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toute une vie en bonne santé

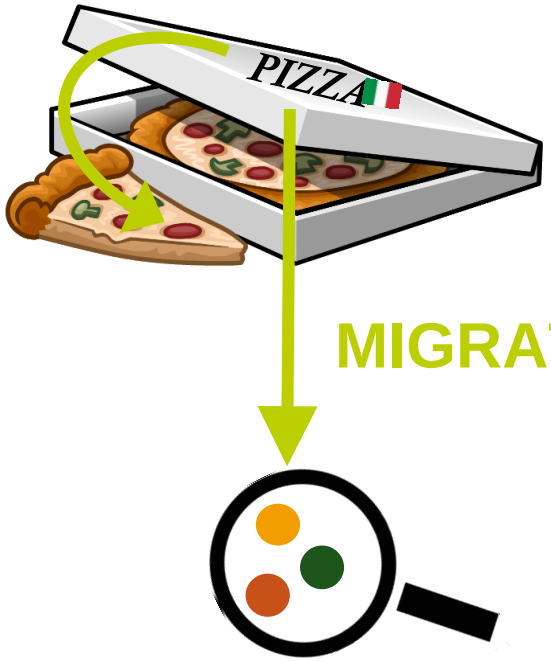
SILIFOOD

A TOOL TO SUPPORT THE RISK ASSESSMENT OF NON-EVALUATED SUBSTANCES

Els Van Hoeck - Head of Service Organic Contaminants & Additives

.be

Food Contact Materials (FCM)



MIGRATION

HAZARD
related to FCM substances

Do FCM substances pose a risk to human health?

EU Commission Regulation 10/2011

Plastic FCM
Positive list of starting substances in Annex I

No such regulation for non-plastic FCM !

➔ **Many non-plastic FCM substances not subjected to (recent) evaluation**

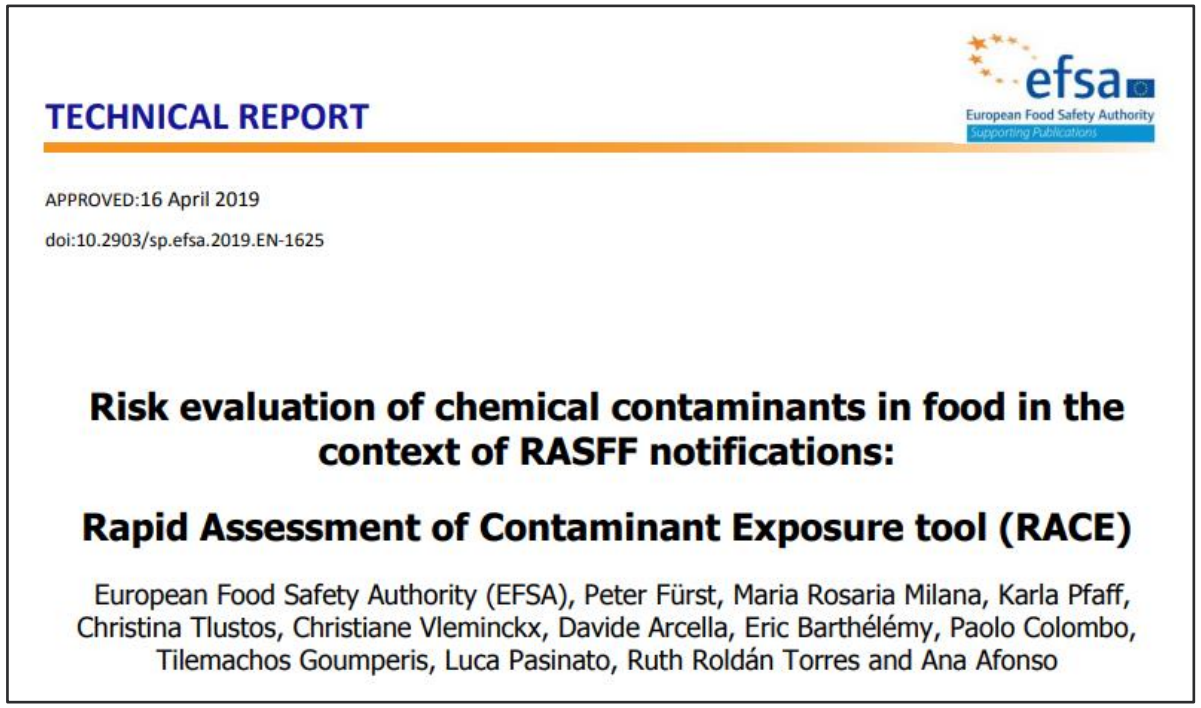
EU Commission Regulation 10/2011

Plastic FCM
NIAS should be risk assessed

Guidance on how NIAS should be assessed is missing!

EFSA Risk Evaluation Methodology: RACE tool

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

The methodology of EFSA requires :

- Information on the evaluation status
- Genotoxicity and carcinogenicity data
- Health-based guidance value (HBGV) or
- Reference points (RP) or
- Cramer Classification (TTC approach)

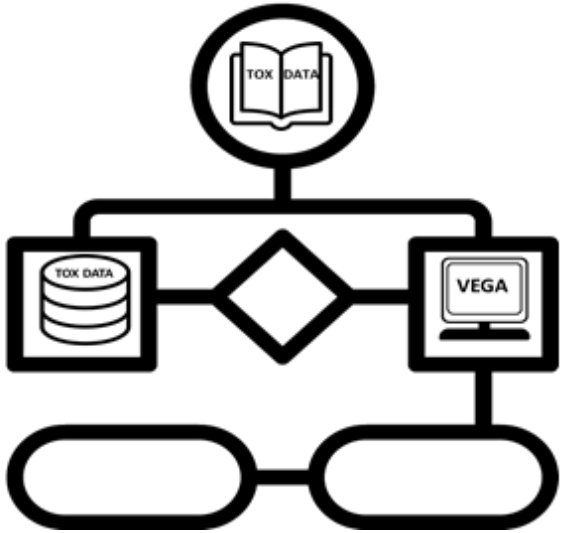
Endocrine (disrupting) activity not taken into account

***In silico* tools not considered to fill the potential data gap**

SILIFOOD Tool

Information sources

In silico predictions



Data requirements

- Evaluation status
- Genotoxicity and carcinogenicity data
- Health based guidance value (HBGV) or
- Reference points (RP) or
- Cramer Classification (TTC approach)
- Endocrine disrupting activity data

Relevant endpoints

- Genotoxicity
- Carcinogenicity
- Developmental and reproductive toxicity
- Subchronic toxicity (NOAEL/LOAEL)
- Endocrine activity
- Bioaccumulation/ bioavailability potential

Selection of information sources

Selection criteria

- **Content**
  (FCM related, toxicological data for risk assessment, …)
- Accessibility of the database
- Possibility of integration in an automated workflow
- Regularly updated information

Selection of information sources

FCM-related lists/databases

FCM database of Sciensano

- Annex I of Regulation (EU) No. 10/2011
- Synoptic Document, 2005
- Swiss Ordinance
- EFSA ESCO reports (non-plastic FCM)
- Council of Europe Resolutions

Not (specifically) FCM related lists/databases

EFSA OpenFoodTox database

ECHA lists of evaluated substances

- Annex VI of the CLP Regulation (Harmonized entries)
- CoRAP list
- Biocide Active substances list

Lists for toxicological concern

Candidate list (ECHA)

