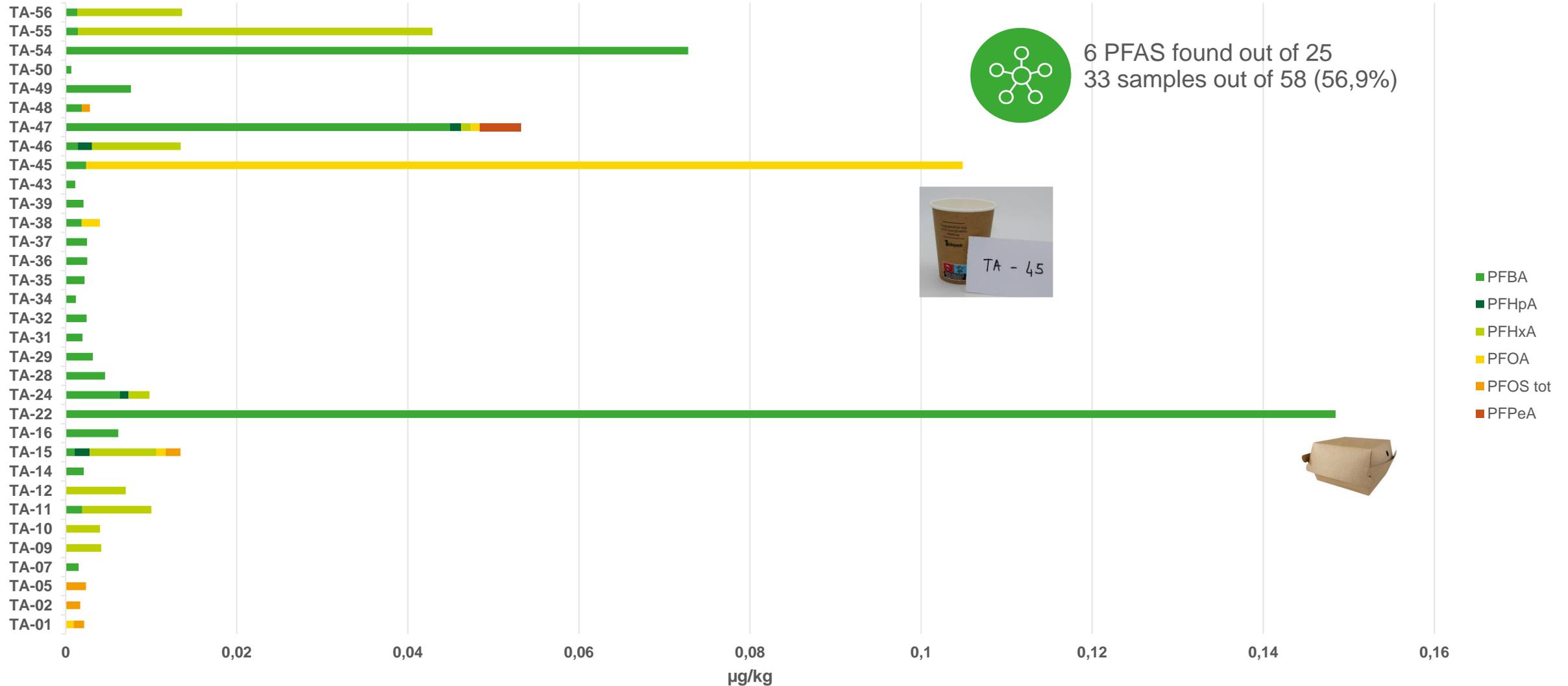


PFAS in straws

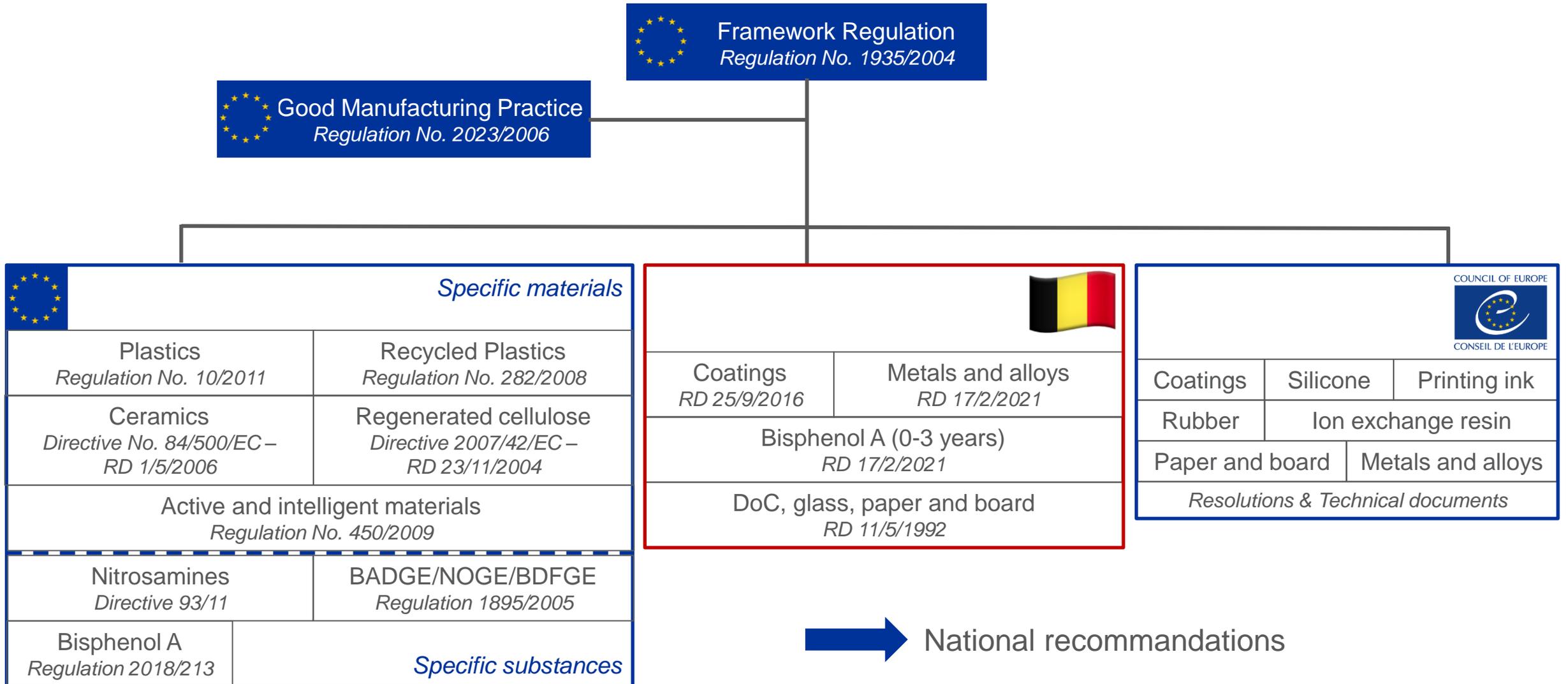


7 PFAS found out of 25
2 samples out of 20 (10%)

PFAS in takeaway articles



FCM legislation & resolutions



