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

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

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

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
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