



Kanton Zürich
Gesundheitsdirektion
Kantonales Labor Zürich

Enforcement's Perspective

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Gregor McCombie

Kantonales Labor Zürich

gregor.mccombie@kl.zh.ch

Why Switzerland?

Symptomatic of

- Lack of importance given to food contact materials in food safety
- Lack of European level working group for enforcement

However we have

- Equivalent legislation
- Good international connections

→ Throughout this presentation 5 issues will become apparent and be highlighted

Issue 1

There is no European level group concerning enforcement

There are European level Groups for

- Legislating
- Chemical analysis

10 People from 9 countries consulted

GR



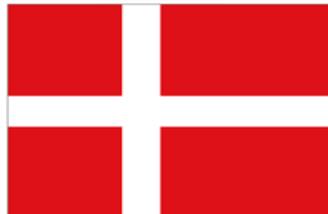
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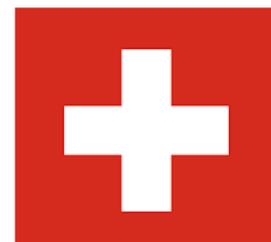
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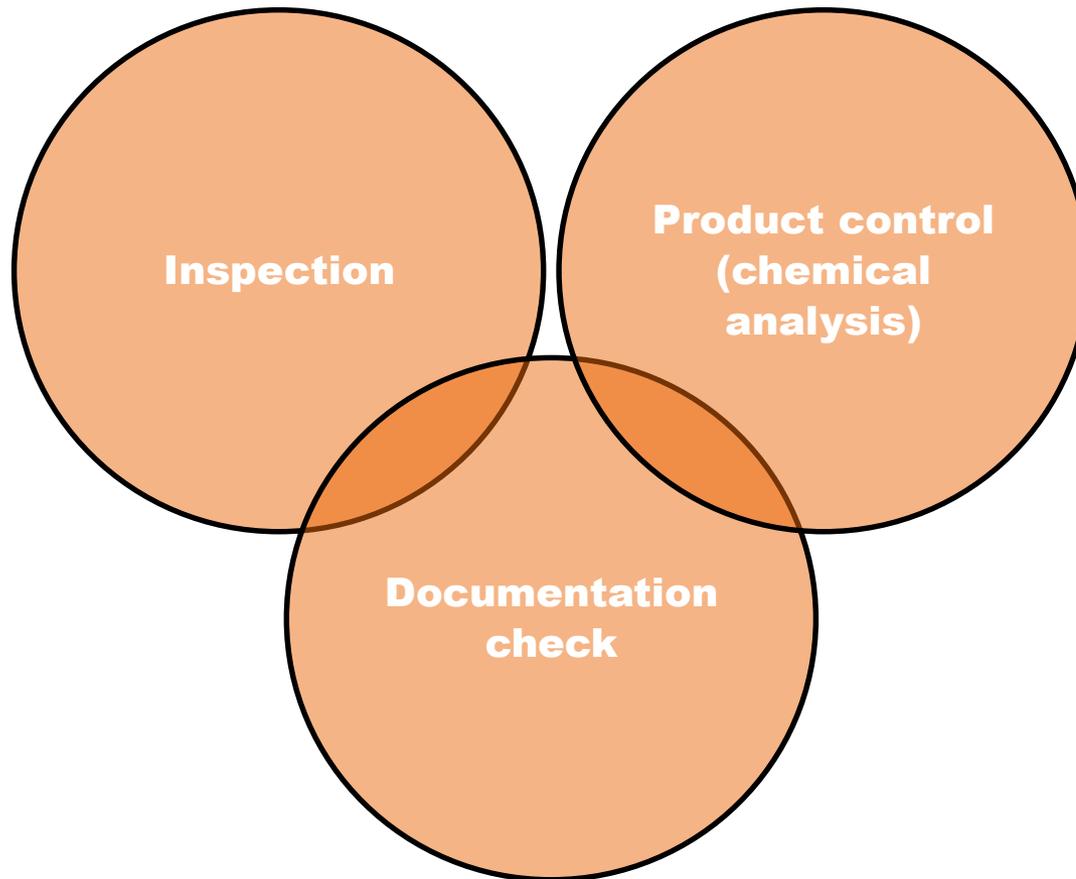
How Does Enforcement for FCM work?

