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Nordic Council of Ministers

Food contact materials

In-house documentation
Nordic check lists to industry and trade

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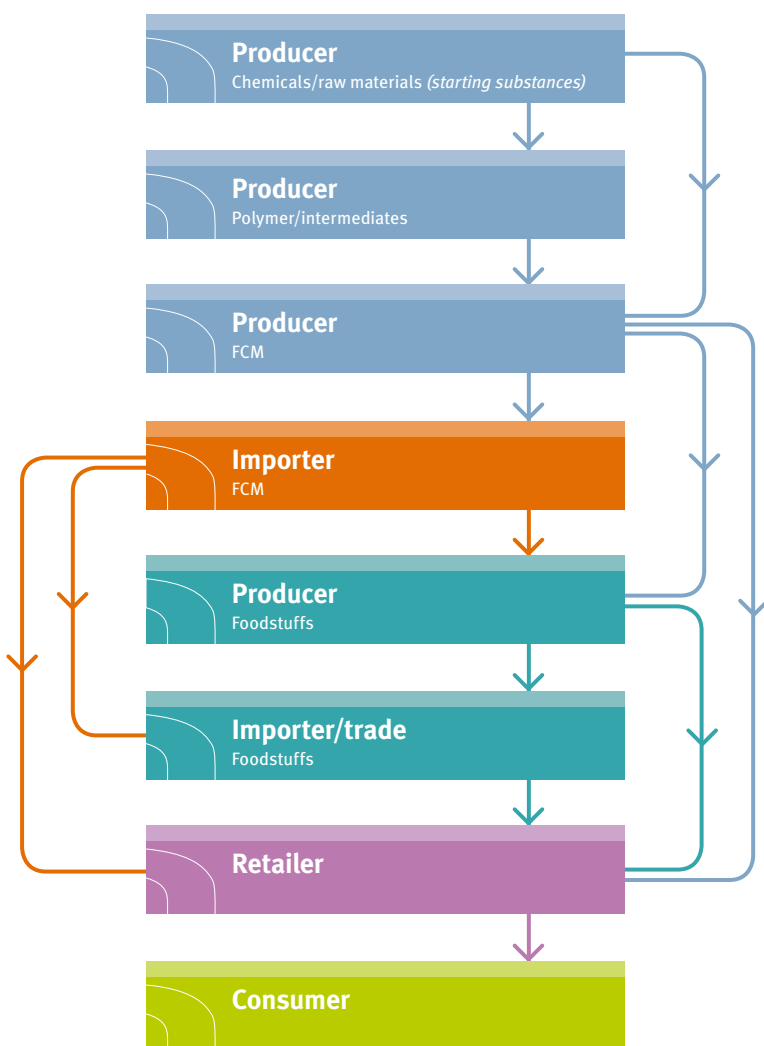
Nordic cooperation is one of the world's most extensive forms of regional collaboration, involving Denmark, Finland, Iceland, Norway, Sweden, and three autonomous areas: the Faroe Islands, Greenland, and Åland.

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Nordic cooperation seeks to safeguard Nordic and regional interests and principles in the global community. Common Nordic values help the region solidify its position as one of the world's most innovative and competitive.

Food contact materials

In-house documentation
Nordic check lists¹⁾ to industry and trade



¹⁾ Extract of report; Full text to be found on <http://www.norden.org/pub/sk/>
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A. Introduction

Food contact materials are a potential source of contamination of all types of foods. Foods are normally in contact with one or several types of food contact materials, like packaging, including multilayer materials, process equipment etc.

Food contact materials shall comply with the legislation and in-house control in industry and trade is a tool to prevent violation of the legislation. Furthermore, in-house control are important pre-requisites to limit this contamination, e.g. in-house control based on declaration of compliance and documentation at the producers and importers.

B. What are food contact materials?

Food contact materials and articles (in the following abbreviated FCM) comprise a broad and complex area. Many different types of materials are used like plastics, paper, metals, woods, lacquers, adhesives, printing inks etc. The materials are used either as single materials or combinations e.g. in complex multilayer materials. Furthermore, many different substances are used in the materials, as e.g. monomers or additives like plasticizers, stabilisers, solvents and pigments. An estimation of the total number of chemicals used is 10.000's and only lower percent of these chemicals have been assessed by the EU Scientific panels in EFSA²⁾ for the use in FCM and possible migration and potentials safety effect on consumer health.

