REACH
Plastics Additives Initiative

The EFSA Food Contact Material Network – 7th meeting

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Parma

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Content

1. **Context, objectives and key features**

2. Overview on plastic additives

3. Comparison of release potential

4. Learning

- Standard approach for prioritisation:
  - Sorting (**groups** of) substances based on risk
    - Indication of hazard and
    - widespread use + potential for exposure
  - main source of information: **REACH Registration dossiers**

- Complementary approach: targeted projects with specific industrial sectors (**sector approach**)
  - Plastic additives (PLASI)
  - Petroleum and Coal (PETCO)
  - Metals (MISA)

PLASI: objectives

1. To contribute to ECHA's Integrated Regulatory Strategy,

   ➢ identify (groups of) substances for further (regulatory) work by authorities

2. To **pilot the "sector approach"** on a group of substances/materials that matter

3. To work together with Industry on clarifying what **use and exposure information is key**

   • for industry to be able to properly **assess** and **communicate** the safe use of chemicals

   • and for authorities to (de)prioritise substances

PLASI: key features

Kick-off: November 2016

- Contribution from >20 sector groups: plastic additives manufacturers, plastics compounders and converters (incl. recyclers)

- REACH registration database as starting point

- Expert input to release ranking approach development (industry, academia & authorities)

- Project coordination: Cefic, ECHA, EuPC & PlasticsEurope

*Web publication available since: February 2019*

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Overview of confirmed plastic additives

418 substances confirmed to be used as plastic additives in EU:

- 9 types of functional additives & pigments
- Additional info: polymer type(s), typical concentration
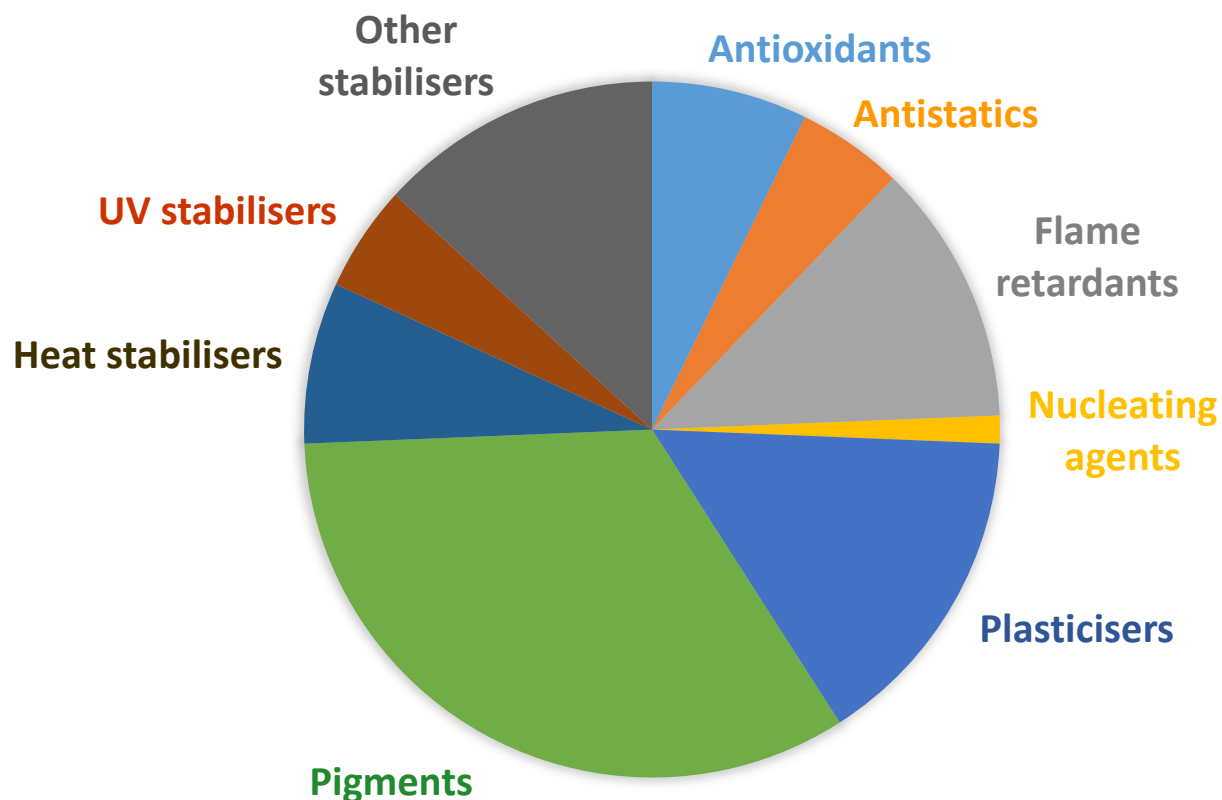
Not all substances in plastic covered

