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Control of declarations of compliance (DoC)





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Summary

Finland, Sweden, Denmark, Norway, Iceland and the Faroe Islands have conducted a joint Nordic project focusing on food contact materials (FCM) in 2013–2015. The FCM area has been prioritized in the Nordic cooperation for many years. The Nordic Working Group for Food Safety (NMF) under the Nordic Council of Ministers funded this joint project. The project has been carried out in synergy with another Nordic project on FCM, funded by the Nordic Working Group for Diet, Food and Toxicology (NKMT) also under the Nordic Council of Ministers. The project funded by NKMT has developed a check list on documentation for FCM, which the current control in the project with a focus on plastic materials, has used.

Food contact materials are used in all stages of food production and can be a general source of contamination of food. Most of the Nordic countries have had a limited focus on the FCM area with the exception of Denmark and Finland. Thus, the aim of the joint project was to control establishments producing, importing or using plastic food contact materials as well as to increase the knowledge of the inspectors performing these controls concerning FCM.

Producers, importers and food producers (users of FCM) were included in the project. Regarding the term “import” in the report we refer to both FCM imported from a third country and FCM traded from another EU or EEA-country. In Sweden and Faroe Islands, the food safety authorities do not have the legal basis in the national legislation for controlling importers and producers of FCM; hence, in these two countries only food producers that are using FCM were inspected. Denmark and Norway controlled FCM producers and FCM importers whereas Iceland and Finland inspected all categories.

During the project period, project description and reporting forms were developed. A joint training session for all the inspectors was also organized where the project material including “The Nordic check list for food contact materials and declaration of compliance and supporting documentation” funded by the NKMT group was introduced. The Nordic checklist was used during the inspections. In this project, it has been focused on control of declaration of compliance (DoC) for plastic food materials since the requirements for a DoC is mandatory in order to

ensure that the FCM complies with the legislation. In addition some products were analyzed for phthalates.

Regarding the results, of the 178 establishments that were controlled 49 were producing FCM, 52 establishments imported FCM and 80 of the establishments were food producers using FCM. Denmark controlled 26 establishments, Finland 72, Iceland 18, Norway 34, Sweden 24 and Faroe Islands 7. In total, documentation following 280 plastic food contact materials was checked. More than 180 of the 280 plastic products controlled are in the categories plastic films and plastic boxes and trays. Examples of other products were plastic gloves, hoses, tubes, gaskets and conveyor belts.

About 2/3 of the 78 FCM controlled at importers were produced inside EU or EEA, mainly from Germany, but also from Finland, Italy, Sweden, Poland and France. 1/3 of the FCM controlled at importers came from third countries, mainly from China. Other third countries were USA and countries in Asia such as, Vietnam, South Korea, Taiwan and Thailand.

The focus areas of the inspections were the establishments' knowledge of the legislation, their systems for traceability, and whether the establishments could provide a DoC. If a DoC was available the documentation were evaluated with regard to; Name and address of the producer/the business operator, the identity of the FCM, the date the DoC was issued, if the DoC was updated, a confirmation that the FCM complied with current legislation, information about migration of chemicals, Dual Use Additives (DUA) and specification on the use. Finally, the total quality of the DoC was evaluated given the grades "good", "partly ok" or "poor".

As for the results regarding the knowledge of legislation, the producers of FCM had the best result with 78% of the establishments demonstrating sufficient knowledge whereas 52% of the importers had sufficient knowledge. With regard to the system for traceability, nearly all establishments had a traceability system, but the quality of it varied.

Of the 280 products controlled, 69 were from producers of FCM, 78 from importers and 133 from food producers using FCM. In total in the Nordic countries, the business operators presented a DoC for 89% of the products. For the rest of the FCMs no DoC was provided. In Denmark and Faroe Islands, all establishments (100%) had a DoC, in Finland 97%, in Iceland 83%, in Sweden 77% and in Norway 76%.

When it comes to the content in the DoCs the report focuses on the results from migration of chemicals to the food, Dual Use Additives (DUA) and specification of use. Concerning migration of chemicals 53% of the DoCs had adequate information about the migration of chemicals

from the FCM to the food. With regard to Dual Use Additives (DUA) 59% of the DoCs presented sufficient information, and concerning specification of use 70% had satisfactory information.

Regarding the total quality of the DoCs, 45% of the DoCs had sufficient information and therefore evaluated as “good quality”. The variation in percentages when it comes to DoCs evaluated as “good quality” varied from 81% in Denmark, 50% in Faroe Island, 45% in Finland, 43% in Sweden, 27% in Norway and 25% in Iceland.

Nineteen samples of soft plastic for use in contact with fatty food were analyzed at the Technical University of Denmark (DTU). The analyzed samples were conveyor belts, gloves, hoses, screw caps/lids and plastic films and the samples were analyzed for phthalates (DBP, DEHP, DiNP, DiDP). Non-compliant products were found in several categories of FCM with an apparent overall frequency violation of 32%. The non-compliant FCM samples were gloves, hoses and conveyor belts were DEHP and DBP were found in amounts higher than the Qm or DiNP higher than the specific migration limit.

The results from this project indicates that the establishments producing, importing or using food contact materials still needs to improve their work issuing and controlling the declarations of compliance for these materials. To achieve this, the food safety authorities should continue their control activities at all stages in the FCM-chain.

Nordic enforcement projects

An enforcement project is a fixed term project that examines compliance with the regulatory framework in a sector for a particular product or group of products. The company inspections are coordinated in terms of timing and content, thereby providing valuable information about the subject at a particular point in time. Generally speaking, a guidance document is prepared and the project begins with a training course for inspectors. In an enforcement project, the inspection body also uses other tools, such as information and collaboration with sector organisations and other bodies, to encourage companies to comply with the regulatory framework.

1. Background and implementation

1.1 Background

Food contact materials (FCM) are used in all stages of food production and can be a general source of contamination of food. FCM has been prioritized in the Nordic cooperation for many years in order to improve knowledge, information/guidance, in-house documentation and control. However both EU's Food and Veterinary Office and ESA, EFTA's Surveillance Authority, have made their remarks to some of the food authorities in the Nordic countries to enhance the control with FCM.

The joint Nordic project focusing on FCM, which is reported here, is a control project funded by the Nordic Working Group for Food Safety and Consumer Information (NMF) under the Nordic Council of Ministers. The project period was from 2013 to 2015. The project has been carried out in synergy with another Nordic project on FCM, funded by the Nordic Working Group for Diet, Food and Toxicology (NKMT) also under the Nordic Council of Ministers. The project funded by NKMT is developing a check list on documentation for food contact materials (declaration of compliance and supporting documentation), which the current control project with a focus on plastic materials has applied and benefited from.

Declaration of compliance (DoC) and supporting documents are necessary to show that FCMs are in compliance with the regulations. The focus of this control project has therefore been on the quality of DoCs, and some analysis of migration of phthalates from food plastic contact materials have also been included.

The producers and importers of FCM enterprises are responsible for the documentation and the quality of it. However, it can be difficult for them to receive enough reliable information and perform tests to ensure sufficient documentation. The authorities have to inspect many different layouts of DoCs and supporting documents. It is often difficult to assess the quality of a DoC and if the background documentation is sufficient. Training of food inspectors, e.g. by practicing inspections, is needed in order to get a harmonized understanding and joint interpretation of the requirements for the documents. Also guidance to

the industry is often needed. Therefore this control project, in synergy with the project on the Nordic checklists, has offered tools to achieve these goals in the Nordic countries.

1.2 Objectives

The expected effects of the project are:

- Increased compliance with the requirements for food contact materials in FCM and food establishments in the Nordic countries.
- An enhancement of competence in the control authorities, FCM establishments and food establishments within the Nordic countries.
- An improved and harmonized interpretation of compliance of FCM in the Nordic countries regarding DoC and supporting documentation.

