LAPPEENRANTA-LAHTI UNIVERSITY OF TECHNOLOGY
School of Engineering Science
Degree programme in Chemical Engineering and Water Treatment

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FOOD SAFETY MANAGEMENT SYSTEM AND PREREQUISITE PROGRAMMES FOR A PAPER MILL

Master's Thesis

Examiners: Professor Satu-Pia Reinikainen, D.Sc. (Tech.)

Associate Professor Eeva Jernström, D.Sc. (Tech)

ABSTRACT

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Food Safety Management System and Prerequisite Programmes for a Paper Mill

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95 pages, 16 Figures, 14 Tables, and 2 Appendices

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Keywords: Food safety management system, prerequisite programmes, paper mill, good manufacturing practice, hazard analysis and critical control point

The aim of this thesis is to map the requirements for a mill to become a food contact material producer and build a food safety management system to a mill.

The first part was to study the legislations worldwide on food contact materials and examine what would it require of a mill to become a manufacturer of food contact material. It was assumed that the market area would first be in the European Union. The Regulations of the EU area were studied more closely than the others. There are many laws on food contact materials around the world, and they vary more or less with each other.

The next thing was to build a food safety management system to ensure that the lack of it does not prevent product development. A product safety handbook was written, and it contains instructions on good manufacturing and hygiene practices with prerequisite programmes. To ensure product safety, a risk assessment and a hazard analysis and critical control point procedure were performed.

Implementing a food safety management system to a mill requires time and resources from both management and personnel. The product safety handbook must contain all the ways to avoid the risks identified in the risk assessment, and the HACCP must be monitored in action for a reasonable period of time and re-evaluated. Whenever a food safety hazard detected or the process, the product or its raw materials change, the risk assessment and the product safety handbook must be re-evaluated.

TIIVISTELMÄ

Lappeenranta-Lahti University of Technology LUT
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Tuoteturvallisuuden hallintajärjestelmä ja tukiohjelmat paperitehtaalle

Diplomityö 2020

95 sivua, 16 kuvaa, 14 taulukkoa, ja 2 liitettä

Tarkastajat: Professori Satu-Pia Reinikainen, D.Sc. (Tech.)
Associate Professor Eeva Jernström, D.Sc. (Tech)

Avainsanat: Tuoteturvallisuuden hallintajärjestelmä, tukiohjelmat, paperitehdas, hyvät tuotantotavat, vaarojen arviointi ja kriittiset hallintapisteet

Tämän työn tarkoituksena on selvittää paperitehtaan mahdollisuutta aloittaa elintarvikekontaktipaperin valmistus ja rakentaa elintarviketurvallisuuden hallintajärjestelmä paperitehtaalle.

Työn aluksi käsitellään maailmanlaajuisesti vaatimuksia elintarvikekontaktimateriaaleille, ja selvitetään mitä paperitehtaalla tulee tehdä, jotta kaikki tarvittavat vaatimukset täytettäisiin ja elintarvikekontaktimateriaalia voitaisiin alkaa valmistaa. Työssä oletettiin markkina-alueen olevan aluksi lähinnä Euroopan Unionin alueella ja siksi tässä työssä käsitellään tarkemmin Euroopan Parlamentin ja Neuvoston asetuksia, sekä EU:n alueen valtioiden lakeja. Elintarvikekontaktimateriaaleille on erilaisia ja eritasoisia vaatimuksia maailmalla, ja ne poikkeavat toisistaan enemmän ja vähemmän.

Työn toinen osa oli kehittää tuoteturvallisuuden hallintajärjestelmä. Tuoteturvallisuuden hallintajärjestelmä kehitettiin, jotta sen puuttuminen ei hidasta tuotekehitystä. Osana tätä työtä kirjoitettiin tuoteturvallisuuden käsikirja, joka sisältää ohjeet hyville tuotantotavoille, hyville hygienia käytännöille sekä muille tukiohjelmille. Jotta tuoteturvallisuus voidaan taata prosessissa, suoritettiin riskiarvio HACCP-järjestelmän periaatteiden mukaan.

Elintarviketurvallisuuden hallintajärjestelmän toteuttaminen tehtaalle vaatii aikaa ja resursseja, sekä johdolta että henkilöstöltä. Tuoteturvallisuuden käsikirjan tulee sisältää kuvaukset tukiohjelmista, joilla voidaan välttää kaikki ne riskit, jotka voivat vaarantaa tuoteturvallisuuden ja jotka riskiarvioinnissa havaitaan. HACCP-järjestelmän toimivuutta on arvioitava sopivan ajan kuluttua uudelleen ja kehitettävä jatkuvasti. Aina kun havaitaan elintarviketurvallisuusriski, tai prosessi, tuote tai sen raaka-aineet muuttuvat, riskinarviointi ja tuoteturvallisuuden käsikirja on päivitettävä.

ACKNOWLEDGEMENTS

First, I would like to thank professor Satu-Pia Reinikainen and associate professor Eeva Jernström for their help and support through this process. Thank you for all the advice and the time you gave me to guide me with this thesis.

I would like to thank my supervisor at Stora Enso for their encouragement and guidance during this thesis process.

I would also like to thank my teachers in secondary school and high school who believed in me and in my ability to reach my dreams despite dyslexia. I hope that you will encourage other young people the way you encouraged me.

Last but not least, I am grateful to Riku, to my parents and siblings, and to all my friends who helped me to get through all the ups and downs of this project. Thank you all for supporting me with my studies and all the side projects that I had in Lappeenranta. I could not have asked for more.

Tara Haikonen

Kouvola 29.2.2020

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LIST OF ABBREVIATIONS

BfR	Bundesinstitut für Risikobewertung;
CFR	Code of Federal Regulation
CoE	Council of Europe
DGCCRF	Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes
DM	Decreto Ministeriale
dm^2	Cubic decimetre
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
EURL-FCM	European Union Reference Laboratory for Food Contact Materials
FAP	Food Additive Petition
FCM	Food contact material
FCS	Food contact substances
FDA	The Food and Drug Administration
FSMS	Food safety management system
FSSC	the Food Safety Systems Certification
GB	The China national standard
GFSI	Global Food Safety Initiative
GRAS	Generally Recognized as Safe
HACCP	Hazard Analysis and Critical Control Point
IAS	Intentionally Added Substances
ISO	International Organization for Standardization
kg	Kilogram
l	Litre
MES	Manufacturing Execution System
mg	Milligram
MS	Member States (of the European Union)
OML	Overall Migration Limit
PDCA	Plan-Do-Check-Act
PRP	Prerequisite Programmes
QM or QMA	Maximum Permitted Quantity
SML	Specific Migration Limit

SMLT	Total specific migration limit
TDS	Technical data sheet
USA	United States of America
µg	Microgram

1 INTRODUCTION

Plastics are the most used material in packaging of food and in disposable tableware. Because the overall consumption increases, the amount of trash increases. The amount of plastics in trash make it harder to dispose the plastics, and the environment load is high, since more and more plastic trash is dumbed to the nature and to the oceans even though the harms of plastic have been known for a long time.

Solutions to decrease the load of plastics on the environment may be found in paper. There is overcapacity in the conventional printing paper industry as one paper machine can produce more paper than before and digitalisation is reducing the sales of books, newspapers and magazines. While the supply-demand relationship in conventional paper products has turned strongly to the supply side, there is a lack of alternative material to plastics.

Conventional paper manufacturing can be modified to produce safe food contact papers. Many fibre-based products are already in the markets but there is still room for plastic-free products since the volume of plastic, paper and board food contact material markets is more than 50 billion euro annually (Simoneau et al., 2016). In Stora Enso, using and reaching the maximum potential of biomass has been a goal and a few examples of the possible applications of biomass are different types of paper and board packaging solutions ("Paperboard materials", 2019, “Speciality papers”, 2019).

On 27 March 2019, the European Parliament accepted the proposal for a directive of the European Parliament and of the Council that will ban single-use plastics like straws. Plastics are widely used and they play an important role in the economy and in many essential applications. Single-use plastics produce unnecessary waste that cannot be recycled, which means that the context of the Circular Economy is not achieved.

In the European Parliament, 28 MEPs abstained, 35 voted against and 560 in favour of the reduction of the environmental impact of single-use plastic products. This decision is actually based on the Commission’s plan, called "Closing the loop – An

EU action plan for the Circular Economy", which was adopted on 2 December 2015, and a strategy of plastic circular economy in the EU declared on 16 January 2018. (Chatain, 2019, European Parliament, 2019)

The European Parliament and the Council laid down the Directive (EU) 2019/204 to reduce and prevent the impact of plastics on the environment and human health and promote the transition to the Circular Economy. The real title of this directive is Directive (EU) 2019/904 *of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment*. In the Directive (EU) 2019/204, article 5 lays down a list of single-use plastics that the Members States shall prohibit. On the list are for example beverage stirrers, plates, food containers made of expanded polystyrene, straws and cutlery. The measures shall be applied according to Article 17 from 3 July 2021. (Directive (EU) 2019/904, 2019)

As a new possible producer of food contact material, the case mill must fulfil the Framework Regulation if it wants to bring food contact material to the market in the EU. This Regulation's real title is Regulation 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*. The Framework Regulation is binding to all the Member States. All the procedures of this Regulation are included in the ISO 22000:2018 standard, which is named *Food safety management systems: Requirements for any organization in the food chain*. The standard is not mandatory to fulfil when bringing food contact material to the market, but it makes it easier to monitor whether the company fulfils all the requirements for food contact material or not. (EN ISO 22000:2018, 2018; Regulation (EC) No 1935/2004, 2004)

There are also numerous differences in regulations globally: for example China, the USA and Canada have their own regulations. Also, some EU Member States like Germany and France have their own regulations despite the EU Framework Regulation.

It is necessary to test all new food contact materials on the market. Testing is a prerequisite for ensuring human health. One bad example of lack of testing is using lead in the soldering of tin containers, which leads to poisonings. (Baughan, 2015)

The aim of this thesis is to build a food safety management for the case mill, including databases for chemicals, pulp and paper packaging materials, HACCP procedures, product safety handbook and templates for personnel product safety training materials. The chemical database also contains calculations for each chemical that may be present in the final paper product. The food safety management system is built to ensure that the lack of it does not prevent product development.

The food safety management system is built to fulfil the requirements in Europe, considering the possibility to expand the marketing globally. The system follows the European Regulations, the main requirements for chemicals based on German standards, American legislation and European lists of allowed and forbidden substances, and industry guidelines by The Confederation of European Paper Industries (CEPI).

2 INTERACTIONS BETWEEN CONTACT MATERIAL AND FOODSTUFF

All residents of the European Union Member States vote for the European Parliament. The election is a direct election and 751 MEPs are elected. One of the three main roles of the European Parliament is legislative. All the regulations made by the European Parliament are legislatively binding and they must be fully applied throughout the EU. The EU regulations are made by the European Parliament and the Council by the proposal of the European Commission. (Europa.eu, 2019a, 2019b)

Directives are made to protect consumers across the EU. Directives are legislative acts that set out goals for EU member states to reach. Individual countries must implement directives, but they may set their laws as they see fit to achieve the goals of the directives. (Europa.eu, 2019a)

According to Regulation (EC) No 1935/2004 Article 1, the Regulation applies to all materials and articles that *are intended to be brought into contact with food* or *are already in contact with food and were intended for that purpose*. Also, if it is reasonable to expect that the material will get in contact with food, the Framework Regulation applies. (Regulation (EC) No 1935/2004, 2004)

The Food Safety Systems Certification, FSSC 22000 Scheme Version 5 divides a food chain into categories and the case mill would belong to category I with other producers of food packing materials. Category I means that company produces material which will be in direct or indirect contact with food or from which substances might possibly transfer into food. ISO 22000:2018 and ISO/TS 22002-4:2013 *Prerequisite programmes on food safety. Part 4: Food packaging manufacturing* by the International Organization for Standardization. These normative documents are included in FSSC 22000. The definition of material is like in Regulation (EC) No 1935/2004. (FSSC 22000, 2019)

There are various ways to measure the safety of FCM. Usually the measures are based on toxicology, migration of substances or microorganisms. (GB 4806.8—2016, 2016; Regulation (EC) No 1935/2004, 2004) The United States of America (USA) regulations are based on an organization's own assessment of whether a substance used in food contact material will migrate to food and then become a food additive. (Baughan and Attwood, 2010)

There are specific rules for food contact substances (FCS) as well, for example lists that include allowed and forbidden substances. Supporting tools for considering whether the FCS is allowed are for example specific migration limit (SML) which is the maximum amount of a substance allowed to migrate into the food. The SML is expressed in mg/kg of foodstuff (milligram per kilogram of foodstuff) or mg/dm² (milligram per cubic decimetre). SML(T) is the total specific migration limit and expressed in mg/kg. Overall migration limit (OML) is the maximum amount of non-volatile substance that migrates from a packaging material or food container to a food simulant expressed in mg/dm² or mg/kg of simulant. OML then measures the inertness of FCM. Maximum permitted quantity (QM) is the maximum permitted amount of a type or group of residual substance that can be in a finished FCM. QM

is expressed as mg/kg of food contact material. If QM is expressed as mg/ 6 dm^2, it is QMA. (ChemSafetyPro, 2018; Simoneau et al., 2016)

3 LEGISLATION ON PAPER AND BOARD FOOD CONTACT MATERIALS IN EUROPEAN UNION

There are and have been differences in the national legislation on food contact materials in the Member States (MS) of the European Union (EU). Efforts have been made to harmonize the laws in the EU level but still there is work to do. The current view in the EU is that all the seal of approval that are done to food contact material must be based on listed substances toxicological evaluation. (Baughan, 2015)

The European Council Regulation No 1935/2004 is binding for all the Member States of the European Union. Also, the Framework Regulation is directly applicable. The main principle in regulation is that food contact materials need to be sufficiently inert (excluding the new active food contact materials) and substances must not migrate to foodstuff such amount of substances that can risk human health. Foodstuff quality and organoleptic properties should also stay the same. (Regulation (EC) No 1935/2004, 2004) This by then means that FCMs must be produced under good manufacturing practice (GMP). (Simoneau et al., 2016)

In the Framework Regulation it is set that all the components of food contact material, in this case paper, must be traceable in every process step and in the product chain. The traceability in this context is the ability to trace and follow the produced material through all stages of product chain meaning manufacture, processing and distribution. The minimum requirement is that all the operations to whom materials are delivered and from whom materials like chemicals are bought must be recognized in the chain. (Regulation (EC) No 1935/2004, 2004)

The Article 15 of the Framework Regulation concerns regulations on labelling of food contact materials (Regulation (EC) No 1935/2004, 2004). There are four main requirements for labels of FCMs. It is set that an FCM must be marked either with words “for food contact” or specific indication as for their use. One example of this is the EU symbol for food contact materials, presented in Figure 1. The information

must be given with electronic or paper documentation accompanying the materials. This can be covered with the Declaration of Compliance (DoC) because all the information about the food contact material is in it. Also, the suitability of material for certain usage can be cleared in a DoC for example whether the material is safe to use in contact with fatty or wet foodstuff. (CEPI, 2019; Regulation (EC) No 1935/2004, 2004)

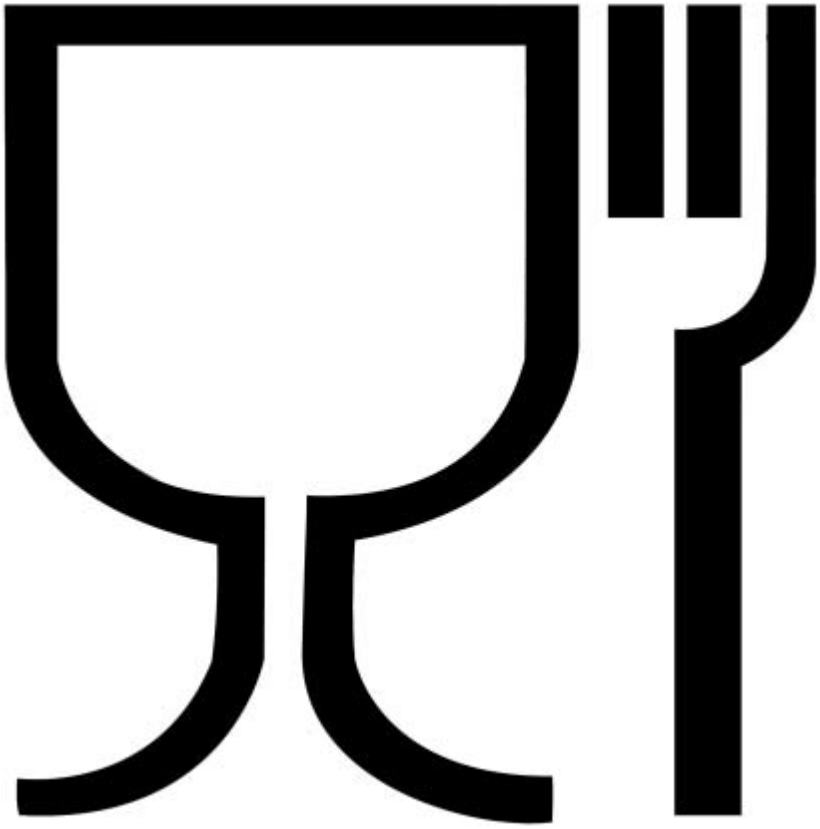

Figure 1 Food contact material symbol

The Figure 1 presents very well-known symbol for food contact material in the EU. This Figure indicates that the material is safe to use in contact with foodstuff. The Figure is not mandatory, but giving the same information using text may be harder or even impossible.

The other two main requirements on labelling in the Framework Regulation are ensuring the traceability of material with adequate labelling and identifying the responsible manufacturer, processor and seller. At a mill, a more familiar word for "processor" is "converter". Therefore, processors are from now on referred as converters. The identification information must contain the name or trade name of

the product, the registered office or address of its manufacture, converter or seller. Again, these can be covered in the DoC. The labelling information should be considered together with traceability guidance documents to avoid duplications in these files. (CEPI, 2019; Regulation (EC) No 1935/2004, 2004)

In the Annex I of the Framework Regulation, food contact materials that are not harmonized in the EU yet may be covered by specific measures. Plastic materials have their own European Commission Regulation (EU) No 10/2011, which is a specific measure within the meaning of Article 5 of the Framework Regulation. Paper and board do not have specific measures. (Regulation (EC) No 1935/2004, 2004)

Paper and board are non-harmonized materials. The EU Member States have various laws and requirements for paper and board. Measurements on chemical safety as well as the type and numerical value of restriction, e.g. compositional and migration limits or quantity in materials, vary across the Member states. The lack of concerted law on food contact materials and substances can cause food safety hazards. Also, risk management is not uniform and the risk assessment tools of the EU are not fully exploited. (Simoneau et al., 2016)

All the diverging requirements in the one lead to a situation in which the country where they are going to bring FCM to markets. Seeking external advice is not bad thing, but it will increase the costs and prolong bringing a new product to the market as well as the authorization of the product. (Simoneau et al., 2016)

It is necessary to produce FCMs in accordance with good manufacturing practice (GMP). The law principles of GMP are presented in the EU Regulation No 2023/2006 and all food contact materials must fulfil them. (Regulation (EC) No 1935/2004, 2004) (Regulation (EC) No 2023/2006, 2006) The manufacture of FCMs might also need to fulfil international standards, for example ISO 9001: Quality Management System standard, to prove to the quality of the product to customers. One law-based requirement is for example the Declaration of Compliance (DoC). With appropriate quality criteria, adequate traceability and high-quality information in the product chain can be achieved. (Simoneau et al., 2016)

The Council Directive 85/572/EEC (full title: *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*) divides foodstuff in eight main categories (with different scales) based on the test simulants that are:

> *Simulant A: distilled water or water of equivalent quality;*
> *Simulant B: 3 % acetic acid (w/v) in aqueous solution;*
> *Simulant C: 15 % ethanol (v/v) in aqueous solution;*
> *Simulant D: rectified olive oil* (Council Directive 85/572/EEC, 1985)

The main categories:

> *01 Beverages*
> *02 Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares*
> *03 Chocolate, sugar and products thereof and confectionery products*
> *04 Fruit, vegetables and products thereof*
> *05 Fats and oils*
> *06 Animal products and eggs*
> *07 Milk products*
> *08 Miscellaneous products* (Council Directive 85/572/EEC, 1985)

Even though this directive concerns plastic materials, it can be noticed that there are various simulants to use with various types of foodstuffs. Different types of foodstuffs are tested with different simulants depending on the pH, alcoholic content as well as other foodstuff properties. Some of these simulants are also used in FCM testing of paper and board. It must be noted that the target country defines some testing as well as SML.

