Ensuring safety and compliance of food contact material

Koni Grob

Kantonales Labor
Zürich

Case of pesticides

- Broad demand for “organic” food…
  - one reason: mistrust in safety evaluation
    - e.g. homeopathic activity profile
- … despite
  - very thorough toxicological evaluation
  - intensive control by trade and authorities

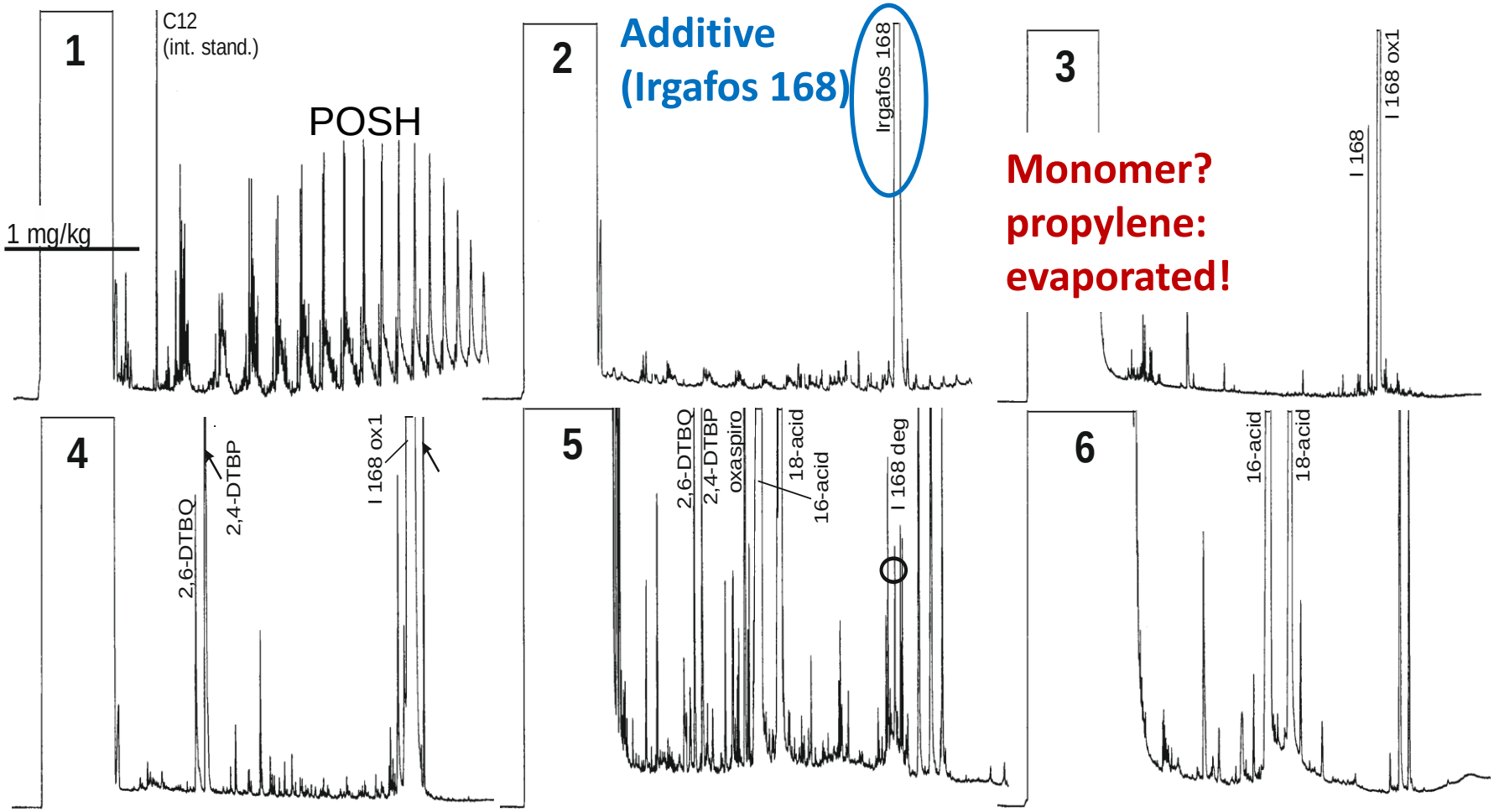
- Estimated exposure by conventionally produced food:
  - common concentrations: 5-50 µg/kg → exposure 10 µg/d
  - sum of many pesticides

