

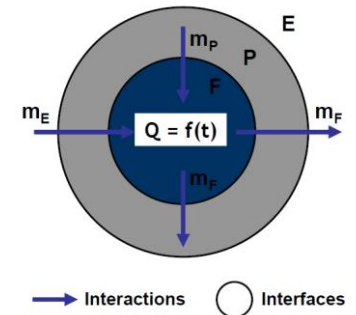
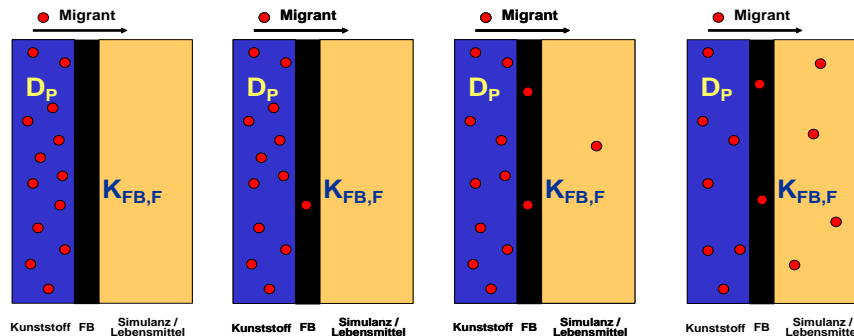


Measuring Migration from FCM: Status Quo and Future Trends

Dr. Thomas Gude

Migration

- There is no absolute inert material available
- There is always interaction between food and material



- Risk assessment of substances is key!
- Actually the law sets the focus on starting substance
- What's about other migrating substances:
 - Degradation products within materials
 - Degradation products of additives
 - Contaminations (i.e. of starting substances)
 - Generally, reaction products
 - Contaminations during processing (Cleaning, Storage etc.)

Background of Migration Limits as an example based on EU No 10/2011

Requirements

derived from Reg 1935/2004, Article 3)

a) Endanger human health (Article 11 – (EU) No 10/2011)	Specific Migration into Simulants and real Food acc. to i.e. EN 13130 Vinylchloride and Organotin-Stabilisators from PVC, Phthalic acids, Acetaldehyde, Antimonoxide in PET, Formaldehyde in Melamine, Additives like UV-Stabilisators, Antistatika etc.	Limits Depends on Toxicology
b) an unacceptable change in the composition of the food (Article 12 – (EU) No 10/2011)	Overall Migration acc.to DIN EN 1186 Water, Acetic Acid, Ethanol and iso-octane, Olive oil Filling, Immersion, Pouch and migration cells	Limits 10 mg/dm ² resp. 60 mg/kg
c) a deterioration in the organoleptic characteristics thereof (Article 3 – (EU) No 1935/2004)	Sensorial testing acc. to DIN 10 955 Odor, Taste and Appearance	Limits Acc. to BfR: 2,5 on a scale from 0-4 (DIN 10955)
d) NIAS Components (Article 19 – (EU) No 10/2011)	NIAS Screening according to? Contaminations, Reaction- and Degradation products	Limit Typically 0.01 mg/kg

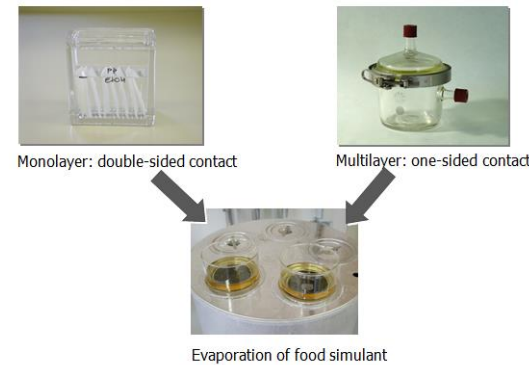
Not everything is plastic!

- The plastic Regulation is made for plastic
- However, how do we handle with non-plastic materials, i.e. paper, lacquers etc. ?

