7th FCM Network meeting, 6-7 November 2019

Prioritisation of authorised plastic FCM substances without an SML

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Trusted science for safe food

European Food Safety Authority

EC Mandate on Prioritisation

Regulation (EU) No. 10/2011

Does not assign a Specific Migration Limit (SML) to approximately 460 substances

Certain substances may require a limit to ensure their authorization is sufficiently **protective of consumers' health.**

Prioritisation based on a set of criteria defined by EFSA-CEP Panel.

- Theoretical knowledge about chemistry and toxicology

-Known migration limiting factors

-Physico-chemical properties of the substances

High priority

Medium priority

Low priority

Deadline: 2nd Quarter 2020

EC Mandate on Prioritisation

Dear Dr Url,

Subject: **Specific Migration Limits (SML) for substances used in plastic Food Contact Materials (FCM) - Review**

Following our own review and discussions with the Member States and the industry, it became apparent that Regulation (EU) No 10/2011 on plastic food contact materials ('the Regulation') does not assign a Specific Migration Limit (SML) to approximately 460 substances that are listed in Table 1 of Annex 1. Certain substances may nonetheless require the specification of a limit to ensure their authorisation is sufficiently protective to health. EFSA should assess for which substances a limit would need to be determined.

For many substances, the absence of a limit is correct because their migration may not be of a health concern or is accounted for otherwise, such as in the overall migration test. However, for certain substances, including volatile substances, this may not be the case. The review of all substances authorised under the Regulation without a specified migration limit is therefore necessary, with the exception of substances for which EFSA published opinions in the context of an application. This review should identify those substances for which EFSA considers that a specific migration limit at or below 60 mg/kg may be required to prevent the transfer of these substances to the food in an amount that could cause adverse health effects.

EC Mandate on Prioritisation

In the first stage, EFSA should prioritise the need for re-evaluation of these substances in groups of high, medium, and low priority, setting apart substances for which there is no apparent need for a SML. The enclosed synoptic list may facilitate this work for the older substances.

The prioritisation should be done based on criteria EFSA deems appropriate, such as based on theoretical knowledge about the chemistry and toxicology of the substances, the absence of such information, known migration limiting factors, volatility and other appropriate information available to EFSA. A call for data should not be conducted at this stage.

In the second stage, based on the list of the priorities established in the first stage, the Commission will provide EFSA with separate mandates for re-evaluation of the individual substances taking into account the assigned priorities.

Criteria

Criteria: Toxicity,
Chemical properties,
"any other appropriate information"

Tools:

- Past FCM evaluations (Synoptic doc.)
- MS evaluations
- FLAV & FA authorisations,
- ECHA & other databases
- QSAR

- Migration limiting factors, volatility, etc.
- Modelling.

Authorised plastic FCMs without an SML

- List and exclusions

Union List *

Limit	Number of Substances
Blank	**452**
SML	263
Group restriction	138
Group restriction + SML	9
Not to be Detected	31
Total	**893**

