



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

Colourants and pigments

(including printing inks) –
provisions in NL

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Content

1. Regulation of FCM in NL
2. Provisions on colourants and pigments



FCM Regulation in NL - Packaging and Food Utensils Regulation

- ❖ 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)



Part A: Chapters on specific materials

1. Plastics
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. Colourants and pigments**
12. Epoxypolymers



Colourants and Pigments (C&P)

Scope

All substances used to impart colour to a material.

They can be added in various ways, e.g. by:

- mixing with the material
- using them in printing inks

Permitted substances

- Colourants and pigments: comply with Art 3 of 1935/2004, and to the provisions specified in this chapter.
- Auxiliaries (processing aids) in C&P: comply with Art 3 of 1935/2004



Regulation Colourants & Pigments, outline:

- ❖ No Positive List!

- ❖ **Restrictions on the colourant or pigment:**
 - Limited extraction of specified cations
 - Limited extraction of primary aromatic amines
 - Specifications for soot and other carbon products

- ❖ **Restrictions on the final article:**
 - SML on specified cations;
 - SML for primary aromatic amines ND
 - No colour release in a filterpaper test



Regulation Colourants & Pigments, details

Restrictions on the colourant or pigment:

- Upon extraction with 0.1 N hydrochloric acid, no more may dissolve from the colourant or pigment than:

Element	extraction (as proportion of colourant/pigment):
Antimony	0.2%
Arsenic	0.01%
Barium	0.01 %
Cadmium	0.1 %
Chromium	0.1 %
Lead	0.01 %
Mercury	0.005 %
Selenium	0.01 %

- Upon extraction with 2 N hydrochloric acid, no more than:
Primary aromatic amines: 0.05%



Restrictions on the colourant or pigment (continued)

For soot and other carbon products (furnace black, channel black, graphite and coke powder etc.):

- Particle size should be within:
 - primary particles: 10-300 nm,
 - aggregated particles: 100-1200 nm,
 - agglomerates: 300 nm - several mm
- Toluene-extractable substances: $\leq 0.1\%$ (by ISO norm 6209)
- UV absorption (386 nm) of cyclohexane extract:
extinction < 0.02 (1 cm cuvette) or < 0.1 (5 cm cuvette)
- Benzo[a]pyrene content: ≤ 0.25 mg/kg of soot.



Restriction on the coloured final product

- The specific migration of ingredients of colourants and pigments must not exceed:

Element	SML (in mg/kg)	Element	SML (in mg/kg)
Antimony	0.04	Lead	0.1
Arsenic	0.01	Lithium	0.6
Barium	1	Manganese	0.6
Cadmium	0.01	Mercury	0.005
Chromium	0.1	Nickel	1
Cobalt	0.05	Selenium	0.01
Copper	5	Zinc	25
Iron	48		

- In a filtering paper test (Part B, Ch.1, §5.3.6), the coloured FCM must not exhibit any colour difference with blank
- Coloured FCM by using aromatic isocyanates or colourants produced by azo coupling: primary aromatic amines should be ≤ 0.01 mg/kg



Risk assessment of printing inks in NL

- No Positive List in place in NL for colourants and pigments
- No submitted dossiers on inks
- No evaluations performed in NL



Dutch Regulation on internet

The Dutch regulation on FCM as notified in 2013 in Brussels 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>

Minor changes (but not on Positive Lists) are made to address the comments made by the COM, but no translation is available of the finally adopted version



Thank you for the attention

Any questions?