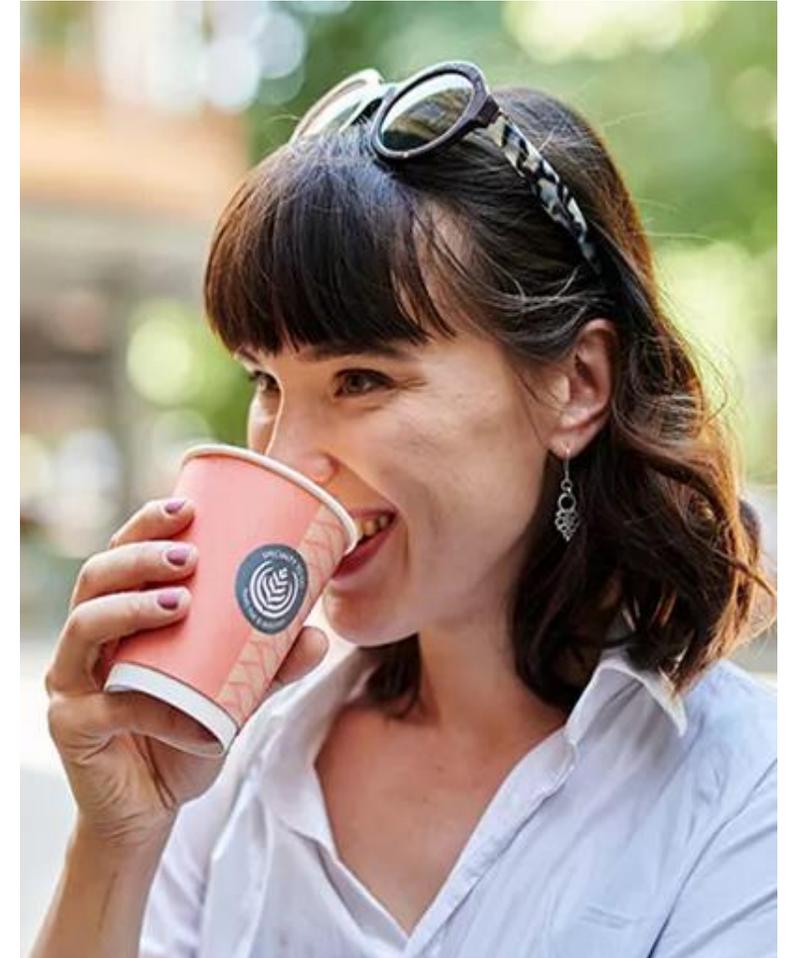
Targeted populations



Children
(3-10 years old, 23 kg)

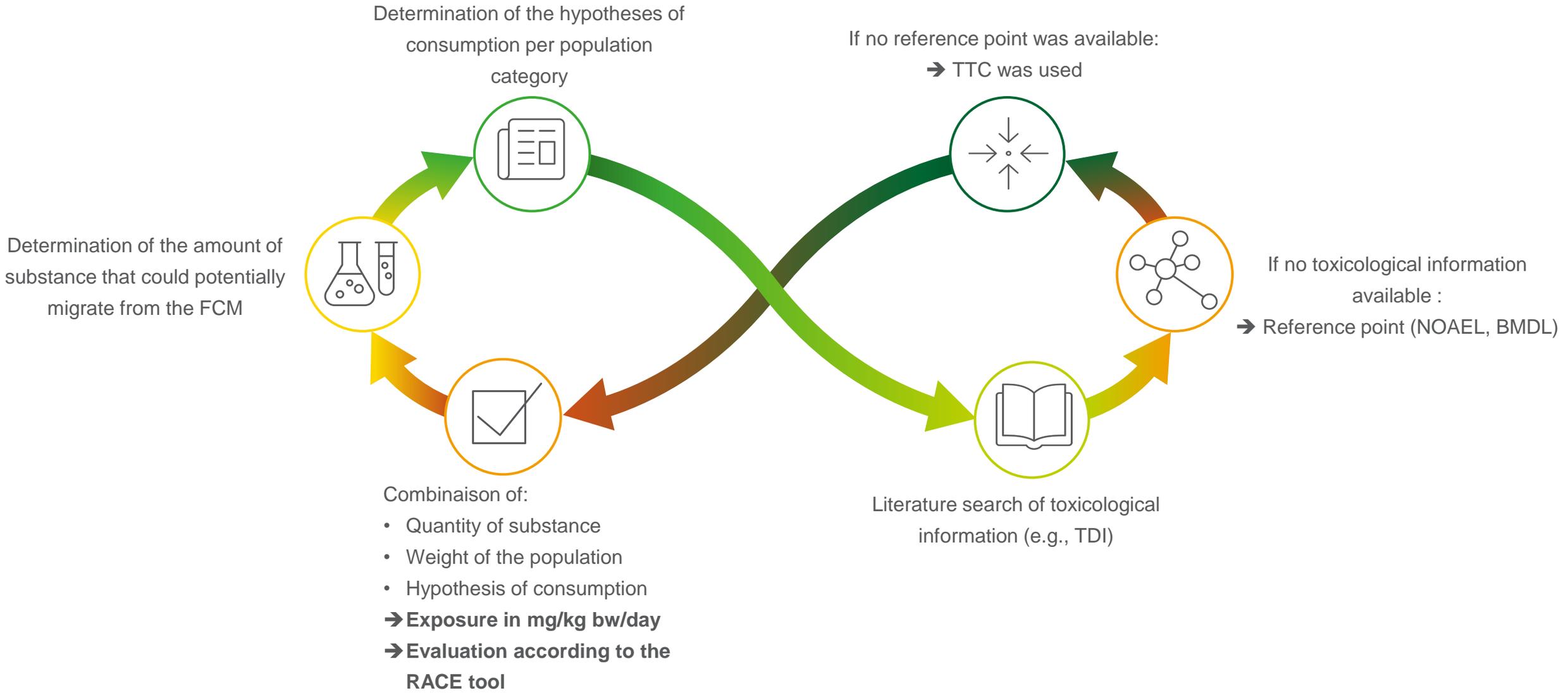


Teenagers
(14-18 years old, 61 kg)



Adults
(18-64 years old, 70 kg)