SIN (Substitute It Now!) list

Endocrine Disruptor lists

Data collected from the selected sources

Data collected in each data sources	FCM DB					EFSA DB	ECHA DB			Specific lists		
	Annex I Regulation (EU) No. 10/2011	Synoptic document 2005	Swiss Ordinance Annex 10	ESCO reports	CoE Resolution	EFSA OpenFoodTox database	CLP harmonized (CMR)	CoRAP list	Biocidal Active Substances list (BPR)	SVHC	SIN list	ED lists
Evaluation status	■	■	■	■	■	■		■	■			
Legal limit (SML) – Restriction & specifications	■	■	■	■	■	■						
Health based guidance value (e.g. TDI/ADI)		■			■	■						
CMR information						■	■	■		■	■	
ED information						■	■	■		■	■	■

Selection of (Q)SAR models

ISTITUTO DI RICERCHE FARMACOLOGICHE MARIO NEGRI · IRCCS

- **Collaboration** with the Institute Mario Negri
- Various **models already developed** for endpoints related to:
  - Human toxicology
  - Physico-chemical properties
  - Eco-toxicology
  - Environmental properties
- **Freely and publicly available**
- **Applicability Domain Index (ADI)** provided for each model's prediction **assessing the reliability** of the predictions

https://www.vegahub.eu/portfolio-item/vega-qsar-models-qrmf/

Selection of (Q)SAR models

ISTITUTO DI RICERCHE FARMACOLOGICHE MARIO NEGRI · IRCCS

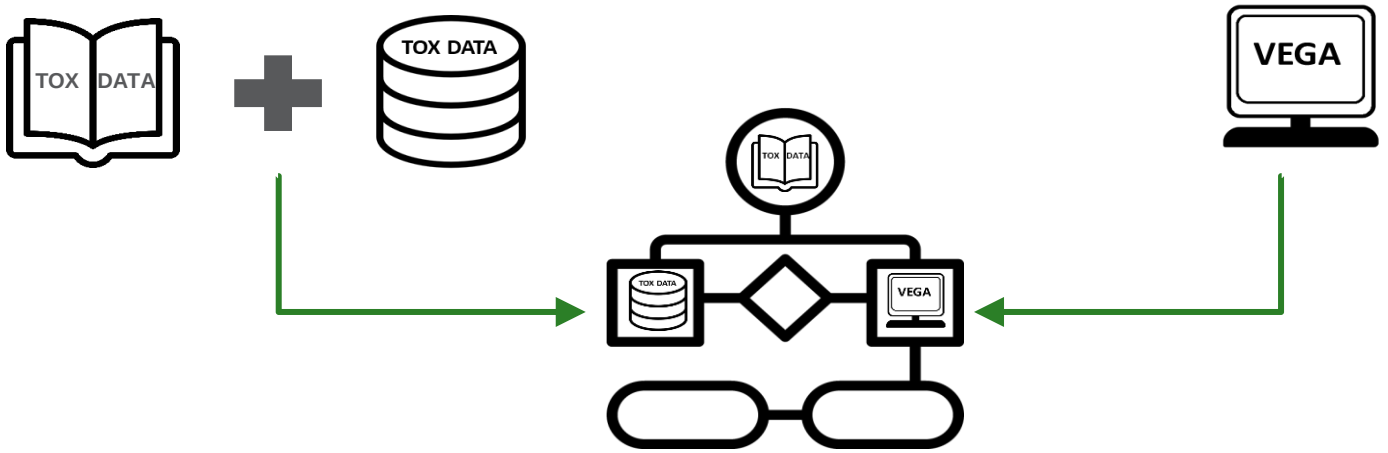
Based on EFSA Note for Guidance *for the preparation of an application for the safety assessment of a substance to be used in plastic Food Contact Materials*

Genotoxicity - Gene mutation (A) - Structural and/or numerical chromosome aberration (B)	• Mutagenic consensus model (A) • Chromosomal aberration model (B) • *In vitro* micronucleus model (B) • *In vivo* micronucleus model (B)
Carcinogenicity	6 models for oral exposure • 5 qualitative models: ANTARES, ISSCAN-CGX, ISS, CAESAR, Oral slope classification model
Developmental and reproductive toxicity	• Developmental toxicity (CAESAR) • Developmental/Reproductive toxicity library (PG)
Subchronic toxicity (NOAEL)	• NOAEL (IRFMN/CORAL)
Bioavailability/Bioaccumulation potential	• LogP model(s)

Additional information on endocrine activity

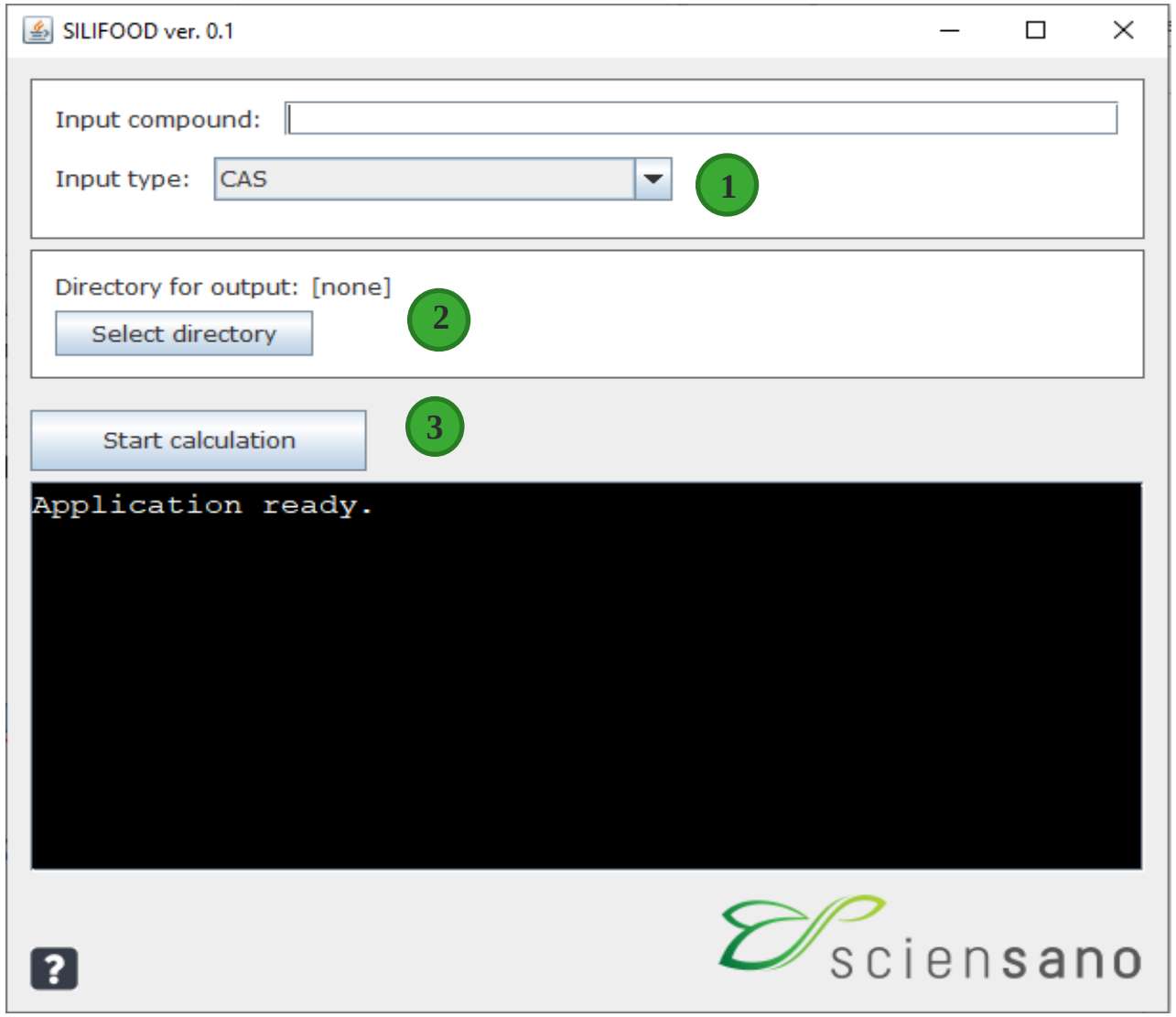
Endocrine activity	• Estrogen receptor binding affinity model • Estrogen receptor mediated effect • Androgen receptor effect • Thyroid receptor alpha effect • Thryoid receptor beta effect

