European FCM regulation: Opportunity for improvement

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Re-evaluation of the EU FCM Regulation

- The Commission re-evaluates the framework Regulation 1935/2004
  - criteria and principals of implementation
- First step: broad consultation (by Ecorys). Some key shortcomings noted:
  - gaps in implementation and weaknesses in enforcement that raise questions on the ability to secure a high level of protection
  - doubts about whether the system of Official Controls adequately enforces the requirements of the FCM legislation
  - reservations about the underlying approach focusing on starting substances (NIAS)
  - more harmonization at EU level is desirable
- **Next step: ideas for improvements!**

Present principals of EU FCM Regulation

Key points of Regulation 1935/2004 (largely derived from 1976!)

- Definition of the tasks
  - protection of the consumers
  - functioning of the European market
- Specification of roles
  - separation of risk assessment from management
    - "… do not endanger human health…" (Art. 3): EFSA to specify requirements to demonstrate safety in guidelines
- Outline of the ways to implement these tasks
  - specific regulations for 17 types of FCMs
    - evaluation of the substances used by EFSA → positive lists
    - testing methods (simulation), basic assumptions (e.g. on exposure)

    → Collective compliance work with strong involvement of authorities
- Declaration of compliance (clarifying responsibility)

Not feasible!

- Only few types of FCMs were regulated by EU over 40 years
- Even for plastics, only monomers and additives are regulated
  → authorization of all substances used is unrealistic
- Reaction products and impurities (NIAS; mostly the majority of the migrants) were not specifically addressed
  – except as part of recent evaluations, but this information is hardly used
- Official control is limited to a few well-known compounds
  – lacking knowledge of what to check
  – lacking adequate measures in case of non-compliance

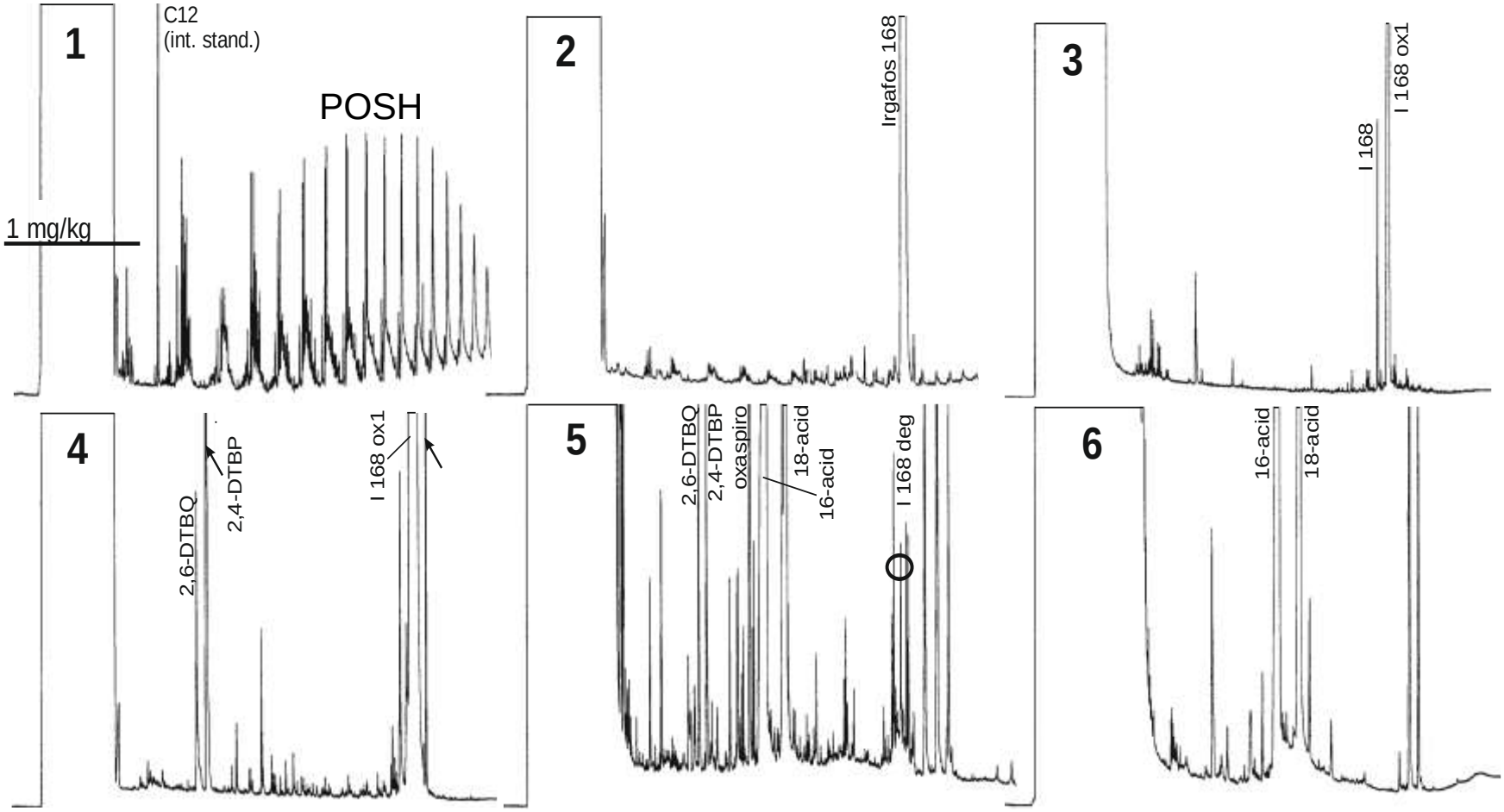
→ Large gap between legal requirements and reality

