



FCM MS WG Group Ceramic

**27 November
2017**

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

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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

(Regulation (EC) No 1935/2004)

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

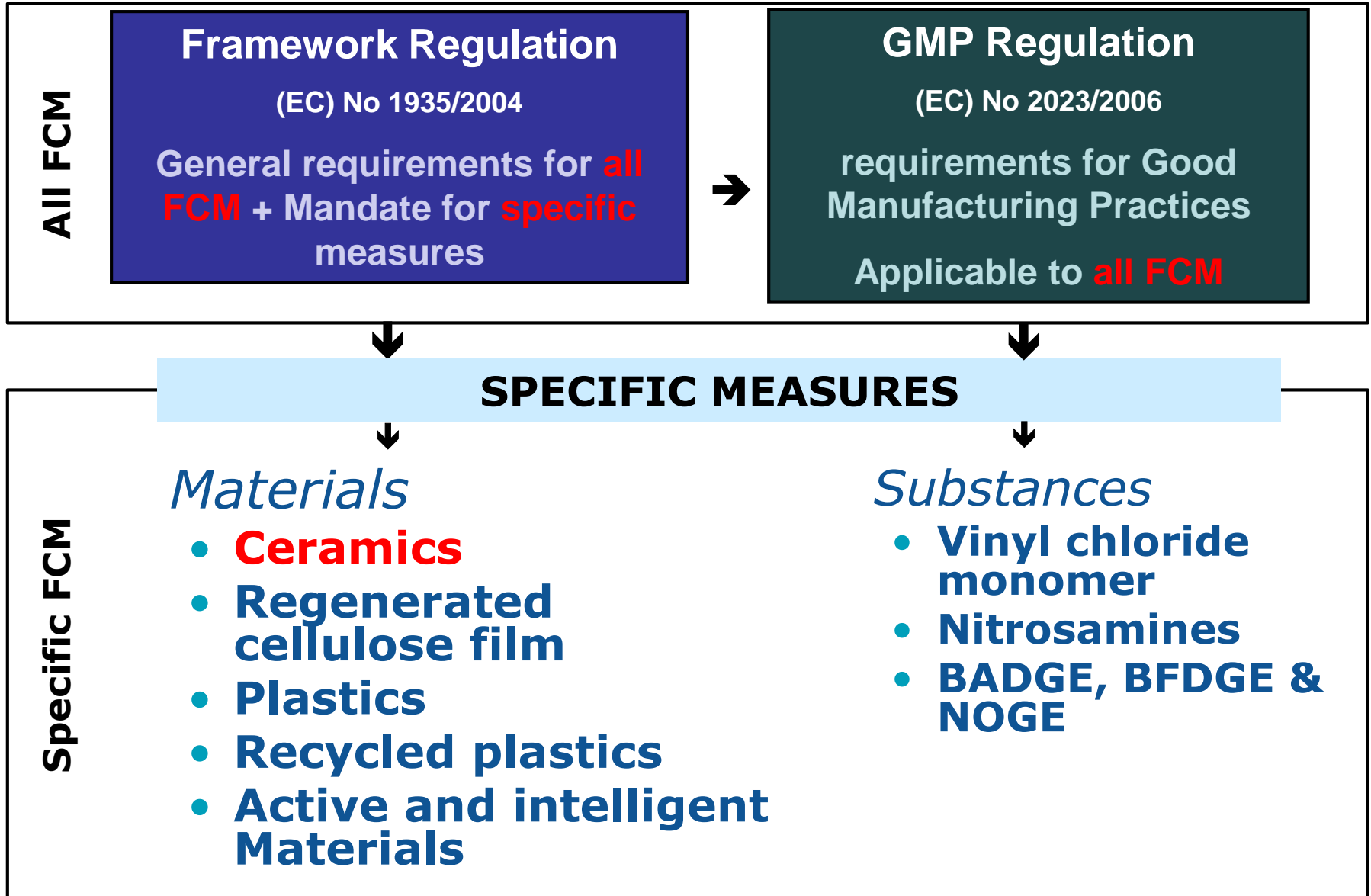
- **requirements on specific measures, e.g. Declaration of Compliance**
- **definitions, traceability and labelling requirements**
- ...