The performance measures of the project have been:

- To develop an electronic reporting form including all the relevant check points for the inspections in addition to the control of documentation.
- To arrange training of food inspectors participating in the project.
- To use the check lists which will be produced in the project funded by NKMT, and then collect feedback from inspectors on the usability of these. The check lists will be part of the training and control and after the control has been carried out, the experience will be used for finishing the check lists in the project funded by NKMT.
- To inspect establishments, such as importers and producers of FCM and food producers (which use FCM). The focus will be on plastic food contact materials.
- To carry out a minimum of inspections in each participating country, ideally 25 establishments both FCM and food establishments (reduced number for the smaller countries).
- To look at DoCs for 1–2 products in each establishment.
- To ask for supporting documentation for 5 products in each country. Products of soft PVC that contain plasticizers (phthalates) are relevant for this type of control.
- To analyse plastic products suspected of containing phthalates and meant for contact with fatty food.

- To publish the results as a project report in English in the “TemaNord-series”.
- To publish the results of the analysis in the project report. The results of the analysis could also be presented in an article formate.

1.3 Organisation

Project owner:	The NMF-working group.
Project manager:	Kristina Landsverk (NO), until 31 January 2015. Ole Fjetland (NO) from 1 February 2015.
Project leader:	Ågot Li (NO).
Project group:	Mette Holm (DK), Mette Christiansen (DK) until 31 March 2014, Charlotte Legind (DK) from 1 April 2014, Bjørg Mikkelsen (FA), Pirkko Kostamo (FI), Merja Virtanen (FI), Liisa Rajakangas (FI), Katrín Gudjónsdóttir (IS), Ingibjörg Jónsdóttir (IS), Julie Tesdal Håland (NO), Signe Sem (NO), Christin Furuhausen (SE), Agneta Tollin (SE), Susanne Ekroth (SE) from June 2013, Åsa Lagerstedt Norström (SE) until June 2013 and from September 2014.
Other contributors:	Bente Fabech (DK), Jens Højslev Petersen (DK), Lisbeth Krüger Jensen (DK), Grimur Olafsson (NO).

1.4 Legal basis

The control project was based on the following legislation:

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28th January 2002, laying down the principles and requirements of food law, establishing the Food Safety Authority and laying down procedures in matters of food safety.
- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27th October 2004 on materials intended to come into contact with food.
- Regulation (EC) No 2023/2006 of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

- Regulation (EU) No 10/2011 of the European Parliament and of the Council of 14th January 2011 on plastic materials and articles intended to come into contact with food.

1.4.1 General requirements

The harmonized legislation on FCM includes the framework regulation with general requirements for all types of FCM and for some materials,¹ like plastics, specific measures. FCM covered by this legislation is in their finished state:

- a. intended to be brought into contact with food
- b. already brought into contact with food and are intended for that purpose
- c. 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.

The general requirements for all types of FCM concern among others safety, labelling and traceability. Concerning safety article 3.1 in the framework regulation says that “FCM shall – under normal and foreseeable conditions of use – not transfer their constituents into foodstuffs in quantities which could:²

- a. endanger human health
- b. bring about an unacceptable change in the composition of the foodstuffs
- c. bring about deterioration in the organoleptic characteristic thereof.

Concerning labelling article 3.2 in the same regulation says:

“The labelling, advertising and presentations of FCM shall not mislead the consumers” and article 15 supplies further requirements e.g. the glass and fork symbol.

Also traceability of a material or article is required and should be ensured in all stages of manufacture, processing and distribution. So the

¹ Regulation (EC) No 1935/2004.

² Regulation (EC) No 1935/2004.

business operator shall identify from and to which establishment materials and articles are supplied.

Good manufacturing practice (GMP) for materials and articles intended to come into contact with food are set out in the GMP-regulation which gives general requirements for good manufacturing practice in the production and distribution of all types of FCM. However, this was out of the scope in the current project.³

1.4.2 Declaration of compliance

There is a general EU requirement for a declaration of compliance (DoC) for food contact materials covered by specific measures in EU and EEA. Additionally, some Nordic countries (Denmark and Norway) have national legal requirements for DoC for all types of materials. To ensure equal legal requirement for controlling documentation in all the Nordic countries, it was decided that the control project should focus on plastic food contact materials since the plastic regulation sets out a requirement for a DoC for all types of plastic materials.⁴

The DoC is a document, which shall be used between trade partners. The DoC gives a summary of the supporting documentation for the compliance work of the food contact material. The intention is that a DoC shall ensure the customer that this food contact material is in compliance with relevant legal requirements. Therefore there should always be a confirmation of the compliance with relevant legislation for the FCM in a DoC. The framework regulation is a general regulation,⁵ and should be mentioned. The GMP regulation is also relevant to mention since FCMs should be produced in accordance with good manufacturing practices laid down in this regulation.⁶ In addition for plastic materials, it shall be referred to the plastic regulation.⁷

Requirements for a declaration of compliance for plastic materials are given in Article 15 and in Annex IV in the plastic regulation.⁸ The DoC should follow the FCM at all marketing stages other than the retail stage. This written declaration shall permit an easy identification of the finished materials and articles or products from intermediate stages of

³ Regulation (EC) No 2023/2006.

⁴ Regulation (EC) 10/2011.

⁵ Regulation (EC) No 1935/2004.

⁶ Regulation (EC) No 2023/2006.

⁷ Regulation (EU) No 10/2011.

⁸ Regulation (EU) No 10/2011.

manufacture or substances for which it has been issued. To be up to date it should be renewed when any changes with consequences for the product or the legislation is made.

The DoC should contain information about the identity of the business operator issuing the documentation and the manufacturer or importer of the material or article. Also, the food contact material must have a unique identity to link the DoC to the actual FCM and the date of issuing should be written in the DoC.

Specification on use for the FCM must be part of the DoC, when restrictions concerning for example types of food, temperature and time of treatment and storage or the ratio of contact surface to volume used in testing of the FCM are present. Also the user of the material or article needs information about the presence in and migration of chemicals, e.g. food additives or so-called dual use additives, from the FCM.

This project concentrated on the required information mentioned above, which was considered to be the most critical in the supply chain for FCM, even though Annex IV in the plastic regulation requires more information,⁹ e.g. information about the substance degradation products.

1.4.3 Regulation of phthalates in plastic FCM

Plastic food contact materials brought on the market in EU and EEA shall comply with the restrictions and specifications for the following phthalates: Dibutyl phthalate (DBP), Butylbenzyl phthalate (BBP), Di- (2-ethylhexyl) phthalate (DEHP), Di-isononylphthalate (DiNP) and Di-isodecylphthalate (DiDP). The EU restrictions for phthalates in plastic FCM went into force in 2008 (plastic regulation).¹⁰ In some cases the phthalates used in FCM are regulated by maximum permitted residual contents (hereafter referred to as Quantum maximum, Qm) and in others by specific migration limits (SMLs). The interpretation of the restrictions in the legislation is not easy and was therefore explained in more detail in a guideline from the EU reference laboratory for FCM (Hoekstra *et al.*, 2011). A table of the critical parameters to control is shown in Annex 1.

Control of the migration limits for phthalates can be performed with the food simulants for plastics. Even though migration testing in food

⁹ Regulation (EU) No 10/2011.

¹⁰ Regulation (EU) No 10/2011.

normally prevails over migration testing in food simulants, for prepacked food there is a risk that it may already contain phthalates from other source than the packaging, e.g. from processing equipment. Only when the background phthalate concentration in the food is well known, migration testing with the food itself is possible. Sanctions will depend on a specific risk assessment that must determine whether the food is considered harmful to health (EU's food law).¹¹

Phthalates are lipophilic, which means that the migration to fat will be higher than to other food types. Therefore the analytical control of this project only included plastic samples used for contact with fatty food. For this the food simulant is D2, which is oil. According to the EU plastic regulation,¹² annex 5, a D-reduction factor between 1 and 5 must be applied to the migration test result before comparing with the specific migration limit. The food simulant D2 reduction factor (DRF) compensates for the higher extraction power of food simulant D2 in comparison with certain fatty foods'. DRF was selected from the EU plastic regulation 10/2011, section 4.2 of Annex V.

