FCM risk assessment in France and Germany (rubber)

Rubber national provisions

Previous national provisions

Decree (1994)

Recommendations (1962)

Update

New national provisions

Decree (2020)

Recommendations (2021)

Specific restrictions

Metals
N-nitrosamine
Aromatic amine
Formaldehyde
PCB
VOC

List of evaluated substances

Substances from Fr. decree and 10/2011

Evaluation by SCF, EFSA, BfR after 1991

Provisional list

2025

- ✓ Substances from french decree and without tox data
- ✓ Substances with generic term
- ✓ Substances with too old RA

2026

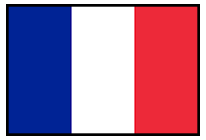
- ✓ Substances from BfR Recommendation without tox data and/or insufficient risk assessment

Risk assessment methodologies

EFSA Note for Guidance

+

National specifications



Substances technological functions

Pros and cons for environment

Theoretical exposure level (TEL)

TEL (µg/person/day) = [0,8 x (MA+MB+MC)/3] + [0,2 x MD]

MA = aqueous
MB = alcoholic
MC = acid
MD = fat

Substances technological functions

Specific migration guidance values

Migration testing conditions

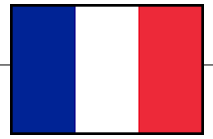
Type of contact	Exemples	Testing conditions
Hot contact + Extended contact	Sterilized jar seals	1h / 121°C or 4h / 100°C (aqueous simulant) + 10d / 40°C (*if any extended contact*)
Extended contact	Jar seals	10d / 40°C
Average length contact	Tubing	24h / 40°C
Short contact	Gloves	2h / 40°C
Buccal contact	Teats and soothers	24h/40°C

Type of contact	Exemples	Testing conditions
> 24 hours	Storage containers, sealing rings for cans	10d / 40°C
< 24 hours	Sealing rings for pressure cookers	24h / 40°C
< 10 minutes	Tubing for milking machines, diaphragms, pistons, fittings	10 min / 40°C
Very short contact or with a very small part of its surface, and does not belong in categories 1 to 3	Conveyor belts	Not required

Simulant :

10/2011
+
water
saliva simulant
nitrosamine testing for bottle teats
milk 3.5% fat
specific migration for bottle teats

Toxicological requirements



Exposure level	Toxicological requirements
< 0,5 µg/ person/day	QSAR (conditional use)
0,5 to 50 µg/ person/day	2 genotoxic tests
50 to 5000 µg/ person/day	As above + 90 days oral toxicity+ data to demonstrate the absence of potential for accumulation in man
> 5000 to 60000 µg/ person/day	As above + Study on ADME + Reproduction and development toxicity+ Long term toxicity / carcinogenicity

Migration	Toxicological requirements
up to 50 µg/kg food	2 genotoxic tests
50 to 5000 µg/kg food	As above + 90 days oral toxicity + data to demonstrate the absence of potential for accumulation in man
> 5000 to 60000 µg/kg food	As above + Study on ADME + Reproduction and development toxicity+ Long term toxicity / carcinogenicity

Risk assessment challenges

NIAS

- NIAS risk assessment according to EFSA Note for Guidance
- No specific method for NIAS (case by case approach)
  - *Identification (analytical difficulties)*
  - *Toxicological testing (quantity difficulties)*
- Not considered in technical dossier in most cases

Migration testing

- Must represent worst case transfer
- Simulant from plastic regulation not adapted to rubbers
  - *Oil simulant : highly absorbed (200% of rubber weight)*
  - *Alternative oil simulant (EtOH95% / isooctane): underestimate migration and rubber degradation*
  - *Alternative milk simulant (EtOH 50%): overestimate migration*
    ⇨ *Not mandatory to use EtOH 50% for milk contact*
    ⇨ *EtOH 15% seems more adapted for milk contact*
- There is a need to develop specific simulants for rubbers