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Agenda

*Ceramics – discussion with Member States*
- focus on limits, additional metals, glass and enamel

*Ceramics – discussion open to stakeholders*
- you can take a 30 minutes break
- please be back at 11:30 (quietly)

~13:30 Lunch

*Ceramics – discussion with Member States*
- views on different topics

*Other agenda points (if time)*
- Amendment to R 10/2011 (short → written position)
- Regulation 284/2011
Revision of Directive 84/500/EC

CERAMIC MATERIALS
Welcome

Please find an unoccupied seat
- at the front

Interpretation
- French, German, Italian, Spanish
- Please don’t speak too fast
  (But not unnaturally slow either)
- Please speak in your own language
  (if French, German, Italian or Spanish)
Who are we?

DG SANTE, Health and Food Safety

SANTE.E.2; food processing technologies

Food Contact Materials
  • Including Ceramic FCM

Bastiaan Schupp
  • printed FCM, Recycling, Ceramics
  • Since 2011 on Food Contact Materials
  • Since 2005 in Commission
  • Chemical engineer
    Chemical risk management
    Process engineering
    Inorganic Chemistry

Jonathan Briggs
  • Evaluation, BPA, ...

Angele Aquilina
  • Our assistant – your first point of contact
EU legislation - rationale

**Ensuring Food safety**
*Food contact materials must not*

- endanger human health
- bring about an unacceptable change in the composition of the food
- bring about a deterioration in the organoleptic characteristics

**Internal market; effective functioning**

- no barriers to trade
- equal and fair competition
- impartiality
What is a food contact material?

Any material:

- Intended to be brought into contact with food
- Already in contact with food and intended for that purpose
- Can reasonably be expected to be brought into contact with food or to transfer constituents to food under normal or foreseeable conditions of use
Framework Regulation

Fully harmonises FCM
• Article 3: Must not endanger human health!
• Commission can adopt specific measures on materials
• Member States can otherwise adopt national provisions

Sets out general procedures and rules
• requirements on specific measures, e.g. Declaration of Compliance
• definitions, traceability and labelling requirements
• ...

Requires Good Manufacturing Practices for all FCM
• Implemented via Regulation (EC) No 2023/2006
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**legislative overview**

<table>
<thead>
<tr>
<th>All FCM</th>
<th>Specific FCM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Framework Regulation (EC) No 1935/2004</strong>&lt;br&gt;General requirements for all FCM + Mandate for specific measures</td>
<td><strong>GMP Regulation (EC) No 2023/2006</strong>&lt;br&gt;requirements for Good Manufacturing Practices&lt;br&gt;Applicable to all FCM</td>
</tr>
</tbody>
</table>

**SPECIFIC MEASURES**

- **Materials**
  - Ceramics
  - Regenerated cellulose film
  - Plastics
  - Recycled plastics
  - Active and intelligent Materials

- **Substances**
  - Vinyl chloride monomer
  - Nitrosamines
  - BADGE, BFDGE & NOGE
Part 0:

INTRODUCING CERAMICS
A short history of the ceramic file

Directives 84/500/EEC in place since 1984

2011: clear that limits are not sufficiently protective

2012: consultation with MS and IND finished
  • required reduction big impact to artisanal and traditional production
  • no certainty on appropriate testing methods
  • DSVs: 400 and 60 fold reduction of Pb and Cd

2013-2017: JRC study on basis of DSVs

2017: restart of discussions
The difficulty

**Trade-off between health protection and businesses**

**Estimate**
- 10 ppb lead limit ~25% articles affected (EU, 2012)
- 100 ppb lead limit ~5% articles affected (DE, 2017)

**traditional and artisanal production particularly affected**
- traditional uses ‘old’ techniques
- artisanal ‘less’ GMP
- (remaining) European industry mostly traditional and artisanal

**SANTE focus is strongly on health protection**
- potential impact to business well understood
Ceramics – objectives of this meeting

Today is informative

In order of importance:
• 1: We inform you on how we approach the issue
• 2: You can ask questions to clarify
• 3: You inform us on your views

Detailed technical consultation in 2018
• prepared on basis of today’s discussion
• first step towards a serious regulatory package

Commission: No decisions, No commitment yet
Programme MS

1. presentation of all issues to MS
2. brief discussion of all issues one-by-one
3. welcome to stakeholders
4. presentation of all issues to stakeholders
5. discussion with stakeholders
6. lunch
7. discussion of all issues with MS only

