

EU Food Contact Materials and Substances Risk Assessment non-plastics focus on coatings

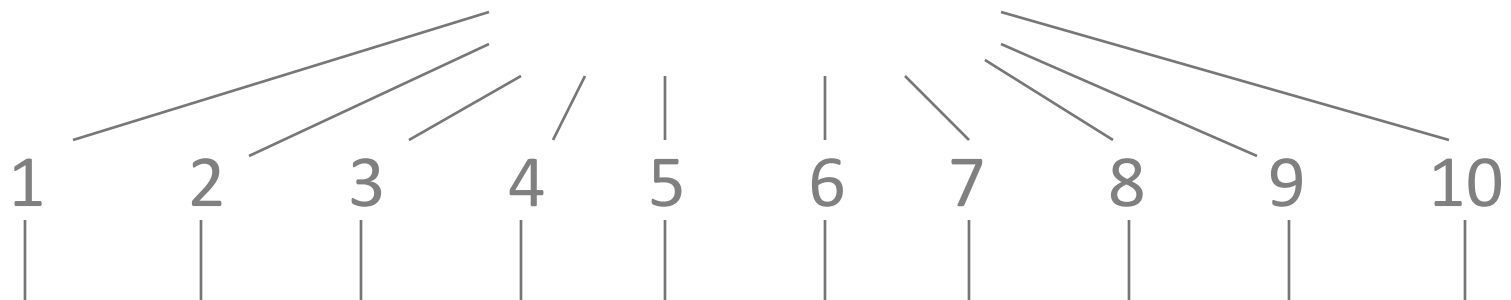
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AICM

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EU Legislation

Regulation (EC) No. 1935/2004 (Framework)
Regulation (EC) No. 2023/2006 (GMP)



Specific Directives and Regulations on Food Contact Materials
e.g. Regulation (EU) No. 10/2011 on Plastic Materials and Articles
intended to come into Contact with Foodstuffs

Current status of legal measures for specific food contact materials according to Regulation (EC) No. 1935/2004

Material	Status	
Active and intelligent materials	REG (EC) No. 450/2009	§§
Adhesives	no activity	0
Ceramics	Directive 84/500/EEC	§§
Cork	CoE	→
Elastomers and rubber	CoE	→
Glass	CoE	→
Ion exchange resins	CoE Res. AP (2004)3	→
Metals and alloys	CoE CM/Res(2013)9	→
Paper and board	CoE Res. AP(2002)1	→
Plastics	REG (EU) No.10/2011	§§
Printing inks	no activity	0
Cellulose	Directive 93/10/EEC	§§
Silicones	CoE	→
Textils	no activity	0
Coatings and lacquers	CoE Res. AP(2004)1	→
Solid paraffine and waxes	no activity	0

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.



Coatings for metal packaging

- As for many other FCM there is no specific legal measure for food contact coatings available on EU level.
- There is no harmonised positive list for starting substances used in food contact coatings available on EU level.
- There is no harmonised procedure how to demonstrate compliance of food contact coatings with EU Framework Regulation (EC) No 1935/2004.

Compliance of coatings for metal packaging

current common procedure

- CEPE Code of Practice for Coated Articles where the Food Contact Layer is a Coating, Ed. 4, 2 Feb 2009
- Council of Europe, Resolution AP(2004)1
- Legal requirements of EU member states, e.g.
 - *Netherlands*: Warenwet, Hoofdstuk X „Deklagen“
 - *Spain*: Royal Decree 847/2011
 - *Italy*: Ministerial Decree of March 21, 1973 (amended)
 - *Belgium*: Royal Decree of September 25, 2016
- US FDA Regulations, e.g. 21 CFR 175.300

Compliance of coatings for metal packaging

current common procedure

- Evaluation of coating composition, starting substances (monomers, resins, additives, catalysts, solvents, pigments ...)
 - ✓ Listed in Regulation (EU) No 10/2011 (plastics)
 - ✓ Risk assessed according to EFSA guidelines
 - ✓ (Listed in national regulations for Food contact coatings)
 - ✓ Risk assessed non-listed substances (IAS and NIAS)
 - Not risk assessed non-listed substances (IAS and NIAS)