Case of FCM

- Overall migration typically 5-30 mg/kg → exposure 1-10 mg/d
  - perhaps half >1000 Da (considered physiologically irrelevant)
  - exposure 100-1000 times higher than for pesticides
- probably in the order of 100,000 substances <1000 Da above TTC for unknown substances
  - <2000 substances properly evaluated
  - majority not even identified
  - (number of pesticides used ~750)
- no intentional "…cides", but probably including substances not even accepted as pesticides
- little control

Why should consumers trust in the safety of FCM more than for pesticides?

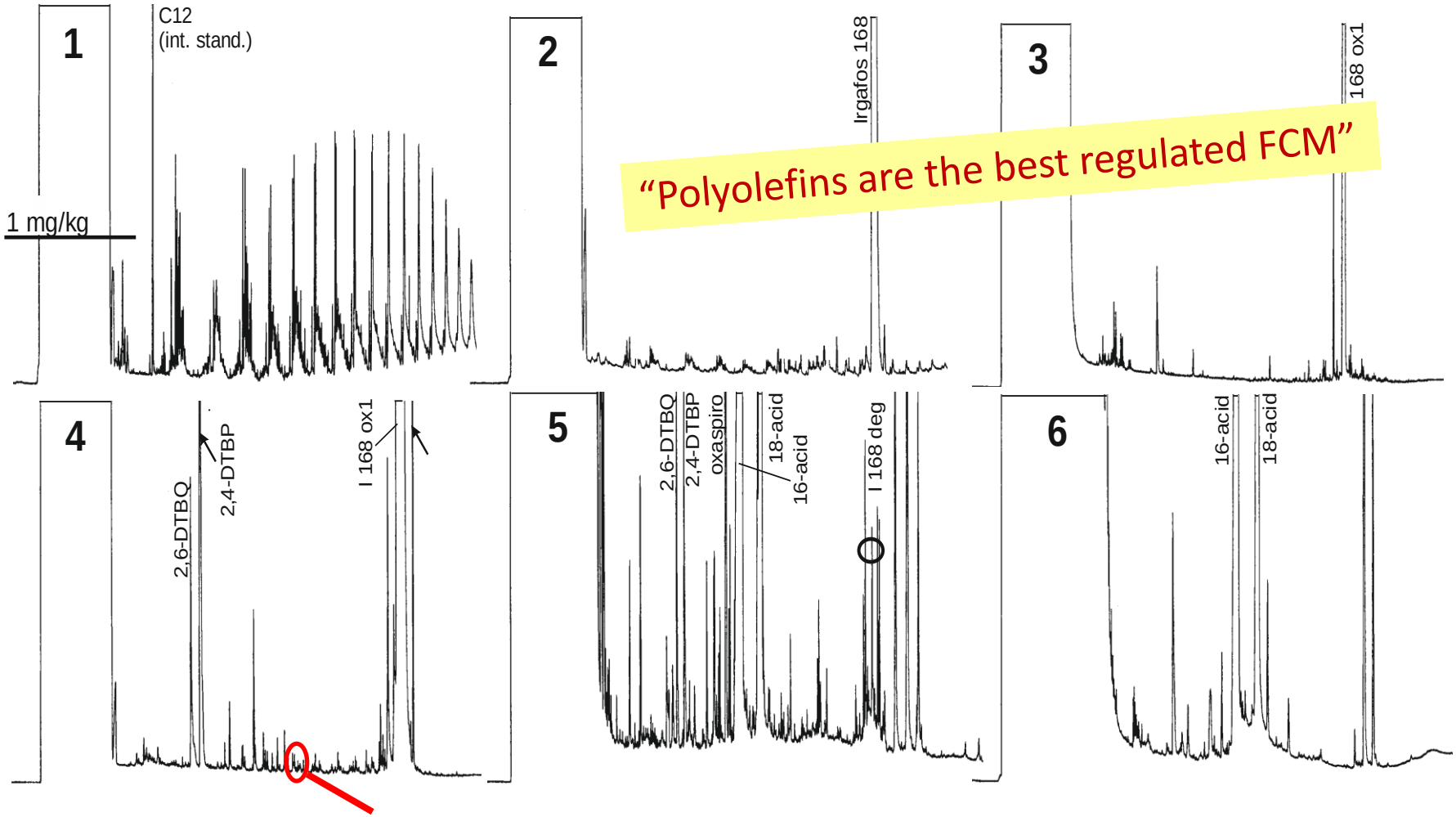
Polypropylene granulate with Irgafos 168



