
norden

Food contact materials – in-house documentation and traceability

Nordic check lists to industry and trade

TemaNord 2008:517

Food contact materials – in-house documentation and traceability
Nordic check lists to industry and trade

TemaNord 2008:517

ISBN 978-92-893-1659-0

Only available as print-on-demand
Print: Ekspressen Tryk & Kopicenter
Printed on environmentally friendly paper
This publication can be ordered on www.norden.org/order. Other Nordic publications are available at www.norden.org/publications

Printed in Denmark

Nordic Council of Ministers
Store Strandstræde 18
DK-1255 Copenhagen K
Phone (+45) 3396 0200
Fax (+45) 3396 0202

Nordic Council
Store Strandstræde 18
DK-1255 Copenhagen K
Phone (+45) 3396 0400
Fax (+45) 3311 1870

www.norden.org

Nordic co-operation

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.

Nordic cooperation has firm traditions in politics, the economy, and culture. It plays an important role in European and international collaboration, and aims at creating a strong Nordic community in a strong Europe.

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.

Contents

Preface 7
Introduction 11
Summary 15
Abbreviations, definitions and terms – the most important terms used 17
1. What are materials and articles for food contact use? 21
2. In-house declaration of compliance – the starting point. 23
2.1 Who should have in-house control? 24
2.2 What is in-house control? 24
2.3 FCM and GMP requirements. 25
2.4 In-house control of and declaration of compliance on FCM. 27
2.5 Prerequisites for evaluation of a declaration of compliance. 28
3. Requested declarations of compliance 29
3.1 Prerequisite for the establishment of in-house documentation. 29
3.2 In-house declaration of compliance and documentation: General requirements and guidance to all types of businesses. 31
3.3 Producers: Chemicals and raw materials. 33
3.3.1 Producers: Chemicals and raw materials, national production. 33
3.3.2 Producers: Chemicals and raw materials, EU production and intra-community trade. 34
3.3.3 Producers: Chemicals and raw materials, Third country production. 34
3.4 Producers: Intermediates. 34
3.4.1 Producers: Intermediates. 35
3.4.2 Producers: Intermediates, intra-community trade. 36
3.4.3 Producers: Intermediates, imports from third countries. 36
3.5 Producers: Final FCM. 36
3.5.1 Producers: Final FCM, national production. 37
3.5.2 Importers: Final FCM, – Intra-community trade. 37
3.5.3 Producers: Final FCM, imports from third countries 38
3.6 Producers: Food industry 38
3.6.1 Producers: Food, national production. 38
3.6.2 Intra Community trade: Pre-packaged foods. 39
3.6.3 Importers: Pre-packaged foods. 40
3.7 Retailers. 40
4. Chemical composition, analysis, and external consultants 43
5. Traceability 47
6. Recommendations for future work 51
Resumé 53
Yhteenveto 55
Samantekt 57
Annex I 59
Annex II Decision tree to analyse the requirements to a specific material 67
Annex III Abstracts of speeches at the workshop 71
1. Own check declaration of compliance and documentation – legal requirements and guidelines, – Which are obliged to comply with which requirements? 71
2. A Joint Nordic frame for a guideline – the Pro's and Con's 72

3. Practical experience with third party control of compliance declarations and supporting documentation 74
4. Practical experience with documentation and control hereof on primary packaging. 75
5. Public food inspection 76
6. The industry check lists, – what is the content of such? – Need for guidance and industry initiatives? 77
7. Importer, producer and user of FCM: IKEA way of securing product compliance – products and materials in contact with foodstuffs 78
8. Food producer/organisation Industry check lists 79
9. FCM: Traceability & own checks – Food (and kitchenware) importer 80
1. Foodstuff packages & near-food products 80
2. Packaging materials at stores 81
3. Kitchenware 81
10. A food industry/organisation – and how can we use these results? 81
Conclusions of FCM and the tasks for the food industry 82

Annex IV Workshop participants 83

Annex V Using migration modelling as a tool for enforcement and risk management 85

Preface

Food contact materials (abbreviated FCM in the following) are a potential source of contaminants of all types of foods. Foods are normally in contact with one or several types of FCM, like packaging, including multilayer materials, process equipment etc. In-house control based on declaration of compliance and documentation at the producers and importers are important pre-requisites or the limitation of this contamination and to ensure compliance with the legislation.

The Nordic countries – Denmark, Finland, Iceland, Norway and Sweden – have had trade agreements and co-operations within many areas for many years. Official opinions and public debates within a specific area in one country will, in many cases, raise questions and debates in the other countries. Frequently, the call for uniform guidance and interpretations is brought forward, especially when the decisions and opinions within a certain area deviate from one other. This could become the case in areas where e.g., guidelines for and control of in-house declaration of compliance and documentation of FCM are following different paths in the countries.

In principle, the establishment of in-house documentation, including declaration of compliance on FCM does not differ from the establishment of documentation on compliance in the in-house documentation of other areas under the food law[1].

In-house documentation, including declarations of compliance with the legal requirements, documentation for the declaration and request of other types of information are based on the assumption, that each link in the chain from producers of chemicals for FCM to the users of the final materials in the food industry and trade take their part of the responsibility for compliance of the final, packaged foodstuffs or the final material or article sold to the consumers. Furthermore, it is important for the food safety aspects that consumers follow the instruction of use on the labels of the FCM sold directly to them.

The area of FCM is sometime regarded as complicated. The control – in industry and trade, and also in the public control requests that the responsible persons have knowledge on

- The different types of materials (to a certain extend)
- Legislation
- Test conditions, methods of analysis e.g., for plastics

[1] EU Regulation no. 178/2004.

- Risk assessments of chemicals and raw materials used in food contract materials, like paper and board, which are only regulated via the general requirements in the legislation.

Industry and trade have to ensure that they have appropriate methods to achieve knowledge and documentation on compliance of FCM, and that they use the experiences they have in building-up and update their HACCP–systems regularly.

The growth in international trade has put pressure on national authorities and international bodies for harmonised standards and uniform guidance to industry, trade and food inspection in order to achieve fair competition, as well as appropriate levels of consumer protection. Guidance has been given for many years from authorities in the Nordic countries, e.g., Finland has had guidance documents for several years, and Denmark and Norway have guidance documents as well. However, initiatives have not been taken beforehand to formulate more uniform guidance for practical use, neither in the Nordic countries nor in EU.

More uniform guidance from authorities e.g. in EU/EEA is regarded as a tool to facilitate the task for industry and trade. The Nordic project group finds it beneficial to have guidance and check lists, and hope that this work can inspire the colleagues in other EU member states and be useful in the EU public food inspection.

The Nordic countries have a long tradition of co-operation in the area of FCM, as well as in many other areas. Furthermore, these countries have similar legislation on the major parts of the area of food packaging. With Denmark, Finland and Sweden being members of the European Union, and Iceland and Norway being associated through the European Economic Agreement (the EEA agreement), the subject of in-house documentation and declarations of compliance for food packaging was dealt with in a project group under the Nordic Council of Ministers.

Members of this project group consist of the following persons:

Denmark	*Bente Fabech* (chairperson), *Per Rathmann Hansen and Jan Petersen,* Danish Veterinary and Food Administration
Finland	*Pirkko Kostamo*; Finnish Food Safety Authority, Evira and *Vesa Tuomaala*, Ministry of Trade and Industry
Iceland	*Grimur Olafsson*, The Environment and Food Agency of Iceland
Norway	*Per Fjeldal*, Norwegian Food Control Authority
Sweden	*Maria Florin*, National Food Administration

Nordic Working Group for Food Control and Consumer Information (earlier included under the Joint Nordic Working Group on Food Control) adopted the project which and it was sponsored by the Nordic Committee of Senior Officials for Food Issues under the Nordic Council of Ministers.

The project group like to thank the interested parties including industry, trade, laboratories, consultants, and retailers, who participated actively and in a fruitful dialogue in a workshop on in-house control (May 2006) together with authorities and provided their valuable contribution in elaborating this document.

Introduction

Food contact materials and articles (in the following abbreviated FCM) comprise a broad and complex area, using many different types of materials like plastics, paper, metals, woods, lacquers, adhesives, printing inks etc. Many of the materials are used in combinations in complex multilayer materials.

Furthermore, many different substances are used, as e.g. monomers or additives like plasticizers, stabilisers, solvents and pigments in the materials. An estimation of the total number of chemicals used is 10.000s and only lower percent of these chemicals have been assessed by the EU Scientific panels in EFSA (European Food Safety Authority, former Scientific Committee for Food (SCF)) for the use in FCM and possible migration and potential safety effects on consumer health.

Substances used in FCM can migrate into the food. Migration of the substances into the food may give rise to toxicological effects on humans.

The legal requirements in EU for this area is found in different regulations and directives, covering the food law[2] and the hygiene regulation[3] In addition to this the FCM regulation no. 1935/2004 and the GMP regulation no. 2023/2006 covers all types of materials, and the production of them. Besides this the specific measures for plastics, ceramics and regenerated cellulose have specific requirements like e.g. the global migration and specific migration limits and conditions for testing. The Control regulation[4] has furthermore requirements to the inspection by member states.

FCM must comply with different sets of requirements around the world. For example in the EU/EEA[5]-area, regulations and directives from the EU-Commission applies (together with national legislation in some countries); while in the United States of America, the FDA regulations applies. Even though the basic requirements are alike, there are also major differences in the risk assessment requirements and the risk management. One of the key elements in all legislative requirements is food safety and protection of consumers. Most regulations include the aspect that FCM shall not endanger human health nor change the organoleptic characteristics of the food.

The responsibility for observation of the legal requirements is on the producing or importing food and FCM industry, including the producers or importers of FCM and foodstuffs. Compliance shall be documented as part of the in-house declarations of compliance in industry and trade.

[2] EU Food Law regulation no. 178/2002
[3] EU hygiene regulation no. 852/2004 (*especially* art. 5, Annex II, chapter X).
[4] EU control regulation no. 882/2004
[5] E.g., in Iceland and Norway

Some enterprises might request disclosure of the recipes of a material, and as such information is often regarded as intellectual properties of the producers. In such cases the information can be exchanged under disclosure agreements either between members of the value chain or between a producer of FCM and a consultant.

Food (and feed) business operators – at all stages of production, processing and distribution within the businesses under their control – shall ensure that foods (or feeds) satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met. However, control campaigns in e.g. Denmark and Norway have revealed a special need for improvement of the in-house documentation on FCM in many sectors and a need for guidance to industry and trade to prevent of problems with non-compliance

The goal for this project has been to develop a Nordic frame for guidance for FCM and food business control and to be used in their in-house control, e.g., based on documents like declaration of compliance. This was achieved by involving expertise of the Nordic Food Authorities, including expertise from the practical food inspection. A workshop was arranged in May 2006, with active and corporative participation of representatives from different types of industries, trade, retailer, consultants, authorities etc. The requirements in the legislation and results of the workshop are the fundamental basis for the final report and proposals for check lists with minimum requirements.

Furthermore, it is a goal that this work be used as guidance and inspiration to authorities, industry and trade in other EU/EEA member states.

The starting point for check lists on in-house declaration of compliance and documentation is the general requirements in the Nordic countries, based on EU Regulation (EC) no.1935/2004 on FCM and the specific EU measures on some types of materials. This is the frame for the regulation in all member states in the European Union and in EEA countries like Iceland and Norway.

Regulation no. 1935/2004 expresses the general requirements as follows:

Food contact materials shall - under normal and foreseeable conditions of use - not transfer their constituents into foodstuffs in quantities, which could:

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

EU legislation on FCM is based on a principle of safety requirements. The specific legislation has existing positive listing of authorized chemicals, which are assessed by EFSA (European Food Safety Authority). For plastics, a positive list on monomers is established, and a limit for overall or total migration of all substances into the food has been established. In addition, specific migration limits are established for a number of specific substances, in accordance with safety evaluations from EFSA. National legislation on packaging exists in the individual EU and EEA[6] countries[7].

The legislation dealt with in this report will *only cover legislation* within the area of FCM, including relevant requirements for declaration of compliance of active and intelligent packaging.

FCM shall comply with the legislation and compliance shall be substantiated by appropriate documentation. In trade between e.g. producers of FCM and producers of food, FCM shall be accompanied by a written declaration of compliance, documenting that they comply with the rules applicable to them. This report addresses the question of appropriate *minimum* requirements to the documentation. The documentation can in some cases be used as declaration of compliance while in other cases, the declaration of compliance can be more like a summary of the documentation. In coming legislation from the EU-Commission, the requirements are expected to be specified successively, including that appropriate declaration of compliance and documentation shall be available to demonstrate such compliance.

Furthermore, traceability of FCM shall be ensured at all stages of production and trade in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by the Regulation and its implementing measures used in their manufacture are supplied. The FCM, which are placed on the market in the Community, shall be identifiable by an appropriate system, which allows their traceability by means of labelling or relevant documentation or information.

Documentation on traceability shall be made available to the competent authorities on demand. Furthermore, the regulation of GMP will come into force in August 2008 requesting quality assurance in the production of both FCM and the intermediates used for FCM.

In addition, producers and users of FCM have to be aware of legislation on chemicals, in general, waste management like the packaging and packaging waste directive etc., and take the relevant precautions needed. As an example, the packaging waste regulation has limits on heavy metals in the packaging materials. This part of the legislation is not men-

[6] EEA stands for European Economic Area, which was established by the EEA agreement

[7] Information can be found at the EU Commission webpage, see Annex I.

tioned here, with some legislation of chemicals, the so-called REACH[8] as an exception. REACH is briefly addressed in Annex I.

[8] EU-regulation no. 1907/2006

Summary

In-house control and the documentation of it, is the basis for the assurance of compliance with the legislation, both in the food area and in the area of FCM. This report is a check list to guide on declarations of compliance, and the target group for the project is industry and trade, both in the Nordic countries and in EU, together with private consultants and laboratories working with the legislation on FCM. One of the goals is also to influence the ongoing work in EU/EEA and contribute to the development of more uniform requirements to FCM, both for products produced in EU and for those in third countries producing FCM for import into EU.

The report and its check lists are elaborated as guidance to industry and trade in their work on assurance of compliance with the legislation of FCM. The legal requirements in EU for this area is found in different regulations and directives, covering the food law[9] and the hygiene, regulation[10] In addition to this the FCM regulation no. 1935/2004 and the GMP regulation no. 2023/2006 covers all types of materials, and the production of them. Besides this the specific measures for plastics, ceramics and regenerated cellulose have specific requirements like e.g. the global migration and specific migration limits and conditions for testing. The Control regulation[11] has furthermore requirements to the inspection by member states.

The Nordic food authorities have elaborated these check lists with the minimum requirements to the documentation needed for compliance with the legal requirements in the in-house documentation in industry and trade . The documentation should be the basis for declarations of compliance. A declaration of compliance can either be identical with the documentation or an extract. The check lists parameters cover minimum requirements for the development of sufficient in-house documentation, in general, in all links of the value chain.