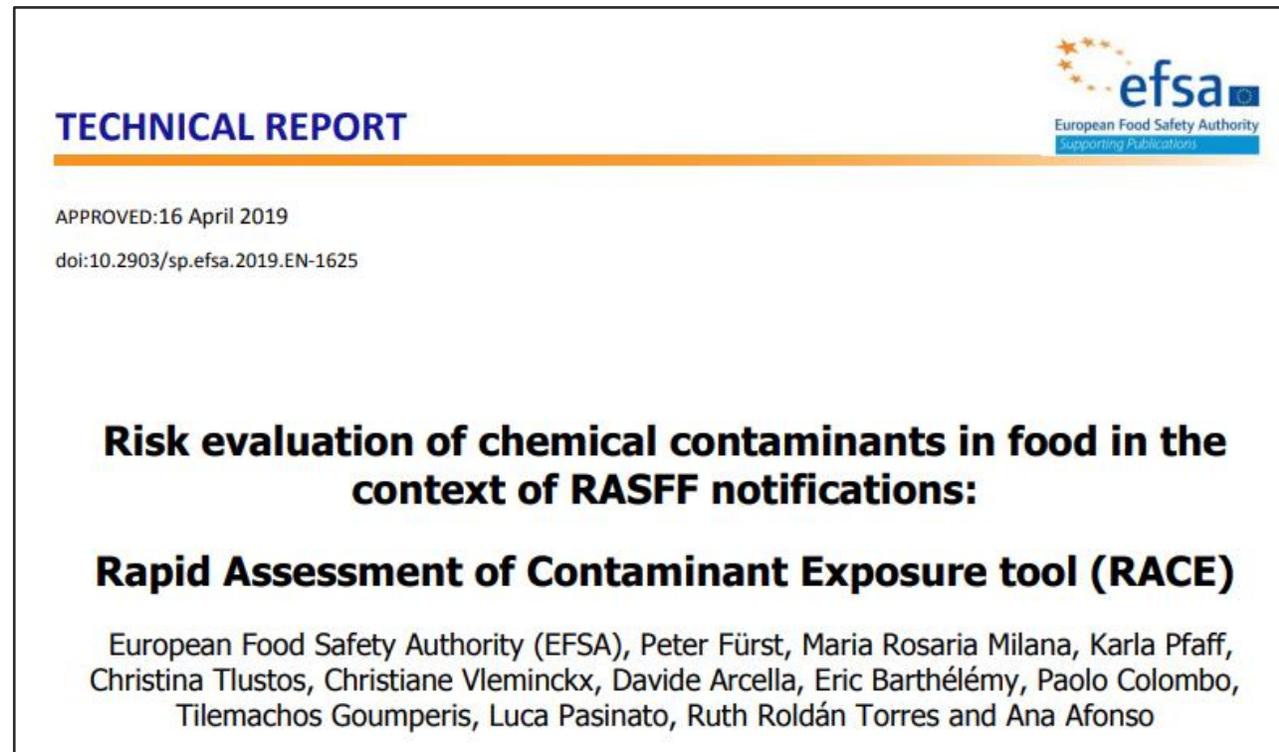
Workflow of the risk assessment



Risk assessment of the quantified migrants

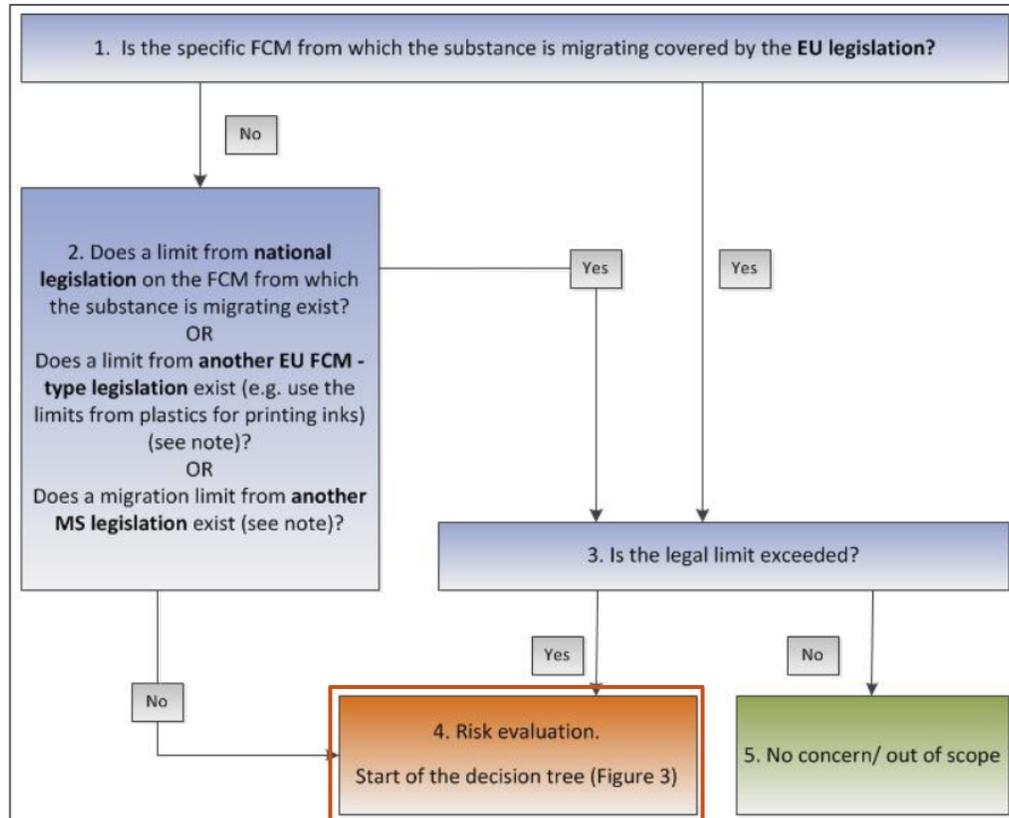
RACE tool

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

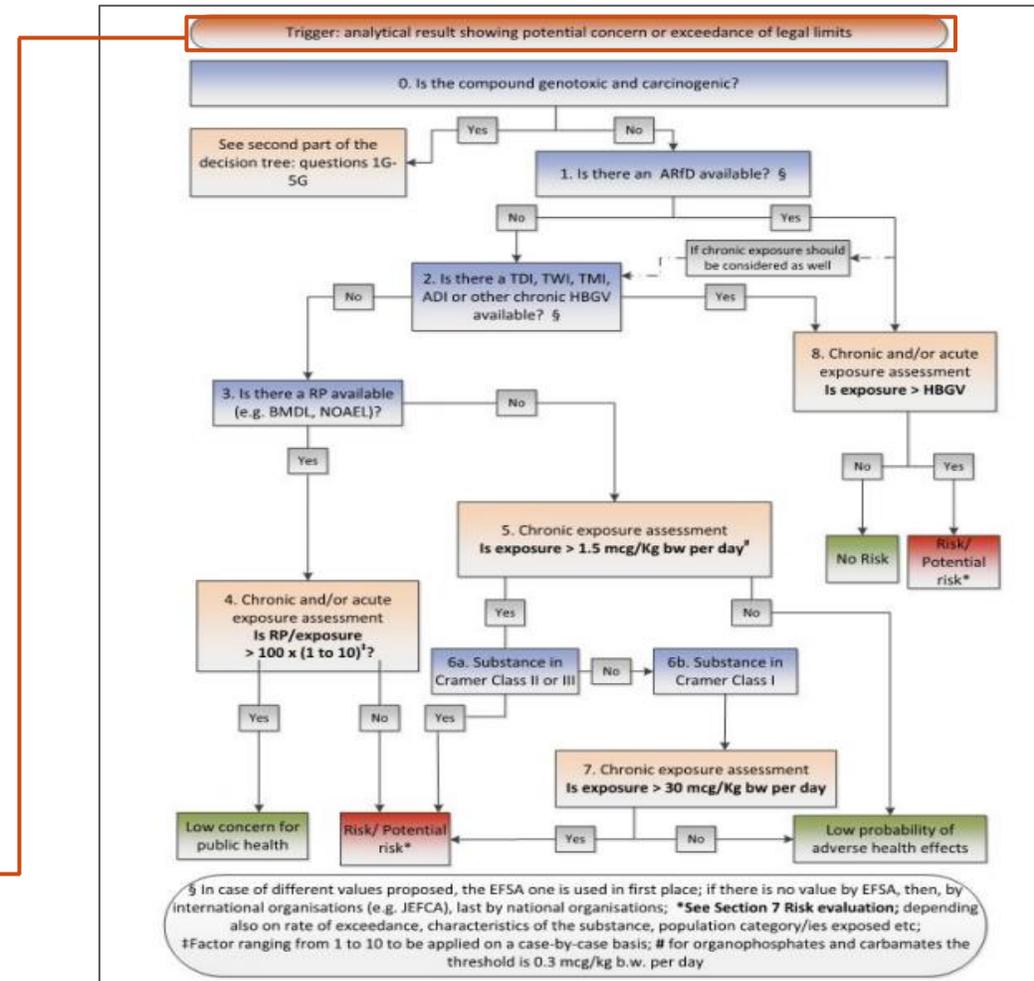


EFSA RACE tool

