Food Contact Materials and Articles
Migration of NIAS

A challenge for analytical chemists and the legislator

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I.
NIAS and the „old“ legal concept

NIAS

non-intentionally added substances

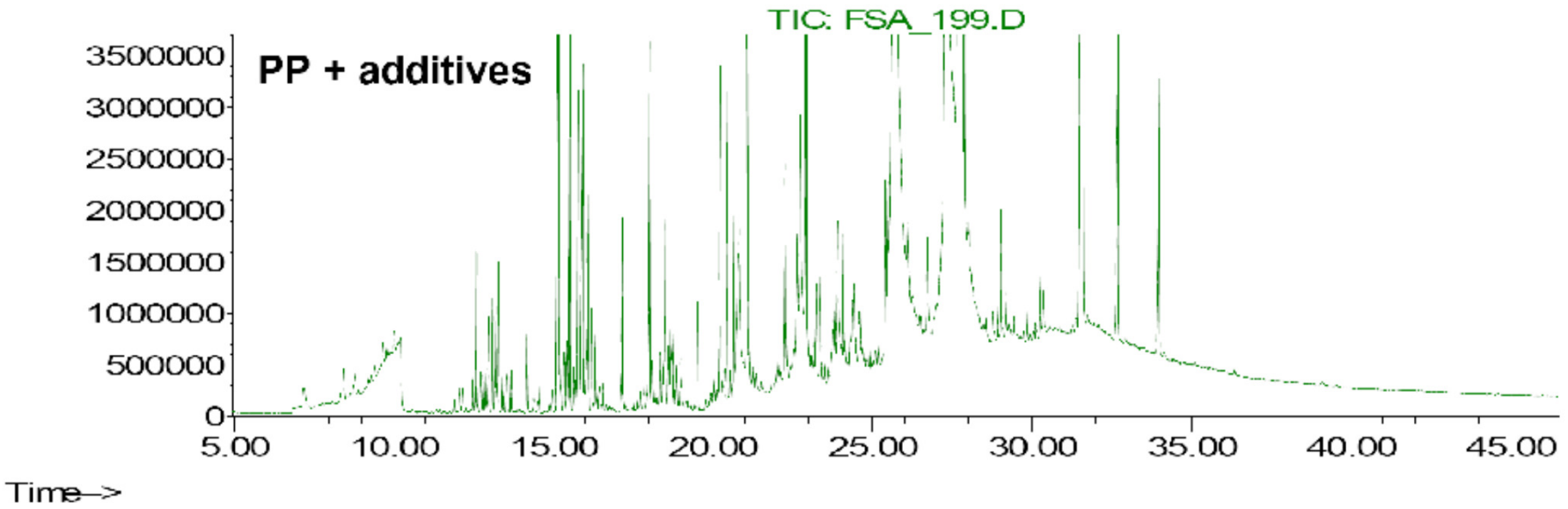
Production of polymeric food contact materials

STARTING SUBSTANCES → **FOOD CONTACT MATERIAL**

- monomers
- pre-polymers
- additives
- production aids
- NIAS (non-intentionally added substances)

- polymer
- oligomers
- residual monomers
- additives and reaction products
- production aids
- NIAS (non-intentionally added substances)

The „Forest of Peaks“



Source: Report FD 07/01. An investigation into the reaction and breakdown products from starting substances used to produce food contact plastics. Food Standards Agency, London. August 2007.

Regulation (EC) No. 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.

Principles of Current EU Legislation on Food Contact Materials

- there shall be a permission for each starting substance used for the manufacture of food contact materials
- the use of the substances will be permitted on the basis of toxicological evaluations.
- toxicological evaluations for starting substances are based on a simple exposure model.
- there are no specific restrictions for the migration of substances which are not starting substances.

