Masterthesis

Ensure Food Safety and Compliance through lean ways of working during Rapid Product Development with a focus on continuous improvement of managing Raw Materials and monitoring Quality during Commercial Production (QMS)

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Research and Development

NPTC Food Singen

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Summary
Answer

The practical part and aim of this thesis were to improve the raw material management and develop a new process for the release of raw materials and to optimize the document for quality monitoring during commercial production. This intend is documented and presented in detail below.

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LIST OF ABBREVIATIONS

AR	Analysis Request
BPM	Business Process Management
BPR	Business Process Reengineering
CCPs	Critical Control Points
CoA	Certificate of Analysis
CP | com. prod.	Commercial Production
CS	Commercial Supplier
DMAIC	Define, Measure, Analyze, Improve and Control
EB	*Enterobacteriaceae*
E. coli	*Escherichia coli*
ERP	Enterprise Resource Planning
FGC	Food Grade Certificate
FSSC 22000	Food Safety System Certification 22000
g	gram
HACCP	Hazard Analysis and Critical Control Points
IFF	International Flavors & Fragrances
kg	kilogram
KPI	Key-Performance-Indicator
L&SSi	Lean Six Sigma
MAD	Major Allergen Declaration
MDR	Master Data Repository
MRLs	Maximum Residue Levels
MRM	Raw Material Management
NDC	Nestlé Development Center
NesTMS	Nestlé Trial Management System
NMS	Nestlé Management System
NQAC	National Quality Assurance Center
NQMS	Nestlé Quality Management System
NPTC	Nestlé Product Technology Center
oPRP	Operational Prerequisite Program
PAS 220	Publicly Available Specification 220
PDCA	Plan, Do, Check and Act
PM	Project Manager
PO	Purchasing Order

PP	Pilot Plant
QA	Quality Assurance
QM	Quality Management
QMS	Quality Monitoring Schemes
RCA	Root Cause Analysis
RD | R&D	Research and Development
RDBMS	Relational Database Management System
RM	Raw Material
SAP	Systems, Applications, and Products in data processing
SDR	Supplementary Data Repository
Site QA	Site Quality Assurance
SOP	Standard Operating Procedure
TPR	Test Product Release
WOW	Way of Working

INTRODUCTION

Nestlé is a global corporation and the worlds' largest food and beverage company. As the biggest player in the food industry the company has around 275,000 employees, more than 2,000 brands and a presence in 188 countries.

The Nestlé Product Technology Center Food Singen is one of three development centers as Nestlé sites worldwide. In addition to the NPTC Food Singen, these include the NDC Solon and the NDC Manesar. These are all part of Nestlé's' PTC & R&D sites, as shown in figure 1.