3.1 National regulations in the EU

As mentioned before, some Member States have their own regulations and laws for food contact paper and board as well as for other food contact materials. In this chapter, paper legislation on national level are introduced.

Requirements in the Member States of the EU are divided into two categories:

1. extractive limits or purity requirements (e.g. Lithuania and Greece);
2. lists of permitted substances in paper (e.g. Italy and the Netherlands). (Baughan, 2015)

The legal systems fall into three main categories by different types of measurements:

1. system of comparable migration limits to the EU system and authorised substances (e.g. the Netherlands);
2. system of recommendations (NB! Not legally binding) for substances to be used in the material (Germany);
3. system of unspecific legislation including a code of industry practice defining the due diligence of business operators (e.g. the United Kingdom). (Simoneau et al., 2016)

Although Category 2 recommendations are not legally binding, many buyers and consumers of food contact materials require the materials to comply with them. Therefore, it is recommendable to use raw materials and packaging materials that follow the recommendations.

Finland

Finland's Ministry of Trade and Industry (Kauppa- ja teollisuusministeriö) published a decision on soluble heavy metals in food contact materials on the 20th of March 1992. The decision is rather old but it still applies to food contact materials except food contact materials for only dry food and ceramic materials that are not especially for kids. (Kauppa- ja teollisuusministeriö, 1992)

The limits for migrating heavy metals are maximum concentrations per square decimetre of FCM surface 0.50 mg of lead, 0.10 mg of cadmium and 2.0 mg of chromium and nickel each. In case the FCM is specially for toddler or kids food the limits are only a tenth of those limits. (Kauppa- ja teollisuusministeriö, 1992)

It is set in the Finnish Food Act 23/2006 21§ that all the operators in the food chain must be approved by the Finnish Food Authority. The organization shall inform the

local food control authority of the location and activities of production. (Elintarvikelaki 23/2006, 2006)

Germany

BfR (Bundesinstitut für Risikobewertung; Federal Institute for Risk Assessment) lays down a series of recommendations for food contact material in Germany. The Framework Regulation is covered in German Food and Feed Code LFGB (Lebensmittel- und Futtermittelgesetzbuch), in which the definition of FCM is the same and the requirements for the safety of FCMs are equal to the Framework Regulation (LFGB, 2019). BfR XXXVI contains some tighter regulations that complement the Framework Regulation (BfR Recommendation XXXVI, 2017).

German BfR XXXVI lists materials that can be used as raw material for food contact materials. Accepted raw materials according to BfR XXXVI are for example fibrous materials: natural and synthetic, fillers, production aids like precipitating and retention agents, and special paper refining agents like wet-strength agents. (BfR Recommendation XXXVI, 2017) The Framework Regulation does not list any allowed or forbidden substances in the production of food contact materials. (Regulation (EC) No 1935/2004, 2004)

Belgium

The Belgian legislation on food contact materials, the Royal Decree of 11 May 1992 on materials and articles intended to come into contact with food, was updated on 12 June 2017 (Koninklijk Besluit van 11 Mei 1992 betreffende materialen en voorwerpen bestemd om met voedingsmiddelen in aanraking te komen Wijzigingen: 12 Juni 2017 (Stbl. 27 Juni 2017)). The main change was to make the DoC to be valid only for five years. The model of DoC is presented as an appendix of updated Royal Decree, and it is similar to the EU model. (Koninklijk Besluit, 2017)

In the Royal Degrees annex 4 paper and board regulations for moist and greasy foods are described. The overall migration limit for every substance is 60 mg/dm^2. Allowed fibres, substances and additives are listed only listed only on a general level and the major requirements are that the substances of paper or board do not endanger human health and the substances are not soluble in water. (Koninklijk Besluit, 2017)

The Netherlands

In the law of the Netherlands food contact paper is divided into two groups: into paper for generic use and into paper that is used for filtering hot liquid or other foodstuff with temperature over 80°C. (Baughan, 2015; Veraart, 2010) In the Commodities Act (Packagings and Consumer Articles) Regulation [Warenwetregeling verpakkingen en gebruiksartikelen], substances that can be used in the product and production are listed. Still, other substances are also allowed but only if they comply with Article 3 of Regulation (EC) No 1935/2004. Also, the specific or total migration limit should not be exceeded. (Commodities Act, 2016)

It is required in the Commodities Act that the manufacturer of the product must know all the substances used in the production as well as their compositions. If the competent authorities request, the compositions must be disclosed. (Commodities Act, 2016)

The Commodities Act specifies requirements for the specific migration limits (SMLs), for the total migration of ingredients, for the residual content (QM), and for the residual content per surface area. Also, the Declaration of Compliance (DoC) is required and specific info of it is in the Commodities Act annex 1. In chapter 2 of the Commodities Act requirements for producing paper are extensively described. (Commodities Act, 2016)

Italy

The Italian legislation on food contact materials was born in the early 1960s. Its main point is to know the components of paper and the possible migrations must be identified through testing. Also, the Italian legislation is older than the first EU regulations on FCMs and the Italian legislation contains some parts that the EU regulations do not even mention. This has caused a situation where both the old and the new Italian legislation and the EU legislation are all still living. (Milana, 2010)

The Italian legislation relays on amounts of components of paper dividing food contact papers into two classes: into those where migration tests are required and those where they are not. It is set that at least 75 per cent of paper must be fibres and at maximum 10 per cent of fillers and 15 per cent of additives migration tests are required. If paper contains at least 60 per cent of fibres and maximum 25 per cent fillers and 15 percent of additives migration tests are not necessary. In this

case, the per cents refer to the dry matter. Also, it is important to product food contact materials with good manufacturing practices. The allowed substances according to the Italian legislation are presented in Annex II part 4 of Decreto Ministeriale (DM) del 21/03/1973 (Decreto Ministeriale, 1973)

France

The regulations in the French law are based on the principle of positive list. It has been found out to be the best way to protect human health, because substances that may endanger human health are not allowed. It is set that the responsibility of the safety of food contact material lies with the manufacturer of a certain material. (Gauducheau and Feigenbaum, 2010)

The positive list is based also on the Note for Guidance of European Food Safety Authority (EFSA) for plastic FCM. If the substance is not found to be genotoxic or does not have structural alerts for genotoxicity and the migration level is low, a threshold of 0.5 μg/kg food is applied. (European Food Safety Authority (EFSA), 2012)

Regulation on colorants used in paper mass is made early, first time in 1912. The currently valid version was made in February 2020 and it presents regulations for colorants used in paper mass and then in paper itself. (La Service Public De La Diffusion Du Droit, 2020)

There are different levels in the reference texts in the France. They are usually binding but knowing that there are no overlaps in texts is hard. Therefore it is necessary to request authorization for the use of constituents of materials and articles in food contact materials with application from the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF, Consumer, Competition, and Frauds Office, under the Ministry of Finances). (Gauducheau and Feigenbaum, 2010)

Northern Europe

The Nordic Council of Ministers is formed by Sweden, Denmark and Norway, which are Scandinavian countries. The Council has a long history of cooperating with Finland and Iceland. (Fabech et al., 2010)

The TemaNord 2008:515 Paper and Board Food Contact Materials is a guideline for manufactures of the product chain of FCMs. The TemaNord is not legally binding unless it is transposed into national legislation in the Nordic Countries. The TemaNord is similar to the Framework Regulation but gives more specific guidelines for the testing of paper and board materials. Whereas the Framework Regulation sets universal rules for food contact materials, the TemaNord 2008:515 gives more specific descriptions of requirements and how to fulfil them. For example, the specific restrictions in TemaNord 2008:515 lay down restriction limits for cadmium 0,002 mg/dm^2, lead 0,003 mg/dm^2, mercury 0,002 mg/dm^2 and pentachlorophenol (PCP) 0,15 mg/dm^2. Also, all substances used in manufacturing paper or board used in contact with foodstuff must comply with at least one of following:

1. Substances evaluated by EFSA
2. Substances evaluated by BfR
3. Substances evaluated by FDA
4. Substances listed in two or more of the sub items above

PCP has been banned in Finland since 2000 and added to the Stockholm Convention on Persistent Organic Pollutants in 2015. Stockholm Convention on Persistent Organic Pollutants is incorporated in Regulation (EU) 2019/1021 of the European Parliament and of the Council on persistent organic pollutants. (Junttila, 2017; Suomen ympäristökeskus SYKE, 2013) For this reason, it is reasonable to assume that PCP is not present in the product. However, the testing of PCP is still in the requirements of the TemaNord 2008:515 (TemaNord 2008:515, 2008).

Food is divided into three different categories in the TemaNord 2008:515:

Type I - Aqueous and/or fatty foodstuffs
Type II - Dry, non-fatty foodstuffs
Type III - Foodstuffs shelled, peeled or washed before consumption

The TemaNord 2008:515 lays down that whenever there is conflict between regulations, the EU regulation must be respected. (TemaNord 2008:515, 2008)

Others

Almost every Member State of the EU has their own legislation alongside the EU legislation or recommendations. All the Regulations of the European Parliament and of the Council are mandatory to every country but Directives are only goals as mentioned before (Europa.eu, 2019a). Regulations are minimum requirements but all MS may have their own stricter legislation.

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It is not always possible to know does a specific MS has its own legislation, because of the difficulty of finding all the laws of European MS in English. Also, it is almost impossible to know which laws and regulations are currently in force.

In 2005, the EU had 25 MS in total. Even the Framework Regulation is in force in every MS, not all the food contact materials are harmonized in the EU level. Lac of non-harmonized material regulations causes a possibility of having 25 different sets of national requirements in the EU. About half of these 25 countries have their own FCM legislation, but this could change rapidly if MS adopt new regulations. (Keller and Heckman LLP, 2005)

The European Union aims to unify also the quality of food contact materials (O'Connor, 2014), and with Regulation (EU) 2017/625 *on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products* unity can be achieved. This Regulation lays down general *rules for the performance of official controls and other official activities by the competent authorities of the Member States*. (Regulation (EU) 2017/625, 2017) All MS must have a reference laboratory which is authorized by the European Union Reference Laboratory for Food Contact Materials (EURL-FCM). The role reference laboratories is important to have identical measuring and testing systems as well as review of results. (O'Connor, 2014)

3.2 Future legislation

Even though many EU Member States have their own legislation for FCMs and some of them are from the beginning of 1900s, the requirement in general is that food must not endanger human health and must not modify the organoleptic characteristics of food.

According to EU mutual recognition and safeguard measures, not every national regulation needs to be followed but the EU level must. Mutual recognition means that the product made and lawfully marketed in an EU Member State can be sold in another Member State even if all the technical rules of the destination country are not complied with. (Regulation (EC) No 2019/515, 2019) Complexity of legislation between Member States may cause incomplete or incorrect applications of mutual recognition (Simoneau et al., 2016). In national legislation every Member State can set bans and limits if there is reason to believe that health or environment can be harmed when using a certain product or substance (Regulation (EC) No 2019/515, 2019).

One specific target of mutual recognition is BPA or Bisphenol A. It is used for example in thermal paper, resins and in plastics. BPA has been used since the 1960s. In paper and board industry, BPA is used in epoxy resin and thermal papers. Food contact materials, like cans for drinks and foodstuff, are coated with epoxy resin. In the EU level, the use of BPA is restricted in thermal papers starting in 2020. The European Parliament's Committee on the Environment, Public Health and Food Safety adopted a law in January 2011 which bans the usage of BPA in infants' feeding bottles. In Denmark, Sweden and Belgium, BPA is forbidden in all food contact materials that may touch the food of children under the age of three. Also, European Parliament's Committee on the Environment, Public Health and Food Safety decided in January 2018 to lower the specific migration limit (SML) of BPA from 0.6 mg/kg to 0.05 mg/kg. In France, all food contact material must be BPA-free. (European Chemicals Agency, 2019)

Safeguard measures are defined in the Framework Regulation. If a Member State reassesses a substance or gets new information that a material endangers human health, the application of the Framework Regulation may be temporarily suspended.

If this procedure takes place, the other Member States and the Commission must be immediately informed. (Regulation (EC) No 1935/2004, 2004)

In the EU Regulations, it is established that the Member States need to have official control that is uniform to the other EU Member States (Regulation (EC) No 1935/2004, 2004; Regulation (EC) No 2017/625, 2017). With this requirement, it is confirmed that the treatment and evaluation of each product in the same category are equable (Simoneau et al., 2016). Regulation (EC) 2017/625 applies to food safety and through this it also applies to food contact materials. Every Member State will designate the authorities to organise and control official activities, such as sample taking, measurements and analysis (Simoneau et al., 2016). The European Union Reference Laboratory for Food Contact Materials (EURL-FCM) maintains a database of National Reference Laboratories (NRLs) (Hoekstra, 2016).

In the Framework Regulation, specific limits on the migration and an overall limit on the migration is mentioned (Regulation (EC) No 1935/2004, 2004). Migration in this case is diffusion of substance from FCMs into the food or vice versa. Migration can in a worst-case scenario endanger human health. (Baughan, 2015)

Brexit may cause some problems when it comes to food contact materials. When this thesis was started, it was not even sure when the United Kingdom was going to leave the EU. The United Kingdom's withdrawal agreement from the EU came in force 1 February 2020 and it started a transition period until the end of 2020 (Salmi, 2020). Now the UK follows EU Regulation 1935/2004 but it cannot be said at this point whether the Great Britain is going to have their own legislation on FCMs. (European Commission, 2019) Therefore it is necessary to follow what happens in Brexit and afterward legislation in case papermills located in the EU want to sell FCM to the Great Britain.

Update of the Framework Regulation has begun, and it has been estimated that it will take 5 to 6 years to complete. The reasons behind update of the Framework Regulation are wide: for example, the Declaration of Compliance is wanted to be made uniform for all FCMs regardless of whether there is a specific material legislation or not. Also, the process of adding a substance to the positive list of substances is nowadays difficult and this process is wanted to be made easier.

(Virtanen, 2017) The European Commission actively works on new legislation on FCMs and the evaluation process is estimated to be ready in 2020 (PackagingLaw.com, 2018).

4 GLOBAL LEGISLATION ON PAPER AND BOARD FOOD CONTACT MATERIALS

Depending on the market to which mill wants to export its products, the national requirements of the target country must also be considered. Although the TemaNord outlines that any of the three approvals (EFSA, BfR, and FDA) sufficiently allows the use of the raw material in the production of paper (TemaNord 2008:515, 2008), the same guidance does not apply everywhere.

Globally there are many different legislations, standards, lists, acts, etc. that make it difficult to list all the possible target country and their requirements on food contact materials. Therefore, whenever paper is marketed to a new country, it must be ascertained whether the paper meets the requirements of country.

An FSMS must be made so that the lack of a system does not restrict product development of FCM. In this paper, the market is initially assumed to be within the EU, so only the most important legislations of other countries will be presented as part of this work.

In the future it is possible that the market is going to expand to China and other Far East countries as well as to North America (mostly to the USA). In the following section, legislation of the USA and the People's Republic of China are presented generally with a short list of other legislation of FCMs worldwide.

4.1 The United States of America

In the United States of America, the first regulation on food contact material was published in 1958. In the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (the Act), it is said that a premarket clearance is required for all substances that will become components of food. (Baughan, 2015)

The food contact substances (FCSs) must be cleared to use in the Food Contact Material manufacturing. According to section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (the Act), an FCS is any component of materials used in manufacturing, packing, packaging, transporting or holding food that does not have any technical effect to food (Federal Food, Drug, And Cosmetic Act, 2019).

FDA itself does not approve products but instead approves the substances that are used to make food contact materials and products. It is a responsibility of supplier of the substance to clear to mill whether the substance is approved by FDA or not.

FCSs that are direct food additives, FDA require premarket authorization (Office of Food Additive Safety, 2018a). The main idea of a clearance is to convince the FDA with data or extrapolations that a substance is safe to use in FCMs. In 1998, the FDA adopted the Federal Food, Drug, and Cosmetic Act of Food Contact Notifications which unified FDAs regulation for FCMs. (Baughan, 2015)

FCSs that are indirect foot additives there are three options adjusted by FDA. First option is that FCS is regulated for its intended use in CFR Title 21 parts on indirect food additives 175 Adhesives and Components of Coatings (Code of Federal Regulations, 1977a), 176 Paper and Paperboard Components (Code of Federal Regulations, 1977b), 177 Polymers (Code of Federal Regulations, 1977c), 178 Adjuvants, Production aids, and Sanitizers (Code of Federal Regulations, 1977d) or 179 Irradiation in the Production, Processing and Handling of Food (Code of Federal Regulations, 1977e). Also, substances that are generally recognized as safe (GRAS) may be used (The Food and Drug Administration, 2019a). Those substances can be used in manufacturing of FCM under conditions of good manufacturing practice. (The Food and Drug Administration, Department of Health and Human Services, 2016)

The second option is to exempt FCS from regulation under the agency's Regulation process (Office of Food Additive Safety, 2018b). The Threshold of Regulation (TOR) lists exemptions issued in Title 21 §170.39 of CFR. If FCS goes to TOR process four criteria must apply:

1. the substance has not been shown to be carcinogenic and by the chemical structure of the substance there is no reason to suspend that substance is a carcinogen;
2. migration of a substance into food is not expected to be more than 1.5 Micrograms / person / day (limitations for each substance can be searched for the Cumulative Estimated Daily Intake database (The Food and Drug Administration, 2012));
3. use of substance in FCM does not have significant adverse impact on the environment;
4. in specific intended conditions, use of the substance does not have a technical effect in or on food to which it migrates. (Code of Federal Regulations, 1977f) (Shanklin and Cahill, 2008)

The third option is to supply a Food Contact Notification (FCN). FCN should be submitted in case a company would like to bring new FCS to market. Description of FCN is under section 409(h) of Federal Food, Drug, and Cosmetic Act (Federal Food, Drug, And Cosmetic Act, 2019).

There are many databases from where substances of Food Contact Materials can be searched. All the indirect additives used in food contact materials that are named in the U.S. regulations, e.g. in CFR 176.170, are listed in the Indirect Additives used in the Food Contact Substances database (The Food and Drug Administration, 2019b). Effective Food Contact Substance Notifications list the effective premarket notifications made by manufactures of substances. The substances on the list have been demonstrated to be safe for intended use. (The Food and Drug Administration, 2019c)

Other databases for food contact substances are the GRAS (Generally Recognized as Safe) Notices database (The Food and Drug Administration, 2019a) for additives that may become part of food and the CEDI (Cumulative Estimated Daily Intakes) database for maximum daily intakes of substances (The Food and Drug Administration, 2012). In the CEDI database, the Chemical Abstract Service (CAS) Registry Numbers, the cumulative dietary concentrations (CDC or CUM DC) as ppb (parts per billion) and Cumulative Estimated Daily Intakes (CEDIs) as mg/kg bw/d (milligram per kilogram of body weight per day) of food contact substances

are listed (The Food and Drug Administration, 2012). In title 21 Part 170 subpart E 170.203 there are definitions of GRAS. According this definition a GRAS notice is a submission that informs the FDA of an organization's point of view that a substance is GRAS under the conditions of its intended use (Code of Federal Regulations, 2016).

With a food contact notification (FCN) process the FDA regulates additives that are food contact substances (FCSs). All notifications for FCSs need to contain a demonstration of safety of the substance in intended use with enough scientific information (Federal Food, Drug, And Cosmetic Act, 2019).