The area of FCM is huge and many different materials are used for a variety of food contact purposes. Therefore there is a special need for check lists in this area. Some examples of materials are plastics, paper, metals and alloys, leather, wood and cork. These materials can be composed of a list of chemicals and raw materials like fibres from woods; and intermediates like printing inks. Some of the materials are produced by reactions of chemicals, e.g. plastic monomers form polymeric plastics.

[9] EU Food Law regulation no. 178/2002

[10] EU hygiene regulation no. 852/2004 (*especially* art. 5, Annex II, chapter X).

[11] EU control regulation no. 882/2004

The check lists set a frame with minimum requirements to all links in the chain from producers or importers of chemicals and raw materials like additives for plastics and raw materials like fibres for paper production to the users of the final FCM and to trade, including intra-community trade in the EU and import from third countries to the responsible retailers. The list is drafted in order to give a starting point for industry and trade when developing their in-house documentation and declaration of compliance. It can be used in present and future work on constructing in-house control documentation and in the future work on improvements of the documentation in order to ensure compliance with the requirements in the legislation, especially the EU regulation no. 1935/2004, but also the specific measures in the area.

It is the goal for this check list to form a basis for the food inspection in the Nordic countries in relation to their work in the control of in-house declaration of compliance in industry and trade.

This project is meant to be a starting point for future work with specification of declaration of compliance needed as appropriate documentation for the individual materials as well as for combined, multilayer materials. Work in this area cannot be static but has to be improved and revised in the future, following the enlargement of the EU legislation in the area. The legal basis for the requirements of declaration of compliance is covered by several part of the EU legislation, like the Food Law, the Hygiene regulation, the regulation on FCM etc.[12]

At the moment (2007), the EU Commission has 2–3 regulations on the agenda. This underlines a continuous demand for updating knowledge and declaration of compliance and documentation for FCM on compliance with food legislation.

The check lists in this report address legal requirements in relation to *food* contact materials and the legislation on possible hazards to human health due to migration or extraction of chemicals from the FCM to the food. Industry and trade would in most cases face supplementary requirements to ensure the technical properties, like permeability of oxygen, strength etc. of the FCM, but this type of requirements are not included in this report. Such requirements can be and are often of importance in relation to the proper function of FCM in protection of the food against e.g., zoonosis and resistance toward physical effect, and such requirements will also have to be addressed by the industry and in relation to specific circumstances relevant to the individual FCM and foodstuffs.

This work has discovered a need for supplementary initiatives, both from industry, trade and authorities. Therefore, the report has some proposals and recommendations for future work in improving and updating knowledge and in-house control on FCM.

[12] Food Law no. 178/2002, Control Regulation 882/2004

Abbreviations, definitions and terms – the most important terms used[13]

Definitions etc. in this section are cited from the EU legislation where possible

Additives are used as the general term for all substances, which are incorporated into plastics to achieve a technical effect in the finished material or article. They are intended to be present in the finished materials or articles (Commission proposal for a plastic implementing regulation, 2006). Some examples are pigments, plasticizers, stabilisers, antioxidants and flame-retardants.

Article means an object, which during production is given a special shape, surface or design that determines its function to a greater degree than does its chemical composition (EU regulation no . 1907/2006 n Registration, Evaluation, Authorisation and restrictions of Chemicals, called "REACH").

Audit means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (EU regulation no. 882/2004).

Business means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing and distribution of materials and articles (EU regulation no. 1935/2004).

Business operator means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the business under their control (EU regulation no. 1935/2004).

Certificate is originating from the Latin word "Certificatum", itself derived from the earlier Latin word "certus" meaning "certain", which covers certificates and declarations with a written declaration on compliance. The word is used to attest or confirm the status of the material or article in relation to the law on FCM and is used for the information of those to whom such materials or articles are passed.

Competent authority means the central authority of a EU Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country (EU regulation no. 882/2004).

Compliance reasons the meeting of the rules and standards laid down in the legislation on FCM and is attested as part of the in-house documentation.

Control body means an independent third party to which the competent authority has delegated certain control tasks (EU regulation no. 882/2004).

Converters are used for all producers of packaging materials who uses one or more of the following processes: laminating, coating or printing**.**

Declaration of compliance see certificate**.**

Documentary check means the examination of commercial documents and, where appropriate, of documents required under (feed or) food law that are accompanying the consignment (EU regulation no. 882/2004).

Dual-use substance is a term used for chemicals, which are used in FCM, and also e.g., as food additives having a technological effect in the food. This may include colour, flavour or the microbiological status of the food. Dual-use additives would not only be covered by the legislation on FCM, but also by other parts of the food legislation.

EEA is the European Economic Area, e.g. participation of Norway and Iceland.

EFSA is an abbreviation for European Food Safety Authority.

Equivalence means the capability of different systems or measures to meet the same objectives; and

[13] Packaging for feed is not covered by the report, but feed is mentioned in some of the definitions, as feed is covered by these definitions in the legislation. In this report the word "feed" is put into parentheses (and that is the case also when animal welfare and health is mentioned) to highlight that the report is on packaging of food for human consumption, only.

«equivalent» means different systems or measures capable of meeting the same objectives.

EU is the European Union.

FCM is an abbreviation for food contact materials and articles.

FDA is the American Food and Drug Administration.

Flavourings

(a) 'Flavouring' means flavouring substances, flavouring preparations, process flavourings, smoke flavourings or mixtures thereof; a) flavouring substance' means a defined chemical substance with flavouring properties which is obtained:

(i) By appropriate physical processes (including distillation and solvent extraction) or enzymatic or microbiological processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation),

(ii) By chemical synthesis or isolated by chemical processes and which is chemically identical to a substance naturally present in material of vegetable or animal origin as described in (i),

(iii) By chemical synthesis but which is not chemically identical to a substance naturally present in material of vegetable or animal origin as described in (i).

(b) 'Flavouring preparation' means a product, other than the substances defined in (b) (i), whether concentrated or not, with flavouring properties, which is obtained by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or microbiological processes from material of vegetable or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation);

(c) 'Process flavouring' means a product which is obtained according to good manufacturing practices by heating to a temperature not exceeding 180°C for a period not exceeding 15 minutes a mixture of ingredients, not necessarily themselves having flavouring properties, of which at least one contains nitrogen (amino) and another is a reducing sugar;

(e) 'Smoke flavouring' means a smoke extract used in traditional foodstuffs smoking processes.

(EU regulation no. 2232/96 and on smoke flavourings EU regulation no. 2065/2003).

Food (or foodstuff) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC (EU regulation no. 178/2002).

Food additives means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods. (EU directives no. 88/344; 89/107; 94/35; 94/36, and see also the Commission webpage for specifications etc., on http://ec.europa.eu/food/food/chemicalsafety/additives/index_en.htm).

Food business means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food (EU regulation no. 178/2002).

Food business operator means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control (EU regulation no.178/2002).

FCM are materials and articles, including active and intelligent FCM which in their finished state are intended to be brought into contact with food, or are already in contact with food and were intended for that purpose; or 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. Materials and articles which are supplied as antiques, covering or coating materials which form part of the food and may be consumed together with this food, or a part of fixed public or private water supply equipment is not regarded to be FCM (EU regulation no. 1935/2004).

Food-contact side means the surface of a material or article that is directly in contact with the food. *Non food-contact side* means the surface of the material or article that is not directly in contact with food (EU regulation no. 2023/2006).

Glass- and fork symbol see symbol.

Good manufacturing practice (GMP) means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof (EU regulation 2023/2006).

Guides National to good practice are covered by the hygiene regulation no. 852/2004, article 8 and "shall be developed and disseminated by food business sectors:

a) In consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;

b) Having regard to relevant codes of practice of the *Codex Alimentarius*".

"Member States shall assess national guides in order to ensure that:

(a) They have been developed in accordance with paragraph 1;

(b) Their contents are practicable for the sectors to which they refer"

HACCP is hazard analysis of critical control points covered by the hygiene regulation no. 852/2004, article 5 and consist of the following:

a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels

b) Identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels

c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards

d) Establishing and implementing effective monitoring procedures at critical control points

e) Establishing corrective actions when monitoring indicates that a critical control point is not under control

f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively

g) Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

Identity check means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of the consignment (EU regulation no.882/2004).

Import means the release for free circulation of (feed or) food or the intention to release (feed or) food for free circulation within the meaning of Article 79 of Regulation (EEC) No 2913/92 in one of the territories referred to in Annex I (EU regulation no. 882/2004).

Inspection means the examination of any aspect of (feed,) food, (animal health and animal welfare) in order to verify that such aspect(s) comply with the legal requirements of (feed) and food law (and animal health and animal welfare) rules (EU regulation no. 882/2004).

Intra-community trade is trade within the Member States in the European Union.

Intermediates are used to cover mixtures of chemicals like lacquers, printing inks etc., which are, used in e.g. multilayer materials.

Introduction means import as defined above, and the placing of goods under the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92.

Master batch term used for a polymer containing a high concentration of pigment, slip, antiblock, antioxidant or other additives. Masterbatchs are produced by mixing polymers and powder of e.g. pigment followed by melting and extrusion and forming the coloured polymer into strings, which are cut in small pieces.

Migration, global (OM) means the sum of the migrations of volatile or non-volatile substances, except water, released from a material or article into food or food simulant (Commission proposal for a plastic implementing regulation, 2006).

Migration limit, overall (OML) means the maximum permitted amount of volatile or non volatile substances, except water, released from a material or article into food or food simulant (Commission directive no. 2002/72 and its amendments).

Migration, specific (SM) means the amount of a specific substance released from a material or article into food or food simulant

Migration limit, Specific (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants (Commission directive 72/2002/EEC)

Non-compliance means failure to meet the requirements of the (feed or) food law, and with the rules for the protection of animal health and welfare (EU regulation no. 882/2004).

Official certification means the procedure by which the competent authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance (EU regulation no. 882/2004).

Official control means any form of control that the competent authority or the Community performs for the verification of compliance with (feed and) food law (animal health and animal welfare) rules (EU regulation no.882/2004).

Official detention means the procedure by which the competent authority ensures that (feed or) food is not moved or tampered with pending a decision on its destination; it includes storage by (feed and) food business operators in accordance with instructions from the competent authority (EU regulation no. 882/2004).

Physical check means a check on the (feed or) food itself which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with (feed or) food law (EU regulation no. 882/2004).

Placing on the market the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves (EU regulation 1935/2004).

Preparation means a mixture or solution composed of two or more substances.

Quality assurance system means the total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use (EU regulation 2023/2006).

Quality control system means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system (EU regulation 2023/2006).

Raw materials are used for ingredients like fibres of wood and cotton, natural rubber, hides and stones.

REACH is the EU regulation no. 1907/2006 on Registration, Evaluation, Authorisation and Restrictions of Chemicals.

Retail means the handling and/or processing of food and its storage 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 (EU regulation no.178/2002).

Sampling for analysis means taking (feed or) food or any other substance (including from the environment) relevant to the production, processing and distribution of (feed or) food (or to the health of animals), in order to verify through their certification and measurement of chemical constituents compliance with (feed or) food law (or animal health) rules.

Specification is used for food additives and flavourings substances and the specification for their identity and purity in the relevant EU directives or Codex Alimentarius standards.

Stages of production, processing and distribution means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer (and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed) (EU regulation no. 178/2002).

Starting substances are used for chemicals and raw materials like wood fibres or natural rubber.

Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (EU regulation no. 1907/2004; “REACH”).

Symbol is used for the glass- and fork symbol, which can be used in labelling of FCM (EU regulation no. 1935/2004).

Traceability (food) means the ability to trace and follow a food, (feed, food-producing animal) or substance intended to be, or expected to be incorporated into a food (or feed), through all stages of production, processing and distribution (EU regulation no. 178/2002).

Traceability (FCM**)**: the ability to trace and follow a material or article through all stages of manufacture, processing and distribution (EU regulation no.1935/2004).

Verification means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled (EU regulation no. 882/2004).

1. What are materials and articles for food contact use?

FCM cover a long list of materials like plastics, paper, rubber, silicones, cork, printing inks, metals and alloys, surfaces coatings, lacquers etc. Many of these materials are normally used in combination e.g. in multi-layer packaging materials. For example a fruit juice carton may consist of plastics, paper, aluminium, adhesives, surface coating and printing inks. Furthermore, many of the materials used are surface coated. Some examples of materials which can be surface coated are aluminium foil and metal utensils.

Furthermore, the materials are used in many different ways and many applications like

- Packaging, wrapping
- Production machinery
- Utensils
- Pipelines (excluding fixed public or private water supply equipment[14])
- Containers – small or big, including ships for bulk transports
- Some types of toys, e.g. toys like coffee cups, soft ice/soft drink machines
- Gloves etc.

Materials and articles covered by EU regulation no. 1935/2004[15] are, materials and articles which in their finished state:

a) Are intended to be brought into contact with food; or
b) Are already in contact with food and were 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. Active and intelligent FCM are covered by the regulation.

The general requirements laid down in EU regulation no. 1935/2004, article 3 covers *all* the layers in FCM and they shall be addressed in the in-house declaration of compliance.

[14] EU Regulation no. 1935/2004, Article 1, 3 and the Annex.
[15] The references to current legal requirements are listed in Annex I.

What type of FCM are not covered?

The regulation does not cover antiques and edible coatings of e.g. edible coatings on cheeses and sausages. Furthermore, construction materials in fixed public water supply equipment are not covered. However, some types of articles like coffee and other vending machines are covered by the definition of construction materials and also by the requirements for FCM.

Active and intelligent packaging, – a new area in the discussion.

The main purpose of food packaging is to protect the food from microbial and chemical contamination, oxygen, water vapours, light, physical damage etc. The types of packaging used have therefore an important role in determining the shelf life of a food. Another purpose is to protect against deformation and impacts of food during transport. In most cases, this role is a rather passive and inert one, but during recent decades, the idea of active and intelligent packaging has received more attention and many commercial products have been introduced and are used in the food area. Finally the FCM is a part of the marketing and branding of a product.

2. In-house declaration of compliance – the starting point.

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 compliant for importers knowledge of the GMP at their suppliers. Control of the activities should be based on HACCP, meaning an analysis of the critical points and procedures that prevent problems. Further the control is based on declarations of compliance from suppliers of raw materials and other ingoing materials in FCM. The customers of an enterprise shall have documentation on compliance from their suppliers and shall ensure appropriate use of the raw materials, intermediates, FCM etc. as described by the supplier

Knowledge and a basic dialog between producers and users, e.g. producers or importers of FCM and the food producers, is an essential part of the in-house control of FCM.

The starting point for establishing the declaration of compliance and in-house documentation is the general requirement, in regulation 1935/2004/EC, article 3 and in the specific measures, e.g. on plastics.