Requires Good Manufacturing Practices for all FCM

- **Implemented via Regulation (EC) No 2023/2006**

legislative overview



Part 0:

INTRODUCING CERAMICS

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A short history of the ceramic file

Directive 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 todays 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**

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HEALTH

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Part II

TESTING AND EXPOSURE

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Part III

MITIGATING MEASURES

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Part IV:

SCOPE AND PROCEDURE

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Part I

HEALTH

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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**

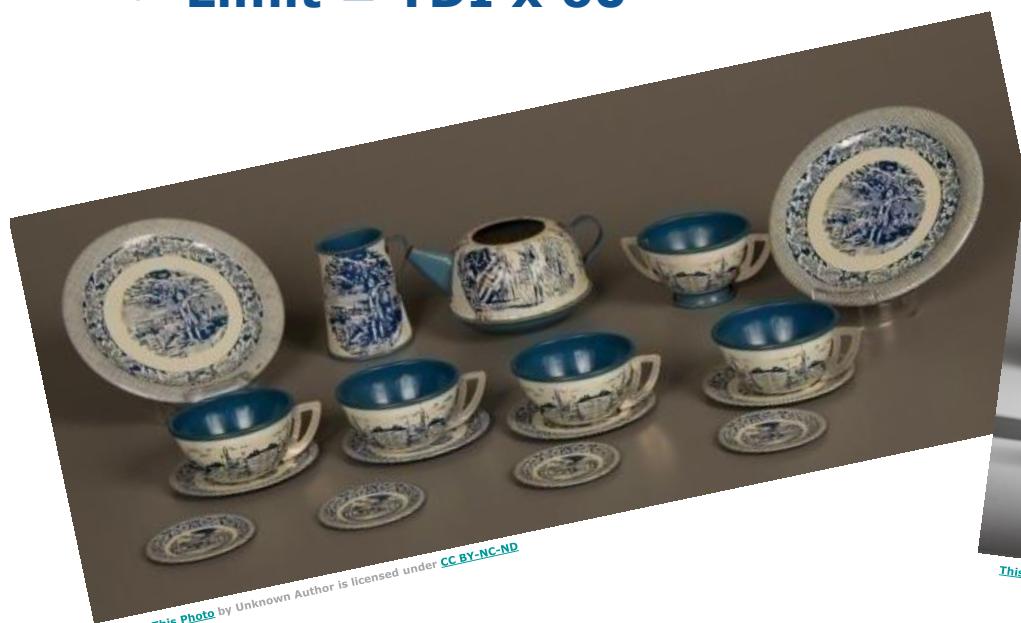
- **indicates the amount of a chemical in food water that a person can consume on a regular basis over a lifetime without any significant risk to health**



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**

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

Metal	DSV	Toxicological Basis
Pb	3 µg/kg food	BMDL ₀₁ of 0.5 µg / kg (EFSA 2010)
Indicative Risk Management:	<div style="border: 2px solid red; padding: 10px; text-align: center; color: red; font-weight: bold;"> <p>i.e. there is no lower safe exposure</p> </div>	<p>The opinion states that no health based guidance value can be derived (e.g. TWI). For a number of end points BMDL₀₁ 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 BMDL₀₁ is considered sufficiently conservative as a management value, the value of 30 µg/day is taken as a substitute for the TDI.</p> <p>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.</p> <p>This is a reduction by a factor 1333 of the current limit.</p>
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

Metal	DSV	Toxicological Basis
Cd	2 µg/kg food	TWI of 2.5 µg / kg (EFSA 2009/2011)
Indicative Risk Management:		<p>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.</p> <p>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.</p> <p>This lowers the current limit by a factor 150.</p>
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

Metal	DV $\mu\text{g}/\text{kg}$	source	high migration	remark	possible to include
Li	600	1416/2016	some @48	CoE 48	yes + evaluate
Al	1000	1416/2016	yes	CoE 5000 ALARA	yes
Ti	-			high NOAEL	no
V	-		some @10	CoE 10	no, evaluate?
Cr	250	EFSA/CoE			yes
Mn	600	1416/2016		CoE 1800	yes + evaluate
Fe	48000	1416/2016		E172; limited data; CoE 40000	yes + evaluate??
Co	50	1416/2016	yes	CoE 20; RIVM; EFSA no data	yes + evaluate?
Ni	20	752		CoE 140	yes
Cu	5000	1416/2016		1.5 mg essential CoE 4000	yes
Zn	5000	1416/2016			yes
As	2	EFSA/CoE	some		yes
Mo	120	EFSA/CoE			yes
Sn	50000	1881/2006		CoE 100,000	yes
Ba	1000	1416/2016	some	CoE 1200	yes

...not yet complete...