All in all, the regulations of the FDA are complex: does the organization need to submit either an FCN or a food additive petition (FAP) and which are the requirements that an organization must fulfil? For this reason, it has been recommendable to contact and consult the FDA to figure out the appropriate protocols (Kerry, 2012). According to the FDA's Food and Cosmetic Information Center (FCIC) Technical Assistance Network (TAN) (e-mail conversation in 18.9.2019), the organization that is interested in a food contact substance notification must contact the Office of Food Additive Safety (OFAS).

4.2 China

In China, the FCMs are regulated as food-related products. If the food-related product is not compliant with the law, it is forbidden to sell it. The National Health and Family Planning Commission (NHFPC) published a series of standards for food contact materials and additives in 2016. In China, these standards create a framework for FCMs. (ChemSafetyPro.COM, 2017)

The National Standard of the People’s Republic of China, GB 4806.1-2016 *National Food Safety Standard: General Safety Requirements on Food Contact Materials and Articles,* is basically the general requirement standard for FCMs. It sets limitations, compliance principles, testing methods and traceability and product information to all kinds of FCMs. The aim is quite similar to the EU Framework Regulation: the composition, taste or odour should stay as it was and food must not endanger human health. The product must be traceable, and the labelling must

contain information about food contact use. Food contact material can be marked with Figure 2. (USDA Foreign Agricultural Service, 2017)

Figure 2 Diagram of Spoon and Chopsticks Symbols, GB 4806.1-2016

Figure 2 is GB 4806.1-2016 version on the Framework Regulation FCM symbol. The symbol can be replaced with text that points out that the specific product is intended to be an FCM.

GB 9685-2016 is the National Food Safety Standard - Standard for Uses of Additives in Food Contact Materials and Their Products. This standard specifies principles for using additives. In Table A.6 of GB 9685-2016, the allowed additives in food contact paper and board are listed under name, CAS number, maximum level as %, SML (specific migration limit) and QM (maximum residue quantity) as mg/kg (milligram per kilogram) and SML(T) (total specific migration limit) as mg/kg. (www.ChineseStandard.net, 2017)

For paper, paperboard and articles made from them the GB 4806.8-2016 sets more specific requirements where GB 4806.1-2016 sets the general requirements. However, it is necessary that these materials also meet the requirements of GB 4806.1-2016. (GB 4806.8—2016, 2016) The *National Food Safety Standard – General Health Code for Production of Food-contacted Materials and Products* GB 31603-2015 must also be covered when producing FCMs to the Chinese market (www.ChineseStandard.net, 2017, pp. 31603–2015).

4.3 Other countries outside the EU

This section describes shortly a few possible market areas for FCMs. The descriptions of legislation by country are short. Therefore, if FCMs are marketed to a new area the person in charge must become familiar with the legislation of the target country in question. The aim of this section is only to give examples of the complexity and scope of FCM regulations.

The Canada legislation is quite similar to the USA. The main difference though is that substances migrated into food from FCSs are not considered food additives. That makes the regulatory analysis a bit simpler. It is accepted in the legislation of Canada to sell and market an FCM product if the product is determined as safe and suitable by the manufacturer. Still, it is quite recommendable to accept the product through a HPFB (the Health Products and Food Branch) NOL ("no objection" letter) to have assurance of product suitability in the Canadian market. (Rulibikiye and Nielsen, 2010)

The Republic of Korea also has its own standards for FCMs. There are standards for eight different FCMs including paper and paperboard. A few clear examples of standards for paper and paperboard are prohibited substances in food contact paper (fluorescence brighteners) and maximum limits for migration of metals. Also, the Republic of Korea requires the importer to submit a document about importing FCMs. After testing the material and founding it safe, the Korea Food and Drug Administration (KFDA) issues a certificate. (Yoon and Lee, 2010) After that it is necessary to test the material in the target country and approve it to be used in the specific purpose.

In addition to the presented legislations, for example, Japan, Israel, India, Southeast Asia, Australia and New Zealand have their own regulations for FCMs (Rijk and Veraart, 2010). Countries that want to integrate into the global economy, such as Israel, define FDA or/and EU food contact regulations as acceptable(Alcalay, 2010). So once the market is clear, the legislation of the target country needs to be considered.

5 CHEMICALS AND ADDITIVES

Generally, in a mill more than 200 different chemicals are used (Data Research Analyst, Worldofchemicals.com, 2014). To get an approval to produce food contact paper, all the chemicals that are used in papermaking processes and in the product need to be approved to be used in FCMs. Processes that need to be taken into concern in this case are the manufacture of Pressure Groundwood pulp, fresh water treatment, papermaking process as well as the chemicals and materials that are used in finishing. Also, the pulp needs to be safe in the making of food contact material even if the pulp is not made in the Mill.

It has been estimated that there are more than 85 000 chemicals used in consumer products. In food contact materials the number is over 6 000. (Wagner, 2014) In the United States, the FDA provides a list on chemicals that are intentionally added to food, but 80 per cent of the chemicals on the list lack enough information on the safe amount of consumption. In 2013, about 93 percent of these chemicals did not have reproductive or developmental toxicity data even though the FDA requires the data. (Neltner et al., 2013)

The regulations on chemicals used in both food and FCMs are necessary. If there are no regulations or any control especially for food and FCM chemicals, they may endanger human health. Unsafe chemicals used in food contact paper may cause health effects from skin irritation to cancer. (Wagner, 2014)

As a part of risk assessment, the chemicals used in the papermaking process must be known. The request for Regulatory Compliance Statement (RCS) must be filled by the suppliers of chemicals. The RCS must confirm that the chemical is safe to use in food contact materials and their applications. It is important that the RCS contains information about the purity of the chemicals, restrictions of use and recommended usage rates as well as purity and testing requirements of the product. The dye and adhesive supplier must provide the same statement but with more attention paid to potential migrants and non-intentionally added substances (NIAS) as a part of purity requirements. A proper RCS provides valuable information to enable and improve risk assessment. (CEPI, 2019)

The positive lists with which the chemical is known to comply shall be given. In the BfR Recommendation XXXVI, the approved substances are listed, and it is a

valuable guideline for every industry producing FCMs. The BfR is one of the national regulations that is recommended to follow but there are many others as well. The local measurements and limits shall be applied to every substance. In a case where no regulations or lists are available, the best practices and guidelines of the industry must be applied. (CEPI, 2019)

According to CEPI (2019) Food Contact Guidelines for the Compliance of Paper and Board Materials and Articles, substances that are not authorised may be used but only if they are not excluded under any relevant paper and board industry commitment. Also, no migration of substance to food or it is lower than 10 μg/kg food; substance is not carcinogenic, mutagenic or toxic to reproduction; the substance is listed to be food additive; the Threshold of Toxicological Concern risk assessment has carried out. The supplier must provide a declaration of safe use of the substances above. (CEPI, 2019)

Many papermills have water circulation systems. It may cause the chemicals to accumulate to water and the total dosage of chemical in paper be higher than the amount of the added chemical. This must be taken into concern when making a risk assessment.

Various factors have effects on the safety, migration volume, requirements on the quality of paper, etc. Possible factors are for example:

- Temperature of contact item
- Time of contact
- Surface-to-volume-ratio
- Food type (e.g. alcoholic, fatty, aqueous/dry, acidic)
- Composition (concentrations of chemicals)
- Contact type (e.g. direct or indirect, are there functional barriers regarding the contact type)

Because of multiple factors, there are also various ways to test the quality of paper. In Table 1 some possible testing standards are listed. (Simoneau, 2009).

Table 1 Standards for Food Contact Material testing

Standard: Paper & board	Title: Paper and board intended to come into contact with foodstuffs
EN 1104	Determination of the transfer of antimicrobial constituents
EN 1230-1	Sensory analysis - Part 1: Odour
EN 1230-2	Sensory analysis - Part 2: Off-flavour (taint)
EN 13676	Polymer coated paper and board intended for food contact - Detection of pinholes
EN 14338	Conditions for determination of migration from paper and board using modified polyphenylene oxide (MPPO) as a simulant
EN 645	Preparation of a cold water extract
EN 646	Determination of colour fastness of dyed paper and board
EN 647	Preparation of a hot water extract
EN 648	Determination of the fastness of fluorescent whitened paper and board
EN 920	Determination of dry matter content in an aqueous extract

In Table 1, there are various standardized tests for the quality of food contact paper and board. The current confirmed standards must be fulfilled when the test is implemented in the mill laboratory.

5.1 Migration and measurements

In Europe, there are a lot of information and tables available on migration limits. Not only the Council of Europe (CoE) *Resolution ResAP (2002) 1: Technical document No. 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs (Version 3)* (CoE ResAp (2002) 1 - td 1, 2009) lists additives. Candidate List of substances of very high concern for Authorisation by European Chemicals Agency (ECHA) based on the REACH Regulation (Regulation (EC) No 1907/2006, 2006). There are various other lists like BFR and other national SML lists, the FDA lists of maximum amounts and SML, etc. Therefore, the listing of specific values is not possible and not all the compounds of used substances are known.

As presented before, there are various standardized testing methods for paper but also for migration testing. In Table 2, some of these standards are presented.

Table 2 Migration Testing Standards for Food Contact Materials

Standard reference: Paper & board	Title: Paper & board
EN 12497	Determination of mercury in an aqueous extract
EN 12498	Determination of cadmium and lead in an aqueous extract
EN 1541	Determination of formaldehyde in an aqueous extract
EN ISO 15318	Determination of 7 specified polychlorinated biphenyls (PCB) (ISO 15318:1999)

As can be seen in Table 2, the three first tests are aqueous extracts. Here again it is necessary to know the end-use purpose to do proper tests.

To test the overall migration (OM), it is necessary to find a food simulant that is close to real foodstuff. The best methods for different FCMs can be found in literature. (Baughan, 2015) At this point, all migration testing is done by other laboratories because of lack of equipment and measuring technology in the mill.

5.2 Intentionally Added Substances (IAS)

Intentionally Added Substances (IAS) generally refer to all substances and raw materials that are either in the positive lists of national regulations and recommendations or risk assessed as safe to use. These substances may be intentionally added to food contact materials during the process. (CEPI, 2019) As mentioned before *Request for Regulatory Compliance Statement* is send to all suppliers to ensure the substances to be suitable for production of food contact material.

There is not a positive list for paper and board materials upkept by the EU, so the Framework Regulation Article 5 applies. Article 5 lists specific measures for materials and articles that are not harmonized materials. For example, it has been set that specific measures can be a list of approved raw materials in the production of FCMs, possible overall limits on migration into or onto food, and possible limits or special conditions of use for a substance that is listed as approved raw material. (CEPI, 2019; Regulation (EC) No 1935/2004, 2004)

5.3 Non-intentionally added substances

In paper making process and in the final product it is possible that non-intentionally added substances (NIAS) are present. NIAS are chemical compounds that are or may be present in the final material but are not added in purpose. For example, they can be raw material impurities, reaction by-products, oligomers or degradation process products. It has been detected that NIAS in paper and board are often of origin of sizing agents, adhesives, surface coatings or printing inks. Also, in paper or board that have recycled materials as raw material, there are more NIAS present than in all virgin products. (Peters et al., 2019)

NIAS can be found via various analyses and sampling. Testing may start either targeted or untargeted, and sampling can go through migration or extraction. (Peters et al., 2019)

The amount of NIAS may be estimated via risk assessment and research. CEPI Food Contact Guideline lists NIAS that have QMA limits set in Germany, France, or Italy. A list of NIAS with their limits and sources is presented in Table 3 below. (CEPI, 2019)

Table 3 NIAS that should be tested

Substance	Maximum Permitted Quantity	Source	Food type
Cadium, Cd	5 µg/l cold water extract	DE:BfR XXXVI	Moist and/or Fatty
	0.5 mg/kg paper or board	FR: DGCCRF	Moist and Fatty
Lead, Pb	10 µg/l cold water extract	DE:BfR XXXVI	Moist and/or Fatty
	3 µg/dm^2 paper or board	IT: DM 21.03.73	All
	3 mg/kg paper or board	FR: DGCCRF	Moist and/or Fatty
Mercury, Hg	0.3 mg/kg paper or board	FR: DGCCRF	Moist and/or Fatty
Chromium, CrVI	0.25 mg/kg paper or board	FR: DGCCRF	Moist and/or Fatty
Pentaclorophenol, PCP	0.1 mg/kg paper or board	FR: DGCCRF	All
Antimicrobial substances	The finished paper or paperboard must have no preserving effect on the foodstuffs with which they come into contact.	DE:BfR XXXVI	All
		FR: DGCCRF	All

In Table 3, column three “Source” refers to the regulations of Germany (BfR XXXVI), France (DGCCRF) and Italy (DM 21.03.73) (BfR Recommendation XXXVI, 2017; Decreto Ministeriale, 1973; La Service Public De La Diffusion Du Droit, 2020). Short descriptions of all these regulations are presented earlier in section 3.1.

It can be seen in Table 3 that NIAS are a remarkable part of getting FCM to markets in Germany, France and Italy. It is recommendable to test the final material for the substances presented in Table 3 to be sure that the material is suitable to be used as FCM.

The RCS file from chemical and other material suppliers may help with detecting NIAS. NIAS must be taken into concern when risk assessment is made and when the material goes to third party testing. Via risk assessment it can, for example, be found out that sizing agents are not safe to use in the production of food contact material and need to be changed.

6 REQUIREMENTS

A food safety management system (FSMS) is a multi-component system consisting of Hazard Analysis and Critical Control Point (HACCP) and prerequisite programs (PRPs). PRPs consist of good manufacturing practices (GMPs) and good hygiene practices (GHP). The overall idea of an FSMS is that an organization builds a comprehensive system of self -monitoring, prevention and preparedness to be able to control and monitor the risks and environment of the process. (Commission Notice 2016/C 278, 2016)

This section leans mostly on the European Union Regulations and recommendations as well as the ISO standards. Other laws around the world (presented in section 4) have been considered and it has been found out that the requirements of the European Union regulations cover the requirements of the counties outside the EU almost completely. It is still advisable to contact each target country once the marketing area has been determined.

The FSMS can be illustrated as a triangle, where in the bottom are the PRPs and traceability tools and in the top is the HACCP analysis. This triangle of FSMS is presented in Figure 3.

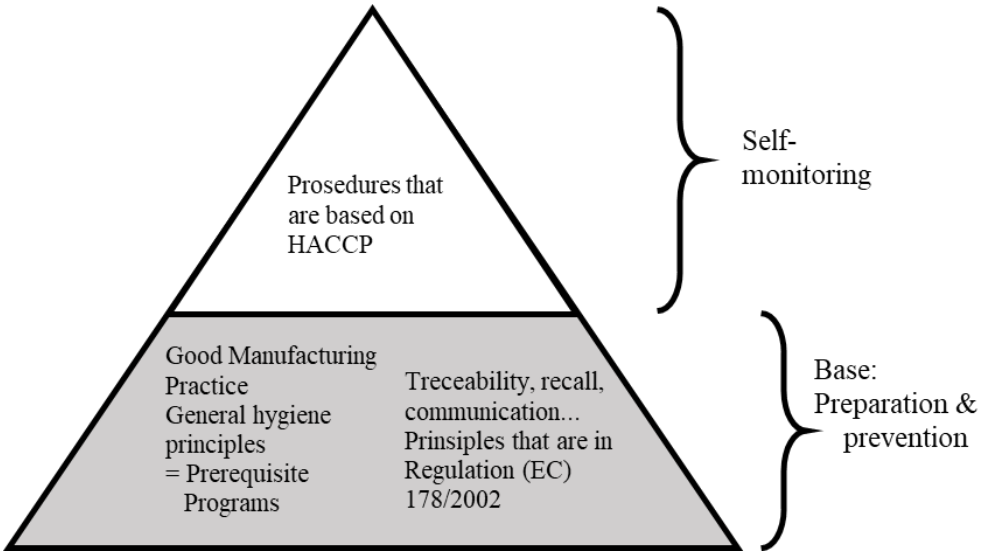

Figure 3 Food safety management system triangle

Figure 3 illustrates the relationship and contents of preparation and self-monitoring. By building a strong base for the triangle the whole food safety management system will be strong. Also, the HACCP is easier to build and update regularly when objectives and targets of the PRPs are clear. PRPs create a base for whole self-monitoring system.

Building of an FSMS starts with knowing the process. The process in this case is very different when compared to for example plastic food contact material making. Paper making process is mechanical: fibres with mostly natural starch and only a small amount of functional chemicals are added to the process in which paper is made. To achieve the sufficient safety level of paper products, also the raw materials and used substances must be high on quality and purity.

It is necessary to implement the PRPs and requirements of the Regulation (EC) No 178/2002 to mill's FSMS. In the Regulation (EC) No 178/2002 (real title: *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*) principles for traceability, recall system, communication between operators, risk assessment, precautionary and consumer protection as well as other relevant pillars of FSMS are listed. (Regulation (EC) No 178/2002, 2002) All the requirements are presented more closely later.

In Figure 4, a simple process flowchart of a papermill is presented. Knowing the process is the key objective for an FSMS.

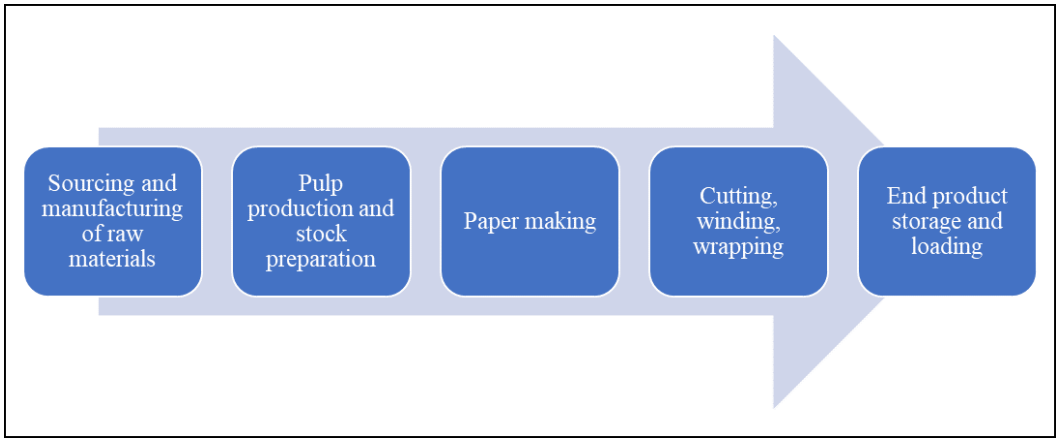

Figure 4 Simple process flowchart of a papermill

The flowchart in the Figure 4 illustrates also the risks in the process. The further the process goes, the higher the risk to product safety may be, as there are fewer subsequent process steps that could eliminate the risk.

There are various issues when it comes to product safety. To have an efficient product safety system, possible contaminants must be known. When knowing how, when and what kind of contamination can happen, it can be avoided in a right way. In Figure 5, contaminant types and things to consider and possibly implement to the PRPs to avoid contaminations.