On-line HPLCxGC-FID
HPLC preseparation on silica gel

R. Castillo, M. Biedermann, A.M. Riquet, K. Grob
Polymer Degradation and Stability 98 (2013) 1679

Thresholds of potential health relevance

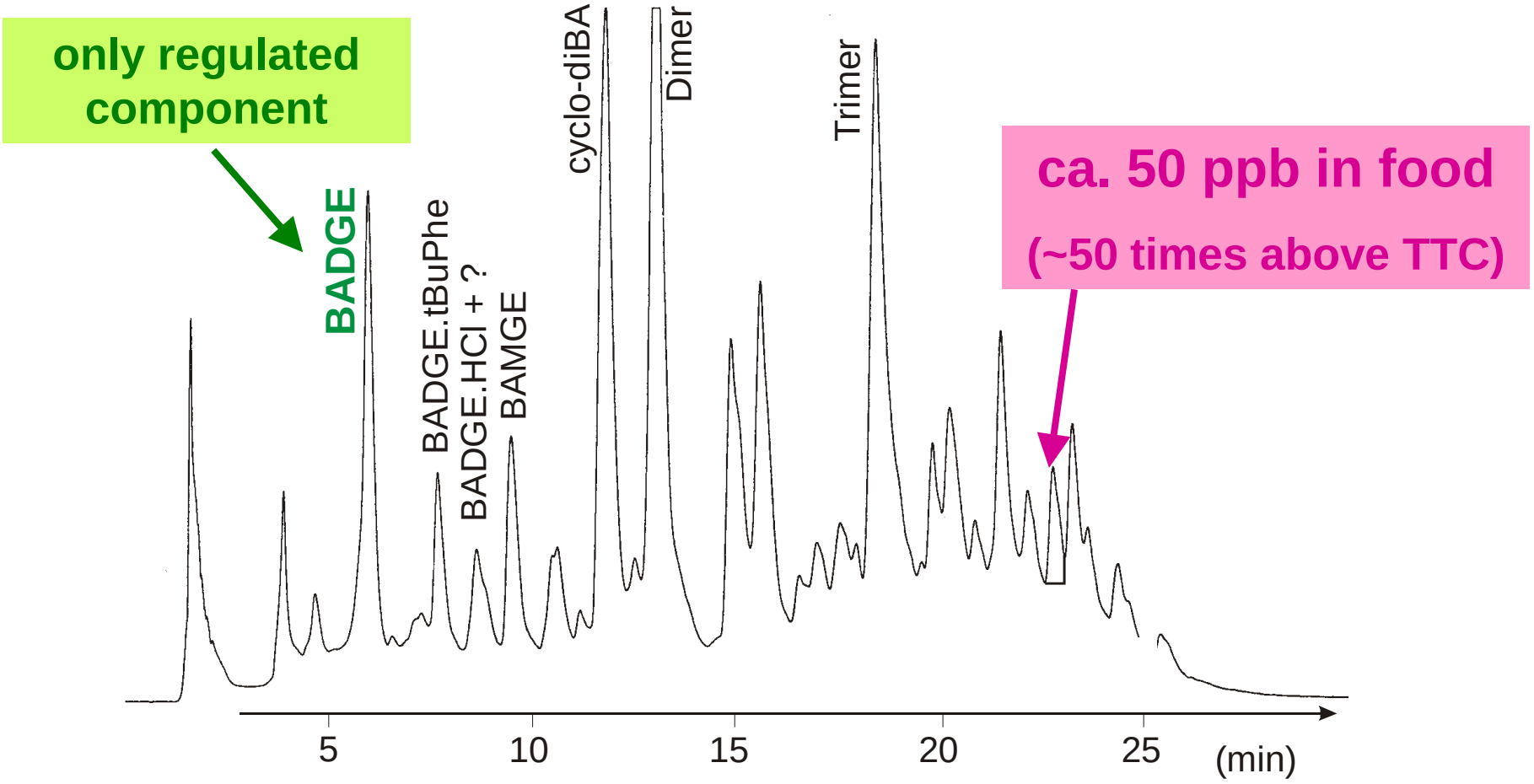


"Polyolefins are the best regulated FCM"

TTC for unknown (0.15 µg/d; 150 g food/day → 0.001 mg/kg/food), corresponds to roughly 0.1 mg/kg plastic