SILIFOOD software implementation



- Stand-alone JAVA application to be installed on computer
- Publicly available with a user manual
- Designed to collect data for FCM single organic substances

How to run the software?



1. **Insert the "input compound" (chemical identifier*) and select the "Input type"** *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 folder selected here.

3. Click on **"Start calculation"** to run the workflow and generated the report.

PDF report – Introduction

sciensano

SILIFOOD FCM - REPORT

SEARCH RESULTS FOR TARGET CAS NUMBER 84-69-5

Engine version: 1.0

Created on: 16 03 2023

1st page of the report

This application consists of an automated workflow developed to streamline and speed up the risk assessment of (non-evaluated) FCM substances. The workflow combines existing toxicological data with (quantitative) structure-activity relationship ((Q)SAR) predictions.

Contact

More detailed information can be found in the user manual. For any questions, please contact us through the following email address: Silifood@sciensano.be

Disclaimer

Sciensano ensures the accurate introduction of information in its in-house FCM database as well as the correct extraction of the toxicological data from the various data sources included in this automated workflow (references on the last page of this report), but cannot be held responsible for the scientific accuracy of this information. The presence of a substance in a data source is not necessarily an agreement for its use in materials and articles intended to come into contact with foodstuffs.

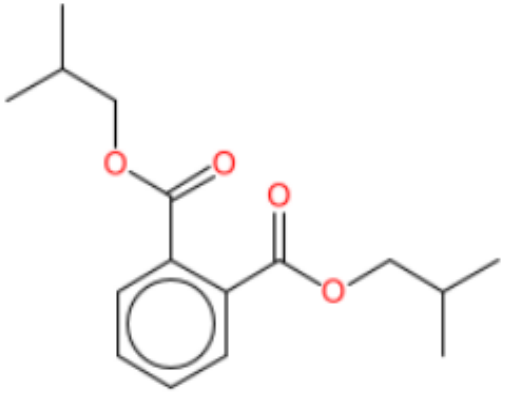
The chemical properties, hazard and Cramer classification provided by the automated workflow are predicted using in silico software. In case the text 'experimental data' is displayed for an in silico prediction, this means that the compound was included in the training set of that model. These data are not generated or checked by Sciensano.

Acknowledgement

This work was conducted with the financial support of the Federal Public Service Health, Food Chain, Safety and Environment (SILIFOOD project number RF21 6349). This application has been developed by Kode Chemoinformatics under the supervision of Sciensano and in collaboration with the Instituto di Ricerche Farmacologiche Mario Negri (IRFMN).

PDF report – Identification of the substance

1. Identification of the substance

Molecular Structure	
Substance name	Phthalic acid, diisobutyl ester (A, B) Diisobutyl phthalate (DIBP) (H) diisobutyl phthalate (E, F, G)
Synonyms	Synonyms not found in data source(s)
CAS number	84-69-5 (A, B, E, F, G, H)
EC List number	201-553-2 (A, E, F, G, H)

Molecular formula	C16H22O4 (A)
Original SMILES	CC(C)COC(=O)C1=CC=CC=C1C(=O)OCC(C)C (A, B) CC(C)COC(=O)c1c(cccc1)C(=O)OCC(C)C CC(C)COC(=O)c1ccccc1C(=O)OCC(C)C (H) CC(C)COC(=O)c1ccccc1C(=O)OCC(C)C (E, F, G)
VEGA SMILES	O=C(OCC(C)C)c1ccccc1(C(=O)OCC(C)C) (A, B, E, F, H) CC(C)COC(=O)c1ccccc1C(=O)OCC(C)C (G)

Data Sources
A - in-house FCM Database B - EFSA OpenFoodTox Database C - CORAP list (ECHA database) D - Biocidal active substances list (ECHA database) E - Annex VI CLP Regulation F - Substances of very high concern (SVHC) list G - SIN list H - ED list

PDF report – Existing data collection

2. Information from Food Contact Material Database

(Last review: 22/11/2022)

Results for compound Phthalic acid, diisobutyl ester

- EU Regulation 10/2011 Annex I

The compound is not present in Annex I of EU Regulation 10/2011

- ESCO Reports

The compound is present in the following ESCO reports:

1) Coatings (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 Materials (1991)

Regulations/recommendations : NL X 3k, 5d, 7h(More information can be found in the EFSA external scientific report of ESCO WG on non-plastic FCM (2012))

Substance Positive List : Y

Restrictions : SML=1, together with phthalic acid, dibutyl ester

Remarks : as plasticizer

2) Paper & Board (ESCO Reports)

1 entry found

SCF List : -

MS : NL

Safety Evaluation MS : A - Substances used for the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork and evaluated at national level after the publication of SCF Guidelines for Food Contact Materials (1991)

Regulations/recommendations : NL II 1.2.2 o(More information can be found in the EFSA external scientific report of ESCO WG on non-plastic FCM (2012))

Substance Positive List : Y

Restrictions : SML = 1 mg/kg alone or with dibutyl phthalate. Will be revised to 0.3 mg/kg within a few years

Remarks : -

- Swiss Ordinance Annex 10 (previously Annex 6)

Evaluation : Part B - Non-evaluated substances

SML [mg/Kg] : -

Notice : -

CMR (preposition amendment) : R1B

PDF report – Existing data collection

3. Evaluation in a non-FCM context

- EFSA OpenFoodTox database

(Last review: 25/10/2022)

If the compound is present in the OpenFoodTox database, a summary of the critical toxicological endpoints and reference values can be available here: https://www.efsa.europa.eu/en/microstrategy/openfoodtox

Present in EFSA OpenFoodTox database	Yes
Substance name in EFSA Database	Phthalic acid, diisobutyl ester

1 entry found in EFSA OpenFoodTox database

Title	Statement of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) on the re-classification of some phthalates for consistency with the new SCF guidelines for food contact materials
Publication date	09-06-2004
DOI	doi:10.2903/j.efsa.2004.1062
URL	http://dx.doi.org/10.2903/j.efsa.2004.1062

- CLP Regulation (EC) No 1272/2008

(Last review: 10/01/2023)

Present in CLP list as CMR	Yes
CLP details	Repr. 1B

- CoRAP List

(Last review: 15/12/2022)