1.5 Project implementation

Plastics are used in all parts of the food production chain and because specific measures for plastic food contact materials are common for all EU and EEA countries, the project group decided to control documentation for plastic FCMs.

Producers, importers and food producers (users) of FCM were included in the project. Import in this project meant import from third countries as well as traded products from an EU and EEA country into one of the Nordic countries. National traders and distributors of FCM have not been a part of the project.

There was a variation between the six countries concerning the type of establishments controlled. In Sweden and the Faroe Islands the food safety authorities do not have the legal basis in the national legislation for controlling producers and importers of FCM. Therefore in these two countries only the users of the final FCM were inspected.

¹¹ Regulation (EC) No 178/2004.

¹² Regulation (EU) No 10/2011.

Project description, training and reporting forms were prepared to give an overview and to provide necessary information for the execution and reporting of the campaign.

The controls have been done as inspections and the inspectors could choose to make an appointment in advance or make the inspections unannounced. The reporting form made by the project group was used together with “The Nordic checklist for food contact materials and declaration of compliance and supporting documentation” prepared by the project funded by the NKMT group.

1.5.1 Training and information

The Nordic project group organised a training session in Sweden in March 2014 where 41 inspectors from the national control authorities from all the six participating Nordic countries attended. This training gave the inspectors an introduction to the FCM legislation and basic knowledge about food contact materials. A visit to a FCM producer was a part of the training. Other points on the agenda for the training were: The Nordic checklist for Declaration of compliance, and the reporting form to be used in the inspections and for electronic reporting in the system QuestBack. The contact point for each country in the Nordic project group was responsible for organizing their own inspections, for giving information to the inspectors and to the food- and FCM industry in their own country.

The project was presented at two conferences: the Nordic Food Control Conference in Gävle, Sweden in January 2014, where plans for the project and training were presented, and the Nordic Food Control Conference in Reykjavik, Iceland in January 2015, where the preliminary results were presented.

2. Results and discussion

One of the most important effects of the project was to improve and harmonize the interpretation of compliance in the Nordic countries regarding DoC and supporting documentation. There is a variation in the Nordic countries regarding the experience of the inspectors' in controlling FCM. In Denmark and Finland the authorities have prioritised this for some years, whereas in the other countries most of the inspectors involved in this project have less experience. These different levels of experience could have resulted in differences in their observations, and this should be kept in mind when evaluating the results.

The number of establishments and products controlled in this project is low, hence the statistical material is limited. The inspectors' observations will still give an indication of the status of the documentation following FCM in the Nordic countries.

The results presented in this section were reported from the inspectors by use of QuestBack, an electronic system based on questions with predefined answers. Some questions were answered by use of free text. The questions asked are available in annex 2 "Questions in the reporting form".

When planning the project, each country should estimate a minimum of inspections. Faroe Islands should carry out at least 8, Iceland 15 and Denmark, Finland, Norway and Sweden 25 inspections each, totally 123 inspections. Sweden and Faroe Islands had to limit their inspections to only control food producers using FCM. Denmark and Norway inspected producers and importers of FCM, while Finland and Sweden inspected all categories.

2.1 Inspections

2.1.1 *Number of inspections and categories of establishments*

Inspections were carried out in 178 establishments. Additionally a few establishments are registered more than once. One establishment is for example registered as an importer as well as a producer when both activities were controlled in the same establishment. This results in a total number of 181 registered establishments as shown in table 1. Out of these are 49 producers of FCM, 52 importers of FCM and 80 food producers using FCM.

Of the 80 food establishments using FCM most of them were producers of meat-, fish- and milk products. Also there were some breweries, bakeries and several other kinds of food businesses using FCM.

Table 1. Number of establishments inspected in each country

Country	Producing FCM	Importing FCM	Food producers using FCM	Total number of establishments registered
Denmark	15	11	0	26*
Faroe Islands	0	0	7	7
Finland	20	17	35	72
Iceland	3	1	14	18
Norway	11	23	0	34
Sweden	0	0	24	24
Total	49	52	80	181

*The number of establishments inspected in Denmark were 34, but 8 inspections were not reported in QuestBack. The results from these 8 inspections are not a part of the results presented in this report.

Of these 178 establishments, the documentation following 280 plastic food contact materials or articles was checked. See table 2.

Table 2. Number of food contact materials (FCM) controlled in each country

Country	At producers of FCM	At importers of FCM	At food producers using FCM	Total number of FCM controlled
Denmark	18	13	0	31
Faroe Islands	0	0	10	10
Finland	31	25	58	114
Iceland	6	1	17	24
Norway	14	39	0	53
Sweden	0	0	48	48
Total	69	78	133	280

2.1.2 Categories of food contact materials

Documentation for different product categories or types of plastic food contact material was controlled.

Table 3. Categories or types of food contact material controlled

Category/type of FCM	Producers/importers	Food establishments	Total
Plastic film (included cling film)	47	61	108
Plastic boxes and trays	42	30	72
Plastic bottles	15	8	23
Plastic gloves	4	5	9
Plastic tubes	7	2	9
Twist caps and gaskets in metal screw caps	3	4	7
Conveyor belts	5	2	7
Others*	24	21	45
Total	147	133	280

*Others include a wide range of different plastic materials and articles intended for contact with food.

When choosing a food contact material for control in a food establishment, the focus was FCM intended for use with fatty food, but other food contact materials were also included. The risk of migration of lipophilic chemicals, e.g. phthalates, from FCM to food is highest for fatty food.

As presented in table 3, more than 180 of the 280 products controlled are in the categories plastic films and plastic boxes and trays (108 and 72). These are articles that are used in most of the food industry and by the food retailers. Plastic articles in plastics intended for food are also sold directly to consumers in different kind of retailer stores, such as Biltema and Ikea. Of the controlled products, there are also more than 20 plastic bottles in addition to other articles such as plastic gloves, hoses, tubes, gaskets and conveyor belts. The total number of food contact materials controlled is not very high, but the type of products can be considered as representative samples for plastic food contact material used in the Nordic countries.

2.1.3 Origin of the imported FCM

When using the term “import” in this project it includes import from third countries as well as traded products from an EU and EEA country into one of the Nordic countries.

At producers and importers of FCM a total of 147 products were controlled. 69 of the products controlled were produced in the Nordic country where the control was carried out, whereas 78 of the 147 products were imported from a third country or an EU or EEA country. Information on the country of origin of the imported food contact

materials was included in the survey. If the food contact material was originated from a third country, it was determined if it was imported directly from the third country or via another country in EU or EEA.

The EU legislation is not directly applicable in third countries. However, if FCMs are imported into EU or EEA it is the importer that is obliged to issue the DoC to fulfil the requirement of the EU legislation. To make the declaration, the importer has to get adequate documentation from the producer or carry out investigation of the food contact material to make this documentation.

About 2/3 of the 78 FCM checked at importers were produced in EU or EEA. The origin of the FCMs and their relative percent were:

- Germany 25%.
- Finland 15%.
- Italy 10%.
- Sweden 8%.
- Poland 8%.
- France 8%.
- 26% other countries in EU (Netherlands, Belgium, United Kingdom, Estonia, Lithuania, Spain).

Of the 26 products imported from third countries (34% of 78), 12 had its origin in China (Figure 1). Most of the import from third countries came directly to the Nordic country where the control was carried out.