Consequently:
- MS will see this presentation 5x
- Time for coffee and discussion outside during point 4
Contents

Part I
HEALTH

Part II
TESTING AND EXPOSURE

Part III
MITIGATING MEASURES

Part IV:
SCOPE AND PROCEDURE

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Part I

HEALTH
Assumptions used to derive limits

Limits based on health based guidance values

- derived on basis of toxicology by conservative
- usually based on no observed adverse effect level

- usually expressed as Tolerable Weekly or Daily Intake
- TWI or TDI expressed in amount per kg of body weight

- indicates the amount of a chemical in food water that a person can consume on a regular basis over a lifetime without any significant risk to health
FCM specific assumption

*a 60 kg adult consumes during lifetime each day 1 kg of food in contact with a material containing the substance of concern*

- not taken into account: children consume more on basis of body weight
- **Limit = TDI x 60**

- **1 kg is about two meals from the same tableware**

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Further Assumptions

Allocation factor

• When exposure originates from multiple sources, we use an allocation factor
• based on known exposure if detailed information available
• based on conventional assumption without such info
• 20% if exposure in the range of tolerable intake
• 10% if exposure above the tolerable intake

Food often based on more refined exposure approach

• limits in the food not representative for limits in FCM
• set for specific foods
# FCM exposure limit for lead

<table>
<thead>
<tr>
<th>Metal</th>
<th>DSV</th>
<th>Toxicological Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pb</td>
<td>3 µg/kg food</td>
<td>BMDL(_{01}) of 0.5 µg / kg (EFSA 2010)</td>
</tr>
</tbody>
</table>

**Indicative Risk Management:**

The opinion states that no health based guidance value can be derived (e.g. TWI). For a number of end points BMDL\(_{01}\) is calculated, of which the lowest is set at 0.5 µg / kg bw / day meaning that 1% of the affected population would be adversely affected at this level (see 8.6.2 of the opinion). Since no NOAEL is reported, and the BMDL\(_{01}\) is considered sufficiently conservative as a management value, the value of 30 µg/day is taken as a substitute for the TDI.

The high exposure to Pb from dietary sources is around 2.43 µg/kg bw/day (146 µg/day). Given that this exceeds the management value an allocation factor is used. At 10%, a daily intake from ceramics of 3 µg / day follows. Given an assumption of 1 kg of food from these ceramics, a **DSV of 3 µg / kg food** could serve as an indicative limit for adults.

This is a reduction by a factor 1333 of the current limit.

**EFSA opinion required:**

No, available risk assessment is sufficient

---

*No apparent reason to change this reasoning*

- DSV of 10 µg / kg food was based on testing considerations
- JRC study confirms this
## FCM exposure limit for cadmium

<table>
<thead>
<tr>
<th>Metal</th>
<th>DSV</th>
<th>Toxicological Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cd</td>
<td>2 µg/kg food</td>
<td>TWI of 2.5 µg/kg (EFSA 2009/2011)</td>
</tr>
</tbody>
</table>

### Indicative Risk Management:

In an EFSA opinion of 2009 which was reconfirmed in 2011 a TWI of 2.5 µg/kg b.w. is proposed. This results in a daily intake limit of 21.4 µg for 60 kg adults. The high exposure from food sources is according to the 2009 opinion 3 µg/kg b.w. per week.

Given that exposure is in the range of the TWI, the allocation factor of 10% is used, and a daily intake from ceramics of 2 µg would be allowable. Given the assumption of 1 kg of food from these ceramics, an **DSV of 2 µg/kg** food could serve as an indicative limit.

This lowers the current limit by a factor 150.

### EFSA opinion required:

No, available risk assessment is sufficient

---

**No apparent reason to change this reasoning**
- **DSV of 5 µg/kg food was based on testing considerations**
- **JRC study confirms this**
Include metals other than Pb, Cd?