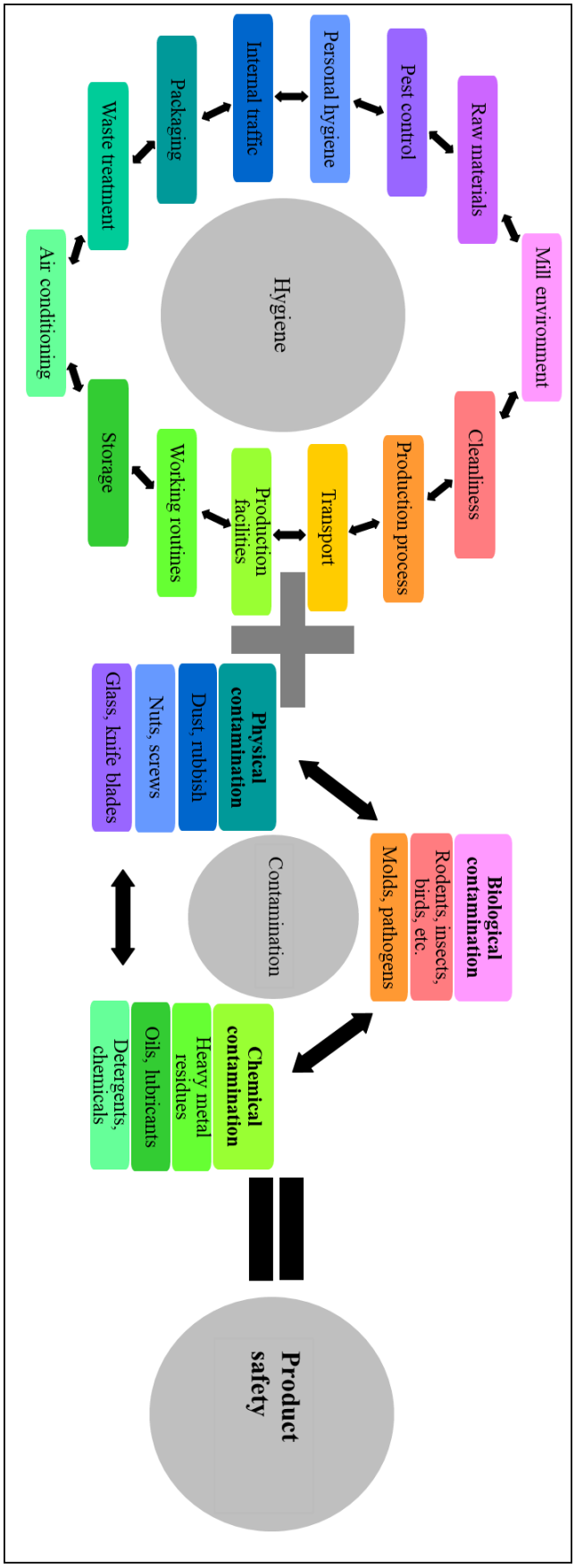

Figure 5 *How hygiene and identification of the contaminants generate product safety*

In the Figure 5, it can be seen that product safety is not that simple thing to control. As a part of good process hygiene there are many different level things such as working routines and waste treatment that have impact on product safety. Good hygiene identification can prevent biological, physical and chemical risks of contamination. These are the building blocks of product safety.

6.1 Good Manufacturing Practice

Good manufacturing practice (GMP) is a requirement within the Framework Regulation. The basic principles of GMP are listed in EU Regulation (EC) No 2023/2006 to ensure harmonized applications of GMP in different business areas as well as across the EU. The EU requires that GMP is applied to every food contact material sector excluding the production of raw materials and substances. (Regulation (EC) No 2023/2006, 2006; Schäfer, 2010) Still, the raw materials used in FCM production must be selected so that the product is safe for food contact. For example, with overseeing chemical purity and quality used in the mill chemicals must be accepted for use. (Schäfer, 2010)

The manufacturing conditions as well as operations must be specified. By doing this, the safety of the process can be ensured, because for example then there is no possibility of an unsafe reaction or degradation products. With the quality management system, the manufacture condition can also be ensured to be safe. (Schäfer, 2010) An organization's quality management system ISO 9001 is related to GMP Regulation. Still, a mill's existent management system needs to be updated to fulfil the food contact material applications in an appropriate way. (CEPI, 2010)

At a mill, the GMP implementation starts with a risk analysis. With a risk analysis, necessary actions to the management system are determined. Another thing to take into concern in risk analysis is the end use of paper. (CEPI, 2010) The principles of a mill's materials, process surroundings, and product control system are presented in Figure 6.

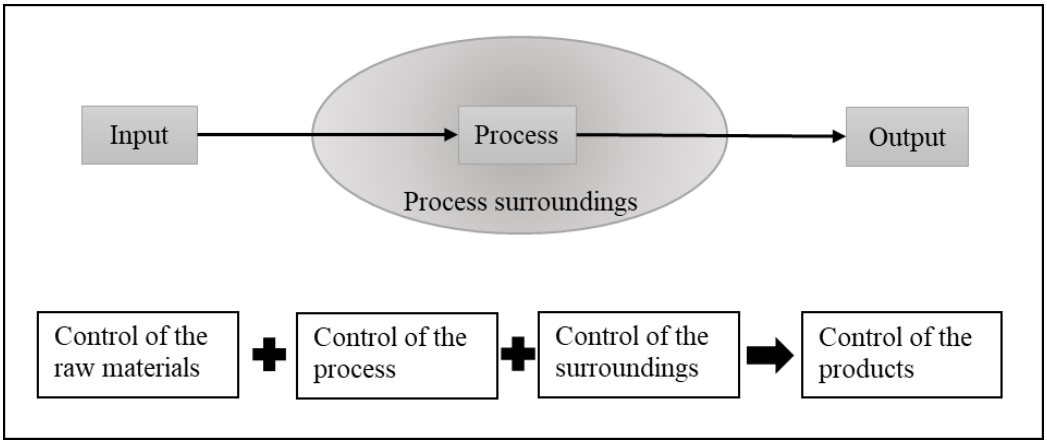

Figure 6 Mill quality management principles

Figure 6 shows that product quality and safety require control of the process. To achieve process control, raw materials, the process and the environment must be controlled. Input of the process covers all the raw materials such as pulp and pressure groundwood, chemicals and process waters. When sources are known and controlled, the process can be controlled. Controlling the process also requires that the process surroundings are known, that the process does not produce by-products or that they are not harmful to product safety, and that the process is clean. When the whole process is controlled from the beginning to the end, the process output is controlled.

The quality control system is mandatory according to the EU Regulation 2023/2006. In the Regulation 2023/2006, it is determined that the achievements and implementation of good manufacturing practice are monitored. Also, the measures to identify and correct the failures in achieving GMP must be part of monitoring. (Regulation (EC) No 2023/2006, 2006) It is in the responsibilities of an organization and management to set up, control, document and maintain the GMP system and other supportive systems. The management must also take care that corrective measurements are implemented directly and made available for inspection to the competent authorities. (CEPI, 2010; Regulation (EC) No 2023/2006, 2006)

The GMP necessitate organisation to maintain specification of food contact material, raw material and additives that are used in the manufacturing, legislations and requirements that are applicable to a mill. The procedures of using of substances

must be documented so that it can be conformed that the using of substances is consistent with the requirements. Also, specifications are required from the facilities that are not under direct control of a mill. (CEPI, 2010)

According to CEPI (2010), testing of frequency must be done with the risk assessment. This means that the possibility of a certain restriction being exceeded in certain circumstances must be inspected and tested. The tests must have statistical and demonstrable basis even if they vary upon numerous factors like raw material, testing accuracy and the process itself. After risk assessment and the initial frequency have been determined, they must be reviewed annually. (CEPI, 2010)

6.2 Good Hygiene Practice

The EU Regulation No 2017/625 is on official controls for authorities to ensure the applications food and feed law. It sets requirements for the authorities to inspect FCMs in their production state. In this regulation, there are requirements for hygiene of packing materials, quality and control. These are the EU Regulation No 852/2004 *on the hygiene of foodstuffs* and for certain products such as EU Regulation No 853/2004 *laying down specific hygiene rules for food of animal origin*. (Regulation (EC) No 852/2004, 2004; Regulation (EC) No 853/2004, 2004; Regulation (EC) No 2017/625, 2017)

The EU Regulation No 852/2004 sets general rules on foodstuff hygiene. Again, it is highlighted that the responsibility of food safety is on the operators and must be ensured through the whole food chain. The HACCP principles must be implemented together with the good hygiene principles. Good hygiene practice (GHP) implementation must be demonstrable with evidence to an authority. The authority of the Member State *shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulations (EC) No 852/2004 and (EC) No 853/2004.* (Regulation (EC) No 852/2004, 2004; Regulation (EC) No 2017/625, 2017)

The General Hygiene Principles must be specified for the field of the organization. For example, the hygiene requirements are different in the beginning of a food chain (e.g. packings, feed) than in the end where actual food is made. The hygiene

principles and their implementation must be documented. The Codex Alimentarius' standard CAC/RCP 1-1969 ‘General principles of food hygiene’ sets a list of rules for hygiene to ensure human health in the food industry. (Codex Alimentarius Commission, 2009)

SFS-EN 15593 is a standard for packing hygiene. The General Hygiene Principles (GHP) are based on risk assessment and hazard analysis. Every operator in the food packing chain must be able to provide evidence and demonstrate that they are able to identify and control possible hazards for good hygiene in their product. (SFS-EN 15593, 2008)

The GHP is presented more closely in the food safety management system (Tuoteturvallisuuden hallintajärjestelmä) in appendix I. It must be taken into notion that also the GHP must be made specifically for a mill. All mills are different somehow and therefore the procedures to ensure food safety cannot be exactly the same.

6.3 Prerequisite Programs

Good manufacturing practice and good hygiene principles are not enough to cover all the requirements in regulations. That is why prerequisite programs (PRPs) are needed. The organization that’s product is part of a food chain must present the descriptions of all applied PRPs. The extent and nature of PRPs should be adapted to the size of the company, including a list of persons in charge and responsibility. (Commission Notice 2016/C 278, 2016)

The Commission Notice 2016/C 278 lists possible PRPs that may be applied to the FSMS. Figure 7 presents parts of this list that should be implemented in an FSMS.

Figure 7 Short introduction to PRPs

Figure 7 gives a short introduction to PRPs. When considering which PRPs to add and implement to a mill, understanding the process and working habits is again the key to success. The Figure above presents those PRPs that are relevant to a mill. Some PRPs may already be in force, for example pest control or waste management.

Infrastructure of a mill must be safe and suitable for FCM production. This means that e.g. structures are sturdy and unbroken, made of nonabsorbent material (when possible) and are easy to clean. The risks of a mill's location must be considered and eliminated wherever possible. If mill premises are large, one or more areas can be designated as areas of higher hygiene. However, the entire paper production area should be a hygienic area and process devices must be cleaned regularly.

A part of infrastructure are also locker rooms/changing rooms, toilets, hand washing places, and lights. Doors of toilets should not open directly to a process area and changing rooms need to be wide enough and enable hygiene working. Handwashing must be made possible when entering high hygiene areas and lights must be unbreakable, protected against breaking and properly covered.

Some parts of PRPs may be covered by contractors. These can be for example cleaning and pest control. It is important to know what kind of cleaning is done and when and how. A list of cleaning items must exist, and all supplies must be suitable for their purposes. Whenever possible, hot water must be used for cleaning.

Pest control must also be controlled and clear about what, when and how. This might need a pest control program that is documented. A few simple ways to increase the effectiveness of pest control are that windows and doors are kept shut whenever possible and covered with insect screen.

All used measuring and process equipment must have maintenance and calibration plans, documents on preformed procedures, and the equipment must be clean and hygienic. Plans as well as documentation must give information about when, what and how procedures are done.

Raw materials can come only from confirmed sources and they must be cleared to use in the manufacturing of FCMs. RCS files are filled by suppliers of raw materials. There must be guides available to storing and using of raw materials available to operators.

All the potential allergens in chemicals as well as in the process should be known. Possible allergens are asked from suppliers via RCS.

Water and air must also be clean and controlled. This can be done by keeping processes of water use and air conditioning cleaned and maintained regularly.

Storages in which the final products or raw materials are held must be kept clean. Also, the storing environment must have a stable temperature as well as humidity whenever possible.

Possible contaminations in the process must be detected. This is done via risk assessment, HACCP. There must be a procedure of actions for a case where a hazard has already happened.

The staff must be trained in the operation of the food safety management system. They should be healthy, their clothes clean for work, and food should not be eaten in the production facilities. First aid kits must be available. Visitors should follow the same rules as staff. In addition, they should complete a statement on their state of health if they go to production facilities.

Not only personnel but also working methods must be known and documented. There must be written working instructions available to personnel and upkept by management.

With proper and well-implemented procedures and PRPs, risk levels and the possibility of contaminations will decrease. Therefore, it is necessary to have understanding on all processes of a mill in order to consider all possible risks and then find all suitable and necessary PRPs.

6.4 Hazard Analysis and Critical Control Point

Hazard Analysis and Critical Control Point (HACCP) is a part of food safety management system for reducing the risks of food safety hazards. Consumers should be able to trust that any foodstuff is safe to eat. That is why HACCP should be applied to every part of food chain including packing material manufactures. Originally HACCP was made in 1960s in NASA’s space program to make sure that the food is safe to eat even in the space. The main idea of NASA’s food control

system was to manage risks throughout the entire lifeline of food. Lifeline of food is from ingredient procurement to storage not forgetting packing and transporting. NASA space program was the reason HACCP to became base for modern food safety standards. (European Commission, 2015; “HACCP Overview,” 2014)

In food supply chains, major failures have been identified recently. Others have been worldwide, like milk powder that was contaminated with melamine in China, and other failures that have been national but still significant, such as *E. coli* in sprouted seeds in Germany or *salmonella bacter*ia in chocolate and peanut butter in the UK and the USA. The question, then, is why the HACCP system is not working? According to Mortimore and Wallace (2013), the implementation of the HACCP system has been poor in all these cases. (Mortimore and Wallace, 2013)

The HACCP system's main point is to identify, control and monitor risks systematically in specific points of the process. Risks that are in the sphere of HACCP's influence can be biological, chemical or physical. HACCP is not meant to be a quality management system but a risk assessment system which focuses on prevention and not on end-product testing. (“HACCP Overview,” 2014; Vinca, LLC, 2019)

The European Parliament has made several regulations about HACCP: for example, the Regulations (EC) No 852/2004 on *the hygiene of foodstuff* and (EC) No 625/2017 on *official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products*. The HACCP risk assessment system is evaluated by the staff of competent authorities. The requirement of authorized evaluation of the HACCP is in the European Parliament Regulation 882/2004. (Regulation (EC) No 852/2004, 2004; Regulation (EC) No 882/2004, 2004; Regulation (EC) No 2017/625, 2017)

To implement risk-based thinking to an organization, a HACCP team must be established. The team should have wide knowledge on processes of the mill and its products. In Figure 8, the structure of a possible HACCP group is presented. This kind of HACCP team structure is good especially for large organizations like mills. (Mortimore and Wallace, 2013)

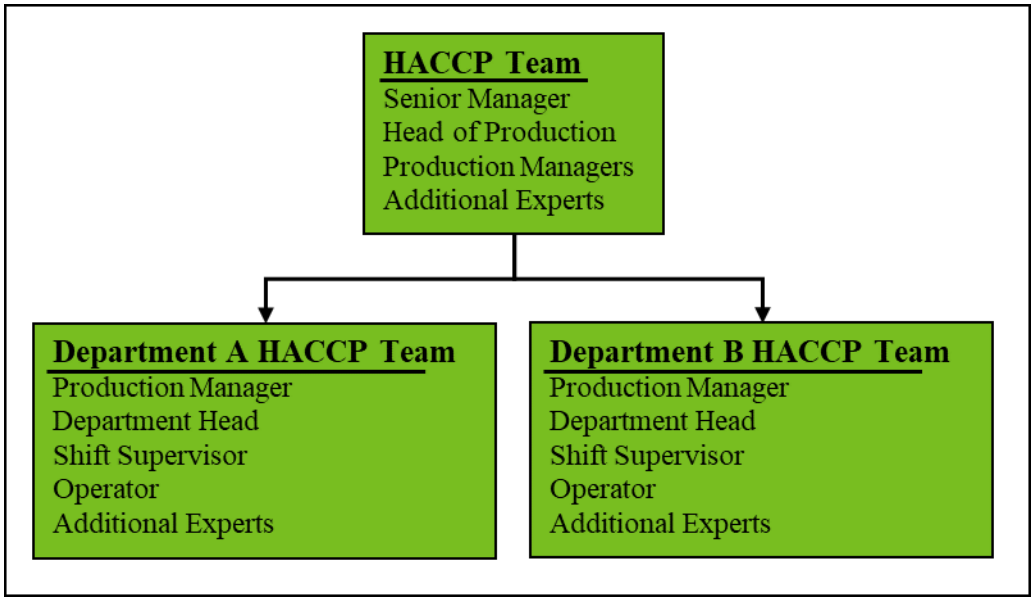

Figure 8 A mill's possible HACCP team structure

Figure 8 illustrates that a HACCP team can have department teams as well. Department teams ensure that the work-related knowledge and habits are taken into concern and later the operation of the HACCP system is reviewed by these experts.

The level of risk varies by location and the final use of material. In Figure 9, the areas, the type of food contact, the type of foodstuff in final use and the level of risk in each part is illustrated.

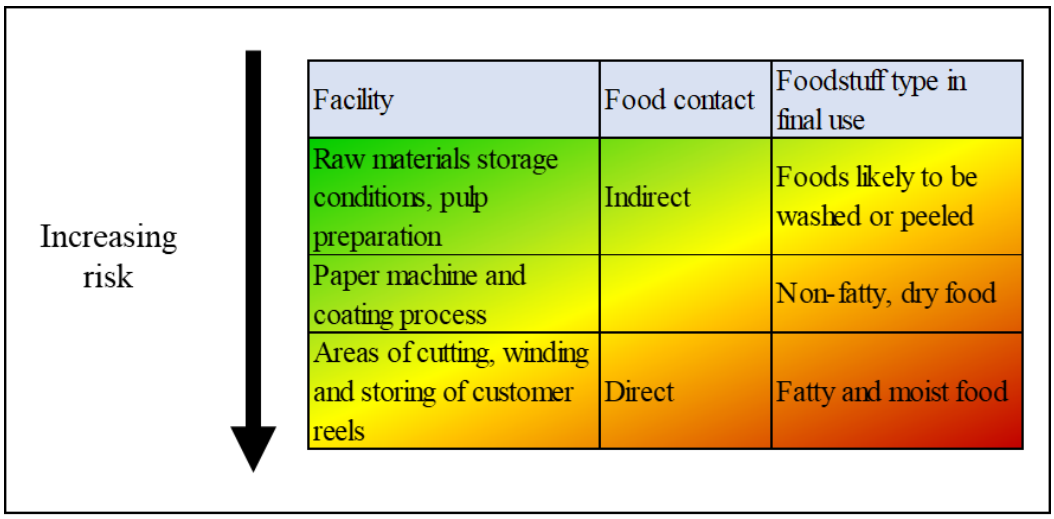

Figure 9 Severity of risk in making food contact paper

Figure 9, illustrates the risk increasing with various parameters. The risk increases when going forward in the paper making process. However, it is not that black and white. Many risks can be eliminated later in the process, e.g. small items that may be present in the pulp are removed by screening before the paper machine. There may also be other kinds of risks, like using a wrong chemical in the process. For example, if a wrong chemical is added into process water or paper pulp, food contact paper may be contaminated.

Different types of contact between food contact paper and foodstuff cause different levels of risk. If the contact is indirect, the risk is not that high. Paper which is coated with plastic or aluminium is one example of indirect contact. The contact can also be direct like with wrapping or baking papers.

The third column in Figure 9 indicates the risk between different types of food and paper. Contact with food that is peeled or washed before eating is not as risky as with a fatty food such as a burger.

All the above examples refer to the finished product that is shipped from a mill to converters. Even the product manufactured in a mill is not final consumer product, like a plate or straw, risk assessment and product development must take into concern a risky nature of the FCM. Customers should be included in product development and the product should be made suitable to their needs (Kärkkäinen et al., 2001).

