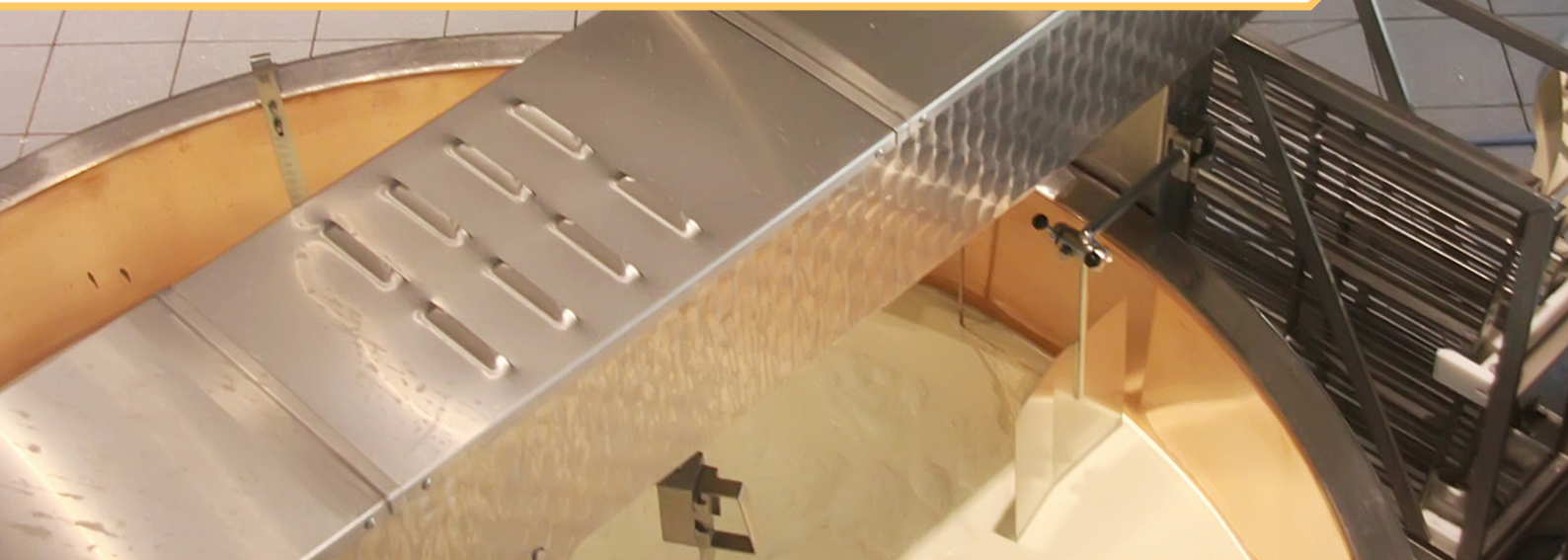


Elastomers and foodstuff

Gaskets and sealing solutions in accordance to EC 1935:2004



New legislation for materials in the foodstuff industry

To improve and ensure public health, higher requirements are now demanded for materials for use in applications or equipment in connection with the production of foodstuff. So far requirements have been based on FDA, USP or various national legislations among the EU countries. With the enactment of EC 1935:2004 with regard to materials and articles for contact with foodstuff, these requirements are however no longer sufficient with regard to the now current legislation.

With the enactment of the EC 1935:2004 regulation, the EU have commenced an unification of the legislation in all EU member states. Material intended for direct contact with foodstuff is designated as food contact material (shortened FCM). These requirements also include elastomers based solutions such as gaskets, seals or custom moulded parts. In addition to the EC 1935:2004, FCM must likewise be in accordance with regulation EC 2023:2006 on Good Manufacturing Practice (GMP).

The requirements for articles certified for contact with foodstuff and the pertaining demands for sufficient documentation, is employed to ensure compliance with current EU legislation. This entails that materials for contact with foodstuff, must not transfer their constituents (migration) to food in quantities that could endanger human health. Furthermore the employed materials must not bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics.

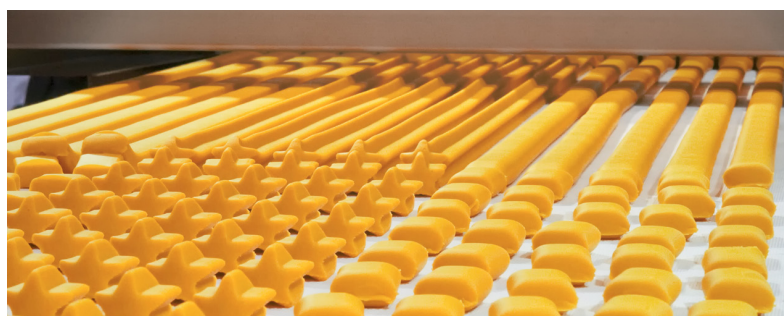
All companies producing or providing solutions for use with foodstuff, are therefore required to be able to substantiate by the use of declarations of conformity and self-regulation, that their products are in accordance with the requirements for FCM.