Pre-decision tree for food contact materials



Decision tree for food contact materials



EFSA RACE tool

Pre-decision tree for food contact materials

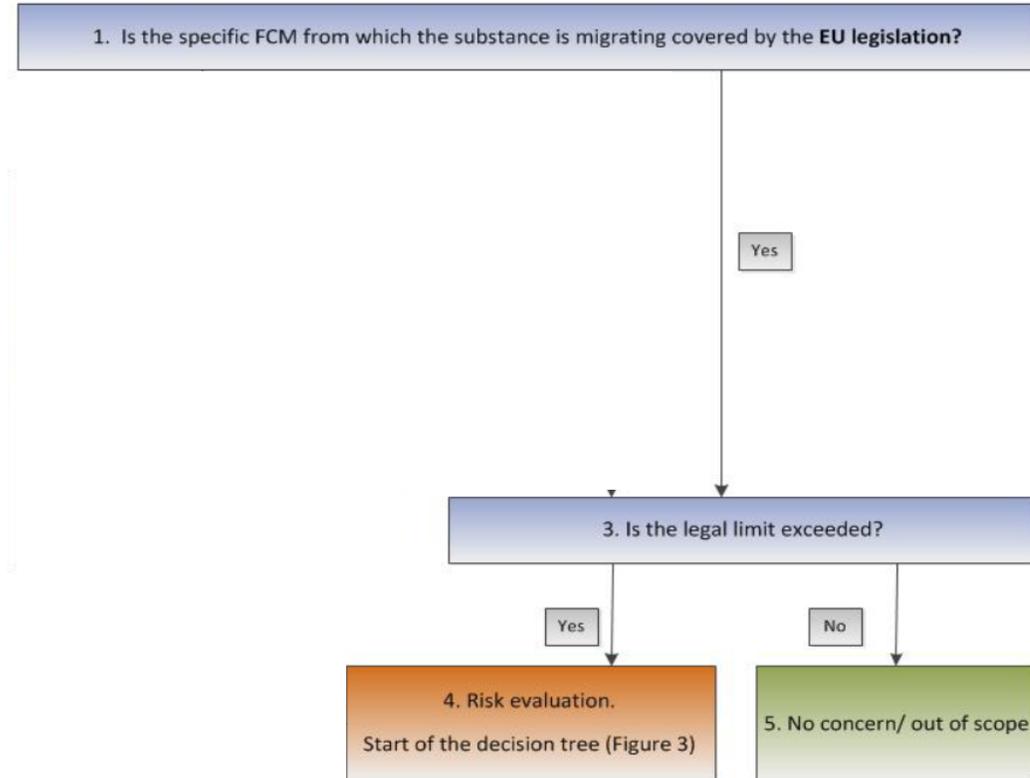
1. Is the specific FCM from which the substance is migrating covered by the EU legislation?