It mostly does not!

«We do some enforcement in order to claim we do it. It achieves nothing.»

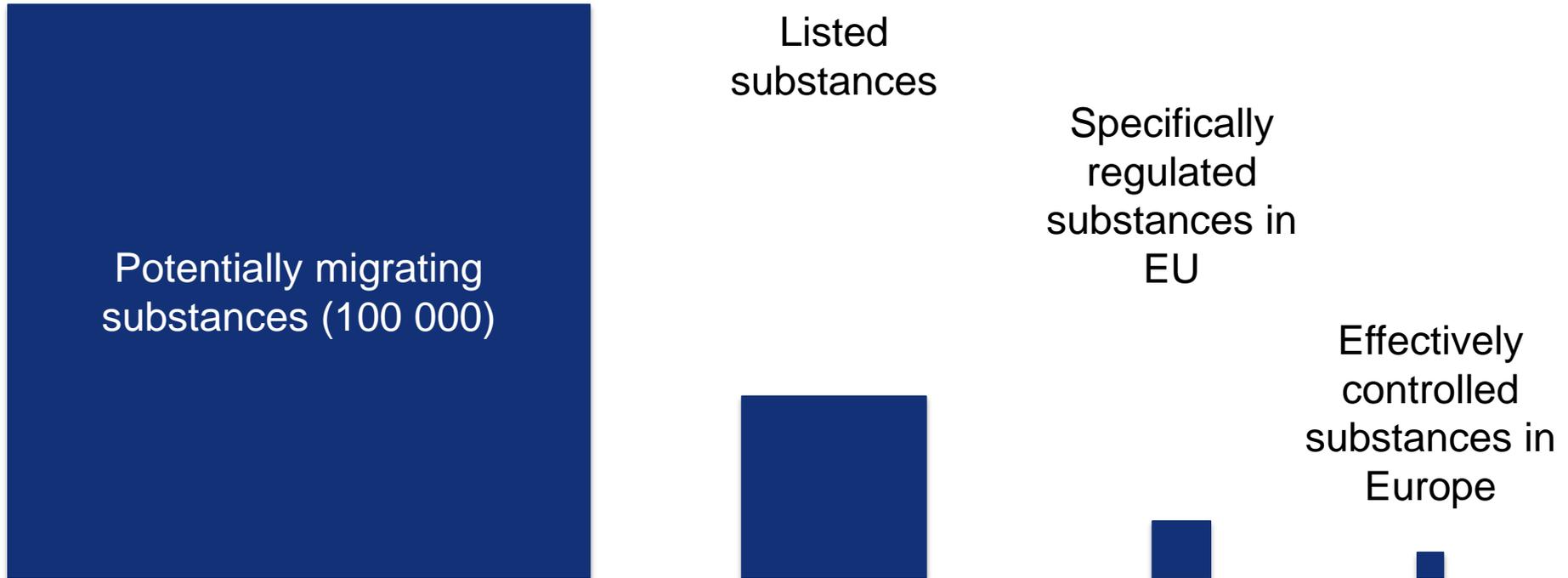
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Enforcement