The general requirements cover *all* types of materials and articles, which shall comply with the following:

> Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
>
> (a) Endanger human health; or
> (b) Bring about an unacceptable change in the composition of the food; or
> (c) Bring about deterioration in the organoleptic characteristics thereof.
>
> The use of active and intelligent packaging shall furthermore comply with relevant legislation like the food additives and the hygiene legislation.
>
> The labelling, advertising and presentation of a material or article shall not mislead the consumers.

This report is focusing on *minimum* requirements for the documentation in the in-house control of FCM in all types of industries and trade, from those who are responsible for the chemicals used in the materials and responsible for compliance with the legislation.

The check lists can be regarded as lists of questions to be asked to suppliers in order to establish an appropriate in-house documentation. Due to the composition, use or specific nature of some materials, additional requirements might be needed. In all cases, specific evaluation and risk assessment would have to be conducted of specific materials and articles, and the specific foods in contact and the processing conditions for the uses.

2.1 Who should have in-house control?

This report is considering in-house control in all links in the production chain from the producers of the chemical substances and raw materials to the users of FCM in the food industry and to the retailers. The figure below illustrates this chain.

FCM are produced from chemicals and raw materials like wood fibres, natural rubber and stones. Furthermore, intermediates like printing inks and surface coatings are used in the final materials. Some of the components are produced by reaction between chemical substances like ethylene as the monomer for polyethylene plastics.

Producers are inspected by the official control, either directly via registration at the food inspection or indirectly in the food industry or food importers. The public food inspection takes into account the in-house declaration of compliance at the industry and trade, including the documentation of the FCM, produced, imported and/or used.

2.2 What is in-house control?

In-house control is defined as the systematic measures taken by the food business operators to ensure that the legal requirements set out concerning FCM are fulfilled. The EU hygiene regulation[16] requires food business operators to put in place, implement and maintain a permanent procedure based on Hazard Analysis and Critical Control Point (HACCP) principles.

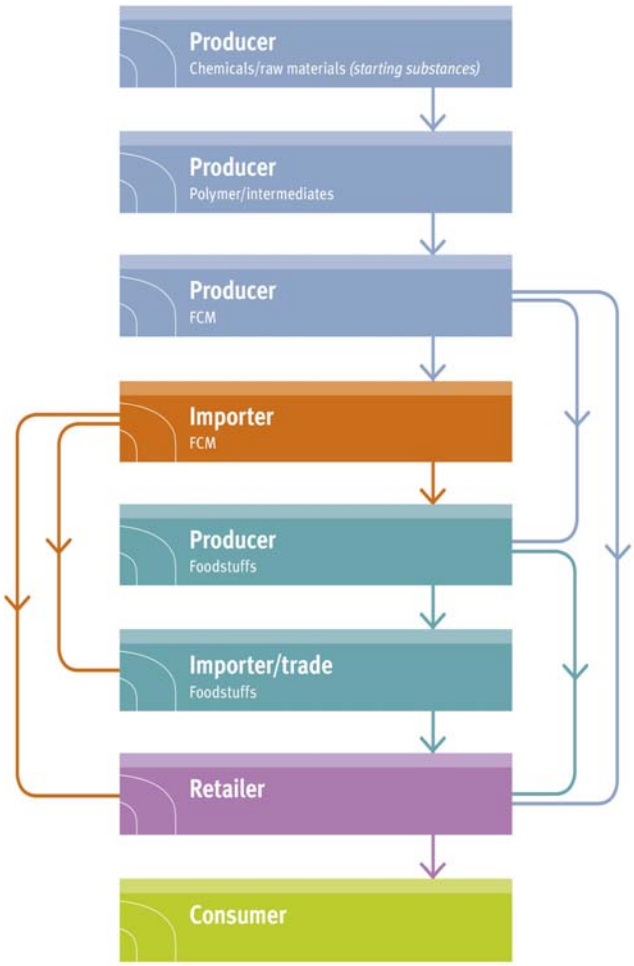
The EU regulation on good manufacturing practice[17] lists requirements for both producers of the final FCM and their suppliers, excluding the producers of the starting substances. However, the suppliers of the starting substances will still have to document food safety and compliance with EFSA guidelines for chemicals used in FCM.

Furthermore, the EU Food Law no. 178/2002 has requirements to the food producers and importers, covering the potential migrants from FCM

[16] Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs, especially article 5, Annex II, Chapter X.

[17] Regulation (EC) no. 2023/2006 of 22 December 2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food

and the EU regulation on control, regulation no. 882/2004 and the framework regulation on FCM no. 1935/2004 cover all types of FCM, including FCM already in contract with foods.



The links in the chain from producers of chemicals, intermediates, FCM to food industry and retailers.

2.3 FCM and GMP requirements.

The requirements for FCM lay down, that the business operator shall[18] establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall:

a) Take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is

[18] Regulation (EC) no. 2023/2006 of 22 December 2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food

necessary to ensure that finished materials and articles comply with the rules applicable to them;

b) Take into account the size of the business run by the operator, so as not to be an excessive burden on the business.

The requirements for in-house control in industry and trade are based on the legislation on hygiene. Here, it is stated that food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. The HACCP principles referred to in the regulation on hygiene (852/2004) consist of the following:

- Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels
- Identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels
- Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards
- Establishing and implementing effective monitoring procedures at critical control points
- Establishing corrective actions when monitoring indicates that a critical control point is not under control
- Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs a–f.
- When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the FCM with the rules applicable to it. Pre-established specifications are specifications in the legislation for purity and identity for substances used, e.g. specifications in the plastics legislation or in the food additives legislation for dual-use and active, migrating substances or it can be specifications related to the actual substances tested in the risk assessment and those that are from the need for the finished product to meet particular technical requirements.

The different operations shall be carried out in accordance with pre-established instructions and procedures. Pre-established instructions include instructions for mixing ingredients, for production like temperatures and holding time for adhesives in multilayer materials and cooling instructions.

The food business operators are responsible for compliance of the food. If food – imported, produced, processed, manufactured or distributed – is considered not to be in compliance, the food business operator shall[19] immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumer products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

Furthermore, the requirements state that the food business operator is responsible for retail or distribution activities that do not affect the packaging, labelling, safety or integrity of the food. They shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

2.4 In-house control of and declaration of compliance on FCM.

In-house control is the basis for production of FCM in compliance with the legal requirements and also very important for e.g. producers or importers of FCM or food in the protection of their brands. If a food producer uses FCM, which gives problems like migration of chemicals in non compliance with the legislation, the problems are linked to the brand of the food producer as a first step and that might have a negative effect of the marketing of the food and then on the brands.

In-house control on FCM is equivalent to the in-house control in food areas. However, the area is often regarded as complicated and producers of FCM and its intermediates, of pre-packaged food etc. would not in all cases automatically give sufficient documentation on compliance in order to meet the requirements of the law. Sometimes the suppliers would only provide declaration of compliance on direct request. This is the case both for suppliers in EU countries and in third countries.

[19] Regulation 178/2002, Article 19.

2.5 Prerequisites for evaluation of a declaration of compliance.

To overcome this problem, the responsible companies in industry and trade need to have the knowledge of or be acquainted with some specific areas essential relevant to their assessment of the declaration of compliance.

The companies responsible shall have

a) Knowledge on the types of materials and combinations of materials
b) Relevant knowledge about the legislation to be able to assess the reliability of the documentation
c) The starting point for the check lists 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 summary:

A HACCP analysis should be a starting point for all links in the value chain, also for FCM producers in the establishment of appropriate in-house control.

For food business operators – HACCP must be followed.

3. Requested declarations of compliance

The responsibility for the compliance of the final FCM[20] is a shared responsibility along the production chain of industry and trade[21].

The production chain consists of all food business operators from producers of the chemicals and raw materials used in the production, the producers of the intermediates to the final FCM. The supply chain includes also the subsequent stages, such as the food industry (the filler), importers and retailers.

3.1 Prerequisite for the establishment of in-house documentation

The starting point for the check lists in this chapter is the following:

a) Legal requirements on FCM, including the suitable test conditions
b) Each link in the chain takes appropriate responsibility. Shared responsibility should limit the risk of duplication of work and prevent failures
c) In-house declaration of compliance and documentation is based on responsibility of suppliers and requirements from customers
d) Each link has knowledge of the types of the relevant materials
e) A declaration of compliance for starting substances should as a starting point, be regarded as adequate in-house declaration of compliance and documentation for intermediates and the final FCM and their compliance with the legislation.

In general,

A declaration of compliance should be sufficient documentation to ensure that starting materials, including chemicals, intermediates and final FCM are in line with existing EU regulation and the minimum requirements in it.

The following check lists are based on the legal requirements in EU regulations and directives and the outcome of the workshop[22] held in May

[20] Annex II Included an example of a decision-tree for the evaluation of declaration compliance.
[21] See Chapter 2.
[22] Abstracts of the speeches from the workshop are found in Annex III and the list of participants in Annex IV.

2006 with participation of representatives from most links in the chain. These include producers of chemical, FCM, producers and importers of foodstuffs, retailer chains and representatives from private consultants working in this area of FCM and in-house declaration of compliance and documentation.

The requirements focus on the responsibility in each link of the chain for compliance of the final FCM and foodstuffs, which have been and/or are brought in contact with the materials.

Each link in this chain has responsibility for the compliance of the FCM with the legal requirements. When the producers of the chemicals used for polymers or additives take the responsibility to ensure that only chemicals supported with data on safety aspects are sold for production of FCM or their intermediates. The data requested are listed in the EFSA guidelines for risk assessment of FCM. The producers of intermediates like surface coatings, printing inks etc. shall base their production on a solid ground by using chemicals for which the safety implications are documented and will then able to take responsibility for the combined intermediates. In the sites of food production and at the retailers, there are the appropriate knowledge of the nature of the foodstuffs and the production conditions under which the FCM are used. Therefore, these links in the chain have responsibility for appropriate use of the FCM in accordance with declarations given by their suppliers.

The requirements mentioned in this report are only requirements related to the legislation on FCM[23] and attention must be paid to other requirements e.g. in the legislation in the environmental area. Furthermore, the food business operators should consider whether FCM contains components, which might cause allergic reactions, e.g., nickel or ingredients listed in EU directive no. 2000/13[24].

The prerequisite for the check lists and the minimum requirements are

a) Industry and trade have a certain level of knowledge regarding quality assurance at their suppliers. This is especially important in relation to imports from third countries as producers in third countries need to know EU legislation
b) The producers of raw materials, especially chemical substances, risk assess the chemicals and their potential uses
c) Producers of intermediates like e.g. printing inks and surface coatings, and final FCM do the same, and so does the food industry
d) Producers and importers of final FCM assess the possible need for instructions of use in relation to specific foods and conditions of use.
e) The food industry assesses the FCM in relation to the specific foods; conditions of uses and shelf live of the final food

[23] Some selected references and links to the sites of interest on the Internet are found in Annex I.

[24] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, and its amendment directive 2007/68/EC.

f) Retails assess labelling and need for instructions of use
g) The consumer uses FCM in accordance with instructions of use.

The responsible parties are e.g. producers of chemicals as suppliers to the users like producers of intermediates or of final FCM, who are the customers.

The basic philosophy of these check lists is that the customers specify their requirements, both requirements that shall ensure compliance with the legislation and other requirements like technical requirement. The suppliers shall fulfil these requirements and besides this, consider if more information would be beneficial to give to their customers.

In the following chapters, proposed minimum requirements for documentation in the individual links of the chain from producers of chemicals to retails.

The sections below, starting with the producers of chemicals and other stating substances for the production of FCM via intermediates like polymers, printing inks and surface coating to producers of FCM, foods and retailers.

The importers and traders in intra-community trade are mentioned in separate sections in order to make it sector specific check lists and facilitate the findings of the appropriate check list for the individual links in the chain.

3.2 In-house declaration of compliance and documentation: General requirements and guidance to all types of businesses

Some of the requirements to in-house declaration of compliance and documentation are the same in all links of the chain from the producers of starting substances to the retailers. These general requirements are listed in this chapter, while *specific requirements* at the individual production/import step are listed in the specific chapters below.

3.2.1 Prerequisite for the in-house declaration of compliance and documentation

a) *Legislation and FCM:* In-house declaration of compliance and documentation is declaration of compliance with national and EU legislation on FCM, including EU regulation 1935/2004.
b) *Legislation and active and intelligent packaging:* For FCM that has an active and/or intelligent function, compliance with the relevant legislation on e.g. food additives or flavourings shall be recognised.
c) *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.
d) *Language*: The in-house declaration of compliance and documentation shall be written in a language understood by industry, trade and the public food inspection. In Denmark, Norway and Sweden accepted languages would be the Scandinavian language and English. Finland accepts Finnish, Swedish and English; and Iceland accept Icelandic and English.
e) *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.
f) *GMP requirements* are fulfilled and documented; see regulation 2023/2006.
g) *Analysis:* There are general points:
    - Sampling for analysis shall take place at critical points, like start of production, after curing time, temperature, hardening of adhesives etc.
    - Analysis should in general follow a standardised method for which the laboratories have an accreditation.
    - Results: presentation of results should include name and address of the laboratory as well as relevant information on compliance with legislation such as testing conditions, temperature and contact time.
h) *Model calculations:* Model calculations of migration from plastics shall follow recognized methods for calculation.
i) *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. As a starting point, the food inspectors control the declaration of compliance and documentation at the link in the chain nearest to the production of the FCM, food or at the importer of FCM and pre-packaged food.

As an example, FCM would be controlled at the producer or importer of FCM. If the food inspectors find a need for control at another link in the chain, the detailed declaration of compliance and documentation should be made *available within a timeframe of maximum 2 weeks on demand*.

3.3 Producers: Chemicals and raw materials

Producers are producers in a country, producers in other EU countries and producers in third countries. The producers in other EU countries and in third countries are dealt with separately in this chapter, in order to enable the industry to get specific guidelines addressing their sector.

In general, chemical substances and other raw materials produced and sold for the production of FCM shall be examined in accordance with the requirements set in the EU regulation 1935/2004 and specific measures on the area.

The assessment of declarations of compliance will be depending of toxicological/chemical data on the chemical substances and raw materials in composed materials. This would be the case even though the regulation on GMP does not cover this link of the production chain.

3.3.1 Producers: Chemicals and raw materials, national production

Information given to customers (users – producers of intermediates and FCM).

Status for the chemicals with respect to:

Minimum requirements in documentation of compliance for chemicals:

a) EFSA opinion of the chemical substances (if available)[25]
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 FCM[26] 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. in specifications for identity and purity in the FCM legislation or in the food additives legislation.

Please, see also chapter 3.2.1.

Raw materials cover e.g. wooden fibres for paper and board, cork and rubber.

[25] EFSA opinions are available on http://www.efsa.europa.eu/en/science/afc.html. It should be noticed that several of the chemicals are specifically covered by the positive lists in EU directives and regulations.