The „old“ exposure model

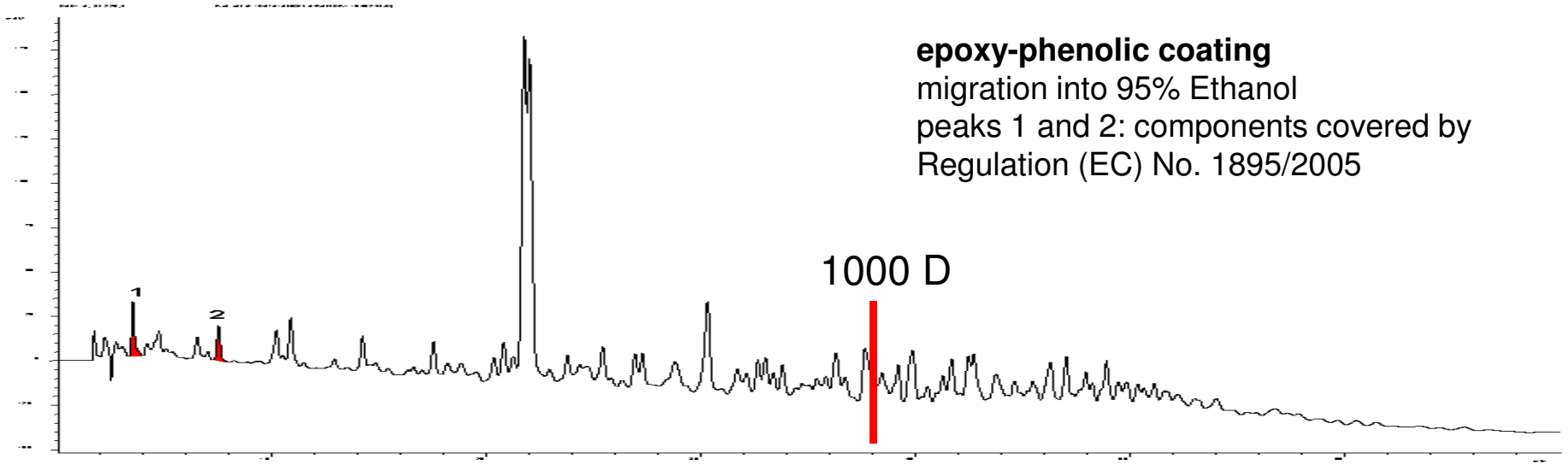
- any consumer has a body weight of 60 kilogram
- every day through his whole life the consumer will eat 1 kilogram of the same foodstuff
- the foodstuff will always contain the substance to be assessed in the same concentration

Demands for new concepts for safety evaluations of FCM

- Safeguard the health of consumers
- Application of more realistic exposure models
- Workable toxicolgical assessments
- Analytical coverage of the relevant substances
- Common acceptance by the involved parties

II.
Analytical approaches for NIAS

Example
Migration from Food Contact Coatings



epoxy-phenolic coating
migration into 95% Ethanol
peaks 1 and 2: components covered by Regulation (EC) No. 1895/2005

- Only 5 to 10 % migrating components are known and evaluated monomers and additives
- The majority of peaks represent migrating substances <1000 D

Source: Chromatogram:T.J. Simat, Presentation, Brussels 2010

Biotests for NIAS Screening

Whole migrate is assessed with a battery of in vitro tox tests

Advantages:

- Coverage of the whole migrate with few tests
- Quick and cost efficient

Disadvantages:

- Does not cover sufficient toxicological endpoints
- For many substances not sufficiently sensitive
- No specific information on particular substances

- Biotests are currently not regarded as an appropriate tool to solve the NIAS problem

Chemical analysis and specific tox assessment

Migrate is screened with an analytical procedure, substances are identified and toxicologically screened

Advantages:

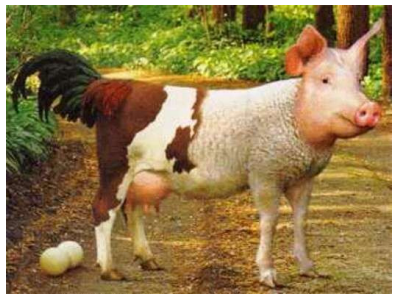
- Very sensitive
- Specific for each substance

Disadvantages:

