EuPC/JRC Joint Project on NIAS Identification

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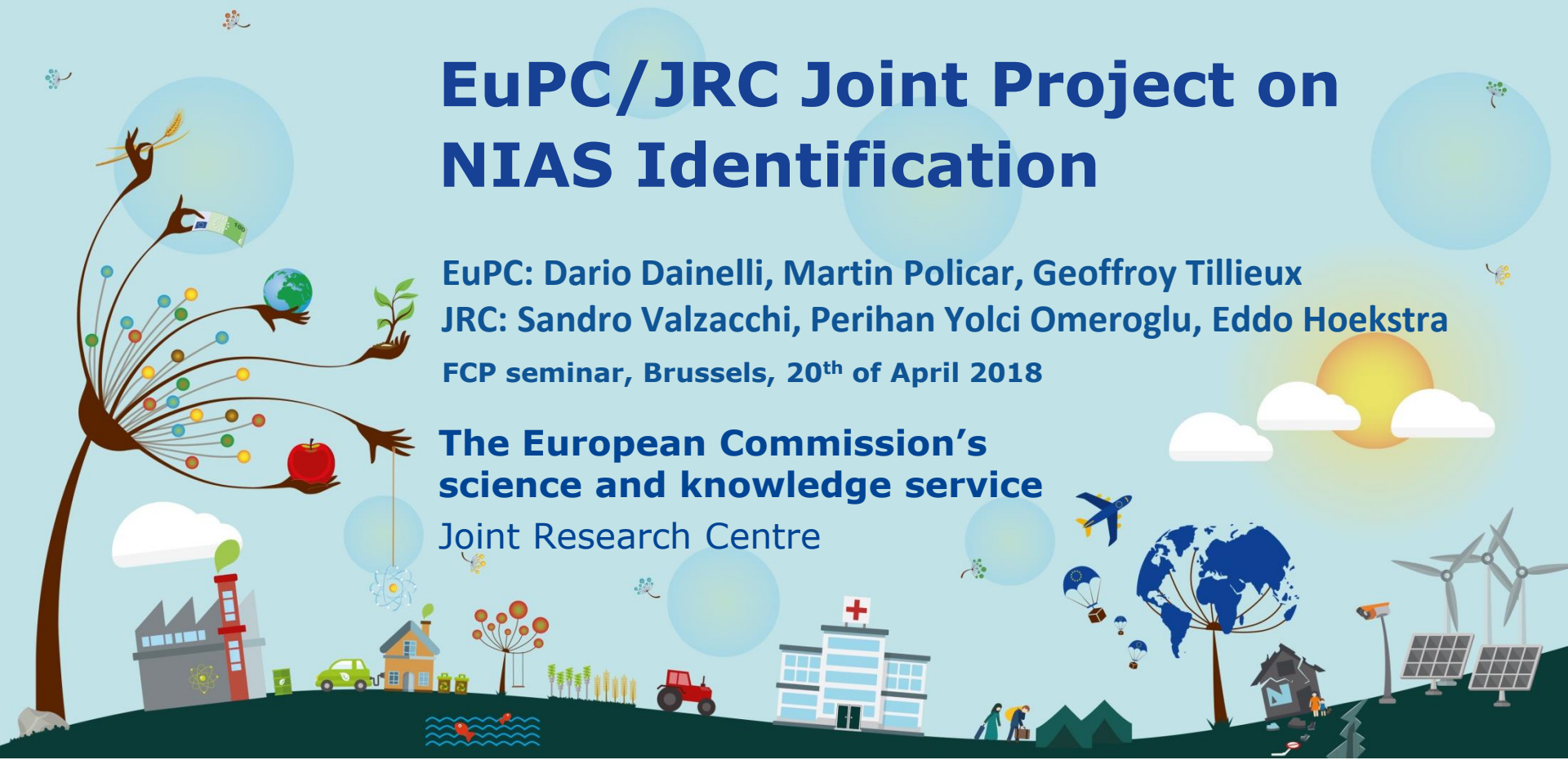
FCP seminar, Brussels, 20th of April 2018