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

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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

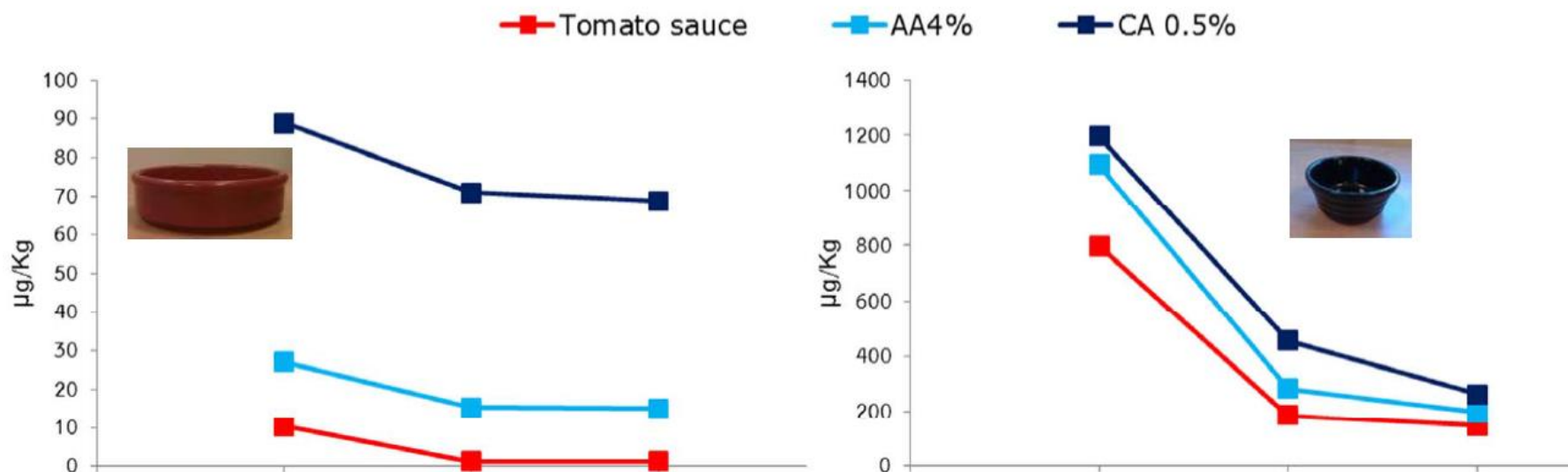
- **hot-fill condition is simulated by 2 hours at 70 °C**
- **acidic food**

Other categories include

- **bakeware (more severe)**
- **rim (different)**
- **glass drinkware (less severe)**