No SML

* As amended by Commission Regulation (EU) 2019/37 of 10 January 2019

2. Authorised plastic FCMs without an SML

- **Step 1:** List and exclusions

EFSA evaluations of "no SML" substances

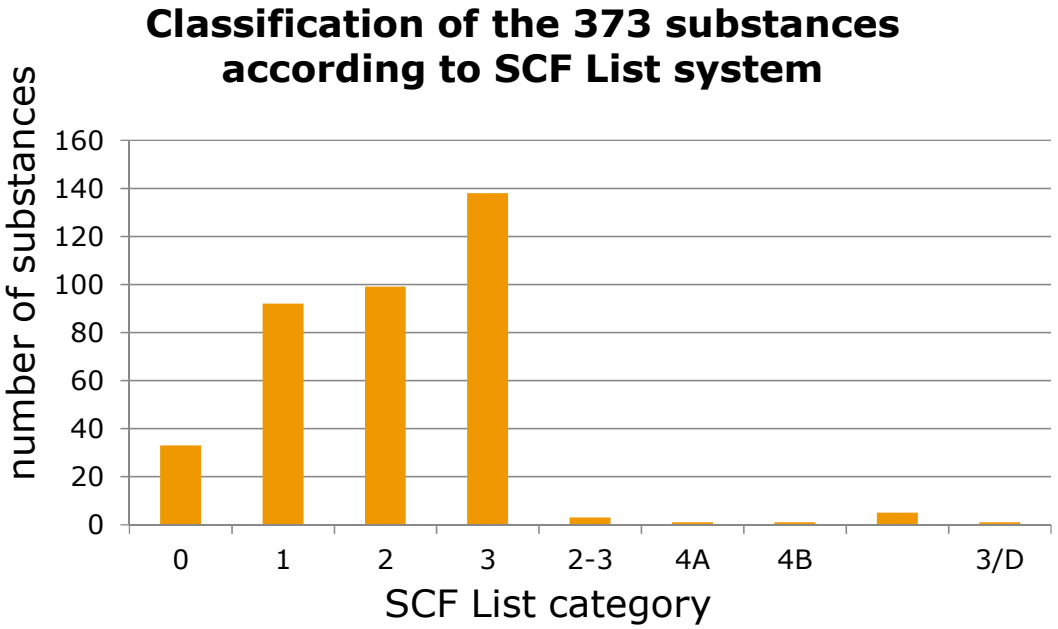
Evaluation	Number of substances	Note
EFSA - Opinion on FCM application	77	AFC/CEF/CEP Panels
EFSA – Opinion on FCM EU mandate	1	BADGE (group SML in R.1895/2005)
EFSA - Report on salts of authorised acids/phenols/alcohols	1	Manganese hypophosphite (Art.6 par.3(a) of R.10/2011)
SCF evaluation or No evaluation	**373**	
Total	**452**	

Only **312** chemical substances with CAS#

SCF evaluations of plastic FCM

- FCM evaluations before EFSA:
  - Scientific Committee on Food (**SCF**), **Synoptic document**

- Updated until 2005, it contains:
  - Substance names, CAS#, REF#, SML and restrictions
  - Evaluation conclusions, short summary of studies
  - SCF list numbering

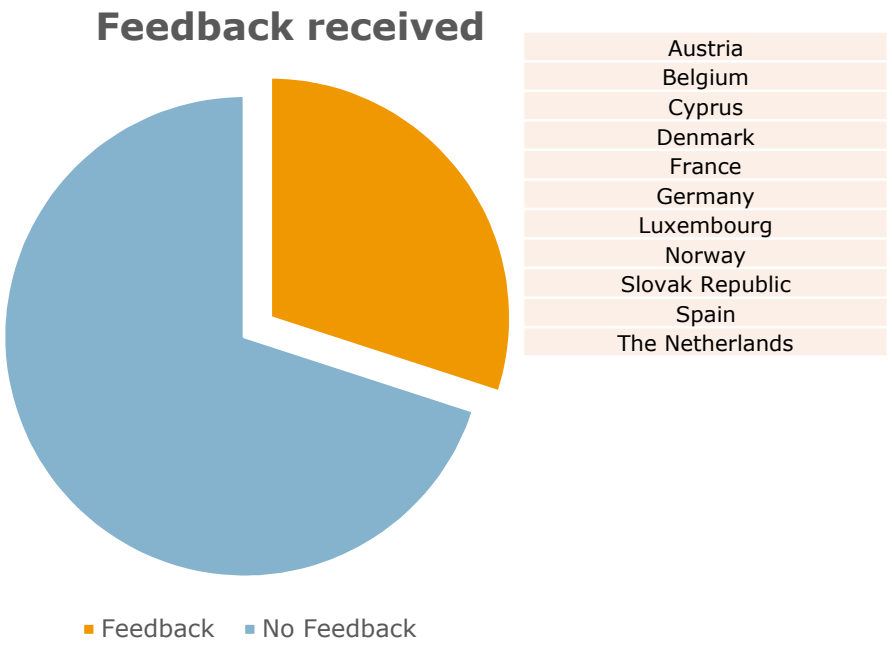


Evaluations at National level

EFSA Focal Points and the FCM Network

37 EU countries were contacted (July 2019)

11 countries responded



Austria
Belgium
Cyprus
Denmark
France
Germany
Luxembourg
Norway
Slovak Republic
Spain
The Netherlands

EFSA Focal Point network comprises members from all 28 EU Member States, Iceland and Norway, as well as observers from Switzerland and EU candidate countries

