8th EFSA Food Contact Materials Network
22-24 November 2022

EFSA activities on phthalates

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Trusted science for safe food

European Food Safety Authority

Background information on mandate

"Re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs)"

1st part:
currently ongoing

Task 1: published
by March 2022
Identification and prioritisation of substances

Task 2:
by Nov 2022
Protocol development
A) Exposure published
B) Hazard → Under publication

Task 3:

- **Call for data** on occurrence in:
  i) food — Via annual chemical monitoring data collection: April-October 2022
  ii) FCMs; — Via ad hoc data collection: June-November 2022
- **Literature search** — Via procurement

2nd part:
upon completion of 1st part

Comprehensive **evaluation of the risks** to public health related to the presence of the prioritised substances in foodstuffs originating from FCMs
(via specific risk assessment mandates from EC)

Terms of Reference request **close collaboration with ECHA**

context:
1S1A* approach

*one substance, one assessment

Task 1: identification & prioritisation

- **Prioritise and identify** those
  - phthalates,
  - structurally similar substances and
  - replacement substances based on the list in annex II to this mandate letter

  that **may be relevant for eventual inclusion in an assessment of the risks** associated with their presence and migration from FCM.
- **Identify existing relevant information**, such as that which may be held by ECHA.
- Identify use and occurrence of phthalates and non-phthalate plasticisers **in FCM other than plastic**, most notably rubber.

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 22 March 2022

doi: 10.2903/j.efsa.2022.7231

Identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Birgit Ahrens*, Evelin Fabjan*, Ronan Nicolas*, Letizia Polci*, Katleen Baert, Katharina Volk and Laurence Castle

Scientific opinion and report on public consultation results available under: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7231

Identification of substances

- Annex II of the mandate = list of substances of potential relevance for the work
  - EC Industry survey
  - MS monitoring data gathered under EC recommendation (EU) 2019/794
  - Authorisation in plastic FCM and regenerated cellulose film (RCF)

→Provisional list:

45 substances

→ Necessary to look beyond Annex II

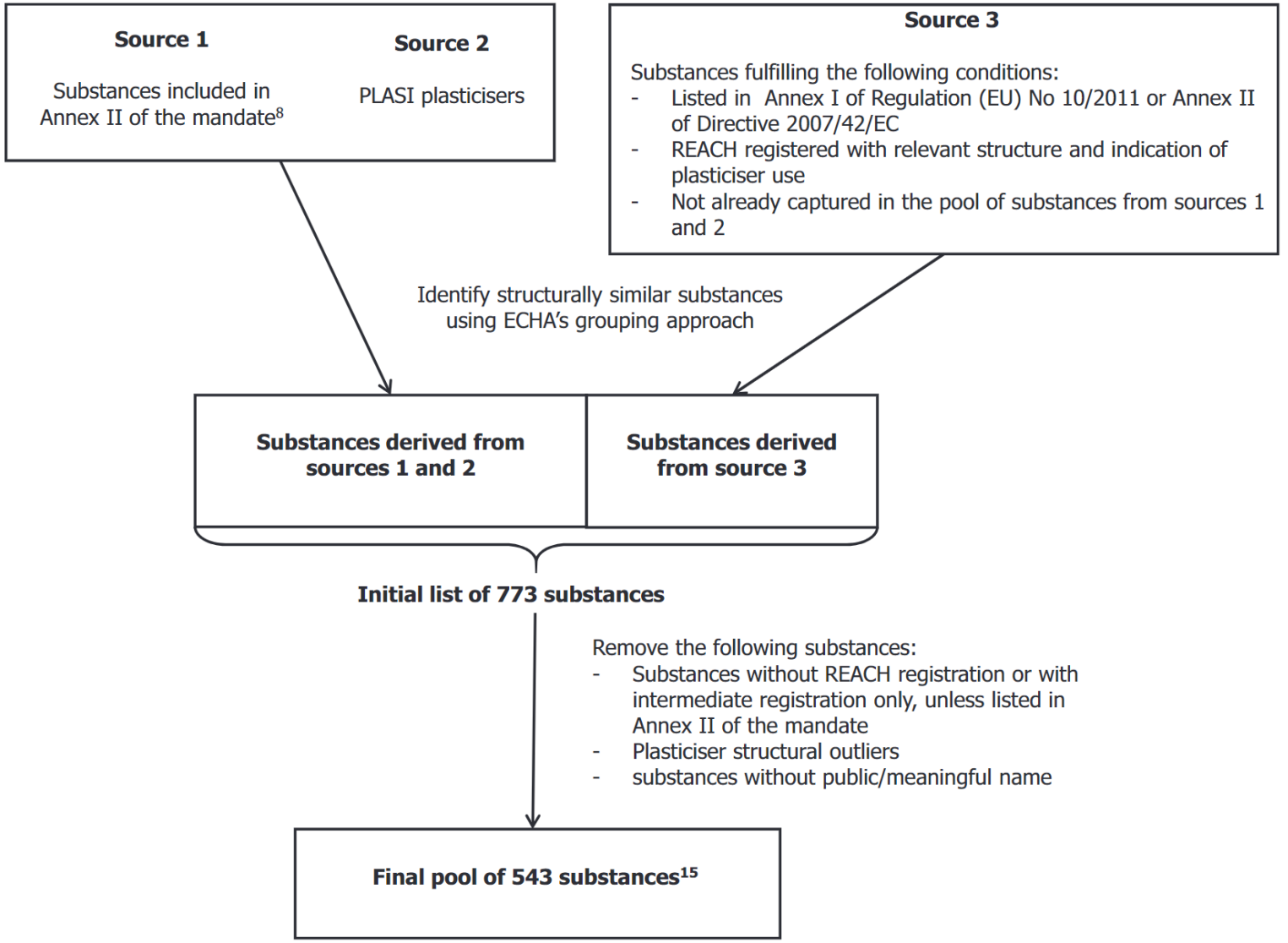


Figure 1: Building the pool of substances

Categorisation of substances

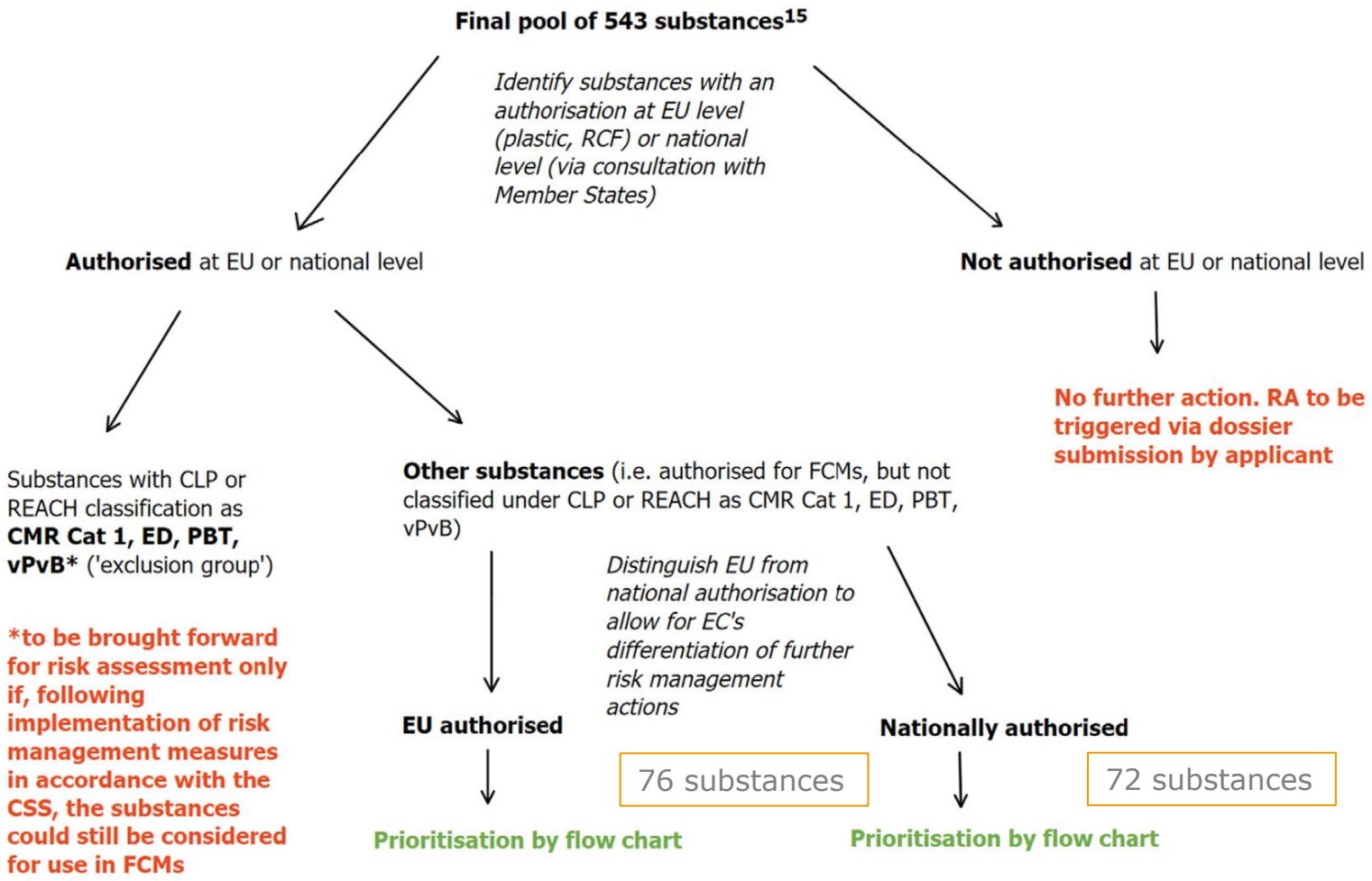


Figure 2: Categorisation of substances

- **European Commission – Chemicals strategy for sustainability (2020)**

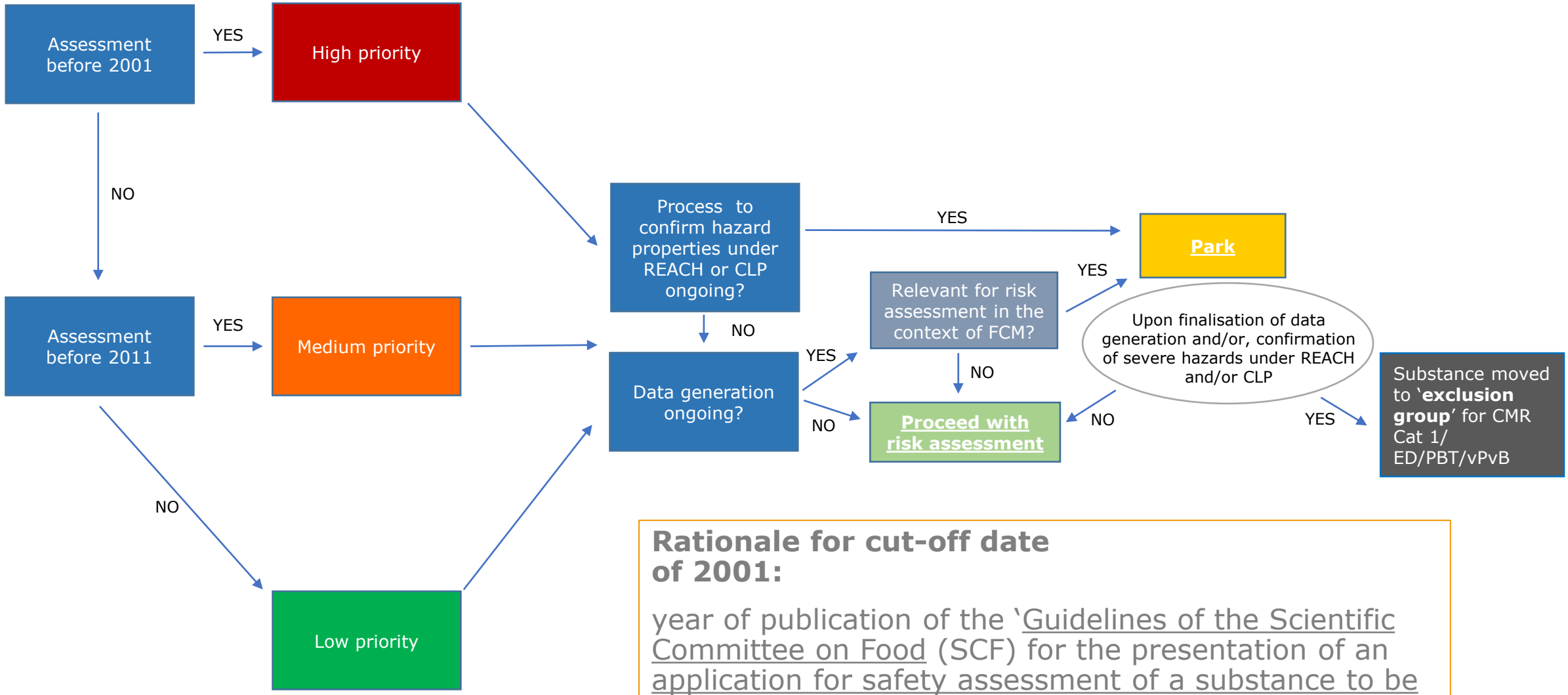
→ "The Commission will:

extend the **generic approach to risk management** to ensure that consumer products – including, among other things, **food contact materials**, toys, childcare articles, cosmetics, detergents, furniture and textiles - **do not contain chemicals** that cause **cancers**, **gene mutations**, affect the **reproductive** or the **endocrine system**, or are **persistent** and **bioaccumulative**…"

Exclusion group

- dicyclohexyl phthalate (DCHP; CAS No 84-61-7)
- dibutyl phthalate (DBP; CAS No 84-74-2)
- benzyl butyl phthalate (BBP; CAS No 85-68-7)
- bis(2-ethylhexyl) phthalate (DEHP; CAS No 117-81-7)
- diisobutyl phthalate (DIBP; CAS No 84-69-5)

Prioritisation of substances



Rationale for cut-off date of 2001:

year of publication of the 'Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation'

Prioritisation results

Priority group		EU-authorised substances	Nationally authorised substances
High	Proposed for risk assessment	54 (36 individual substances; 7 group entries)	55
	Parked	5	11
Medium	Proposed for risk assessment	10 (7 individual substances; 3 group entries)	2
	Parked	4	1
Low	Proposed for risk assessment	0	1
	Parked	3 (2 group entries)	2

- Top-heavy distribution of substances

→ **Refinement of the ranking** of substances within and possibly between their priority groups **needed**

→ Information collected via **calls for data in support of the exposure assessment** will be used.