C. EU legislation

Regulation no.1935/2004 on materials and articles intended to come into contact with foods is the framework regulation covering all types of FCM. The general requirements are as follows:

FCM shall – under normal and foreseeable conditions of use – not transfer their constituents into foodstuffs in quantities, which could:

- a. Endanger human health
- b. Bring about an unacceptable change in the composition of the foodstuffs or
- c. Bring about deterioration in the organoleptic characteristics thereof.

This regulation applies to FCM, including active and intelligent FCM, which in their finished state are:

- a. Intended to be brought into contact with food; or
- b. Already brought into contact with food and are intended for that purpose; or
- c. Can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

The regulation does not apply to FCM which are supplied as antiques, covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, and which form part of the food and may be consumed together with this food nor to fixed public or private water supply equipment.

In addition to the general legislation, EU has specific legislation on plastic, ceramics and regenerated cellulose and on good manufacturing practise at the producers of food contact materials and the intermediates used for the production of FCM.

The responsibility for observation of the legal requirements is on the producer, user or importer of FCM and processed and pre-packed food.

An overview of the EU and Nordic legislation on FCM can be found on the relevant webpages, please see addresses below.

²⁾ European Food Safety Authority, former Scientific Committee for Food

D. In-house control

The starting point for establishing in-house declaration of compliance and documentation is the legal requirement.

What is in-house control? In-house control is defined as the systematic measures taken by the business operators to ensure that the requirements set out concerning food contact materials are fulfilled.

In-house control at the producers and importer of FCM (and food) is the basis for a sustainable production or import. The control comprises GMP in the production, and for importers, knowledge of the GMP at their suppliers. Control on the activities should be based on HACCP and on declarations of compliance for raw materials and other ingoing materials like FCM from suppliers.

Who should have in-house control? All links in the production chain from the producers of the chemicals substances and raw materials over the users in the food industry to the retailers should have in-house control.

Documentation and declarations of compliance: Compliance shall be documented as part of the in-house declarations of compliance in industry and trade.

Prerequisites for evaluation of declaration of compliance: The responsible companies in industry and trade need to have the knowledge of or be acquainting with some specific areas essential to their assessment of the declaration of compliance.

The responsible companies shall have

- a. Relevant knowledge of the types of materials and combinations of materials
- b. Relevant knowledge about the legislation, including test conditions³⁾ to be able to assess the reliability of the documentation
- c. The starting point for the check lists for the establishment of appropriate in-house documentation is that all links in the chain from the producers of chemicals and other starting substance are responsible for compliance of the final FCM
- d. In-house documentation based on knowledge and trust between trade partners

In general, a declaration of compliance should as a starting point be regarded as adequate in-house documentation for starting substances, intermediates and the final FCM and their compliance with the legislation.

In-house control shall ensure that starting materials, including chemicals, intermediates and final FCM are complying with existing EU legislation and national legislation (if any) and the minimum requirements in it.

³⁾ The test conditions for e.g. plastics are included in EU directives, but not discussed in details in the background report for this brochure.

E. Check lists as guidance for in-house control

The check lists below are meant to be used as guidance with minimum requirements for the industry and trade in the process of the establishment of in-house documentation in each link in the chain from the producers of chemicals and other raw materials to the food producers and the retailer.

General requirements and guidance for in-house control of all types of FCM

- a. *Legislation*: In-house declaration of compliance and documentation is declaration of compliance with national and EU legislation on FCM, including EU regulation 1935/2004.
- b. *Updating*: The declaration of compliance shall always be updated, when there are changes such as changes in the legislation or if changes are made in the composition or production of the FCM (including intermediates). In general, the documentation shall be revised periodically e.g. once a year.
- c. *Language*: The in-house declaration of compliance and documentation shall be written in a language understood by industry and trade and the public food inspection. In Denmark, Norway and Sweden accepted languages would be the Scandinavian languages and English. Finland accepts Finnish, Swedish and English, and Iceland accept Icelandic and English.
- d. *Knowledge of suppliers and customers*: All links in the chain should have some knowledge of the legal frame under which their suppliers and customers work. A dialog between the stakeholders is needed.
- e. *GMP requirements* are fulfilled and documented, see regulation 2023/2006.
- f. *Analysis*: There are two general points:
 - Sampling for analysis shall take place at critical points, like start of production, after hardening of adhesives etc.
 - Analysis should in general follow a standardised method for which the laboratories have an accreditation.
- g. *Model calculations*: Model calculations of migration from plastics shall follow recognized methods for calculation.
- h. *Documentation availability*: In general, detailed information on the FCM should be kept in each individual link of the chain and not necessary given to customers.

The declaration of compliance and documentation shall be available for authorities on request.