2: Simulant representative of food

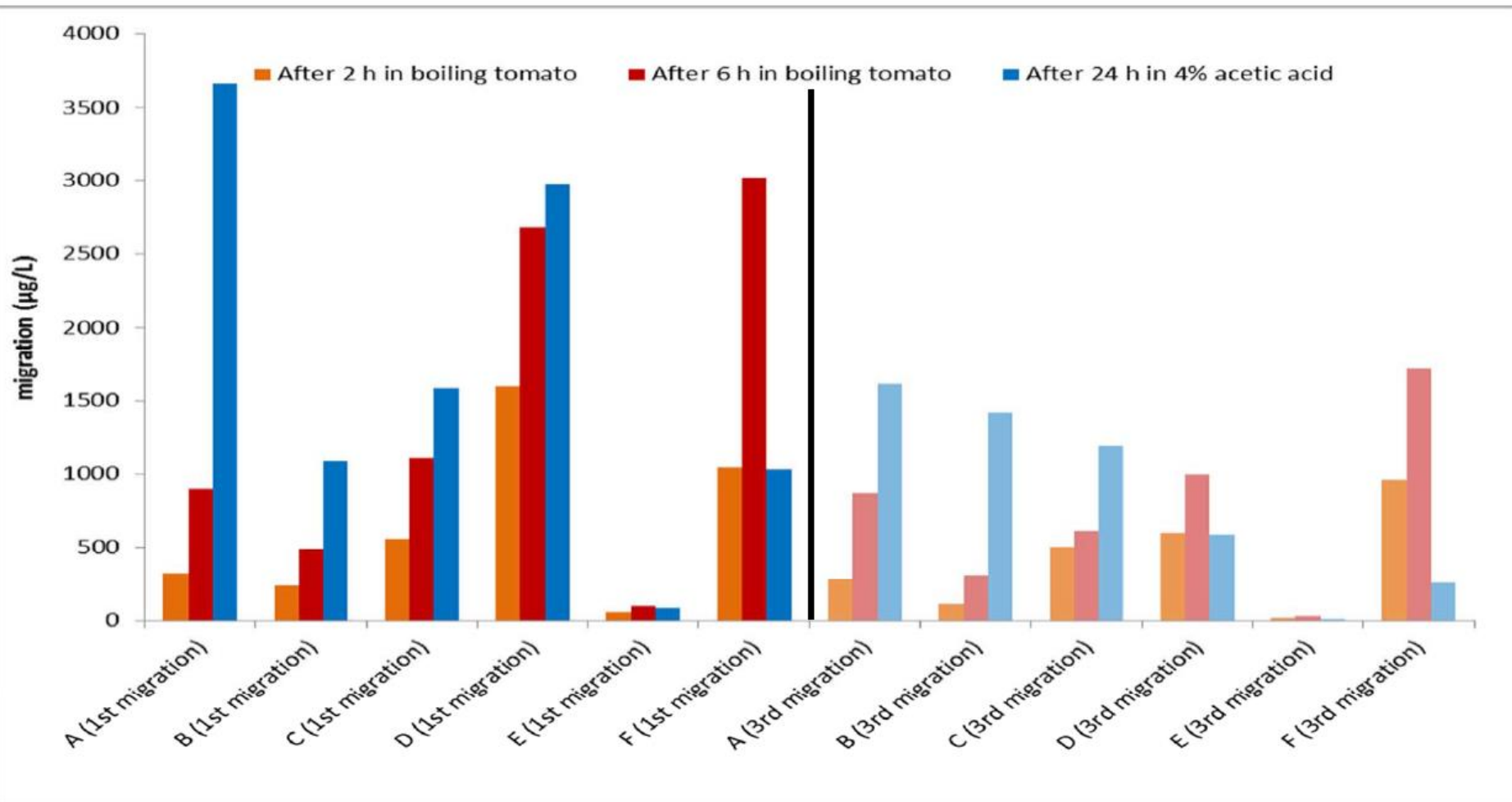
Figure 5: Typical types of migration profiles for migration of Pb from tableware into acetic acid 4 % (22 °C, 24 h), citric acid 0.5 % (70 °C, 2 h) and acidified tomato sauce. The successive three points on the graph represent migration I, II, III.