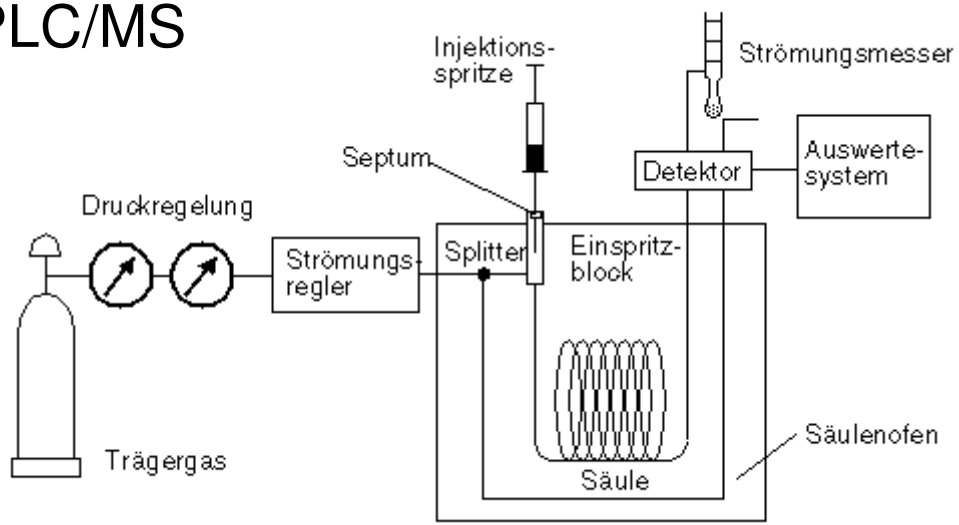
- Very complex analytical task
- Not workable without exclusion of components
- Toxicological evaluation too expensive and time consuming