Present in CoRAP list	No

- Biocidal Active substance list

(Last review: 10/01/2023)

Present in the biocide active substances list	No

PDF report - Inclusion in lists and bioavailability

4. Inclusion in lists of substances of concern

- Candidate List (ECHA)

(Last review: 10/01/2023)

Present in the Candidate list (ECHA)?	Yes
Substance Name	Diisobutyl phthalate
Reason for inclusion	Toxic for reproduction (Article 57c)#Endocrine disrupting properties (Article 57(f) - human health)

- SIN List

(Last review: 19/12/2022)

Present in the SIN list?	Yes
Substance Name	diisobutyl phthalate
Reason for inclusion	Classified CMR according to Annex VI of Regulation 1272/2008

- Endocrine Disruptor Lists

(Last review: 15/12/2022)

Present in the ED lists?	Yes
Substance Name	Diisobutyl phthalate (DIBP)
Which list?	List I- Substances as endocrine disruptors at EU level
Reason for inclusion?	Health Effect

5. Bioavailability/Bioaccumulation potential

Molecular Weight [Da]	278.38
Number of hydrogen bond donor	0
Number of hydrogen bond acceptor	4
Polar Surface area [Angstroms^2]	52.6
Rotating bond	8
LogP model (Meylan/Kowwin)	4.11 (EXPERIMENTAL value)

Bioavailability: Yes

Based on the following criteria:

Lipinski rule: No more than one violation of these criteria	
LogP	≤ 5
Molecular weight	≤ 500 g/mol
Hydrogen bond donors	< 5
Hydrogen bond acceptors	< 10
Additional criteria	
Polar surface area (Angström)	≤ 140
Number of rotating bonds	≤ 10

(Van Bossuyt *et al*., 2016)

PDF report – VEGA models predictions

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 (MODERATE reliability)
In vivo Micronucleus activity [IRFMN model]	NON-genotoxic (GOOD reliability)

Carcinogenicity studies

Carcinogenicity [CAESAR model]	NON-Carcinogen (MODERATE reliability)
Carcinogenicity [ISS/Benigni-Bossa alerts model]	Carcinogen (GOOD reliability)
Carcinogenicity [ISSCAN-CGX model]	Carcinogen (MODERATE reliability)
Carcinogenicity [Antares model]	Carcinogen (MODERATE reliability)
Carcinogenicity oral Slope Factor model [IRFMN]	NON-Carcinogen (GOOD reliability)

Reproductive and developmental toxicity

Developmental Toxicity [CAESAR model]	NON-Toxicant (LOW reliability)
Developmental/Reproductive Toxicity library [P&G model]	Toxicant (GOOD reliability)

NOAEL

Subchronic oral toxicity data (90-day study) (NOAEL) [CORAL model]	38.07 mg/kg (GOOD reliability)

Endocrine activity

Estrogen Receptor Relative Binding Affinity Model [IRFMN model]	**Active (EXPERIMENTAL value)**
Estrogen receptor-mediated effect [CERAPP model]	Possible NON-active (GOOD reliability)
Androgen receptor-mediated effect [COMPARA model]	**NON-active (EXPERIMENTAL value)**
Thyroid receptor alpha effect [NRMEA model]	**Inactive (EXPERIMENTAL value)**
Thyroid receptor beta effect [NRMEA model]	**Inactive (EXPERIMENTAL value)**

Colour code:

Active/ Toxicant	
Possible Active or Possible NON-active	
Inactive/ NON-Toxicant	

PDF report – VEGA models predictions

7. Information to support the Threshold for Toxicological Concern (TTC) approach

The TTC approach can only be applied in some conditions, for more information, please refer to the software user guide

Cramer Classification

Cramer class [ToxTree model]	Low (Class I)

The workflow does not check if the exclusion criteria apply
nor if the substance belongs to a specific class
(mutagen and/or carcinogen, organophosphate or carbamate)

PDF report – References list

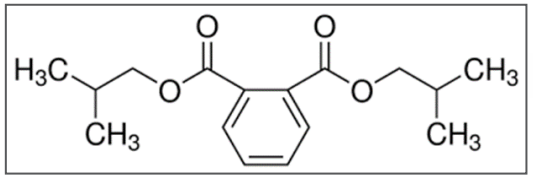
Source's name	References	Last update
EU Regulation 10/2011 - Annex I	European Commission. 2011. Commission Regulation (EU) No.10/2011 of 14 January 2011 on Plastic Materials and Articles Intended to Come into Contact with Food . Text with EEA Relevance. 012 OJ L (COM) http://data.europa.eu/eli/reg/2011/10/oj/eng (October 19, 2020).	22/11/2022
Synoptic Document (2005)	EC, 2005. "Synoptic Document": Provisional List of Monomers and Additives Notified to European Commission as Substances Which May Be Used in the Manufacture of Plastics or Coatings Intended to Come into Contact with Foodstuffs. Sanco D3/AS D, p. 2005.	22/11/2022
Swiss Ordinance Annex 10 (previously Annex 6)	Annex 6 of the Ordinance of the FDHA on articles and materials of 23 November 2005 (RS 817.023.21)	22/11/2022
ESCO Reports	European Food Safety Authority; Report of ESCO WG on non-plastic Food Contact Materials. Supporting Publications 2012:139 [63 pp.]. Available online: www.efsa.europa.eu	22/11/2022
Council of Europe (CoE) Resolutions	Council of Europe Resolutions https://www.edqm.eu/en/food-contact-materials-and-articles	22/11/2022
EFSA OpenFoodTox database	https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox (December 14, 2021).	25/10/2022
Annex VI of the CLP Regulation (EC) No 1272/2008	https://echa.europa.eu/fr/information-on-chemicals/annex-vi-to-clp (May 11,2022)	10/01/2023
CoRAP List	https://echa.europa.eu/en/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table	15/12/2022
Biocidal Active substances list (ECHA)	https://echa.europa.eu/en/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances (February 23, 2022)	10/01/2023
Candidate list (ECHA) or List of Substance of Very High Concern (SVHC)	https://echa.europa.eu/substances-of-very-high-concern-identification-explained (June 14, 2022)	10/01/2023
SIN list	https://sinlist.chemsec.org/ (October 14, 2021).	19/12/2022
Endocrine Disruptor Lists	https://edlists.org/ (February 15, 2022).	15/12/2022

Lists and databases will be updated on a regular basis

Case study with Diisobutyl phthalate : Background

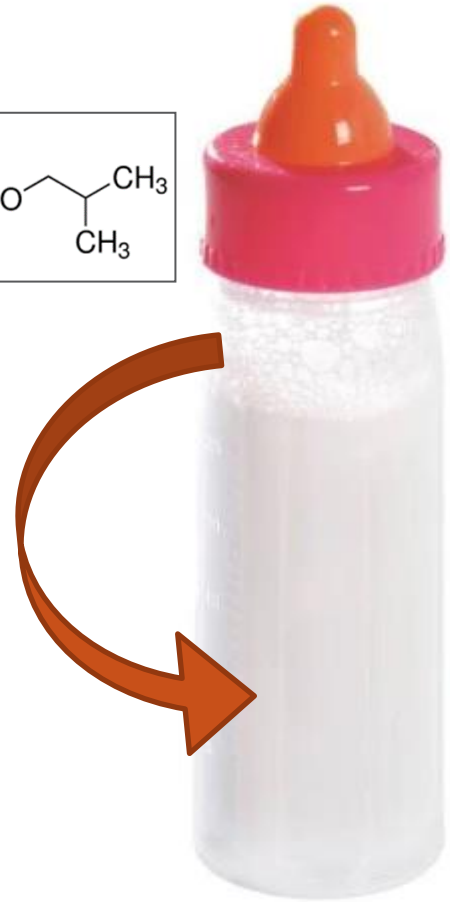
- **Diisobutyl phthalate (DiBP) known to migrate from different FCM**