  – hardly any FCM complies with safety requirements according to EFSA

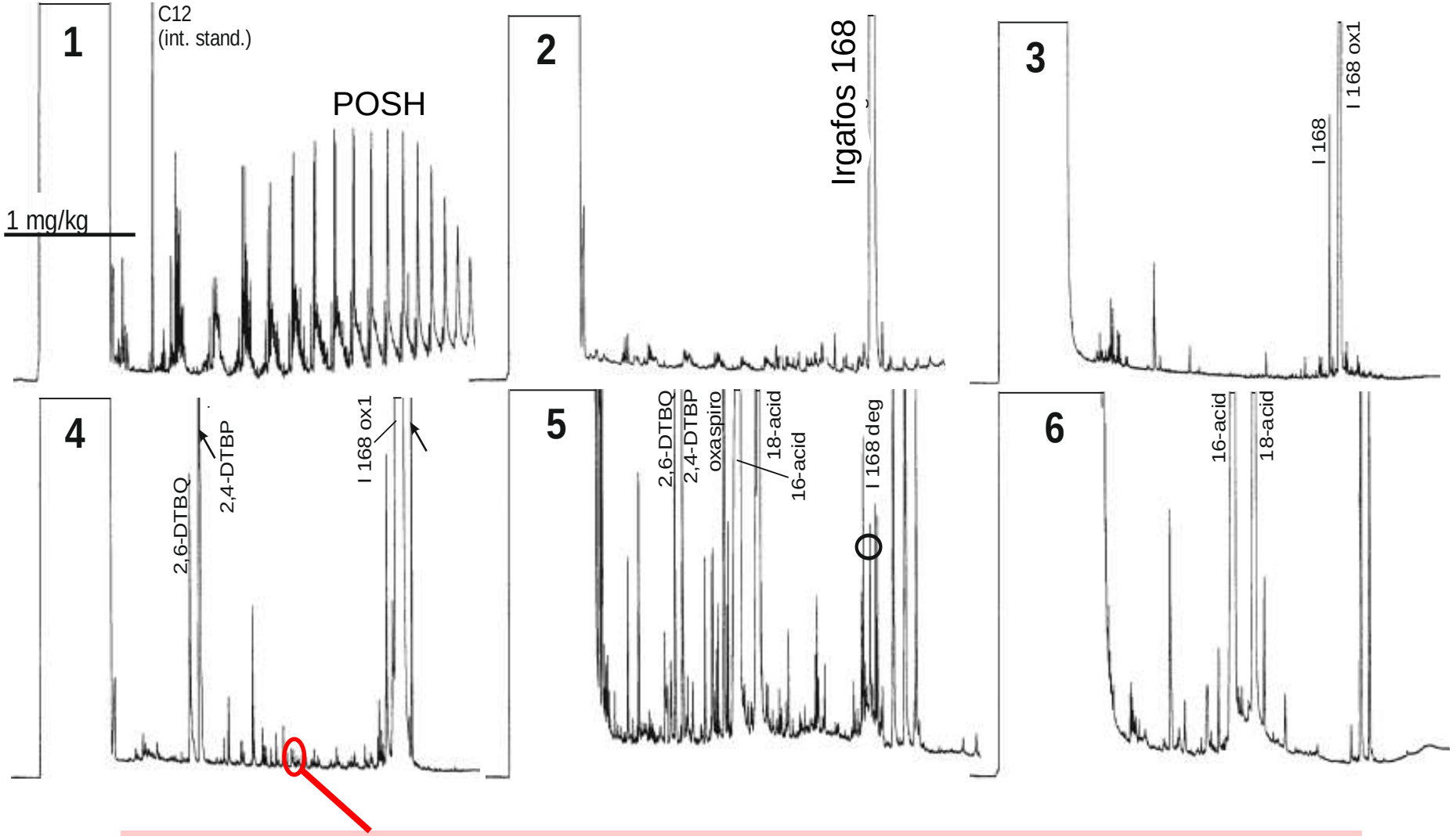
- Implementation of EFSA Guidance for all migrating substances (including NIAS) widely regarded as not feasible