Testing of metals can be done simultaneously

- multiple results in one test

we can only set limits if adequate scientific information is available on toxicology

we also need a relevant reason
<table>
<thead>
<tr>
<th>Metal</th>
<th>DV µg/kg</th>
<th>source</th>
<th>high migration</th>
<th>remark</th>
<th>possible to include</th>
</tr>
</thead>
<tbody>
<tr>
<td>Li</td>
<td>600</td>
<td>1416/2016</td>
<td>some @48</td>
<td>CoE 48</td>
<td>yes + evaluate</td>
</tr>
<tr>
<td>Al</td>
<td>1000</td>
<td>1416/2016</td>
<td>yes</td>
<td>CoE 5000 ALARA</td>
<td>yes</td>
</tr>
<tr>
<td>Ti</td>
<td>-</td>
<td></td>
<td>high NOAEL</td>
<td></td>
<td>no</td>
</tr>
<tr>
<td>V</td>
<td>-</td>
<td></td>
<td>some @10</td>
<td>CoE 10</td>
<td>no, evaluate?</td>
</tr>
<tr>
<td>Cr</td>
<td>250</td>
<td>EFSA/CoE</td>
<td></td>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>Mn</td>
<td>600</td>
<td>1416/2016</td>
<td></td>
<td>CoE 1800</td>
<td>yes evaluate +</td>
</tr>
<tr>
<td>Fe</td>
<td>48000</td>
<td>1416/2016</td>
<td></td>
<td>E172; limited data; CoE 40000</td>
<td>yes + evaluate??</td>
</tr>
<tr>
<td>Co</td>
<td>50</td>
<td>1416/2016</td>
<td>yes</td>
<td>CoE 20; RIVM; EFSA no data</td>
<td>yes + evaluate?</td>
</tr>
<tr>
<td>Ni</td>
<td>20</td>
<td>752/2017</td>
<td></td>
<td>CoE 140</td>
<td>yes</td>
</tr>
<tr>
<td>Cu</td>
<td>5000</td>
<td>1416/2016</td>
<td></td>
<td>1.5 mg essential CoE 4000</td>
<td>yes</td>
</tr>
<tr>
<td>Zn</td>
<td>5000</td>
<td>1416/2016</td>
<td></td>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>As</td>
<td>2</td>
<td>EFSA/CoE</td>
<td>some</td>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>Mo</td>
<td>120</td>
<td>EFSA/CoE</td>
<td></td>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>Sn</td>
<td>50000</td>
<td>1881/2006</td>
<td></td>
<td>CoE 100,000</td>
<td>yes</td>
</tr>
<tr>
<td>Ba</td>
<td>1000</td>
<td>1416/2016</td>
<td>some</td>
<td>CoE 120</td>
<td>yes</td>
</tr>
</tbody>
</table>
Include metals other than Pb, Cd?

Table requires some verification

First consultation with Member States

- EFSA: general observations, need for evaluation
- JRC: confirmation of feasibility

- Note all limits are for hollowware, cat 2 under D 84/500
Part II

TESTING AND EXPOSURE
Testing

Two types of testing

- conventional limit → severe testing, extraction
- health based limit → testing representative for exposure

the Directive uses limit based on extractable quantities

- i.e. a conventional limit

new limits based on health based guidance value

testing must be representative for exposure
1: Link the limit to usage via testing

Main category is tableware including servingware

- ceramic tableware foreseeably used with hot foods
- coffee, tea, soup
- hot-foods

“hot-fill” means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.

Conservative approach

- hot-fill condition is simulated by 2 hours at 70 °C
- acidic food

Other categories include

- bakeware (more severe)
- rim (different)
- glass drinkware (less severe)
2: Simulant representative of food

Figure 5: Typical types of migration profiles for migration of Pb from tableware into acetic acid 4 % (22 °C, 24 h), citric acid 0.5 % (70 °C, 2 h) and acidified tomato sauce. The successive three points on the graph represent migration I, II, III.

Conservative:
- Acidified tomato sauce as reference for food (Ph 3.5)
- Simulants (acidic acid and citric acid always overestimate)
Testing Conditions Bakeware

Bakeware gives inconclusive results
- food may be more severe in some cases (D, E, F)

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Suggested Representative Conditions

For tableware (hollowware):
- maintain 24 hrs, 22°C, 4% Acetic Acid
- 3 consecutive migrations, 3rd migration counts
- 3rd migration in practice 2-12 times less severe (~6.5 average)

Rim test
- tableware conditions
- ISO 6486-1 and EN 1388-2
- using wax on the non-tested portion of article

For Bakeware – no change!
- no clearly confirmed conservative testing condition
- maintain 24 hrs, 22°C, 4% Acetic Acid, 1st migration
- maintain category 3 Directive (i.e. 3x more severe)
- confirmation in food? (acidified tomato sauce?)