Figure 1. Origin of food contact material imported to the Nordic countries

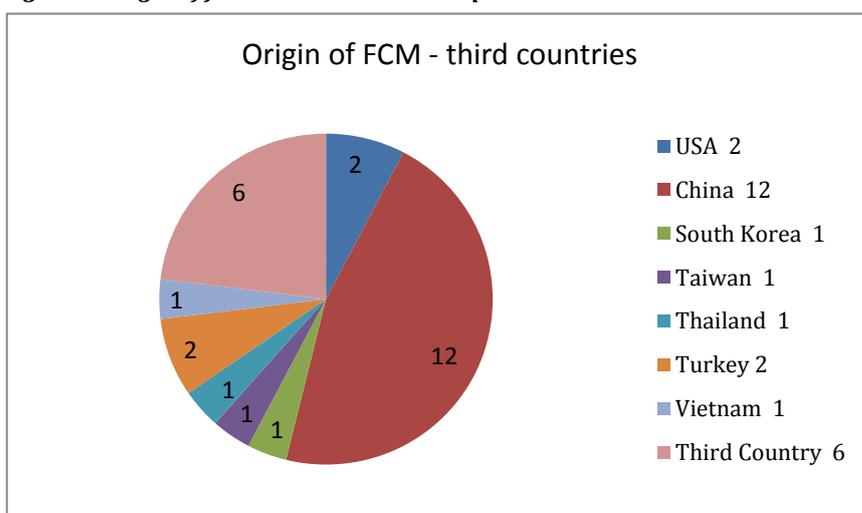


Figure 1 shows the origin of 26 of the 78 products checked at importers of FCM. The rest (52) had its origin in EU or EEA countries.

Table 4 demonstrates that of the 14 imported products without a DoC, eight of them had its origin in a third country. This demonstrates that getting a DoC is also a challenge when trading FCM inside EU and EEA. Thus, it is important that the authorities in all EU or EEA countries are controlling their producers of FCM.

Table 4. The origin of FCMs without a declaration of compliance (DoC) and imported to a Nordic country

Country of inspection*	Originated in a third country	Originated in EU/EEA	Total
Denmark	0	0	0
Finland	2	0	2
Iceland	0	0	0
Norway	6	6	12
Total	8	6	14

*Faroe Islands and Sweden did not inspect producers and importers of FCM.

2.2 Knowledge of legislation

The business operator producing, importing or using FCM is responsible for the compliance with the requirements in the legislation. They should therefore have knowledge of the relevant legislation. The inspectors asked if the business operator could give an account of the legislation for food contact materials, i.e. the framework regulation,¹³ the GMP regulation and the specific regulation for plastic.^{14, 15} The results of the establishments' knowledge of the legislations is shown in table 5 given the evaluation "yes", "partly" or "no".

Table 5. The business operators knowledge of legislation

Type of establishment	Yes	Partly	No	Total
Producer of FCM	38 (78%)	11(22%)	0(0%)	49 (100%)
Importer of FCM	27(52%)	19(37%)	6(11%)	52 (100%)
User of FCM	28(35%)	37(46%)	15(19%)	80 (100%)
Total	93(51%)	67(37%)	21(12%)	181(100%)

¹³ Regulation (EC) No 1935/2004.

¹⁴ Regulation (EC) No 2023/2006.

¹⁵ Regulation (EU) No 10/2011.

Table 5 shows the variation in how much the establishment knew about the most relevant legislation concerning plastic food contact materials.

The producers of FCM had the best score with 78% of the establishments demonstrating sufficient knowledge about the relevant regulations. This is in comparison with the importers where only 52% could demonstrate the same knowledge. This is a serious shortage since it is related to the responsibility of the importers to control a DoC or to issue one when they did not receive DoC. The connection between the business operator's lack of knowledge and lack of a DoC for imported products, underlines this.

The relation between lack of knowledge and lack of DoC was not a finding when controlling food establishments. Most of the products controlled in these establishments did have a DoC, even though some of the business operators had no knowledge of the legislation. This could be a result of the fact that the supplier has to fulfil the legal requirement of providing a DoC to their customers. An important issue is whether a food establishment is capable of using the important information given in the DoC so that they ensure the correct use of FCM. The project result indicates that those who demonstrate knowledge of legislation and have a DoC for their FCM also read and follow the specifications for use.

2.3 System for traceability

According to article 2 in the framework regulation traceability is defined as the ability to trace and follow a material or article through all stages of manufacture,¹⁶ processing and distribution. Article 17 in the same regulation gives further requirements to the business operators concerning traceability. This means that they should be capable of tracing and following their food contact materials one step backwards and one step forwards in order to facilitate control, recall of defective products, consumer information and attribution of responsibility.

The inspectors checked if the establishment had a system for traceability. The reported results show that nearly all the inspected establishments had a system, but in some of them these were of poor quality.

Another issue is the traceability between food contact material and DoC. It was controlled if the actual FCM was described in a way that it

¹⁶ Regulation (EC) No 1935/2004.

could clearly be linked to the presented declaration of compliance. The results indicate that the identification of the FCM did not always give a clear link to the DoC.

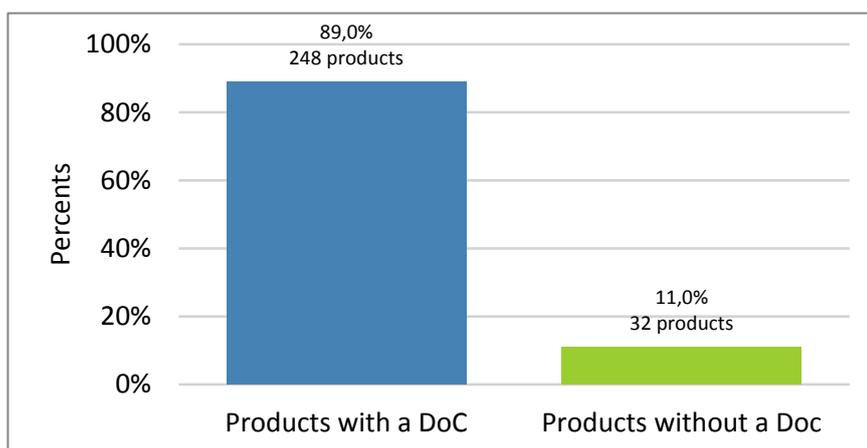
2.4 Declaration of compliance

2.4.1 *Did the establishments have relevant documentation?*

The main focus for the project was to control that the business operator had the relevant documentation for their food contact materials and that it complied with the requirements for a declaration of compliance (DoC) as set out in the plastic regulation.¹⁷ So if they had this documentation, the inspectors checked if the information given in the document was relevant according to the plastic regulation.

The documentation for a total of 280 products was controlled in the project. 69 of the products were from producers of FCM, 78 from importers of FCM and 133 from the users of the final FCM, i.e. food establishments. Of these 280 products, the business operators could present a DoC for 89% of the products as shown in figure 2.

Figure 2. presents in the first column the percentage and the total number of products with a DoC and in the last column percentage and number of products without a DoC



¹⁷ Regulation (EU) No 10/2011.

The results varied between the participating countries as shown in table 6. In Denmark and Faroe Islands all the FCM (100%) had a Doc, in Finland 97%, in Iceland 83%, in Sweden 77% and in Norway 76%.

