German Federal Institute for Risk Assessment

Closing data gaps for exposure assessment of food additives - BfR MEAL study as an example

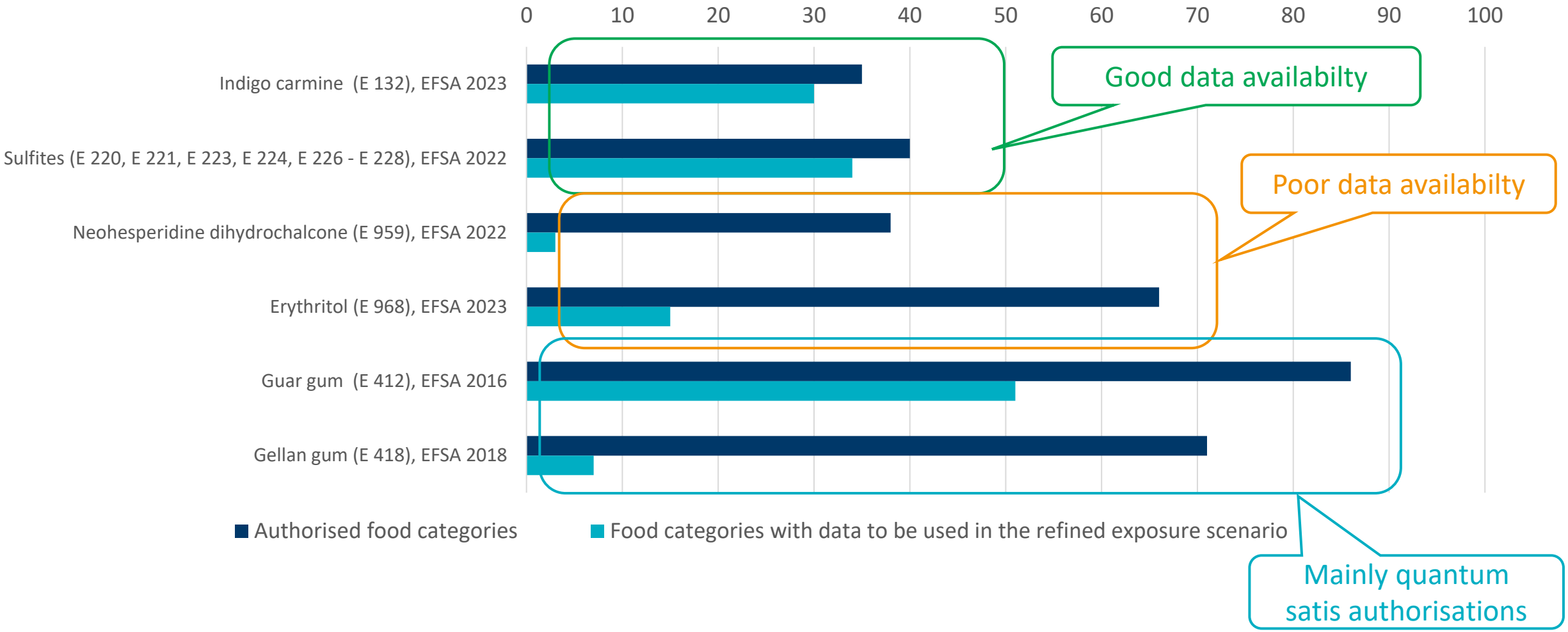
26th November 2024, Berlin

Oliver Lindtner, Sebastian Ptok, Irmela Sarvan
Unit Dietary Exposure and Aggregated Exposure
Department Exposure

Data sources for food additives exposure assessments

Maximum permitted levels	Analytical data	Use levels	Produkt databases with label information
• No real information on use • Overestimation of exposure • Missing values for quantum satis authorisations	• Most realistic information • Biased if not representative • Mainly of interest if food additive is labeled or in case of natural occurrence	• Limited information on market relevance, possible biases • Data sources and methods not known	• Clear indication of the type of products • Direct match to food consumption possible • No quantification, presence data only

Data availabilty for EFSA exposure assessments on food additives



Need of monitoring data for EFSA evaluations of food additives -1-

Neohesperidin DC (E 959)

- 4.294 analytical data were submitted by MS
- *“The vast majority (99.9%) of these results were left-censored (below LODs/LOQs).” (EFSA 2022)*
- *“Overall, no suitable analytical results for neohesperidine dihydrochalcone (E 959) in foods were available for the exposure assessment.” (EFSA 2022)*
- Only 3 out of 38 food categories where neohespiridine is authorised could be considered in the “refined scenario”. All of them based on use levels submitted by food industry.