Claiming it is non plastic	Claiming it is non plastic, but
therefore no testing	testing follows plastic as much as possible
Only starting substances are assessed	Assessing, what is migrating
No testing rules – it is not necessary (!?)	Rules available, but not perfect – overestimation possible
Willingness to develop rules not really visible	Adjusting of existing rules

How we test today?

- Overall Migration (unspecific testing): OM
 - Following mainly rules for plastic
 - Useful to exclude individual substances and to demonstrate a kind of inertness of materials
 - Using other time/temperature conditions as for specific testing – useful?
 - There is a gap between overall migration values and specific substances – to what extend?
 - Olive Oil testing (for fatty food – to what fat extend?)
 - “Nobody” knows really why it is used – it is a nightmare and gives a lot “interesting” values



How we test today?

- Specific Migration (specific testing): SM

- Plastic:

- Focus only on listed starting substances
 - Redundancy or no testing on several stages of the value chain
 - Discussion on NIAS (non intentionally added substances) starts combined with interest on really migrating substances

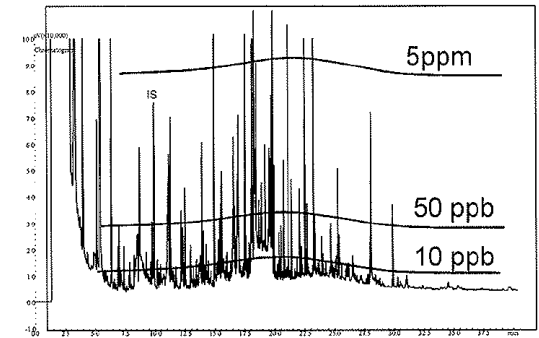
- Non-Plastic

- No clear positive listing for starting substances
 - Interest on really migrating substances increases (?)

- Do we use the wrong approaches?

- If no, everything might be ok?

- If yes, what are the alternatives?



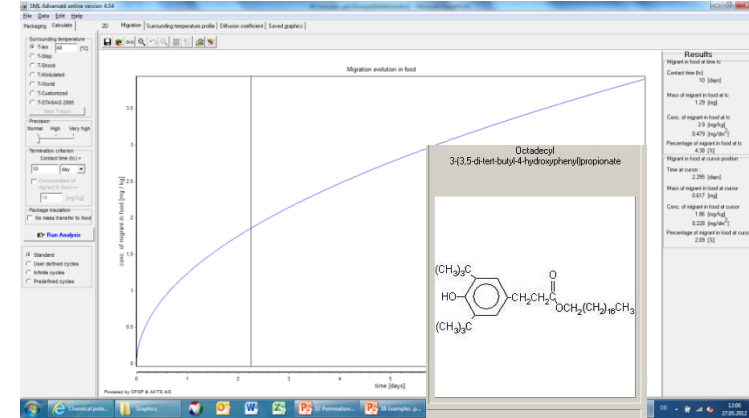
Alternative: Modelling

Disadvantages:

- Complex mathematics
- Physico-chemical Data necessary
- Quantitative data of known ingredients in materials necessary (limited by intellectual property)

Advantages

- Very good estimation for known substances
- Cheap(er)
- Avoids “useless” testing
- Best alternative for substances with SML > 1 mg/kg



Alternative: “New” Testing Approaches

If testing is necessary, we have to differentiate between

a. Target-Analysis

Name and Structure of substance of interest **are known**, references are also available