Overview **contains only**

- Substances registered > 100 t/a under REACH
- Identification based on non-confidential data

Not covered:

- Other additive types such as fillers, blowing agents, lubricants (function less plastic-specific)
- Monomers, polymers, cross-linkers, ….
- Transformation and degradation products

Additional list of 183 possible plastic additives

418 confirmed by industry **+** 183 possible plastic additives **=** Plastic additives overview for authority work

- 418 confirmed by industry sectors; registered > 100 t/a

- 183 possible plastic additives > 100 t/a
  - Uncertain status by IND; no function information in registration data base
  - Identified (partly) based on non-public data

Data analysis

- Around 15% false positives and false negatives in registration data base (based on PLASI data from industry)

- 60% not under REACH regulatory scrutiny so far

- 79 substances overlap between PLASI List and FCM positive list for plastic materials

- Project enabled vertical communication in supply chain; information available:

  - Function for 90% of substances

  - Concentration and polymer-matrix about 60%

  - Article type and transformation product < 40%

- Mass-flow data to material types and article types still mostly lacking.

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Method for comparing the release potential

- Two indicator values for the **relative** release potential of different additives used in plastics
    - Release in direct contact (dermal/oral/water)
    - Volatilisation to air
  - Drivers for subsequent environmental exposure not taken into account:
      - Mass-flow to product types [lack of data]
      - Biodegradation
- Applied to additives which had not been under regulatory scrutiny so far [summer 2018]
- The method is **not**
  - comparing exposure (per route) and risks
  - tested against measured data sets

![ECHA - European Chemicals Agency]

Driving mechanism for release
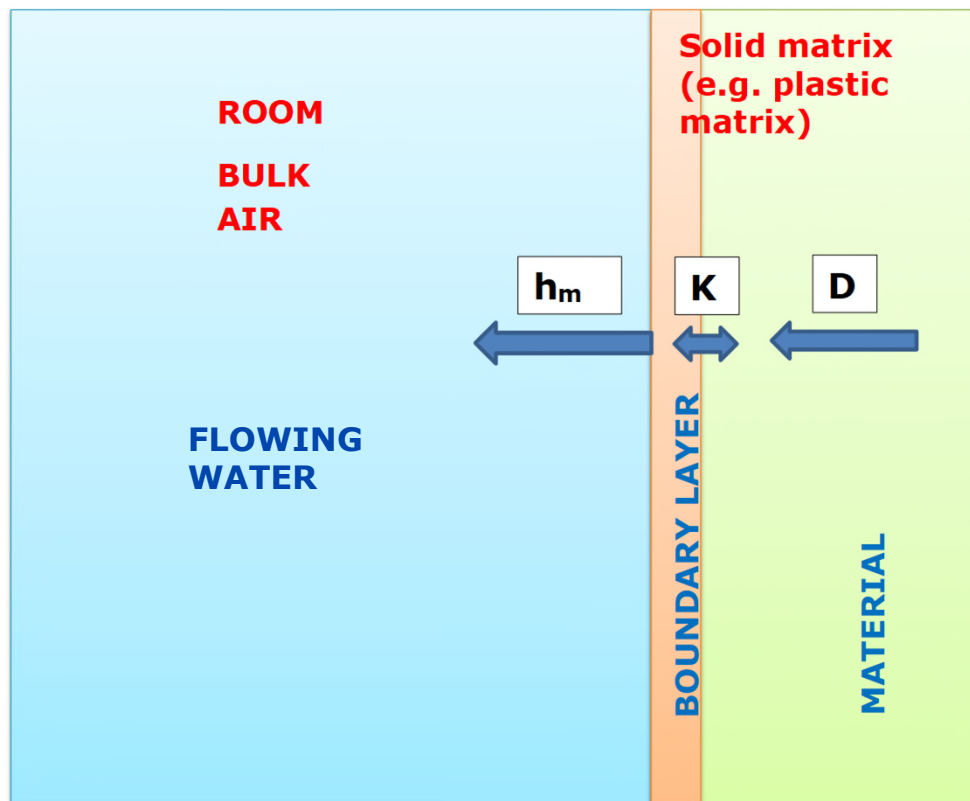
- **Diffusion** (m^2/s), speed of movement in the matrix
  - Diffusivity of polymer
  - MW of substance
  - Temperature