Yes

3. Is the legal limit exceeded?

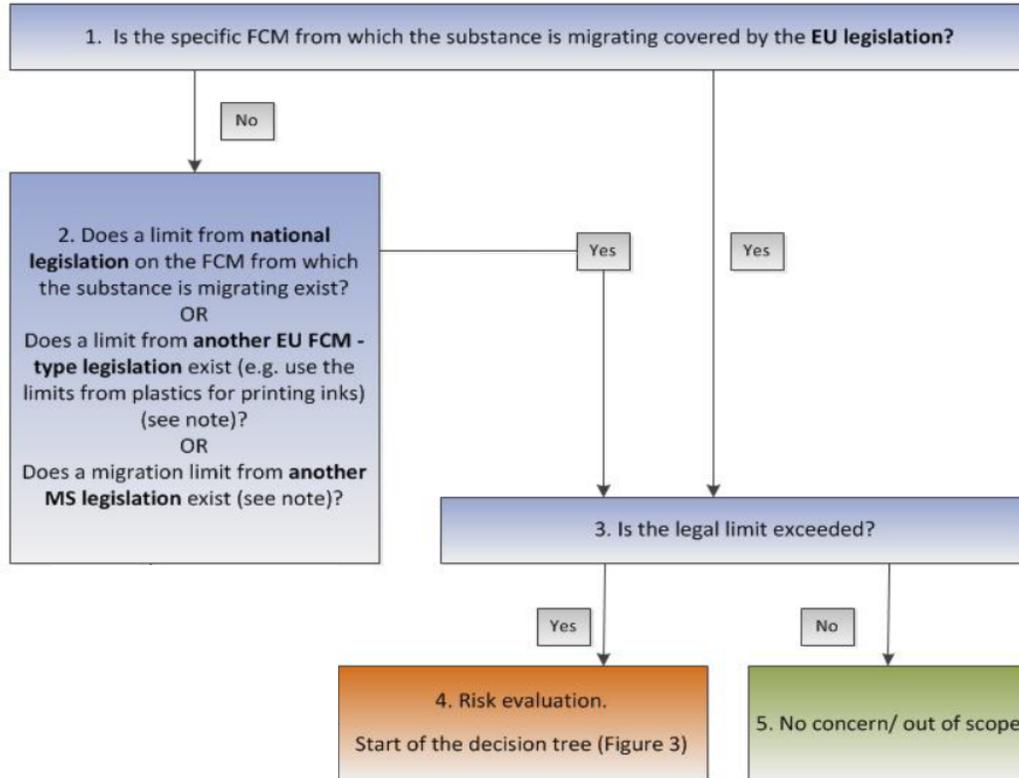
EFSA RACE tool

Pre-decision tree for food contact materials



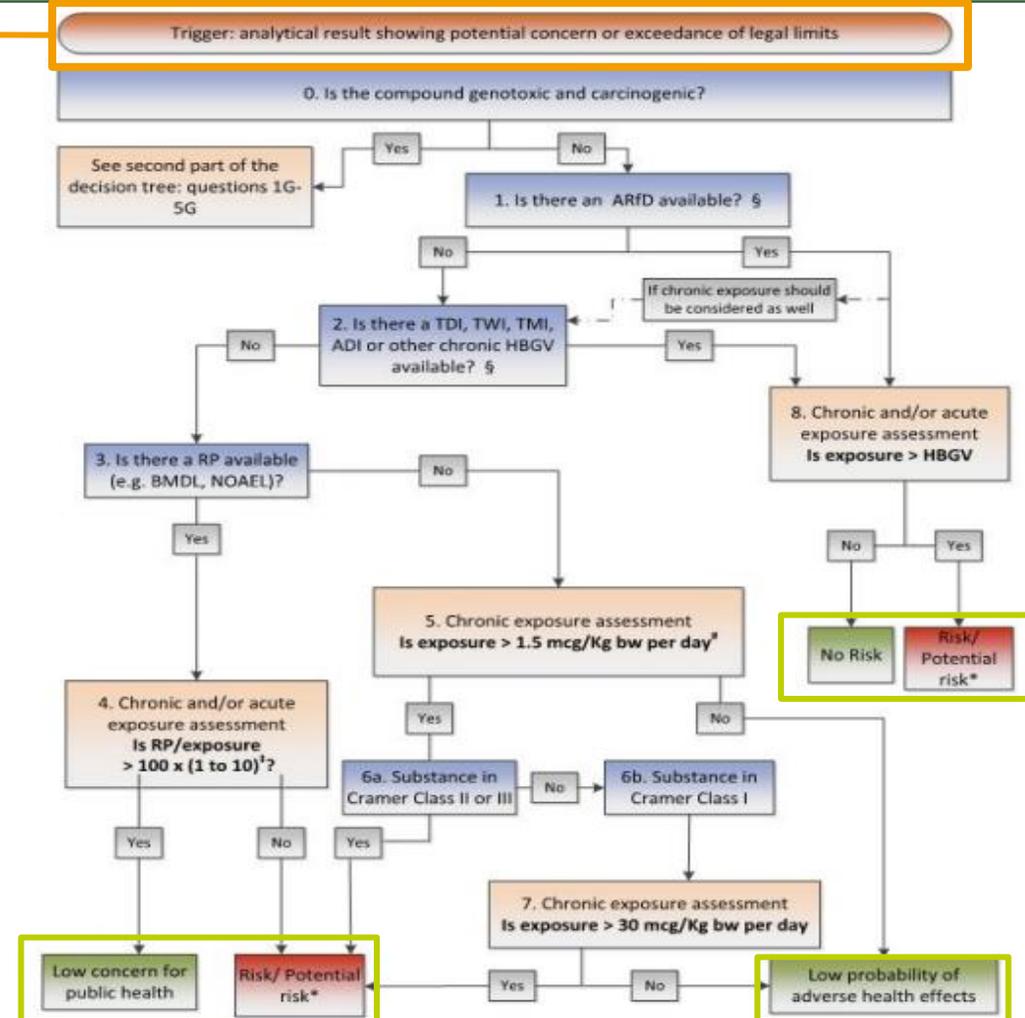
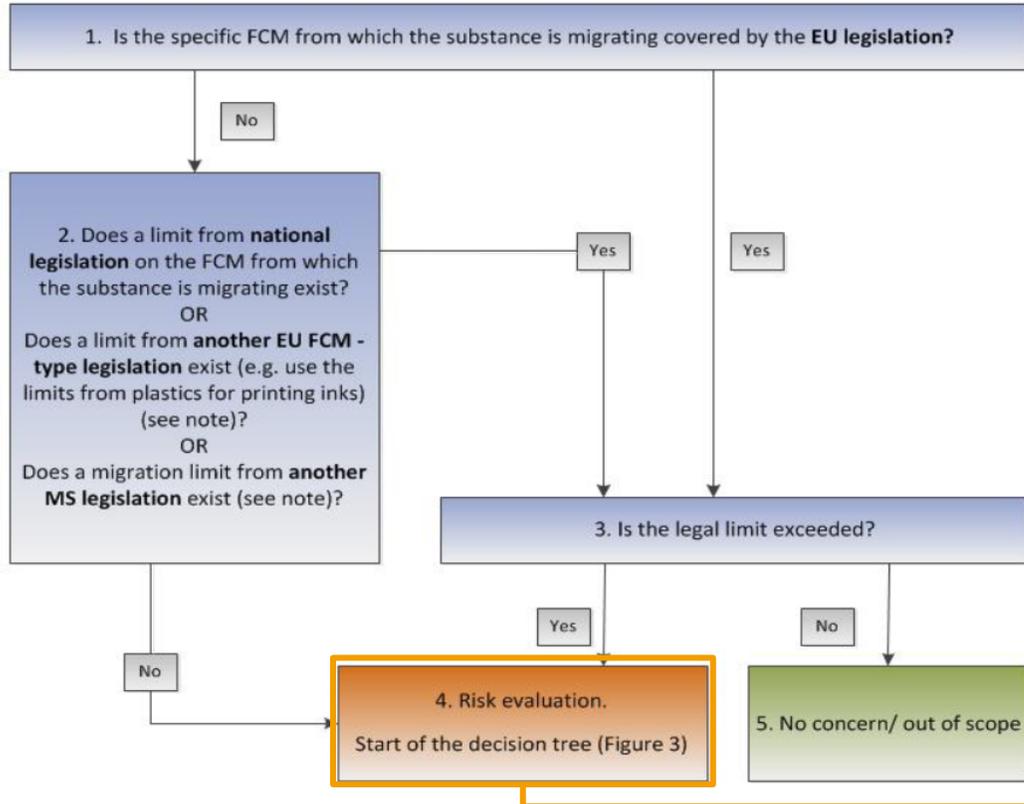
EFSA RACE tool