b. Non-Target-Analysis

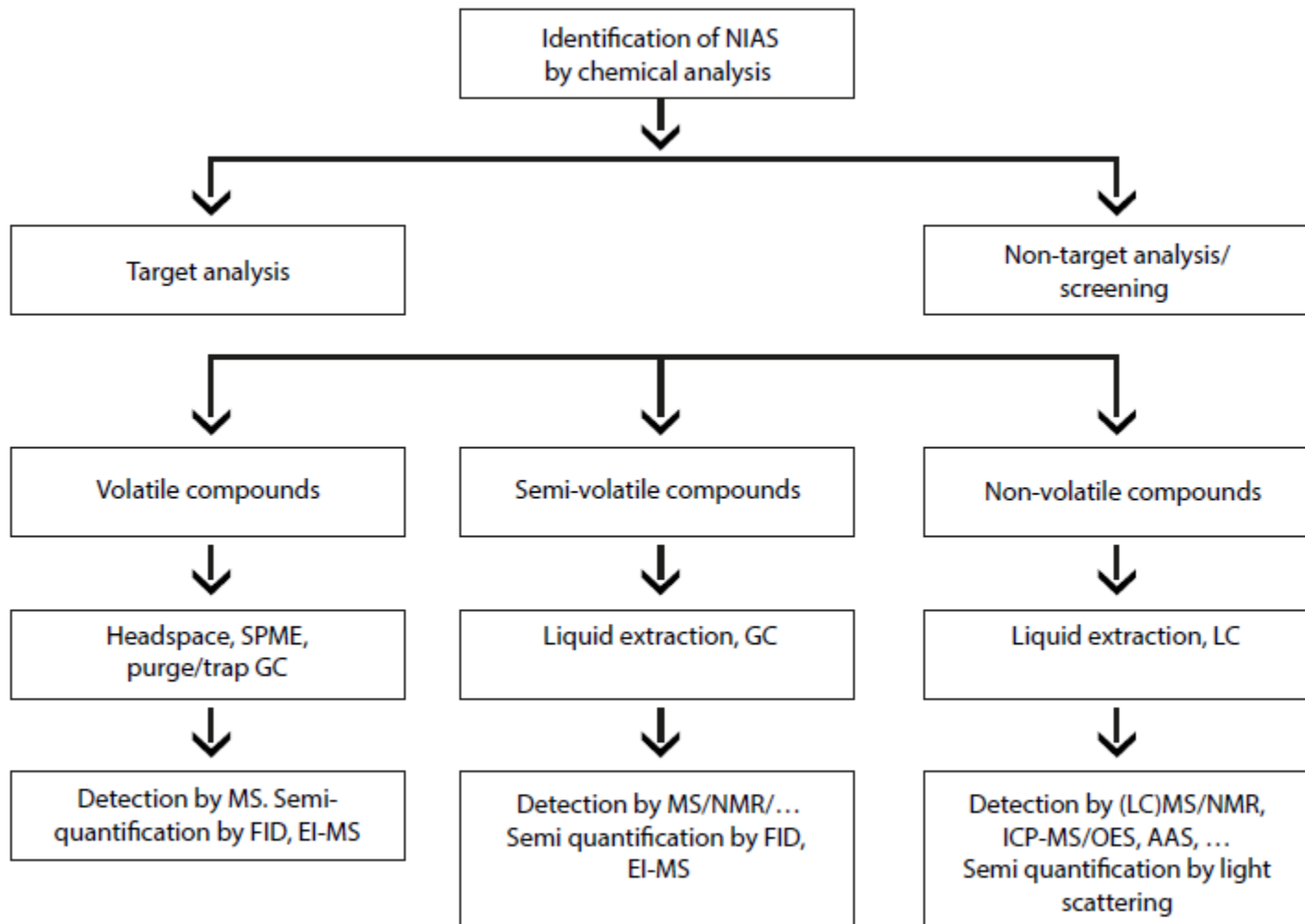
Name and Structure of substance of interest are **not known** from the beginning – based on results following alternatives are given

- i. Known Substances, which can be confirmed by help of references, or
- ii. Unknown Substances, which can be identified or even not and can possibly semi-quantified by using marker substances, or
- iii. Unknown substances staying unknown – most difficult!