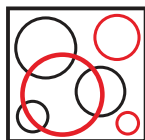
When does the regulation for food contact material apply?

Gaskets and sealing solutions are subject to the regulation for FCM if they are intended for, or within predictable application can be expected to come into direct contact with foodstuff. The regulations for FCM are therefore applicable for all gaskets and seals in applications or equipment that could possibly come into contact with foodstuff during employment. Gaskets and seals are exempted from the regulation for FCM if they do not come in contact with foodstuff within their intended or predictable application.

All EU member states must abide by the regulations of EC 1935:2004 – regardless of whether equipment or solutions are supplied to countries within or outside the EU. In case of export to the U.S., equipment and applications containing FCM must therefore be both EC 1935:2004 and FDA certified.

“Gaskets and sealing solutions are subject to the regulation for FCM if they are intended for, or within predictable application can be expected to come into contact with foodstuff.”





Requirements for FCM documentation

When supplying FCM related articles, our self-regulation ensure that A/S Gunnar Haagensen comply with the required level of documentation. All our foodstuff-approved items are supplied with the statutory documentation for FCM articles in accordance to EC 1935:2004 and EC 2023:2006. This ensures that our customers are in possession of all required documentation and information for the configuration of their own declarations of conformity as well as self-regulation.

- **Declaration of conformity**

A declaration of conformity is a supplier guarantee, which is passed on in the chain of production or trade from vendor to customer. The declaration is a confirmation that articles and materials delivered by A/S Gunnar Haagensen abide by current regulations and legislation with regard to elastomer based solutions intended as FCM.

- **Background documentation**

This documentation establishes the validity of the content in the declaration of conformity. The documentation outlines the results and test conditions for the migration reports, which demonstrate the applicability of each individual material compound as FCM. This background documentation is supplied in the shape of a certificate of conformity for each compound.

- **Technical datasheet**

All items are delivered with a technical datasheet on the employed compound. This datasheet contain compound description, a summary of physical properties as well as field of application for the type of foodstuff with regard to contact with aqueous and/or fatty foods.

- **Certification for sales of FCM**

All companies who market, produce or import items for use in applications with direct contact with foodstuff, must be registered and approved by the Danish Veterinary and Food Administration. A/S Gunnar Haagensen is registered by the Danish Veterinary and Food Administration. Our current control report can be found at www.findsmiley.dk

- **Traceability and GMP**

To ensure a high quality assurance, as well as to establish a traceable methodology, all FCM items are handled via our quality control system in accordance with ISO 9001:2008 and GMP. All items are supplied with full traceability by batch numbering. This ensures an easy identification and recall of faulty materials.

- **Labelling**

All FCM materials are supplied with correct labelling in accordance to EC 1935:2004. This include the For Food Contact logo, item number, A/S Gunnar Haagensen name and address as well as full traceability via batch numbering.

Compounds in accordance to EC 1935:2004

We offer a wide range of foodstuff certified elastomers for both O-rings as well as custom moulded parts. Our range of approved elastomers is expanded on a continual basis. Contact us for any additional information with regard to available elastomers in accordance with EC 1935:2004.

Elastomer	Compound nr.	Colour
Nitrile (NBR)	366470	Black
Silicone (MVQ)	714177	Red
EPDM	559270	Black
EPDM	55641	Black
Viton (FKM)	514642	Green
Viton (FKM)	514674	Blue
Viton (FKM)	514694	Blue
Viton (FKM)	514672	White
Viton (FKM)	514304	White
Viton (FKM)	514682	White
Viton (FKM)	514670	Black
Viton (FKM)	514683	Black
Viton (FKM)	514712	Black
Viton (FKM)	514115	Black
Viton (FKM)	514660	Black
Viton (FKM)	514680	Black
Viton (FKM)	514690	Black

Regulation under development

The regulation regarding FCM is still under development in the EU. A more comprehensive regulation is currently under preparation. As a result hereof, new requirements for migration and test conditions can be introduced for FCM. Contact us therefore always in case of questions regarding FCM approved gaskets and sealing solutions.