→ Expected input to calls: information/data on the prioritized substances as regards migration from and occurrence in FCM, as well as occurrence in food

Task 2a: exposure assessment protocol

- With a view to ensuring transparency and efficiency during the second part of the mandate, establish a **protocol** for:
  - a) A **dietary exposure assessment** of the prioritised substances, with the aim of addressing the relative contribution from FCM to dietary exposure considering data on migration from FCM and eventual comparison of these contributions with the overall exposure of EU consumers;

TECHNICAL REPORT

ENDORSED: 22 March 2022

doi:10.2903/sp.efsa.2022.EN-7288

Protocol for the exposure assessment as part of the risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food

European Food Safety Authority (EFSA),
Francesca Romana Mancini, Maria de Fátima Tavares Poças, Evelin Fabjan[a], Stefano Frattini[a], Niko Hellsten[a], Evgenia Stojanova[a], Katleen Baert, Claudia Cascio, Marios Georgiadis, Irene Munoz Guajardo, Katharina Volk and Laurence Castle

a: European Chemicals Agency (ECHA)

Protocol and report on public consultation results available under: https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2022.EN-7288

Assessment questions and sub-questions

- Q1: **Dietary** exposure
- Q2: Dietary exposure from **FCMs**
- Q3: **Overall** exposure

Table 1: Questions and sub-questions to be answered for the exposure assessment

Q1		What is the overall chronic and/or acute dietary exposure to the prioritised substances in different population groups and age classes in the EU?
	SQ1.1	What are the concentrations of the prioritised substances in food in the EU?
	SQ1.2	What are the consumption levels of food among the different population groups and age classes in the EU?
Q2		How much of the chronic and/or acute dietary exposure to the prioritised substances originates from FCMs in the different population groups and age classes in the EU?
	SQ2.1	In which FCMs do the prioritised substances under study occur, and in what concentrations and at what frequency of use (market share)?
	SQ2.2	In which step(s) of the food chain is the FCM used? How often and under what conditions of use is the FCM used in the food chain?
	SQ2.3	What is the concentration of the prioritised substances that migrated into food from each identified FCM (SQ2.1), during the relevant step(s) of the food chain (SQ2.2)?
	SQ2.4	What is the reliability and representativeness of the results obtained from testing for composition and migration?
	SQ2.5	What are the consumption levels of relevant foods in which the migration/concentration due to FCMs was assessed under SQ2.3, in different population groups and age classes in the EU?
Q3		How does dietary exposure due to FCMs compare with the overall (dietary and non-dietary) exposure of EU consumers?
	SQ3.1	What are all the actual uses of the prioritised substances and the possible sources and routes of non-dietary exposure?
	SQ3.2	What is the non-dietary exposure to the prioritised substances from the individual uses identified under SQ3.1?
	SQ3.3	What is the overall (dietary and non-dietary) exposure to the prioritised substances measured through human biomonitoring (HBM)?

Q: question; SQ: sub-question.

Evidence needs for Q2 (dietary exposure from FCMs)

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SQ2.1

- **FCMs** in which the substances are intentionally used or may be present unintentionally;
- **concentration of the substances in FCMs**;
- information on **market share**.

SQ2.2

- **Step(s) in the food chain** (e.g. processing, packaging,…) in which the FCM is in contact with food under a given time/temperature, surface-to-volume (s/v) ratio and single vs repeated-use conditions, and where migration might occur.

SQ2.3

- **Concentrations** of the substances in **food** that **migrated** from the FCM (alternatively food simulants or migration modelling data).

SQ2.4

- **Description of the FCM** (e.g. nature of the material, chemical composition, type of article, thickness, number and order of layers if it is a multilayer, sampling year);
- **test conditions** (s/v ratio, food simulant, time and temperature conditions);
- **test method** used and **LOD/LOQ.**

SQ2.5

- **Individual consumption data for the foods** for which migration data were obtained in different population groups and age classes in the EU.