Need of monitoring data for EFSA evaluations of food additives -2-

Erythritol (E 968)

- 187 analytical data were submitted by two MS only
- Only 30 analytical values could be used for the exposure assessment, belonging to 8 out of 66 food categories (+7 with use levels provided by food industry)
- That means that mean concentration is based on very few and data for those food categories
- Very probably not fully representative for all MS of the EU
- Food categories with potential high impact to exposure due to relevant consumption were not considered in the refined scenario, like “fermented milk products”, breakfast cereals, desserts. For all three example FC products were on the EU market relying on market product database MINTEL GNPD

BfR MEAL Study - an approach to close data gaps by representative data

BfR

BfR MEAL Study – First German Total Diet Study

Criterion 1

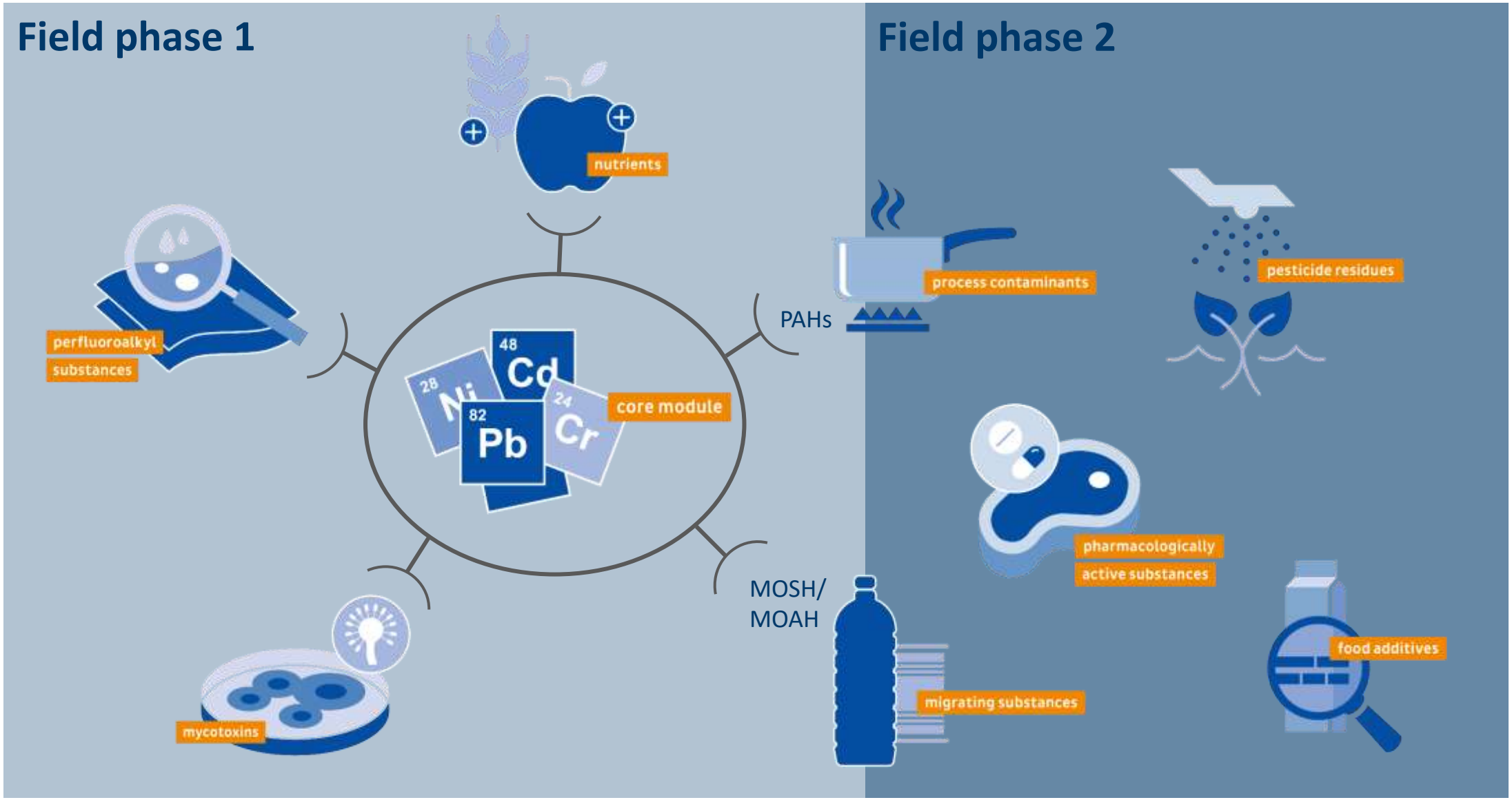
- Representative for the German population
- Covers at least 90 % of the German diet
- Includes highly contaminated foods, although they are consumed rarely (< 10 %)