There are various resource and guides for implementing HACCP principles effectively with seven steps that are given in the EU Regulation 852/2004 ((Regulation (EC) No 852/2004, 2004). The Finnish Food Authority (Ruokavirasto) has also published a seven-step guideline which will be used as a base for a HACCP system (Finnish Food Authority, 2019). This seven-steps guideline is the same as in Codex Alimentarius: Food Hygiene and can also be found in the ISO 22000-2018 standard. (Codex Alimentarius Commission, 2009; EN ISO 22000:2018, 2018)

The first step in implementing HACCP is risk assessment. It includes making a process flowchart and a description about the product. The description of the product must contain a list of used raw materials, characteristics, delivery as well as a description of use and possible limitations of the product. In this step of

HACCP process microbiological, chemical, physical and mechanical risks are sought and listed. When the seriousness of hazards is evaluated, the focus should be on health hazards and not on other quality defects. (Finnish Food Authority, 2019; Ruokavirasto, 2019a)

The second step is to detect the critical control points (CCPs) of the process. A CCP is a specific part of the process that can be controlled and with control the effect of the hazard can be minimized or eliminated. With a CCP, one or more hazard appearances can be affected. For example, CCP cause a possibility of a health hazard. This hazard can be measured and estimated is the result of the measurement below an acceptable level. Result can be a value or an indicator of the level of the measurement. The CCP hazard should be controllable and a corrective actions should be described and put into action quickly, if the acceptable level is exceeded to ensure food and product safety. (Ruokavirasto, 2019b) In Figure 10 is a decision tree to help identifying the real CCPs and to show that not all critical parts are CCPs

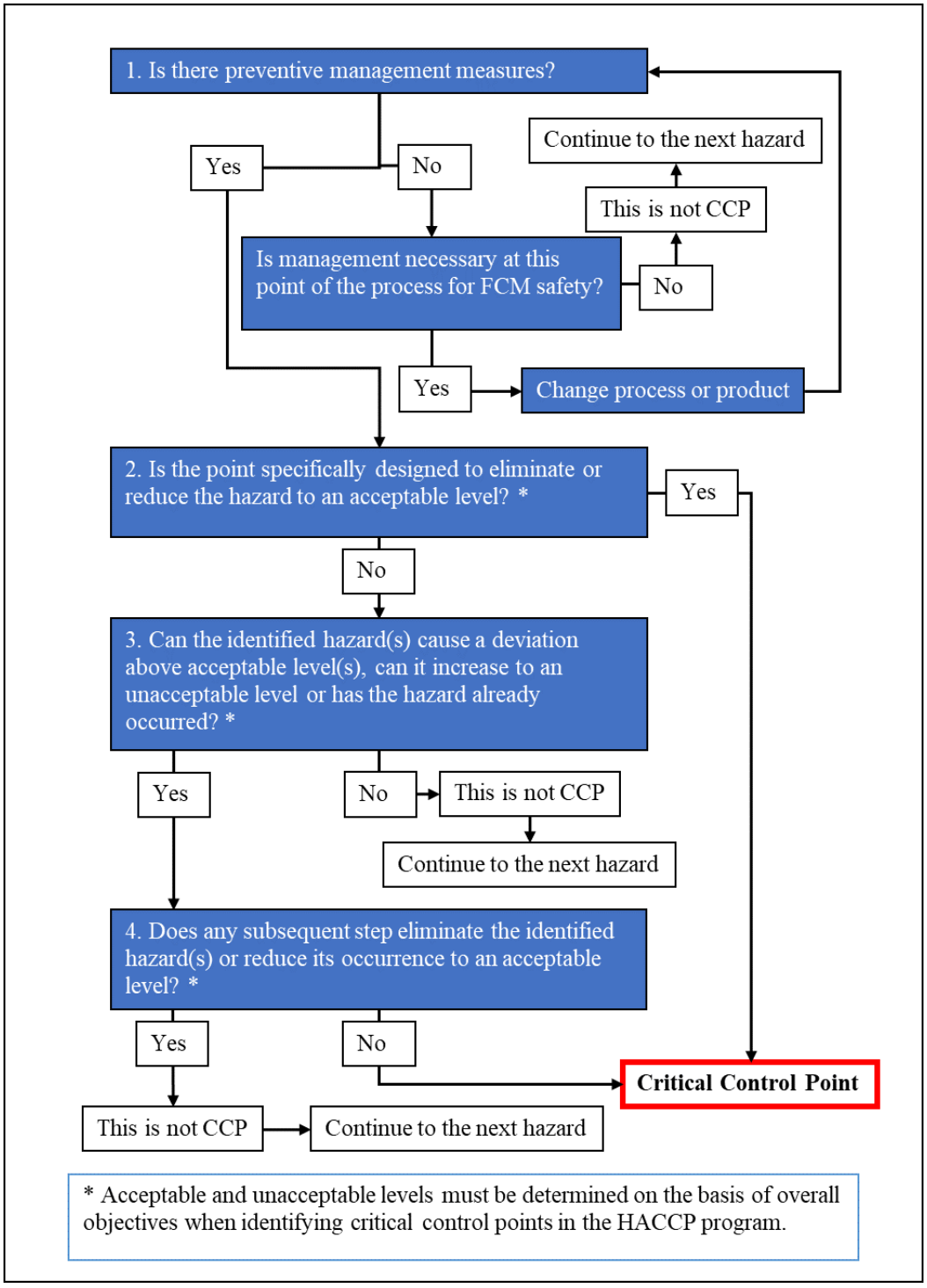

Figure 10 Decision tree for identifying CCPs

In Figure 10, a decision tree for identifying CCPs is presented. In practice, the decision tree is a series of four questions that determine whether a point is a CCP or not. The first question asks whether there are preventive measures for the risk. Based on the answer, the questions move on. The "no" answer to the first question

leads to the question of whether risk management at this stage of the process is necessary for food safety. If "yes", the process needs to be changed somehow. If "no", the risk in question is not a CCP and the risk assessment will continue to the next risk on the risk list.

If the answer to question 1 is "yes", next up is question 2 of the decision tree: is this current point of process specifically designed to eliminate the hazard or reduce it to an acceptable level. Acceptable and unacceptable levels are decided case by case when making a risk assessment. A "yes" answer to question 2 means that the risk is a CCP. If the answer is “no”, one continues to question 3: can the identified hazard(s) cause a deviation above acceptable level(s), can it increase to an unacceptable level or has the hazard already occurred.

If the answer to question 3 is “no”, then the risk is not a CCP and risk assessment continues with the next risk on the list. If the answer to question 3 is “yes”, continue to question 4: Does any subsequent step eliminate the identified hazard(s) or reduce the occurrence to an acceptable level? Again, the acceptable and unacceptable levels must be defined case by case. If the answer to question 4 is "yes", then the risk is not a CCP and risk assessment continues with the next risk on the list. If the answer is “no”, then the risk is a CCP.

The decision tree helps identifying the CCPs. The questions start from the top (Question 1) and all questions must be answered until either “Continue to the next hazard” or “Critical Control Point” is reached.

The third principle of HACCP is to determine the target levels and critical limits. The target level or critical limit can for example be a biological, chemical or physical property of a consumed product. Properties can be for example preservative content or organoleptic properties such as taste, odour or appearance. A critical point can have various critical limits and they can be based on e.g. official regulations or research results. The HACCP team of an organization can set an alert threshold to alert when are a critical limit is being approached. (Ruokavirasto, 2019c)

When CCPs and target levels are determined, monitoring policies are established. That is the fourth principle of HACCP. The monitoring police ensure that all critical control points are under control. Monitoring the critical control points is carried out

continuously with pre-agreed measurements and/or observations. Monitoring policies require work instructions that comprehensively describe what is being tracked, which method is used, how often the monitoring is done and by whom, how the tracking result is being recorded, and who is being notified of deviation. (Ruokavirasto, 2019d)

Determination of remedial measures is the fifth principle of HACCP. The purpose of this section is to determine the corrective actions to be taken when monitoring the Fourth Principle to detect a deviation in CCP control. The remedial measures must be designed for the CCP in question and after the procedure, there must be demonstrable management and hazard prevention. Examples of remedial measures include temperature correction, pH adjustment, and production process corrections. If the product is manufactured during an incident, corrective measures must be taken to ensure product safety. One example is withdrawal. Once the situation is brought under control, the cause of the deviation will be investigated and eliminated, and corrective action will be taken to prevent recurrence. All corrective actions and reorganisations shall be documented in the HACCP records. (Ruokavirasto, 2019e)

The sixth principle of HACCP is the development of verification policies and validation of the HACCP program. This section sets out authentication policies to ensure that the entire HACCP system is operational. Validation assesses whether the HACCP program is properly designed, implemented and enough to ensure product safety. Verification may include chemical, physical or microbiological examinations or organoleptic assessments. Verification shall be carried out according to an agreed timetable and whenever a hazard is detected. Validation shall be performed during the deployment phase of the HACCP system, and whenever a process or product is modified, or a health hazard or critical limit is repeatedly exceeded. (Ruokavirasto, 2019f)

The final section of the HACCP principles is "HACCP Documents and Records and Their Management". HACCP documents are the plans and instructions that are created when the HACCP system is developed, and that guide its implementation. These may include product descriptions, monitoring and measurement guidelines, raw material information, and product approval criteria. HACCP records are records and stored information generated during the implementation and

maintenance of the HACCP program. Critical control point measurements, corrective actions, verification and validation generate various forms of records and reports, all of which are HACCP records. It is important that the information is identifiable, traceable and made in such a way that it cannot be altered. All these records should be retained long enough. The Finnish Food Authority proposes that the records be kept for two years and at least 6 months beyond the shelf life of the product. (Ruokavirasto, 2019g)

All in all, the HACCP implementing will take time. It is not easy to know all the risks at first or find real risks to product safety. This in why HACCP should be a project and a way of working rather than one quick series of meetings.

Data on hazards, risks and occurrences should be documented and collected for example in Manufacturing Execution System (MES). Documented information must be used in HACCP group meetings.

6.5 Declaration of Compliance

In every step of food contact material chain, excluding retail, a Declaration of Compliance (DoC) must accompany the product. The requirement behind a DoC is to indicate the responsible operator of each step in the chain and to show that the Framework Regulation is complied with. The Framework Regulation is again the highest requirement in the EU when it comes to paper and board materials that require a written declaration and documents stating that the product complies with applicable rules and recommendations. Though there is no set format for a DoC when it comes to paper and board FCMs in the EU level, this document is still needed. The Finnish Food Authority an CEPI have made clear guidelines for making a DoC. (CEPI, 2019; Finnish Food Authority, 2019; Regulation (EC) No 1935/2004, 2004)

A DoC does not only point out the responsible operator, but it also shows that the product is safe and suitable for the purpose it is made for. Also, a DoC informs the client, so that they know that the product is manufactured following the current legislation and good manufacturing practices. Also, a DoC ensures that the material or product is used correctly in the next step of the chain. (CEPI, 2019; Finnish Food

Authority, 2019) It is recommendable to update a DoC in every two years or whenever changes in process or in raw materials are made.

General instructions for DoCs made by The Finnish Food Authority's general and the CEPI Food Contact Guidelines for the Compliance of Paper and Board Materials and Articles vary a bit. In Table 4, these two are presented. (CEPI, 2019; Finnish Food Authority, 2019)

Table 4 Comparison of the Finnish Food Authority and CEPI Food contact guidelines requirements of DoC

Finnish Food Authority	**CEPI Food contact guidelines**
Date	Date
Trade name of product and identifying information (traceability information)	Trade name, description of the product including other relevant identifying information (traceability information).
	Identity and address of manufacture
Information on the composition and structure of the contact material (e.g. virgin fibres or recycled, inks)	Generic product description
Information on raw materials that are allowed with limitations	Statement to downstream operators about known migrants with SML limitations (for paper in BfR XXXVI or other relevant lists of authorized substances), and intentionally added substances that, based on risk assessment can potentially migrate to food.
	If there is risk that purposely added dual use substances migrates to food list of substances that have quantitative restrictions is needed
Information on whether co-formulants have been used (if so, their name and E-code)	
Requirements of law that material manufacture is based on. Least fulfil the requirements of the Framework Regulation and other material specific laws.	Statement of the product fulfilling the requirements of the Framework Regulation and Food Contact Guidelines.
	Statement of fulfilling other material laws for non-harmonised products, if existing
Information that the Regulation (EC) No 2023/2006 quality management system is in use while manufacturing.	

Results of studies or model calculations performed	
Foodstuff types for which the material is suitable for	End use definition and possible restrictions e.g. maximum temperature and food type
Restrictions of temperature of use	
Restrictions of lifetime of use	
Also required for paper:	
Indication of whether the fibre used is recycled or virgin; bleached or unbleached	

In Table 4, it can be seen that even though the target of a DoC is the same in both the Finnish Food Authority's requirements and the CEPI food contact guidelines, the content is not. Also, there are various other guidelines like annex IV of Regulation (EC) No 10/2011 *on plastic materials and articles intended to come into contact with food* Declaration of Compliance that may also be used as model of DoC (Regulation (EC) No 10/2011, 2011).

In Table 4, DoC contents, the Finnish Food Authority's requirements and the CEPI food contact guidelines are in columns. The requirements are sorted to have similar requirements in the same row. The order of DoC requirements does not have to be same as here. According to these two templates, a DoC must contain at least the date, tradename of the product with other identification and traceability information, description of the product, information on raw material limitations, statement that the product fulfils the Framework Regulation, and definitions of possible end use.

There are mostly minor differences between the requirements of the Finnish Food Authority and the CEPI food contact guidelines. CEPI requires the identity and address of the manufacture. This is usually already covered in the Technical Data Sheet (TDS) of the product.

CEPI also does not require testing reports to be included in a DoC, but the Finnish Food Authority does. This does not mean that CEPI does not guide mills to test their product but the statement of fulfilling all necessary requirements is enough in a DoC.

The only major difference between the Finnish Food Authority's requirements and the CEPI Food contact guidelines is that CEPI does not require information if dual use substances (also known as E numbers or co-formulants) are added. They must be noticed in testing and if there are no risk of dual use substances migrating to foodstuff, no acts are needed. The Finnish Food Authority states that dual use substances need to be listed whenever they are used in manufacturing of product.

Again, paper characteristics and end-use of the material define more precisely which DoC format to use. The target country may also set some limitations or requirements on a DoC and those must be checked when marketing to new areas.

6.6 Standards

The European Council Regulation No 1935/2004 sets a framework for all food contact materials. Every material which is placed on the market and can come in contact with foodstuff should comply the requirements of the Regulation. The Regulations obligates an organization to list the used substances and make sure that the substances undergo safety assessment prior to usage. (Regulation (EC) No 1935/2004, 2004)

Authorisation of manufacturer of food contact material and safety assessment needs to be equal in Communities. To ensure this, the Regulation demands that the safety assessment needs to be carried out by the Authority at Community level. (Regulation (EC) No 1935/2004, 2004)

ISO 9001 covers not only the process but also the persons that are necessary for the effective implementation of a quality management system. Persons' competence for doing certain work must be determined. Persons' must have sufficient knowledge about the quality policy and operations as well as their effect to quality and consequences of non-compliance of quality system. (EN ISO 9001:2015, 2015)

The aim of the ISO 14001 (full title: *Environmental management systems. Requirements with guidance for use*) is to provide a framework to keep balance with environment and socio-economic needs. The ISO 14001:2015 defines the requirements for an environmental management system. (EN ISO 14001:2015, 2015)

According to the ISO 22000, it is good to use the process approach when a food safety management system, an FSMS, is developed and implemented in company. Also, safe production of food contact material(s) can be improved with a process approach when developing and implementing an FSMS and meeting applicable regulatory requirements. A comprehensive process management system can be achieved with the PDCA cycle. PDCA stands for Plan-Do-Check-Act. In Figure 11, there is a graphic of the PDCA model. (EN ISO 22000:2018, 2018)

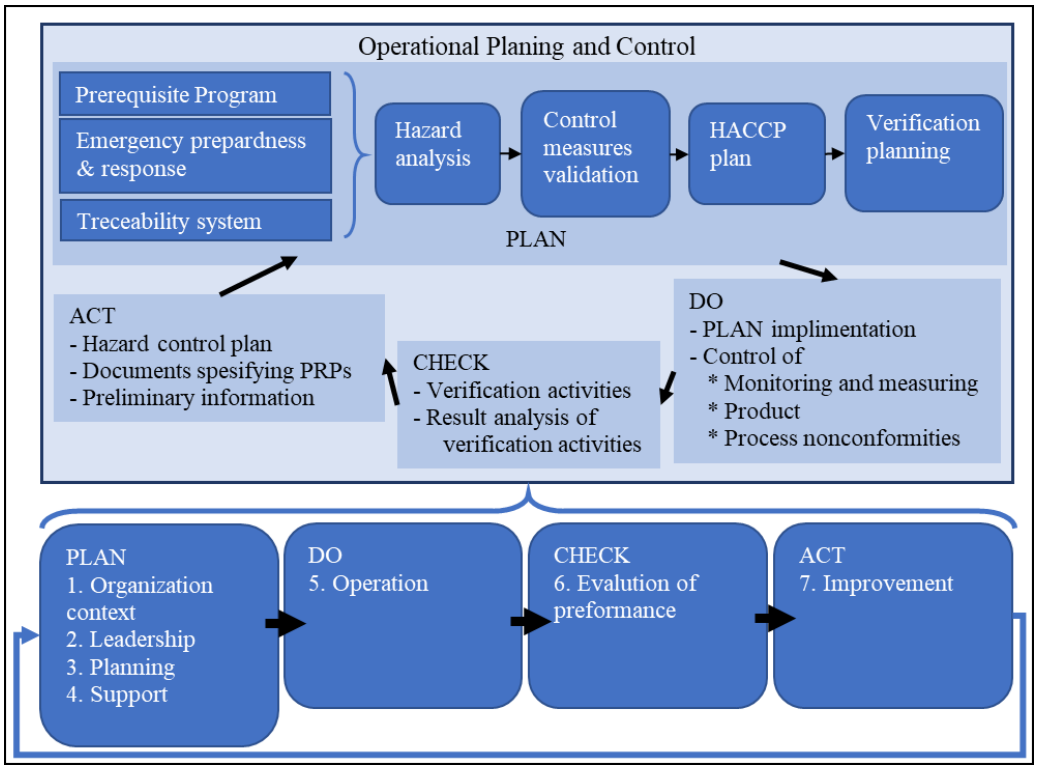

Figure 11 The Plan-Do-Check-Act cycle

Figure 11 illustrates the PDCA model. ISO 22000 contains principles of other management systems, like the ISO 9000 series. ISO 9001:2015 is "Quality management systems. Requirements (ISO 9001:2015)" of which SE has a certificate: *the company has been found to conform to the Quality Management System standard: ISO 9001:2015*. The seven principles of "organizational planning and control" management in ISO 22000 are organization context, leadership, planning, support, operation, evaluation of performance and improvement. (EN ISO 22000:2018, 2018) (EN ISO 9001:2015, 2015)

ISO 22000 lays down mandatory procedures and they are also mentioned in the Framework Regulation. Some of these thirteen procedures come up also in ISO 9001:2015. (EN ISO 22000:2018, 2018) (Regulation (EC) No 1935/2004, 2004) (EN ISO 9001:2015, 2015)

The general requirements of ISO 22000:

- An organization must have a Food Safety Policy which is developed by top management.
- There must be objectives that will drive the organization and personnel's efforts to comply the Food Safety Policy.
- A management system plan and the system itself must be documented.
- The system performance records must be maintained.
- A Food Safety Team must be formed. The personnel of this team must be qualified.
- Communication procedures with stakeholders outside the organization (customers, regulatory, etc.) as well as for internal communication must be in force.
- Plan on what to do in case of an emergency (especially regarding the FSMS).
- Management must have meetings for reviewing and evaluating the performance of the FSMS.
- Personnel must be trained, infrastructure must support the FSMS, and adequate resources must be provided to ensure food safety.
- The HACCP plan must be followed.
- A traceability system must be in force.
- A corrective action system and control of nonconforming product must be in force.
- A withdrawal procedure must be established and documented.
- Measuring and monitoring devices must be controlled.
- An internal audit program needs to be started and maintained.
- A Food Safety Management System must be built to be continually updated and improved.

The ISO management system standards 9001, 14001 and 22000 are slightly uniform. One goal of ISO 22000 is to enable organizations to integrate their FSMS

with other management systems and standards they already have and to work with the process approach by combining it with risk-based thinking and the PDCA cycle. (EN ISO 22000:2018, 2018)

FSSC 22000 is based on ISO 22000 and 9001 requirements. Also, it covers some additional requirements and Prerequisite Programs (PRPs) that are based on a certain field of technical specifications, in this case ISO/TS 22002-4. The Global Food Safety Initiative (GFSI) recognized and benchmarked FSSC 22000 in February 2010, which confirms the recognition and acceptance of the standard(?) in global food industry. (FSSC 22000, 2019) Thus, FSSC 22000 is more global than ISO 22000.