Task 3: calls for data

- Establish a **call for data** on occurrence of the prioritised substances in food to support dietary exposure estimates. Data on migration levels from plastic and rubber FCMs as well as other materials which may be relevant such as printed paper and board should also be collected, where available. This should include articles throughout the whole food chain, including food manufacturing and processing equipment, as well as packaging, kitchenware and tableware. A search and identification of potentially relevant literature on exposure should also be started as part of this task

Task 3: calls for data

→ Two calls for data launched:

Occurrence in food

- Via Chemical Monitoring data collection (**ChemMon2022**, contaminants domain)
- Data on presence of plasticisers in foods, e.g. after migrating from FCMs or as background contaminants
- Data reporting targeted to:
  - Occurrence data in food collected and analysed during food monitoring campaigns
  - Data on plasticiser concentration in the respective food's packaging, if applicable
- Reporting period: 1st April – 1st October 2022

Occurrence in/migration from FCM

- Via ad-hoc data collection **Plasticisers_FCM_2022**


Instructions for the data reporting on plasticisers in and migrating from Food Contact Materials

European Food Safety Authority (EFSA)

Abstract

This document is aimed to provide instructions to data providers on how to report data to EFSA on "migration of plasticisers from Food Contact Materials" and "Concentration of plasticizers in Food Contact Materials". It provides the description of the data model created for this purpose, together with the rules for data quality validation.

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- Data on migration of plasticisers from FCMs (using food/food simulants) and data on concentration of plasticisers in FCMs, generated through experimental studies on FCMs before their actual use (e.g. obtained from the supplier).
- Reporting period: 1st June – 1st November 2022

Plasticisers_FCM_2022: data elements

- Examples of data elements:

Sample identification	• Country of sampling • Country of origin • Year/month/day of sampling
Sample Description	• Format (e.g packaging, processing articles) • Material • Intended food/use conditions
Concentration test parameters	• Solvent • Test parameters
Migration test parameters	• Food/food simulant • Contact mode/temperature/time
Result	• Result value • LOD, LOQ

Plasticisers_FCM_2022: catalogues

- Examples of catalogues (= list of pre-defined data model entries)

FCMFORMAT	
CODE	**NAME**
FCMF0001A	Kitchenware
FCMF0002A	Packaging
FCMF0003A	Processing articles
FCMF0004A	Transport packaging
FCMF0005A	Food Containers for Cold/Ambient or Hot use
FCMF0006A	Food Preparation Utensil
FCMF0007A	Food Preparation Wear
FCMF0008A	Food Serving Implements
FCMF0009A	Food Serving Utensils
FCMF0010A	Kitchen Small Appliances
FCMF0011A	Food Preparation Utensil for Cold/Ambient use (FPU/CA)
FCMF0012A	Utensil used at ambient temperature for short time
FCMF0013A	Food Preparation Utensils for Cold/Ambient or Hot use
FCMF0014A	Utensil used at ambient or hot temperature for short time
FCMF0015A	Cutting board (not for storage)
FCMF0016A	Kitchen countertop
FCMF0017A	Colander or similar
FCMF0018A	Bowl
FCMF0019A	Microwave material (only warming up or defrosting)
FCMF0020A	Masher or similar
FCMF0021A	Cheese draining article or similar
FCMF0022A	Food Preparation Utensils for Hot use
FCMF0023A	Article that could be used during cooking/frying/grilling
FCMF0024A	Pan or similar

PARAM	
CODE	**NAME**
RF-00012910-PAR	1,2,3-propanetriyl trioleate
RF-00012986-PAR	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters
RF-00012903-PAR	1-methyl-1,2-ethanediyl dioleate
RF-00012923-PAR	2,2-Bis(hydroxymethyl)-1,3-propanediyl dioleate
RF-00012973-PAR	2,2-dimethylpropane-1,3-diyl dibenzoate
RF-00012916-PAR	2-ethylhexyl diphenyl phosphate
RF-00012924-PAR	Anhydro-D-glucitol trioleate
RF-00012959-PAR	Bis(1-methylheptyl) adipate
RF-00012963-PAR	Bis(2-(2-butoxyethoxy)ethyl) adipate
RF-00012956-PAR	Bis(2-ethylhexyl) azelate
RF-00012961-PAR	Bis(2-ethylhexyl) sebacate
RF-00012972-PAR	Bis(2-ethylhexyl) succinate
RF-00012988-PAR	Bis(2-propylheptyl) hexanedioate
RF-00012983-PAR	Bis(2-propylheptyl) phthalate