Criterion 2

- Foods are prepared as consumed

Criterion 3

- Similar foods are pooled together to one sample to reduce the number of samples


Field phase 1
Field phase 2
nutrients
perfluoroalkyl
substances
core module
48
Cd
28
Ni
82
Pb
24
Cr
mycotoxins
PAHs
process contaminants
pesticide residues
pharmacologically
active substances
MOSH/
MOAH
migrating substances
food additives

‚Food Additives' module of the BfR MEAL Study

Object of the module

– Providing data on average levels of food additives in prepared foods for different food categories of Annex II of Regulation (EC) No 1333/2008

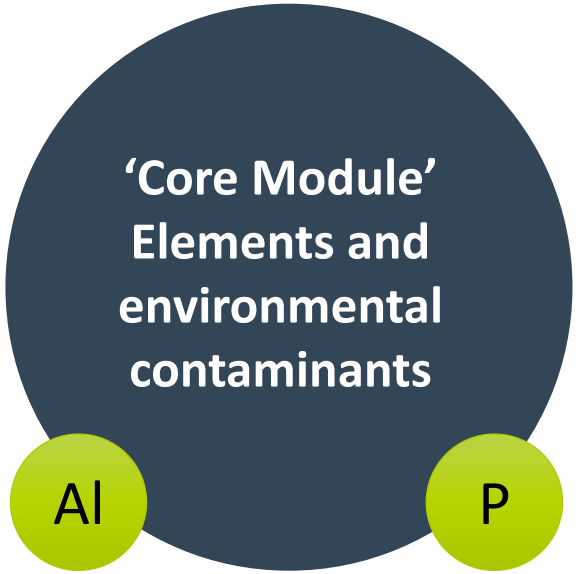
– Providing data on average levels of substances in prepared foods from sources other than food additive use (e. g. natural occurrences in foods)

Stepwise approach of selecting food additives

- Review of EFSA Opinions on the re-evaluation of food additives from 2012 – 2018 (data gaps, uncertainties in exposure estimates)
- Compiling information on the availability of validated analytical methods
- Prioritizing of food additives by expert group advising the BfR MEAL study and by EFSA.