To achieve effective ISO 22000:2018 and FSSC 22000, the way of thinking must become and be risk-based. The ISO 22000 standard divides risk-based thinking to an operational and organizational level. A risk itself is an effect of uncertainty. In organizational risk management, a risk can be positive or negative. Nevertheless, an organization must plan and accomplish actions to fulfil the requirements of ISO 22000. In the operational level, HACCP and operational level principles are the key to risk-based thinking. To be sure that food is safe to, eat the subsequent steps in the HACCP model are mandatory for limiting hazards and the possibility of them to an acceptable level. On the other hand, risk management is based on human health in the Framework Regulation: every food contact material should be as inert as possible, and they must not endanger human health (Regulation (EC) No 1935/2004, 2004). The words are different, but the contents are the same. Risk identification is the key to preventing unwanted effects, increasing the effectiveness of an FSMS and achieving even better results. (EN ISO 22000:2018, 2018)

Both ISO 22000 and FSSC 22000 require an organization to evaluate and control present microbiological hazards. ISO 22000 requires measurements every time there is a possibility of a microbiological hazard. It also covers air quality measurements if there is a reason to suspect that the air might become or has been contaminated in the process. All these hazards must be controlled and prevented if possible. (EN ISO 22000:2018, 2018) In FSSC 22000, documenting all the procedures are the key element. SE has an ISO 14001:2015 certificate which means that the documentation required in FSSC is almost covered.

Allergens must be documented (FSSC 22000, 2019) because they are food safety hazards (EN ISO 22000:2018, 2018). A risk analysis with control measures and an elimination plan must be done for all the possible sources of cross-contamination of allergens (FSSC 22000, 2019). A list of substances and products causing intolerance and allergies is included in the European Parliament and the Council Regulation (EU) No 1169/2011 and in the US FDA Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

Monitoring is important when it comes to any FSMS. Monitoring gives short- and long-term information about its target. With a good monitoring system, failures and deviations can be detected along with critical points and parameters. (EN ISO 22000:2018, 2018).

6.7 Traceability

Paper can be processed in thousands of different ways before use. For example, paper leaves the Mill as reels that are cut in smaller reels. That reel is cut again at the coating factory, from where it continues to another independent box making operator. This makes the process chain very complex and highlights the importance of a traceability chain. (CEPI, 2019)

The requirements of the Framework Regulation on traceability are presented earlier. In brief, a product must be traceable through the whole food chain, from raw materials to the final packed product.

The ISO 9001 requires that products are traceable. Also, laboratory experiments and measurements need to be traceable. An organization shall manage the identifiability of individual outputs and maintain documented records to enable traceability. (EN ISO 9001:2015, 2015) ISO 9001 is recommended for a product recall procedure. (CEPI, 2019)

In the Food Contact Guidelines published by CEPI, guidelines for traceability are set. There is no single set of rules that fulfil the requirements of traceability: some of the elements are additional whereas others are mandatory. This is a bit problematic because the systems vary between operators. It is every business

operator’s choice how they confirm traceability and if there is an existing system that is wide enough, there is no need to duplicate that. There are two traceability systems in wide use in the paper industry: the FEFCO Bar Code Standard for Corrugating Materials and the CEPI Unit Identifier. Whatever system is used it must be open to external audit. (CEPI, 2019)

The main traceability chain for food contact paper starts at the dry end of a paper machine where paper reed is made. The key of traceability is the reel number. If the reel is cut, also those smaller reels or batches of sheets need to be numbered. It is recommendable to have a sample of each batch. If contamination is suspected the batch sample can be helpful in identifying and locating the time and source of contamination. Possible contamination ways are microbiological, chemical and physical contaminations. In a case where contamination is suspected, the material batch must be recall. (CEPI, 2019)

Documents that are relevant for traceability must be retained for a certain period. Some national laws require a specific period, but if such legislation is not available, the current management system sets the scope. In some cases, the customer may have requirements for sample keeping and those can be agreed upon in a deal. (CEPI, 2019)

In Figure 12, the traceability in the paper supply chain is outlined. This is not a list of mandatory requirements, but more of a depiction of a possible way to fulfil the traceability requirements of the Framework Regulation.

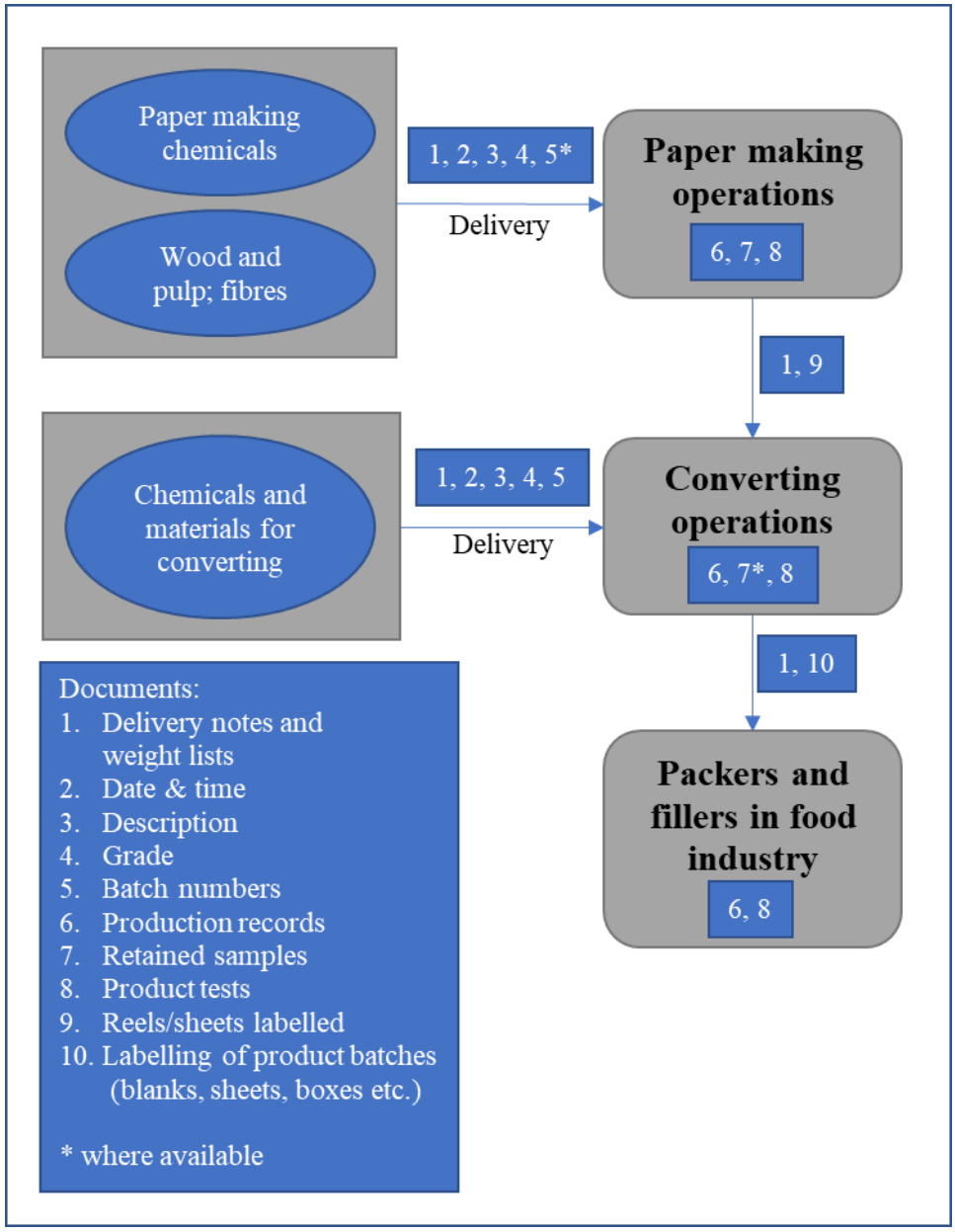

Figure 12 Traceability in the supply chain of paper making

It can be seen in Figure 12 that information about paper must go through the whole supply chain. With good communication between links in the supply chain, it can be ensured that the food contact paper is safe to use for its purpose (CEPI, 2019). In Figure 12, the first box at the top left represents all the materials and substances that are needed to make paper. Pulp can be made from wood or it can be recycled. Paper making chemicals are for example starch, dyestuffs, functional chemicals and minerals.

It is necessary to know what the delivered substance is. For example, dyestuff that comes to a factory with a truck is retained in a barrel and pumped via a pipeline to a paper machine. If it is later discovered that the paper migrates colour to food and the source is the dyestuff, traceability of paper and the substances in it is necessary. If there is not enough information about the dyestuff, it is impossible to know what has gone wrong and the paper is not safe to use as FCM. One point of traceability then is to make withdrawal possible.

To confirm the traceability of the product through the whole food chain, all the suppliers and customers (converters) must be known. In Figure 13, a possible chain is illustrated.

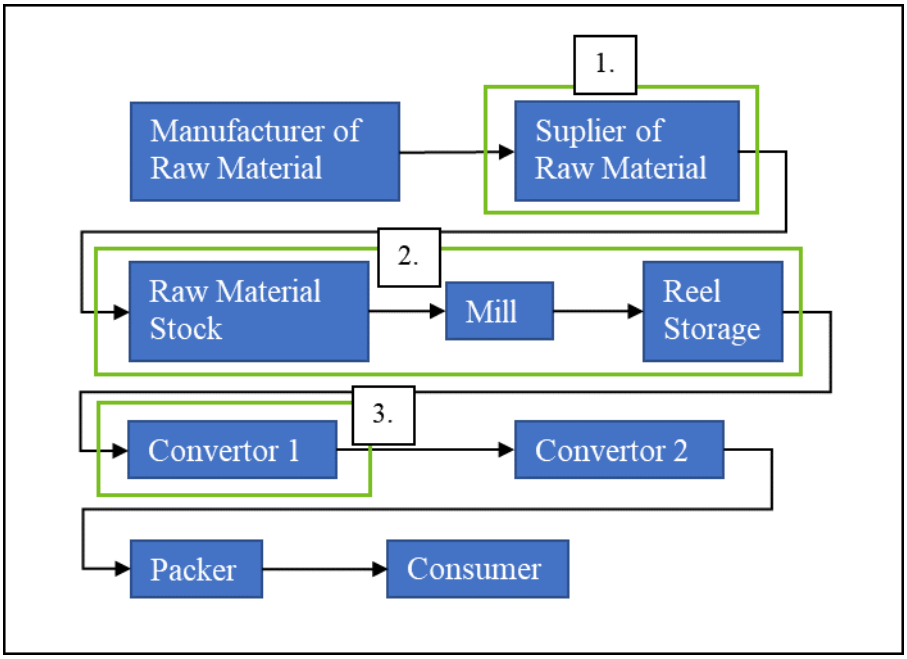

Figure 13 A possible food contact material chain

Part of an FSMS is to know where products come from and where they are going. In Figure 13, the idea of knowing the previous and the next step is explained. The manufacturer and the supplier of raw material can be different. Number 1 in Figure 13 presents the link in a food chain before the mill. To confirm the traceability, it is not necessary to know whether the product is manufactured by or for the supplier, but the link before the manufacturer of paper must be known. For example, the supplier brings chemicals to mill but does not manufacture them. They still need to

provide information of the manufacturer whenever asked by the next link in the chain.

Number 2 in Figure 13 is the mill. It is possible to have both a raw material stock and reel storages outside or inside the mill. In most cases, they are part of the mill, so the mill itself, the raw material stock and the reel storages are treated as one entity in this example of a food chain.

A third significant part of a food chain from the perspective of a mill is the convertor (number 3 in Figure 13). As told before, it is possible to have many convertors before paper gets its final form before going to consumer. Again, it is not necessary to know where the product goes finally, but the next link must be known.

6.8 Labelling

As presented earlier, the labelling of food contact material must provide information that the product is intended to be used as food contact material. Depending on the markets to where the product is sold, different symbols may be used (compare the Framework Regulation in section 3 and the Chinese standards in section 4.2). The labelling must provide information which can be used to trace the specific manufacturing time and the raw materials of paper from the MES.

6.9 Requirements to a mill

All in all, there are many things to do to achieve an effective food safety management system. They are all linked together more or less. In subchapter 6.3 on Prerequisite Programs requirements of an FSMS for a mill are presented. The components of good manufacturing practice, that are not presented before, and the level of requirement are presented in Tables 5-7. The information on Tables is collected from the CEPI and EU requirements as well as from standards.

Table 5 General components in GMP system for papermaking

General Components	Comments	Level of requirement
Quality management systems, e.g. ISO 9001 or equivalent		1
Implementation of a food safety management system to a quality system	Internal audits on the implementation of an FSMS as a part of quality system	1
Management responsibility in ensuring the integration and implementation of a GMP system	Management has the ultimate responsibility for GMP, set up, maintaining, review, documentation, personnel training etc.	1
Personnel training on GMP and documented training records	Mill personnel and contractors working in the mill area must be trained in GMP requirements and hygiene aspects. If in a certain area the risk is low, informal briefings may suffice.	1
Risk analysis	Risk analysis must be performed by a team of experts (see HACCP team). Continuous maintaining and reviewing at least once a year. If major changes on process or product take place, risk analysis must be revised.	1
Project person or team for implementation and maintenance	This may help getting the FSMS in force at the mill. It's advisable to have a named person in charge.	2

In Table 5, the general components of GMP are presented. The first column is the component, and in the second column comments on components are presented. The third column of the Table represents the level of the components necessity. 1 means that the part is necessary for GMP and 2 means that the part is strongly advised to be implement in GMP.

There are five general components that have a main role in GMP of a food safety management system. The first one is a quality management system. It must be implemented, which is the second component, and it must become a part of GMP. To make GMP a part of everyday work, management must ensure system integration and implementation, which is the third component.

The fourth component of GMP is personnel training. Every person, including contractors, working in the mill area must be trained in GMP and training records must be documented. If there is an area in which the risk to food safety is minor, contractor training can be informal. The fifth main component is performing risk analysis. Risk analysis must also be maintained and reviewed regularly. If major changes on process or product takes place, risk analysis must be revised.

The last component in Table 5 is naming a person (or a team) to oversee FSMS implementation and maintenance. It not necessary but may help the project to be completed.

Table 6 Specification of components in GMP system

Specification	Comments	Level of requirement
Review regulations and requirements, customer requirements, and regulations and procedures for other food contact materials	If there is a person in charge, this may be part of their job. Otherwise, this is not necessary for an organization to do, but information can be obtained from outside.	1
Testing the product	The product made by a mill should be tested according to relevant regulatory measures. There should be documented procedures for sampling and testing.	1
Explaining the measures	Measure(s) must be listed as a part of a quality system. There must be documented guidelines for measures as well as for determining the testing frequency of regulatory measures. If the measures are not performed, there must be documented reasoning.	1 and 2
Substance input equipment	Accuracy of substance input must be verifiable. There must be equipment that measures the dosage of substance to ensure product safety.	3

Table 6 presents specifications of GMP components. The first column of Table 6 is the specification of a component, and in the same way as in Table 7 (on p. 61), comments are in the second column and the level of necessity of a component in the third column. 1 means that the part is necessary for GMP, 2 means that the part

is strongly advised to be implemented in GMP and 3 means part is required only if the risk assessment level is too high whether organization already fulfil the requirement or not.

It is necessary to stay active regarding food contact material regulations because they are very diverse. The information on updates does not have to come from inside of the organization but can be obtained from the outside.

A product that is food safety material must be tested according to relevant regulatory measures. Also, measurements must be listed and documented with guidelines for determining testing frequency. In case the measures are not preformed, documented reasoning must be done.

The last specification in Table 6 is about substances. All substance inputs must be verifiable with measurements of dosages of substances.

Table 7 Quality control and raw materials as components in the GMP system

Components in the GMP system	Comments	Level of requirement
Quality control system of the GMP	The implementing and achievement of the GMP must be monitored and recorded. The measures that needs to be corrected and all failures of GMP system must be included into this monitoring.	1
End use	All possible applications of the end use of the manufactured FCM must be analysed and documented. The customers should provide details of the end use, but this is not mandatory. If no information on the end use is available, the customer should be announced that they are in response for the safe use of a product.	3
Recipes	Recipes of the manufacturing of FCM must be complied. With the recipes used raw materials can be detected along the process. Without the recipes of the product a mill cannot allocate responsibility to a supplier if the raw material is defective.	2

Table 7 presents role of quality control of the GMP, end use, raw materials and recopies as a component of the GMP system. The format of Table 7 is the same as in two previous Tables. The first component of this Table is on quality control system of the GMP. Good implementing and achievement of the GMP requires that there is records on the progress of the system execution.

The second component of Table 7 is end use. Knowing the end use application of an FCM ensures the safe use of an FCM. If a consumer does not provide information on the end use it is a responsibility of the consumer to use FCM as a safe way.

The last component in Table 7 are recipes that must be complied. If there are no recipes, a mill cannot allocate responsibility to a supplier.

At Stora Enso Paper Oy, the ISO 9001, ISO 14001 and ISO 50001 certificates have been issued to the divisions. This means that the local operator (the mill) must fulfil the requirements and the systems have also been audited at the local level. Despite the other ISO systems issued to the division, ISO 22000 must be made specially to mill. One important thing behind a separate ISO 22000 certification is the specialty of each mill when compared to others.

Usually, food contact papers are made from chemical pulp, not mechanical pulp. Ground wood pulp contains all the ingredients that are present in wood such as cellulose, resins, gums and lignin. Chemical pulp is made either by digesting wood chips in acid or alkaline solution and washing the pulp afterwards. Pulp that is made chemically does not contain any dissolving components, such as cellulose. Mechanical pulp may be used in food contact paper but usually those papers are not used in direct contact with foodstuff. (Brennan, 2006)

The goal of case mill is to start with one or a few paper grades that will be suitable to be used as FCM. Because both coated and uncoated materials are produced in the case mill, all used chemicals are not safe to use with food contact materials. It is a tendency of the case mill to only take in products that are safe to use with FCMs, but it is not always possible.

7 CONCLUSIONS OF LAWS, REGULATIONS AND REQUIREMENTS

As has been proven in the previous chapters, laws, regulations and recommendations on Food Contact Materials are not simple or easy to follow. Different countries and states of the USA may have their own regulations that can be slightly, totally or to some extent different to other regulations.

In order to meet all the requirements of a specific market, one must know the laws of the target country well. Another option may be to consult food contact material experts in that country. Also, getting an FSMS certificated to a standard e.g. ISO 22000 or FSSC 22000, may help in getting clearance.

Table 8 bring together the requirements of FSMS based on the laws and regulations which are presented earlier in this paper.

Table 8 Table of Necessity of the Elements of FSMS

Element	Details	Necessity
Labelling	Detailed documents of system that is used to label materials and articles that are placed to market but not yet in contact with foodstuff. Documents are for illustrating how the labelling requirements are complied with.	Mandatory
Traceability	Documents of how to recall products and information of traceability. Both documents are for illustrating how the traceability requirements are complied with.	Mandatory
Substance and raw material identification and verification	Composition of the manufactured material. Because paper and board are not harmonised materials in EU legislation, DoC or similar documents from raw material suppliers of chemicals and polymers (if used) that are authorised for use in defined process.	Mandatory
Purity criteria	Defined in the DoC based on information given by the chemical and additive suppliers.	Mandatory
Dual use substances	Defined in risk assessments: is there a possibility to substances to transfer to foodstuff. DoC must contain the adequate information of substances.	Mandatory
Good manufacturing practice	Organization must fulfil the Regulation (EC) 2023/2006 on good manufacturing practice. The Organization must keep documentation on the quality control and assurance applications.	Mandatory

Good hygiene practises	Regulations (EC) No 852/2004 on the hygiene of foodstuff, lays down that the safety of foodstuff must be ensured by all the manufactures through a food chain. General hygiene practises must be followed.	Mandatory
HACCP	Risk-based thinking is the base of the FSMS and HACCP or equivalent procedure on risk assessments is required worldwide.	Mandatory
Risk assessment	Possible migrants must be identified, defined and documented. Migration and sensory testing results and worst-case calculations based on risk assessment of intentionally added substances and NIAS included. Risk assessment covers the overall compliance of the material and article. It must be notified that there are multiple sources of substances.	Mandatory
Substances intended to be used behind a functional barrier	If paper or board is coated there is possibility to use substances that are not normally allowed to use in paper but there must be enough written information confirming that substance is not harmful, mutagenic, carcinogenic or toxic. Also, it must be confirmed that the substance is not intentionally manufactured to be in nanoform.	Mandatory but unlikely to be many affected materials.
Identification and risk assessment of Non intentionally added substances (NIAS)	GMP has significant role to identification, managing and minimising of NIAS. Results from testing of known NIAS and migration models need to be documented. Toxicological information of NIAS are also needed but sometimes not possible to get.	Mandatory, but sometimes NIAS are hard to identify and document.