Producers: Chemicals and raw materials

Chemical substances and other raw materials produced and sold for the production of FCM shall have documentation for compliance with the requirements set in the EU regulation 1935/2004 and specific measures on the area.

Producers cover the national producers, producers in EU and importers into EU from third countries. Information given to customers (users – producers of intermediates and FCM):

Minimum requirements in declaration of compliance for chemicals:

- a. EFSA opinion of the chemical substances (if available)⁴⁾
- b. Producers self-assessment and declaration of compliance and documentation on toxicological testing (in-vitro and in-vivo) in accordance with the EFSA requirements for FCM⁵⁾ and
- c. Risk assessment of compliance from other countries following guidelines and data requirements equivalent to the EFSA requirements, like BfR or FDA.
- d. Restrictions in other legislation, e.g. if the chemicals are regulated as food additives, including the requirements for purity and identity.

Please, see also the general requirements.

Minimum requirements in declaration of compliance for raw materials:

- a. Wooden fibres, see Nordic report on paper and board
- b. Other raw materials: EFSA or other international risk assessments
- c. Risk assessment of compliance from other countries following guidelines and data requirements equivalent to the EFSA requirements, like BfR or FDA.

Please, see also the general requirements.

⁴⁾ EFSA opinions are available on <http://www.efsa.europa.eu/en/science/afc.html>. It should be noticed that the directives and regulations specifically cover several of the chemicals.

⁵⁾ Such documentation would sometimes be regarded as private property. If such documentation is regarded as confidential, an abstract with the conclusion of the toxicological risk assessment can be forwarded at the first step.

**Producers:
Intermediates like e.g., formulations of printing inks, surface coatings, lacquers,
polymers or master batches**

Producers of intermediates like formulations of printing inks etc. have the responsibility of selecting chemicals, for which a risk assessment is available, and to produce products, which will comply with the legislation when used in accordance with guidance or instructions of use given to the user.

Producers cover the national producers, producers in EU and importers into EU from third countries.

Minimum requirements to suppliers of chemicals and raw materials

- a. Name and address of the supplier
- b. Traceability
- c. Chemical name and CAS-number or for raw materials, generic name e.g. fibres of wood (species)
- d. Declaration of compliance and documentation on risk assessment of the chemical
 - Chemicals e.g., monomers and additives on positive lists in the legislation
 - EFSA assessment, including report no. (if available)
 - Industry risk assessment conducted in accordance with EFSA guidelines
 - Risk assessment of compliance from other countries following guidelines and data requirements equivalent to the EFSA requirements, e.g. BfR or FDA.
- e. Risk assessment should include the intended use
- f. Information on components subject to specific restrictions, e.g. specific migration limits or TDIs
- g. For dual-use additives, declaration of compliance and documentation on specifications on purity and identity and quantitative content and information on quantitative content in the FCM.
- h. Information on quantitative content of substances functioning as surface active biocide
- i. If needed, advice on restrictions in use of the final FCM.

Please, see also the general requirements.

Declaration of compliance and documentation to the customers shall fulfil the demands of the customer.

Producers:

Final food contact materials and articles

Producers of final FCM are producing the FCM from the chemical raw materials and/or from intermediates. Materials can be suitable for contact with a wide variety of foods under many different conditions of use, while others would have a limited area of use.

Producers cover the national producers, producers in EU and importers into EU from third countries.

Minimum requirements to suppliers of chemicals, raw materials and intermediates

- a. Name and address of the supplier
- b. Traceability
- c. Declaration of compliance and documentation on risk assessment of the chemical
 - Are the chemicals e.g., monomers and additives on positive lists in the legislation
 - EFSA assessment, including report no. (if available)
 - Industry risk assessment conducted in accordance with EFSA guidelines
 - Risk assessment of compliance from other countries following guidelines and data requirements equivalent to the EFSA requirements, e.g. BfR or FDA.
- d. Risk assessment shall include the intended use
- e. Information on components subject to specific restrictions, e.g. specific migration limits or TDIs (e.g., global migration for plastics, specific migration limits in mg/kg to foods)
- f. For dual-use additives, declaration of compliance and documentation on specifications on purity and identity and quantitative content and information on quantitative content in the FCM.
- g. Information on quantitative content of substances functioning as surface active biocide
- h. For active or intelligent components, information on maximum (intended) migration, efficacy and instructions of use shall be requested.
- i. If needed, advice on restrictions in use of the final FCM.

Please, see also the general requirements.

Declaration of compliance and documentation to the customers shall fulfil the demands of the customer.