Polypropylene film treated with pulsed light, made of 2 substances: propylene and Irgafos 168

Extract; on-line HPLCxGC-FID, HPLC preseparation on silica gel



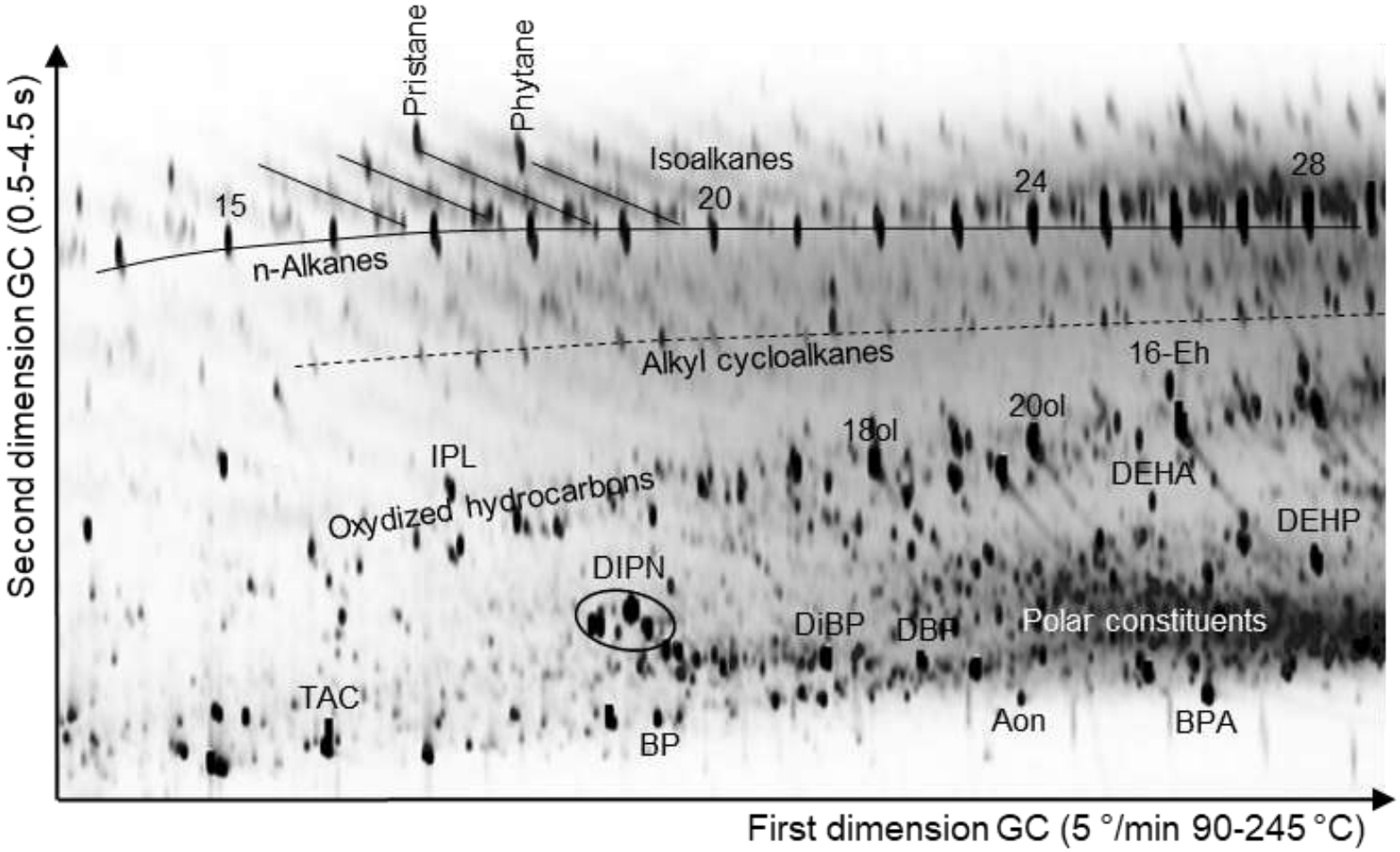
Comprehensive on-line HPLC-GC for screening potential migrants from polypropylene into food: The effect of pulsed light decontamination as an example. R. Castillo, M. Biedermann, A.M. Riquet, K. Grob. Polymer Degradation and Stability 98 (2013) 1679-1687