  (211 entries in the FCCmigex database and 99 references)



- DiBP not present in Annex I ➔ Present in plastic as **NIAS**

- Migration study with polycarbonate replacement **baby bottle** showed migration of DiBP from 1 bottle (out of 24) (Onghena *et al.*, 2016)



- Previous risk assessment performed by Sciensano in 2016 (Mertens *et al.*, 2016)

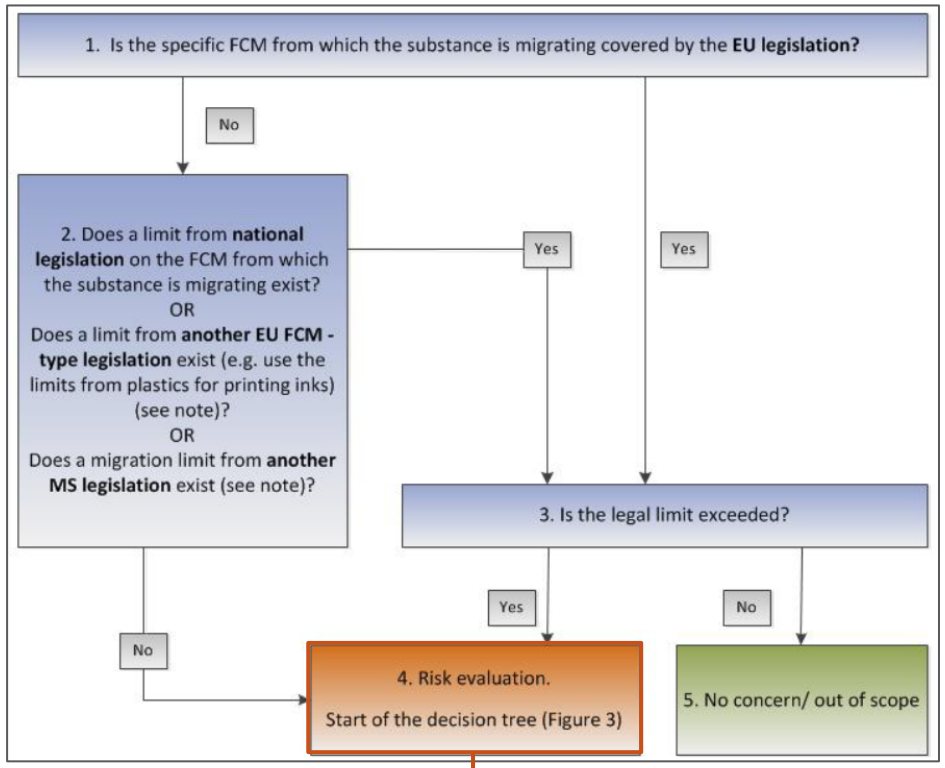
- Worst-case daily exposure scenario calculated at **3.5 µg kg^{-1} bw day^{-1}**

  (infants of 3 kg drinking 100 mL 6-7 times a day) (Mertens *et al.*, 2016)

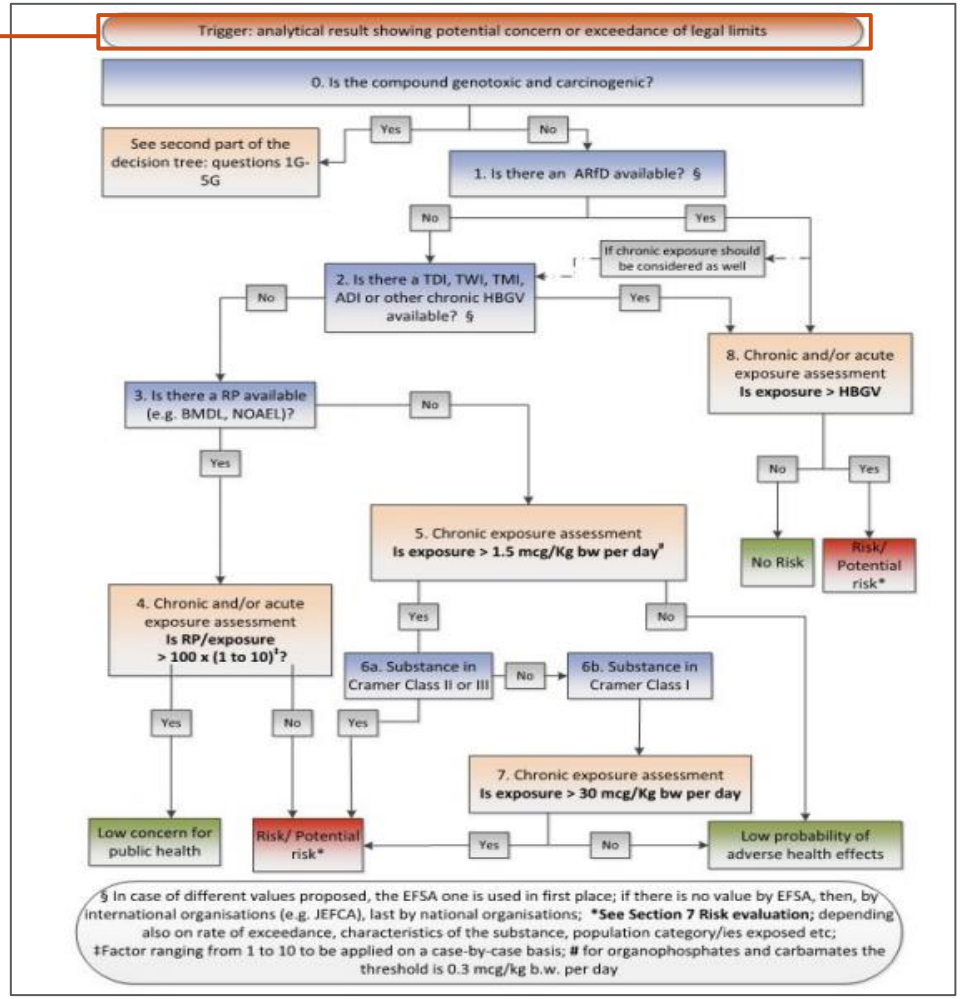
➔ Application of the **RACE tool <u>with data collected by the SILIFOOD tool</u>**

Risk assessment of DiBP based on EFSA RACE tool

Pre-decision tree for food contact materials



Decision tree for food contact materials



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

Collection of data with SILIFOOD

Step 1. Molecule input/ Identification of the substance

Step 2. Data collection: Evaluation data in the context of FCM use

Step 3. Data collection: Evaluation data in a non-FCM context

- EFSA OpenFoodTox database
- ECHA lists of evaluated substances

Step 4. Presence on a specific list of toxicological concern

Collection of existing data

Step 5. Bioavailability/bioaccumulation potential assessment

Step 6. Hazard identification by (Q)SAR predictions

- Genotoxicity
- Carcinogenicity
- Reproductive and developmental toxicity
- NOAEL (subchronic oral toxicity data: 90-day study)
- Endocrine activity