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)**

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**

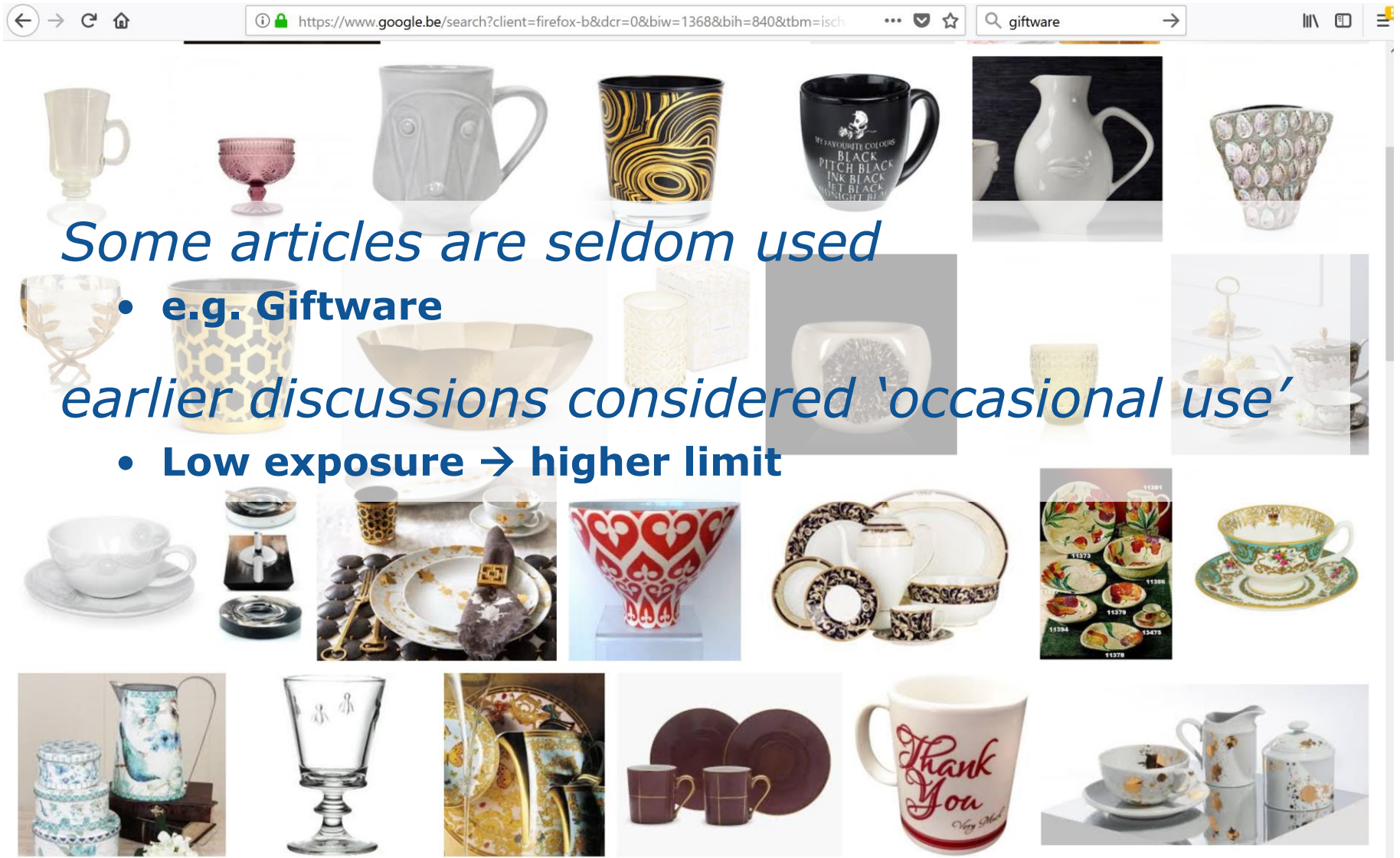
Nevertheless correction factor suggested

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

If applied: Lead 30 $\mu\text{g}/\text{kg}$, Cadmium 20 $\mu\text{g}/\text{kg}$

- **same approach to other metals**

Occasional use



Some articles are seldom used

- e.g. Giftware

earlier discussions considered 'occasional use'