**Producers:
Food industry**

The food producing industry is responsible for compliance with the legislation of the FCM they use for specific uses. Declaration of compliance and documentation in this link shall address the specific types of food contact and the specific conditions. The food business operator should have a dialog with the supplier on this.

Producers cover the national producers, producers in EU and importers into EU from third countries.

Minimum requirements to suppliers of final FCM

- a. Name and address of the supplier
- b. Traceability
- c. Declaration of compliance and documentation on risk assessment of the chemical in the FCM
 - Are the chemicals e.g., monomers and additives on positive lists in the legislation
 - EFSA assessment, including report no.
 - Industry risk assessment conducted in accordance with EFSA guidelines
 - Risk assessment of compliance from other countries following guidelines and data requirements equivalent to the EFSA requirements, like BfR or FDA.
- d. Risk assessed includes the intended use, like food types in contact, temperatures, contact time etc.
- e. Information on analysis of migration, including specific test conditions, simulants used or analysis in foods, duration of the test etc.
- f. For dual-use additives, declaration of compliance and documentation on specifications on purity and identity and quantitative content and information on quantitative content in the FCM.
- g. Information on quantitative content of substances functioning as surface active biocide
- h. For active and intelligent packaging, information on efficacy
- i. For active, emitting packaging, information on minimum and maximum migration.
- j. Information on recognised mathematical calculations on migration or other calculations on other calculations on potential migration where knowledge of the quantitative content of chemicals in the FCM is used.
- k. Advice on conditions and restrictions of use of the final FCM.

Please, see also the general requirements.

Declaration of compliance and documentation to the customers shall fulfil the demands of the customer.

Retailers⁶⁾

Retailers are many different types of enterprises. They are handling and/or processing and storing food at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.

In general,

- Retailers with production of food are regarded as producers of food and should have the same declaration of compliance and documentation
- Retailers with own import of pre-packed food or FCM, are regarded as importers of FCM and/or packaged food and should have the same declaration of compliance and documentation
- Retailers with a central trade or production organisation should have access to declaration of compliance and documentation on request.

The table lists the requirements for documentation at the different retailers:

Type of retailer	Requirements for documentation		Remarks
	Produce from national or inter-community trade (EU)	Imports for third countries	
Retailer type: Food production/sales of pre-packaged food			
Production: baker, butcher, restaurant, take-away etc.	Same as for food producers	Same as importers of FCM	Relevant labelling
Without production: Import of pre-packaged food or sales of pre-packaged food from national producer/importer	No documentation**	Same as importers of food	
Groups of stores with central trade or production organisation buying produce from importers or producers as mentioned above	If FCM is used in own production, same as food producers If no production, no documentation**.	Same as importers of food	
FCM for sales to the final consumer.			
From supplier	No documentation**, except for ceramics	Same as importers of FCM	
Sales to consumers	No documentation**	No documentation**	Relevant labelling

* Please note, that the labelling requirements have to be fulfilled. The requirements for labelling are found in regulation no. 1935/2004, and include information on whether the FCM is usable in contact with foods, contact time and temperature and other relevant instructions of use.

Sales of FCM are prohibited, if the labelling is in a language not understood by the consumers.

**It has to be noted, that “No documentation” means that compliance with the legislation must be documented at the supplier to the retailer, e.g. at food producer who deliver pre-packaged food must have the appropriate documentation.

⁶⁾ Trade via Internet is covered by the same requirements as other retailers.

F. EU and Nordic sites with overview on legislation, guidance etc.:

An overview of the EU and Nordic legislation on FCM can be found on the webpages below⁷⁾:

EU Commission:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

Danish Veterinary and Food Administration:

www.fvst.dk/fødevarerikkerhed/materialer_og_genstande.

Finnish Food Safety Authority:

<http://www.evira.fi>

The Environment and Food Agency of Iceland:

<http://english.ust.is>

Norwegian Food Safety Authority:

<http://www.mattilsynet.no/mat/mattrygghet/emballasje>

Sweden National Food Administration:

http://www.slv.se/templates/SLV_Page.aspx?id=8093

⁷⁾ Other parts of the food legislation are relevant to food contact materials, e.g.,

