



**Ministry of Environment
and Food of Denmark**
Danish Veterinary and
Food Administration

Danish FCM inspection and control

Food Packaging Forum
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Outline

Why is FCM control important?

The Danish FCM enforcement system

Some recent results – PFAS in paper and board

View to the future



A nice cup of coffee



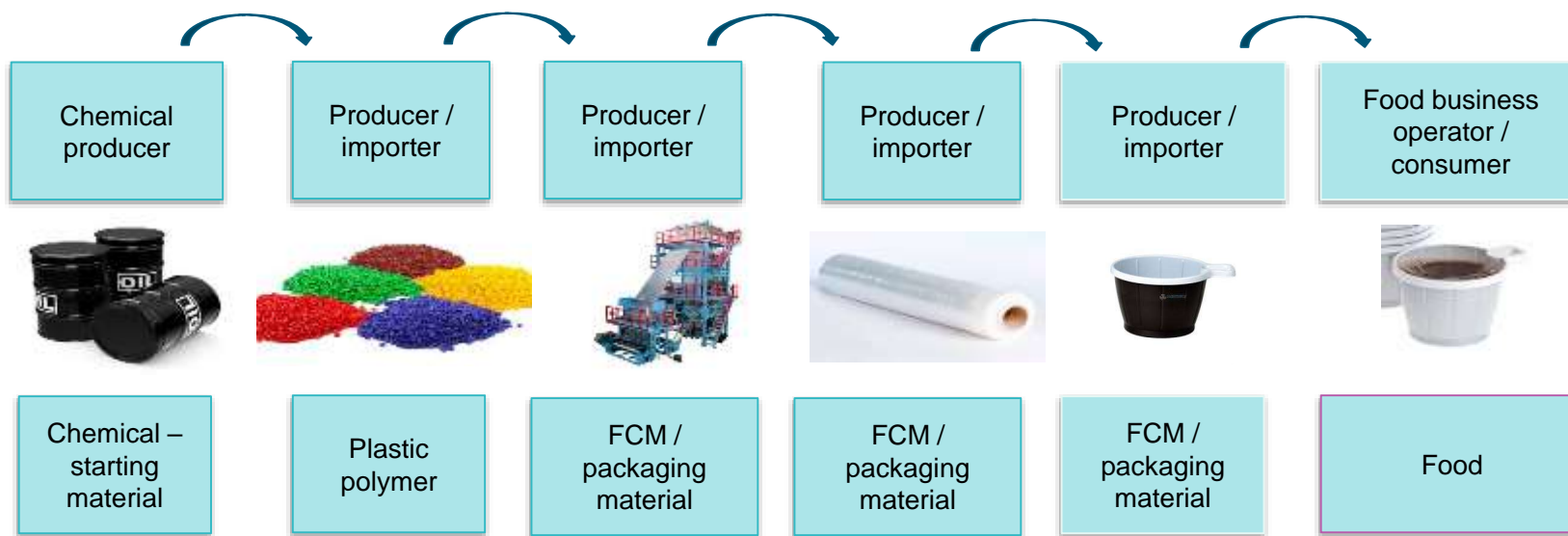
Harmonised and partly harmonised material types

All FCM must be safe

– no migration in harmful amounts, no damage of the food



The main principles behind the FCM regulation



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

Plastic (10/2011)

Import restriction (284/2011)

Lacquer with BPA
(2018/213)

Epoxyderivatives (1895/2005)

Active and intelligent
packaging (450/2009)

Recycled plastic (282/2008)

Regenerated cellulose

Ceramics

Biocides

Glass and mouth rim

Declaration of compliance

Use suitable FCM

Registration

DK order 1248/2018

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 intelligent materials and articles, 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 consumers.

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”

Groups of substances	Example of single substance	Action level (microgram/kg food) 2015/2019
Group 1 Perfluorinated carboxylic acid (PFCA) and precursors (C ₄ -C ₁₆), eg. FTOH, mono-, di- og tri-PAPs (4:2-16:2)	PFOA	5/0,05
Group 2 Perfluorosulfonic acid (PFSA) and precursors (C ₅ -C ₁₁), eg PFOSA	PFOS	5/0,10

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)

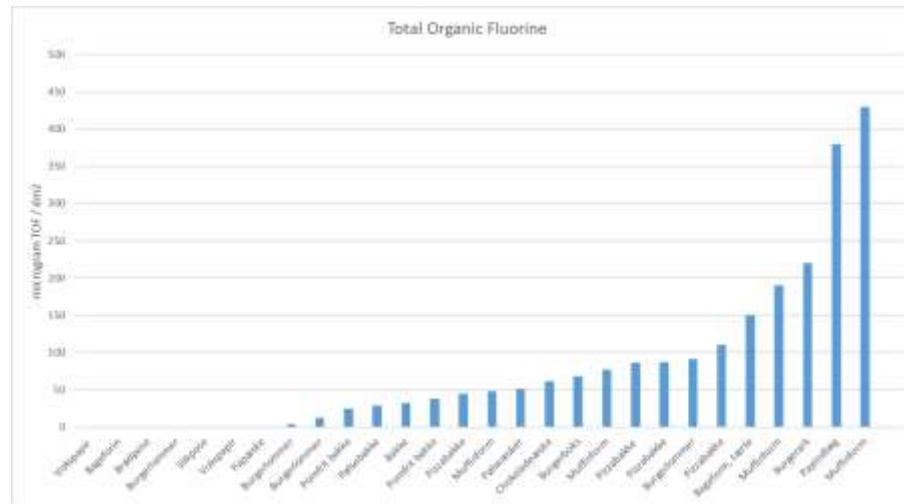


Results

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



<https://www.foedevarestyrelsen.dk/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/Kontrolresultater/2018/Fluorede%20stoffer%202018.pdf>



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 it's way



Experience from the FCM inspections in Denmark

It is getting better!

DK FCM establishments:

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!