The European Commission's science and knowledge service

Joint Research Centre



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JRC sites

Headquarters in Brussels and research facilities located in **5 Member States:**

- Belgium (Geel)
- Germany (Karlsruhe)
- Italy (Ispra)
- The Netherlands (Petten)
- Spain (Seville)

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Role as EU Reference Laboratory for FCM

EURL-FCM (Joint Research Centre)

- Access to analytical methods and calibrants
- Assess performance of NRLs
  - ✓ Proficiency testing in areas of issues or needs
- Organisation of training for NRLs, OCLs, etc.
- Scientific/technical advice to EC
  - ✓ Anticipatory work
  - ✓ Draft technical guidance documents

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Proficiency test migration + temperature control

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JRC VALIDATED METHODS, REFERENCE METHODS AND MEASUREMENTS REPORT

EURL-FCM-02-2016
Proficiency Test Report

Temperature control during migration test and quantification of migrated FCM No 500 by article filling

E. Tsochatzis, J.F. Alberto Lopes, P. Robouch and E.J. Hoekstra

2018

Joint Research Centre

EUR 29121 EN

National Reference Laboratory network

The European Union

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Scope of EuPC/JRC project

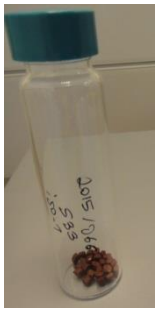
- Identify IAS and NIASs migrating from common plastic FCM in the EU
  - ✓ Use worst case migration test conditions
  - ✓ Develop in-house libraries both for GC-MS and LC-MS
  - ✓ Highlight problems during routine testing
- Assign scores for NIAS to establish a potential hierarchy of concern
- Develop proposals to address any substances of potential concern

DISCLAIMER

- This work does not represent the position of the European Commission

Samples

- 70 Food contact material from EuPC
  - 63 different plastic FCM
    - ✓ food packing films
      - (non-)printed
    - ✓ trays
    - ✓ Bottles and preforms
    - ✓ caps
    - ✓ cutlery
    - ✓ machine parts that contacts with food
- 5 resins
  - PP, PS, PET, and other specific polymer)



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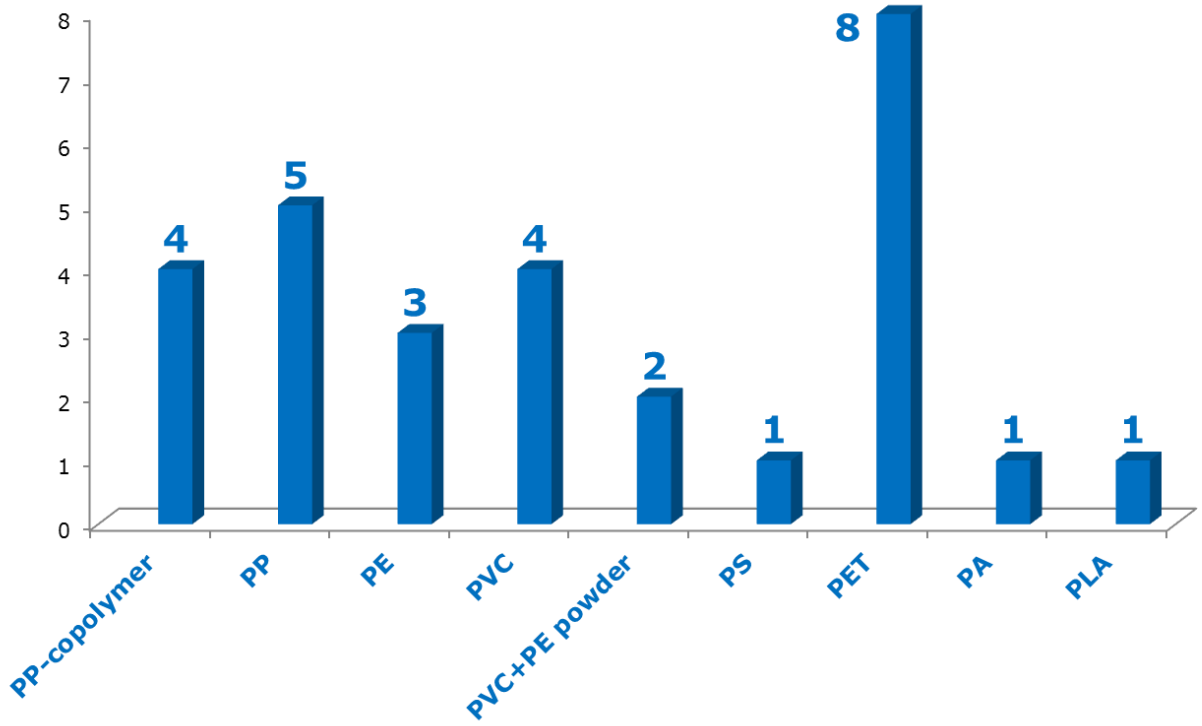
Monolayers (29)



