



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

# FCM regulation – how to reach safe articles

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# **FCM regulation – how to reach safe articles**

**The main principles in the FCM regulation**

**Responsibility in the supply chain**

**Compliance work and risk assessment**

**Control and inspection**

**Ideas to consider**



# 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?

Compliance work

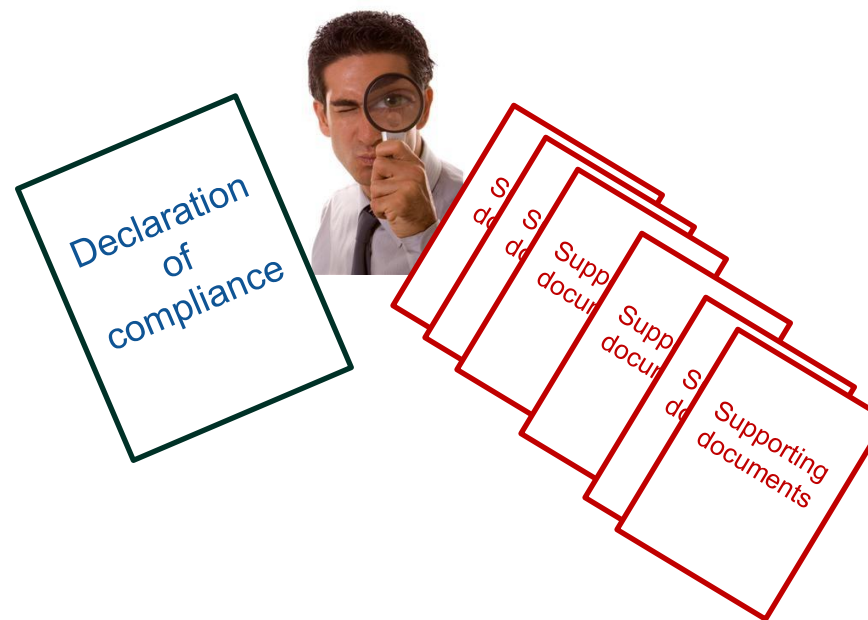
Positive lists

Risk assessments

Documentation – flow

No approval of final articles

Public control and inspection of FCM operators in the whole chain



# Harmonised and non-harmonised material types

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

Framework regulation reg.1935/2004  
Good Manufacturing Practice reg. 2023/2006

## Harmonised

Plastic reg.10/2011  
Recycled plastic reg. 282/2008  
Ceramics (Pb and Cd) dir. 84/500  
Some epoxy derivatives reg.1895/2005  
BPA in coatings reg. 213/2018  
Regenerated cellulose dir. 42/2007

**Non-harmonised** – MS regulation, recommendations, CoE, self assessments:  
Paper, board, metal & alloys, printing inks, some additives in plastics... **1935/2004**



## **Improvements and possible shortcuts – for discussion**

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

**Alternatives to EFSA assessments of specific substances?**

**Risk assessments from supplier of chemicals – relevant for food contact**

**Database of industry assessments?**

**Minimum hazard cut offs – eg. no CMR?**

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

**FCM default included in REACH restrictions**

**Reevaluation of authorised substances – when new data, periodically, when assessed in other legislation?**

**Multiple use of substance – common assessment, allocation?**



**Thank you – looking forward to the discussions!**