[26] 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 as the first step.

Minimum requirements in documentation of compliance for raw materials:

a) Wooden fibres, see the Nordic report on paper and board, under production
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.
d) Producers declaration of compliance and documentation on toxicological testing (in-vitro and in-vivo) in accordance with the EFSA requirements for FCM[27]

Please, see also chapter 3.2.1.

3.3.2 Producers: Chemicals and raw materials, EU production and intra-community trade

Information given to customers (users).

The information, which should be given to customers are the same as from national production.

3.3.3 Producers: Chemicals and raw materials, Third country production

Information given to customers (users).

The information, which should be given to customers are the same as from national production.

3.4 Producers: Intermediates

Producers of intermediates like formulations of printing inks, surface coatings, lacquers 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 include domestic producers, producers in other EU countries and producers in third countries. These producers are dealt with separately in this chapter, in order to enable the industry to get specific guidelines addressing their sector.

[27] 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.

In general, the intermediates, which are intended to be used in the production of FCM, shall be examined in accordance with the requirements set in the EU regulation no. 1935/2004 and specific measures on the area, including the GMP regulation no. 2023/2006. As the assessment of declarations of compliance will be depending on data on the chemical substances and raw materials in the intermediates used for the production of composed materials.

3.4.1 Producers: Intermediates

General requirements toward suppliers of chemicals and raw materials

As a minimum, the following documentation shall be available for chemicals used for the production of intermediates for FCM production:

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 should be 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 TDI's
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 chapter 3.2.1

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

3.4.2 Producers: Intermediates, intra-community trade

Minimum requirements to suppliers of chemicals and raw materials

The information, which should be requested from suppliers are the same as from national production.

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

3.4.3 Producers: Intermediates, imports from third countries

Minimum requirements to suppliers of chemicals and raw materials

The information, which should be requested from suppliers are the same as from national production.

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

3.5 Producers: Final FCM

Producers at this stage are the companies producing final FCM from the chemical raw materials and from intermediates. The FCM industry uses the term converters for the producers of FCM.

Producers include domestic producers, producers in other EU countries and producers in third countries. These producers are dealt with separately in this chapter, in order to enable the industry to get specific guidelines addressing their sector.

Many different materials are used as FCM, including many different combinations of materials like multilayer plastics and paper materials, including adhesives, metals layers, surface coatings and print inks. Some of the materials, like stainless steel are composed of a few chemicals, like iron, cobalt and nickel; while other are composed of many chemicals, like printed and surface coated multilayer materials.

Some materials are suitable for contact with a wide variety of foods under many different conditions of use, while others would have a limited area of use.

The producers of final FCM are users of chemicals and intermediates and responsible for compliance of the final FCM. In order to fulfil their responsibility, they shall have adequate information from their supplier. Producers of FCM have the responsibility of selecting chemicals and intermediates, 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.

In general, FCM are intended to be used in contract with foods shall be examined in accordance with the requirements set in the EU regulation no. 1935/2004 and specific measures on the area, including the GMP

regulation no. 2023/2006. The assessment of declarations of compliance will be depending of data on the chemical substances and raw materials in the intermediates used for the production of composed materials.

3.5.1 Producers: Final FCM, national production

Declaration of compliance and documentation from suppliers (producers of raw materials and intermediates) should have information about the following:

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 TDI's (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 chapter 3.2.1

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

3.5.2 Importers: Final FCM, – Intra-community trade

The requirements for FCM in intra Community trade are the same as the requirements to domestic production.

The pre-requisite is that producers for FCM in all EU and EEA countries do follow the same requirements as domestic producers in the Nordic countries and that public food inspectors control FCM in the production sites. This requirement is harmonised in the EU regulation on Good Manufacturing Practice for FCM, valid from August 2008[28].

The requested declaration of compliance and documentation would therefore be the same as specified for producers of FCM, see chapter 3.5.1.

3.5.3 Producers: Final FCM, imports from third countries

The requirements for FCM imported from third countries are the same as the requirements to domestic production. The pre-requisite is that producers for FCM in third countries do follow the same requirements as domestic producers in the Nordic countries.

The requested declaration of compliance and documentation from importers into the Nordic countries shall therefore be the same as specified for producers of FCM, see chapter 3.5.1.

3.6 Producers: Food industry

The food producing industry is responsible for compliance with the legislation of the FCM they buy and use for specific uses.

Food producers use many different types of materials and articles, like process equipment, packaging, gloves and utensils like knives and cutting boards. These FCM would be in contact with many different types of food under many different conditions and for a different time period. 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 dialogue with the supplier on this.

3.6.1 Producers: Food, national production

Declaration of compliance and documentation from suppliers (producers of final FCM) shall cover the following information:

[28] Regulation no. 2023/2006 of 22 December 2006

Minimum requirements to suppliers of final FCM.

a) Name and address of the supplier
b) Traceability[29]
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 assessment shall include 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 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 chapter 3.2.1

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

3.6.2 Intra Community trade: Pre-packaged foods

The requirements for packaged foods in intra Community trade are the same as the requirements to domestic production.

The pre-requisite is that producers for FCM in all EU countries do follow the same requirements as domestic producers in the Nordic countries and that public food inspectors control FCM at the production sites. This requirement is harmonised in the EU regulation no. 2023/2006 of 22 December 2006 on Good Manufacturing Practice for FCM, valid from August 2008.

[29] See also chapter 5.

The requested declaration of compliance and documentation would therefore be the same as specified for producers of FCM, see chapter 3.6.1.

3.6.3 Importers: Pre-packaged foods

The requirements for packaged foods imported from third countries are the same as the requirements to domestic production.

The pre-requisite is that producers for FCM in third countries do follow the same requirements as domestic producers in the Nordic countries.

The requested declaration of compliance and documentation would therefore be the same as specified for producers of FCM, see chapter 3.6.1.

3.7 Retailers

Retailers are many different types of enterprises. They are handling and/or processing food at the point of sale or delivery to the final consumer. Retailers include distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets. Trade via Internet is covered by the same requirements as other retailers.

The main principle of both in-house control and public control should preferably be at the link in the chain where mistakes or failures can occur and be prevented. The producing or importing industry for FCM and the industry that uses the FCM, e.g. pre-packaging of food is responsible for compliance testing.

As a starting point, retailers who purchase or sells pre-packaged foods coming from the EU or EEA area would not be obliged to have in-house documentation. If problems on compliance are found, e.g. by the public control, more in-depth control etc. should, – as a first step be performed as the step of production, either of the FCM or the foodstuffs[30].

Retailers can be organised in different ways:

a) Individual stores *with production* of food, e.g. a baker, butcher, restaurant, take-away etc.
b) Individual stores *without production*, but trading with importers or producers mentioned above. This includes e.g. retailers selling produce from a), like pre-package bread from a baker or sausages from a butcher.

[30] It shall, however be highlighted that every enterprise has responsibility for the food and/or the FCM which they are selling.

c) Groups of stores with a central trade organisation (or a central production organisation) buying produce from importers or producers as mentioned above, e.g. supermarket chains who have a central trade office who trade products and sell them via individual outlets.
d) Groups of stores with mixture activities corresponding to a–c above.
e) Retailers buying FCM and selling FCM to the final consumers. E.g. supermarkets or department stores selling e.g. kitchen utensils or producers of e.g. glass or ceramics.

In addition to this, the retailers can trade both food and FCM

In general,

a) Retailers with production of food are regarded as producers of food and should have the same declaration of compliance and documentation
b) 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
c) 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**
	Produces from national or intra-community trade (EU)	Imports from third countries	
Retailer type: Food production/sales of pre-packaged food			
Production: baker, butcher, restaurant, take-away etc.	Same as 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	
Groups of stores with mixture activities, see a–c above.			
FCM for sales to the final consumer.			
From supplier[31]	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.

[31] For ceramics the documentation shall also be available in at the retailer.

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, including potential use in microwave ovens and other relevant instructions of use. Sales of FCM are prohibited, if the labelling is in a language that is 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.

4. Chemical composition, analysis, and external consultants

Evaluation of compliance with the legal requirements will include evaluation of e.g. migration of chemicals from the FCM to the food and the content in the foods. The evaluation of potential or actual migration can be done in different ways, like

- Calculations based on knowledge of the recipes of the materials
- Calculations based on mathematical modelling for plastic monolayer materials or
- Analytical testing.

The calculations based on recipes can be worst case calculations e.g. based on the assumption that the entire amount of a chemical is migrating from the FCM into the food.

The use of mathematical modelling is accepted in accordance with the plastics directive and is used in practise in the in-house control in some companies. Some more information is given in Annex V.

Analytical testing is often used in the evaluation of plastics and compliance. The decisions of which chemicals to test and how often testing should be done, should be taken on the basis of knowledge of the supplier and the quality assurance in the production, the compositions etc.

If a company does not have special resources in the area of FCM and the evaluation of compliance with the legislation in the field of EC or different national legislation, the company would often turn to a competent consultant. It is a matter of great importance from the point of compliance with regulations. It is reasonable to initiate the production from relevant starting points. According to the EU Regulation No 1935/2004 FCM materials and articles shall be manufactured in compliance with good manufacturing practice so that they do not transfer their constituents into food in quantities, which could “endanger human health or bring about an unacceptable change in the composition of the food or deterioration in the organoleptic characteristics thereof “.

Consultants and external laboratory testing are involved in the assessment of compliance of FCM when companies need an external partner to e.g. assess confidential information for the supplier, or if they either have no laboratory facilities or need external analysis for some reasons e.g., requirements from customers.

The company requesting support from external consultant shall order the service from the consultant giving the following information:

a) Markets where the product is going to be sold
b) Legislation in accordance to which compliance shall be evaluated. When needed, the consultant should assist in evaluation of relevant legislation
c) Processing conditions of the FCM, intended use of the FCM, including food processing conditions and/or how consumer is advised to use the FCM
d) Shall tests be conducted in order to fulfil the legislation on the specific type of material(s) or if a broader approach is requested? The consultant should assist in determining the scope of order.

The laboratory must, preferably, know the composition/recipe for the material in order to perform the necessary tests and analyses. If this information is not available the laboratory can only perform a global migration, which would be insufficient in relation to the requirements in the legislation e.g. on plastics.

According to the request the laboratory has the responsibility for

a) Reporting the identification of the sample, e.g., by using photos to describe and identify the sample
b) Performing the test in high quality manners
c) Test according to the legislation current in the specific country (market)
d) Performance of the tests according to appropriate methods for the current case and current standards if existing
e) Report the exact results – a statement is not sufficient
f) Report the standards followed or method-description and detection limit
g) Test Report – a supporting document
h) Laboratories can comment on the result according to the test that they have performed.

The consultant can only make a statement concerning the compliance with regulation in question, if he/she has details of the complete composition of the polymer, complete knowledge of the use of the polymer and the complete knowledge of legislation in the countries where it is going to be sold.

The client is responsible for the content of the written declaration. The client can use supporting document like this for issuing the Declaration of Compliance

Statements of compliance should *not* have a wording like – e.g. “This statement complies for two years”. E.g. changes among starting materials

and their suppliers cause need for a new statement of compliance and so does changes in the legislation.

5. Traceability

The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. With due regard to technological feasibility, food business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by the EU Regulation no. 1935/2004 and its implementing measures used in their manufacture are supplied. The information shall be made available to the competent authorities on demand.

The Nordic project group finds that the interpretation of how traceability of FCM should be interpreted in practice should follow the guidelines and interpretation in the food and feed area as close as possible, taking into account the differences in the safety problems.

The basic principle for traceability in the food area, is that the food business operator should be able to trace one step backwards and one step forward.

In general, some food scares (like BSE and dioxin crisis) have demonstrated that the identification of the origin of food but also of FCM is of prime importance for the protection of consumers. In particular, traceability helps facilitate the withdrawal of foods and FCM and enables consumers to be provided with targeted and accurate information concerning products, which should be withdrawn from the market. Traceability does not itself make food safe. It is a risk management tool to be used in order to assist in containing a food safety problem.

Traceability has different objectives such as food safety, fair-trading between operators and reliability of the information provided to consumers. The legislation introduces the traceability requirement with in particular the objective to ensure food safety and to assist in enabling unsafe food/feed to be removed from the market.

Traceability is meant to ensure that targeted and accurate withdrawals or recalls can be undertaken, appropriate information can be given to consumers and food business operators, risk assessment can be performed by control authorities and unnecessary wider disruption of trade can be avoided.

The responsible food business operators should:

a) Be able to identify from whom and to whom a product has been supplied
b) Have systems and procedures in place that allow for this information to be made available to the competent Authorities upon their request.

The requirement relies on the "one step back-one step forward" approach which implies for food business operators that:

a) They shall have in place a system enabling them to identify the immediate supplier(s) and immediate customer(s) of their products
b) A link "supplier-product" shall be established (which products supplied from which suppliers)
c) A link "customer-product" shall be established (which products supplied to which customers)

Nevertheless, food business operators do not have to identify the immediate customers when the customers are final consumers.

Although traceability is not a new notion in the food and FCM chain, it is the first time that the obligation for all food business operators to identify the suppliers and direct recipients of their food/feed is stipulated explicitly in a horizontal community legal text. Consequently, the legislation creates a new general obligation for food business operators.

The materials and articles, which are placed on the market in the Community, shall be identifiable by an appropriate system, which allows their traceability by means of labelling or relevant declaration of compliance and documentation or information.

Regulation 1935/2004, article 17, paragraph 2 have the additional text: "…technological feasible..". This text should take care of situations where the concern on food safety should be balanced with the efforts needed to trace back, e.g. in the processing of paper:

- Would this be necessary due to food safety aspects to be able to trace back to the each of the trees in the forests? – or
- For recyclates to trace back to containers for household glass, metals or paper?

The general opinion of the project group is that for recycled materials, the safety concern should be considered together with detailed requirements of traceability. As an example, glass is gathered in containers around the country in some countries, like e.g. in Denmark. Glass can contain metals like lead and cadmium, and can be polluted by crystal glass. However, the recycled glass can be subject to in-house control as in-coming raw materials and the final FCM glass can be analysed for content or migration of these metals. The cost of the registration of the content of individual contains might not lead by increased food safety, as the control of recycled glass cannot be conducted as the glass is coming from individuals.

The grey area in the table below shown a proposal for to which extend materials and articles it should be possible to trace back in the chain for materials and articles for food contact.

Traceability, schedule on request for

Steps in production	Virgin materials	Recyclates	Raw materials of natural origin
Raw materials	Monomers Additives Etc.	Paper*[32] Plastics* Metals* Glass*	Trees* Cork* Natural rubber*
Intermediates	Polymers Mixtures of additives etc.	Sorted raw material	Pulp
Production of final FCM	Plastics/multilayer Metals Rubber Silicones	Paper Plastics Metals Glass	Paper Cork Rubber
Food industry, uses	Packaging Machinery Utensils		
Retailers	FCM and packaging for packaged food.		