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Multi-layers (35)

- 2 to 10 layers
- 30 different type of layer composition
- Layers include OPP, EVA, PVC, PE, PET, EVOH, and specific polymers
- Examples of layer composition
  - ✓ PE/PE/PE
  - ✓ PA/PP
  - ✓ PET/PE/PET
  - ✓ EVOH/PP/PP/PP/PE
  - ✓ EVA/EVA/PETG/R-PET/PETG/PETG
  - ✓ VLDPE/VLDPE+EVA/PA/VLDPE+EVA/PVDc/VLDPE+EVA/PVDc/VLDPE+EVA/EVA/PA/EVA/PET

Selection migration test conditions

- Worst case foreseeable conditions specified by producer

Simplifications:

- In case of samples with more than two food simulants
  - ✓ maximum two food simulants for each sample
  - ✓ preference for D2
  - ✓ one aqueous food simulant with higher organic phase
- Food simulant D2 was replaced by isooctane

food simulant A: 20 °C/10 d (5); 40 °C/10 d (7); 60 °C/10 d (22)
food simulant C: 20 °C/10 d (1); 40 °C/10 d (4); 100 °C/3 d (1)
food simulant D1: 20 °C/10 d (1); 40 °C/10 d (7); 60 °C/10 d (18)
Isooctane: 20 °C/10 d (9); 40 °C/10 d (3); 40 °C/2 d (16); 60 °C/10 d (13)
food simulant E: 20 °C/10 d (1); 60 °C/10 d (4); 100 °C/1 h (1); 121 °C/2 d (1)

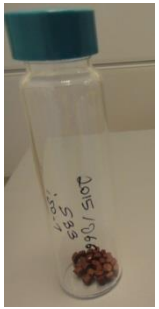
Sample preparation

Petri dishes for rigid multilayer sample (0.14 dm^2/1 g; 2 samples)

Pouch for flexible mono/multilayer (1 dm^2/25-50 ml; 25 samples)

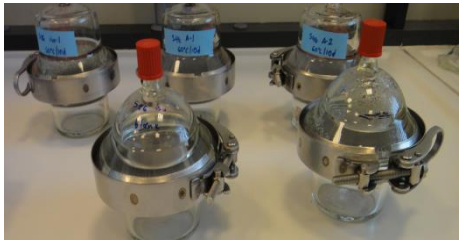
Immersion for rigid monolayer (1 dm^2/100 ml; 21 samples), caps, machine parts, cutlery

Filling for trays, bottles (real S/V; 11 samples)



Immersion for resins (25 pieces/20 ml; 7 samples)

Cell for rigid multilayer (0.5 dm^2/60 ml; 4 samples)



Problems during migration test

- Delamination with isooctane (no problem with A and D1) (4x)
  - ✓ Test with D2
- Evaporation of ethanol and/or isooctane through multilayer (5x)
  - ✓ Monolayers: immersion
  - ✓ Multilayers: food and D2 resp.
- Shrinkage of multilayer in D1 and isooctane (1x)
  - ✓ Test with food
- Precipitation/suspension after 24 h in extract C (1x), D1 (2x) and isooctane (19x)
  - ✓ Filtration of solution
  - ✓ Test with D2
- Boiling with multi-layers
  - ✓ Non-pouchable