Pre-decision tree for food contact materials



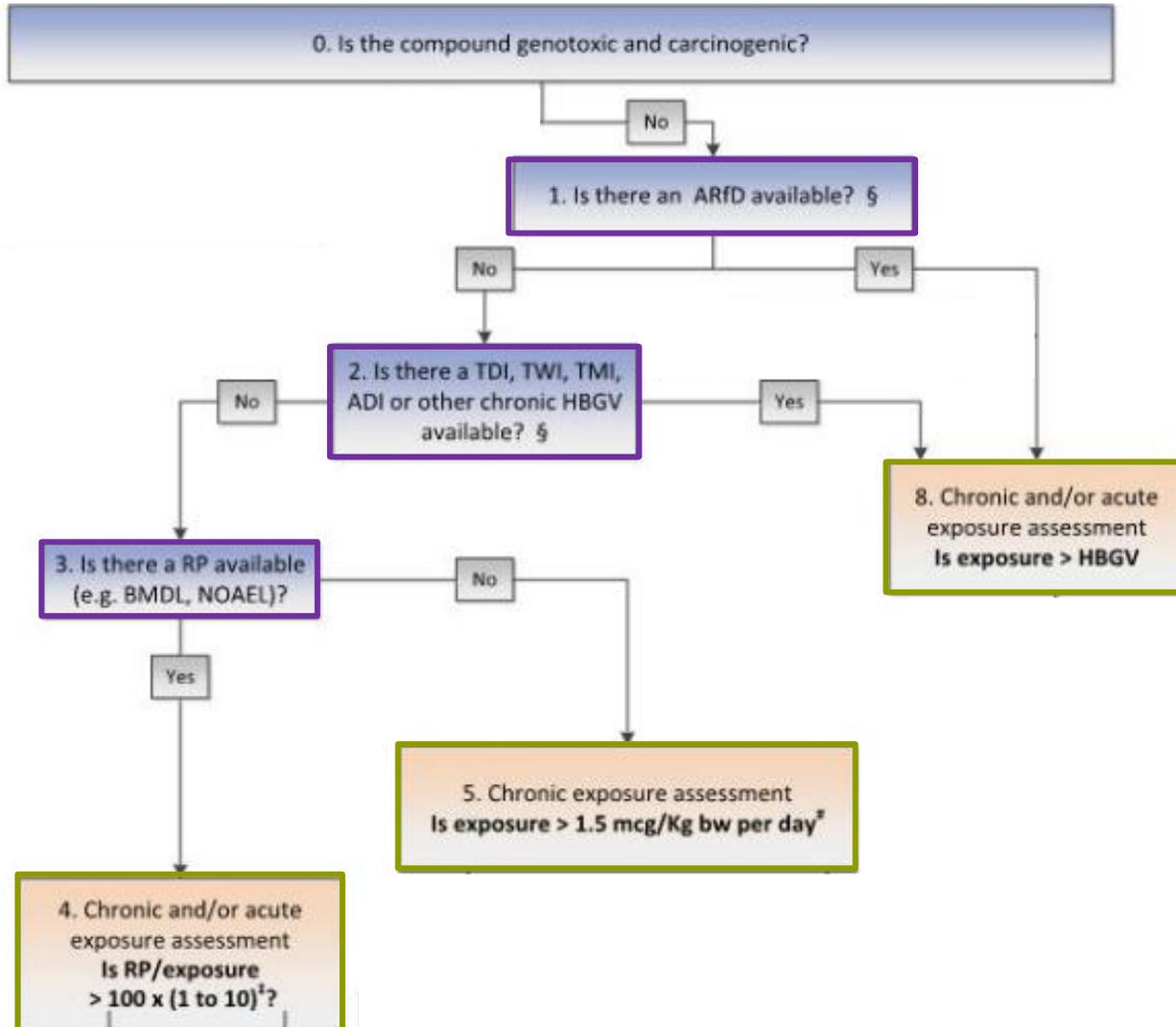
EFSA RACE tool

Pre-decision tree for food contact materials



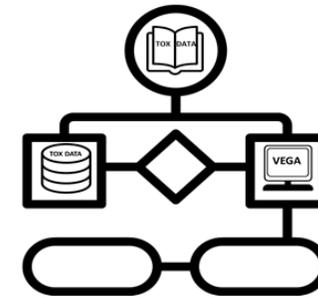
§ In case of different values proposed, the EFSA one is used in first place; if there is no value by EFSA, then, by international organisations (e.g. JEFCA), last by national organisations; *See Section 7 Risk evaluation; depending also on rate of exceedance, characteristics of the substance, population category/ies exposed etc; †Factor ranging from 1 to 10 to be applied on a case-by-case basis; # for organophosphates and carbamates the threshold is 0.3 mcg/kg b.w. per day

Application of the EFSA RACE tool



Next steps:

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



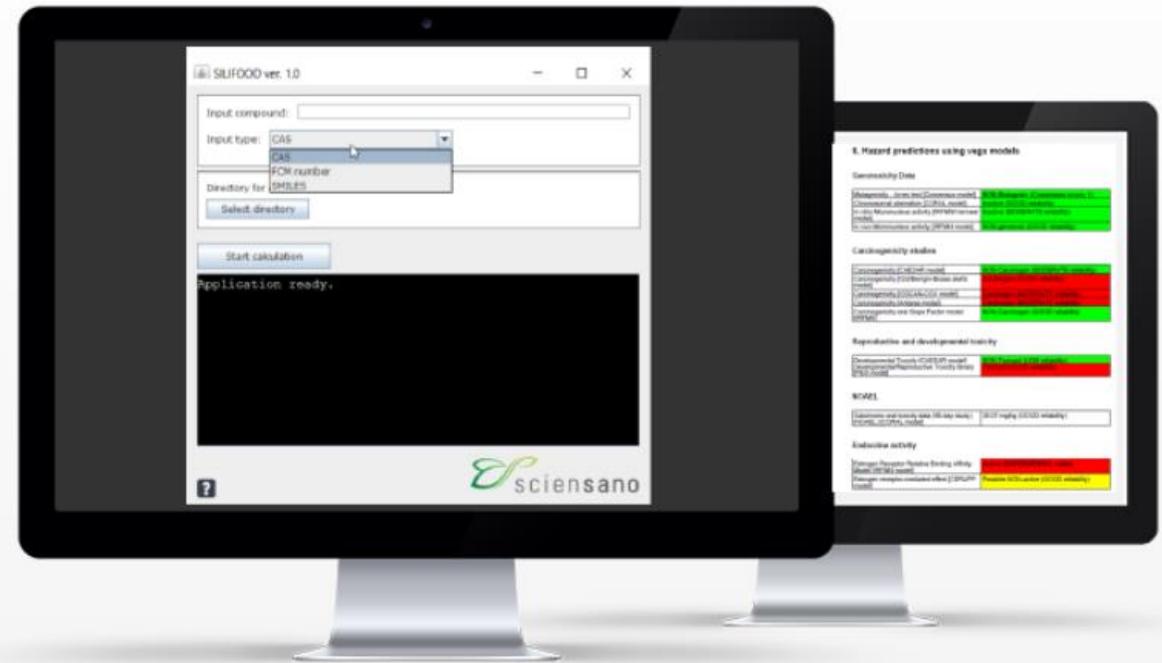
<https://www.vegahub.eu/portfolio-item/silifood/>