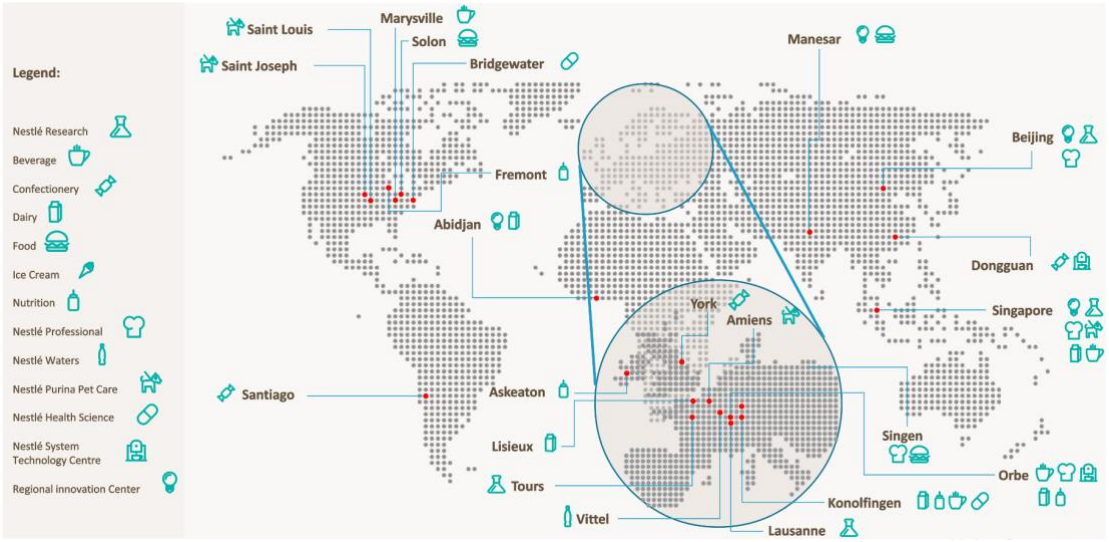

Figure 1 Worldwide network of Nestlé's' R&D locations (R&D Locations | SharePoint)

The NPTC Food Singen does culinary research on different product categories. Such as ambient culinary dry and wet (e.g., soups and dressings) and chilled and frozen (e.g., protein-based meal solutions). The Site QA team at NPTC Food Singen is responsible for the site compliance and supports with all quality compliance matters like releases for raw materials and finished products, food safety management systems, hygiene, and Nestlé Integrated Management System.

In form of this thesis the focus was set to work on continuous improvement for the raw material management of trials and commercial production on site and the quality monitoring during commercial production. For this a new process for the release of raw materials on site was developed and additional measures were taken as well as the quality monitoring document for commercial production was revised.

THEORETICAL FRAMEWORK

In the following, the Nestlé Product Technology Center Food Singen is referred to as NPTC. This chapter aims to present a comprehensive review and analysis of the existing information that are relevant for the investigation of the research problem. The theoretical framework serves as the foundation of any research project as it provides a theoretical context for interpreting the results and guides the researcher towards the appropriate methodology and data analysis techniques.

1. THE SITE QA TEAM AT NPTC SINGEN

The purpose of the "One Global Food" QA Community, which consists of the centers (Singen, Solon and Manesar) together with colleagues from R&D Singapore, Nestlé Research and NQAC is to support the Global Food Business along the complete value chain. This is done by having an initiative-taking view on the management of different areas such as chemical contaminants, allergens, microbiology, foreign bodies, sensory, applied methods, and ingredients quality. But also, by delivering food training programs, specified for the needs of the business and local teams, and supporting the development of mHACCP and if requested, the review of existing HACCP studies. Or by managing quality compliance in NPTC Food sites and providing Central Technical Acceptance (NPTC SINGEN[2]).
The site compliance is the responsibility of the Site QA team, which supports the NPTC with all topics around quality compliance such as releases, food safety management systems, or hygiene. The responsibilities of the Site QA team at NPTC are the following (NPTC SINGEN[3]):

- Site compliance with Food Safety Management System (FSSC 22000) & Nestlé Management System (NMS) for quality (ISO 9001)
- Quality & food safety support for commercial production and trials execution
- Release of incoming materials and finished products
- Management of internal and external audits to support continuous improvement process
- Microbiological lab compliance and testing support
- Pathogen & hygiene and water monitoring
- Pest control
- Microbiological support to projects

2. LEGAL AND NESTLÉ INTERNAL REQUIREMENTS

By providing a theoretical understanding of the legal and Nestlé internal requirements, this section aims to provide insights on how Nestlé as an organization can develop and implement effective compliance

strategies. These legal requirements, management systems, and standards are critical components of any organizations' operations, particularly when it comes to ensuring compliance with laws and regulations.

2.1. Legal requirements

In Europe, the legal requirements for the food industry when it comes to raw material management and commercial production are governed by the European Union (EU) regulations. The following sub-chapters describe some of the most important legal provisions at EU level. Overall, the EU regulations aim to ensure the safety and quality of food products, protect consumer health, and prevent fraud and misrepresentation in the food industry.