- Low exposure → higher limit

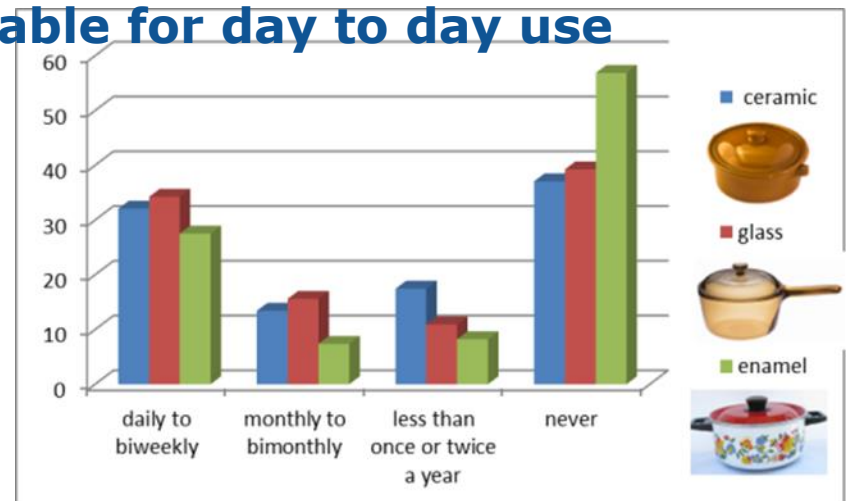
Occasional use

However,

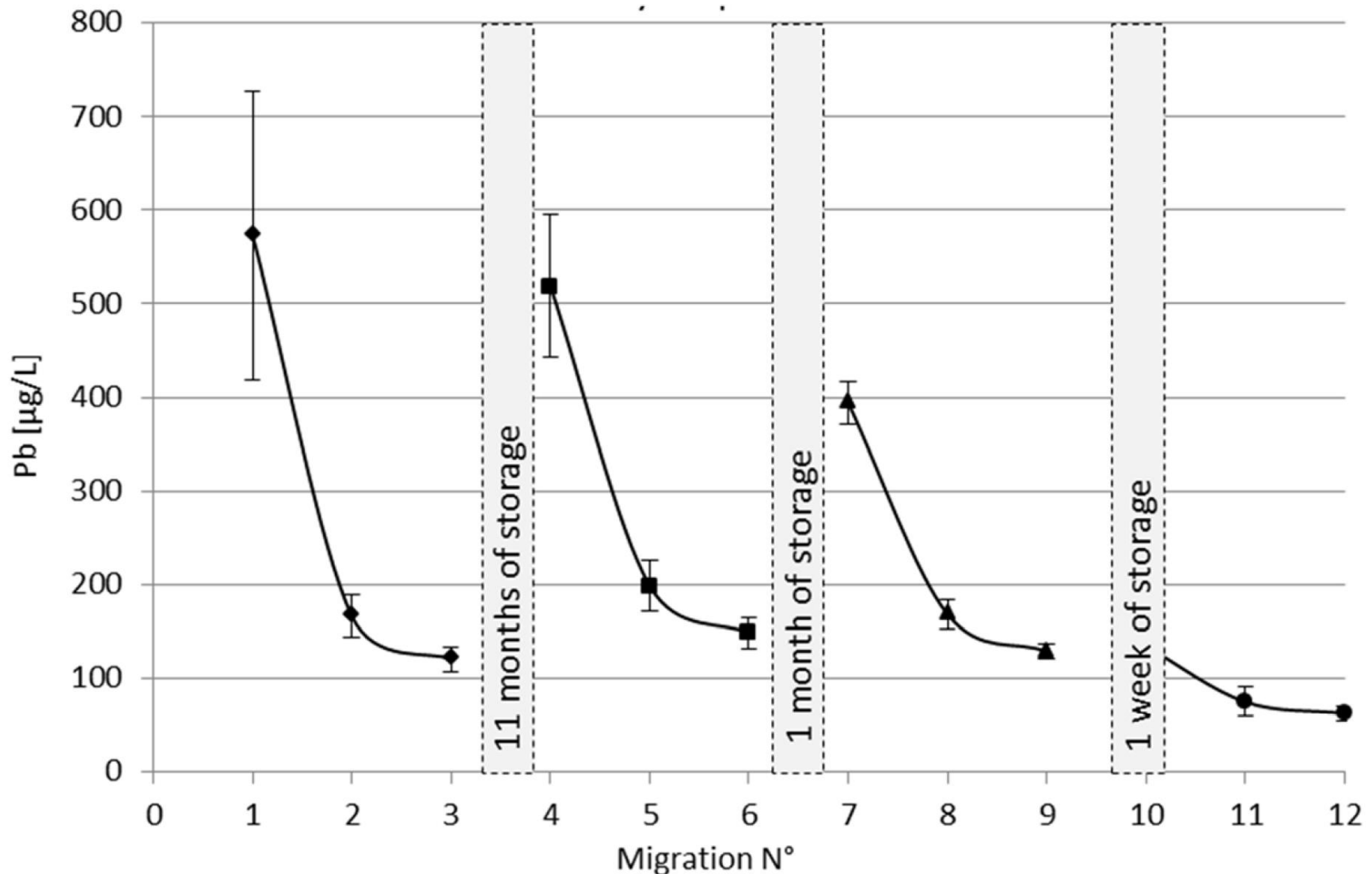
- **No clear scientific proof**
(migration behaviour and use by consumers → JRC report)
- **what happens after a couple of years?**
- **very difficult to explain to consumers**
- **arguments over compliance**
- **would work only for very specific articles**