Target-Analysis

- «rule of thumb» = only testing, if $SML < 1 \text{ mg/kg}$ (including non-listed substances)
- Production-based variations at SML-level $< 1 \text{ mg/kg}$ may lead to an exceeding of limits
 - Substances with $SML > 1 \text{ mg/kg}$ do not exceed the SML in $>95\%$ of all cases – this can be solved by the manufacturer
 - Therefore documentation besides Declaration of Compliances (DoC) necessary, showing how and which target substances were tested
 - Substances with $SML < 1 \text{ mg/kg}$ have to be tested as part of a self control program by the end of the value chain at least (food manufacturer)
 - Frequency can be determined by own criteria
 - **Prerequisite: the information on SMLs $< 1 \text{ mg/kg}$ has to be forwarded**
- Target-Analysis should be combined as much as possible with Non-Target-Analysis Techniques like Screening approaches

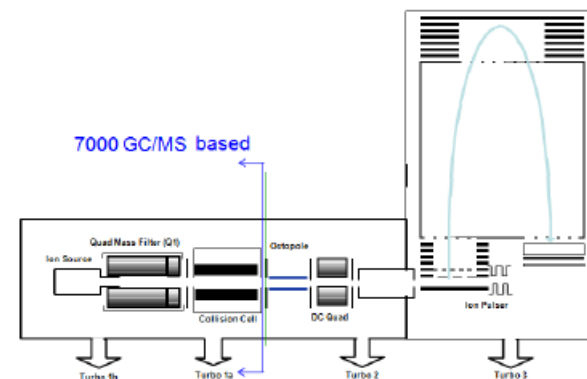
Principle Testmatrix*



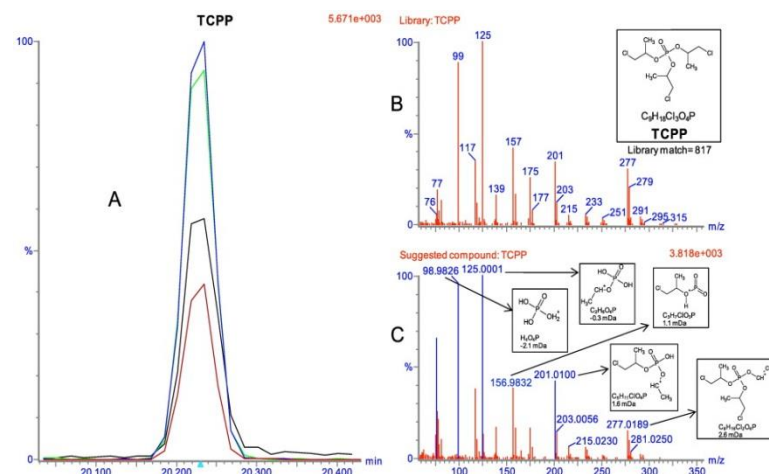
*ILSI: Guidance on Best Practices on the Risk Assessment of Non Intentionally Added Substances (NIAS) in Food Contact Materials and Articles, July 2015

Screening- Approaches

- Huge amount of different substances can be covered
- Individual methods causing to high costs
- Screening methods have
 - Advantages:
 - lower costs
 - More information with one method
 - Able to cover not only FCM substances – SVHC also
 - Disadvantages:
 - Not yet standardized
 - But harmonisation begins especially for GC/MS



Agilent 7200 Accurate-Mass Quadrupole Time-of-Flight GC/MS System Concepts Guide The Big Picture



Chemical Analysis – a possible DIN norm!?

Deutscher
Verband



Unabhängiger Prüflaboratorien

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European Court of Justice rules on SVHCs in articles

Threshold applies to components, not entire product

10 September 2015 / Europe, Priority substances

In a landmark ruling, the European Court of Justice (ECJ) has said the 0.1% threshold for notifying SVHCs in articles applies to “each of the articles incorporated as a component of a complex product” rather than to the entire article.

The court’s decision contradicts the view adopted by the European Commission and Echa’s guidance on requirements for substances in articles, and backs that taken by five EU member states and Norway.