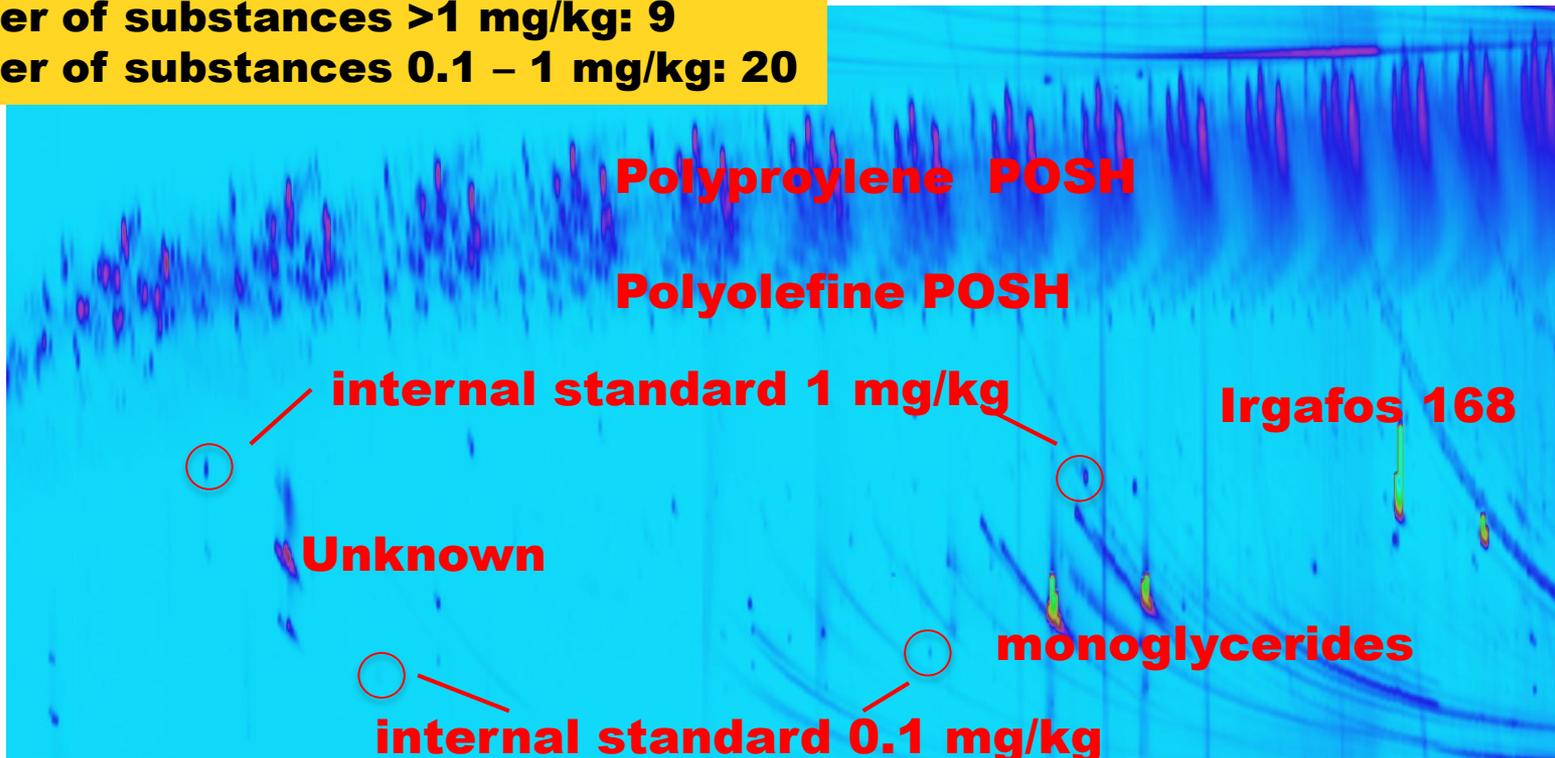
Chemical analysis

Number of Migrating Substances



Polyolefin extract by 2-dimensional gas chromatography (GCxGC)

Oligomer content: 1000 mg/kg
Number of substances >1 mg/kg: 9
Number of substances 0.1 – 1 mg/kg: 20



Issue 2

There are too many substances

i.e. are >80 photoinitiators necessary for making printing inks for FCM?

Summary Chemical analysis

Enforcement works for some substances where

- There are clear limits of migration
- There is specific legislation (e.g. Reg. 284/2011)
- There was a «scandal» (e.g. ITX)
- It is easy to measure, though irrelevant for protecting consumer's health (e.g. overall migration)

Many MS do no or virtually no chemical analysis of FCM

- Those who do, check only a few substances
- The EURL has been given an impossible job (i.e. provide methods for all substances)

Inspection

What works

Denmark

- National legislation for registration of FCM businesses
- Specially trained inspectors (but they don't work full time on FCM)
- Making stakeholders aware of the importance of FCM for food safety

DoC

- It enables checking the competence of business operators
- Detection of misuse of FCM

What does not work

Most of European FCM enforcement

- No knowledge of relevant business operators
- Not sufficient expertise for checks

Conceptually

- Check of the compliance work that went into final FCM products
- Too low European inspection density
- Checks of the business operator's risk assessment upon which the DoC was issued