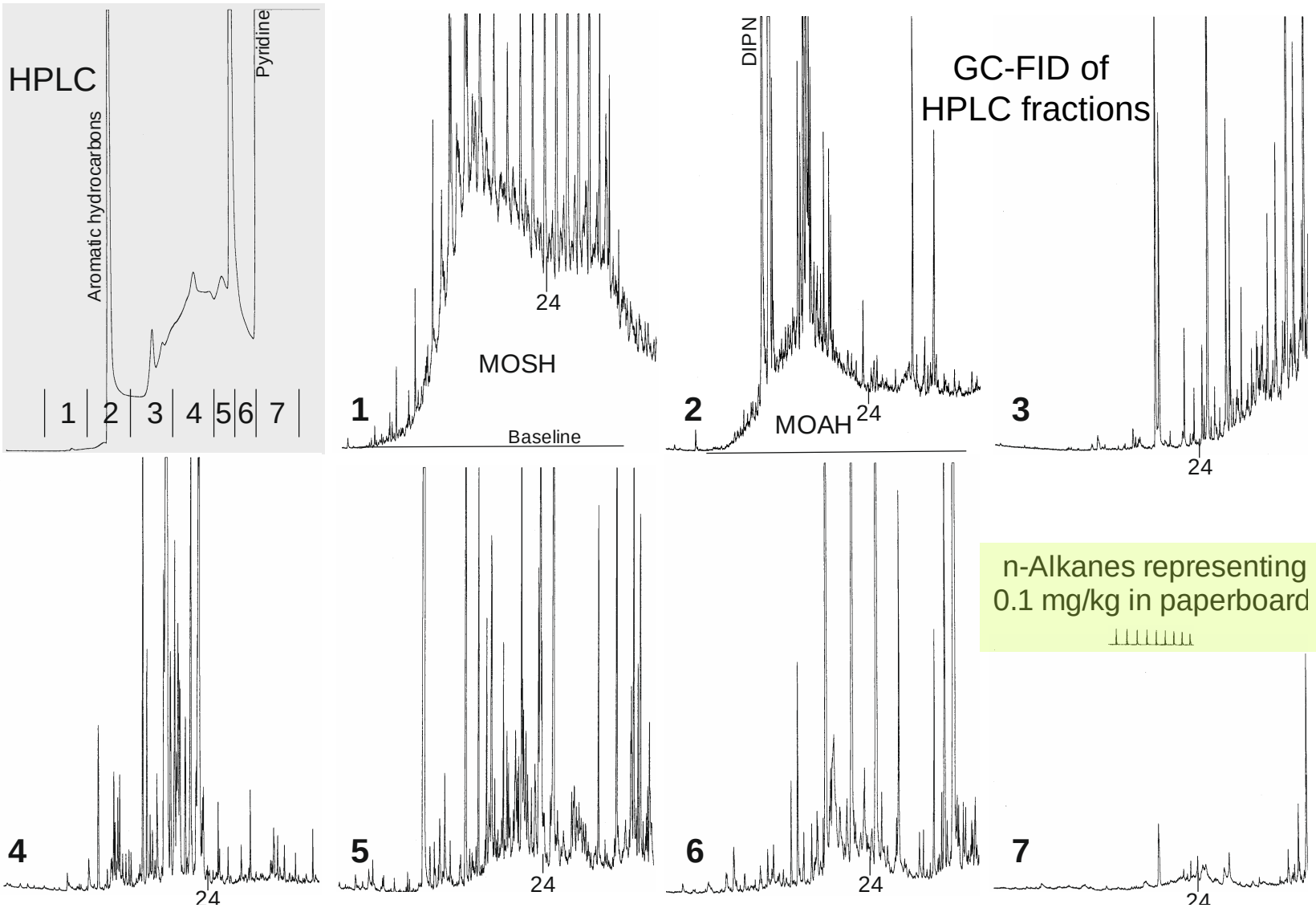
Migration from epoxy-phenol can coating

Simulation of sterilized oily foods, NPLC, fluorescence

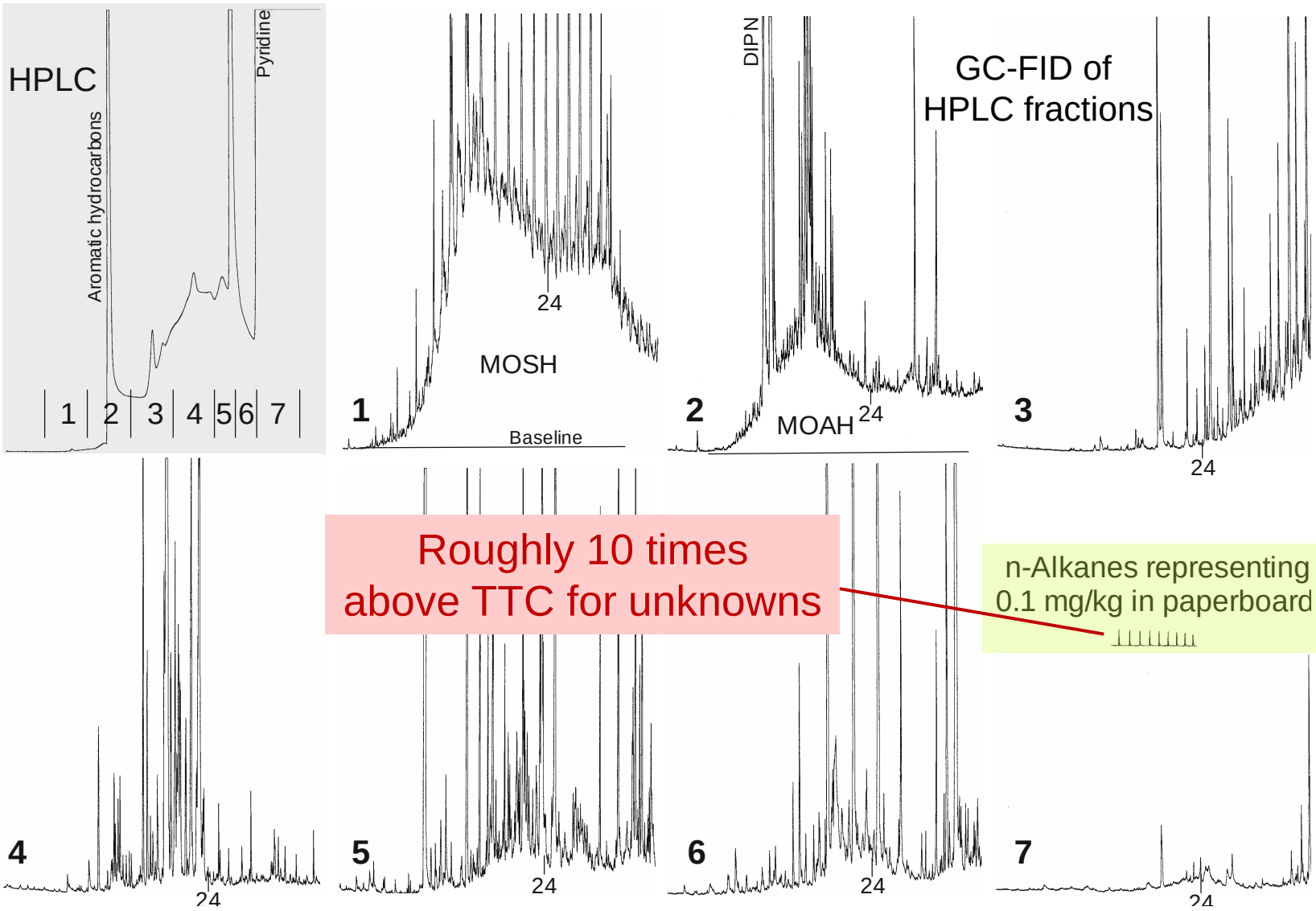


K. Grob, P. Camus, N. Gontard, H. Hoellinger, C. Joly, A.C. Macherey, D. Masset, F. Nesslany, J.F. Régnier, A.M. Riquet, P. Saillard and D. Ribera. Food Control 21 (2010) 763–769.