0.1 mg/kg plastic, estimated to correspond to TTC for potentially genotoxic carcinogens (1 g plastic/100 g food; high migration; 150 g food consumed per day → 0.001 mg/kg food)

Recycled paperboard

Extract, analyzed by GCxGC/FID

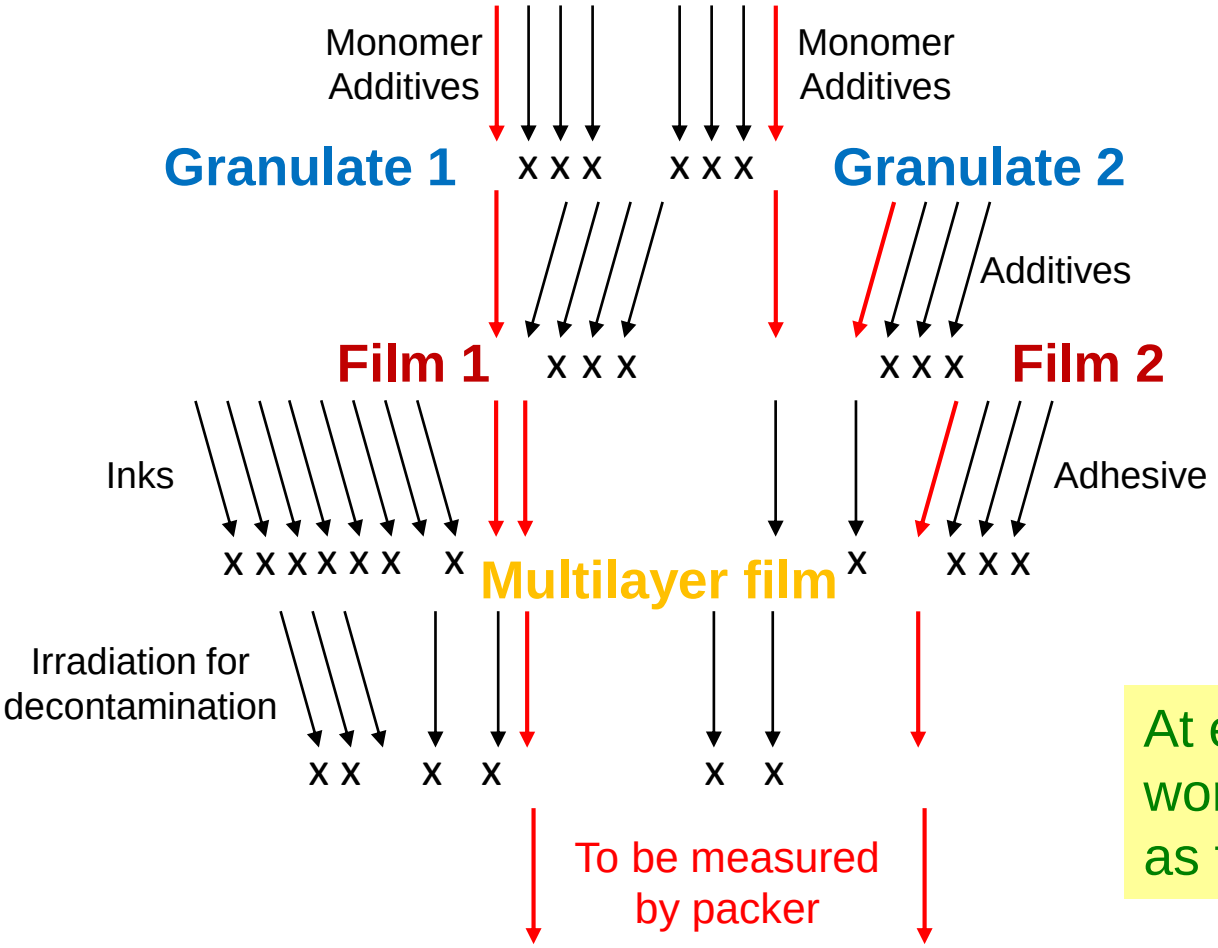


Every visible spot represents a substance that may exceed **10 ppb** in food if migration is high.

1. Self-control by industry is the only way

- All migrating substances except those officially evaluated/listed must be assessed by the producers
  - which means often 95-99 % of all migrating substances!
- Industry must no longer wait for authorities telling them what to do and how to do it!
  - collaboration in associations (many producers have the same problems)
- Design of FCM for safety from the raw material
  - involvement of every contributor to a FCM
    - producers (should) know what they do
    - share work
  - filter out substances of potential concern

Compliance work through the manufacturing chain



Introduction of a substance

x = concluded compliance work

Compliance work delegated to customer

At each step, compliance work should be concluded as far as possible.

Concluded compliance work

Effect on regulation

- Regulation should focus on implementing and supporting self-assessment by the producers
  - specification of requirements/criteria to ensure safety (→ EFSA)
  - support industry in best using data (establishing lists)
  - providing the means to trigger implementation by the market
- Since most migrating substances are to be assessed by the producers, focus should shift from pre-use assessment to control of assessments by industry
  - strengthen role of control authorities
  - increased efficiency by European collaboration, sharing the work
  - harmonization of control procedures throughout Europe
  - harmonization of evaluation on safety assessment
  - harmonized measures to implement compliance

2. Better use of data: better listing

Listing of approved substances

- Separation of FCMs into 17 types did not prove suitable
- All lists with adequately approved entries should be combined and include
  - name the approval body and year of approval
  - reference value for safety
  - link to related opinion or document (e.g. EFSA, BfR or Anses)
- Not only substances used, but any approved
  - reaction products and impurities approved during, e.g.
    - an authorization process (e.g. EFSA opinions)
    - control of compliance work by enforcement

Listing approved substances and materials for food contact in Europe: ideas for a better use and further evolvement of the present system. A contribution for discussion. K. Grob. Journal of Consumer Protection and Food Safety 12 (2017) 271–281.