Comparison with the exposure

SILIFOOD Tool

SILIFOOD

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



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 |

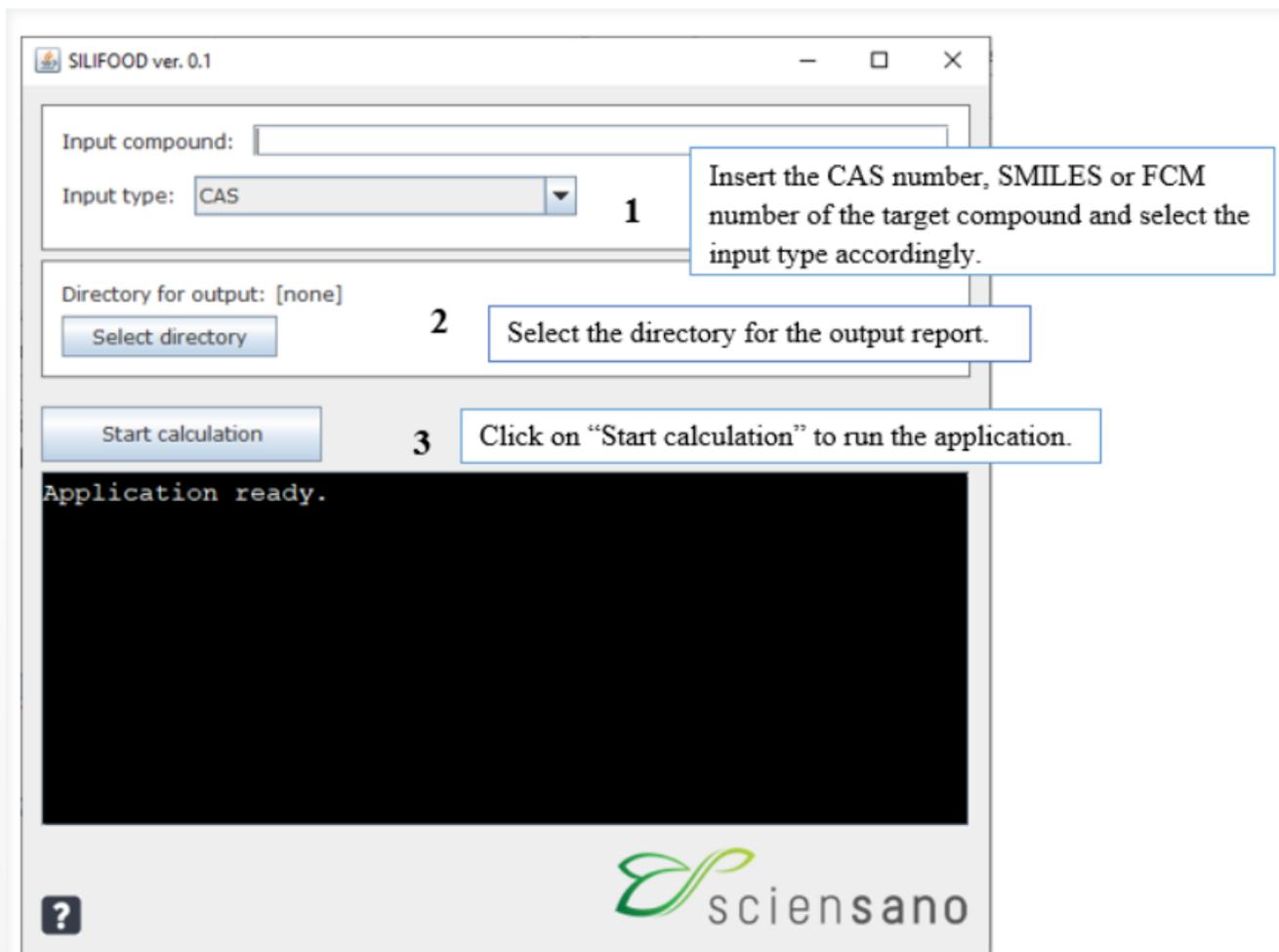
ADI: Acceptable Daily Intake, **CLP:** Classification, Labelling and Packaging, **CMR:** Carcinogenic, Mutagenic, toxic for Reproduction, **CoRAP:** Community Rolling Action Plan, **ED:** Endocrine Disrupting/ Endocrine Disruptor, **SML:** Specific Migration Limit, **SIN:** Substitute It Now!, **SVHC:**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



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

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 | CCCC(CC)COC(=O)C1=CC=CC=C1C(=O)OCC(CC)CCCC (A, B) CCCC(CC)COC(=O)c1c(cccc1)C(=O)OCC(CC)CCCC (H) CCCC(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) CCCC(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 I-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) |

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 |



| | |
|-----------|----------------|
| 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 | 8/59 |
| 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

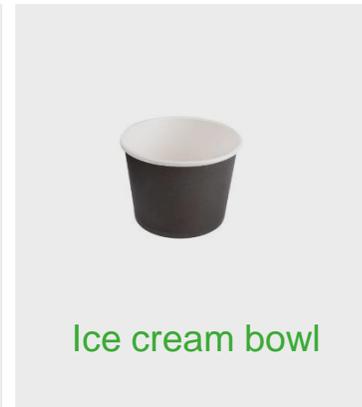
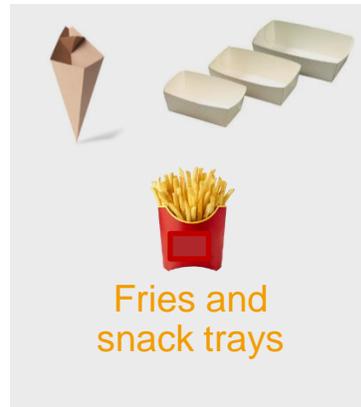
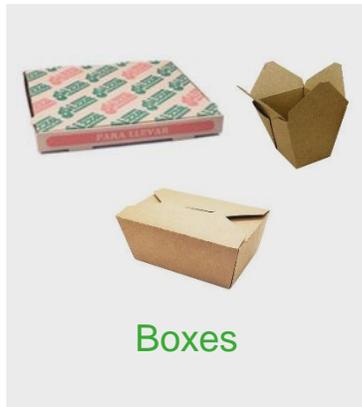
02

