

Belgian activities on the evaluation of coatings

16th February 2017

Belgian activities on the evaluation of coatings

- Belgian Royal Decree on coatings
- Evaluation of substances in Belgium
- Evaluation of the migration of substances from coatings
- Yearly control plan - Belgium

Royal Decree on varnishes and coatings intended to come into contact with food

70388

BELGISCH STAATSBLAD — 18.10.2016 — MONITEUR BELGE

FEDERALE OVERHEIDS DIENST VOLKSGEZONDHEID,
VEILIGHEID VAN DE VOEDSELKETEN
EN LEEFMILIEU

[C – 2016/24201]

25 SEPTEMBER 2016. — Koninklijk besluit betreffende vernis en deklagen die bestemd zijn om in aanraking te worden gebracht met voedingsmiddelen

SERVICE PUBLIC FEDERAL SANTE PUBLIQUE,
SECURITE DE LA CHAINE ALIMENTAIRE
ET ENVIRONNEMENT

[C – 2016/24201]

25 SEPTEMBRE 2016. — Arrêté royal concernant les vernis et revêtements destinés à entrer en contact avec les denrées alimentaires

<http://www.health.belgium.be/nl/vernis-en-deklagen>

Published on the 25th of September 2016 in Belgisch Staatsblad

Overview of the Royal Decree



- Art. 1 Scope
- Art. 2 Definitions
- Art. 3 General provision
- Art. 4 Composition of the monomers
- Art. 5. Composition of the additives
- Art. 6 Overall migration
- Art. 7 Specific migration
- Art. 8 Verification of the specific migration
- Art. 9 Declaration of compliance
- Art 10. Mutual recognition

Scope of the Royal Decree



The provisions of this Decree apply to varnishes which, in the finished state, are intended to come into with food and are designed for that purpose.

The following types of varnishes are covered:

- Varnish for metal materials and articles;
- Varnish for flexible materials and articles;
- High performance varnishes.

Substances migrating from coatings



Monomers

Other starting substances

Additives

Oligomers

Impurities

Breakdown products

Other non-intentionally substances

*Substances covered
by the Royal Decree*

*Substances **NOT** covered
by the Royal Decree*

Substances authorized by Royal Decree



Additives, monomers and other starting substances can be used in the manufacture of varnishes, **if they are:**

- ✓ Included in European Regulation No. 10/2011, applying the same restrictions/specifications except when the use in specific plastics is stated
- ✓ Approved by a EU Member State applying the more stringent restrictions/specifications
- ✓ Positively evaluated by EFSA, or scientific institutes with equivalent competences

Substances authorized by Royal Decree



Additives, monomers and other starting substances can be used in the manufacture of varnishes, **on the condition that:**

- ✓ They comply with Art.3 of EU Reg. 1935/2004
- ✓ They do not transfer their constituents to foodstuffs in quantities exceeding 10 µg/kg of food or simulant
- ✓ They are not classified as CMR according to the criteria laid down EU Reg. 1272/2008 and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures (+ nano)
- ✓ They are not genotoxic based on QSAR predictions, in case of absence of *in vitro* and *in vivo* toxicological data following EFSA's criteria
- ✓ The principle of non-migration (i.e. LOD < 10 µg/kg) is applied

Substances authorized by Royal Decree

Additives, monomers and other starting substances can be used in the manufacture of varnishes, **if they have been subjected to:**

- ✓ An evaluation carried out by the *Belgian Superior Health Council* in accordance with

*Royal Decree of 30th of January 1979
laying down the procedure for inclusion on the lists of authorized substances in articles and substances intended to come into contact with food, as well as the amendments to these lists.*

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Evaluation of substances in Belgium

Royal Decree of 30th of January 1979

laying down the procedure for inclusion on the lists of authorized substances in articles and substances intended to into contact with food, as well as the amendments to these lists.

Overview of the procedure

Submission of the dossier

to DG Animal, Plants and Food of
FPS Health, Food chain safety and Environment

Evaluation of the dossier

By Belgian Superior Health Council

Publication in 'Belgisch Staatsblad'

(Only in case of changes in the list of
authorized substances)

Notification to the petitioner

By the Minister of his deputy

Evaluation of substances in Belgium



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General requirements:

- ✓ The dossier should be submitted in an official Belgian language.
Annexes can be provided in English
- ✓ 1 substance/dossier
- ✓ Evaluation are performed only after receipt of the payment.

The contribution is laid down in the Royal Decree of 13 November 2011 establishing the fees and contributions to 'Begrotingsfonds voor grondstoffen en producten'

The contribution for a new substance is €500

Evaluation of substances in Belgium

Submission of the dossier

to DG Animal, Plants and Food of
FPS Health, Food chain safety and Environment

The following information is required in the dossier:

- ✓ Chemical name of the substance
- ✓ Primary and/or secondary function of the substance
- ✓ Frequency of use: Regularly/Rarely/only specific use
- ✓ Purpose of use: as packaging material with (in)direct contact, coating material with (in)direct contact
- ✓ Method of use: 'as is' or dissolved
- ✓ Substance already authorized in other countries?
- ✓ Purity of the substance

Evaluation of substances in Belgium

Submission of the dossier

to DG Animal, Plants and Food of
FPS Health, Food chain safety and Environment

The following information is required in the dossier:

- ✓ Migration potential in function of different kinds of food, intended t/T application
- ✓ Physical and chemical properties of the substance:
 - ✓ Chemical formula,
 - ✓ Composition,
 - ✓ Solubility,
 - ✓ Spectral characteristics
 - ✓ Chromatographic characteristics,
 - ✓ Identification methods
- ✓ Data on the toxicity of the substance and its metabolites:
 - ✓ Acute and chronical toxicity,
 - ✓ CMR,
 - ✓ allergic reactions
 - ✓ Impact on enzymes

Evaluation of substances in Belgium

Submission of the dossier

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Conclusion

- ✓ No specifications of the required information is given in the Royal Decree
- ✓ However, the application form and the 'Note for guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation' from EFSA are provided to the petitioner by DG Animal, Plants and Food of the FPS Health, Food chain safety and Environment
- ✓ **'Number of applications already received in Belgium: 0**

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Evaluation of the dossier

By Belgian Superior Health Council

Belgian Superior Health Council

- ✓ The submission will be evaluated by the Expert working group 'Nutrition and health, including food safety'. The working group consists of approx . 40 experts. When deemed necessary, additional experts can be invited.
- ✓ Next, the evaluation will be validated by the Committee of the Superior Health Council' consisting of 40 named members.
- ✓ Final decision is taken by DG Animal, Plants and Food of the FPS Health, Food chain safety and Environment

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Verification of the overall migration



- Procedure is similar to the evaluation of the overall migration described in EU Regulation 10/2011 (OM1-9)
- Coatings on metal packaging are excluded
- Specific procedure for the overall migration with 3% acetic acid for High performance varnishes:
3% Acetic acid is used for the migration, but only the chloroform soluble organic material is weighed and compared to the overall migration limit.

Verification of the specific migration

Flexible FCM

Procedure according to
EU Reg. 10/2011

Metal FCM

Procedure according to
EU Reg 10/2011

*Exception: the use of 5 g/L citric acid as
simulant B instead of 3% Acetic acid*

High capacity FCM

Specific procedure
described in the Royal
Decree

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Yearly control plan - Belgium

Analysis included in the yearly control plan in Belgium

- ✓ Evaluation of the migration of BADGE from coatings used on metal packaging

Methodology:

Simulant: 5g/L Citric acid

t/T conditions: 10 days at 60°C

Analysis by UPLC-Fluorescence



Thank you for your attention!