Migration Tests
Screening of migrates

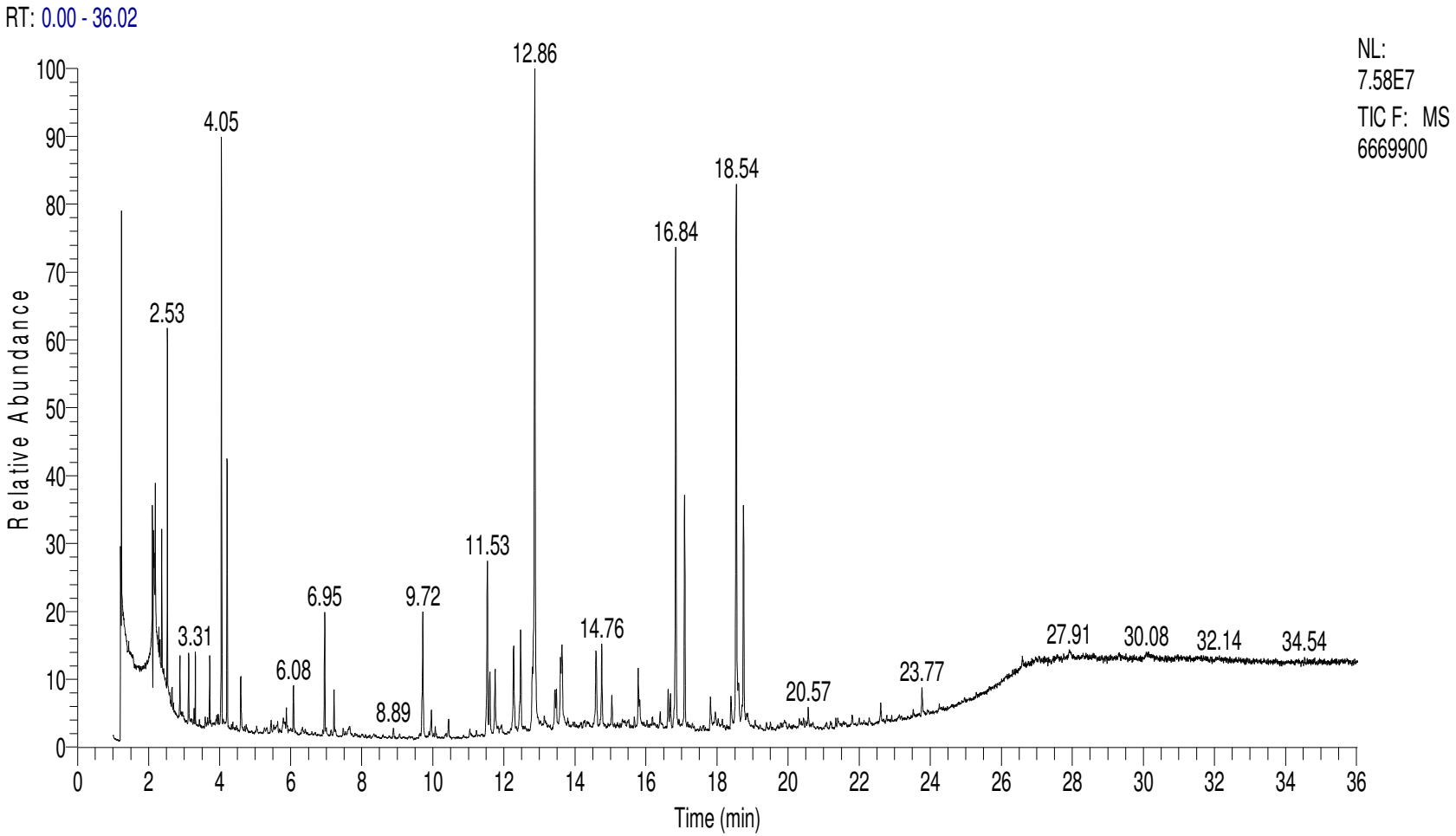
- Detection of a wide range of substances with high sensitivity
  LOD = 10 ppb
  (+ rapid + low costs)