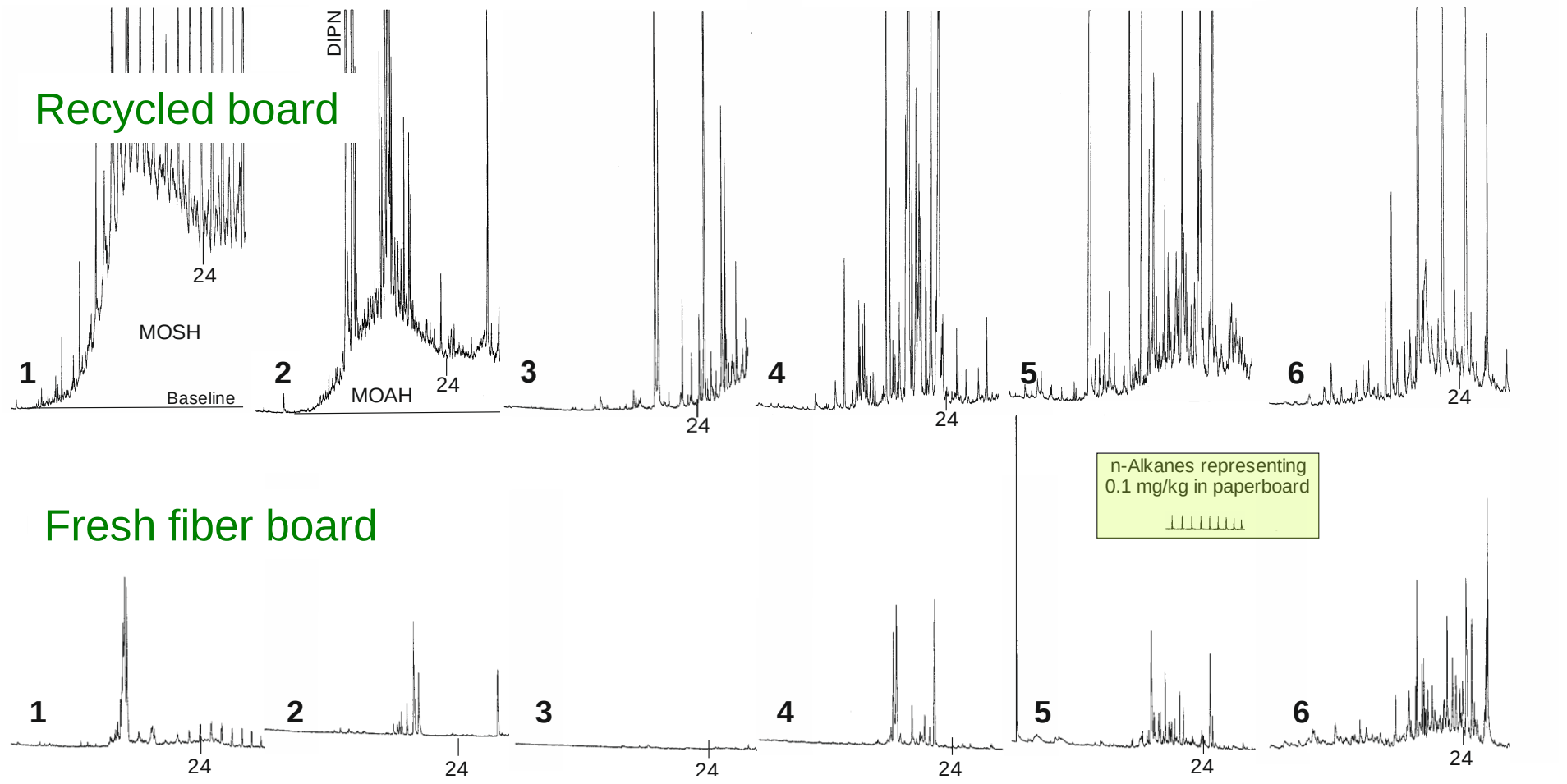
Recycled paperboard: HPLCxGC-FID



Recycled paperboard: HPLCxGC-FID

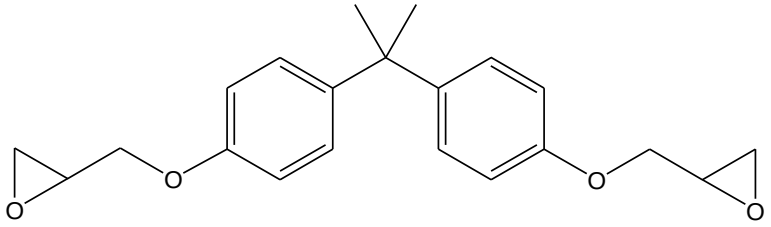


Comparison with fresh fiber board

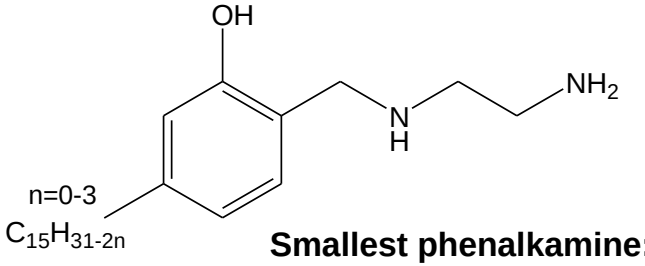


Coatings for water pipes

- Relevant aspects:
  - Residual material after curing
  - Chemical release, e.g. by chlorine
  - Partial degradation in biofilms
- ~1 kg coating/person in a building
- 9.6 % of the coating <1000 Da
- Analysis in water
  - required detection limit 75 ng/l
  - required reconcentration for HPLC-MS in full scan
    - 13,000 for epoxy derivatives
    - >70,000 for phenalkamines
  - too many interfering substances



Bisphenol A diglycidyl ether (BADGE)



Smallest phenalkamine: Mannich base of Cardanol

Gap in feasibility: factor 100-1000

- Assumption: all <1000 Da materials migrates into water over 10 years → analysis in extract
  - chronic toxicity → no matter whether migrated in first days or over 10 y
  - 1 % of the water is consumed, average stagnation
  - average migration: 250 µg/d coating <1000 Da
  - TTC of 0.15 µg/d → 0.06 % of the migrate
- Comprehensive chemical analysis/identification of unknowns at 0.06 % in a mixture is far out of reach
- In-vitro test on genotoxicity? sensitivity to detect 0.06 % in a mixture???

Conclusions:

1. many persons daily exposed
2. daily many additional buildings treated
3. hardly any information about safety
4. technical feasibility 100-1000 times from target

Compliance work for food contact materials: feasibility of the legally required safety assessment of an epoxy/amine-based coating for domestic water pipe restoration. J. Tillner, K. Grob, Food Additives and Contaminants (doi.org/10.1080/19440049.2014.916421)

Main problem: ORPIs

Oligomers, Reaction Products, Impurities

"Non Intentionally Added Substances" (NIAS): inadequate term

- insinuates reduced responsibility
- alludes to jurisdiction taking intention into account for the specification of penalty
- Not intended → no need for compliance work