Glass drinkware
- 2 hrs, 22°C, 4% Acetic Acid, 3rd migration
Frequency for verification of compliance

*How often should business operators test?*

**No obligatory testing for business operators**
- Authorities can always verify compliance by means of testing

**Testing burden under control of business operators**
- e.g. when changing of composition
- never if not using problematic materials

*When tested, samples should be compliant*
Are the test conditions realistic?

Do the conditions correctly represent actual exposure?

**hot-fill condition:** overestimation

**regular food @pH 3.5:** overestimation

**acetic acid:** overestimation

**usage (1kg/day):** about right (high-users)

**children:** underestimation?

**the conditions likely overestimate!**

- by how much is not really clear
- they must overestimate, because of conservativeness
Visible damage after testing

the same plate looks still OK after 4 years home use
Conclusion on conditions vs exposure

Conditions possibly too severe to represent exposure

However large uncertainty

- Big variation between different samples
- Interaction with foods not well understood
- Aging/cracks
- Usage by high users

Nevertheless correction factor suggested

- presently conventionally set at factor 10
- thus assumes an overestimation of 10
- still conservative?

If applied: Lead 30 µg/kg, Cadmium 20 µg/kg

- same approach to other metals
Occasional use

Some articles are seldom used

- e.g. Giftware

earlier discussions considered ‘occasional use’

- Low exposure $\rightarrow$ higher limit
Occasional use

However,

- **No clear scientific proof**
  (migration behaviour and use by consumers → JRC report)
- **what happens after a couple of years?**
- **very difficult to explain to consumers**
- **arguments over compliance**
- **would work only for very specific articles**

*No intention to continue this concept*

- **kitchen and tableware suitable for day to day use**
Occasional use → not for crystal
Effect realistic exposure on compliance

Compliance:
- DSV 3 µg/kg 80%
- simulated 3rd migration (6.5x) 83%
- correction factor 10x 85%

LT data, exceedance of DSV 3µg/kg
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Part III

MITIGATING PROVISIONS

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Reduce impact on business

Need to reduce impact of lower limits to businesses
• 5-15% expected to be non-compliant

First priority remains health protection
• mitigation measures should not lower the level of health protection

Artisanal and Traditional production has limited, if any, possibility to adapt to lower limits
The burden of lower limits

cost for verification of compliance
  • testing, ...

administrative burden

more restrictions on creativity
  • less attractive products

lower consumer trust

non-compliant articles that can no-longer placed on the market
  • complete loss of business
Possible mitigating provisions

No proposals, just possibilities
- Consultation and refinement needed

the eventual provisions need to be acceptable
- health
- market (e.g. too complicated, consumers, trade)
- regulation (e.g. legal, complexity, general policy)

Types of mitigating provisions
- quality control
- labelling
- communication to consumers
- 2\textsuperscript{nd} limit
- derogations
Mitigating provisions

*The cure should not be worse than the disease*

Subject to *intense consultation*

*Industry is encouraged to think constructively*

*Everything in this section is optional*
I: Specific Good Manufacturing Practices (GMP)

**Purpose:** to reduce testing frequency

**What:** specific provisions to ensure constant quality
- Composition of starting materials
- Processing conditions
- Cross contamination (e.g. use clean kilns)
- Documentation

**How:** Via annex to Regulation (EC) No 2023/2006
- Industry is already subject to this regulation
- requires quality control and assurance systems
- Annex allows to set out specific rules
II: Provisions aimed at supply chain

**Purpose:** to reduce need for testing
- to facilitate quality control
- to provide adequate **materials** and **instructions** in particular to micro enterprises

**What:** provisions aimed at suppliers of intermediate materials to ensure, e.g.,
- Declaration of compliance + adequate information
- composition of constant quality
- supplies of certain materials, including labels

**How:** via specific provisions in the Regulation
II: example

Communication to small businesses (and hobbyists):
III: obligatory permanent labelling

**Purpose:**
to communicate on compliance
- to communicate to consumers
- to facilitate market/import controls

**What:**
requirement to apply permanent labelling
- e.g. via Decals, Relief, ...
- already common

**How:**
as part of provisions in the Regulation
- not stand-alone – will be used for a specific reason – only if needed
- e.g. dual limits, ornamental, transition
- rules could be specific to materials or type of use
IV: Dual limits

**Purpose:** to provide market access to otherwise not compliant articles
- above primary limit still permitted for food contact

**What:** secondary limit with clear restrictions
- If primary limit would be 30 µg/kg, the secondary could be 300 µg/kg
- between primary and secondary limit usage permitted subject to restrictions
  e.g. not for acidic foods, developing children, ...