- Analytical techniques: GC/MS, purge&trap-GC/MS, headspace-SPME-GC/MS, HPLC/LSD, HPLC/FLD, HPLC/MS



Screening of the Migrate



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Evaluation sceme for NIAS

- Substances with a molecular weight > 1000 Dalton do not raise toxicological concern and therefore can be ignored
- Non-CMR substances which do not the tolerable exposure level of 10 µg/person/day are regarded as safe
- Based on a realistic exposure model a level of interest (LOI) can be defined
- Number of remaining substances which require evaluation is usually small
- Application of quantitative structure activity relationship (QSAR) studies and Cramer Classification

Risk assessment

RISK

=

HAZZARD **X** **EXPOSURE**

Level of interest (LOI)

- Condition: the surface of a given material to which one consumer is exposed through his daily diet is known (probabilistic modelling based on consumption data).

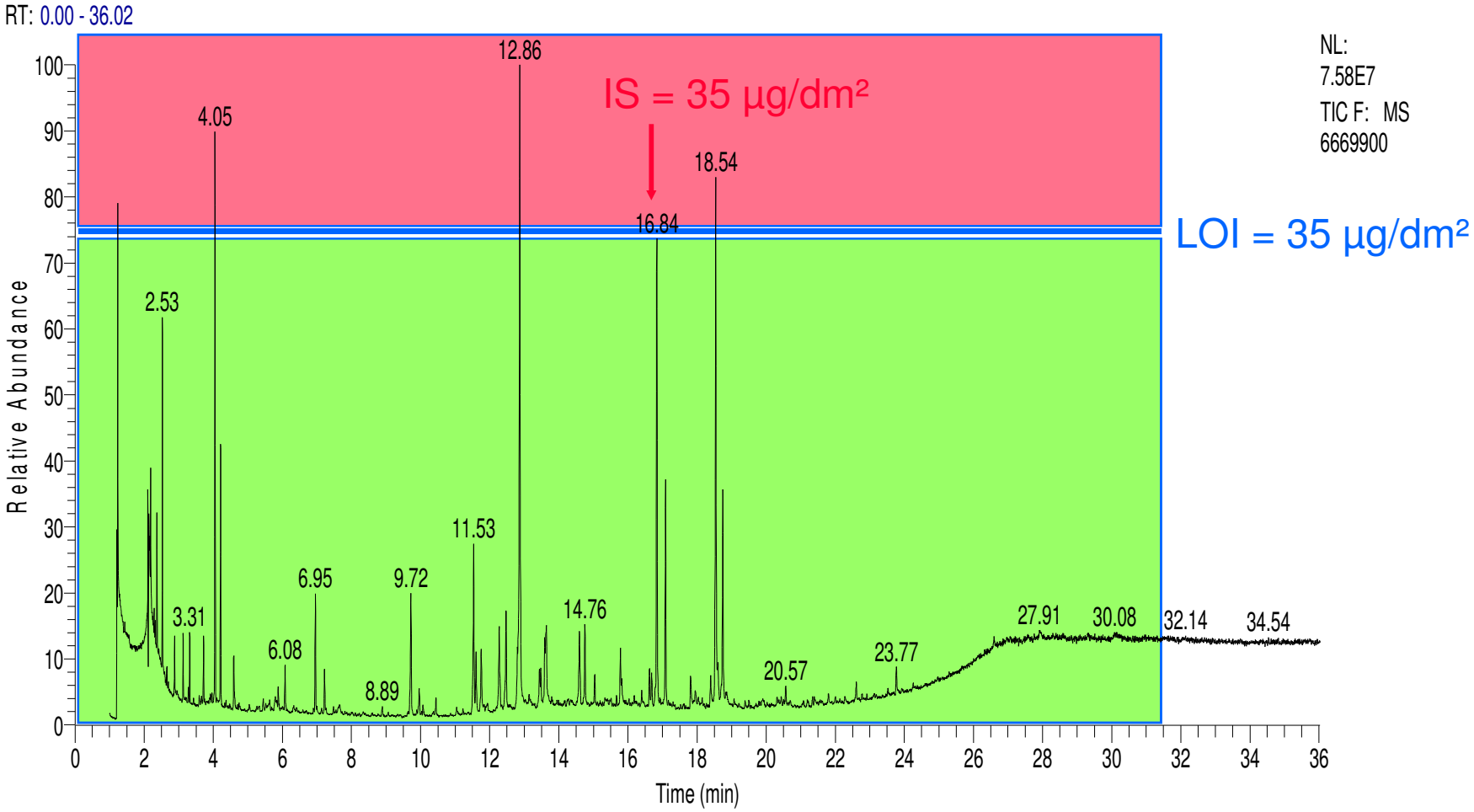
- The exposure to any substance migrating from this surface is:

Exposure = Migration X Surface

- Applying a tolerable exposure level (TEL) of 10 µg/person/day the level of interest (LOI) can be calculated for a specific material:

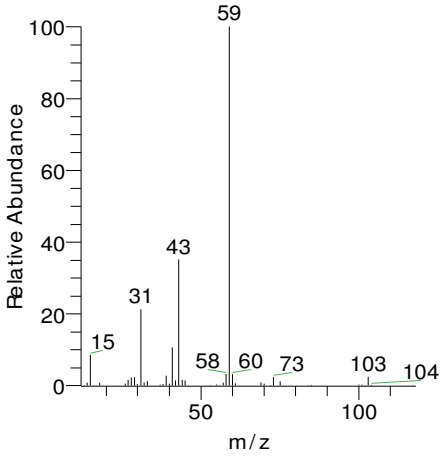
LOI (µg/dm²) = TEL / Surface

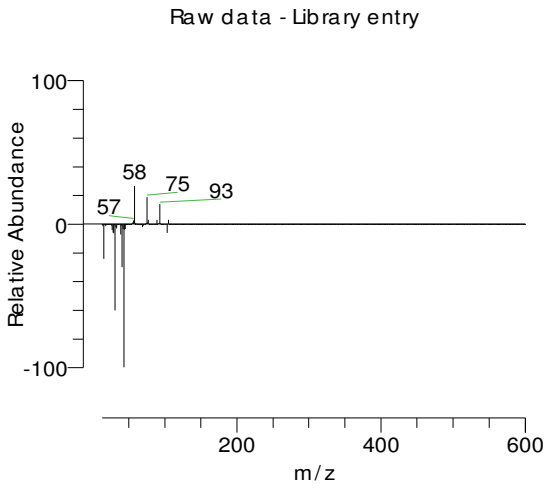
Screening of the Migrate

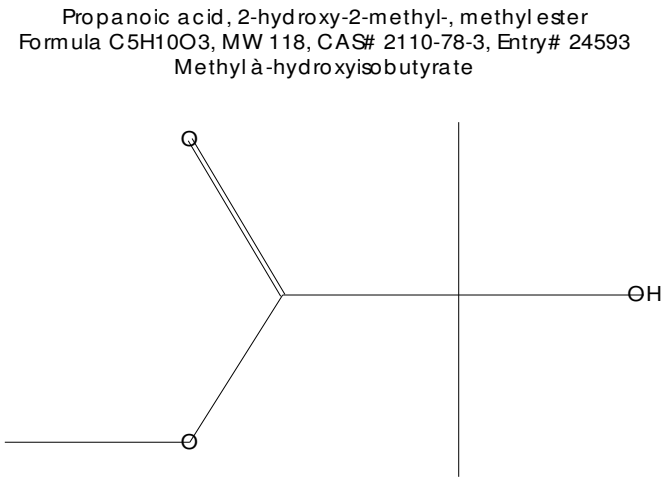


Screening of the Migrate

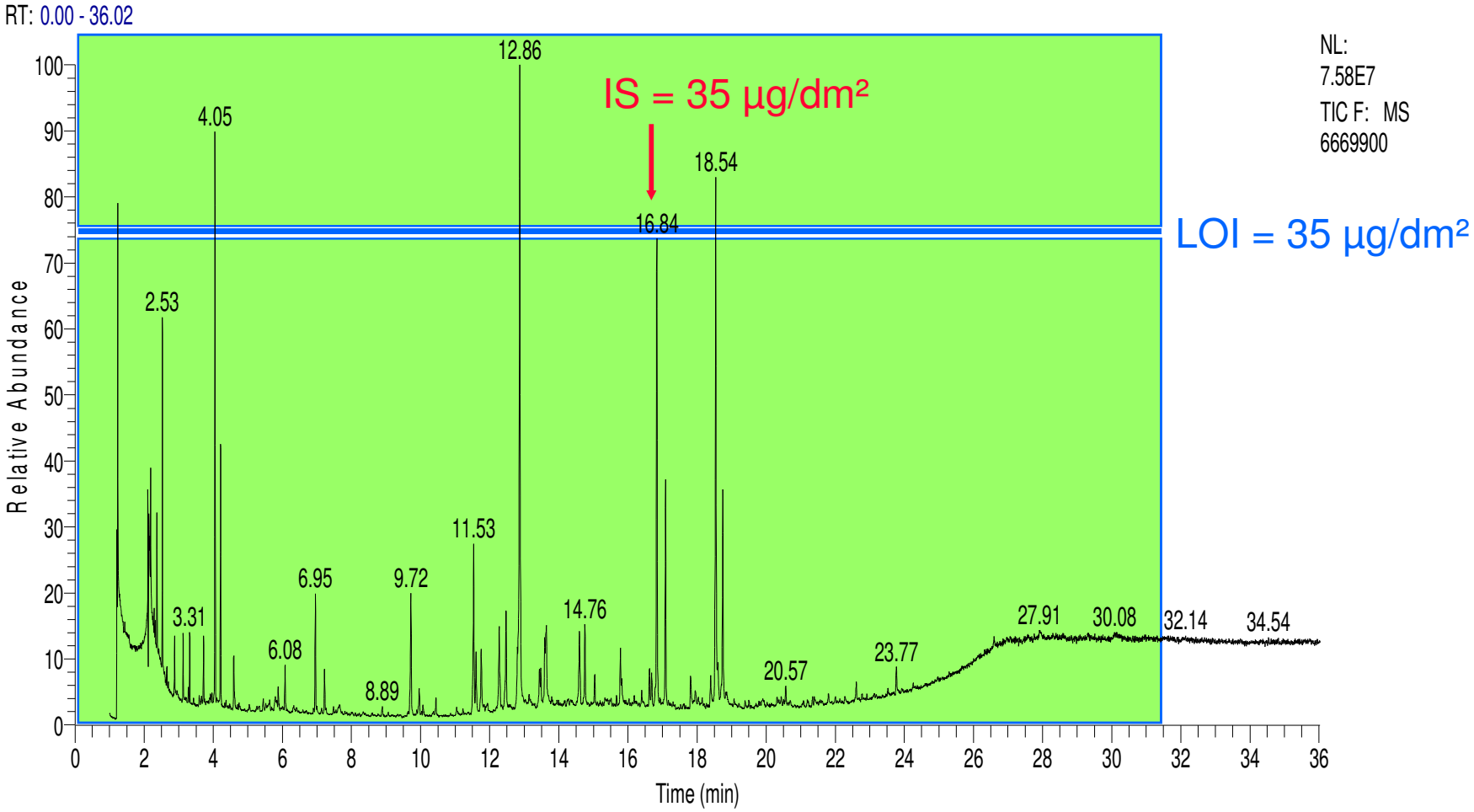
Identification of peaks







Screening of the Migrate



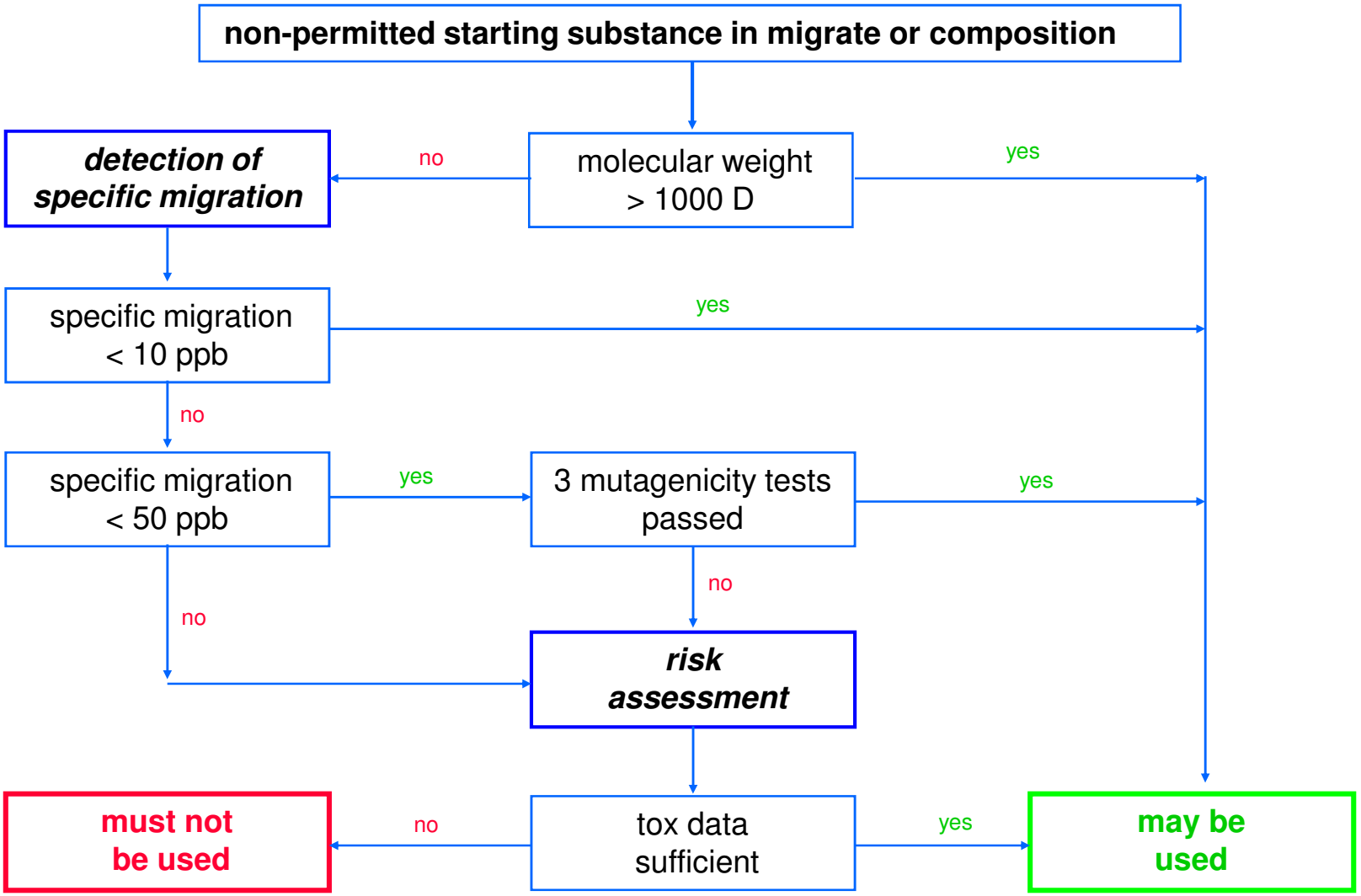
III.
Legislative approaches

Good Manufacturing Practice GMP

Regulation (EC) No. 2023/2006
on good manufacturing practices for material and articles intended to come into contact with foodstuffs

- relevant for the manufacturing, processing and trade of food contact materials; **not** relevant for the manufacture of starting substances
- requires the processing in accordance with the principles of good manufacturing practice
- requires the application of an effective and documented quality assurance system
- requires the application of an effective quality control system
- valid since August 1, 2008

How to treat known non-listed starting substances*



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* according to EuPIA proposal for starting substances for printing inks

CoE Resolution AP (2004)1

Coatings intended to come into contact with foodstuffs

3.4. They should not transfer migrating components not referred to in Article 3.2. of MW < 1000 D in quantities, which could endanger human health. These non listed substances of MW < 1000 D should be subjected to appropriate risk assessment taking into account dietary exposure as well as toxicological and structure activity considerations.