OR reconsider time-Temperature

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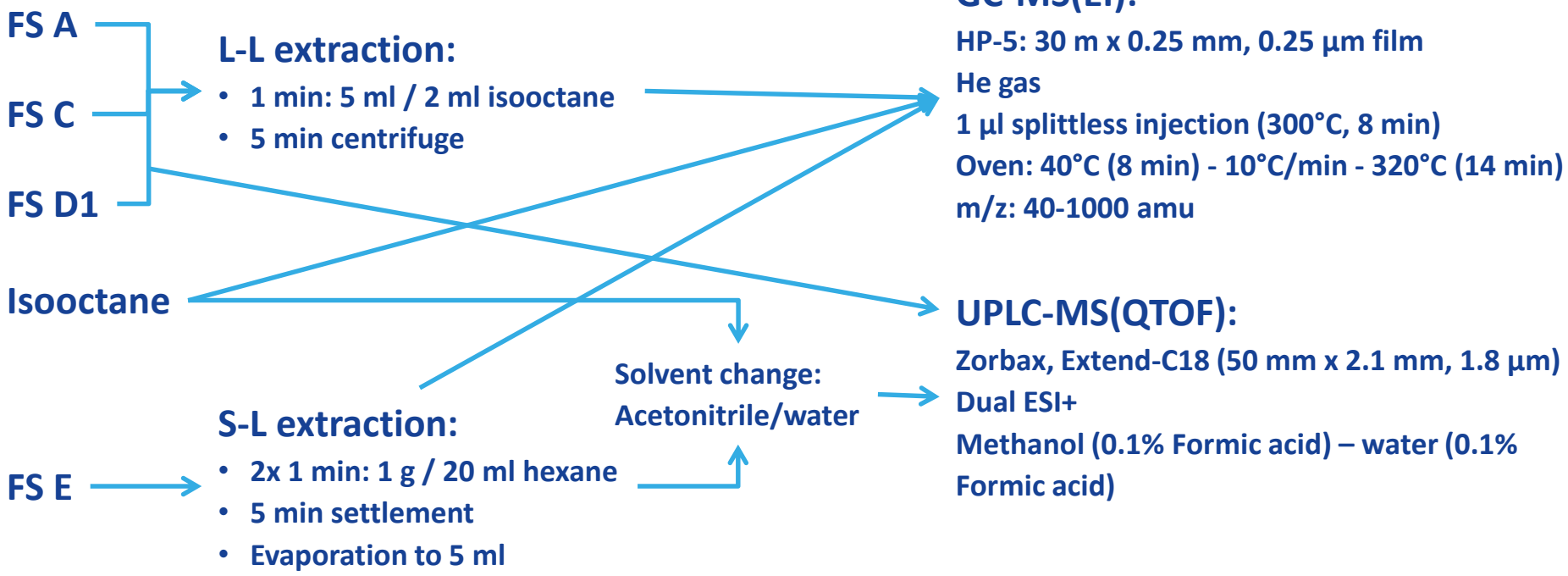
Migration solution preparation for analysis



NIAS: Criteria for scoring

Cramer score

- Identification of the Cramer Class using in-silico tools (Toxtree, OECD Toolbox)
  - Class I: score-5; Class II: score 0; Class III: score +5

