



# Independent third-party testing labs: what role can and should they play in enforcing FCM regulations?

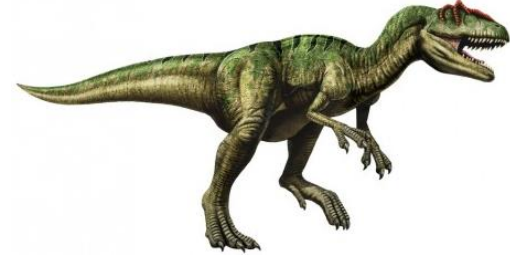
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# Third-Party Testing – Why and How?

- Any actor in the value chain of FCMs is using services of third-parties:
  - to demonstrate own research is «correct» – second opinion, if own lab is available
  - to convince clients by a kind of independency
  - to create supporting documents for in-house as well as for external use (on demand)
  - to receive a statement of compliance
  - to receive the «absolution» – there is no «problem»
- Clients of third-party services are providing as much as possible information to the lab
  - Mainly secrecy agreements or non-disclosure agreements (NDAs are signed)



# Third-Party Testing – In the Past



- Listed substances were forwarded to the lab under a NDA
  - Substances were individually tested – only these substances
  - For plastic it was the state-of-the-art approach
- For materials without positive listings – the majority as inks, adhesives, lacquers, paper etc – generic approaches are performed.
  - i.e. paper: hot and cold water extracts – no migration
  - or only those substances were tested with listing in the Plastic Regulation
- **RESULT:** A statement of compliance/harmlessness or in an improved version a Declaration of Compliance was issued
  - Third party gave a kind of guarantee (cave disclaimer)

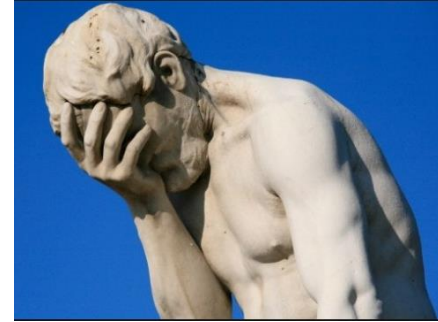
# Third-Party Testing – Actual Situation

- In recent years it became obviously, that the so called listed substances, especially in plastic do not in any way migrate
- Migration to a high(er) extend of non-listed substances, oligomers, NIAS (non-intentionally listed substances)
- This questions the value of lab statements focussing only on listed substances
- Especially, if GMP has to be confirmed – this is by definition a producers duty and cannot be confirmed by a lab
- **RESULT:** labs provide analytical reports including an assessment, but this reports are only supporting documents and not a Declaration of Compliance
  - Responsibility is also in written form at the manufacturer



# Third-Party Testing – Actual Problems

- The more complex the product the more information on chemical formulations is needed
  - Many NDAs have to be signed
  - Completeness of information cannot fully be controlled
- Results are more complicated to interpret as the switch from target analysis to non-target analysis is done
  - “unknown” signals present
  - how to assess “unknowns”
- The follow-up of results can take several months up to the decision “we cannot solve the issue”
- There is still a tendency to “misuse” lab results – “absolution”
  - Some results can only be interpreted if several parties work together



# Enforcement Labs/Authorities

- Actually we have three kinds of enforcements labs in the FCM world:
  - Labs/Authorities not interested in FCM as it is not seen as major contributor on food safety
  - Labs/Authorities testing and complaining
    - only formalism, i.e. wrong language in the DoC, or
    - few selected parameter. i..e phthalates, plasticizer, BPA, mineral oil etc.
  - Labs/Authorities are very active
    - in research (i.e. mineral oil)
    - in inspecting companies (packaging and food)

**This labs having as well as third-party labs problems to receive all information**



# The «New» EU Approach



Disclaimer: I do not have all details, if already known. Therefore the following is only a personal view!

## The Approach:

- Third-party labs checking all relevant information, performing tests, assess results and give at the end a kind of certificate, which will be accepted by authorities
- For this task a special accreditation of labs is needed
- Tasks are besides testing also assessments, i.e. toxicology
- Authorities can overrule third party "results/assessments"
- A similar system exists already i.e. in the toy world
  - Several «notified bodies» in several member states

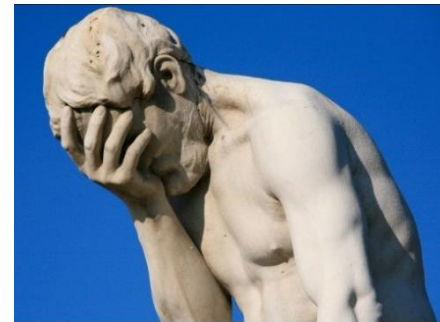
# Does this new Approach work?



- **Simply spoken: NO!**
- How many notified bodies are allowed per member state – only one – what is with the others?
- How to harmonize the work of the notified bodies – by accreditation
  - However labs are actually accredited under ISO 17025 – do we see a harmonised world?
- What happens if a raw material supplier is using Lab A, which is a notified body, and a converter is using Lab B – as it is now! Does Lab A overrule Lab B?
- Are notified bodies only allowed to work at a certain step in the value chain, i.e. final products – this would mean we are running into a licensing system
- So - questions over questions–may be based on a lack of info



# What are the general problems?



- Lack of transparency
  - Difficult to solve considering intellectual property rights
- Lack of harmonised testing rules for all materials
- Lack of harmonised assessments – exposure yes or no to be considered
- Lack of final positive lists

This is only for the EU – if we have a look worldwide we can observe that more and more FCM Regulations show up, which are not directly harmonised either with EU or FDA.

However raw materials, intermediates and final products are traded worldwide

# What could be an alternative?



## For the Enforcement:

- Make the system more simple, i.e. positive list
  - Follow the «Swiss» way done with printing inks:
    - Asking industry, what is actually used as it is used
    - Put it in a list and set restrictions based on the info given resp. generally available
    - Do it for all not yet harmonised materials
- The scientific clearance of this list can be done afterwards not before – that is impossible
- **Finally:** enforce!
  - Based on harmonised enforcement body rules
  - So no need to set-up a parallel system

# What could be an alternative?

Remember:  
No problem

## For the (Food) Industry:

- Do a mind shift – go away from supplier hopping
- For existing products perform only plausibility tests – a full compliance in a strong sense cannot be achieved anymore
- When starting new projects bring from the beginning all potential suppliers along the (complete) value chain to the same table
  - Define a compliance strategy
  - Define testing protocols – what is the homework of each partner avoiding double/triple testing of the same
- **Finally:** do not force to receive lab reports saying “there is no problem”- the opposite would be better!
- However here also - questions over questions – may be it is to complicated – therefore ....

# .....the system must be more simple

If you can't explain it **simply**, you don't understand it well enough.

– Albert Einstein

