BfR
German Federal Institute for Risk Assessment

Proposal for harmonisation of the safety assessment of rubbers

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Elastomers – special materials for food contact

Rubber and TPV

- Non-vulcanised elastomers are covered by Regulation (EU) No 10/2011
- Manufacturing involves vulcanisation and elevated temperatures
  → NIAS are to be considered
- Additives are mostly not covalently bound → migration is likely
- Depending on their composition elastomers can exhibit divers chemical properties
  → choice of simulant / must be suitable for intended use
- Elastomorers are often „hidden“ food contact materials (food production, seals) BUT elastomeres are also for use in child feeding/care → migration conditions for testing of products should reflect reality

Rubber – national provisions

Previous national provisions

Decree (1994)

Recommendations (1962)

Update

New national provisions

Decree (2020)

Recommendations (2021)

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

BfR Recommendations XXI – structure of revised version (July 2021)

XXI. Commodities based on elastomers, manufactured from natural and synthetic rubber

- Explanations
- List of evaluated additives and manufacturing aids

XXI/1: Commodities manufactured from natural and synthetic rubber for food contact

- Consumer goods made of elastomers in contact with food (category 1-4)

XXI/2: Special commodities manufactured from Natural and Synthetic Rubber

- Special consumer goods made of elastomers, which are listed under § 2 para. 6 No 3 or No 5 of the German Food and Feed Code (formerly special category).

XXI/3: Commodities for food contact manufactured from cross-linked thermoplastic elastomers (TPV)

- (in preparation)

BfR Recommendation XXI – Key points of revision

EVALUATED SUBSTANCES

- Evaluation by SCF, EFSA or BfR (after 1991)
- Specific migration guide values as far as possible
- All purity requirements of Regulation (EU) No. 10/2011 are adopted

SUBSTANCES THAT HAVE NOT YET BEEN CONCLUSIVELY EVALUATED

- Substances used for a long time, listed in Rec. XXI
- Limitation of max. use
- Transition period of 5 years

  incl. notification period of 2 years

Rec. XXI → **Rec. XXI/1 and XXI/2**

Application to BfR

Procedure of pre-registrations Germany

Applicant sends email stating:

- chemical name of the substance
- not applicable for group listings
- CAS no and EC no
- purpose of use (e. g. vulcanisation accelerator or filler)
- name and email address of contact person

➔ Only applicable to substances already listed in BfR Recommendation XXI/1 or XXI/2

BfR:

- Confirmation of receipt
- Provision of file reference number

✓ Pre-registration is confidential

✓ No list will be published prior to July

✓ More than one pre-registration for one substance ➔ contact can be mediated

Pre-registered substances – example vulcanisation accelerators

List of pre-registered accelerators

- Of 126 individual pre-registrations 73 were vulcanisation accelerators → 17 different ones
- Previous German provisional list contained 36 accelerators (now 17)
- French provisional list contains 20 vulcanisation accelerators → 13 are overlapping in both lists
- 4 unique to German provisional list; 7 unique to French provisional list

Dissolution of generic entries – example Factice

Provivional list I

Factice	unsaturated vegetable or animal oils reacted with sulphur, chlorosulphur or hydrogen sulphide

Provivional list II

List of pre-registered factices

Toxicological requirements

ANSES	
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

BfR	
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

Proposals for harmonisation / work in progress

- Shared risk assessment / mutual acceptance of risk assessment for newly assessed substances
- Compare existing positive lists and identify commonalities and differences
- Discuss harmonisation of testing methods for finished articles
- New BfR-Recommendation for vulcanised thermoplastic elastomers (TPV) → Comparison with French decree

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