- *Food Law:*
Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 on general principles and requirements in the food law, on establishment of the European Food Authority and procedures related to food safety.
- *Official control:*
Regulation (EC) no. 882/2004 of the European Parliament and of the Council of 29. April 2004 on official control performed to ensure the verification of compliance with (feed and) food law, animal health and animal welfare rules.
- *Hygiene:* Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 on hygiene of foodstuff.
- *Food additives:*
http://ec.europa.eu/food/food/chemicalsafety/additives/index_en.htm
- *Food flavours:*
http://ec.europa.eu/food/food/chemicalsafety/flavouring/index_en.htm
- *FCM:* EU Commission
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm
- *FCM/risk assessment:* EFSA, AFC-panel (risk assessors for FCM):
http://www.efsa.europa.eu/science/afc/afc_guidance/722_en.html

Decision tree for requirements for declaration of compliance and documentation

Step	The material consist of	Requirement to be fulfilled	Nordic guidance from the homepages	Supplementary information
1	One layer? Several layers? Does the material contain chemicals regulated in other parts of the EU legislation?	If a) → Requirements at steps 3 a-s (type of material) If b) → Requirements at step 3-a-s (for the individual layers ⁸⁾ . When information is available on contents of chemicals under point c), see also → step 2		
2	Food additives, flavourings or other chemicals covered by specific regulation	Overview of the EU requirements are found on Food additives http://ec.europa.eu/food/food/chemicalsafety/additives/index_en.htm Flavourings http://ec.europa.eu/food/food/chemicalsafety/flavouring/index_en.htm		Food additives are regulated in positive lists and permitted to be used in specific foods within specific restrictions in the food and labelling requirements.
3-a	Adhesives	Regulation 1935/2004	Assessment of the individual components	Additives, solvents etc.
3-b	Cellulose regenerates	Regulation 1935/2004 Commission Directive 93/10/EEC as amended by Directive 93/111/EC and Commission Directive 2004/14/EC	This sets a positive list of authorised substances and the conditions under which they can be used.	Polymers, additives
3-c	Ceramics.	Regulation 1935/2004 Council Directive 84/500/EEC as amended by Directive 2005/31/EC	Maximum levels on lead and cadmium + Assessment of the individual components	Clay, silicium oxide, additives, surface coating
3-d	Cork	Regulation 1935/2004	Assessment of the individual components	Bark of <i>Quercus suber</i> , possibly additives and surface coatings

⁸⁾ A multilayer material can consist of layers of e.g. plastics, metal, printing inks, adhesives and surface coating.

Step	The material consist of	Requirement to be fulfilled	Nordic guidance from the homepages	Supplementary information
3-e	Glass	Regulation 1935/2004	DK: Maximum levels on lead and cadmium + Assessment of the individual components	
3-g	Leather	Regulation 1935/2004	Assessment of the individual components	Hide, possibly additives
3-h	Metals and alloys	Regulation 1935/2004	Assessment of the individual components + Council of Europe Guideline	Metals, possibly surface coatings and printing inks
3-i	Paper and board, recycled	Regulation 1935/2004	Only for contact with foodstuff that are shelled or peeled before ingestion	Fibres, additives, contaminants like chemicals and microbes
3-j	Paper and board, virgin	Regulation 1935/2004	Nordic guideline	Fibres, additives
3-k	Plastics	Regulation 1935/2004 Commission Directive 2002/72/EC amendments (Directives 92/39/EEC, amended by Directive 2004/1/EC, Directive 2004/19/EC and Directive 2005/79/EC. Basic rules for migration tests are supplied in Council Directive 82/711/EEC and amendments 93/8/EEC and 97/48/EC, Council Directive 85/572/EEC gives a list of food simulants to be used in migration tests for the various types of foodstuffs.	Positive list for monomers, incomplete list of additives + Assessment of the individual components	Polymers, additives
3-l	Printing inks	Regulation 1935/2004	Assessment of the individual components	Colours, pigments, additives, solvents processing aids
3-m	Rubber	Regulation 1935/2004	Assessment of the individual components + maximum level on nitrosamines in soothers.	Polymers, additives
3-n	Silicones	Regulation 1935/2004	Assessment of the individual components	Polymers, additives

Step	The material consist of	Requirement to be fulfilled	Nordic guidance from the homepages	Supplementary information
3-o	Stone	Regulation 1935/2004	Assessment of the individual components	Different stones, possibly with surface coatings
3-p	Surface coatings, including lacquers and heavy duty coatings	Regulation 1935/2004	Assessment of the individual components	Additives, solvents etc.
3-q	Textiles	Regulation 1935/2004	Assessment of the individual components	Cotton, linen, wool, possibly with additives
3-s	Wood	Regulation 1935/2004	Genuine Nordic species like pine, beech, oak and birch can be used, for other species assessment of the individual species.	Different wood species, possibly with surface coatings and printing inks



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