Issue 3

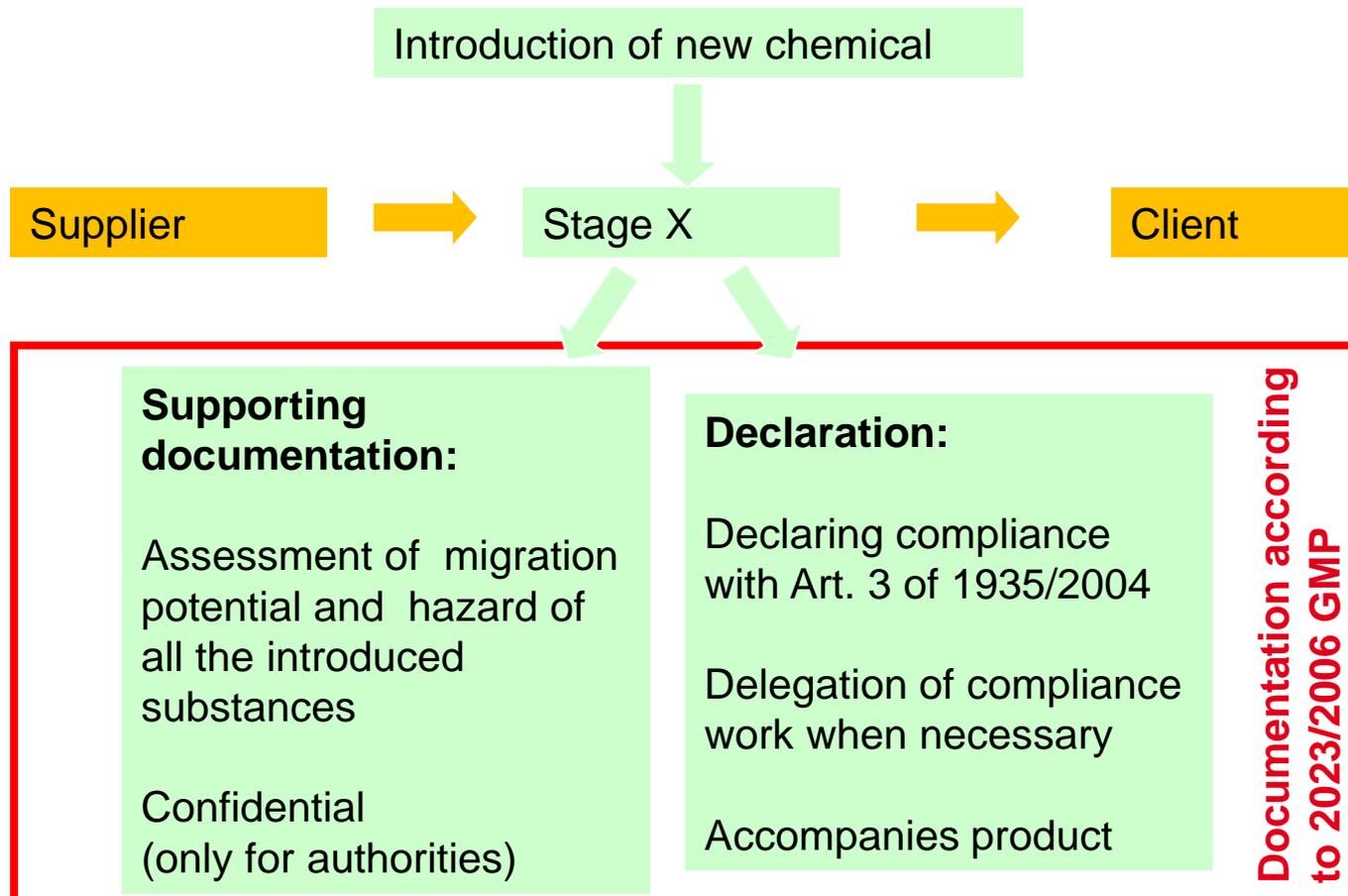
Lack of allotted resources for FCM controls