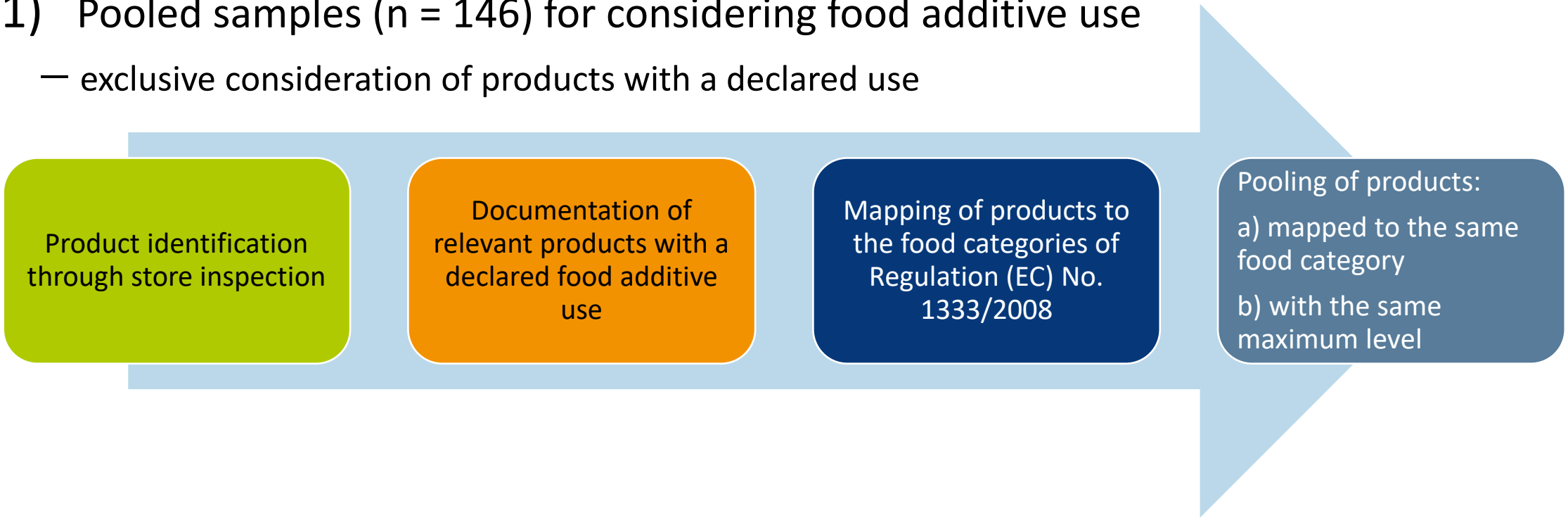
Selected food additives of the BfR MEAL Study

Function	Food additive (group)	INS number
Preservative	**Sorbates**	200 – 202
	Benzoates	210 – 213
	Sulfites	220 – 228
	Nitrites	249 – 250



Module foodlist

1) Pooled samples (n = 146) for considering food additive use
   - exclusive consideration of products with a declared use



1) Pooled samples (n = 85) for considering sources other than food additive use like natural occurrence
   - Information on relevant foods was taken from literature and national monitoring programs

Extract of the resulting food list

Food additives use: Food category according to Annex II, (EC) No 1333/2008		Benzoates[§]	Sorbates[§]	Sulphites[$]	Nitrites[*]
		No. of samples (subsamples)			
12.4	Mustard	-	-	2 (9)	-
12.6	Sauces	3 (11)	4 (32)	-	-
12.7	Salads and savoury based sandwich spreads	10 (36)	12 (47)	-	-
14.1.4	Flavoured drinks	5 (21)	6 (42)	1 (1)	-
14.2.2	Wine and other products and alcohol free counterparts	-	1 (2)	3 (51)	-
14.2.3	Cider and perry	-	-	1 (13)	-
14.2.4	Fruit wine and made wine	-	-	1 (1)	-

[§]expressed as sorbic acid/ benzoic acid; [$]expressed as SO_2^-; [*]expressed as NO_2^-

Natural occurrence: FoodEx2 top-level catagory	Analyt	No. of samples (subsamples)
Vegetables and vegetable products	nitrites	9 (135)
Starchy roots or tubers+products	nitrites	4 (60)
Legumes, nuts, oilseeds and spices	nitrites	1 (15)
Fruit and fruit products	benzoates	5 (75)
	nitrites	2 (30)
Meat and meat products	nitrites	11 (165)
Fish, seafood and invertebrates	nitrites	8 (160)
Milk and dairy products	benzoates	13 (195)
	nitrites	4 (65)
Animal and vegetable fats and oils	nitrites	1 (15)
Fruit and vegetable juices + nectars	nitrites	1 (15)
Water and water-based beverages	nitrites	4 (51)
Food products for infants and toddlers	nitrites	4 (80)
Composite dishes	nitrites	17 (335)
Seasoning, sauces and condiments	nitrites	1 (20)

Different sampling for sweeteners:

- soft drinks only
- products instead of pools analysed

Results (for individual soft drink products)