2.1.1 General Food Law Regulation (EC) No 178/2002

The EU Regulation No 178/2002 is the General Food Law Regulation that establishes the general principles and requirements of food law in the European Union. The regulation aims to ensure an elevated level of protection of human health and consumer interests in relation to food.

The key provisions of the regulation include:

1. Traceability: Food businesses must be able to identify the origin and movement of food products at all stages of production, processing, and distribution.

2. Risk analysis: Food safety risks must be identified, assessed, and managed throughout the food chain.

3. Precautionary principle: Where there is scientific uncertainty about the safety of a food product, precautionary measures must be taken to protect human health.

4. Transparency: Information about food products and their safety must be made available to consumers and other stakeholders.

5. Cooperation: Member states must cooperate with each other and with the European Commission to ensure the effective implementation of food law.

The General Food Law Regulation is a cornerstone of the EUs' food safety framework, providing a comprehensive and integrated approach to ensuring the safety and quality of food products in the EU (REGULATION (EC) No 178/2002).

2.1.2 Hygiene of Foodstuffs Regulation (EC) No 852/2004

The EU Regulation No 852/2004 is the Hygiene of Foodstuffs Regulation that sets out the hygiene requirements for food businesses in the European Union. The regulation aims to ensure that food is produced and managed in a hygienic and safe manner, from farm to fork (REGULATION (EC) No 852/2004).

The key provisions of the regulation include:

1. General hygiene requirements: Food businesses must ensure that their premises, equipment, and facilities are designed, constructed, and maintained in a way that prevents contamination and facilitates cleaning and disinfection.

2. Personal hygiene: Food handlers must maintain a high level of personal hygiene, including wearing appropriate clothing and washing their hands regularly.

3. Training and supervision: Food businesses must ensure that their staff is trained and supervised in food hygiene matters.

4. Hazard Analysis and Critical Control Points (HACCP): Food businesses must implement a HACCP-based food safety management system to identify and control hazards that could affect the food safety.

5. Documentation and record-keeping: Food businesses must keep records of their food safety management system and make them available to the competent authorities upon request.

2.1.3 Specific Hygiene Rules for Food of Animal Origin Regulation (EC) No 853/2004

The EU Regulation No 853/2004 lays down specific hygiene rules for food of animal origin in the European Union. The regulation aims to ensure that food of animal origin, including meat, fish, eggs, and dairy products, is produced, and managed in a safe way and is an addition to the Regulation No

852/2004. Additional to the key provisions of the Regulation No 852/2004 it defines specific hygiene requirements for different types of food of animal origin (REGULATION (EC) No 853/2004).

2.1.4 Food Information to Consumers Regulation (EU) No 1169/2011

The EU Regulation No 1169/2011 is the Food Information to Consumers Regulation that sets out the requirements for food labeling in the European Union. The regulation aims to ensure that consumers have access to clear, accurate, and meaningful information about the food they buy and consume (REGULATION (EU) NO 1169/2011).

The key provisions of the regulation include:

1. Mandatory information: The regulation sets out the mandatory information that must be provided on food labels, including the name of the food, ingredients, allergens, and nutritional information.

2. Allergen labeling: Food businesses must highlight the presence of allergens in the ingredients list, using a specific format.

3. Nutritional labeling: Food businesses must provide information about the nutrition on the label, using a standardized format.

4. Country of origin labeling: For certain types of food, such as fresh meat, fruits, and vegetables, the country of origin must be deposited on the label.

5. Legibility and visibility: The information on the label must be legible and visible, using a font size and style that is easy to read.

2.1.5 Microbiological Criteria for Foodstuffs Regulation (EC) No 2073/2005

The EU Regulation No 2073/2005 is the Microbiological Criteria for Foodstuffs Regulation that defines the microbiological criteria and limits for foodstuffs in the European Union. The regulation ensures that the food is free from harmful microorganisms that could provide a possible risk to human health (COMMISSION REGULATION (EC) NO 2073/2005).