Table 6. FCMs with a Declaration of Compliance (in number and %)

Type of establishment	Denmark	Faroe Islands	Finland	Iceland	Norway	Sweden	Total
Producer of FCM	18 (100%)	.	30 (96,8%)	6 (100%)	13 (93%)	-	67
Importer of FCM	13 (100%)	-	23 (92%)	1 (100%)	27 (69,2%)	-	64
User of FCM	-	10 (100%)	57 (98,3%)	13 (76,5%)	-	37 (77,1%)	117
FCM with a DoC	31 (100%)	10 (100%)	110 (97%)	20 (83%)	40 (76%)	37 (77%)	248 (89%)
Total number of FCM	31	10	114	24	53	48	280

The plastic regulation requires that all plastic food contact materials shall have a declaration of compliance (DoC).¹⁸ The declaration of compliance shall give the business operator adequate information to make him capable of using the food contact material in a way that does not affect the food in a negative way. As presented in table 6 89% of the products did have a DoC. This could be considered as a good result. However when the inspectors checked the quality of the DoC, the results indicate that in the majority of the DoCs there were a lack of important information.

In this project we have not controlled all the requirements there is for a DoC, as mentioned in 2.4.2. It is also important to notice that all the details from the reported results are not presented in tables or figures in this report. We have chosen only to present the results related to the most important information the DoC should give the business operator:

- Migration of chemicals to the food.
- Dual Use Additives in the food contact material.
- Specification on use of the food contact material.

¹⁸ Regulation (EU) No 10/2011.

The results from the control of this information are presented in the tables 7 and 8.

Migration of chemicals to the food: Table 7 demonstrates that only 53% of the DoCs in the project had adequate information about the migration of chemicals from the FCM to the food. The reported results from the Nordic countries vary from 35% in Iceland and Norway to 77% in Denmark and 80% in the Faroe Islands.

Table 7. Number of products with a DoC with adequate information of migration

DoC from:	Denmark	Faroe Islands	Finland	Iceland	Norway	Sweden	Total
Producer of FCM	13	.	18	2	1	-	34
Importer of FCM	11	-	10	0	13	-	34
User of FCM	-	8	33	5	-	18	64
Nr of Doc with adequate info	24	8	61	7	14	18	132
(%)	(77%)	(80%)	(55%)	(35%)	(35%)	(49%)	(53%)
Total nr of DoCs	31	10	110	20	40	37	248

Lack of or incomplete information about migration of chemicals could be of importance for the business operators using the food contact material, either as an intermediate material in the manufacture of a final FCM or as a final product in direct contact with food. The business operator needs to take migration into account, e.g. by considering any limitations for correct use of the FCM. Adequate information may include analysis of migration (both overall and specific), including specific test conditions, simulants used and duration of the test. This information is for example very important for business operators which will use the material as an intermediate in their own production of a FCM. For end users such as food producers, it could be sufficient to give information which states that only chemicals on the Union list in the plastic regulation are used and that testing results are below the specific migration limits.¹⁹ When 47% of the DoCs did not have adequate information of migration of chemicals, this could entail a risk of migration of chemicals from the food contact material to the food, e.g. by incorrect use of the food contact material.

Dual Use Additives (DUA) covers substances present in plastic food contact materials, which at the same time are authorised as food additives and flavouring. Information of Dual Use Additives (DUA) in the food contact material is of importance for the food producers who are adding additives or flavouring to their food. It should always be

¹⁹ Regulation (EU) No 10/2011.

mentioned in the DoC when such substances are used, together with information on their migration. This is necessary so that these substances can be considered in relation to the relevant food legislation.

59% of the DoCs had sufficient information about DUAs when it was relevant. 25% of the DoCs did not have any information about DUAs even though other information indicated that such content in the FCM was present.

Table 8. Number of DoCs with adequate information about DUA

DoC from:	Denmark	Faroe Islands	Finland	Iceland	Norway	Sweden	Total
Producer of FCM	12	.	18	2	2	-	34
Importer of FCM	10	-	6	1	12	-	29
User of FCM	-	2	37	8	-	16	63
Number of Doc with adequate info (%) when relevant	22 (88%)	2 (40%)	61 (63.5%)	11 (61%)	14 (40%)	16 (46%)	126 (59%)
Partly info	2	1	10	2	14	5	34 (16%)
No info	1	2	25	5	7	14	54 (25%)
Not relevant	6	5	14	2	5	2	34
With a DoC	31	10	110	20	40	37	248

Table 8 shows the variation in the information about DUA in the DoC between the Nordic countries. "Not relevant" means that there were no indications of the use of DUA in the FCM, and then it is not required to mention DUA in the DoC. 100% in this table is related to number "With a DoC" minus number "Not relevant".

The results in this project indicate that the business operators issuing DoCs should be more aware of the use of DUA in their products. Some DoCs inform that DUA are used, but the customer has to contact the supplier to get to know which they are. To give adequate information there should be specified in the DoC which additives are present.

Specification of use for the FCM is required when there are restrictions related to type of food it can be used for, temperature of treatment and storage or information about the ratio of contact area to volume used when testing the food contact material. The inspectors controlled if there were specification on use in the DoC when this was relevant due to information given elsewhere, either in the DoC or other

available information about the FCM. For example if the migration testing was done at a low temperature with a non-fatty simulant.

This kind of information was considered necessary for most of the FCM controlled. 70% of these products did have adequate information in the DoC and 19% had some information about specifications for use.

If there are any restrictions, specifications of use are important for the user of the final food contact material. Lack of this information gives a risk for use of the FCM in a way that could endanger human health, give unacceptable changes in the composition of the food or give organoleptic changes in the food. This would be a breach of article 3.1 in the framework regulation.²⁰ It is a good observation that as much as 70% of the products, where this information was needed, did have specifications for use in the DoC. But the business operators should always have in mind the importance of giving this information in the DoC. Also it is satisfactory to notice that most of the food producers reported that they did follow the specifications on use in the DoC.

2.4.2 The total quality of the Declaration of compliance

When the inspectors checked the information in the DoC, they gave an evaluation of the total quality of the DoC. The requirements for a DoC are described in this report in section 1.4.2. It is worth to underline that the inspectors did not check all the requirements to a DoC given in the plastic regulation. Since this project was the first control project for documentation following plastic FCM, we chose to control the requirements in the plastic regulation which were suitable as a starting point for the inspectors (see “Questions in the reporting form” annex 2). The grade “good” does not mean perfect, but that the information given in the DoC is sufficient. In addition, it should be mentioned that the grades are given as individual evaluations by the different inspectors.

Even though 89% (248 of 280 – see table 6) of the products had a DoC, the reported results show that there is a wide range in quality. Only 45% (111 of 248) had a documentation that gave adequate information about the food contact material. The results are shown in figure 3.

²⁰ Regulation (EC) No 1935/2004.

Figure 3. Percentage distribution of the quality of the DoCs of the 248 DoCs controlled

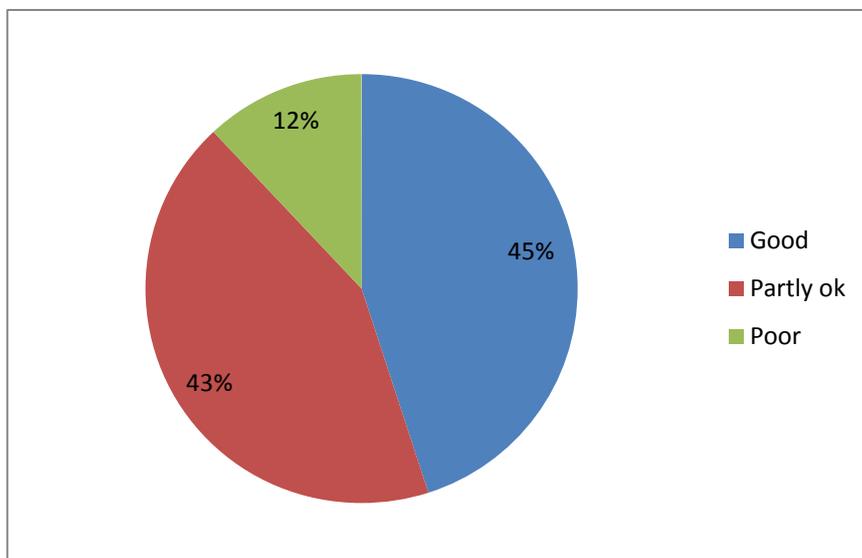


Figure 3 is showing the results of the evaluation of the 248 DoCs controlled. (The number of DoC in each category is: DoC of quality Good: 111, Partly OK: 107, Poor quality: 30).