Compliance of coatings for metal packaging

current common procedure

- Evaluation of coating composition, starting substances (monomers, resins, additives, catalysts, solvents, pigments ...)
- Overall and specific migration tests reflecting intended conditions of application of the coating.
Analytical procedures similar to methods for plastics (with exemptions, e.g. simulant B 3% acetic acid)
- Non-targeted screening for NIAS (volatile, semi-volatile, non-volatile)
- Organoleptic tests (DIN 10 955)
- Evaluation of compliance of the coating with framework requirements (Regulation (EC) No 1935/2004)

Compliance of coatings for metal packaging

current common procedure

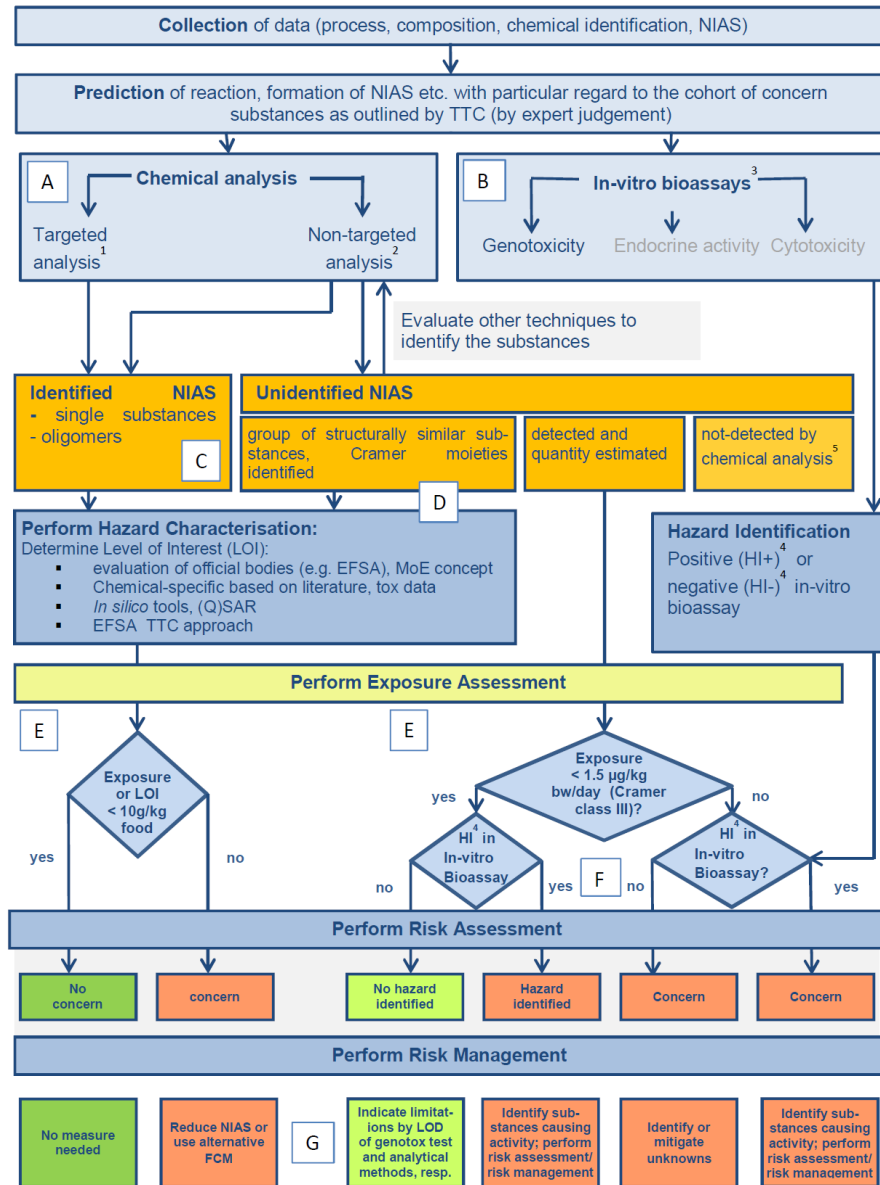
- Evaluation of coating composition, starting substances (monomers, resins, additives, catalysts, solvents, pigments ...) including risk-assessments where needed
- Overall and specific migration tests reflecting intended conditions of application of the coating.
Analytical procedures similar to methods for plastics (with exemptions, e.g. simulant B 3 % acetic acid)
- **Non-targeted screening for NIAS (volatile, semi-volatile, non-volatile)**
- Organoleptic tests (DIN 10 955)
- Evaluation of compliance of the coating with framework requirements (Regulation (EC) No 1935/2004)