The key provisions of the regulation include:

1. Microbiological criteria: The regulation sets out the maximum levels of harmful bacteria and other microorganisms that are allowed in food, including *Salmonella, Listeria monocytogenes,* and *Escherichia coli.*

2. Sampling and testing: Food businesses must conduct sampling and testing to ensure that their products meet the microbiological criteria set out in the regulation.

3. Corrective actions: If a food product does not meet the microbiological criteria, corrective actions must be taken to prevent the product from reaching consumers.

4. Documentation and record-keeping: Food businesses must keep records of their sampling and testing activities and make them available to the competent authorities upon request.

2.1.6 Maximum Residue Levels (MRLs) for Pesticides in or on Food and Feed of Plant and Animal Origin Regulation (EC) No 396/2005

The EU regulation No 396/2005 sets maximum residue levels (MRLs) for pesticides and veterinary drugs in food and animal feed. It aims to ensure that food and feed products are safe for human and animal consumption, and to harmonize the rules for pesticide and veterinary drug residues across the EU. The regulation also establishes procedures for monitoring and enforcing compliance with MRLs and requires risk assessments to be conducted before new MRLs are established (REGULATION (EC) No 396/2005).

2.2. ISO 9001

The ISO 9001 is a global quality management system that helps organizations to manage and improve their quality management practices. It is widely recognized as the leading standard for quality management and is designed to help organizations consistently meet or exceed customer expectations while complying with applicable laws and regulations. The ISO 9001 standard covers a range of quality management processes, including customer satisfaction, leadership, risk management, and continuous improvement. The certification process involves an assessment of the organizations' quality management system and its compliance with the ISO 9001 standards. ISO 9001 is particularly popular in manufacturing, healthcare, and service. By adopting the ISO 9001 standard, organizations can

effectively manage their operations, reduce risks, increase efficiency and effectiveness, and deliver high-quality products and services to their customers (ISO 9001:2015).

2.3. FSSC 22000

The FSSC 22000 (Food Safety System Certification) is a food safety management system that provides a framework for organizations to manage and improve their food safety practices. It is designed to help businesses ensure the safety and quality of their food products, thereby reducing the risk of foodborne illnesses and protecting consumers. FSSC 22000 is based on the ISO 22000 standard and incorporates the requirements of other international food safety standards such as HACCP and PAS 220. It also includes additional requirements specific to the food sector, such as food fraud prevention and allergen management. The certification process involves an assessment of the organizations' food safety management system and its compliance with the FSSC 22000 standards. Once certified, organizations can display the FSSC 22000 logo on their products and marketing materials, demonstrating their commitment to food safety and quality (FSSC 22000).

2.4. Hazard Analysis and Critical Control Points (HACCP)

Hazard Analysis and Critical Control Points (HACCP) is a food safety management system that identifies, evaluates, and controls hazards in the food production process. It is designed to reduce the risk of foodborne illnesses and ensure the safety and quality of food products. HACCP is widely recognized as the most effective food safety management system and is widely used in the food industry. The HACCP approach involves identifying potential biological, chemical, and physical hazards that can occur in the food production process and establishing critical control points (CCPs) to monitor and control these hazards. The system also establishes corrective actions when necessary. HACCP provides a preventive approach to food safety management, reducing the reliance on end-product testing and inspection. By adopting HACCP, organizations can ensure that their products are safe for customers, protect their reputation, and comply with regulatory requirements. HACCP standards and regulations are recognized internationally, and many countries and organizations have adopted HACCP as a food safety management system for themselves (MOTARJEMI, 2014).