In Table 8, the elements of an FSMS are listed to help understanding the system and all its parts. The system seems complex because it contains multiple parts. The FSMS will be simple to control after all the parts are implemented to a mill's everyday functions.

8 FOOD SAFETY MANAGEMENT SYSTEM FOR CASE MILL

Next chapters (8-11) will describe the building and implementation of a food safety management system (FSMS) to case mill (hereafter refer also as the Mill) at a general level. The FSMS is based on the laws, regulations, recommendations and standards on food safety, food contact materials and Prerequisite Programmes (PRPs). The system as well as the risk assessment, in this case HACCP, should be built specifically with the object in mind, since the content of the system may vary depending on the systems already in place, factory processes, staff training, and the chemicals and materials used.

A part of HACCP and FSMS is to know all the raw materials that are used in the paper making process as well as all the materials that will be in contact with a paper reel. Contact materials are packaging materials of a paper reel such as cores, fibre-based wrapping materials, tapes, glues, hot glues and so on. The list of all these materials is made to confirm that all steps and supplies are considered.

Information about raw materials (e.g. chemicals, fillers and pulps) and packaging materials is asked from the suppliers. The request templates were already made by another division that has more experience about food safety. The template was modified to the needs of the Mill. Used materials are listed in Excel files as well as in the manufacturing system of the Mill. Based on the questionnaire, Excel databases were developed, and suppliers' responses were filled in. Three Excel files were made: one for chemicals, fillers, deformers and so on; one for pulp; and one for packaging materials including e.g. cores, glues, tapes and wraps.

Stora Enso Paper Oy and the sites (such as the case mill) have a system for traceability in force because of the Quality Management System standard: ISO 9001:2015, traceability is conformed to the extent required. Also, Stora Enso Paper Oy and the sites (such as the case mill) have the Environmental Management System standard: ISO 14001:2015. Also, the case mill has some certificates on its own. One example is EU Ecolabel on printing papers.

One part of the risk assessment is to recognize that it is not always possible to trace the paper back to raw materials. (CEPI, 2019) For example, in papermaking case mill uses pressure groundwood (PGW) that is produced at the Mill, pulp that is bought from outside the Mill and wet broke that is made from the Mill's own paper

that does not fulfil the quality requirements. There might e.g. be spots of water on the surface of the paper.

There are few concerning FCMs and different fibres. PGW pulp can be bleached or unbleached. Light mixing of PGW pulps is almost impossible to avoid. This may cause the batch to be contaminated for use as FCM.

Another fibre-related problem is pulp that is bought outside the Mill: how it can be sure that pulp is admitted to use in FCMs? The suppliers will confirm the use of the pulp they produce in FCMs made from it. Still, the pulp bale may be contaminated in transport e.g. with or by pests.

9 HACCP SYSTEM TO PAPERMILL

Implementation of the food safety management system at the Mill started from process knowing with presentations of the HACCP system and how to implement it to this mill. The process was walked through to get a wide understanding on possible hazards. A process flowchart to support HACCP especially at this Mill was made. The necessity and background of HACCP was presented to the Senior Manager, the Head of Production and the Production Managers of departments. The idea was that these individuals would later form the HACCP team.

The purpose of the presentation was to explain how the FSMS is progressing and how should the system implementation be continued. Shortly after starting, it was noticed that the approach was wrong. The presentation contained a lot of information about the background and requirements of the FSMS and the HACCP, but the information did not seem to be interesting enough or the scope was too large.

The risk assessment process was started after the presentation. HACCP follows the steps presented in Figure 14.

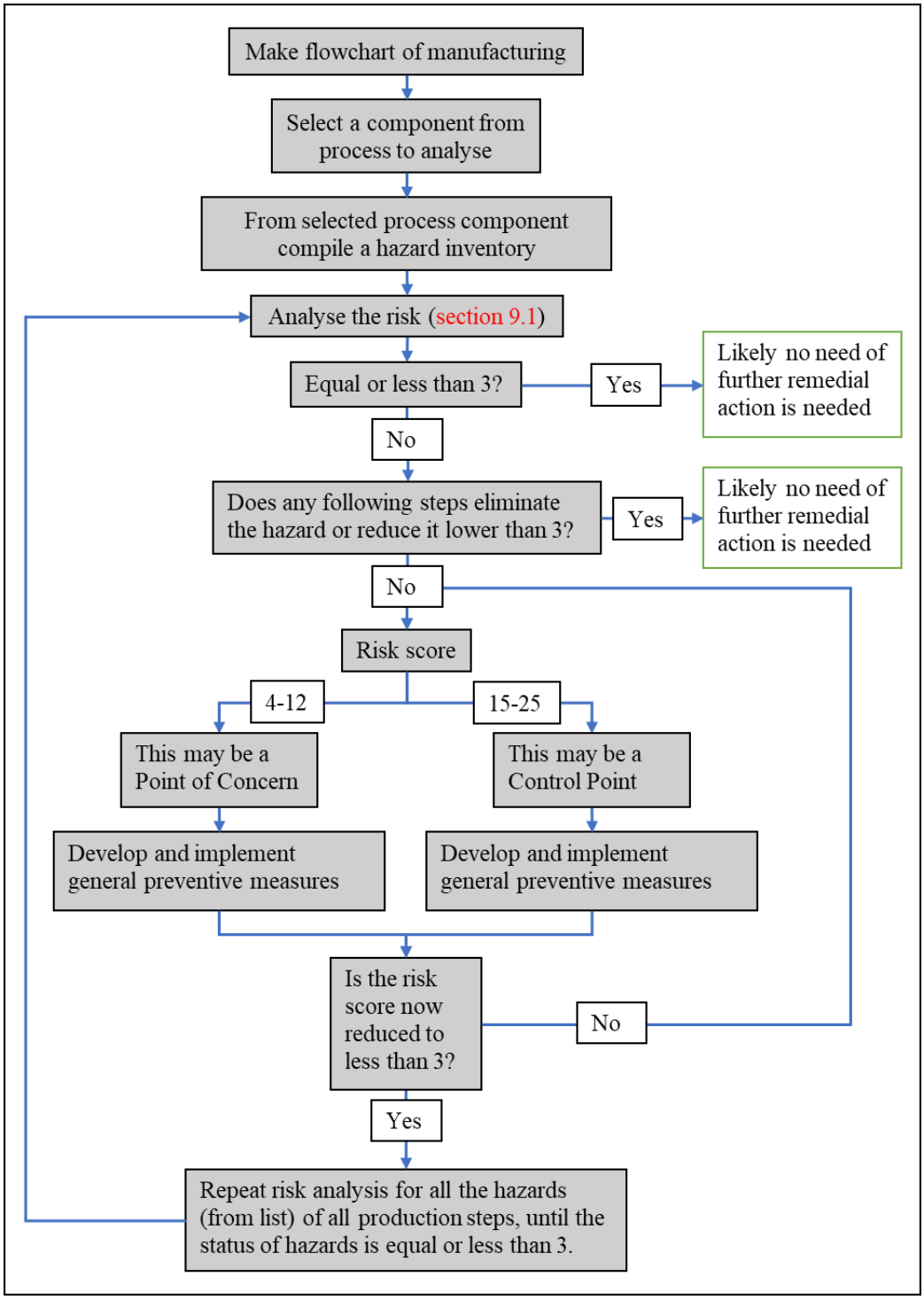

Figure 14 Risk assessment guidelines

The risk assessment was done using the format presented in Figure 14. It must be noticed that the model is not perfectly exact and remedial actions on presented three levels (3 or less; 4-12; 15-25) can overlap. Thus the numeric values should be only guidance for actions.

First part of risk assessment is to make a flowchart. To make a valuable HACCP, a simple process flowchart was made, and it is presented in Figure 15.

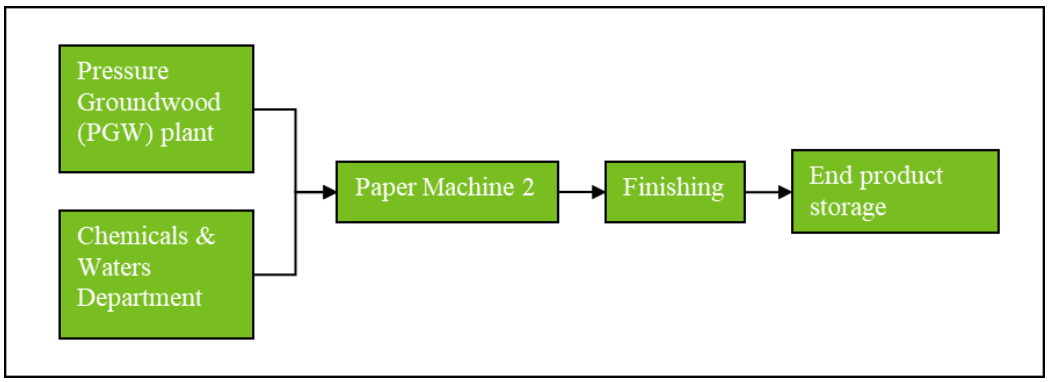

Figure 15 Process flowchart for HACCP

In Figure 15, the process was divided into five parts: the fiber department (pressure groundwood plant), the chemical and waters department, paper machine 2 area, the finishing and the end product storage. After the presentation the task was to create risk lists for all the five departments.

Preliminary risk lists based on written material and recommendations were made before department meetings. The risk lists were reviewed in department's meetings with the staff of each department, including operators, shift supervisors and Production Managers when possible. Before listing, the FSMS and its background was briefly presented. This presentation was simpler than the one that was given to The Production Managers earlier, but retrospectively the scope was still a bit too wide. The aim of the presentation was to give enough information to make sure that the personnel understands why the risk list is necessary to do with them and not by the HACCP team at higher level.

When initiating the actual shift training on the food safety management system, it should be borne in mind that not all legal backgrounds need to be fully understood. A future training program could highlight the importance of the FSMS through examples based more the Mill operations than legal points.

In the risk lists, the personnel of each department commented and described how risks affect their daily work and how they try to avoid those risks. This was an excellent approach in the departments, but it should have been taken earlier,

probably at the beginning of the project. Though, at the beginning of the FSMS project, there was not enough knowledge among the personnel to get risk lists done properly. An example of a risk list is presented in Table 9.

Table 9 Example of a risk list with descriptions

Process step	**Description of the hazard**	**Accept-ability of the hazard**	**Description of hazard management**	**Occur-rence**	**Effect**	**Risk**	**PRP, o-PRP, CCP**
Stocks: Paper mass	Foreign objects in the paper mass	Not acceptable	Centrifugal cleaning and screening before the paper machine to remove foreign objects from paper mass.				
Stocks: Chemicals	Wrong chemical is imported to the Mill	Not acceptable	Acceptance inspection must be done to all materials that are imported to the Mill area and they must correspond to what has been ordered.				
Process and Mill areas: Pests	Pests at the Mill area or in the process area	Not acceptable	Pest control programme in force. If pests are detected in the process area, immediate action might be needed. Keep doors and windows closed if possible. All openings must be covered.				
Silos: Dirt	Dirt in the silos may end up in the process	Somewhat acceptable	Washing lists and plans for silos. Impossible to get silos fully clean from previous paper mass.				

Table 9 presents a few possible risks that may occur in various departments of the Mill to demonstrate the target of risk lists. This kind of a list were made in all the five departments. Four last columns in Table 9, which are Occurrence, Effect, Risk and PRP, o-PRP, CCP, were not filled in order to demonstrate risk evaluation later in this paper.

The risk lists made by the departments were extensive, and some risks were pointed out and added to primary lists. Some risks that popped out had not been even considered or noticed before, and they required actions on the product safety handbook and the total risk assessment. The risks included e.g. air vents and other holes in silos and compressed air used as a cleaning tool. All holes in silos must be blocked or netted somehow to avoid any contaminants or objects entering the silos. Compressed air cannot be used for cleaning, because it only increases the amount of dust in the air and does not actually clean anything.

Once the lists were completed by each department, the leaders of all departments read the lists to make sure that potential risks were not overlooked. This was a difficult task as time was short and the impact of risks was not always clear between departments.

9.1 Risk evaluation

By following the process presented in Figure 14 (on p. 70), the next step is to analyse the listed risks. When evaluating risks, it must be noted that every risk is unique. Even if the same risk has been spotted in different parts of the process, the risk values are not directly comparable to each other.

Risk evaluation is ideally done in the HACCP group, because the group has a wide understanding of the process. The whole group was included not only to get the risk values in the same format, but also to teach the members of the group more about HACCP and the FSMS.

All the risks on the lists by the departments will get a value, as presented next. The procedure is based on the HACCP procedure in the CEPI food contact guidelines. A HACCP risk calculation and classification may be done in various ways but CEPI

(2010) presents a way which is changeable and easy to implement to any paper mill. In Figure 16, the risk areas are presented.

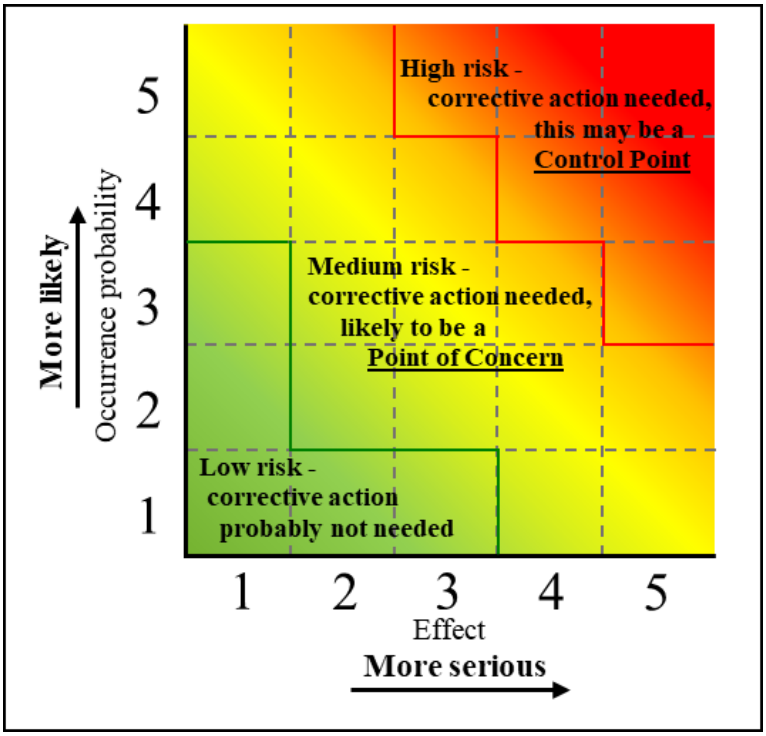

Figure 16 Risk Matrix

In Figure 16, "Effect" refers to a contamination hazard on food or to the effect of the process on the consumer via packaged foodstuff. "Occurrence" in this case is the probability of the occurrence of a hazard. Keys to the effect and occurrence ratings are presented in Tables 10 and 11.

Table 10 The key to effect rating

Rating	Effects and Seriousness	Scope
1	No effect on health or only a minor inconvenience	Harmful to one or a few customers
2	Small effect on health, e.g. a slight allergic reaction	Harmful to one or a few customers
3	An effect on health: illness or injury e.g. stomach disorder or damaged teeth.	Harmful to a few customers
4	A serious effect on health: hospitalisation but not life-threatening injuries	Harmful to numerous customers
5	A major disaster and a serious effect on health. Fatal or permanent illness or injury	Harmful to numerous customers

Table 11 The key to occurrence rating

Rating	Occurrence	The frequency of the event
1	Highly unlikely	Almost never, once in 5 years
2	Very unlikely	Rarely, perhaps every 6 months
3	Possible	Once a month
4	Probable	Once a week or more
5	Frequent	Possibly several times an hour

After evaluating the risk by the keys for effects and occurrence rating, the risk value is calculated with equation 1.

$$Risk\ value = Effect \cdot Occurrance \quad (1)$$

The value by then is set in the area of Figure 16 (on p. 73). If the value is in the green area, that means the risk is low and remedial action is not normally needed. The highest risk score in the low risk area (green area) is three, but the aim is to make the risk score decrease to two or less. (CEPI, 2010)

If the risk score is 4-12, the risk is in the yellow area which means that the risk is medium and remedial action is necessary. In yellow area result may indicate of a Point of Concern and the risk may be overcome by a general remedial measure that is applied to the whole process. (CEPI, 2010)

The red area in Figure 16 is a high-risk area and remedial action is necessary. The risk score in this area is from 15 to 25 and it indicates that there might be a Control Point. The risk might be overcome by a specific remedial measure which is applicated to a certain point of the process. According to CEPI (2010), in paper manufacturing, the existence of high-risk Control Points may indicate poor manufacturing control. Those Critical Points are not probably found in correctly run operations, no matter whether they produce FCMs or not. In case of Critical Points are found, remedial measures must be done urgently and documented properly. (CEPI, 2010)

Take pests as an example. They are not acceptable at any stage of the process, but the risk value is different at different stages of the process. At the beginning of the process, before trees are barked, pests do not pose a significant risk because the

trees are barked and rinsed before they are grinded. The frequency of occurrence, in turn, is dense: birds are likely to fly over a wood yard often. Thus, the risk value would be of effect 1 (No effect on health or only a minor inconvenience; Harmful to one or a few customers) and of occurrence 4 (Probable; once a week or more), so the rating would be 4. In Figure 16, it can be seen that this may be a point of concern. There is no need for special actions because of all the process steps in papermaking and the existing pest control program. Also, the pest control is part of the PRPs (Prerequisite Programmes).

When comparing the risk of pest infestation at the beginning of process with the already finished paper (not wrapped yet), the risk rating significantly higher. The pest or its debris may end up in the finished paper and then further processed and, in the worst-case scenario, to the consumer. Even if the doors and other possible openings are usually closed and, if necessary, netted, pests can still be in the same room The risk value of effect would be 2 (Small effect on health, e.g. slight allergic reaction; Harmful to one or a few customers) and of occurrence 3 (Possible; once a month). The risk rating is 6.

From this example it can be noticed that the risk evaluation must be made case by case. At different process steps, the effect and occurrence of the same risk can be different.

Table 12 is filled with risk values loosely based on the evaluation by the HACCP team.

Table 12 A completed example of a risk list with descriptions

Process step	Description of the hazard	Accept-ability of the hazard	Description of hazard management	Occur-rence	Effect	Risk	PRP, o-PRP, CCP
Stocks: Paper mass	Foreign objects in the paper mass	Not acceptable	Centrifugal cleaning and screening before the paper machine to remove foreign objects from paper mass.	2	2	4	o-PRP
Stocks: Chemicals	Wrong chemical is imported to the Mill	Not acceptable	Acceptance inspection must be done to all materials that are imported to the Mill area and they must correspond to what has been ordered.	1	1	1	PRP
Process and Mill areas: Pests	Pests at the Mill area or in the process area	Not acceptable	Pest control programme in force. If pests are detected in the process area, immediate action might be needed. Keep doors and windows closed if possible. All openings must be covered.	3	3	9	o-PRP
Silos: Dirt	Dirt in the silos may end up in the process	Somewhat acceptable	Washing lists and plans for silos. Impossible to get silos fully clean from previous paper mass.	1	3	3	PRP

Table 12 is a filled version of Table 9 (on p. 71), and it thus includes the risk values of the HACCP risk evaluation. The last column of Table 12 is for indicating which kind of actions are needed in risk management. If the risk is marked with PRP

(prerequisite programmes) it means that there is or are described basic condition(s) and activate(s) to ensure food safety; o-PRP (operational prerequisite programme) means that there is or are control measure(s) to eliminate and manage significant food safety hazards; CCP is a process step that has specific control measure(s) to eliminate and manage significant food safety hazards.