3. Requirements must be implementable

- EFSA requirements may be not satisfiable
  - “impossible tasks” paralyze producer’s activity and hinders enforcement
  - better less, but really implemented! No illusion: presently ten thousands of substances migrate with little or any safety assessment
- Reasons for (overly?) tough EFSA requirements
  - striving for “absolute” safety
  - often inadequate exposure assumption: 6 dm2/person/day, 60 kg person, consumption every day at SML
    - requirements may be insufficient for young children
    - far too severe for special application (e.g. seal of oven door)
- Difficult general coherence
  - foods naturally contain toxic substances at sometimes rather high level
  - cooking results in wild chemistry
  - “long history of safe use” waves toxicological assessment

→ Regulation should adjust rules

- Tier for non-genotoxic substances: 50 ppb or Cramer III (1.5 µg/kg body weight/day = 90 µg/d for 60 kg person)?
- 10 ppb or TTC for genotoxic substances as detection limit?
- Present assumptions may strongly overestimate exposure
  - Problem: open listing. Substance can be used for any/all FCMs
- Better exposure estimates presuppose SMLs for specific materials and applications
  - SMLs for a substance used, e.g., in a seal of baking ovens could be high (low exposure), but must be low when used in, e.g., beverage bottles
- Exposures from different applications have to be added (→ allocation factors)
  - unknown number of applications: how to share a TDI?
  - new application reduces SMLs of old ones?

4. Strong drivers for implementation

- Compliance work is costly
  - though costs are negligible compared to marketing costs
- Present drivers for implementing rules:
  - enforcement authorities
    - weak: control merely for few substances, missing adequate measures
  - NGOs, media
    - often inadequate, only on well known issues
- Main driver should be the packers and the food industry
  - would prefer approved FCMs – but must be able to trust in an approval
    - missing access to compliance documentation (declarations of compliance are often not adequately supported)

→ list of approved materials/applications (intermediate and final products)

Listing approved materials/applications

- Reasons for listing approved materials/applications:
  - better exposure estimation
  - driver for privileging materials with solid compliance work
  - assessing all potentially migrating substances and their level of migration
- To be listed:
  - material type (general chemistry), product name of the producer
  - range of approved applications (e.g. temperature, food type…)
  - approving body; year
  - substances remaining to be checked for migration by the user
- Approval bodies
  - EFSA, national risk assessors (current petitioning process)
  - enforcement authorities (approval through document control)
  - **certified private bodies evaluating against EFSA guidelines**
    - **guided and checked by authorities**

5. Effective enforcement

- Focus on compliance work of producers, i.e. documentation
  - controlling and implementing self-control by producers
  - reveals chemistry of the material and compliance work performed → is analytical control advisable?
  - checking systematic compliance with restrictions
  - presupposes documentation of the whole chain of manufacturers
- European collaboration
  - harmonized procedures and evaluation
  - prevention of multiple control → Listing of approved substances and materials
  - concerted measures in case of non-compliance
- Specialized document collection centers

The European system for the control of the safety of food-contact materials needs restructuring: a review and outlook for discussion. K. Grob. Food Addit. Contam. A . 9 (2017) 1643–1659.

6. Work plans for transition

- The majority of FCMs do not comply with present rules
- Authorities cannot remove all non-compliant FCMs from the market
  - many non-compliant FCMs must be tolerated
    - how to explain to consumers?
  - compliance work may need years to complete. What in the meantime?

- First question: can a non-compliant FCM stay on the market?
- If yes: industry to submit a work plan to close gaps
  - describing the gap and planned work with timelines
  - authorities approve the work plans and check progress
  - work plans are acceptable in the Declaration of Compliance

Work plans to get out of the deadlock for the safety assurance of migration from food contact materials? A proposal. K. Grob. Food Control 46 (2014) 312-318.

Conclusions

FCMs were neglected for a long time

Comparison with pesticides: 100 times more substances, 100 times higher concentrations → large backlog

1. Authorities lack resources: focus on self-control of producers
2. Better listing: approved substances and materials/applications
3. Easing EFSA Guidance: better rules considering exposure
   → SMLs related to material and application
4. Packers and food industry should be main driver → lists
5. More effective enforcement, collaboration throughout Europe
6. Management of presently many non-compliant FCM: approved work plans

- Don’t forget: most work needs to be done only once
  - identification of the (mostly few) toxicologically critical substances