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

Risk assessment : MOAH

Scenario 1 : 10%

28/59 samples at potential risk



Children Potential risk

Potential risk

Potential risk

Potential risk

Low concern

Potential risk

Teenagers Potential risk

Potential risk

Potential risk

Potential risk

Potential risk

Potential risk

Adults Potential risk

Low concern

Potential risk

Potential risk

Low concern

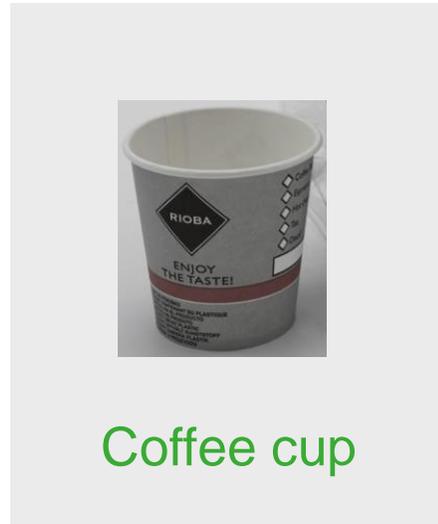
Potential risk

BMDL10 : 0.49 mg kg⁻¹ bw day

Risk assessment : MOAH

Scenario 2 : 1%

2/59
samples at potential risk



Children

Potential risk

Potential risk

Teenagers

Potential risk

Potential risk

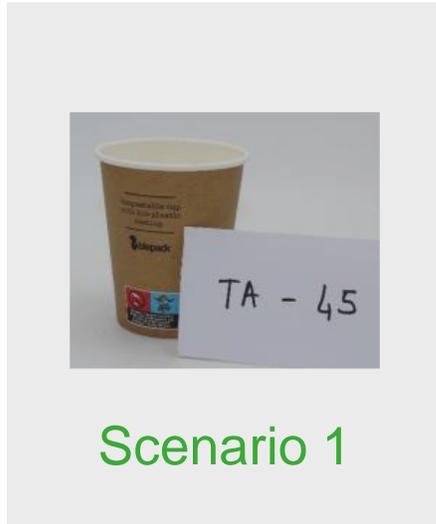
Adults

Potential risk

Potential risk

Risk assessment : PFAS

Scenario 1 :
Σ EFSA-PFAS



Children

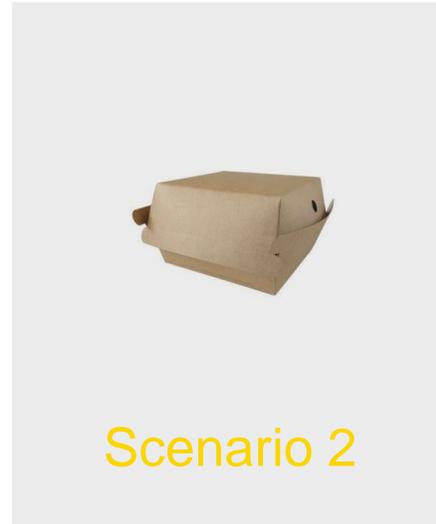
NA

Teenagers

Potential risk

Adults

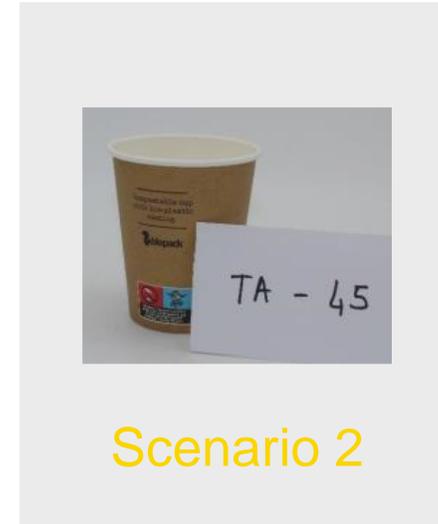
Potential risk



Potential risk

No risk

No risk



NA

Potential risk

Potential risk

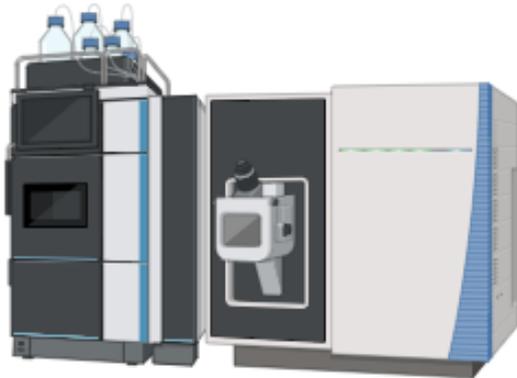
Scenario 2 :
Σ all detected PFAS

Targeted screening

Target screening method by LC-HRMS of

~ 100 substances

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



LC-Orbitrap

22 substances were identified

At least **1** substance was detected
in **100%** of the samples

Substances most often detected

- Benzoic acid, butyl ester (97%)
- 4-Ethoxybenzoic acid, ethyl ester (97%)
- 2-Methyl-4-isothiazolin-3-one (73%)

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

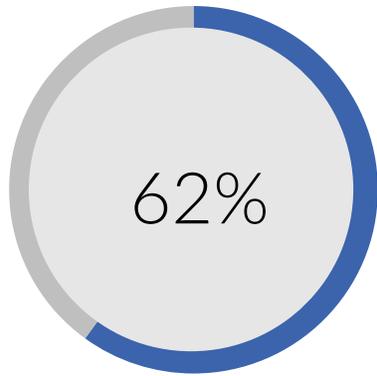


Where could come these
substances from?

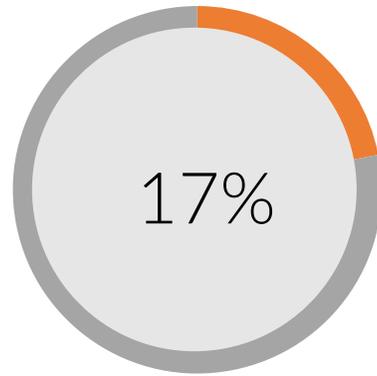
Untargeted screening

| Substance name | Hypothesis of use in paper and board FCM |
|---|--|
| 1-Eicosanol (629-96-9) | Used in coatings |
| Bis(2-ethylhexyl) Fumarate (141-02-6) | Possibly used to facilitate dye setting |
| α -Methylstyrene (98-83-9) | Always found in association with styrene. Intermediate product used in the production of plasticizers, resins and polymers. Used in coatings |
| 1-Tetradecene (1120-36-1) | Used as a chemical intermediate in dye |
| Hexadecanoic acid, ethyl ester (628-97-7) | Rheology control agent for coating compositions |
| Styrene (100-42-5) | Substances used for the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork. Used in coatings, |
| Bis(2-ethylhexyl) phthalate (117-81-7) | Processing aids and additives: as plasticizer Used in curable adhesives and in polymer production |
| Phthalic acid, hex-3-yl isobutyl ester (no CAS) | Plasticizer – Possibly used in coatings |
| Diethylene glycol dibenzoate (120-55-8) | Naturally occurring substance formed in hardwood |
| Tetracosane (646-31-1) | Used to increase wetting stability |

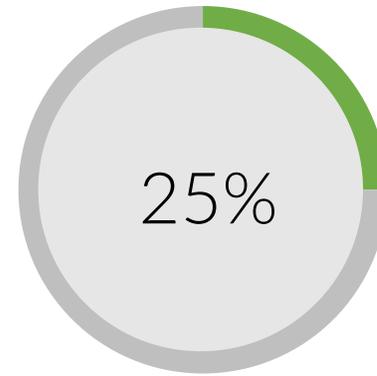
Untargeted screening



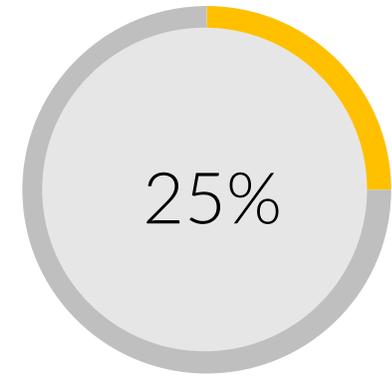
**(Potential)
Carcinogen**



**(Potential)
Mutagen**



**Endocrine
Disruptors and/or
toxic to reproduction
and development**



No concern

Conclusion

Thank you