- **Partition** (-), tendency to move from surface to another layer

- **Mass transfer** (m/s), transport velocity of the substance from the boundary layer to air

- **Concentration** determines the amount available for release

Models applied

- Release in dermal contact [proxy also for oral and water]
  - Diffusion model (Delmaar, CEM USEPA) and partitioning between plastic surface – skin
    - matrix-specific diffusion coefficients available from literature on food contact material
    - partitioning from literature: experiments with food-simulants and calculation method based on $\log_{kow}$
    - Log_{kow} based on modelling (to support comparability across the data set)
  - Standard scenario applied: 2 hands, 1 hour contact
- Release to indoor air
  - Emission model in Consexpo Web (emission from solid large surfaces)
  - Standard scenario applied: 10 m2 x 0.5 cm of plastic panel in standard room

Relative release potential (log scale)

Subst name	Mol weight (Da)	Vapour pressure (Pa)	Water solub. (mg/L)	log Kow (-)	Technical function	Polymeer Matrix	Conc. in polymer (%)	Release indicator (dermal)	Release indicator (inhal)
A	403.0	5.63E-04	4.85E-02	5.6	plasticiser	PVC (soft)	35	-2	-2
B	637.0	4.21E-21	2.19E-06	9.61	n.a.	PA	0.5	-7	-10
C	403.0	1.65E-11	1.26E-01	5.12	n.a.	n.a.	35	-2	-8
D	218.0	3.31E-01	5.80E+04	0.36	plasticiser	PVC (soft)	10	0	0
E	795.0	3.28E-22	6.60E-11	13.7	heat stabiliser	Polyolefin-I	2	-6	-9
F	553.0	1.39E-18	2.75E-04	7.79	antioxidant	Polyolefin-I	1	-5	-9
G	255.0	5.93E-16	2.70E+00	-2.28	flame retardant	PUR	30	0	-8
H	685.0	9.51E-14	4.68E-06	10	UV/light stabiliser	PMMA	1	-7	-9
I	593.0	1.06E-15	2.05E-10	14	Other stabiliser	Polyolefin-I	0.3	-7	-10
L	355.0	1.29E-03	1.14E-05	10.2	n.a.	n.a.	35	-4	-3
M	350.0	1.10E-11	2.30E+03	0.51	n.a.	n.a.	35	0	-9
N	214.0	9.48E-06	1.34E+05	-0.19	flame retardant	ABS	25	-3	-4
O	414.0	1.95E-12	2.20E+00	3.57	nucleating agent	Polyolefin-I	2	-3	-9
P	451	9.83E-10	4.97E+01	2.9	UV/light stabiliser	Polyolefin-I	0.8	-3	-8
Q	224.0	6.28E-03	2.33E+02	2.51	Other stabiliser	PVC (soft)	2	-2	-2
R	254.0	2.32E-10	2.80E+03	-2.61	heat stabiliser	Polyolefin-I	2	-1	-5
S	733.0	1.07E-14	2.95E-12	15.1	antioxidant	Polyolefin-I	0.2	-7	-10
T	483.0	4.05E-06	4.78E-08	12	plasticiser	PVC (soft)	35	-4	-4

Learnings

- Communication in supply-chain is key for improving knowledge on uses of additives
- Weak points in REACH registration dossiers
  - use/functions descriptions inaccurate or too broad
  - mass-flow data to material/article types lacking
  - Chemical Safety Assessment for additive in materials (articles) often missing (=> no communication via ext-SDS)
- Hardly possible for the additive producer to assess the release from complex multi-layer matrices => focus on mono-material?
- Basic chemical-physical properties and the concentration may help to focus attention
  - Note however: 30% UVCBs and multi-constituent organics

Potential follow up

- Evaluate impact of project for industry and authorities
- Provide industry with guiding principles for
    - proper use description in their registration dossiers
    - Chemicals Safety Assessment for additives in plastic materials
- Compounders/converters to extend the sector use map to article service life
- Explore how compounders can make their knowledge available for generic safety assessments for additives
- Test ranking method against measured migration data sets (if available)
- Better understand/estimate
    - the transfer from article surface to skin
    - the intake of semi-volatiles via house dust

If you wish to go deeper...

Further details on PLASI can be found at:

https://echa.europa.eu/plastic-additives-initiative

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you!

