Danish FCM inspection and control
Outline

Why is FCM control important?

The Danish FCM enforcement system

Some resent results – PFAS in paper and board

View to the future
A nice cup of coffee
Harmonised and partly harmonised material types

All FCM must be safe
– no migration in harmful amounts, no damage of the food
The main principles behind the FCM regulation

- Chemical producer
- Producer / importer
- Producer / importer
- Producer / importer
- Producer / importer
- Food business operator / consumer

Chemical – starting material
Plastic polymer
FCM / packaging material
FCM / packaging material
FCM / packaging material
Food
Who is responsible for the safety of the final material – and the coffee?

Compliance work

Positive lists

Risk assessments

Documentation – flow of information

No approval of final articles

Public control and inspection of FCM operators in the whole chain
### FCM regulation

**EU framework regulation (all FCM) 1935/2004**

**GMP regulation (all FCM) 2023/2006**

### EU specific measures

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**DK order 1248/2018**

- Biocides
- Glass and mouth rim
- Declaration of compliance
- Use suitable FCM
- Registration

**DK order 1404/2018**

- Fluorinated substances
Harmonised & non-harmonised

Active and intelligent materials and articles
Adhesives
**Ceramics** (partly)
Cork
Rubbers
Glass
Ion-exchange resins
Metals and alloys
Paper and board
**Plastics**
Printing inks
**Regenerated cellulose**
Silicones
Textiles
**Varnishes and coatings** (partly)
Waxes
Wood

Is harmonisation risk based?
Declaration of Compliance
– a Danish requirement for all FCM

The Declaration of Compliance is the most important tool for the information to flow

In Denmark we require ~ the same content as for plastic (reg 10/2011 annex IV)

Supporting documentation is necessary to issue a DoC
DK inspections at FCM establishments

~ 1000 FCM establishments registered at DVFA (producers, importers and whole sale)

Inspection on site

Performed by specialised regional DVFA inspectors

Focus on documentation, compliance work, GMP

The inspection may result in guidance or more severe sanctions - remarks, enjoining orders, injunctions, prohibitory orders, administrative fines or reporting to the police

Results of the inspection reported in control report. Public (at the establishment and online) www.findsmiley.dk
What is inspected at a FCM establishment?

Own checks

- Quality assurance system (GMP regulation 2023/2006)
- Traceability

Declaration of compliance, DoC

- In DK for all types of FCM
- The inspector selects products
- The business operator shows the relevant DoC and on demand:

Supporting documentation

- Details of the compliance work (DoCs from suppliers, test results etc.)
Analytical control of FCM

1-4 material types yr\(^{-1}\)

~ 100 samples yr\(^{-1}\)

Sampling at first point (producer, importer, whole sale)

Compliance control – specific SMLs or regulation 1934/2004

Analytical testing at DVFA laboratory, Technical University of Denmark or private laboratory

Follow up by the regional inspectors

RASFF, AAC and public announcements if necessary
Recent results from the Danish FCM control

Control of per- and poly fluorinated alkylated substances in FCM of paper and board

30 samples of packaging material (without food) – risk based

Samples from first responsible business operator in DK – importer, trader (or manufacturer)

(illustrations do not represent the tested items)
Legal basis – Regulation 1935/2004

Article 3
General requirements

1. Materials and articles, including active and inert ingredients, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof.

2. The labelling, advertising and presentation of a material or article shall not mislead the consumer.

DVFA recommendation (since 2015) not to use PFAS in FCM of paper and board
**Test of PFAS in paper and board**

DTU accredited test for 24 specific substances

“Action levels”

<table>
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<th>Groups of substances</th>
<th>Example of single substance</th>
<th>Action level (microgram/kg food) 2015/2019</th>
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<td><strong>Group 1</strong></td>
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<td>Perfluorinated carboxylic acid (PFCA) and precursors (C₄-C₁₆), eg. FTOH, mono-, di- og tri-PAPs (4:2-16:2)</td>
<td>PFOA</td>
<td>5/0,05</td>
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<tr>
<td><strong>Group 2</strong></td>
<td></td>
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<tr>
<td>Perfluorosulfonic acid (PFSA) and precursors (C₅-C₁₁), eg PFOSA</td>
<td>PFOS</td>
<td>5/0,10</td>
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**Total Organic Fluorine**

Indicator value as one tool to distinct added PFAS from the background level

10 microgram/dm²
Test conditions

**Screening**
extraction in ethanol/methanol, ultrasound, 1 h, 60 °C.

**Specific test (24 substances)**
”migration test” from FCM for non fatty food: 10% ethanol, 2 h, 70 °C.
”migration test” from FCM for fatty food: 50% ethanol, 2 h, 70 °C

LC-ESI-MS/MS, 24 standards

**Total Organic Fluorine**
Combustion ion chromatography (F⁻ subtracted)
Results

**Screening**: 9 out of 30 samples showed PFAS

**Migration**: 24 specific PFAS < LOD in all samples

**Total Organic Flourine**: 20 out of 30 samples contained TOF > 10 µg/dm²

Follow up

No non-compliance to art. 3 can be concluded

No "migration" of the 24 specific PFAS > LOD

TOF can only be used to indicate no PFAS

New Danish order:
– ban of PFAS in FCM of paper and board on the market on its way
Experience from the FCM inspections in Denmark

It is getting better!

DK FCM establimens:

Interested in the FCM regulation

Want to comply and to be responsible

Often find the regulation difficult

Appreciate the dialogue with DVFA (general and specific)

Use the official control in their marketing (e.g., to open new export markets)

Common wish for more harmonised regulation

Find the requirement for DoC for all FCM relevant
Improvements in the FCM area – a view to a better future

All FCM must be safe – no migration in harmful amounts, no damage of the food

More focus on FCM control in EU MS

Declaration of Compliance for all material types

Wish for more EU harmonised FCM regulation

Alternatives to EFSA Risk assessments of specific FCM substances?

Database of industry assessments?

Minimum hazard cut offs – eg. no CMR allowed in FCM?

Information in the REACH registration, restrictions and authorisations to be used in the FCM assessment?

Reevaluation of authorized /regulated substances – when new data, periodically, when assessed in other legislation?
Thank you!