*Only, if

FCM are marketed with special claims like sustainable production or coming from especially contaminated areas or from areas especially affected by unknown events like disasters on atomic power plants and following heavy nuclear contamination.

=> Traceability should be on all steps.

An example, – equipment for processing.

An example of considerations of the details in traceability could be production machinery.

In a production equipment is used a plastic tube, tightened by a silicone gasket to feed a mixer. The mixer consists of stainless steel. The producer of the stainless steel uses steel plate from the cheapest supplier on the market at the time for purchasing the different parts for the mixer. The outlet for the powder is a stainless steel tube tightened by a silicone gasket. The mixer is sold to different companies using it as production equipment.

The requirements on traceability do not specify how detailed the individuals parts of the equipments should be traceable. The producer will have to balance to possibilities for safety problems, which force him/her to withdraw the mixer from the market and the cost of e.g. batch labelling. If the part can be identified precisely, the cost of withdrawing can be limited, but on the other hand this should be compared with the cost of e.g. batch labelling.

[32] See also the Nordic report on paper and board, under production.

6. Recommendations for future work

The establishment of appropriate in-house declaration of compliance and documentation is an ongoing process. The EU risk assessments of chemicals and raw materials is in progress, industry is improving guidelines and advise and the EU legislation is developing these years, both in the area of FCM and in other, related areas. Knowledge of reaction products and degradation products has to be addressed in an appropriate way, also in the in-house assessment of the FCM and the intermediates used in them.

However, knowledge is also still missing on different items, like test methods and test conditions for different materials, and guidelines in trade, industry, national food administration and food inspection on what can be regarded as sufficient in-house declaration of compliance and documentation in improving.

Furthermore, the declarations of compliance will differ in individual cases as the materials and their uses differs very much, both concerning composition, risk of migration and stability in contract with the food under different processing conditions. Therefore more work will need to be done in the future.

The recommendations given in this chapter is reflecting questions and needs raised during the project. The responsibility to start work on the areas mentioned, is not only the responsibility on the Nordic countries, the EU Member States or the Commission, it is the responsibility of several involved stakeholders.

Recommendations for future work:

Better dialogue between food producers and packaging producers

a) More harmonised EU/ESA legislation or standards on FCM - internationally e.g. in EU and in Codex Alimentarius in order to facilitate international trade
b) The EU Commission should be encouraged to arrange for a workshop with Member States on in-house documentation on FCM
c) The EU Commission should elaborate guidelines in corporation with the member states, including check lists with minimum requirements for documentation of compliance for all types of FCM

d) The EU Commissions should establish a forum for discussions and agreements of interpretations of the harmonised legislation
e) Training courses or workshops in developing declaration of compliance where the whole chain - from producers of chemicals, intermediates and FCM to food industry are participating would be a step forward
f) Seminars addressing the Nordic and EU/ESA industries and other responsible companies on documentation and declaration of compliance
g) Industrial organisations should continuer the effort on the development of compliance declarations on specific materials and articles
h) EU/EEA coordinated control companies on FCM should be considered
i) The EU network of reference laboratories should establish a forum for discussion of analysis and test conditions. This could be an internet forum
j) The EU network of reference laboratories should establish a list of laboratories working on analysis of FCM.
k) The 3rd parties laboratories should preferable make standardised reports
l) The EU/DG JRC should be encouraged to arrange for proficiency testing and invite private laboratories to participate
m) Research and development of on-line testing methods should be started in order to facilitate less costly industry in-house testing
n) The Nordic Council of Ministers should conduct a project on joint information to importers on FCM
o) The Nordic Council of Ministers, the group for corporation on control should arrange for training of food inspectors in the area of FCM and coordinated control on in-house documentation for FCM.
p) Joint Nordic efforts in the food inspection, including coordinated Nordic control campaigns of in-house documentation and declaration of compliance

Resumé

Egenkontrol og dokumentation for kontrollen er basis for kvalitetssikring af at lovgivningskrav overholdes. Det gælder både for fødevarer og for materialer og genstande, der anvendes i berøring med fødevarer (kaldet materialer og genstande). Denne rapport omfatter en tjekliste til brug for udarbejdelse af overensstemmelseserklæringer. Målgruppen for rapporten er industri og handel, både i de nordiske lande og i EU, samt private konsulenter og laboratorier som arbejder med området: materialer og genstande bestemt til kontakt med fødevarer. Det er desuden et mål at søge at påvirke det igangværende arbejde i EU/EES og at bidrage til at alle formulerer ensartede krav til materialer og genstande, både til produkter, der fremstilles i EU/EES og til produkter, der fremstilles i 3. lande til eksport til EU.

Rapporten og dens tjeklister er udarbejdet som vejledning til industri og handel til brug i deres arbejde med at sikre overensstemmelse med gældende regler for FCM. De lovgivningskrav, der er fastsat i EU for FCM findes i forskellige direktiver og forordninger, og omfatter desuden EU's fødevareforordning, hygiejne og GMP forordningerne. Herudover er der særregler for materialer som plast, keramik og celluloseregenerater. Disse regler omfatter bl.a. grænse for total og specifik migration samt testbetingelser. Kontrolforordningen stiller krav til den offentlige kontrol i EU's medlemslande.

De nordiske fødevaremyndigheder har udarbejdet tjeklister med minimumskrav til den dokumentation, der skal foreligge som del af egenkontrollen i industri og handel for, at de materialer og genstande, som virksomhederne er ansvarlige for overholder gældende lovgivning.

En overensstemmelseserklæring kan enten være identisk med den grundlæggende dokumentation eller det kan være et ekstrakt. Tjeklisterne omfatter de krav, der generelt skal overholdes som et minimum i en dækkende egenkontroldokumentation.

Området: materialer og genstande er stort og omfatter mange forskelligartede materialer som bruges i berøring med mange forskellige fødevaretyper. Derfor er der specielt behov for vejledning på dette område. Materialerne er fx plast, papir, metaller og legeringer, læder, træ and kork. Materialerne kan være sammensat af forskellige kemiske stoffer og råmaterialer som træfibre og halvfabrikata som trykfarver. Nogle af stofferne er reaktionsprodukter af enkelt stoffer. Der gælder fx plastpolymere.

Tjeklisterne i rapporten er rammen for de minimumskrav som stilles til alle led i kæden fra producenter eller importører af kemiske stoffer og råvarer, fx additiver til plast og råvarer som fibre til papirproduktion til brugerne af de færdige materialer og genstande i fødevareproduktionen

og handlen indenfor EU og med 3. verdenslande. Tjeklisterne er tænkt som et udgangspunkt for industri og handel ved udarbejdelse af deres egenkontrol dokumentation og overensstemmelseserklæringer. Listerne kan herunder bruges ved opdatering af eksisterende overensstemmelseserklæringer, som bruges som dokumentation for at gældende regler er overholdt, fx EU forordning 1935/2004 og særdirektiverne for fx plast.

Det er også et mål, at listerne kan være udgangspunktet for fødevarekontrollens kontrol af materialer og genstande i de nordiske lande.

Rapporten er tænkt som startpunkt for specifikation af de krav til overensstemmelseserklæringer, som er nødvendige forudsætninger for at virksomhederne har dækkende dokumentation både for enkelt materialer og flerlagsmaterialer. Arbejdet er ikke statisk. Der vil også fremover være behov for at forbedre og revidere dokumentationen bl.a. som følge af udbygningen af regelsættet på området i EU. Hjemlen til at stille krav finde i flere dele af EU regelsættet, fx i reglerne om materialer og genstande og i hygiejneforordningen.

For tiden (2007), har EU Kommissionen 2–3 forordninger på dagsordenen. Dette understreger det fortsatte behov for at opdatere viden, overensstemmelseserklæringer og dokumentation for at materialer og genstande overholder reglerne på området.

Tjeklisterne i denne rapport forholder sig til de krav, der er på området materialer og genstande bestemt til kontakt med fødevarer, herunder beskyttelse af forbrugere mod sundhedsrisici. Industri og handel stilles desuden overfor andre krav, fx tekniske krav som oxygengennemtrængelighed, fysisk styrke af materialer og genstande. Denne type krav er ikke omfattet af denne rapport, selvom de kan være meget væsentlige i forhold til materialernes funktionalitet, funktion i forbindelse med beskyttelse af fødevarerne mod udefrakommende forurening, fx med mikroorganismer. Sådanne krav bør industri og handle opstille ud fra de konkrete krav i produktion, transport og opbevaring.

Arbejdet med rapporten har vist, at der er behov for yderligere initiativer på visse områder, både fra industri og handel og fra myndigheder. Rapporten har derfor nogle forslag og anbefalinger for fremtidigt arbejde med at forbedre og opdatere viden på området og for at forbedre virksomhedernes egenkontrol med materialer og genstande.

Yhteenveto

Omavalvonta ja sen dokumentointi muodostavat perustan lainsäädännön noudattamisen varmistamiselle sekä elintarvikkeissa että elintarvikkeen kanssa kosketukseen joutuvissa materiaaleissa (myöhemmin FCM, food contact materials). Tämä raportti ja muistilistat on laadittu ohjeeksi kaupan ja teollisuuden yrityksille FCM-lainsäädännön noudattamisen varmistamisessa. Raportti sisältää FCM-materiaalien vaatimustenmukaisuuden toteuttamista varten laadittuja muistilistoja. Se on tarkoitettu Pohjoismaiden ja Euroopan unionin kaupalle ja teollisuudelle sekä FCM-lainsäädäntöä soveltaville yksityisille konsulteille ja laboratorioille. Yhtenä tavoitteena on myös vaikuttaa EU- ja ETA-alueella tehtävään lainsäädäntötyöhön yhdenmukaisten vaatimusten aikaansaamiseksi sekä EU:ssa että sen ulkopuolella valmistettaville FCM-tuotteille.

FCM-tuotteita on säädelty useilla EU-asetuksilla ja direktiiveillä, jotka liittyvät elintarvikkeisiin[33] ja hygieniaan[34]. Lisäksi eri materiaaleista ja niiden valmistuksesta määrätään asetuksessa elintarvikkeen kanssa kosketukseen joutuvista materiaaleista ja tarvikkeista (FCM-asetus, 1935/2004) ja asetuksessa elintarvikkeen kanssa kosketukseen joutuvien materiaalien ja tarvikkeiden hyvistä tuotantotavoista (GMP-asetus, 2023/2006). Edelleen muoveille, keraamisille tarvikkeille ja regeneroidulle selluloosalle on asetettu kokonaissiirtymän raja-arvoja ja ainekohtaisia siirtymäraja-arvoja sekä säädetty testausolosuhteista. Valvontadirektiivissä[35] määrätään lisäksi tarkastuksista, joita jäsenvaltioiden on suoritettava.

Pohjoismaiset elintarvikevalvontaviranomaiset ovat laatineet tämän ohjeen, joka sisältää minimivaatimukset toimijoiden omavalvontadokumentaatiolle, jotta vaatimustenmukaisuus toteutuisi kaupan ja teollisuuden alalla. Tämän dokumentaation tulee muodostaa perusta vaatimustenmukaisuus -ilmoituksille. Dokumentaatio tai osa siitä voi toimia vaatimustenmukaisuutta koskevana ilmoituksena. Muistilistat sisältävät vähimmäisedellytykset riittävälle omavalvonnan kehittämiselle kaikissa pakkausketjun vaiheissa.

Soveltamisohje on tarpeen, koska FCM-alue on laaja, ja koska elintarvikkeiden kanssa kosketukseen joutuvia materiaaleja ja niiden käyttötarkoituksia on useita. Näitä materiaaleja ovat mm. muovit, paperi, metallit ja metalliseokset, nahka, puu ja korkki. Materiaalit voivat muodostua kemikaaleista ja raaka-aineista kuten puukuiduista sekä osatuotteista kut-

[33] EY:n elintarvikeasetus 178/2002.
[34] EY:n hygienia-asetus 852/2004 (erityisesti 5 artikla, liite II, luku X).
[35] EY:n valvonta-asetus 882/2004.

en painoväreistä. Jotkut materiaaleista valmistetaan kemiallisten reaktioiden avulla; esim. monomeerimuoveista tehdään polymeerimuoveja.

Muistilistat asettavat vähimmäisvaatimukset pakkausketjun kaikille toimijoille kemikaalien (kuten muovin lisäaineet) ja raaka-aineiden (kuten paperintuotantoon käytetty kuitu) tuottajista ja maahantuojista aina FCM-materiaalien loppukäyttäjiin ja kaupan alaan, mihin kuuluvat EU:n sisäinen kauppa, tuotteiden maahantuonti EU:n ulkopuolisista maista ja vähittäismyynti. Muistilistat on laadittu yritysten omavalvontadokumentaation hallitsemiseksi ja vaatimustenmukaisuus -ilmoitusten tekemiseksi. Niitä voidaan edelleen käyttää omavalvonnan ja sen dokumentaation kehittämiseksi, jotta se paremmin vastaisi erityisesti FCM-asetuksen mutta myös alan erityislainsäädännön vaatimuksia.

Muistilistojen tarkoitus on myös ohjata kaupan ja teollisuuden alalla tapahtuvaa omavalvonnan ja dokumentaation vaatimustenmukaisuuden toteutumisen valvontaa Pohjoismaissa.

Projektin on edelleen tarkoitus toimia tulevaisuudessa perustana yksi- ja monikerrosmateriaalien vaatimustenmukaisuutta koskevien ilmoitusten tarkemmalle määrittelylle. Ohjeita on päivitettävä jatkuvasti sitä mukaa kun EU:n lainsäädäntö tällä alalla laajenee. Vaatimustenmukaisuutta koskevat ilmoitukset perustuvat useisiin EU:n säädöksiin kuten elintarvikeasetukseen, hygienia-asetukseen ja FCM-asetukseen[36].

Tällä hetkellä (v. 2007) EU:n komissiolla on 2–3 asetusta työn alla. Tästä seuraa, että tietoja ja vaatimustenmukaisuutta koskevien ilmoitusten sekä FCM-dokumentoinnin menettelyjä on jatkuvasti päivitettävä elintarvikkeita koskevan lainsäädännön noudattamisen varmistamiseksi.

Raportin muistilistat käsittelevät FCM-materiaaleja koskevia elintarviketurvallisuuteen perustuvia lainsäädännön määräyksiä. Kaupan ja teollisuuden alan yritysten on useimmissa tapauksissa noudatettava muitakin FCM-materiaaleja koskevia vaatimuksia, joita ovat mm. hapenläpäisykykyä ja lujuutta koskevat tekniset vaatimukset, mutta näitä ei ole käsitelty tässä raportissa. Tällaiset vaatimukset voivat olla merkityksellisiä määriteltäessä FCM-materiaalien tarjoamaa suojaa esim. zoonooseja ja fyysisiä vaikutuksia vastaan. Teollisuus joutuukin ottamaan nämä vaatimukset huomioon eri FCM-materiaalien ja elintarvikkeiden edellyttämällä tavalla.