The figure shows that in 55% of the DoCs, the quality (given the evaluation “partly ok” or “poor”) was not good enough to provide the business operator the needed information according to the requirements. The results from this project indicate that in future control it is important to focus on the quality of the DoC.

Table 8 presenting the variation in frequency of DoCs with the quality “good” between type of establishments and countries.

Table 8. Number of DoCs with quality “good”

Type of establishment	Denmark	Faroe Islands	Finland	Iceland	Norway	Sweden	Total
Producer of FCM	16	.	15	5	2	-	38
Importer of FCM	9	-	9	0	9	-	27
User of FCM	-	5	25	0	-	16	46
DoC with quality “good”	25	5	49	5	11	16	111
% Good	81%	50%	45%	25%	27%	43%	45%
Total nr. with DoC	31	10	110	20	40	37	248

The variation in quality “Good” between the countries was from 81% of the DoCs in Denmark, 50% in Faroe Island, 45% in Finland, 43% in Sweden, 27% in Norway and 25% in Iceland. The results indicate the differences between Denmark and the other Nordic countries when it concerns the total quality of the DoC. This is a very interesting finding that probably reflects the activities of the Danish authorities in

controlling and guiding the industry the previous years. Denmark has focused a great deal on FCM which is also confirmed by these results.

2.5 Analysis of phthalates

At about 10% of the performed inspections, samples were taken for analytical control of compliance with legislation. Food inspectors sent samples of soft plastic to be used in contact with fatty foods to the laboratory DTU-Food (Technical University of Denmark) together with the DoC (if any) and any other documents available containing information about restrictions of use of the FCM. The following procedure was used in the laboratory:

1. Identification of the plastic polymer.
2. Determination of the phthalate concentration in the plastic, if any.
3. Study of declared area of use with respect to food type, contact time, temperature, single or repeated use.
4. If relevant, determination of migration after one or three migration tests from the FCM to a fatty food simulant (oil) during realistic exposure conditions.
5. Conclude from the test results if samples were compliant or not.

Finally a certificate with results and an assessment of the result was send to the food inspector.

2.5.1 *Sample material*

In the autumn 2013 and winter 2014 nineteen samples were taken by food inspectors from the national food safety authorities in the Nordic countries. Detailed description was given to the inspectors on which type of samples to take and they got the table (see table in Annex 1) with an interpretation of the legislative text. Specifications were prescribed concerning relevant sample types as well as size and number of items per sample. Dependent on country, sampling was performed at producers, importers of FCM or at producers and retailers of food. The inspectors were also encouraged to collect and investigate all relevant documentation available including declarations of compliance and any supporting documentation.

2.5.2 Chemicals, laboratory equipment and procedures used

A summary is presented here, but all details on materials and methods are available elsewhere (Petersen and Jensen, 2010).

To avoid problems in the analyses, utility items and solvents used were of high purity and blank values of phthalates were carefully controlled. Further all glassware was heated overnight at 450°C before use.

The following standard substances of high purity were used: Di-butylphthalate (DBP, CAS-nr. 84-74-2), Butyl-benzylphthalate (BBP, CAS-nr. 85-68-7), Di-ethylhexylphthalate (DEHP, CAS-nr. 117-81-7), Di-isonylphthalate (DiNP, CAS no 28553-12-0 or 68515-48-0), Di-isodecylphthalate (DiDP, CAS no 68515-49-0 or 26761-40-0). Deuterium labelled substances used as internal standards were: Ring-D4-DnBP; 3,4,5,6 Ring D4-BBP; Ring D4-DEHP; 3,4,5,6 Ring D4-DnOP and 3,4,5,6 Ring D4-DnNP.

For identification of plastics attenuated total reflectance Fourier Trans-form InfraRed (FTIR) spectra were recorded and compared to a digitalised polymer library (Spectrum One, Perkin Elmer). Some samples (like PVC) were easily dissolved. Extracts of dissolved and precipitated plastic were cleaned by centrifugation in a Hereaus Megafuge. Plastics that were troublesome to dissolve (like some laminates) were extracted using a Büchi Universal Extraction System.

When migration tests were performed with the fatty food simulant oil (D2), time and temperature conditions where selected from the plastic regulation and the guideline on testing conditions from the European Network of FCM Reference laboratories (Simoneau, 2009) taking into account in any restrictions in use mentioned in the DoC.²¹ Phthalates were extracted from oil using a procedure described by the European Reference laboratory (Bratinova *et al.*, 2010) with minor modifications. As required the simulant D reduction factor and surface/volume corrections were applied to the result before comparing to the SML.

Phthalates present in extracts from plastics and oil was determined by gas chromatography (Agilent 6890A) with electron ionisation and mass selective detection (Agilent 5973). One ion was used for quantification and two others for verification of identity (qualifier ions).

²¹ Regulation (EU)No 10/2011.

2.5.3 Quality assurance

The Danish accreditation body (DANAK) supervise the methods applied in DTU-Food, Department of Food Chemistry, also those applied for the determination of phthalates in plastic and in food simulants. Routines are established for the daily quality control of the methods taking into consideration a suitable composition of analytical assays with respect to the number of samples that are analysed in multiplicity, laboratory/solvent blanks and known samples for the control chart.

2.5.4 Results of the analysis

The food inspectors were asked to take samples of soft plastics, preferentially from polyvinyl chloride (PVC) or polyvinylidene chloride (PVDC) like hoses for milk and food, gloves for single or repeated use, conveyor belts, screw caps with gaskets and cling film all expected to contain a high concentration of plasticisers. A survey of the samples taken for analytical control in the enforcement campaign is shown in table 9.

Table 9. Distribution of samples taken for analytical control in the different Nordic countries

Sample type	No of samples	The Faroe Islands	Iceland	Finland	Norway	Sweden	Denmark
Conveyor belt	3				1		2
Gloves, single use	2				1	1	
Gloves repeated use	1				1		
Hose	4			1	1	1	1
Screw cap/lid	4		1	1	1	1	
Plastic film	5	1	1	1			2
Total	19	1	2	3	5	3	5

Non-compliant products were found in several categories of FCM with an apparent overall frequency of violations of 32% (see Table 10). All non-compliant samples belong to FCM like gloves, hoses and conveyor belts were DEHP and DBP were found in amounts higher than the Qm. This result confirms the last year's findings in Danish enforcement campaigns. For hoses and conveyor belts, the DoC was seldom in place and time, temperature, and food-type restrictions for their use were not appropriate.

Table 10. Number and frequency of samples violating the restrictions for phthalates in FCM as stated in Regulation EU 10/2011

Sample type	No of samples	No of samples with DBP, DEHP or DiNP > Qm	No of samples with DiNP or DiDP > SML	Frequency of violation according to sample type (%)
Conveyor belt	3	1	1	67
Gloves, single use	2	2		100
Gloves, repeated use	1	1		100
Hose	4	1		25
Screw cap/lid	4			0
Plastic film	5			0
Total	19	5	1	32

Table 10 shows results of analysis concluded with non-compliance for six of the nineteen products. For one of these products (gloves) there were given specification for use which the food producer did not respect

Former control campaigns in Denmark have shown a high frequency of findings of phthalates in the gasket of lids imported from outside the EU. It seems that other plasticisers than phthalates are now used in gaskets in lids and screw caps and in plastic film including a few cling films.

In several instances the DoC was not of satisfactory quality for selection of appropriate area of use. In cases where supporting documentation was provided the traceability to the actual sample was not always good. However, the availability and quality of documentation seems to be improving over time showing that it is actually possible for a responsible enterprise to fulfil the legislative requirements.