<https://chemicalwatch.com/37147/european-court-of-justice-rules-on-svhcs-in-articles>

Leitfaden:

Screening von Erzeugnissen gemäß der REACH-Verordnung auf SVHC

(Substances of Very High Concern)

Guideline:

Screening products for SVHC according to the REACH regulation

IMPRESSUM

VUP - Deutscher Verband Unabhängiger Prüflaboratorien (Herausgeber)
VUP-Projektgruppe „REACH-SVHC-Analytik“ (Verfasser)
Version: 01.08.2013, Dr. Thomas Gude

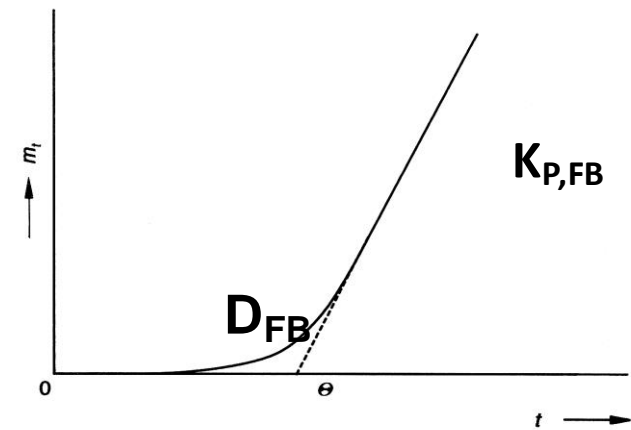
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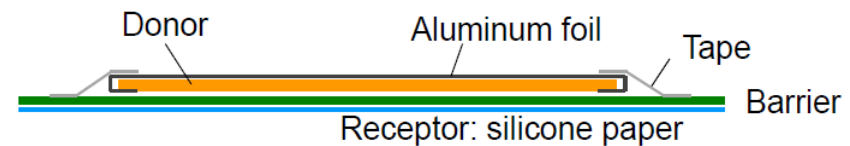
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Alternatives: Barriers?!

- Barriers should help to avoid migration
- However, what is a barrier – many ideas, but less solutions
- Barriers should change the food characteristics
 - not any food likes a tight atmosphere
- Barriers themselves should have migration behaviour
- No standardized method available how to test barrier performance
- Projects are ongoing:
 - Inner bag, mainly plastic
 - Coatings of Cardboard
- **Critical:** 2D- versus 3D-Testing of barriers



2D-Testing



3D-Testing



SVI –Projects: Goal

- A «Guideline» should be developed for 2-D Testing
- Criteria: < 1% Migration of Surrogate substances
- Based on «relative» results –materials will be compared, however each material may have a barrier functionality related to shelf life
- User of the guideline can select the material fit for the intended packaging solution based on comparable data
- Barrier-Manufacturer can test their products according to this guideline comparable for the user
- Important: it is not the goal to differentiate between a “good” and a “bad” barrier – it is the goal to help for the right barrier decision
- **3-D Testing (real life testing) is in any case necessary**



Future Trends



- Migration quite complex and time consuming
 - at least 4-5 weeks
- Increasing demands for non FCM substances, i.e. SVHC, absent-by-design list, RSLs (restricted substance lists) of retailer and/or major food manufacturer
 - How to combine?
- Worst Case Extraction of final packaging solutions combined with screening approaches – much faster
 - However, results have to be carefully interpreted:
 - no positive finding: no problem ?
 - Positive findings on restricted substances: material not to be used resp. which material is the critical part
 - Positive findings of FCM: migration studies

Interaction Food/Material is a complex issue and needs knowledge of nobel price laureat

- Food does not only have contact to materials in the final packaging
- Food raw materials, food intermediate products etc. are also having contact to materials
- transport container, production environment and equipment are also sources for interactions
- It is not only the direct contact – it's complex!

«The» Solution of a complex problem

