National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Coatings in NL

Regulation and risk assessment of Coating as FCM in The Netherlands

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- General provisions
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- Organisation
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Packaging and Food Utensils Regulation in NL

Part A: Requirements on materials

- General requirements (Chapter 0)
- Specific Materials (Chapter 1 to 12)

Part B: Methods for examination

- Examination of Packaging and Utensils (Chapter 1)
- Examination of purity of raw materials and additives (Chapter 2)
- Guidance on risk evaluation based on TTC principle (Chapter 3)

Part A: Chapters on specific materials

1. Plastics (PPA's and AP's)
2. Paper and board
3. Rubber
4. Metals
5. Glass and glass ceramics
6. Ceramics and enamel
7. Textile
8. Regenerated Cellulose
9. Wood and cork
10. **Coatings**
11. Colorants and pigments
12. Epoxypolymers

General provisions (Chapter 0) (1)

- Applicable to all FCM's regulated on the national level,
- except for products already allowed in other MS which apply same level of protection (mutual recognition)
- Great similarity to Plastics Directive, EU regulation prevails

Requirements:

- Composition of each material compliant with Positive Lists
- Compliant with restrictions and specification in the positive lists
- Migration restrictions applicable to all final FCM, inclusive monolayers, multilayers, multimaterials-multilayers (except wax coatings)
- Suitable quality and purity of used substance for intended purpose
- Nano materials of authorised substances shall comply with article 3

General provisions (2)

Substances not listed but allowed:

- Solvents (except regenerated cellulose)
- Salts of listed acids, phenols and alcohols
- Polymers with Mw >1000 Da
- Oligomers, composed of authorised monomers, used as monomer
- Substances not CMR and no migration (<10 ppb), direct contact allowed
- Not-Intentionally-Added-Substances (NIAS; up to the level set by TTC approach)

Part B: Methods for examination

S/V ratio's in for testing compliance with SML and OM:

- Containers <.05 l or >10 l but <25 l: 6 dm²/kg
- Only partial contact: 3 dm²/kg
- Containers >25 l and <10.000 l: 2 dm²/kg
- Containers >10,000 l: 0.3 dm²/kg
- small contact area or very short contact time: 0.5 dm²/kg
- Flowing contact (e.g. tubing): 0.1 dm²/kg
- All other: Actual ratio

Simulants

If incompatible with the material, alternative simulants can be used

Coatings, Chapter 10
(revised version, yet to be notified)

All coatings are regulated in Chapter 10, consisting of:

Part 1 General provisions for coatings

Part 2 PL's for general purpose coatings

Part 3 PL's for coatings for specified applications

- Wax coatings (solvent free)
- Metallic coatings
- Temperature resistant coatings
  - Fluor polymer based
  - Inorganic and non-fluor based coatings

Part 1: General provisions on coatings

Scope: Coatings on any substrate

Excluded:

- Adhesives
- Coatings on regenerated cellulose
- Printing inks (transparent printing inclusive)
- Coatings and printings where contact with food is excluded

Declaration of compliance (DoC) needed

Similar to DoC as in Regulation (EU) No 10/2011, but:

› Dual use substances (food additives) only to be declared if migration exceeds 5% of the limit in foodstuffs.

› Purity requirements only applicable to toxic components in the food additive (e.g. PAH, metal content)

Part 2: General purpose coatings

Authorised substances

- Substances according to EU Regulation 10/2011
- Substances authorised in NL Ch.1 (AP's and PPA's for plastics)
- Colorants and pigments compliant with Chapter 11
- Monomers and additives listed in chapter X (PL for coatings)
- Temporary allowed substances:
  - Substances are waiting for additional information on identity, use and/or toxicological data.
  - Deadline: 1 year after publication

CEPE list is combined with Dutch lists, as far as possible (with publically available toxicity data)

Part 3: Specific purpose coatings (1)

3.1 Wax coatings

- List of waxes and polymers
- List of additives (very restricted)

Restrictions:

- As maximum quantity in formulation (no migration requirements)
- Maximum coat weight: 50 g/m^2 (or 100 g/m^2, in case of discontinued contact)
- In case of contact with fatty food:
  - Only for food with fat content < 40%
  - Only for products for discontinued contact

Part 3: Specific purpose coatings (2)

3.2 Metallic coatings

- Scope: metal coatings applied by vaporization
- PL and restrictions: Subject to Chapter 4 (on metals)