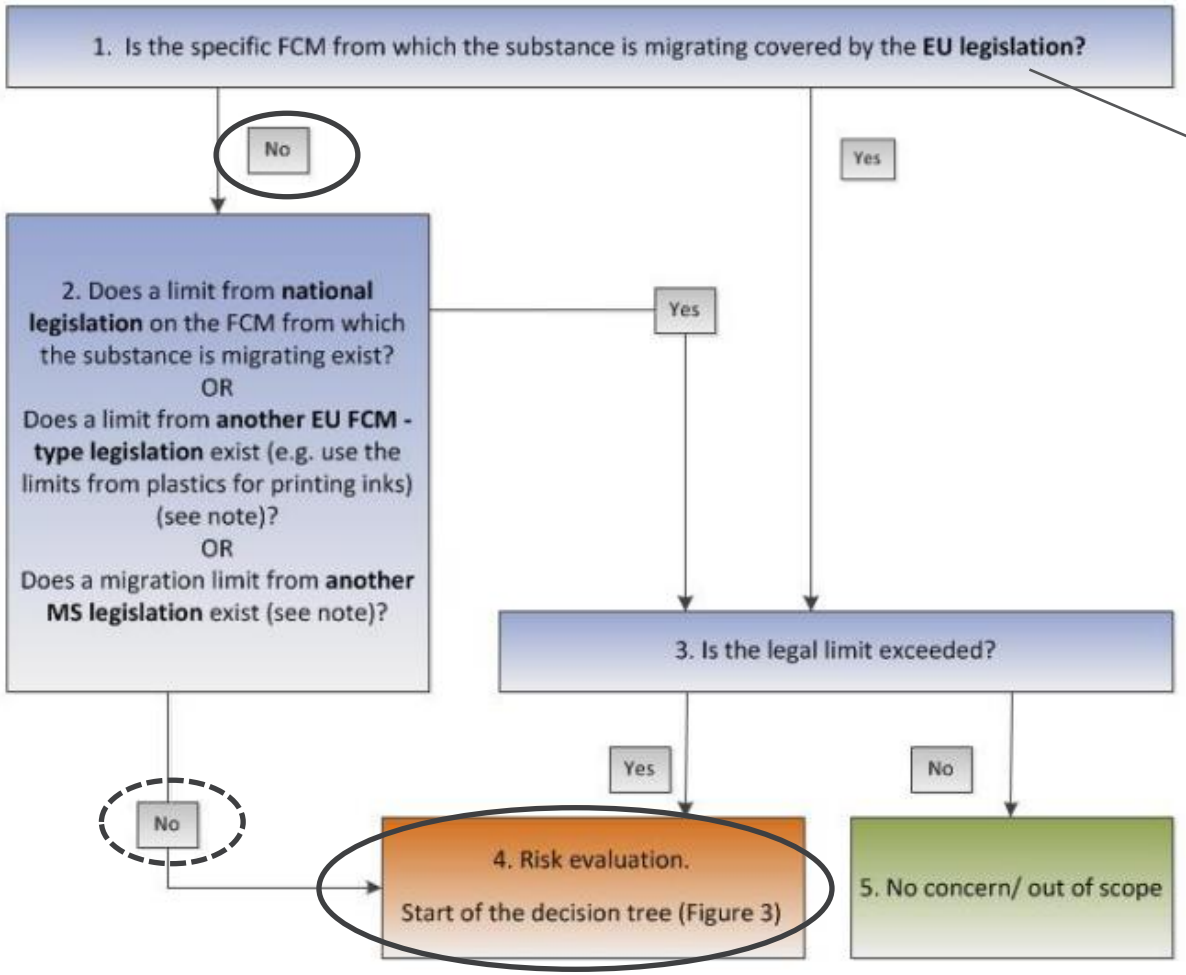
Use of *in silico tools*/ (Q)SAR models to fill potential data gap

Step 7. Application of the Threshold of Toxicological Concern (TTC) approach

Use the TTC approach

Risk assessment of DiBP based on EFSA RACE tool

Pre-decision tree



2. Information from Food Contact Material Database

(Last review: 22/11/2022)

Results for compound Phthalic acid, diisobutyl ester

- EU Regulation 10/2011 Annex I

The compound is not present in Annex I of EU Regulation 10/2011

2) Paper & Board (ESCO Reports)

1 entry found

SCF List : -

MS : NL

Safety Evaluation MS : A - Substances used for the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork and evaluated at national level after the publication of SCF Guidelines for Food Contact Materials (1991)

Regulations/recommendations : NL II 1.2.2 o(More information can be found in the EFSA external scientific report of ESCO WG on non-plastic FCM (2012))

Substance Positive List : Y

Restrictions : SML = 1 mg/kg alone or with dibutyl phthalate. Will be revised to 0.3 mg/kg within a few years

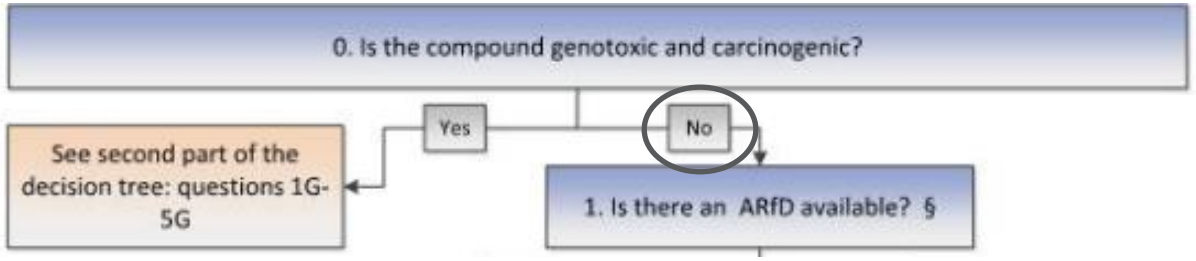
Remarks : -

SML for paper & board only for informative purpose and not applicable in this case

➔ The risk evaluation started with the decision tree

Risk assessment of DiBP based on EFSA RACE tool

Decision tree for food contact materials



- Classification on the Annex VI of CLP Regulation? R1B
- Genotoxicity study in EFSA OpenFoodTox database? No data

No clear indication that the compound is a genotoxic carcinogen

1st step: Is the compound genotoxic and carcinogenic?