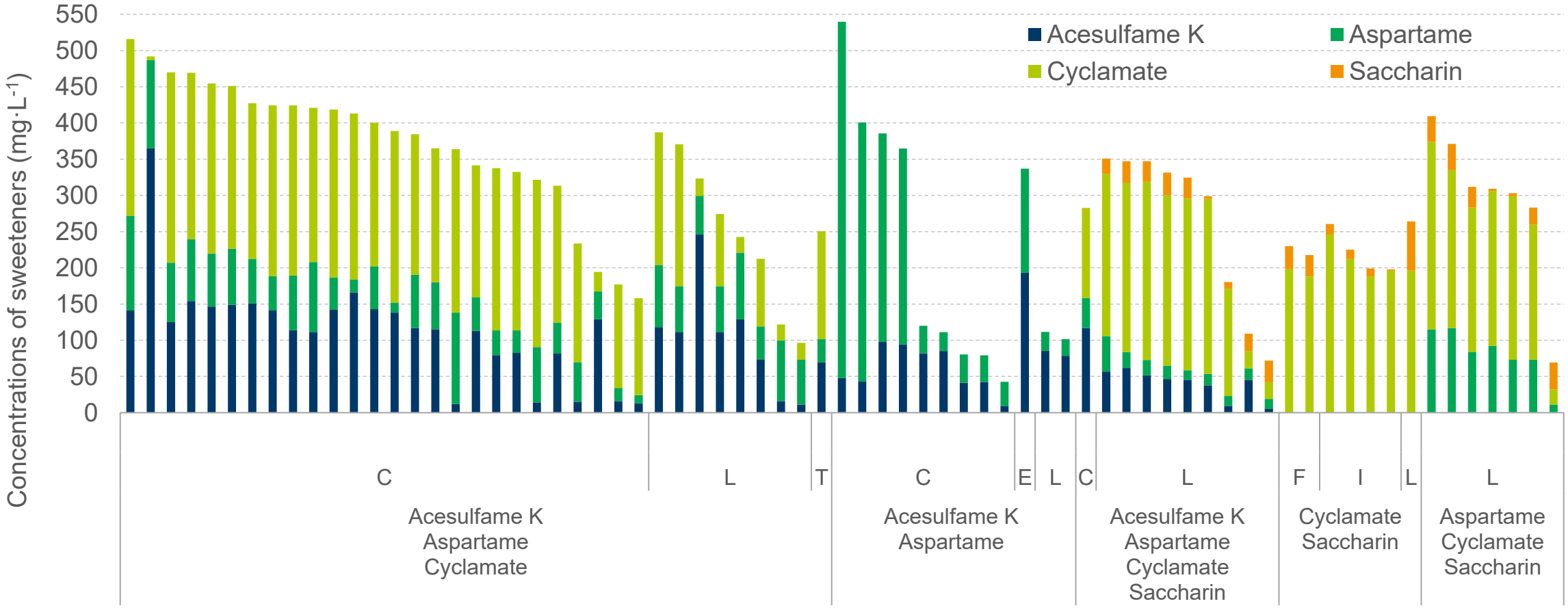
Sweeteners	Energy-reduced			No added sugar		
	n	Mean ± SD	Range	n	Mean ± SD	Range
Acesulfame K	5	43.0 ± 43.8	9.31 – 105	65	92.8 ± 66.1	4.70 – 365
Aspartame	3	19.7 ± 23.2	0.05 – 45.3	64	74.9 ± 82.3	11.0 – 492
Cyclamate	9	144 ± 87.7	7.80 – 246	59	172 ± 79.7	5.10 – 263
Saccharin	8	19.7 ± 20.4	1.90 – 68.2	22	22.9 ± 12.0	0.59 – 37.1
Sucralose	1	93.2	–	10	41.3 ± 40.5	1.90 – 127
Steviol glycoside$	6	23.9 ± 9.14	14.7 – 38.1	2	0.72 ± 0.13	0.63 – 0.81

n = number of samples with detected sweetener; SD = standard deviation; $ calculated as steviol equivalent (EFSA 2010)

Non declared sweeteners (n = 3) Possible exceeding of the maximum level (n = 3)