Työn kuluessa on havaittu, että jatkotoimenpiteet ovat tarpeen niin kaupan, teollisuuden kuin viranomaistenkin taholla. Raportti sisältääkin ehdotuksia ja suosituksia siitä, miten FCM-tietämystä ja omavalvontaa voidaan parantaa ja päivittää.

[36] EY:n elintarvikeasetus 178/2002, valvonta-asetus 882/2004 ja FCM-asetus 1935/2004

Samantekt

Innra eftirlit og skráningar sem því fylgja eru trygging þess að löggjöf sé fylgt, bæði hvað varðar matvæli og efni og hluti í snertingu við matvæli (hér eftir kallað: „efni og hlutir"/EOH). Þessar leiðbeiningar eru ætlaðar sem gátlisti fyrir skriflega yfirlýsingu og markhópurinn er seljendur og framleiðendur á Norðurlöndunum og innan EB, ásamt ráðgjöfum og rannsóknarstofum sem vinna með efni og hluti. Markmiðið er einnig að hafa áhrif á þá vinnu sem fer fram innan EB/EES og stuðla að meira samræmi í kröfum vegna EOH bæði innan EB en einnig frá þriðju ríkjum sem framleiða EOH, sem flutt eru inn til EB.

Skýrslan og gátlistarnir sem henni fylgja eru hugsuð sem leiðbeiningar til iðnaðar og verslunar til að tryggja að löggjöf um EOH sé fylgt. Löggjöf innan EB á þessu sviði er að finna í mismunandi reglugerðum og tilskipunum, þar má nefna reglugerð um almennar meginreglur og kröfur[37]og reglugerð um hollustuhætti[38]. Að auki ná reglugerðir nr. 1935/2004, um efni og hluti í snertingu við matvæli og reglugerð nr. 2023/2006 um góða framleiðsluhætti, yfir allar gerðir efna og hluta og framleiðslu þeirra. Í sérreglugerðum um plast, leirhluti og sellulósafilmu er einnig að finna sérákvæði, svo sem um mörk vegna heildarflæðis efna og sértækt flæði og aðferðir til að mæla það. Í reglugerð um matvælaeftirlit[39] er að finna nánari ákvæði um eftirlit.

Matvælaeftirlitsstofnanir á Norðurlöndum hafa unnið þessar leiðbeiningar þar sem fram koma lágmarkskröfur sem gerðar eru til skráninga til að uppfylla lögbundnar kröfur vegna innra eftirlits framleiðenda og seljenda. Skráningarnar eru grunngögn vegna skriflegra yfirlýsinga. Skrifleg yfirlýsing getur ýmist verið samhljóða þessum gögnum eða útdáttur úr þeim. Grunnþættirnir í gátlistanum teljast lágmarkskröfur sem gerðar eru til innra eftirlits almennt í öllum þáttum framleiðslukeðjunnar.

Efni og hlutir er víðtækt svið þar sem mörg mismunandi efni eru notuð í mismunandi tilgangi. Því er þörf á sérstökum leiðbeiningum á þessu sviði. Sem dæmi um efni má nefna plast, pappír, málma og málmblöndur, leður, tré og kork. Sum þessara efna geta verið samsett úr kemiskum efnum eða öðrum hráefnum svo sem trjákvoðu og prentbleki. Við framleiðslu annarra efna geta verið notuð kemisk efni, til dæmis er plast framleitt með fjölliðun úr einliðum.

Gátlistinn sem fylgir skýrslunni er rammi fyrir þær lágmarkskröfur gerðar eru til allra þátta í framleiðslukeðjunni, allt frá framleiðendum og

[37] Reglugerð EB um matvælalög nr. 178/2002
[38] Reglugerð EB nr 852/2004 um hollustuhætti við framleiðslu og dreifingu matvæla
[39] Reglugerð matvælaeftirlit nr. 882/2004

innflytjendum á kemiskum efnum og hráefnum eins og aukefnum í plasti og kvoðu til pappírsframleiðslu, til þeirra sem nota tilbúin efni og hluti í matvælaframleiðslu og í viðskiptum innan og utan EB. Gátlistinn er hugsaður sem útgangspunktur fyrir iðnaðar- og verslunarfyrirtæki við framkvæmd innra eftirlits og skriflegra yfirlýsinga um að lögum og reglum sé fylgt. Gátlistana má einnig nota við uppfærslu á núverandi skriflegum yfirlýsingum um að reglum sé fylgt og á það sérstaklega við EB reglugerð 1935/2004 en einnig um fleiri ráðstafanir á þessu sviði. Gátlistarnir eiga einnig að nýtast opinberum eftirlitsaðilum við eftirlit með innra eftirliti.

Þessu verkefni er ætlað að vera upphaf frekari vinnu sem þarf að fara fram vegna skriflegra yfirlýsinga um bæði einlaga og marglaga efni í snertingu við matvæli. Þessi vinna þarf að vera í sífelldri endurskoðun þar sem stöðugt er unnið að viðbótum á lögum á þessu sviði. Lagagrunn fyrir kröfu um skriflega yfirlýsingu vegna efna og hluta í snertingu við matvæli er að finna í ýmsum þáttum EB löggjafarinnar, lög um matvæli, reglugerð um hollustuhætti og reglugerð um efni og hluti í snertingu við matvæli.

Þegar þetta er skrifað (2007) eru 2–3 reglugerðir á dagskrá framkvæmdastjórnar EB. Það undirstrikar stöðuga þörf á að endurnýja þekkingu á þessu sviði.

Gátlistarnir í þessari skýrslu snerta kröfur í löggjöf um efni og hluti og löggjöf um hugsanlega hættu sem heilsu neytenda kann að stafa af flæði efna úr EOH í matvæli.

Framleiðendur og seljendur EOH þurfa í mörgum tilfellum að uppfylla frekari kröfur um tæknilega eiginleika, svo sem um gegndræpi súrefnis, styrkleika o.fl., en slíkar kröfur eru ekki efni þessarar skýrslu. Þær kröfur geta verið mikilvægar til að matvælaumbúðir skili hlutverki sínu og verji matvæli fyrir ytri áhrifum svo sem mengun. Þessar kröfur beinast til iðnaðarins og skoða þarf bæði EOH og matvælin í hverju tilfelli fyrir sig.

Í tengslum við þessa vinnu hefur komið í ljós að þörf er á frumkvæði bæði frá iðnaði, verslun og yfirvöldum. Því eru í skýrslunni tillögur að framtíðarvinnu við endurskoðun og endurnýjun þekkingar á sviði innra eftirlits er varðar efni og hluti í snertingu við matvæli.

Annex I

Legal requirements and selected references.

Legislation on FCM lists a number of requirements. This Annex intends to give a short overview of the FCM legislation, but it must be recognised that it is important to have detailed knowledge of the content of the full texts.

The EU Commission has a detailed overview on its webpage: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm This page has links to the individual EU directives and regulation, and also an overview on national legislation in the Member States.

The Nordic countries have information on their WebPages; too; please find the addresses below.

A. Legal requirements.

FCM is a board area comprising many different materials like plastics, rubber, metals and alloys, paper and board etc., and combination materials of these materials. Laminates can consist of e.g. plastics, metals, printing inks, surface coating etc.

All types of FCM are covered by the requirements in EU Regulation 1935/2004 and for some, also special measures exist like for plastics and cellulose regenerates.

*The general requirements in Article 3 states that m*aterials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

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

The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Requirements on hygiene, control and in-house control are found in other parts of the legislation, please see below.

B. National guidelines

The EU hygiene regulation addresses national guidelines (Article 8) for good practise. As an example, these guidelines are named Code of sectors (of industry or trade). The Codes are guidance documents for good hygienic practise and recommendations on issues relevant for productions, e.g., the use of FCM. The Codes is regarded as support for the individual enterprises in a sector in compliance of the requirements on hygiene and in-house control. It is a task for the sectors to elaborate the Codes.

The Codes does address typical elements and processes used in the sector e.g. described as flow diagrams and description on how to comply with the relevant legal requirements in practise. The Codes shall address examples of risk assessments, critical control points, surveillance procedures and procedures for correction of failures in the sector.

These Codes are not in-house control programs for individual industries, but are used as guidance, support and inspiration for those industries that develop in-house control programs.

C. In-house documentation

Requirements on in-house control, including documentation with declaration of compliance are found in several parts of the harmonised EU legislation:

1. Food Law regulation no. 178/2002
2. Control regulation no. 882/2004
3. FCM regulation no. 1935/2004 (FCM)
4. Hygiene regulation no. 852/2004 and
5. GMP regulation no. 2023/2006 (FCM)

In-house control and documentation of this control shall ensure compliance with the requirements on food safety, including the requirements in the EU Regulation 1935/2004 on FCM. The individual companies have the responsibility to develop, maintain and update the necessary in-house documentation.

In-house control is the systematic routines that the industry and trade have to perform to ensure that the requirements in the legislation on food, including FCM are fulfilled. In-house control is a daily supervision and a periodical control of compliance with the legislation.

The in-house control shall ensure that industry and trade have procedures to the surveillance of

- Products will not endanger human health
- Compliance with relevant legislation

All companies shall have in-house control programs independent of size. This is a EU requirement. In-house control shall ensure food safety, qual-

ity, and hygiene and prevent failures. The in-house control program shall be developed in the individual enterprises and address the individual productions, trade pattern, products etc. Documentation of in-house control is an on-going process, including registration of failures and corrections of these.

In the Nordic countries, the requirements of registration of the industries and importer differ and so do the public control activities of industry and trade. However, as the EU regulation no. 2023/2006 on GMP will come into force in 2008. This regulation has a list of requirements to the producers of FCM, and the Nordic countries are in a process (2007) of reconsidering the implications of this regulation on public registration and control of these industries.

D. References, food contacts materials legislation – Some selected references and links

1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
2. Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food
3. Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs. (Unofficial consolidated version) with foodstuffs. (Unofficial consolidated version) (Plastics: Basic rules for testing migration)
4. Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs. (Ceramics)
5. Council Directive 85/572 of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (Plastics: list of simulants for testing migration)
6. Commission Directive 93/8/EEC of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (Plastics: Basic rules for testing migration – 1st amendment)
7. Commission Directive 93/10/EEC of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (Cellulose regenerated: Consolidation of 83/229/EEC)

8. Commission Directive 93/11/eec of 10 December 1993, amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (Cellulose regenerated: Amendment)
9. Commission Directive 97/48/EC of 29 July 1997 amending for second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (Plastics: Basic rules for testing migration – 2nd amendment)
10. Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact (Plastics: Codification of 90/128/EEC + 7 amendment)
11. Commission Directive 2004/14/EC of 29 January 2004 amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs
12. Commission Directive 2004/1/EC of 6 January 2004 amending Directive 2002/72/EC as regards the suspension of the use of azodicarbonamide as blowing agent
13. Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs
14. Commission Directive 2005/31/EC of 29 April 2005, amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs
15. Commission Directive 2005/79/EC of 18 November 2005 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food.

E. References to other parts of the food legislation, relevant to food contact materials

1. 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 procedures
2. 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.
3. Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on hygiene of foodstuff
4. Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

5. Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption, as amended by Directive 94/34/EC;
6. European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs;
7. European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs, amended by Directives 96/83/EC and 2003/115/EC and Directive 2006/52/EC;
8. European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners;
9. Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, and its amendment directive 2007/68/EC.

F. EU guidelines

Some guidance is found on the Commission and the EFSA websites:

- EU Commission
  http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm
- EFSA, AFC-panel (risk assessors for FCM):
  http://www.efsa.europa.eu/science/afc/afc_guidance/722_en.html

G. Nordic sites with overview on legislation, guidance etc.:

Denmark

FCM: Danish Veterinary and Food Administration
www.fvst.dk/fødevaresikkerhed/materialeroggenstande.

Food Additives: http://www.foedevarestyrelsen.dk/Foedevaresikkerhed/Teknologi_tilsaetningsstoffer/forside.htm

Finland

Finnish Food Safety Authority Evira
http://www.evira.fi

Iceland

The Environment and Food Agency of Iceland
http://english.ust.is

Norway
Mattilsynet: http://www.mattilsynet.no/mat/mattrygghet/emballasje
Emballagekonventionen: http://www.emballasjekonvensjonen.no

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

Normpack: http://www.stfi-packforsk.se/templates/STFIPage____910.aspx

H. Other international FCM sites of special interest

In cases where no specific legislation is in place, information for the support of the in-house documentation can be e.g. on the sites listed below.

Please note, that this information might be useful as guidance, *but it will be necessary to evaluate the basis for* and the content and relevance of the references used. As an example, resolutions from the Council of Europe might not be based on the risk assessment of the chemicals listed.

Council of Europe
http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/Food_contact/presentation.asp#TopOfPage

BfR
http://bfr.zadi.de/kse/index.htm?lang=en

FDA/USA
http://www.cfsan.fda.gov/~dms/opa-notf.html

UK/Food Standards Agency
http://www.food.gov.uk

I. Other legal requirements, an example to be recognised

The use of FCM is covered by different parts of the EU legislation, like e.g. the solid waste legislation. This report does only address legislation in the food area. However, legislation on chemicals in the EU (REACH) has some implication on the knowledge of the chemicals used in FCM. Therefore, this legislation is briefly mentioned here.

Regulation no. 1907/2006 on Registration, Evaluation, Authorisation and restrictions of Chemicals "REACH".

The EU legislation on chemicals, REACH has some requirements of relevance for the use of FCM. This Annex does not intend to give details on REACH but only to recognise this legislation and its relevance for FCM.

Definitions (Article 3)

1. *Substance*: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
2. *Preparation*: means a mixture or solution composed of two or more substances;
3. *Article*: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

The new European chemicals legislation, REACH (enters into force 1 June 2007, and the new European Chemicals Agency starts operations in Helsinki. The REACH regulation will significantly improve protection of human health and the environment while encouraging innovation and keeping the EUs chemical industry competitive. The Agency, which is responsible for managing the implementation of the new requirements, will launch a website providing key information such as guidance documents, helpdesks and other tools relating to REACH.

New requirements for chemicals

REACH is the most ambitious chemicals legislation anywhere in the world combining the ambition for the highest health and environmental protection with enhancing the competitiveness of European industry.

REACH requires the registration over a period of 11 years of some 30,000 chemical substances in use today, which will be coordinated by the new Agency. This process will allow information gaps on their hazards to be filled and appropriate risk management measures to be identified to ensure their safe use. The onus will be on industry to generate the data required and to identify the measures needed to manage the risks.

The Agency will also run the evaluation of those chemical substances that are suspected of posing a risk to health or the environment and the authorisation system for the use of substances of very high concern, foreseen by REACH.