MS - Type of Feedback

Positive feedback: 7/11 countries (Austria, Denmark, France, Germany, Netherlands, Norway, Slovakia) → Suggestions/Comments on the strategy/National RA

Lack of feedback: 3/11 countries (Cyprus, Luxemburg, Spain) → No evaluation available at National level or not foreseen as activity

Hybrid feedback: 1/11 countries (Belgium) → No evaluation available at National level, evaluation strategy development for non-evaluated substances

MS - FCM Substances

Feedback:

- RA opinions

- Suggestions/comments/support

(e.g. Netherlands → electronic secretariat notes of SCF-FCM Panel + SDS's of substances)

- taurine, salts (**FCM 90**)
- waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity (**FCM 94**)
- white mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstocks (**FCM 95**)
- α-tocopherol (**FCM 110**)
- linoleic acid (**FCM 112**)
- ethanol (**FCM 113**)
- benzoic acid (**FCM 116**)
- methanol (**FCM 117**)
- 2-propanol (**FCM 118**)
- acetone (**FCM 119**)
- 1-butanol (**FCM 123**)
- L-(+)-tartaric acid (**FCM 161**)
- o-cresol (**FCM 174**)
- styrene (**FCM 193**)
- p-cresol (**FCM 213**)
- 1-butene (**FCM 222**)
- 2-butene (**FCM 224**)
- m-cresol (**FCM 235**)
- cyclohexylamine (**FCM 240**)
- terephthalic acid, dimethyl ester (**FCM 288**)
- chlorine (**FCM 522**)
- lecithin (**FCM 528**)
- beeswax (**FCM 531**)
- starch, edible (**FCM 564**)
- terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol) (**FCM 696**)

25 substances
out of 373

Flavourings & Food Additives

- **Other Union Lists**

  - **Authorised flavourings** (no additional data required, no restrictions applying. R1334/2008)

    51 FCMs without an SML

  - **Authorised food additives** (No Concentration Limit or >60 mg/kg., R1338/2008, Annex II, Part E):