And lack of competence at local enforcement level

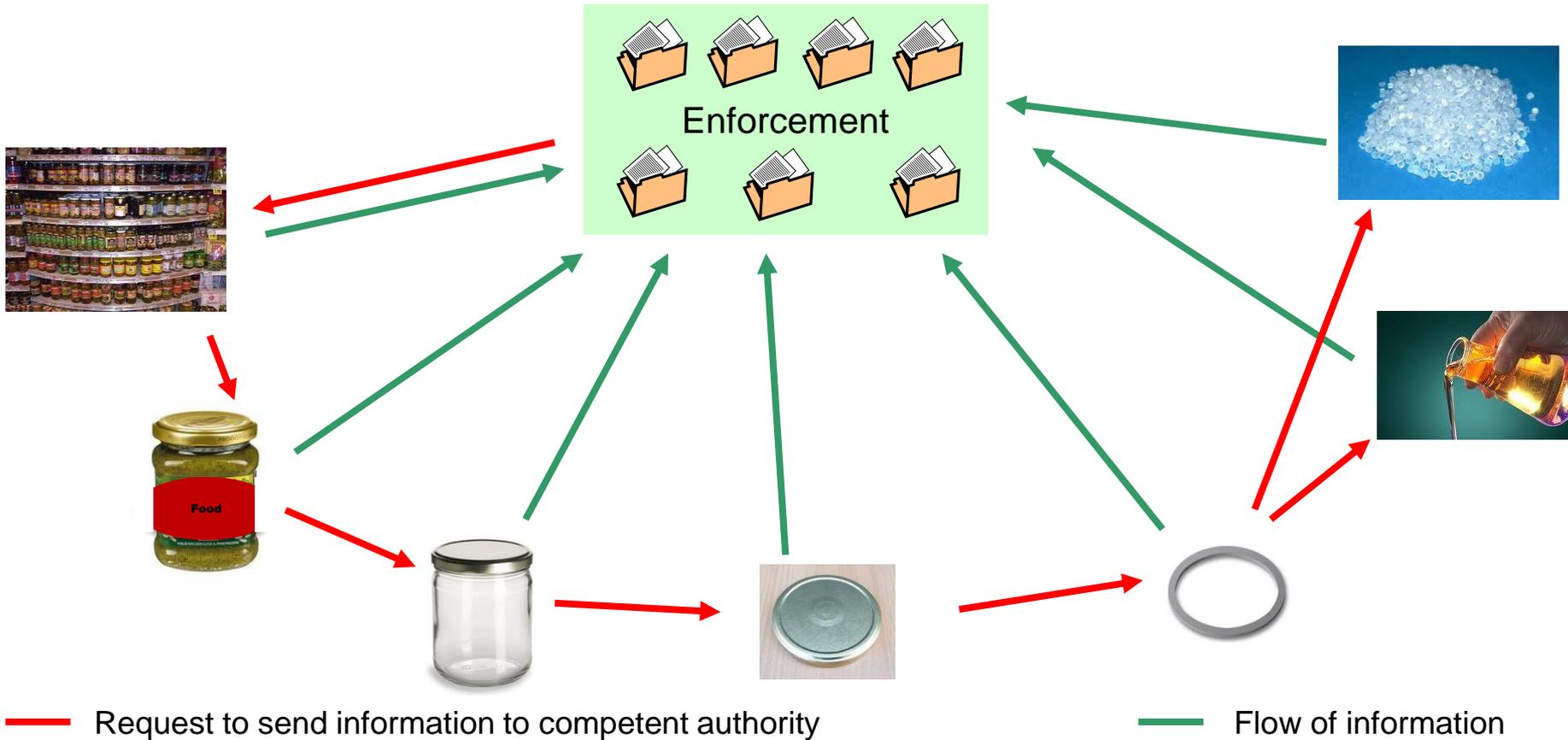
Documentation check

Reg. 2023/2006

GMP Concept



Collecting compliance work



GMP Projects

German pilot project on GMP enforcement

- Enforcement collecting data directly (also from abroad) works
- Collecting data via competent authorities was deemed not to work

Swiss polyolefin campaign on the safety assessment of granulate producers

- Data collection works
- International experts evaluated the received data
- The rules for scientifically recognised principles for risk assessing substances are available and clear (from EFSA)
- There are gaps in the safety assessment (i.e. NIAS)

These campaigns are not standard in European enforcement

Issue 4

There is a lack of knowledge on risks associated with migration from FCM

There are too many substances that are unidentified with unknown toxicity and migration behaviour

Measures

Order improvement

- In inspections business operators can be ordered to act, but only for superficial reasons as the whole chain of business operators is not involved