Existing data

***In silico* predictions using the VEGAHUB**

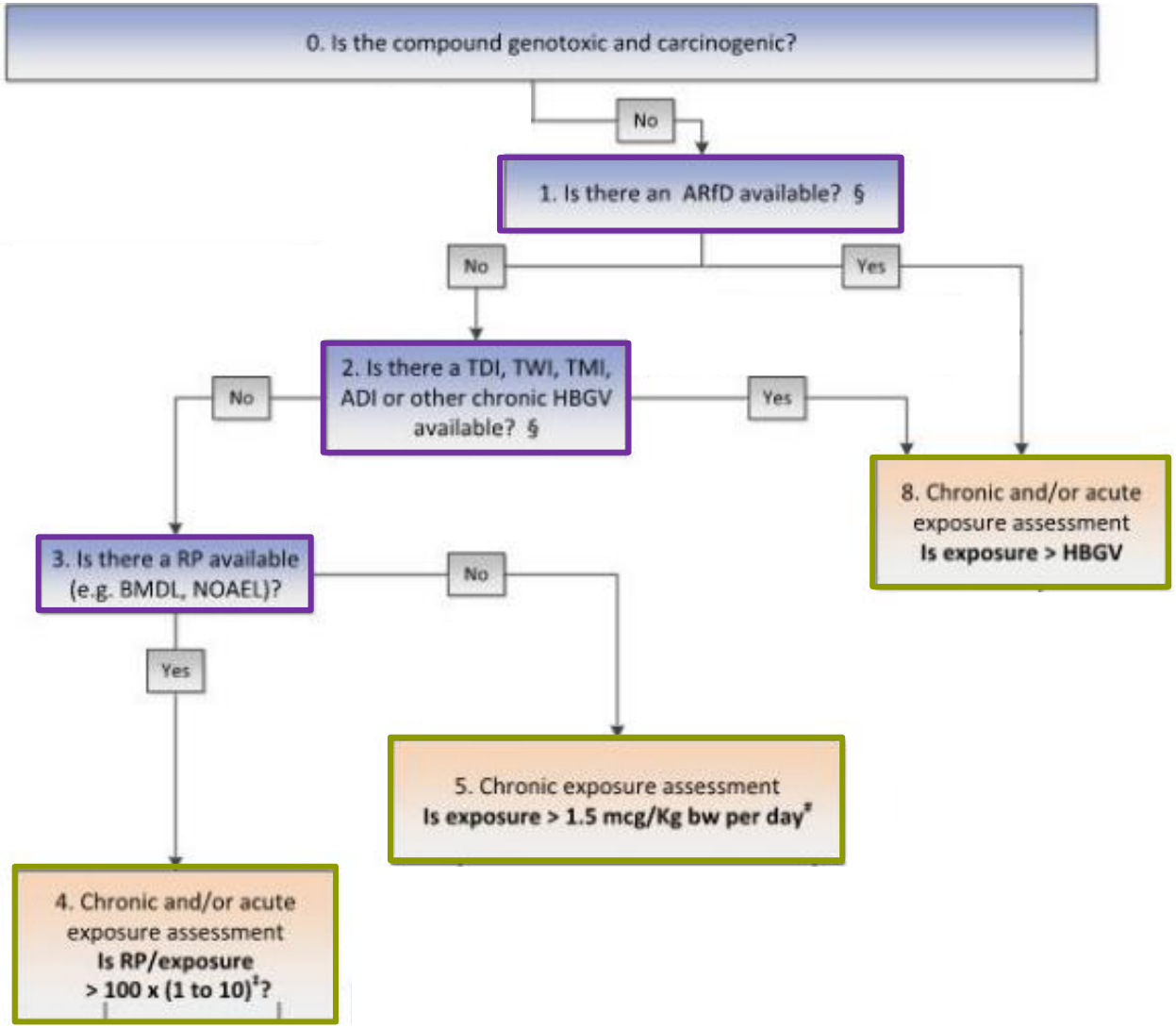
Genotoxicity Data

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 (MODERATE reliability)
In vivo Micronucleus activity [IRFMN model]	NON-genotoxic (GOOD reliability)

Carcinogenicity studies

Carcinogenicity [CAESAR model]	NON-Carcinogen (MODERATE reliability)
Carcinogenicity [ISS/Benigni-Bossa alerts model]	Carcinogen (GOOD reliability)
Carcinogenicity [ISSCAN-CGX model]	Carcinogen (MODERATE reliability)
Carcinogenicity [Antares model]	Carcinogen (MODERATE reliability)
Carcinogenicity oral Slope Factor model [IRFMN]	NON-Carcinogen (GOOD reliability)

Risk assessment based on EFSA RACE tool (Theory)

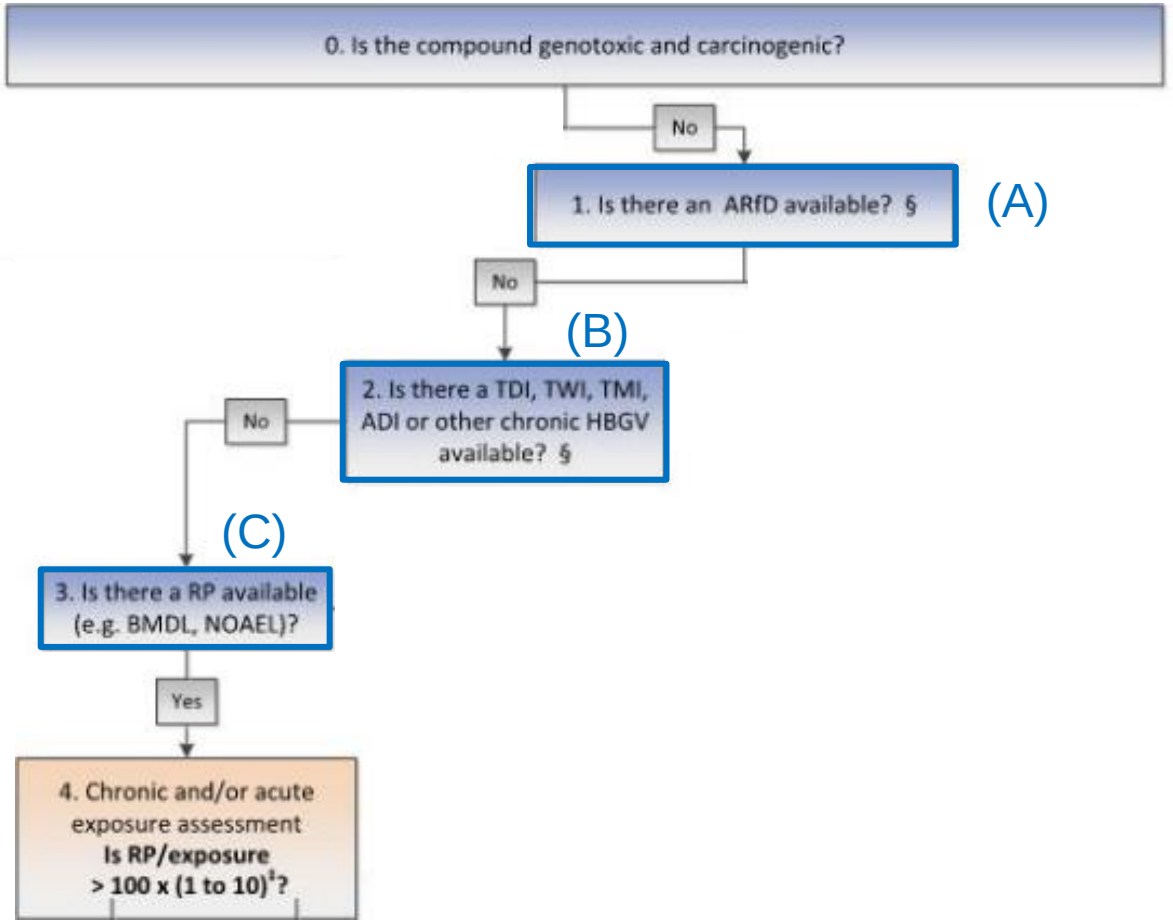


Next steps:

Collection of/Search for a reference value

Comparison with the exposure assessment:

Risk assessment of DiBP based on EFSA RACE tool



Next steps:

Collection of/Search for a reference value:

A) An **ARfD** (for acute exposure),

B) A chronic **HBGV** (TDI, TWI, TMI, ADI or other) or

C) A **Reference Point (RP)**

Data collected by the SILIFOOD tool

A) No

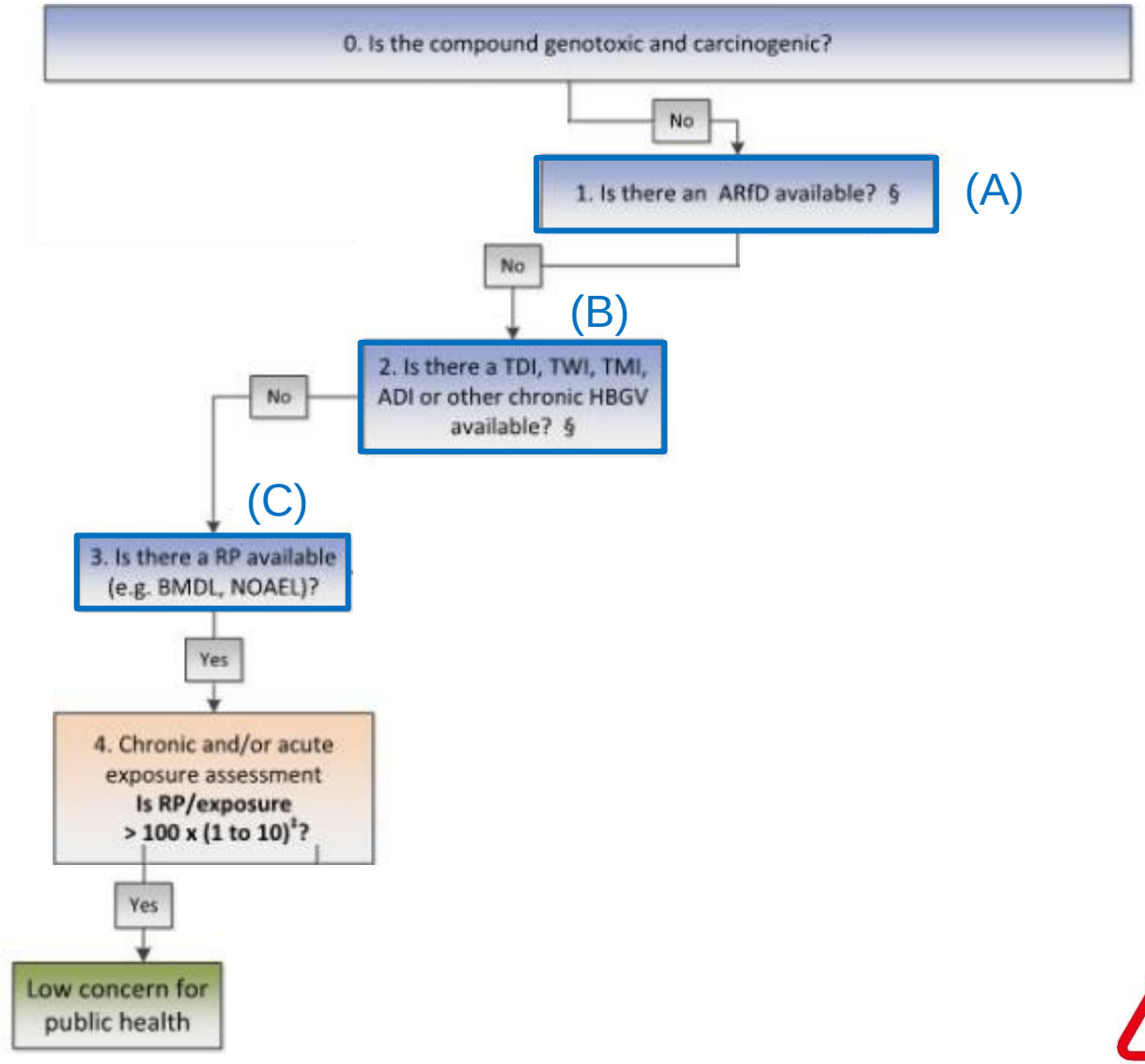
B) No

C) No RP in existing data,
BUT NOAEL predictions with good reliability

NOAEL

Subchronic oral toxicity data (90-day study) (NOAEL) [CORAL model]	38.07 mg/kg (GOOD reliability)

Risk assessment of DiBP based on EFSA RACE tool



Next steps:

Comparison with the exposure assessment

Ratio RP/ Exposure > 300*

(MoS generally accepted by the EFSA Working Group (EFSA, 2019))

Exposure data collected from previous studies

Exposure: 3.5 µg/kg bw/day (Mertens *et al.*, 2016)

$$\frac{\text{Reference point}}{\text{Exposure}} = \frac{38.07 \text{ mg/kg bw/day}}{3.5 \text{ µg/kg bw/day}} = 10\,877$$

Low concern for public health ⇐ **> 300**

* Additional uncertainty factor could be needed to deal with predicted value but no consensus on it so far

Evaluation of the potential ED activity

Information from data sources:

- Endocrine Disruptor Lists

(Last review: 15/12/2022)

Present in the ED lists?	Yes
Substance Name	Diisobutyl phthalate (DIBP)
Which list?	List I- Substances as endocrine disruptors at EU level
Reason for inclusion?	Health Effect

- Candidate List (ECHA)

(Last review: 10/01/2023)

Present in the Candidate list (ECHA)?	Yes
Substance Name	Diisobutyl phthalate
Reason for inclusion	Toxic for reproduction (Article 57c)#Endocrine disrupting properties (Article 57(f) - human health)

Supported by VEGA models

Endocrine activity

Estrogen Receptor Relative Binding Affinity Model [IRFMN model]	**Active (EXPERIMENTAL value)**
Estrogen receptor-mediated effect [CERAPP model]	Possible NON-active (GOOD reliability)
Androgen receptor-mediated effect [COMPARA model]	**NON-active (EXPERIMENTAL value)**
Thyroid receptor alpha effect [NRMEA model]	**Inactive (EXPERIMENTAL value)**
Thyroid receptor beta effect [NRMEA model]	**Inactive (EXPERIMENTAL value)**

DiBP is identified at EU level to be endocrine disruptor/ to have endocrine disrupting properties for human health

Conclusion & future perspectives

- A (semi-)automated workflow has been **developed and implemented in a publicly accessible and user-friendly software**
- The **inclusion of the *in silico* models** in addition to the data sources allows **to fill data gaps**
- The data collected from the tool **support the risk assessment of non-evaluated substances**
- Combination of the hazard collection with **migration or exposure data or predictions** (VERMEER FCM, MERLIN-EXPO)
- **Software** and **user manual** will be made **publicly available on the VEGA Hub website**
- Software/application extension integrated to **update** the lists and databases on a **regular basis**

General information

Applicability of *in silico* tools to support the risk assessment of non-evaluated substances migrating from food contact materials (RF 21/6349)

- Project partners:
  - Coordinator: **Ilse Van Overmeire,** Service Risk and Health Impact Assessment [RHIA]
  - Promotors : **Birgit Mertens** [RHIA]
    Els Van Hoeck, Service Organic Contaminants and Additives [OCA]
  - Scientific collaborator: **Camille Streel** [RHIA]

- Start-Finish dates: 01/10/2021 – 31/03/2023
- Project duration: 18 months
- Financed by the Belgian Federal Public Service – Health, Food Chain Safety and Environment

federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

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