3. Conclusion

This Nordic control project included 181 establishments producing, importing or using food contact materials. Some have a national distribution of their products and some distribute their products in an international market.

The results presented in this report indicate that there is a need for more knowledge in the establishments of the legislations for FCM. It is also important with continuously control activities in the Nordic countries to increase the compliance with the legal requirements for food contact materials. The difference in the results from Denmark and Finland compared to some of the other Nordic countries indicates that better compliance with the requirements for a DoC is a result of the activities of the authorities in controlling and guiding the industry. It is especially important that importers and producers of FCM enhance their knowledge and compliance with the legal DoC requirement. To achieve this, it is essential that the Competent Authorities have the national legal basis in place to control them.

In this project we have focused on declarations of compliance (DoC) for plastic food contact materials. It is not easy to set a standard for a good DoC. The use of the Nordic check list made this challenging work easier for the inspectors, but still it can be difficult to decide whether the quality is satisfactory. Using the grade "Good" in this project did not mean perfect, but that the information given in the DoC was sufficient related to what was asked for.

It is positive that most of the inspected establishments did have a DoC. This indicates that many of the business operators are aware of the requirement for a DoC. However, it is not satisfactory when only 45% of the DoCs contained sufficient information for the user of the food contact material. To get documentation that meets the purpose of a DoC, both the supplier and the customer in the FCM chain are responsible for checking if the DoC is in compliance with the legislation.

The analysis of 19 food contact materials gave as a result an overall frequency of violations of 32%. This result corresponds to the last year's findings in Danish enforcement campaigns on FCM. Since phthalates are endocrine disrupters, extra cautious limits on how much phthalate can migrate into food, has been set in the EU legislation. The results from the analysis show that it still important to include phthalates in the controls of the competent authorities.

Sammendrag

Finland, Sverige, Danmark, Norge, Island og Færøyene har gjennomført et felles nordisk tilsynsprosjekt med fokus på matkontaktmaterialer i 2013–2015. Området matkontaktmaterialer har blitt prioritert i det nordiske samarbeidet i mange år. Den nordiske arbeidsgruppen for matforvaltning og forbrukerinformasjon (NMF) organisert under Nordisk ministerråd, har finansiert dette felles prosjektet. Prosjektet har vært utført i synergi med et annet nordisk prosjekt om matkontaktmaterialer, finansiert av Nordisk arbeidsgruppe for kosthold, mat og toksikologi (NKMT) også under Nordisk Ministerråd. Prosjektet finansiert av NKMT har utviklet en sjekkliste for dokumentasjon for matkontaktmaterialer, og dette tilsynsprosjektet har dermed kunne benytte dette materiellet.

Matkontaktmaterialer brukes i alle faser av matproduksjon og kan være en generell kilde til forurensning av mat. De fleste av de nordiske landene har hatt et begrenset fokus på området matkontaktmaterialer med unntak av Danmark og Finland. Dermed var målet med et felles prosjekt å kontrollere virksomheter som produserer, importerer eller bruker matkontaktmaterialer av plast, samt å øke kunnskapen til inspektørene som utfører disse kontrollene.

Produsenter, importører og matprodusenter (som bruker matkontaktmaterialer) ble inkludert i prosjektet. Når det gjelder begrepet "import" i denne rapporten, refereres det til både matkontaktmaterialer importert fra et tredjeland og matkontaktmaterialer importert fra et annet EU- eller EØS-land. I Sverige og Færøyene, har tilsynsmyndighetene ikke hjemmel i nasjonal lovgivning til å kontrollere importører og produsenter av matkontaktmaterialer; dermed har disse to landene kun inspisert matprodusenter som bruker matkontaktmaterialer. Danmark og Norge valgte å kontrollere produsenter og importører av matkontaktmaterialer, mens Island og Finland inspiserte alle kategorier. I løpet av prosjektperioden ble prosjektbeskrivelse og rapporteringsskjemaer utviklet, og en felles opplæringskonferanse for alle inspektørene ble gjennomført. Under opplæringskonferansen ble prosjektet materialet, inkludert "The Nordic check list for food contact materials and declaration of compliance and

supporting documentation” fra NMF-gruppen gjennomgått. Denne sjekklisten ble brukt under inspeksjonene.

I tilsynsprosjektet var fokuset kontroll av samsvarserklæringer for matkontaktmaterialer av plast. Dette fordi kravet om samsvarserklæring er obligatorisk for å sikre at matkontaktmaterialene er i samsvar med lovgivningen. I tillegg ble utvalgte produkter analysert for ftalater.

Når det gjelder resultatene, ble 178 virksomheter kontrollert. Av disse var det 49 som produserer matkontaktmaterialer, 52 som importerer matkontaktmaterialer og 80 matprodusenter som bruker matkontaktmaterialer. Danmark kontrollerte 26 virksomheter, Finland 72, Island 18, Norge 34, Sverige 24 og Færøyene 7 virksomheter. Totalt ble dokumentasjon for totalt 280 matkontaktmaterialer av plast kontrollert. Mer enn 180 av de 280 plastproduktene som ble kontrollert var i kategoriene plastfilmer, plastbokser og plastskåler. Eksempler på andre produkter var plathansker, slanger, rør, pakninger og transportbånd.

Om lag 2/3 av 78 matkontaktmaterialer som ble kontrollert hos importører var produsert i EU eller EØS, hovedsakelig i Tyskland, men også i Finland, Italia, Sverige, Polen og Frankrike. 1/3 av matkontaktmaterialene kontrollert hos importører kom fra tredjeland, hovedsakelig fra Kina. Andre tredjeland var USA og land i Asia som, Vietnam, Sør-Korea, Taiwan og Thailand.

Fokuset under inspeksjonene var virksomhetenes kjennskap til regelverket, systemet for sporbarhet, og om virksomhetene kunne fremvise en samsvarserklæring. Hvis en samsvarserklæring var tilgjengelig, ble dokumentasjonen vurdert med hensyn til; Navn og adresse på produsent, identiteten til matkontaktmaterialene, datoen samsvarserklæringen ble utstedt, om samsvarserklæringen var oppdatert, en bekreftelse på at matkontaktmaterialene overholdt gjeldende regelverk, informasjon om migrasjon av kjemikalier, Dual Use Additives (DUA) og spesifikasjoner for bruk. Til slutt, ble den totale kvaliteten på samsvarserklæringen vurdert og gitt karakterene ”god”, ”delvis ok” eller ”dårlig”.

Når det gjelder virksomhetenes kjennskap til regelverket, hadde produsentene av matkontaktmaterialer best resultat. Blant produsentene hadde 78 % av bedriftene tilstrekkelig kunnskap, mens blant importørene hadde 52 % av importørene god nok kunnskap. Vedrørende sporbarhetskravet hadde nesten alle et system for sporbarhet, men kvaliteten på sporbarhetssystemet varierte.

Av de 280 kontrollerte produktene, var 69 fra produsenter av matkontaktmaterialer, 78 fra importører og 133 fra matprodusenter.

Totalt i Norden kunne det fremvises en samsvarserklæring for 89 % av alle produktene. For de resterende 11 % ble ingen erklæring fremlagt. I Danmark og Færøyene hadde alle (100 %) produktene en samsvarserklæring, i Finland 97 %, på Island 83 %, i Sverige 77 % og i Norge 76 %.

Når det gjelder innholdet i samsvarserklæringene, fokuserer rapporten på informasjonen om migrasjon av kjemikalier, Dual Use Additives (DUA) og spesifikasjoner for bruk. Når det gjelder migrasjon av kjemikalier hadde 53 % av samsvarserklæringene tilstrekkelig informasjon om migrasjon fra matkontaktmaterialene til maten. Med hensyn til Dual Use Additives (DUA) hadde 59 % tilstrekkelig informasjon og om spesifikasjoner for bruk 70 %.