No intention to continue this concept

- **kitchen and tableware suitable for day to day use**



Occasional use → not for crystal

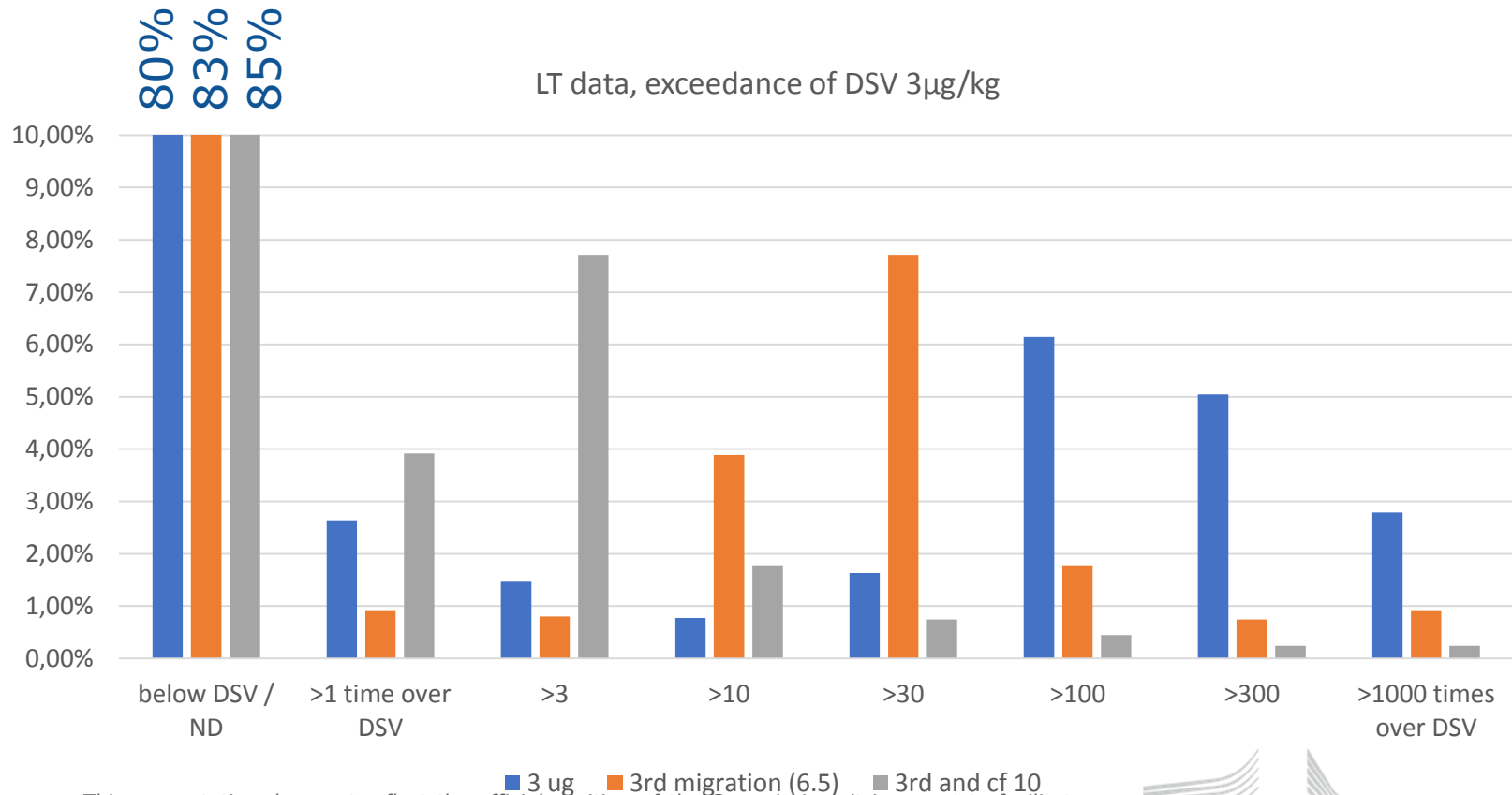


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Effect realistic exposure on compliance