**Softer variant:** no restrictions, just information
- e.g. above 30 until 150 µg/kg still allowed provided information to consumers is given

**How:** provisions in the Regulation
- additional rules for verification of compliance
- communication to consumers via leaflet, labelling
V: National Derogations

**Purpose:** to provide market access to otherwise not compliant *culturally valuable* articles

**What:** variant on dual limit
- Member States may provide derogation to Articles considered culturally valuable
- criteria in legislation
- secondary limit can be tailored and controlled
- leaflet

**How:** provisions in the Regulation
- provide for derogation by MS on basis of criteria
- communication to consumers via leaflet, labelling
VI: Harmonised information leaflet

**Purpose:** to communicate to consumers
- supplements dual limit approach; possible wider use

**What:** a harmonised text for a compulsory leaflet
- either in packaging or handed to consumer at point of sale
- provides information on what artisanal and traditional products are; indicates correct usage (e.g. no acidic foods), warns for potential health risk if not used properly

**How:** provisions in the Regulation
- setting out limits, additional rules for verification of compliance
- communication to consumers
VII: Transition periods

**Purpose:** to facilitate smooth transition
- after entry into force of the Regulation (t=0 months)

**What:** non-compliant Articles allowed time on market
- production allowed until t = X months
- placing on the market for end-users until t = Y years
- (for replacement until t = Z years Z>>Y)
- also for supply chain

**How:** provisions in the Regulation
- very common provisions
- labelling
VIII: Ornamental articles

**Purpose:** to communicate to consumers that an article is not meant for food contact

- some articles could foreseeably be used as FCM while not intended for that purpose

**What:** labelling indicating ‘not for FCM’

**Why:** to avoid confusion over compliance and use

**How:** provisions in the Regulation

- burden of proof of suitability for ornamental use only on business operator
- labelling
# Overview of labelling

<table>
<thead>
<tr>
<th>cat.</th>
<th>limit</th>
<th>description</th>
<th>indelible labelling</th>
<th>other labelling</th>
<th>restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>primary</td>
<td>unrestricted use</td>
<td></td>
<td></td>
<td>unrestricted use&lt;br&gt;labelling voluntary</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>secondary</td>
<td>Restricted use</td>
<td></td>
<td>leaflet at point of sale</td>
<td>not for everyday use&lt;br&gt;not to be used in contact with acidic foods&lt;br&gt;not for small children/pregnant women</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T</td>
<td>present</td>
<td>transition</td>
<td></td>
<td>leaflet at point of sale</td>
<td>same restrictions as for category R.&lt;br&gt;not to be placed on the market after 202X for sale to end-users</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O</td>
<td></td>
<td>ornamental</td>
<td></td>
<td></td>
<td>not to be used in contact with food&lt;br&gt;labelling voluntary (becomes discretion of inspector)</td>
</tr>
</tbody>
</table>

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conclusion mitigating measures

*setting appropriate limits is the primary objective*

three types of measures for mitigating impact

- to facilitate quality control
- dual limit
- to communicate to authorities and consumers

measures for mitigating impact from lower limits

- optional
- only if acceptable to legislator (health protection, complexity)
- only if not worse than the cure

subject to intense consultation

- alternative approaches, details
- member states + stakeholders
Part IV:

SCOPE AND PROCEDURE
Scope: glass, enamelled metals

Reasons to extend scope

- **health protection**: why ceramics and not glass, enamel?
- harmonisation of FCM widely requested
- clarity; the same limits will apply (EU and materials)
- glass and enamelled metals similar to ceramics
- harmonised tailoring of provisions (testing, labelling)

Reasons not to extend

- if it would delay the measure
- no clear support from concerned industries
- no political support (Member States, Commission)
next steps

- tentatively on basis of this discussion the next steps:

1: We draft a regulatory package
   - Regulation with options

2: Written consultation with Member States
   - limits, testing (NRLs), mitigating options, questionnaire

3: Written consultation with industry
   - mostly on mitigating options

4: Technical meeting
   - finalisation of technical draft

If required!

5: Consultation on technical draft
   - support/no support article level

6: Political validation, planning

7: Draft proposal

8: Technical Meeting + Vote in SC

9: PRAC (3 months) followed by adoption