ORPIs: usually major part of the migrate

- the overall migration usually far exceeds the sum of the specific migrations measured
- ORPIs typically constitute
  - 95-98 % of the migrate from can coatings
  - 60-90 % for polyolefins

Attempt of the 1970ies

1. Safety assessment of the starting substances → lists
2. Overall migration limit (OML) = a kind of threshold of toxicological concern for other migrating substances
3. Simple and standardized simulation

Largely stopped around 2005: **task cannot be reached!**

1. Industry refused further collaboration («we do it ourselves»)
2. far more sensitive toxicological end points

   → OML does not ensure safety
3. Too many materials und substances to get under control
   - >5000 substances for printing alone?
4. Simulation often has severe shortcomings or is inadequate

Compliance declarations render problems utterly obvious

- Only FCM with declarations stating completed compliance work can be marketed…
  - refers to all migrating substances (including ORPI – Article 3!)
  - compliance work must be documented
- …but compliance work can be concluded for hardly any FCM

- Operators at end of chain are compelled to cheat:
  - disclaimer or
  - acceptance of declarations including unsupported claims
- All involved are aware of this…
  - “artists” create carefully hidden disclaimers
  - retailers/brand owners force suppliers signing unrealistic declarations
  - enforcement authorities are unable to react
  - media learned about a wonderful subject to create scandals

How to get out of deadlock?

→ more flexible and pragmatic approach required

- readily feasible compliance work should be done in the near future
- for more difficult work, studies are to be initiated
- due to technical limitations, at least temporarily some incomplete compliance work must be tolerated, provided no health risk is apparent

Proposed way out: work plans

1st step

Rendering reality acceptable

Honest declarations of compliance, declaring gaps in compliance work

- Vendors must have the possibility to accept these
- Authorities have to tolerate incomplete compliance with legal requirements

Situation rendered acceptable through work plans on filling the gaps as far as reasonably feasible

→ gaps temporarily acceptable if linked to work plans

2nd step

Specification of gaps

- The responsible operators (producers, producer associations or other consortia) define the gaps, e.g.
  - oligomers from PP
  - reaction products and impurities of additives

  → **Gap descriptions (GD)**
  - All gaps have to be covered by a GD by a given time

- GDs are registered, e.g. by EFSA
  - Publicly available for control by customers and authorities:
    - general description of subject matter
    - products involved and owners of the GD

3rd step

Elaboration of work plans

Main steps:

1. Chemical background/expected types of relevant substances
2. Estimate of amounts in the FCM and potential migration
3. Analytical approach
4. Expected limitations in the analytical work
5. Planned approach for toxicological evaluation
6. Estimated time lines, with milestones for larger projects

Work plans must be specific and realistic

4th step

Discussion and approval of the work plans

Work plans are submitted to authorities with adequate competence (e.g. EFSA, BfR, Anses)

- Does the subject matter merit a work plan?
  - Sheer carelessness is not acceptable
- Is the work plan best choice and acceptable?
  - Identification work with regard to comprehensiveness and detection limit
  - Approach for toxicological evaluation?
  - Are limitations convincingly justified
  - Time lines and milestones?
- Is the envisioned safety assurance promising to be satisfactory?
  - Otherwise GD is inacceptable and the product must be phased out

Progress must be periodically reported

- Serious failures result in withdrawal of the GD from the list

5th step

Application to compliance declarations

- Approved GD can be used for compliance declarations: final compliance declarations must be conclusive, either by
  - supporting documentation (concluded work, as today) or
  - gaps specified by GDs
- Control:
  - GD must be approved and registered (→ registration)
  - supplier must be (co)owner of the work plan
    - his product must be included in the work described by the GD
  - the date of completing the work plan/milestones must not be exceeded

A new approach is needed!
work plans?

- Deblock the present situation
  - Enables temporary acceptance of incomplete compliance work…
  - … but ensures that reasonably feasible work is done
- Work plans provide room for flexibility
- Feasible on the basis of existing legislation
  - Legislator cannot reduce requirements
  - Enforcement authorities to insist on compliance work
  - Risk assessment authorities to check the work plans