If a risk score for a potential hazard is over 4, it is a point of concern in many cases. Concern points may be handled with both PRPs and o-PRPs depending on the nature of the hazard.

10 LABORATORY ANALYSIS

It is necessary to know how much chemicals the final paper is allowed to contain and might contain. There are chemicals and substances in use that have an SML and an OML based on the regulations of the EU, the FDA, the BfR, etc. The migration can and should be tested, but with calculations the risks of chemicals are simpler to understand.

There are various calculating models on migration that can be used. In this case, a simple calculation can be done based on the assumption that 100 % of added chemical will transfer from 6 dm^2 of paper to 1 kg of food (European Food Safety Authority (EFSA), 2012). The calculations are also made to the critical parts of the substances listed by chemical suppliers. Suppliers have returned the RCS documents in which the maximum amount of certain dangerous, harmful, toxicological or other how regulated parts are listed with their CAS numbers.

Based on the information gotten from MES and RCS information's given by suppliers, the possibility of the product being suitable to use as FCM has been investigated. Both calculations and analysis were made. The analysis where done by Stora Enso Research Laboratory in Imatra.

Calculations are not presented here more specifically because neither the markets for the food contact product of the Mill nor the product itself have been decided yet. Nevertheless, from the calculations a coated paper grades with the currently used

raw materials and those grades that contains optical brighteners as a raw material does not comply the regulations.

Because there is not final product selected, there is not yet customer, application of paper is not described, the analysis was done to two possible grades of paper. Analyses that where done to paper samples were selected to find out if it is even possible to manufacture the FCM in this type of mill where both FCM and printing papers are manufactured. Not all the analyses that were done to paper samples are presented here. Most significant analysis and results are presented in Table 13.

Table 13 Analyses results

Analysis	**Extraction**	**Upper limit**	**Sample 1**	**Sample 2**
Fluorescent whitening agents	Water	0 mg/l	> 0 mg/l	> 0 mg/l
	3% Acetic acid	0 mg/l	0 mg/l	0 mg/l
	Olive oil	0 mg/l	0 mg/l	0 mg/l
Colour fastness	Water	0 mg/l	0 mg/l	0 mg/l
	3% Acetic acid	0 mg/l	0 mg/l	0 mg/l
	Olive oil	0 mg/l	0 mg/l	0 mg/l
MCPD	Water	12 µg/l (1	< 12 µg/l	< 12 µg/l
DCP	Water	2 µg/l (1	< 2 µg/l	> 2 µg/l
Biocide residuals	Water	n.d. (1	n.d.	n.d.
FDA extractions	Water	< 7,8 mg/dm^2 (2	> 7,8 mg/dm^2	> 7,8 mg/dm^2
	Chloroform soluble matter	< 7,8 mg/dm^2 (2	< 7,8 mg/dm^2	< 7,8 mg/dm^2
	n-Heptane	< 7,8 mg/dm^2 (2	< 7,8 mg/dm^2	< 7,8 mg/dm^2
	50 % EtOH	< 7,8 mg/dm^2 (2	< 7,8 mg/dm^2	< 7,8 mg/dm^2

In Table 13, some analysis results are presented to demonstrate whether the products comply with requirements. In Table 13:

MCPD 3-monochloro-1,2-propanediol

DCP 1,3-Dichloro-2-propanol

(1 BfR XXXVI

(2 FDA 21 CFR § 176.170.

n.d. Not detectable

It can be seen from Table 13 that there are some problems when it comes to FCM requirements. There are fluorescent whitening agents detectable in water extractions in both samples. This means that if it is not possible to confirm that no optical brightening agents (OBA) are present in the paper when the FCM production starts, the product is not necessarily suitable for all markets. OBAs are used in other paper grades that are manufactured in the Mill but not intentionally added to possible food contact paper grade, though it is possible that OBAs may transfer from process circulation waters or from broke to paper. With the current way of papermaking, the tested paper grades are not suitable to be use as FCM with aqueous foodstuff.

The amount of DCP in sample 2 extract was more than 2 µg/l which means that the transfer limit is exceeded, and this paper is not suitable to be used as FCM according to BfR XXXVI. Also, the results of FDA extraction with water are more than 7,8 mg/dm^2 which means that analyses on chloroform soluble matter must be done. The results on chloroform soluble matter are lower than 7,8 mg/dm^2. Both samples are compliant with FDA. In Table 14, possible condition of use and type of food that samples 1 and 2 can be used are presented. *Type of food* and *condition of use* are equal to FDA CFR 21 §176.170 tables 1 and 2.

Table 14 Type of food and conditions of use that samples 1 and 2 can be used with

Type of Food / **Condition of use**	**I**	**II**	**III**	**IV A**	**IV B**	**V**	**VI A**	**VI B**	**VI C**	**VII A**	**VII B**	**VIII**	**IX**
A	x	x	x	x	x	x		x		x	x	x	x
B	x	x	x	x	x	x		x		x	x	x	x
C	x	x	x	x	x	x		x		x	x	x	x
D	x	x	x	x	x	x	x	x	x	x	x	x	x
E	x	x	x	x	x	x	x	x	x	x	x	x	x
F	x	x	x	x	x	x	x	x	x	x	x	x	x
G	x	x	x	x	x	x	x	x	x	x	x	x	x
H 1.	x	x	x	x	x	x		x		x	x	x	x
H 2.	x	x	x	x	x	x		x		x	x	x	x
I													
J													

Table 14 indicates that the samples are suitable to be used in various conditions of use and with various food types. According to the Code of Federal Regulations Title 21 §176.170, food types are divided into following categories:

I. *Non-acid, aqueous products; may contain salt or sugar or both (pH above 5.0).*
II. *Acid, aqueous products; may contain salt or sugar or both, including oil-in-water emulsions of low- or high-fat content.*
III. *Aqueous, acid or non-acid products containing free oil or fat; may contain salt, including water-in-oil emulsions of low- or high-fat content.*
IV. *Dairy products and modifications:*
    A. *Water-in-oil emulsions, high- or low-fat.*
    B. *Oil-in-water emulsions, high- or low-fat.*
V. *Low-moisture fats and oil.*
VI. *Beverages:*
    A. *Containing up to 8 percent of alcohol.*
    B. *Non-alcoholic.*
    C. *Containing more than 8 percent alcohol.*
VII. *Bakery products other than those included under Types VIII or IX of this table:*
    A. *Moist bakery products with surface containing free fat or oil.*
    B. *Moist bakery products with surface containing no free fat or oil.*
VIII. *Dry solids with the surface containing no free fat or oil (no end test required).*
IX. *Dry solids with the surface containing free fat or oil.* (Code of Federal Regulations, 1977b)

In the Code of Federal Regulations Title 21 §176.170, the conditions of use are categorized in the following manner:

A. *High temperature heat-sterilized (e.g., over 212 °F).*
B. *Boiling water sterilized.*
C. *Hot filled or pasteurized above 150 °F.*
D. *Hot filled or pasteurized below 150 °F.*
E. *Room temperature filled and stored (no thermal treatment in the container).*
F. *Refrigerated storage (no thermal treatment in the container).*
G. *Frozen storage (no thermal treatment in the container).*
H. *Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:*
    1. *Aqueous or oil-in-water emulsion of high- or low-fat.*
    2. *Aqueous, high- or low-free oil or fat.*
I. *Irradiation*
J. *Cooking at temperatures exceeding 250 °F.* (Code of Federal Regulations, 1977b)

10.1 Laboratory experiments to add to the case mill

Based on the HACCP done with the Production Managers, some laboratory experiments should be added when the FCM manufacturing or testing starts. Before there is no product to use as FCM, the experiments are not required.

Many chemicals and raw materials are tested by chemical suppliers regularly. Therefore, chemical tests are not needed at first.

Various process waters are used in the manufacturing of paper. Therefore, all the water towers and sources, like raw water, chemically purified water, and circulation waters, must be tested to be sure that no microbes are present in the water, because they may transfer to paper.

Because the case mill may start to manufacture both FCM and non-FCM, a wide laboratory analyses in either the Research Laboratory or an external laboratory are needed. If the Mill's own laboratory were to acquire all the supplies needed for analysing FCM, it would probably not be cost-effective due to the various paper grades. The frequency of a wide analysis must be based on HACCP and on how often FCM is manufactured.

11 DESCRIPTION OF THE PRODUCT SAFETY HANDBOOK

The good manufacturing practice (GMP) and the good hygienic practice (GHP) are requirements of the EU Regulations and a part of the prerequisite programs (PRPs) ((Commission Notice 2016/C 278, 2016, p. 01; Regulation (EC) No 852/2004, 2004; Regulation (EC) No 2023/2006, 2006, p. 20). The PRPs ensure food and product safety with an effective risk analysis. To implement the PRPs as well as possible, a product safety handbook (PSH) has been made. The PSH of the Mill is based on the requirements and materials of the food safety regulations presented earlier in this paper.

At case mill, the Hazard Analysis and Critical Control Point (HACCP) risk assessment was used. Based on the HACCP risk lists and risk evaluation, the PSH was evaluated and supplemented to cover all the PRPs and o-PRPs which appeared in the risk assessment.

The PSH contains descriptions of what kinds of PRPs (GMP and GHP) are in use or about to be in use in the Mill and how they are implemented. The PSH is one part of the food safety management system (FSMS). In Appendix II, the table of contents of the PHS is presented.

When building a PSH, various things must be taken into concern. The first thing is to define a purpose and a scope for the PSH. The first chapter describes, for example, which documents and/or standards form the basis of the PHS and what is the scope of the food safety management system of the Mill.

In the next chapter of the PSH, abbreviations and definitions are listed and explained. It is important to understand the abbreviations and definitions in order to comprehend the whole PSH.

Chapter 3 describes all the operating instructions that have an impact on food safety. This chapter is extensive but remarkable. The requirements of authorities and customers on the product are defined and explained with scopes and instructions on how to fulfil them.

Personnel and visitors may have a significant or even hazardous impact on food safety. Responsibilities as well as instructions with rules on training and working are defined and described.

Marketing, including product design and a food contact validation model, may have limitations when it comes to manufacturing food contact material. For example, marketing must take into concern which regulations the product complies with and to which applications it is suitable for. Product design as well as process development must be performed under the conditions of product safety. The food contact validation must be done to every manufactured lot. The food contact validation model must be made specifically to the Mill and not copied from another place because each mill is somewhat different.

All the raw materials used in the manufacturing and packaging of the product must be bought from reliable sources and suppliers by the person in charge. The raw materials must be approved for specific use and conditions with aw Regulatory Compliance Statements (RCS) filled by the suppliers. Subchapter 3.6 defines how this is done and what kind of measure are needed with raw materials.

All the information on raw materials, products, marketing, etc. that has an effect on food safety must be documented and filed. The filing is described in subchapter 3.7 of the PSH.

Chapter 4 is about manufacturing, prerequisite programmes and critical control points of the food safety management system. Subchapter 4.1 is about hazard analysis and has descriptions of the hazards. The hazard analysis is done with the HACCP system. To understand and implement the hazard analysis better, subchapter 4.2 describes the mill area and environment as well as the indoor and working areas.

Subchapters 4.3 to 4.5 define and describe the measures of waste management and cleanliness, hygiene and the Mill maintenance. In subchapter 4.6, pest control operations and programmes to avoid birds, rodents, insects and other pests are presented.

There are productive goods that have food safety requirements. Such productive goods are taken for a closer inspection in subchapter 4.7. The PSH describes requirements for raw water, room and compressed air and lighting more specifically. Requirements on transportation, packaging and warehousing of the products are presented in subchapter 4.8.

Chapter 5 of the PSH is on the error, hazard and incident management. This chapter is divided into subchapters 5.1 on monitoring information and records, 5.2 on handling of defective products, 5.3 on preventive and remedial measures, and 5.4 on the product recall program. The aim of Chapter 5 is to describe how to act when an error, a hazard or an incident happens.

The PSH is made to fulfil the requirements and the needs of the Mill specifically and it must achieve the status of a working instruction. Some parts that are presented in this paper earlier are not inspected that closely in the PSH. Instead, they are

discussed shortly because they are already covered in the other operations and systems of the Mill. These include, for example, waste disposal, pest control, cleaning and preventive maintenance.

PSH should and must be included in the orientation of both the Mill's own personnel and all those who work in the Mill area. To get an FSMS effectively implemented, trainings should take place. In those trainings, the PSH must be explained to every member of personnel.

12 CONCLUSIONS

The market area for fibre-based food contact materials has expanded since the European Parliament accepted the proposal on banning single-use plastics to improve circular economy (Chatain, 2019). The EU Member States must ban certain single-use plastic products such as straws, plates and cutlery, and that measures to ban those products shall be applied from 3 July 2021. (Directive (EU) 2019/904, 2019)

The demand of fibre-based food contact materials has also increased as the impact of plastics on the environment must be reduced. It has been estimated that more than 80 % of marine litter is plastic and in the European Union alone up to 500 000 tonnes of plastic waste enters the oceans every year (COM/2018/028 final, 2018).

Digitalization has decreased the demand of books, newspapers and magazines, and one paper machine can produce more paper than before. These factors have caused overcapacity in the printing paper industry.

Present day printing paper machines may offer a solution to both the overcapacity and the increasing demand of fibre-based disposable materials. The manufacture of printing paper products can be modified into the manufacture of food contact papers.

The aim of this thesis was to review worldwide legislation on food contact materials, which is the most relevant matter to the case mill. While legislation was reviewed, a food management system and prerequisite programmes were created

for the case mill. A base for an FSMS system, including HACCP instructions and a product safety handbook (PSH) with databases for food safety chemicals and raw materials, was created for the Mill. The PSH contains descriptions of Prerequisite Programmes, Good Manufacturing Practises and Good Hygiene Principles.

There are many different laws, regulations, requirements and recommendations on FCMs globally, and in some cases, it is hard to find a still valid version of the right document, an English translation, or a version that is available for free. Also, usually regulations are hard to understand without enough experience on the laws of a particular country.

To manufacture FCM, the process of the case mill does not require changes, but the safe working procedures to ensure product safety must be defined. It is necessary to ensure that everybody who works at the Mill area knows what the food safety management system is and how to work to not endanger product safety.

Even though there are no major changes to working at the mill or to the process, there might be some challenges with manufacturing both FCM and other products. For example, the goal is to only order and use raw materials that are safe and approved to use in the manufacture of FCM. Still, some of the paper grades are or may be challenging to manufacture with only the approved raw materials. Especially chemicals may cause issues to food safety.

Process waters and broke may cause a risk because there are two paper machines in the case mill, and at first, only one machine will manufacture food contact material. Process waters may mix up between the paper machines if there is lack of water in one of the machines. Also, it was discovered that there is a risk that different kind of broke may mix due to the working procedures. Risks may occur due to careless work or pulping of wrong product at the wrong time. Broke itself is not an issue, but if there are any raw materials that are not approved to be used in the manufacturing of FCM, the product in which broke is used is not safe to be used as FCM anymore.

The compliance of the manufactured FCM is based on the Regulatory Compliance Statements on the raw materials and analyzing the manufactured products. Even if only approved raw materials are used, non-intentionally added substances may be

present. With regular and effective product and process testing, NIAS can be detected and removed from the process.

If the time for this master's thesis project would have been for example one year, the order of building and implementing the system could have been different. The product safety handbook should have been finished first and then implemented in the Mill. Only after that the HACCP system should have been introduced and the first round of hazard system carried out. The product safety handbook and HACCP were made at the same time to ensure that all the food safety risks are covered in the product safety handbook when possible.

The whole FSMS of the Mill requires additional work. The HACCP should be reviewed within a short period of time, for example after three months, and the PHS must be updated whenever new risks are detected or something in the process changes. Work on the raw material database should continue as not all the raw materials are on the lists.

Upkeeping the FSMS should be simple after the system is implemented to the organization. Getting the FSMS effectively installed in the Mill will require systematic and well-organized trainings for both the Mill's own and the stakeholders' personnel.

13 ATTACHMENTS

Annex I Request for a Regulatory Compliance Statement, Questions on Additives

Annex II Product safety handbook of the Mill, Table of Contents

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Request for Regulatory Compliance Statement, questions

1. This statement is valid for:
   - Product
   - Producer
   - Production site
   - Product type
2. Are any preservatives used in the production and/or storing of this product?
3. The production site's management system supports the requirements of Article 17 of Regulation (EC) No 1935/2004 and traceability is confirmed.
4. This additive can be used in the production of paper and board products that need to comply with Article 3 of Regulation (EC) No 1935/2004: General requirements on materials and articles intended to come into contact with food.
5. Does the product comply BfR Recommendation XXXVI Paper and Board for Food Contact? If there are any limitations, please list them.
6. Does the product comply BfR Recommendation XXXVI/2 Paper and Paperboard for Baking Purposes? If there are any limitations, please list them.
7. Are there any other relevant BfR Recommendations that this product complies? If there are any limitations, please list them.
8. a) Does the product fulfil the requirements of the U.S. Food and Drug Administration (FDA) Code of Federal Regulation (CFR) Title 21 parts 170 through 189 and/or other applicable FDA regulation and/or Food Contact Notifications (FCNs), for the use of the product in the production of paper and paperboard in contact with aqueous and fatty foods? Please, list sections and possible limitations.

   b) Does the product have any limitations regarding food types (I-IX) and conditions of use (A-H+J) as referred to in FDA CFR 21 §176.170

   c) Are any of the components in the product cleared through an FCN?

9. Does the product comply Chinese Food Safety Standard for the Use of Additives for Food Contact Materials and Articles, GB9685-2016 and are there announcements from National Health Commission (NHC), for use in paper?

10. Does the product comply Chinese Food Safety Standard for General Safety Requirements for Food Contact Materials and Articles (GGS), GB 4806.1-2016?
11. Is this product manufactured in China? If yes, does it comply Chinese Food Safety Standard for General Hygienic Standard for Production of Food Contact Materials and Articles, GB 31603-2015?
12. Is this product free from substances listed in the Candidate List of Substances of Very High Concern for authorization on the ECHA homepage, or below the limit of 0.1% (w/w)?

    Can this product be used in packaging material with regard to EC Directives on packaging and packaging waste: 94/62/EC and 2004/12/EC.

    a) Are the sum of lead, cadmium, mercury and hexavalent chromium below 100 ppm.

    b) This product is free from substances or preparations classified as dangerous for the environment or below the trace level(s) of 0.1% (w/w).
13. Does the product contain substances listed in: Chemicals known to the state to cause cancer or reproductive toxicity; Safe drinking water and toxic enforcement act of 1986, (Proposition 65) intentionally added or as impurities? If does, please list the substances with CAS numbers and concentration in the delivered product.
14. Does the product contain compounds and/or substances (including degradation products) with a Specific Migration Limit (SML) and/or residual content per food contact surface area (QMA) according to Regulation (EU) No 10/2011, as amended until Commission Regulation (EU) No 2019/37? If does, please list the substances with CAS numbers and concentration in the delivered product.
15. Does this product contain compounds and/or substances (including degradation products) that are authorized food additives or authorized flavourings by Regulation (EC) No 1333/2008 or Regulation (EC) No 1334/2008 as amended, so called dual use substances? If does, please list the substances with CAS numbers and concentration in delivered product.
16. Is this product free from Genetically Modified Organisms (GMO)?

17. Is this product free from potential food allergens that are listed in Regulation 1169/2011 Annex II, and the major food allergens given in the US Food Allergen Labelling and Consumer Protection Act of 2004 Sec. 203?
18. Is this product free from substances originating from animals?
19. Is this product free from substances originating from plants?
20. Is this product free from ethanol originating from wheat?
21. Is this product free from phthalates?
22. Is this product free from substances classified as carcinogenic (C), mutagenic (M), or reprotoxic (R), so called CMR- substances, according to the CLP Regulation (EC) No 1272/2008 as amended?

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