Withdrawal or recall of products

- Only works for exceedance of a limited number of substances
- To my knowledge there has never been a withdrawal of an FCM product in Europe due to insufficient safety assessment

Fines

- Limited impact at a local level

Rapid alerts

- To my knowledge there has never been a rapid alert due to insufficient safety assessment

Issue 5

There is a lack of adequate measures

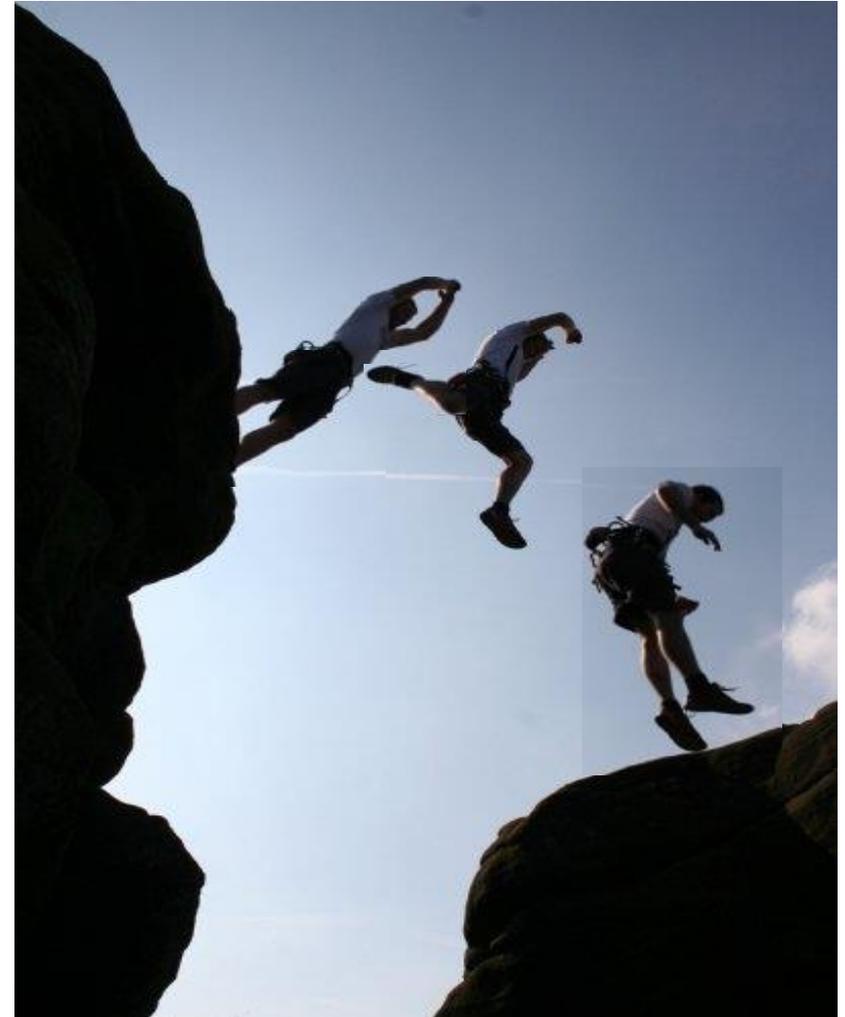
(This point may have massive implications for food law)

Take Home Messages

FCM are a hugely underestimated source of food contamination

There is a gap between requirements for and reality of the safety of FCM

Enforcement is currently not able to adequately protect consumers



Enforcement's Perspective

Effectiveness

- FCM legislation has achieved the goal of protecting consumer's health for a very limited number of Substances
- For most FCM there is no systematic evaluation for compliance with Art. 3 (1935/2004)

Efficiency

- Theoretically, safety assessments should be performed by business operators and checked by enforcement
- In reality the public ends up financing much of the safety evaluation

Relevance

- There is a lack knowledge on potential danger to consumer's health from FCM

Coherence

- Lack of coherence with respect to regulated types of materials
- Lack of coherence with respect to risk/ressources in other food safety areas (e.g. pesticides)

EU added Value

- It enables (at least) a limited amount of consumer protection

Message for the Evaluators

For enforcement's perspective we can be contacted any time

We can provide contacts, background information of this talk and a host of examples

We have had many thoughts on how to improve the situation, which did not make it into this presentation