



FOOD CONTACT MATERIALS SERVICES BY ROYAL HASKONINGDHV

Food contact materials (FCMs) are all materials and articles that are in contact or intended to come into contact with food. To ensure safe use, many health and safety requirements must be met. Royal HaskoningDHV provides scientific and technical support to industry to comply with the complex legislation in the Netherlands and the EU Member States.

Food Contact Materials (FCMs)

Both for users and manufacturers of FCMs, it is of the utmost importance that products are safe for their intended use and comply with the relevant legislation. A multitude of substances are used in the manufacture of FCMs. There is a potential that these substances can be released from the FCM and migrate to the food product, resulting in unintentional ingestion. Therefore, the safe use of FCMs must be ensured. By performing a comprehensive

risk assessment, it is investigated whether undesirable health effects can occur due to the potential migration of these substances.

Depending on the outcome of this risk assessment, a substance may or may not be permitted for use in FCMs.

FCM Services by Royal HaskoningDHV

The legislation in the field of food contact materials are complex and can be different at national and the EU level. Royal HaskoningDHV supports the industry to comply with the regulations in force in the Netherlands, the EU and member states. Our consultants comprehend the responsibilities of business operators regarding raw materials, intermediates or finished food contact materials.

Tailored regulatory advice regarding FCM compliance, safety assessment, study monitoring, or technical support can safeguard product continuity. To offer integral solutions for the registration of FCMs, Royal HaskoningDHV collaborates closely with Charles River Laboratories.

We support business operators in the:

- Chemical industry (including additives, glues, inks)
- Food packaging industry
- Rubber and plastics industry
- Paper industry
- Coatings industry
- Food companies

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Regulatory Compliance

- **European regulations:** Regulation (EC) 1935/2004 describes the general rules to which FCMs must comply but does not give specific guidelines on how their safety can be demonstrated.
- **National regulations:** The Regulation (EC) 1935/2004 does not currently address certain FCMs (eg: glue, ink, paper and cardboard, dyes, rubber and elastomers) in such cases specific national regulations apply. When no regulations are available, the manufacturer is still responsible for ensuring product safety.

Royal HaskoningDHV offers guidance, clarification and interpretation of the current regulations for FCMs.

Together with the client, a material specific testing strategy can be prepared to derive the required information in accordance with (inter)national regulations.

To offer integral solutions for the registration of FCMs, Royal HaskoningDHV collaborates closely with **Charles River Laboratories**. From complete programs to stand-alone assessments, Charles River Laboratories provides the analytical and toxicological test support required for successful FCM registration. Thus, ensuring reliable support for substance evaluation, test proposals and implementation of your tailor-made test strategies.

- **Harmonization:** The European Council aims to harmonize the non-EC-regulated materials within the EU. This mainly takes place through material-specific resolutions consisting of +lists or migration restrictions. In addition, databases are available indicating which substances are still regulated at a national level.
- **FCM materials and non-intentionally added substances (NIAS):** For (new) substances that are to be used in the manufacture of FCM, a safety assessment is required. A dossier containing migration, toxicity and exposure data should be submitted to the government for evaluation. NIAS identification and safety assessment is a vital part of this process.

Royal HaskoningDHV supports the industry regarding the regulatory developments and requirements for material applications. In addition to performing risk assessments and tolerable dose calculations, we advise our clients regarding substance identification and the relevant toxicological or chemical evaluations available (i.e. REACH) or required for delivering a compliant product.