Risk assessment for IAS and NIAS

principles and sources

- Following EFSA principles as described in Opinion published on January 28, 2016 (EFSA Journal 2016;14(1):4357)
- Following TJIG TSC33 *NIAS Guidelines for Coated Rigid Metal Packaging Intended for Direct Food Contact* (Ver. 1.7.2 May 2018)
- Taking into account ILSI *Guidance on Best Practices on the Risk Assessment of NIAS in Food Contact Material and Articles* (ILSI Europe May 2015)
- **Risk = Hazard X Exposure**
An appropriate exposure assessment as well as a hazard assessment are required for the risk assessment.

Risk assessment for IAS and NIAS



Risk assessment for IAS and NIAS

hazard assessment

- Use of available adequate toxicological data for the substance (oral exposure, relevant concentrations)
- In case no toxicological data are available:
 - ❖ For unknown substances (NIAS screening):
demonstrate that presence of genotoxic substances is unlikely (bioassay, chemical analysis, argumentation)
 - ❖ For identified substances:
 - Application of the EFSA TTC (threshold of toxicological concern) concept including determination of Cramer Class (I, II or III)
Remark: TTC is **not** applicable for: high potency carcinogens, inorganic substances, metals and organometallics, proteins, steroids, known or predicted bio accumulative substances, nanomaterials, radioactive substances, organophosphates and carbamates)
 - *in-silico*-Tools, (Q)SAR, MoE concept
- Determine Level of Interest (LOI)

Risk assessment for IAS and NIAS

exposure assessment

- Determine concentration of the migrant in food/food simulant.
- Take into account for each type of food the amount consumed by the relevant consumer group.
EFSA Comprehensive Food Consumption Database may be used.
- The exposure assessment can also be performed by using the FACET® exposure tool.

Risk assessment for IAS and NIAS

determination of risk

- Use TTC approach when presence of genotoxicity could be demonstrated to be unlikely, no other source of toxicological data is available and the substance does not belong to the TTC exclusion groups.
- Otherwise an LOI of 10 $\mu\text{g}/\text{kg}$ food may be used as a pragmatic compromise until analytical techniques are developed that allow to measure the substance efficiently at 0.0025 $\mu\text{g}/\text{kg}$ bw per day.
- Define appropriate risk management measures.

Risk assessment for IAS and NIAS

why common sense of all involved parties is required

- Transparency and a gentle flow of information within the supply chain is needed to efficiently apply the risk assessment and risk management concept
- Risk assessments based on publicly recognised rules need to be carried out also by industry or accredited private bodies in order to manage the enormous workload and comply with time-to-market logic.
- For the time being compromises have to be accepted because available analytical tools often do not allow to identify substances or to reach sufficiently low LODs and bio-assays do not have sufficient sensitivity.

Change of Paradigms

Past

Safety and compliance of FCM/FCAs had to be demonstrated with technically and economically reasonable measures (GMP)

Presence (and Future?)

Safety and compliance of FCM/FCAs has to be demonstrated by a full risk assessment for **all** migrating substances which can be detected by available analytical procedures. („forest of peaks“ and NIAS)

Balanced Risk Management ?

Food

- ca. 1000 unknown components (e.g. roasted coffee)
- exposure: ca. 1 g/person/day
- Only food additives as well as few flavour components and contaminants/pesticides are risk assessed and risk managed

Food Contact Materials

- ca. 50 unknown components (e.g. resinous coating)
- exposure: ca. 0,0001 g/person/day
- Any migratable known or unknown component needs to be risk assessed and risk managed

**Thank you very much for
your attention!**

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