MTX_PACKMAT	
CODE	**NAME**
A07PD	Ceramic or earthenware
A07PE	Edible material
A07QB	Leaf (wrapper)
A07QA	Husk (wrapper)
A07PR	Plastic
A16RP	Polyethylene Terephthalate (PET, PETE)
A16RQ	Polyethylene (PE)
A16RR	High Density Polyethylene (HDPE)
A16RS	Low Density Polyethylene (LDPE)
A16RT	Polyvinyl Chloride (PVC)

Task 2b: hazard assessment protocol

- With a view to ensuring transparency and efficiency during the second part of the mandate, establish a **protocol** for:
  - b) A **hazard exposure assessment** for the prioritised substances, detailing the criteria for inclusion and appraisal of the toxicological evidence publicly available since 2005 and not yet assessed by EFSA

TECHNICAL REPORT

ENDORSED: 26 October 2022

doi:10.2903/sp.efsa.2022.EN-NNNN

Protocol for the hazard assessment as part of the risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food

European Food Safety Authority (EFSA),

Claudia Bolognesi, Emanuela Corsini, Riccardo Crebelli, Rex FitzGerald, Claude Lambré, Francesca Mancini, Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölfle, Chantra Eskes, Marios Georgiadis, Irene Munoz Guajardo, Katharina Volk, Laurence Castle

→ Final endorsement of protocol as revised after public consultation: 26 October 2022

Assessment questions and sub-questions

Table 1: Questions and sub-questions to be answered for the hazard assessment

Q1		**Hazard identification**
	SQ1.1	Is the substance directly or indirectly genotoxic?
	SQ1.2	Does exposure to the substance at any life stage cause any adverse effects[(a)] in humans?
	SQ1.3	Does exposure to the substance at any life stage cause any adverse effects in non-human mammals?
	SQ1.4	What is the mode of action[(b)] or adverse outcome pathway[(c)] of the substance?
	SQ1.5	What is the substance's toxicokinetic profile in humans?
	SQ1.6	What is the substance's toxicokinetic profile in non-human mammals?
Q2		**Hazard characterisation**
	SQ2.1	What is the substance's dose–response relationship for effects identified in SQ1.2 in humans?
	SQ2.2	What is the substance's dose–response relationship for effects identified in SQ1.3 in non-human mammals?

Outline of the hazard assessment protocol

- **Methods for answering the questions and sub-questions**
  1. Eligibility criteria
  2. Retrieval of studies
  3. Study selection process
  4. Data extraction from included studies
  5. Systematic appraisal of genotoxicity studies and weight of evidence assessment
  6. Systematic appraisal of toxicity studies other than genotoxicity
  7. Narrative appraisal of mode of action, adverse outcome pathway and toxicokinetic studies

1. Inclusion/exclusion criteria, e.g. language, time, publication type, study type, endpoints, population

2. Bibliographic databases, search terms, reference management

3. Title & abstract → full text screening

5. Assessment of reliability (Klimisch) and relevance (EFSA guidance documents)

6. Assessment of external (Scirap) and internal validity (adapted NTP-OHAT)

Outline of the hazard assessment protocol

- **Weighing the body of evidence**
  1. Organisation of the body of evidence for relevant endpoints
  2. Assessment of the likelihood of a health effect
  3. Integration of human and non-human mammal evidence for the final assessment of the likelihood of a health effect in humans

- **Method for performing hazard characterization**
- **Uncertainty analysis**
- Plans for **updating the protocol**, and for **updating the literature searches** and dealing with newly available evidence

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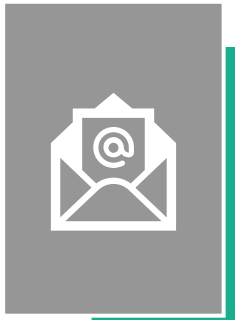

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