The REACH authorisation system will strongly encourage companies to switch to safer alternatives. All applications for an authorisation will need to include an analysis of alternatives and a substitution plan where a suitable alternative exists. REACH will also enable more rapid total or partial bans where unacceptable risks are detected. In addition, measures are foreseen to ensure that animal testing is kept to the strict minimum and to encourage the use of alternative testing methods.

The Agency has launched a multilingual website at http://echa.europa.eu. The website serves as a single access point for general information on

chemicals, guidance documents and other tools on how to comply with the REACH legislation. From 1 June 2008 it will also provide an interface for on-line registration of substances.

Further information:
Information on REACH is available at:
http://ec.europa.eu/enterprise/reach/index_en.htm or
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
European Chemicals Agency (ECHA):

(From EU press release on REACH, 1 June 2007).

Annex II
Decision tree to analyse the requirements to a specific material

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[40]) 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: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm#93-10 and Commission Directive 2004/14/EC: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm#04-14	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 *Querqus suber,* possibly additives and surface coatings
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

[40] A multilayermaterial can consist of layers og 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-i	Paper and board, recycled	Regulation 1935/2004	See the Nordic report on paper and board, in press	Fibres, additives, contaminants like chemicals and microbes
3-j	Paper and board, virgin	Regulation 1935/2004	See the Nordic report on paper and board, in press	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
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

Annex III
Abstracts of speeches at the workshop

The Annex contains abstracts of the speeches given at the workshop held in May 2006, in order to highlight some of the information contributing to the background knowledge for the project.

1. Own check declaration of compliance and documentation – legal requirements and guidelines, – Which are obliged to comply with which requirements?

by Maria Florin, Livsmedelsverket, Sweden.

On FCM, a quality assurance system and declaration of compliance and documentation of compliance is the basis for sustainable production, import and use of FCM – in industry as well as in trade.

On January 1st 2006, a new legislation on food hygiene and food safety came into force through four EU-regulations. There are mainly two of these Regulations that deal with FCM. Firstly, *Regulation (EC) No 852/2004* Annex II, Chapter V deals with Equipment requirements. In that chapter, paragraph 1 b) states that all articles, fittings and equipment with which food comes into contact are to (…) be of such materials (…) as to minimise any risk of contamination. Secondly, in *Regulation (EC) No 882/200***4**, we find an explicit demand on inspections carried out: Article 10 requires that the Member States carry out inspections in the field of FCM. In the same regulation, the Articles 11–12 state provisions on sampling and analysis as well as ruling the competent authorities to designate official laboratories.

In *Regulation (EC) No 1935/2004* we find the framework on materials and articles intended to come into contact with food. In the framework, antiques of all materials are excluded. Article 2 defines traceability on the matter as: the ability to trace and follow a material or article through all stages of manufacture, processing and distribution. The general requirements are stated in Article 3 of the Regulation. These requirements are general, and for all to comply with. The Article also states that the consumers must not be misled by the way in which a product is labelled, marketed and presented. In Article 15, requirements on labelling are set

out. An important exception is for articles that, because of their characteristics, are clearly intended for food contact. Depending on weather you are a producer or a retailer, the labelling requirements apply differently. In Article 16, there are rules set for declaration of compliance. Materials and articles shall be accompanied by a written declaration stating that they comply with the rules applicable to them. Appropriate declaration of compliance and documentation shall be available to demonstrate such compliance. The documentation shall be made available to the competent authorities on demand. The Article 17, on traceability, shall apply from the 17th of October 2006. Article 24 is for the Member States to comply with; it presents inspection and control measures.

The Regulation (EC) No 1935/2004 is, as mentioned, a frame work. On some of the areas set out in Annex I of the Regulation, there is specific EC legislation (i.e. the Directive 2002/72/EC relating to plastic materials and Articles intended to come into contact with foodstuffs) in force; on other areas, such as paper and board, there is work in progress in order to present EC-legislation on that specific area. There are also a number of useful guidelines on the matter; these exist both on national and international levels.

2. A Joint Nordic frame for a guideline – the Pro's and Con's

By. Per Fjeldal; Mattilsynet, Norwegian Food Safety Authority

The starting point is: What is the relationship between own-check documentation and in-house control? It is important to acknowledge, that own-check documentation is the written part of the in-house control/quality assurance system.

The legal basis is that in-house control for FCM producers/importers is already a part of national law in Denmark, Norway and other countries, and the legal measures of importance are:

- Hygiene Regulation requires HACCP (Article 5)
  - In-house control for food business operators…While the Control Regulation describe official control with FCM (Article 10, paragraph 2 (iv))
- The EU-regulation for good manufacturing practice (GMP) (EMB/1110) requires:
  - An implemented quality assurance system (article 4)
  - Documentation system (article 7)

In the EU, the legal basis for written Declarations are the EU regulation 1935/2004, article 16 (1) paragraph 1, article 16 (1) paragraph 2.

Detailed requirements is given in the 4th amendment of plastics directive 2002/72/EC, but it would be beneficial to have guidance on the EU-level, especially with respect to Article 9, paragraph 2 (f):

- "Adequate information relative to all substances used"
- Some points concerning "Written declarations/documentation" versus "own-check documentation" are that the collection of written declarations should be implemented in the quality assurance system. This should be done by all downstream users, including the food producer.

Article 9 in the Plastics Directive could serve as the basis for the quality assurance for all producers of FCM and collection of Written Declaration is specifically mentioned in Article 9.

Concerning a Nordic guideline, some advantages are the following:

- This could serve as a starting point for design of check lists
- Could give clues on which questions should be asked to the upstream supplier
- Could serve as a source of information
- Should clarify what is necessary information about single substances used in the production of FCM
- Including their migration
- Harmonized interpretation in northern Europe
- Less obstacles to free trade
- Less recourses used by the food business operators

Drawbacks:

- Some of the food business operators may not agree with the outcome of the workshop, but the question is then: Is this really a drawback?
- Maybe it is important to highlight on what this disagreement is really about?
- The guideline has to be harmonized in the EU!
- May be a joint Nordic initiative could be an input or a starting point for development of a EU-guideline?

The main goal with own-check documentation is that this would enable the downstream user to verify that FCM are produced in compliance with detailed requirements in specific measures, and give confidence that the products comply with the general rules of Article 3 in the framework regulation.

Spin off could be to improve the consumer confident on specific brand names – more sales!!

A concluding remark is, that own-check documentation has no value if it is only a pile of paper collected by the downstream user. The main focus on this workshop therefore should be:

- What information is needed to verify compliance and to ensure that the products are safe
- How to ask the right questions and how to interpret the answers
- More than: Relating the own-check documentation to details in the proposed Articles and Paragraphs in coming EU-measures

3. Practical experience with third party control of compliance declarations and supporting documentation

By Svend A Svendsen, Emballasjekonvensjonen/Matforsk,
www.emballasjekonvensjonen.no

The Norwegian Packaging Convention, EK, is a membership organisation with members from the packaging and food industry and the supermarket chains. It was established more than 30 years ago before the first specific EC-Directive was adopted. The initiative was taken by the producers of PVC and PVC-film to be able to provide conformity with some national regulation. At that time the German BfR-recommendations.

Today EK has 130 members and the power of the EK-system is the requirement of the framework regulation for written conformity declarations put forward by the food industry.

The EK board of directors has entered an agreement with the Norwegian Food Research Institute, Matforsk, to operate the EK-Declaration system and a centre of expertise.

To obtain an EK-Declaration applicant must provide written statements to demonstrate compliance with detailed requirements of EC and national regulation. This includes Compliance Declarations, CDs, from producers of raw materials, CDs from the converters, and Supporting Documentation, SD, regarding the restrictions (e.g. SMLs).

What we receive is very much dependent on the applicant being a converter or an importer of the material. Importers struggle hard to obtain relevant documents from the packaging producers. Nordic EK members among the converters are generally able to provide relevant CDs and SD.

New members generally provide insufficient documents, even if we send check list ahead of the application. Old members seem to provide relevant documents with the application, when they update the EK-declaration every other year, or when new materials are produced.

The last 2 to 3 years the EC-Regulation has become more detailed and more complicated. The general requirement of the Framework Directive, *Article 3*, has been emphasised by the food safety authorities. I believe that we now have a difficult situation for converters, food industry and third party control organisations like EK. This is the right moment for all

those involved to come together and try to set up acceptable guidelines for Compliance Declarations and Supporting Documentation.

4. Practical experience with documentation and control hereof on primary packaging.

by Niels Juul Mortensen, Arla Foods Amba, Denmark.

Through certifying agencies' and authorities' control of the packaging area, we have over time experienced inconveniences with documentation as well as legislation.

Regarding documentation we have experienced that authorities require all documentation to be in Danish, which is inconvenient when trading globally. Differences in local authorities' interpretation of what the documentation should comprise have been a problem, just as a requirement that the documentation should be kept locally not at a central place has been inconvenient.

Furthermore, it appears to be bureaucratic that documentation should follow each packaging delivery, even though it is the same packaging consignment one receives.

Trading directly with packaging manufacturers instead of agents facilitates procurement of documentation, and minor suppliers often don't understand the extent of the documentation, which is required.

The legislation itself is complex and therefore difficult to understand for ordinary food experts. The interpretation of the legislation is difficult to get from The Danish Veterinary and Food Administration, and when asking local regions, there might be different interpretations.

Migration limits must comprise analysis uncertainty and natural variation, which cannot be avoided, and one must be sure to state simulators that may cover the food, which the packaging is used for.

To mention actual legislation specifically in the documentation generates a lot of up-dating work, when legislation is changed.

Furthermore, it would be desirable if EU-legislation were sufficient, instead of Danish Regulations, as foreign suppliers are rarely able to relate to a Danish Regulations.

Finally a draft for a packaging certificate was discussed. The packaging certificate collects the documentation necessary in order to document the appropriateness of the packaging for the food in question.

5. Public food inspection

by Allan Bagge, FVST-Region East, Denmark.

The starting point for the food inspection is regulation 1935/2004 of 27 Oct. 2004 on materials and articles intended to come into contact with food, and especially article 3, general requirements concerning migration. The migration must not:

1. Endanger human health
2. Bring about an unacceptable change in the composition of the food
3. Bring about a deterioration in the organoleptic characteristics

Labelling, advertising and presentation shall not mislead the consumer

In addition to this, compliance with the EU directives on e.g. plastics, implemented in the Danish statutory order on materials and articles intended to come into contact with food has to be controlled.

In Denmark, the establishment shall be registered at the Regional Veterinary and Food Administration, who will inspect each establishment is inspected once a year.

Inspection include: Hygienic standard, in-house control system among other things.

The in-house control system shall cover:

1. Labelling
2. Declaration about compliance (wholesale)
3. Documentation
4. Traceability (27. Oct. 2006)
5. Corrective actions

As an example, the in-house control in the production of plastic bottles has cover the following points

1. Raw materials (supplier gives certificates)
2. Transportation, internal
3. Clean rooms to prevent dust
4. Documentation (foreign bodies, visual check)
5. Analysis: Yeast, mould, total count
6. Traceability, carton label, item no., order no., production date, label no. and controller

In the case of import and wholesale (e.g. bags polypropylen, polyethylen)

1. Declaration from the supplier about compliance
2. Migration analysis every second year (supplier)

3. Labelling, including name of the establishment, item no., batch no., quantity of the coli and sales document about compliance
4. Acceptance of consignment: item no., batch no., quantity, labelling
5. Deviation report and corrective actions
6. Traceability, batch no. on each carton and each item
7. Maintenance
8. Cleaning
9. Suspicion of non-compliance: Contact the RVFA

6. The industry check lists, – what is the content of such? – Need for guidance and industry initiatives?

by Paul Ackermann, Tetra Pak Research, Stuttgart, Germany

Board based packaging materials for packing liquid food are composed of up to seven layers – plastics, aluminium foil, board, printing ink – each having its individual task in the material structure to ensure the requested performance in the finished package. Such a material is a so-called multi-material plastic multi-layer, which was intended in the draft "Super-Regulation" to come into the scope of a Plastic Regulation. This Regulation is on hold, so there is currently no specific measure for such multi-material plastic multi-layers. However, as with all food packaging materials, the Framework Regulation (EC) No. 1935/2004 and its Article 3 apply.

Assessment of compliance and in-house for these materials may be made on basis of applicable Directives, national regulations and recommendations, Council of Europe Resolutions, industry guidelines and standards.

Considering the complex material structure, the specific knowledge of relevant legislation required and the high volumes of material manufactured every day it is impossible to control each and every lot of the finished material individually. So the principal method to achieve compliance has to be: Designing the final structure of the packaging material for compliance. Continuous compliance has then to be ensured by a combination of choice and strict specification of raw materials, composition of laminates and production techniques (See also Code for Good Manufacturing Practices issued by Flexible Packaging Europe – FPE). The complexity requires a matrix organisation for compliance assessment and documentation with input from and shared responsibilities of different organisation in the company, all with their own check lists.

Check lists, documentation exchanged as basis for in-house and responsibilities for each of the following organisations are described:

- Designer / Product Development with responsibility for material structure and its suitability for the intended use
- Product Safety Unit having the specific knowledge on regulatory requirements for FCM and responsibility for approval.
- Base Materials Unit with responsibility for raw material performance and specifications
- Package Performance Unit establishing packaging material specifications
- Purchasing that follows established guidelines
- Material Production that applies Quality Management Systems, Hygiene Standards and Quality Assurance in manufacturing of the finished materials

All these activities are the basis for documentation provided finally to the food packer:

- Packaging material specification for each packaging material type containing description of properties and dimension
- Declaration of compliance which is practically in line with the requirements set out in the draft for a 4th amendment of Directive 2002/72/EC (though such a declaration is legally requested in Regulation (EC) No. 1935/2004 only for materials and articles which are regulated by a specific measure. However, in their absence national provisions for such declarations may be adopted)

7. Importer, producer and user of FCM: IKEA way of securing product compliance – products and materials in contact with foodstuffs

by Ylva Roos IKEA of Sweden

IKEA is responsible for the entire flow from product development to the retailing stage. Clear routines and division of responsibilities have been established regarding product compliance. Roughly described, the flow looks as follows:

1. *Laws & Standards* department (IKEA of Sweden) defines and interprets valid legislation in IKEA sales countries. As a rule, the strictest law in any country is applied to be able to sell the product on any market.
2. The laws and test requirements are communicated through *specifications*, which are part of the agreement with the supplier.
3. *Risk analysis* is an important step and is made by the product development team and communicated to the supplier and the test labs. This

step includes e.g. foreseeable use of an item, exposure time and temperature of use.

4. The *supplier* is responsible for fulfilment of the specifications. Products are sent to IKEA approved test labs for verifying testing. IKEA rules on quality assurance are part of the business agreement and secure consistency in production and traceability of materials.
5. *The Laws & Standards department approves test labs*. To be approved, the test labs must have quality routines in place and competence in compliance and test methods.
6. *Final product approval* is made at IKEA of Sweden when test reports and other documentation are in place. Verifying tests are performed yearly and when changes to the product have been made.