Angående den totale kvaliteten på samsvarserklæringene, ble i gjennomsnitt 45 % av samsvarserklæringene vurdert til å være av "god kvalitet". Variasjonen mellom landene var fra 81 % med "god kvalitet" i Danmark, 50 % i Færøyene, 45 % i Finland, 43 % i Sverige, 27 % i Norge og 25 % på Island.

Nitten prøver av myk plast til bruk i kontakt med fet mat ble analysert ved Danmarks Tekniske Universitet (DTU). De analyserte prøvene var transportbånd, hansker, slanger, skrukorker, lokk og plastfilmer. Prøvene ble analysert for innhold av ftalater (DBP, DEHP, DINP, DIDP). Innenfor flere kategorier matkontaktmaterialer ble det funnet produkter i strid med regelverket, og 32 % av prøvene var ikke i henhold til lovgivningen. Disse produktene var hansker, slanger og transportbånd, og det ble påvist DEHP og DBP i mengder høyere enn Qm eller DiNP over spesifikk migrasjonsgrense.

Resultatene fra dette prosjektet viser at virksomheter som produserer, importerer eller bruker matkontaktmaterialer må forbedre sitt arbeid vedrørende utstedelse og kontroll av samsvarserklæringer. For å oppnå trygg mat bør samtidig matmyndighetene videreføre sin kontrollaktivitet i alle ledd i næringen når det gjelder produksjon, import, bruk og salg av matkontaktmaterialer.

Appendices

Annex 1. Critical parameters to control and consequences of the implemented rules in July 2008

Regulation of "classical" Phthalates in the fourth amendment to the plastics directive: Survey of the critical parameter to control in enforcement work

PM-no	Substance	SML	Qm	Parameter to control in single use Food Contact Material *)			Parameter to control in repeated use Food Contact Material			Limit in fatty food simulant **)
		(mg/kg food simulant)	(% in the plastic)	Fatty food	Infant food	Non-fatty food	Fatty food	Non-fatty food	Infant food (non-fatty)	(mg/kg simulant D)
74560	Phthalic acid, benzyl butyl ester (BBP)	30	0.1		Qm		SML		SML	30–150
74640	Phthalic acid, bis(2-ethylhexyl)ester (DEHP)	1.5	0.1			Qm		Qm	SML	Not of relevance
74880	Phthalic acid, dibutyl ester (DBP)	0.3	0.05			Qm		Qm	SML	Not of relevance
75100	Phthalic acid, diester with C8-C10 (DiNP)	9 (SML(T) incl. DiDP)	0.1	Qm			SML		SML	9–45
75105	Phthalic acid, diester with C9-C11 (DiDP)	9 (SML(T) incl. DiNP)	0.1	Qm			SML		SML	9–45

*) Usually packaging made from glasses with lid containing a plasticized gasket is considered a single use material.

**) taking D-reduction factor in consideration (info for planning of method validation). When simulant D is 50% ethanol no reduction factor is of relevance.

Annex 2. Questions in the reporting form

QUESTIONS FOR FCM PRODUCERS AND IMPORTERS

1. Does the establishment have knowledge about the legislation?
 2. Does the establishment have system for traceability?
 3. Does the establishment have a DoC for the product?
 4. Does the DoC include the name and address of the producer of the FCM/the business operator?
 5. Does the DoC include information about the identity of the materials/the articles?
 6. Does the DoC include information about the date of issuing the DoC?
 7. Is the version of the DoC updated (and relevant)?
 8. Does the DoC include a confirmation that the FCM or intermediates comply with current legislation, including regulation 1935/2004, 2023/2006, 10/2011 and any specific measures?
 9. Does the DoC include information about migration of chemicals (related to specific migration limits (SML) and the overall migration limit (OML))
 10. Does the DoC include information about any dual use additives, if relevant?
 11. Does the DoC include specifications on the use of the material or article?
 - (i) type or types of food with which it is intended to be put in contact;
 - (ii) time and temperature of treatment and storage in contact with the food;
 - (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article.
 12. With reference to questions 4–11 what is the quality of the DoC?
-

QUESTIONS FOR FOOD PRODUCERS

1. Does the establishment have knowledge about the legislation?
 2. Does the establishment have system for traceability?
 3. Does the establishment have a DoC for the product?
 4. Does the DoC include the name and address of the producer of the FCM/the business operator?
 5. Does the DoC include information about the identity of the materials/the articles?
 6. Does the DoC include information about the date of issuing the DoC?
 7. Is the version of the DoC updated (and relevant)?
 8. Does the DoC include a confirmation that the FCM or intermediates comply with current legislation, including regulation 1935/2004, 2023/2006, 10/2011 and any specific measures?
 9. Does the DoC include information about migration of chemicals (related to specific migration limits (SML) and the overall migration limit (OML))
 10. Does the DoC include information about any dual use additives, if relevant?
 11. Does the DoC include specifications on the use of the material or article?
 - (i) type or types of food with which it is intended to be put in contact;
 - (ii) time and temperature of treatment and storage in contact with the food;
 - (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article.
 12. With reference to questions 4–11 what is the quality of the DoC?
 13. With reference to specification of use (question 10), do the establishment follow the instruction of use?
-

Annex 3. Testresults from analysis of phthalates

Sample type	Food Safety Authority	Origin of sample (when different from sampling country)	Phthalate conc. in plastic (%)		Phthalate in fatty food simulant (mg/kg)			Comments possibly about non-compliances
			DBP	DEHP	DiNP	DEHP	DiNP	
Conveyor belt	Denmark	Italy	0,28	-	High content	-	-	DBP in plastic >0.05%
Conveyor belt	Norway	Germany	-	-	High content	-	27 (27–25–28)	DiNP in food simulant > 9 mg/kg Test in 30 min@70°C (D2-red factor of 3)
Conveyor belt	Denmark		-	-	-	-	-	
Film	Denmark	France	-	-	-	-	-	
Film	Finland		-	-	-	-	-	
Film	Iceland	Germany	-	-	-	-	-	
Film	Denmark	Germany	-	-	-	-	-	
Film	Norway	Norway	-	-	-	-	-	
Film, single use	Faroe Islands	Finland	-	-	-	-	-	
Gloves, repeated use	Norway	Taiwan	-	28 (31–25–29)	-	-	-	DEHP in plastic >0,1 %
Gloves, single use	Sweden	China	-	-	34	-	-	DiNP in plastic >0.1 % The food producer did not respect DoC
Gloves, single use	Norway	China	-	-	43	-	-	DiNP in plastic >0,1%
Hose	Sweden	Italy	-	0,08	< 0,1%	< 0.3 triple	-	declared to be free from DEHP test at 2 hour@40°C
Hose	Finland	Finland	-	-	-	-	-	
Hose	Denmark		-	26 (26–24–27)	-	-	-	
Lid	Finland	Germany	-	-	-	-	-	
Lid	Iceland	France	-	-	-	-	-	
Lid	Norway	Italy	-	-	-	-	-	
Lid	Sweden	Italy	-	-	-	-	-	

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Nordic project food contact materials

Denmark, Finland, Faroe Islands, Iceland, Norway and Sweden have in 2013–2015 conducted a Nordic project on food contact materials. Food contact materials are used in all stages of food production and can be a general source of contamination. The food safety authorities in most of the Nordic countries have had a limited focus on the FCM area with the exception of Denmark and Finland. The aim of the project was therefore to control establishments producing, importing or using plastic food contact materials as well as to increase the knowledge of the inspectors performing these controls. The focus of the inspections was to control the declaration of compliance (DoC) for plastic food contact materials. The requirement for a Doc is mandatory in order to ensure that the FCM complies with the legislation. In addition some products were analyzed for phthalates.

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