Sample score

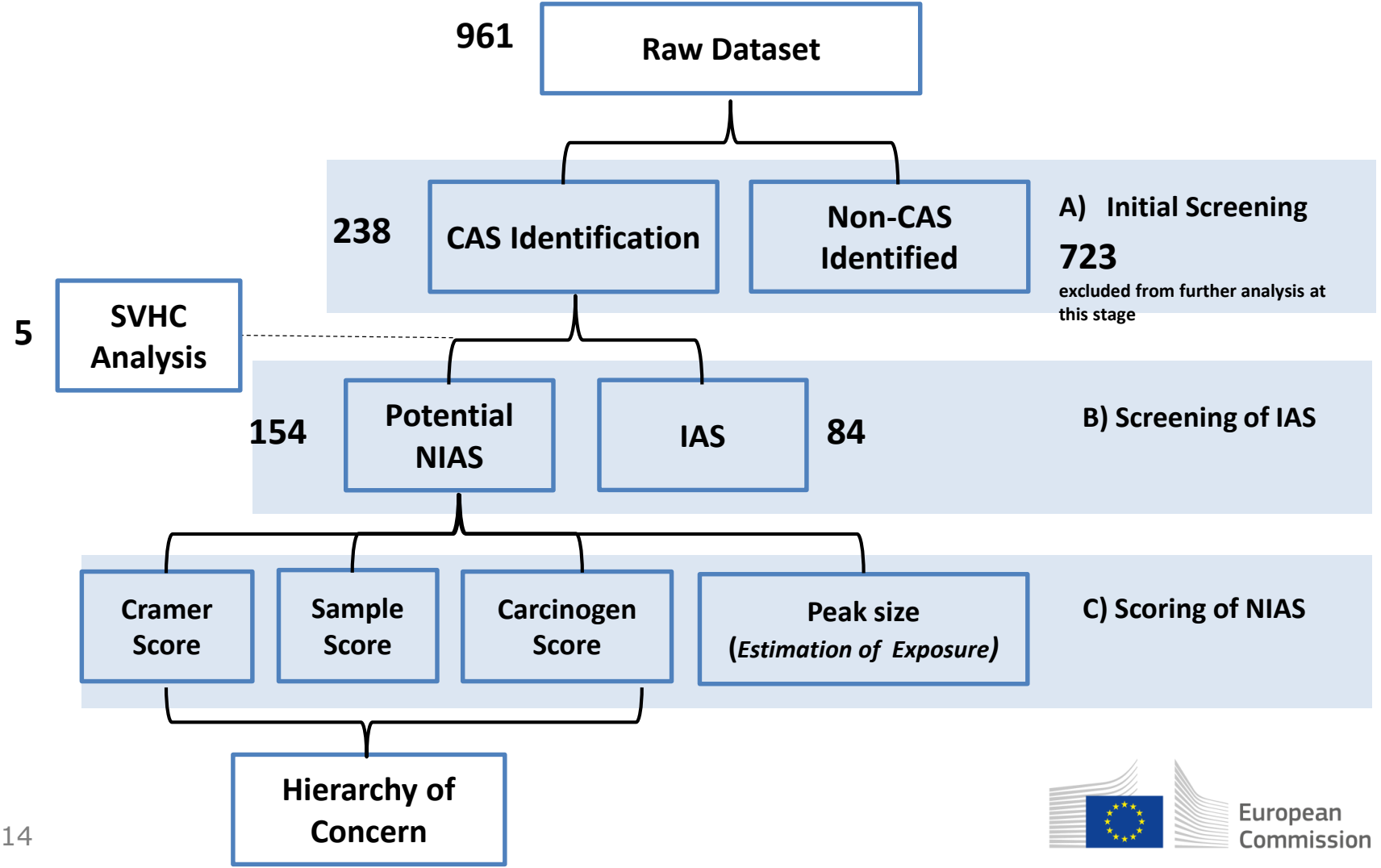
- Occurrence of a NIAS throughout all analysed samples
  - ✓Score: N of samples in which the NIAS has been identified

Carcinogen score

- Segregate potential CMR and assign maximum concern score
  - CMR: score 10; Non-CMR: score 0

Peak size

- No quantitative analysis
- Only as Small, Medium, High (not used as scoring system)



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TOTAL SCORE

Score	<0	0-5	6-10	11-15	16-20	>20	*TOTAL*
N	28	9	88	12	15	1	*154*

FREQUENCY OF OCCURRENCE

Frequency	1	2	3-4	5-6	7	>7	*TOTAL*
N	88	20	25	13	2	6	*154*

Next steps

- Focus on score >12 for further investigation
- Clarify mechanism of high occurrence ≥7
- Risk Assessment based on Matrix Exposure tool,
  - ✓ priority to substances exceeding a score threshold
- Pilot Risk Assessment [Scheme]

- Quantification
- Development of multi-analyte methods for covering all substance categories
- In-house library-building is necessary

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