This secures a safe product through the distribution chain, to the IKEA stores and finally to the customer.

Routines for reporting and handling deviations in compliance issues are well established in the organisation.

Obstacles to fulfilment of legislation mainly concerns interpretation of the legislation, and guidelines on what is regarded as a safe product when standardised test methods are missing. There are sometimes import obstacles when legislation is not harmonised.

8. Food producer/organisation Industry check lists

By Gitte Hestehave, Danish Food and Drink Federation

Danish Food and Drink Federation have very much focus on FCM. Our members often seek advice and have a lot of questions about the issue. The questions also include the self-control system: What is enough to check to be sure that FCM are safe and the regulations are followed? Therefore we have written guidelines on FCM for our members:

The guidelines have 3 main subjects:

1. The legislation
2. What should the packaging producers know about the foods?
3. What should the food producers know about the packing materials?

In the guidelines we summarize the legislation as a whole, and we refer to the Danish Veterinary and Food Administration's homepage.

Here are some examples, which it could be relevant to inform the packaging producers about:

Food category; Grease/oil-containing product; Filling/brine; Salt content; pH value; A_w (water activity); Alcohol level; Consistency; Filling

conditions: temperature, headspace, volume, contact area; Closing conditions; Pasteurisation/autoclaving; Transportation; Storage.

The food producers have the responsibility for their products incl. the FCM sold to the retailers or final consumer. We suggest a solemn declaration for the suppliers of the packaging materials. The food producers fill out relevant information about the foods and then let the packaging producers sign the declaration. We request our members to be in dialogue with the packing suppliers. It always gives the best result if you talk together and are able to solve problems together. It means you have.

9. FCM: Traceability & own checks – Food (and kitchenware) importer

by Matti Kalevo, Kesko Oyj, Finland

Kesko Food Ltd. is an affiliated company of Kesko Corporation, the latter being the leading trading company in Finland. Kesko Food employees about 9800 persons and it's turnover in year 2005 was about 3 800 M€. This scores up the market share of 34%, which makes Kesko Food to be the number two in Finnish food markets. Number of stores is 1041.

Product Research Unit of Kesko Food is responsible of the product safety and product quality of the assortment of Kesko Food. Product Research Unit is also responsible of the product development (together with suppliers) of the private label products of Kesko Food. Product research Unit consists of four teams: research team, laboratory, test kitchen, and consumer service. All of these teams are more or less involved also in packaging matters.

1. Foodstuff packages & near-food products

Control of foodstuff packages could be seen as part of the normal routine QA activities, which of course focus mainly on the food products themselves. These routines include e.g.:

- Procedures to select the most appropriate products for Kesko Food's assortment. Some sensory evaluation and testing is carried out for packages, too.
- One page (total 15) of the specification form of the private label products is dedicated to packaging items. Questions are asked about traceability and traceability coding, suitability for use in food contact, and material declarations.

- Being the audit committed by a third party international standard organisation or by Research Unit itself, also some attention is paid for safety and handling of packaging materials.

Control of near-food (private label) products is as much as appropriate equal to foodstuff (private label) products.

2. Packaging materials at stores

Besides products, that are meant to be sold and paid, Kesko Food supplies also "loose" packaging materials to its stores. E.g. plastic bags, paper/plastic wrappers, and tubs of all kinds. These materials are controlled, so that they:

- Are suitable for use in food contact (if valid).
- Have traceability coding.
- Are printed according the guidelines of Kesko Food.

Some laboratory and test kitchen testing is also done for these materials.

3. Kitchenware

Kesko Food and Keswell (another affiliate of Kesko Co.) import also kitchenware. Product Research Unit's Speciality Goods Research Engineer is responsible of quality management of these products. These activities include the assurance that kitchenware products fulfil the requirements of EU and Finnish (some conflict between these two!) legislation. Some chemical testing, e.g. heavy metals, is also carried out.

10. A food industry/organisation – and how can we use these results?

By Jens Munk Ebbesen, Head of Food Department, Danish Meat Association

The Danish Meat Association is an organisation representing

- Slaughterhouses (beef, poultry and pork)
- Cutting plants
- Meat product factories
- Egg industry

Food Department is working in the fields of veterinary and food legislation, national and international (EU, USDA, etc.), veterinary problems

related to the meat industry, hygiene and meat inspection, export problems, Salmonella surveillance and communication and on other zoonoses.

Food contact materials are part of the work and for the food industry, the results of the workshop are of interest because, the industry has a list of interests like safe products, image (public opinion, consumer). Furthermore the food industry has responsibility, and likes to have influence on developing and implementation of legislation.

The food industry has an interest in guidelines to facilitate an easier "daily life" for the industry.

The starting point is that the legislation is ccomplicated, just for experts; it is changing very often and there can be conflicts between national legislation and EU legislation, and third country supplier's focus on EU legislation. Therefore guidelines from national authorities on own-check documentation would be helpful.

The wish list for the guideline is that it should be as "simple" as possible and as un-bureaucratic as possible. There should preferable not be a request for documentation for each delivery (only if conditions and/or compositions change) but the documentation could be found centrally, and e.g. at the link of the suppliers of FCM.

The suppliers of FCM shall be responsible to fulfil the demands in specifications and in the legislation. They shall issue Declarations of compliance and relations between FCM suppliers and food industry should be established.

Subjects of relevance for the contact between the FCM supplier and the food industry are the following:

- Dialog
- Information flow
- Thrust and confidence

Conclusions of FCM and the tasks for the food industry

- FCM has got growing attention
- Own-check plans/documentation are key issues
- The legislation is complicated and harmonization needed
- Guidelines from authorities needed
- Clear roles of responsibility needed

- Increase of knowledge and competence is needed
- Check lists as very useful tools

Finally, exchange of experience is needed e.g. during workshops, networks etc.

Annex IV
Workshop participants

Participants	Company	Category
Finland		
Vesa Tuomaala	Min. of Trade and Industry	Authority
Pirkko Kostamo	Evira, the Finnish Food Safety Authority	Authority
Representative of	Stora Enso Oyj	Packaging producer
Birgit Aurela	KCL (Oy Keskuslaboratorio-Centrallaboratorium Ab)	Laboratory, consultant
Siru Kauko	Finnish Customs Laboratory	Laboratory, consultant
Tanja Virtanen-Leppä	Valio	Food industry
Merja Virtanen	City of Tampere	Authority
Mats Hägerström	Huhtamäki Oyj	Packaging producer
Marjut Salmisalo	Huhtamäki Oyj	Packaging producer
Denmark		
Laila Lundby	Danish Dairy Ass.	Food industry
Lisbeth Højrup	Danish Meat Association	Food industry
Gitte Hestehave	Danish Council of Industries	Food industry org.
Kirsten Jacobsen	De Samvirkende Købmænd	Retailer organisation
Jessie Hallas	Coop Norden AB	Retailer chain
Jørgen Bentzen	Dansk supermarked	Retailer chain
Tine Skriver	HTS	Retailer/importer org.
Lars Blom	Plastindustrien i DK	Packaging organisation
Malene Villadsen	Polyprint	Packaging producer
Lone Alstrup	EmballageIndustrien	Packaging organisation
Jane Pors	Eurofins Denmark A/S	Laboratory, consultant
Bente Fabech	NVFA	Authority
Per Rathmann	NVFA	Authority
Rikke Benyahia	NVFA	Authority
Iceland		
Grimur Olafsson	EFA	Authority
Baldvin Valgarðsson	Iceland Dairies	Food industry
Norway		
Siv Hæreid	Elopak	Food packaging industry
Paul Aitkenhead	Mills	Food industry
Atle Pedersen	Rieber & Søn	Food industry
Inger Elisabeth Næss	Stabburet	Food industry
Inge Erlend Næsset	Stabburet	Food industry
Sofia Lindgren	Orkla Foods	Food producer
Svend Svendsen	Emballasjekonvensjonen	Consultant laboratory
Per Fjeldal	Mattilsynet	Authority
Sweden		
Niklas Warén	ICA	Retailer
Kristina Salmén	Normpak	Consultant
Lennart Stolpe	Billerud	Food industry
Jan Erik Winlund	Iggesund, Paperboard	Packaging producer
Per-Arne Allroth,	Amcor Flexibles	Packaging producer
Bertil Nilsson	Rexam	Packaging producer

Ulla Stöllman	Orklafoods	Food industry
Evelyn Jansson Elfberg	Livsmedelsverket	Authority
Kettil Svensson	Livsmedelsverket	Authority
Maria Florin	Livsmedelsverket	Authority
Invited speakers		
Paul W. Ackermann	Tetra Pak (Research) GmbH	Packaging producer
Niels Juul Mortensen	Arla Foods	Food Producer
Allan Bagge	FVSA, region east	Food inspection
Gitte Hestehave	Danish Council of Industries	Food industry org.
Ylva Roos	Ikea of Sweden	Producer and importer
Svend Svendsen	Norwegian Packaging Convention	Consultant laboratory
Matti Kalervo	Kesko Oyj	Food importer
Jens Munk Ebbesen	Danish Meat Association	Industry organisation

Annex V
Using migration modelling as a tool for enforcement and risk management

By Jens Hoejslev Petersen, National Food Institute, Technical University of Denmark.

The use of mathematical modelling is accepted due to directive 2002/72/EC.

The verification of compliance with the SML's may be ensured by the determination of the quantity of a substance in the finished FCM provided that a relationship between that quantity in the plastic and the value of the specific migration of the substance has been established either

- By adequate (analytical) experimentation or
- By the application of generally recognised diffusion models based on scientific evidence

Since the responsible FCM industry know (or have direct or indirect access to) the composition of the materials they use, diffusion modelling is an excellent opportunity to obtain the necessary documentation required for their own-check programme in a very economically way.
In the "Practical Guide" the EU Commission recommends that also the enforcement authorities use modelling as a tool in enforcement work to avoid long and expensive analysis. However, it is underlined that

- Modelling alone is only sufficient proof for compliance, while
- Experimental measurement is needed to verify non-compliance

In the "Practical guide" guidance is given with respect to listing of the required obligatory information needed for using predictive modelling:

- The basic formulas to use in predictive diffusion modelling
- The polymers for which modelling can be applied
- A list of authorised substances suitable for migration modelling
- A survey of limitations in the practical use of modelling, in example
  - FCM must be a homogeneous monolayer plastic
  - The compound must be homogeniously distributed
  - The polymer must not be swelling.

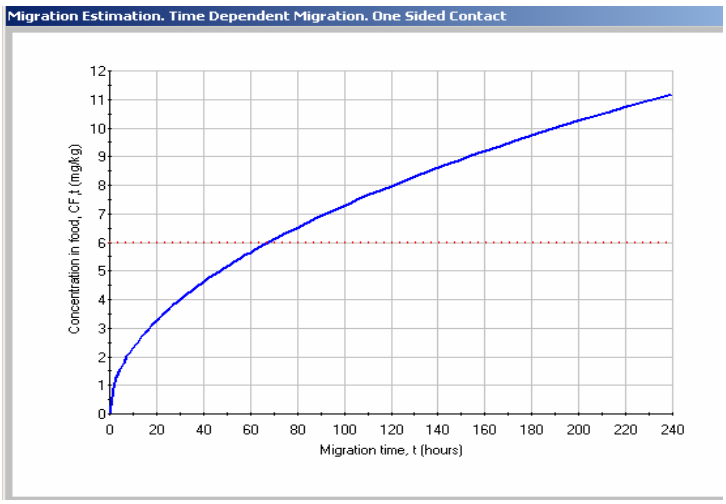
In the public enforcement, it should be considered whether modelling could be implemented as a tool for the routine food control. *The traditional enforcement approach* includes a highly specialised laboratory, which make the planning and obtain samples from retail shops, the FCM-industry or the food industry. The food inspector must follow up on results, potentially with sanctions.

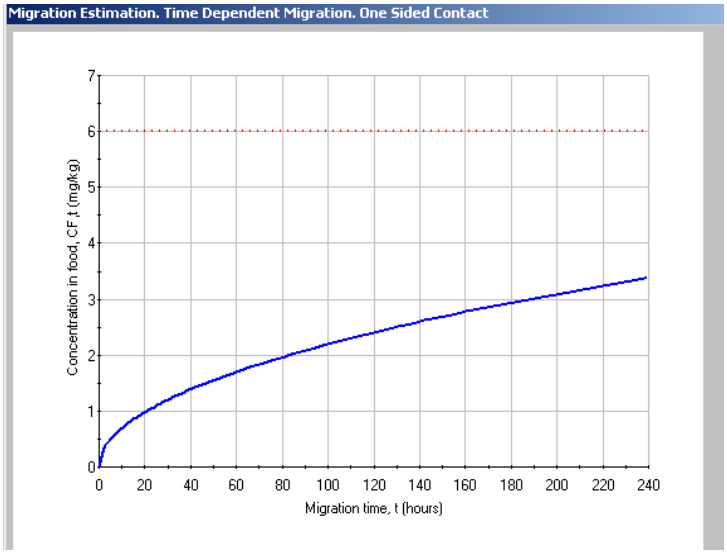
When using the modelling approach, in principle, the food inspector is responsible for all steps from sampling to follow-up, including selection of appropriate software. There are different types of software on the market, like the freeware: SMEWISE/MULTIWISE (INRA, France) and commercial softwares like Migratest Lite 2001 (Fabes) and SML (Bundesamt für Gesundheit/AKTS, Swiss). More information can de found at the homepage for the FCM Central Reference Laboratory at http://crl-fcm.jrc.it/. As examples, it can be mentioned that the software Migratest Lite is not too difficult for the non-expert to use, it has a rather user-friendly interface and a report with a survey of all variables can be printed out

The input data needed for a model calculation is:

Polymer	**Migrating substance**	**Food/Food simulant**
Type Thickness Density	Name, PM or CAS nr. Molecular weight, Concentration in food Solubility in food	Aqueous/fatty Density of food D-reduction factor Soon to come: FRF
Size and shape		**Contact**
Contact area Volumen of food Single/double sided contact		Time Temperature Combinations hereof

After input of these basic data, the effect on migration to the food coming from changes in parameters like storing temperature or packaging size. An example of this is shown below:





Migration of Irganox 1076: Contact area increased from 6 to 20 dm²/kg food

Overall conclusions on practical use of the mathematical modelling in enforcement are that mathematical modelling of migration can be a useful tool for food inspectors as well as for producers of final plastic materials, provided data about composition of the materials were easily accessible. However, to ensure a more widespread use in enforcement, the burden of proof should preferably be on the producer/importer when experimental testing is needed to demonstrate non-compliance.

In the chemical enforcement laboratory, mathematical modelling of migration can be a useful supplement to experimental measurements.