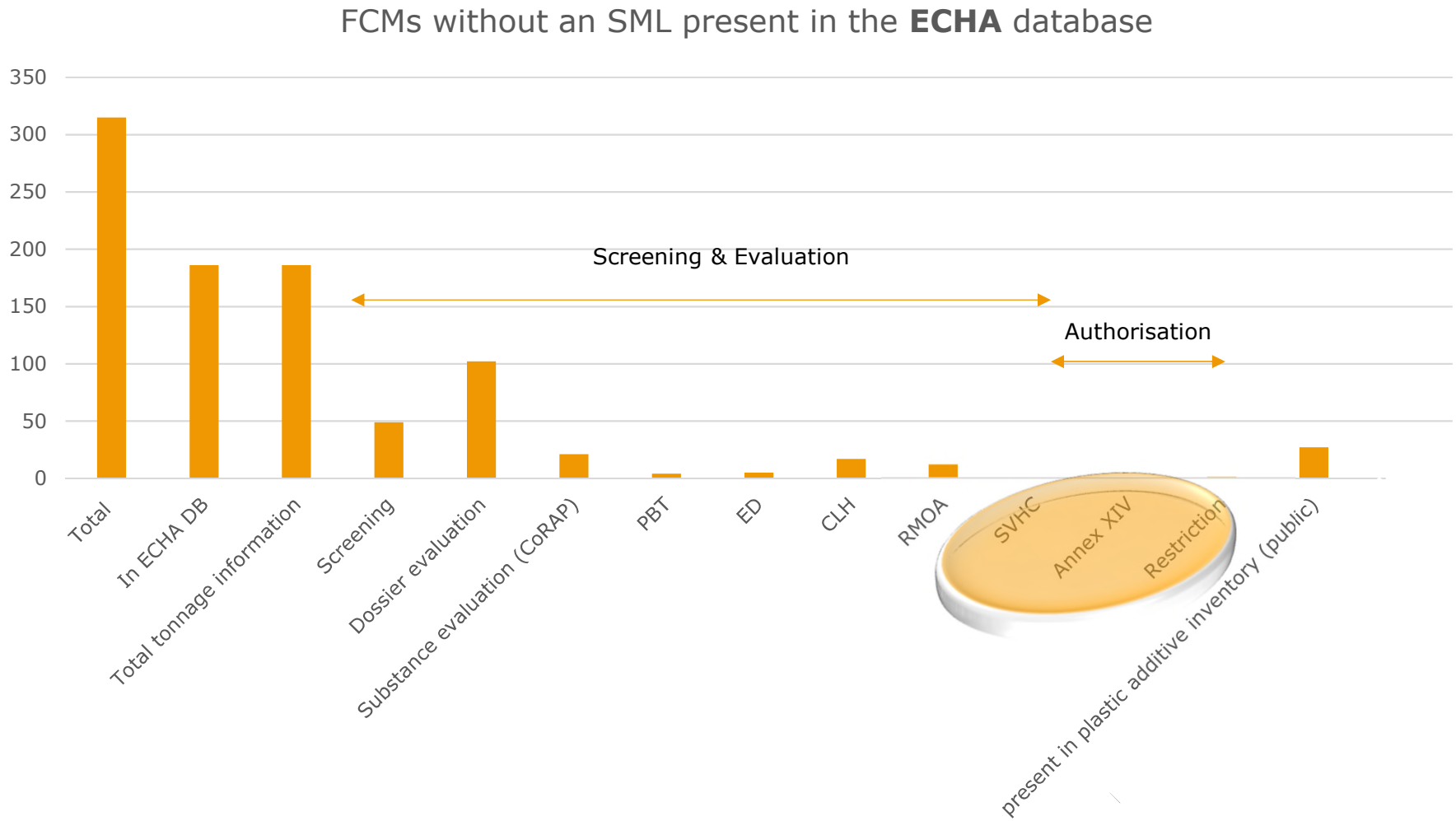
    52 FCMs without an SML

Databases

ECHA

- Effectively responded to our request - searched the **registrations under REACH and CLP** to provide information on the FCM substances
- ECHA provided information on its **Plastic Additives Initiative** (for prioritization)
- Option for formal collaboration (access to **confidential data**)

Databases


FCMs without an SML present in the **ECHA** database
350
300
250
200
150
100
50
0
Screening & Evaluation
Authorisation
Total
In ECHA DB
Total tonnage information
Screening
Dossier evaluation
Substance evaluation (CoRAP)
PBT
ED
CLH
RMOA
SVHC
Annex XIV
Restriction
present in plastic additive inventory (public)

Databases

IARC Classification groups 1,2A,2B and 3: **15 substances**

Other DBs?

In silico platforms used:

- OECD QSAR Toolbox (version 4.3)

→ Updated and several databases

→ ECHA

- VEGA (version 1.1.4)

→ Evaluation of the applicability domain (reliability of the prediction)

(The applicability domain (AD) of a QSAR model is the physico-chemical, structural or biological space, knowledge or information on which the training set of the model has been developed, and for which it is applicable to make predictions for new compounds)

QSAR considerations

- Identification of relevant endpoints

- Endpoints: prioritisation on the basis of relevance

→ considering the reliability of the single models)

- Models comparison (2 platforms)

→ Agreement in the prediction among the 2 software for the same substance

- Grouping approach

→read-across for those compounds with no prediction

Exposure

- **Exposure**
  - Migration potential (modelling)
  - Substances not used any more?
  - Migration limiting factors

- ***Other prioritization exercises - for example:***

  - EFSA, emerging risks team:

    Toxicity (ECHA, IARC)+ exposure (biodegradation via modelling): 212 priority substances (0 FCM without SML)

  - ECHA, plastic additives initiative

    Toxicity (ECHA) + release (modelling): approx. 400 substances (27 FCM without SML in the public list)

On-going and next steps

- **Complete - review the sources of information**
  1. SCF evaluations, MS feedback, ECHA, IARC: *Extract information, review relevance.*
  2. Flavourings and Food Additives: *Review RA used for authorization*
  3. QSAR update, conclude on endpoints
  4. Migration modelling

- **Conclude on ToR and methodology**
  1. Interpetation of ToR
  2. Scoring system
  3. A pilot with a small number of substances representing possible low, medium and high priority groups
  4. Drafting & finalisation

Prioritisation of authorised plastic FCM substances without a limit

Many thanks to:

Member States for the feedback on RA

ECHA for the database search and productive discussions

EFSA FCM Working Group of experts

EFSA FCM team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