Metals (chapter 4)

- Listed: metals and alloys as starting materials
- Restrictions:
  - SML's for elements of the starting materials
  - QM's (in %) for impurities: Pb, Cd, As, Bi, and Sb
  - SML's tin: according Regulation (EC) No 1881/2006

Part 3: Specific purpose coatings (3)

3.3 Temperature resistant coatings

- Scope:
  - High temperature applications (baking, frying)
  - Coatings for medium high T (<140°C). Conveyor belts, knifes
  - Positive list on fluorine based coatings
    - Monomers
    - Binding agents
    - Additives

- Restrictions:
  - Only for coatings sintered during manufacture
  - Only for coatings used on repeated use articles
  - Both overall migration limits and specific migration limits apply

Dutch Regulation on internet

The Dutch regulation on FCM as notified in 2013, and an amendment from 2016, can be found at (translated in EN, DE, FR):

http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2013&num=407 (slightly differing from the final version with regard to the formulation of the adoption of the mutual recognition principle)

http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=208

Chapter 10 on coatings will most probably be updated end of the year.

Substance evaluation for coatings in The Netherlands

National Commission on FCM

- National Committee is “G4”

The ‘4’ refers to the intention that 4 parties are represented:

ministry (VWS) / enforcement (NVWA) / industry / experts

Currently 8 members: 1 from ministry (H. Rang),
1 industry representative, 5 experts, 1 secretariat.

Meeting frequency G4: 3 or 4 times a year
Agenda items: petitions / legislation / hot-items / news from EU
Scope: Maintenance of positive lists for non-harmonised FCM

Evaluations in NL

Experts for non-tox part: former workers of TNO (3)

Experts for toxicity-part: RIVM (2)

Number of applications in the last 3 years: 21 total

Number of which are on coatings: 9

- monomers: 4 (2 based on EFSA evaluations)
- Polymeric additives: 3 (1 based on EFSA evaluations)
- Polymer catalyst: 1
- Dispersant: 1 (for coating on Paper & Board)

6 accepted, 3 currently under evaluation

Data requirement for coatings

Dossier conform SCF guidelines, P-SDS needed, in English

Tox data

Data on identity, physical/chemical properties, use, authorization, migration and residual content of the substance and related substances (reaction- and breakdown products, oligomers).

- Tested material should be a typical sample coating
- Testing conditions used: according to 10/2011 (t, T and simulants) based on the proposed uses (taking the worst case)
- S/V: 6 dm^2 per kg food (calculated)

Data requirement for coatings

Tox-part

For 'all' substances identified that migrate to food in amounts of:

- ≤ 0.05 mg/kg: show absence of genotoxic potential
- between 0.05 – 5 mg/kg: reduced core set of data
- > 5 mg/kg: core set (no experience)

Differences with SCF guidelines:

For <0.05, also accepted: OECD 471 & 487 (AMES & in vitro MN)

For 0.05-5 mg/kg might be accepted: OECD 422 (instead of 408)

Combined (OECD 422) versus 90-day (OECD 407)

Con's

- Shorter exposure (female: ±38 days; male: 28 days)
- Lower no. rats/group for analysis: 5 versus 10 (but not in an extended OECD 422-study)

Pro's

- (Initial) information on the possible effects on reproductive performance
- New test with animals might be avoided

Acceptance

Case by case, if supported by other data, and only if MOE » 100

NIAS assessment

Risk assessment of NIAS part of evaluation?

Reaction- and breakdown products specific for the substance, arising in probably all uses: YES

Reaction products varying from coating to coating, depending on recipe: NO (responsibility of producer)

Impurities: insignificant impurities: NO

monomers in polymeric additives: YES

Oligomers

Show acceptability by, eg.:

- Determination of fraction of oligomers <1000 D that migrate (or assume 100% migration of residual content).
- Compare Mw distribution with conventional coating

Assumption: Toxicity oligomers ≤ or « monomers.

Type of restrictions in legislation

Restriction as SML (or if not measurable, as QMA):

- For starting substance
- For reaction- and/or breakdown products (with *)

An FRF might apply

* = not to be used as starting substance

Other type of restrictions:

- as % of starting substance, for impurities (only when needed)
- Restrictions on use condition (excluding type of food, …)

No restrictions on oligomers set so far

Thank you for the attention

Any questions?