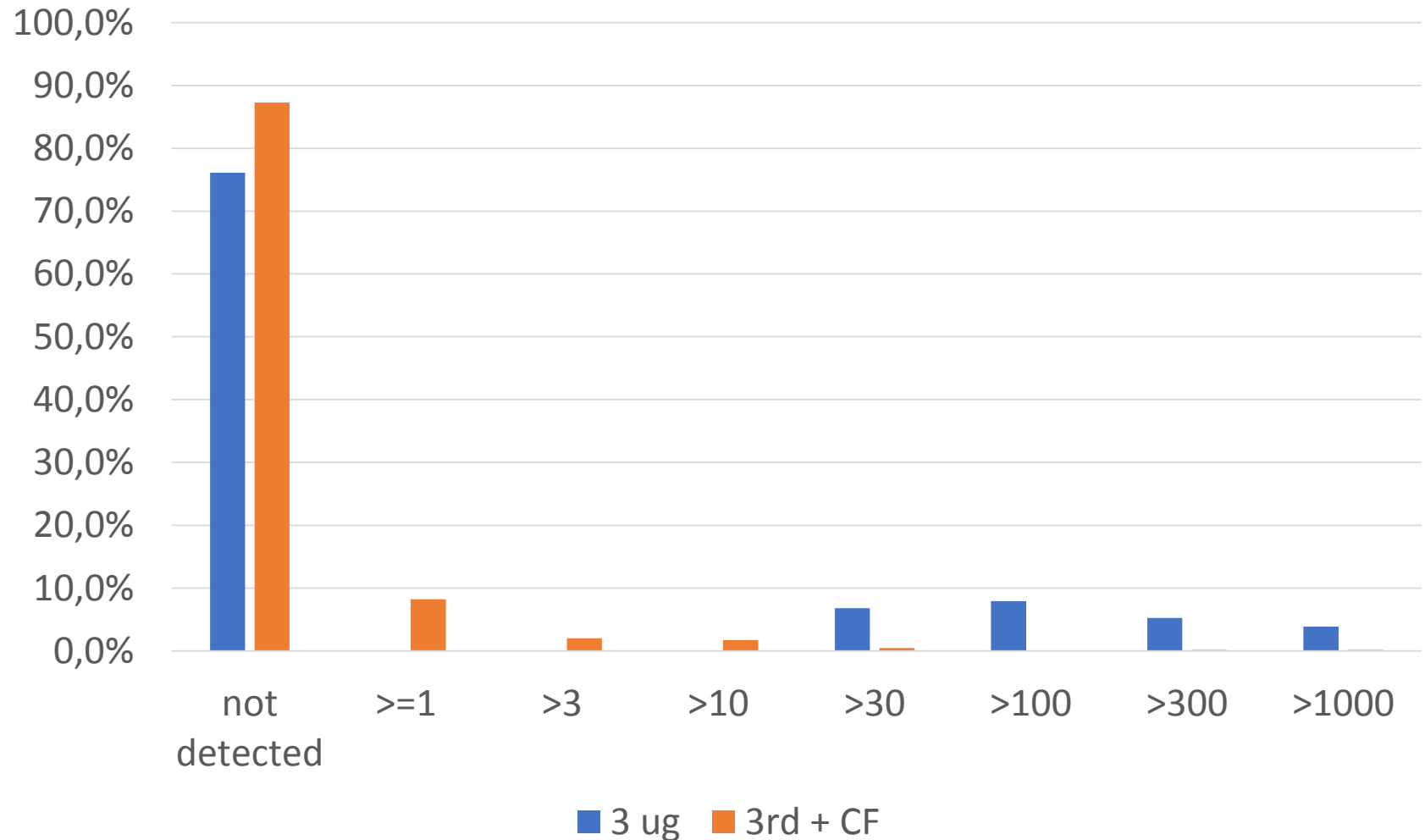
Compliance:

- **DSV 3 $\mu\text{g}/\text{kg}$ 80%**
- **simulated 3rd migration (6.5x) 83%**
- **correction factor 10x 85%**



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Norwegian data



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**
- **2nd 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

cat.	limit	description	indelible labelling	other labelling	restrictions
A	primary	unrestricted use			<ul style="list-style-type: none"> unrestricted use labelling voluntary
R	secondary	Restricted use		- leaflet at point of sale	<ul style="list-style-type: none"> not for everyday use not to be used in contact with acidic foods not for small children/pregnant women
T	present	transition		- leaflet at point of sale	<ul style="list-style-type: none"> same restrictions as for category R. not to be placed on the market after 202X for sale to end-users.
O	<ul style="list-style-type: none"> not tested; no GMP; high migration 	ornamental			<ul style="list-style-type: none"> not to be used in contact with food labelling voluntary (becomes discretion of inspector)

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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

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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*