Regulation (EU) No. 10/2011

on plastic materials and articles intended to come into contact with food

Whereas:

…

(20) During the manufacture and use of plastic materials and articles reaction and degradation products can be formed. These reaction and degradation products are non-intentionally present in the plastic material (NIAS). As far as they are relevant for the risk assessment the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance. However it is not possible to list and consider all reaction and degradation products in the authorisation. Therefore they should not be listed as single entries in the Union list. Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.

CEPE Code of Practice

on plastic materials and articles intended to come into contact with food

ANNEX VI

RISK ASSESSMENT FOR MIGRANTS FROM COATED ARTICLES IN CONTACT WITH FOODSTUFFS.

…

- Decomposition or reaction products, also known as non intentionally added substances (NIAS) are formed either during the manufacture of the resin or during the curing process. Their full characterisation including hazard and risk assessment of all individual identified peaks is not feasible.

In order to demonstrate compliance with article 3 of the Framework Regulation (EC) No 1935/2004, the following must be considered:

- By defining the end use application(s) of the coating, it may be possible to estimate a limit of migration equating to an exposure of < 1.5 µg/person/day. In this case, the reaction product does not deserve any further toxicological evaluation. This process may utilise probabilistic modelling for exposure assessments.

- If the level of 1.5 µg/person/day is exceeded, then it is necessary to apply other considerations using universally recognised techniques, such as SAR (Structural Activity Alerts) and Cramer classes for toxicological thresholds where if the structure of a substance is broadly known, higher levels of migration may not require toxicological testing of that substance.

For risk assessments made for foodstuffs stored in large containers, the size of the containers (volume ratio to contact area) should be taken into account.

Summary

- Requirements of framework Regulation (EC) No. 1935/2004 cover all food contact materials and articles and all migrating substances
- Specific requirements for FCM with respect to NIAS are still missing
- Demonstration of safety and compliance with respect to NIAS and non-listed substances should take into account exposure
- The concept of a level of interest (LOI) could be a way forward in order to demonstrate safety for the large number of non-evaluated substances possibly migrating from food contact coatings
- Any concept for demonstration of compliance of food cantact materials will need broad acceptance and convention

Thank you very much for your attention!

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