BfR

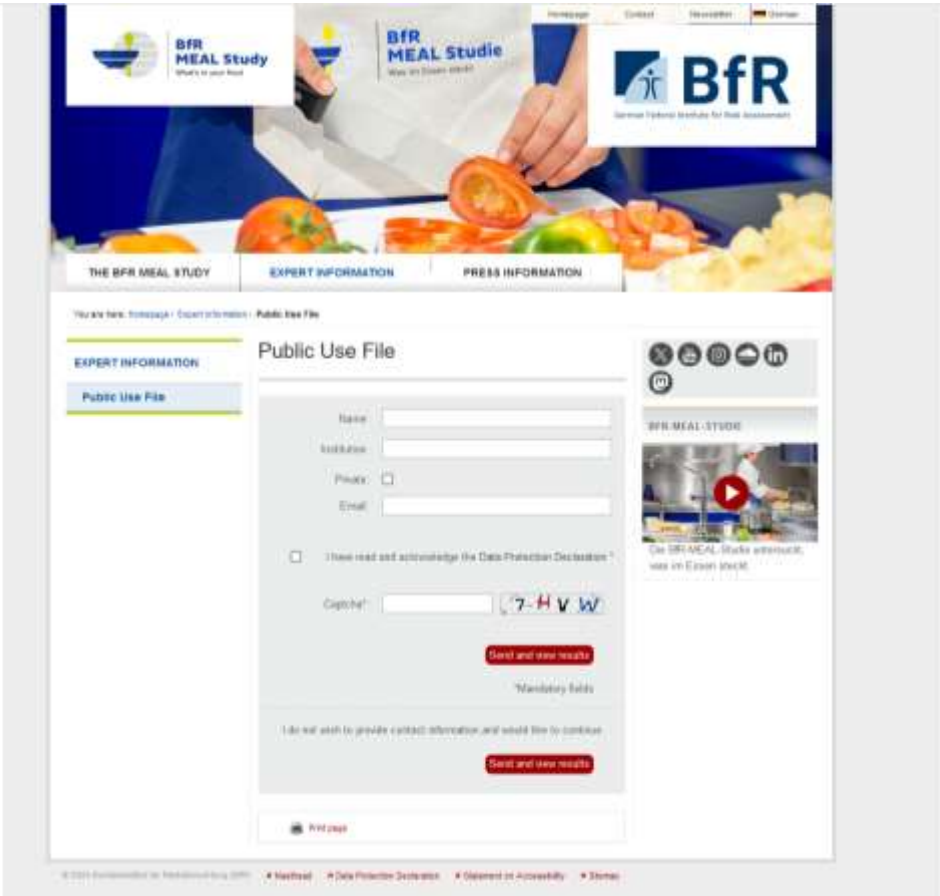
Concentrations of sweeteners in single products, sorted according to product groups and the five most common combination of sweeteners



C = Cola-type drinks; L = Lemonades; T = Tea-based cold drinks ; E = Energy drinks; F = Fruit juice drinks; I = Isotonic drinks

Results are/will be available as Public use file

https://www.bfr-meal-studie.de/en/public-use-file-en.html



Conclusions 1

- **Monitoring of food additives is crucial for reliable exposure assessments**
- **Analytical data enable the most reliable and realistic exposure assessments**
- **Monitoring activities should aim to cover all authorized food categories**
- **Prioritization of food additives and foods to be analysed in the monitoring should take into account also exposure related criteria, like**
  - Availabilty of data
  - Considering quantum satis authorizations
  - Frequency and amount of consumption
  - Availability on the market
  - Natural occurrence and other uses, than food additives only

Conclusions 2

- **Principals of the TDS design could also guide monitoring of food additives**
  - Analysing highly consumed foods
  - Representative sampling of foods from the market
- **Total Diet Studies as the German BfR MEAL Study can complement the food additive monitoring activities.**
- **Sweetener exposure and risk assessments needs to adress the combined use of sweeteners.**

Thank you!

Paulina Heinze

Sebastian Ptok

Irmela Sarvan

Department Exposure at BfR

BfR
German Federal Institute for Risk Assessment

Oliver Lindtner
T +49 30 18412-23400
oliver.lindtner@bfr.bund.de

German Federal Institute for Risk Assessment
bfr.bund.de/en

valid for texts produced by the BfR
images/photos/graphics are excluded unless otherwise indicated

BfR | Identifying Risks – Protecting Health

With support from
Federal Ministry of Food and Agriculture
by decision of the German Bundestag

Consumer health protection to go

BfR2GO – the BfR Science Magazine

bfr.bund.de/en/science_magazine_bfr2go.html

Follow us

- @bfrde | @bfren | @Bf3R_centre
- @bfrde
- youtube.com/@bfr_bund
- social.bund.de/@bfr
- linkedin.com/company/bundesinstitut-f-r-risikobewertung
- soundcloud.com/risikobewertung
- threads.net/@bfrde
- bsky.app/profile/bfrde.bsky.social