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Sensitivity analysis

Sensitivity - Partitioning

Difference in ranking for dermal route - Without and with partitionning

Sensitivity – release route (2)

Sensitivity - release route (2)

Difference in ranking between dermal and inhalation exposure

Outliers: 30%

61.18%

Frequency
Cumulative %

Difference in ranking position between dermal and inhalation exposure

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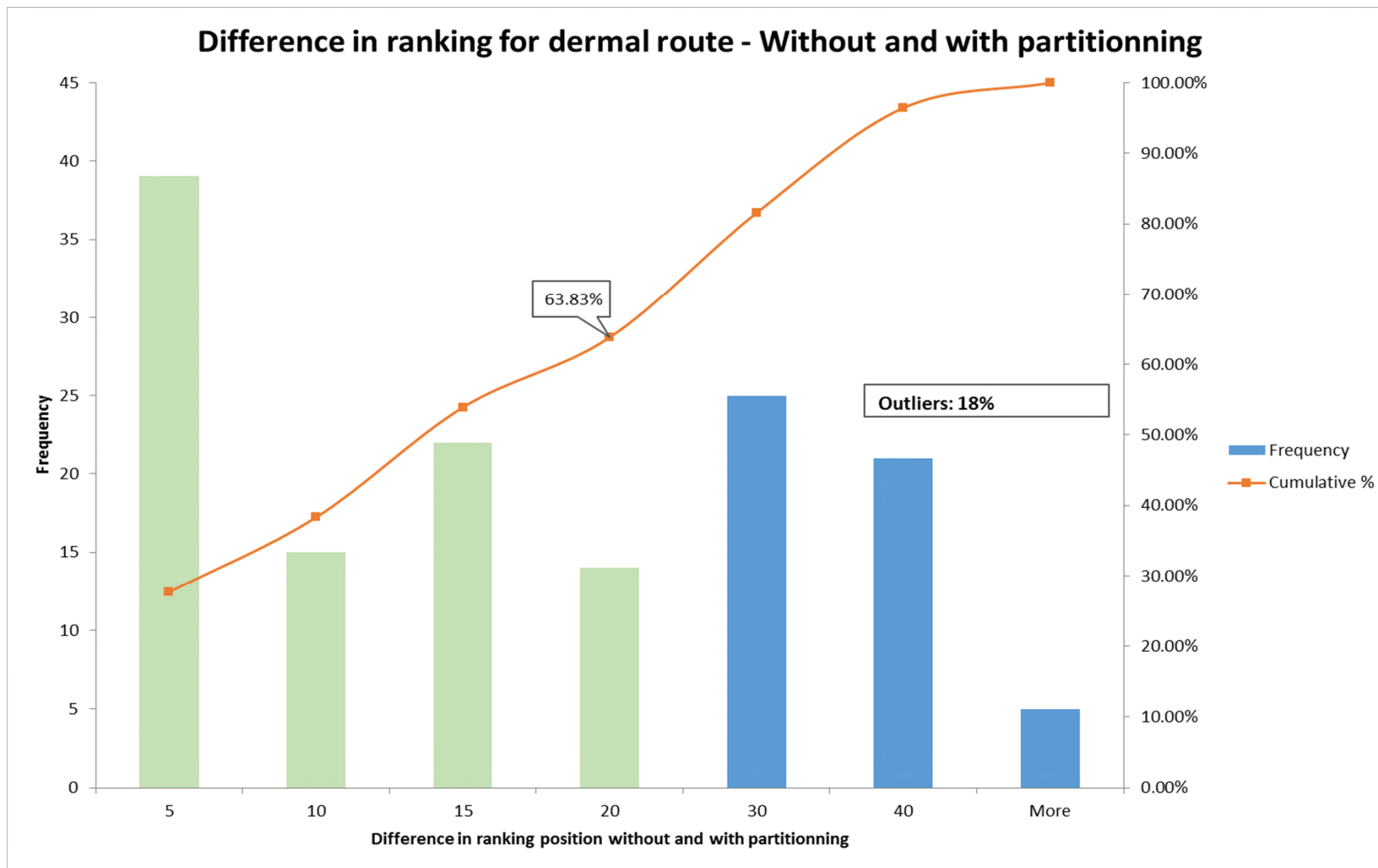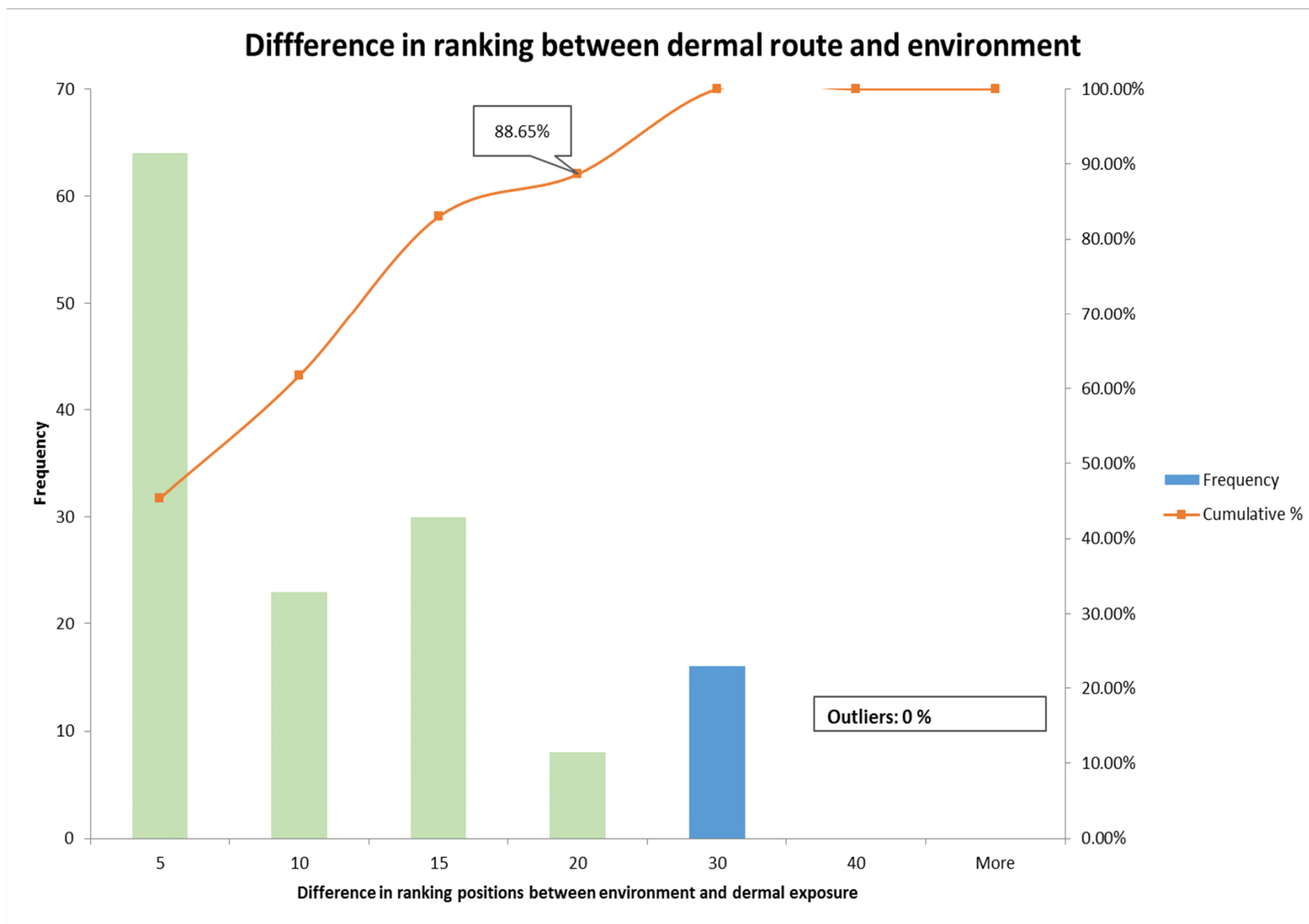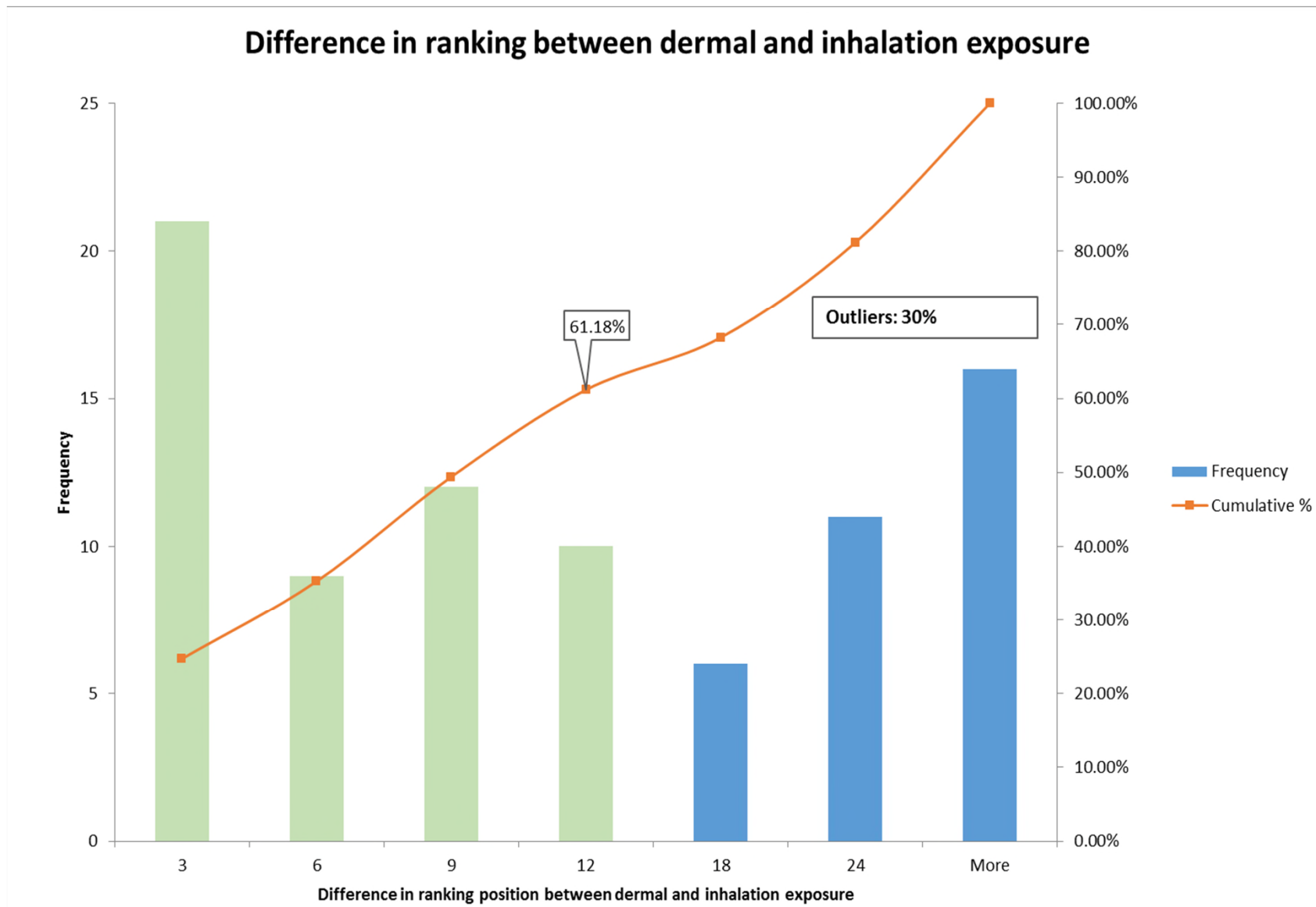
Relative release potential of UVCB constituents (log scale)

Name	Mol weight (Da)	Vapour pressure (Pa)	Water solub. (mg/L)	log Kow (-)	Technical function	Polymer matrix	Conc. in polymer (%)	Release indicator (dermal)	Release indicator (inhal)
A1	204.0	9.30E-04	3.82E+03	1.21	n.a.	n.a.	35	0	-3
A2	457.0	6.30E-09	6.33E-05	9.18	n.a.	n.a.	35	-4	-8
A3	849.0	2.73E-17	2.28E-19	22.5	n.a.	n.a.	35	-5	-8
B1	331.0	9.51E-08	1.25E-01	5.63	n.a.	n.a.	35	-2	-6
B2	569.0	9.35E-13	5.31E-09	13.1	n.a.	n.a.	35	-4	-8
B3	892.0	2.64E-18	6.53E-21	23.9	n.a.	n.a.	35	-5	-8
C1	326.4	5.38E-04	6.80E-01	4.8	plasticiser	PVC (soft)	35	-2	-2
C2	348.0	1.65E-03	1.93E-02	6.46	plasticiser	PVC (soft)	35	-2	-2
C3	384.6	1.85E-03	1.70E-04	8.61	plasticiser	PVC (soft)	35	-3	-2

Table 3: Release potential comparison for different constituents in the same substance