2.5. Nestlé Management System (NMS) and Nestlé Quality Management System (NQMS)

The Nestlé Management System (NMS) is a comprehensive system developed by Nestlé that covers all aspects of the company's' operations. It is based on the principles of continuous improvement, customer focus, and leadership and is designed to ensure that Nestlé's' products and services meet or exceed customer expectations while maintaining the highest safety and quality standards. The NMS includes a range of tools and processes, such as the Nestlé Quality Management System (NQMS), which covers all aspects of food safety and quality management, and the Nestlé Environmental Management System (NEMS), which addresses the company's' environmental impact and sustainability. The NMS also includes training programs and performance monitoring and reporting frameworks to ensure that all employees are aligned with the company's' objectives and contribute to its success. The NMS is regularly reviewed and updated to reflect changing customer needs, industry standards, and best practices. By adopting the NMS, Nestlé can effectively manage its operations, reduce risks, increase efficiency and effectiveness, and deliver high-quality products and services to its customers.

The NQMS covers every aspect of food safety and quality management from sourcing raw materials to the distribution of finished products. The system is based on internationally recognized standards such as ISO 9001 and includes a range of tools and processes, including HACCP and Good Manufacturing Practices (GMPs). The NQMS also includes programs for continuous improvement and customer feedback to ensure that Nestlé is meeting customer needs and expectations. By adopting the NQMS, Nestlé can ensure that its products are safe and of high quality (NESTLÉ, 2014).

3. CONTINUOUS IMROVEMENT AND PROCESS OPTIMIZATION

Continuous improvement and process optimization are critical components of the food industry, particularly when it comes to ensuring customer satisfaction, complying with regulations, and maintaining competitiveness. This process involves identifying areas of improvement in the production process, developing, and implementing strategies to address them, and continually monitoring and evaluating the effectiveness of these strategies. By continuously improving and optimizing the production process, food companies can deliver high-quality products, reduce waste, and improve resource utilization. This ultimately leads to increased customer satisfaction, higher productivity, and reduced costs. In the food industry, where consumer safety and regulatory compliance are paramount, continuous improvement and process optimization are essential for ensuring that products comply with safety standards and laws. In this section, theoretical framework that examines the importance of

continuous improvement and process optimization in the food industry will be provided. Discussing how organizations can develop and implement strategies for continuous improvement and process optimization, the benefits of adopting such strategies, and the challenges involved by implementing them.

Continuous improvement also builds as a part of the NQMS and is an element to achieve and maintain consumer trust and preference and to reach the goal of "Zero Defects and No Waste" through excellence and competitiveness. The owner of each process must apply a continuous improvement approach to develop their process. According to Nestlé continuous improvement should include the following steps (NESTLÉ, 2014):

- Identifying areas for improvement by evaluating quality-related data, results of verification activities and occurrence of issues
- Defining and selecting the improvement targets
- Developing and implementing strategies to meet the targets
- Verifying that the targets are achieved, and changes are formalized

3.1. Lean and Six Sigma as models for continuous improvement

Lean and Six Sigma are two widely used and recognized initiatives for continuous improvement and are often hybridized as Lean Six Sigma (L&SSi). Their implementation in the sector of the food industry is still growing. But results show that it can lead to a reduce of costs and an increase of the productivity, which determines quality strategies to remain competitive. The main barriers to implement these initiatives are human factors and the food industry characteristics. Nevertheless, based on the basic structure, a framework for continuous improvement can be derived (COSTA et al., 2018).

Lean is originally a term to describe the production system of Toyota with a way to specify value, align the actions that create value in the best sequence, and effectively perform these activities without interruption upon request. It provides a fundamental framework for enhancing efficiency, reducing waste, and reducing variability (WOMACK et al., 1990).

Six Sigma is also an initiative for continuous improvement and was originally developed by Motorola. It works by finding and eliminating causes of mistakes or defects in processes by focusing on outputs that are of critical importance for the customers. Important to be successful with this model is a step-by-step approach or roadmap for the improvement (SNEE, 2010). As an example, for this the DMAIC method can be used, which stands for define, measure, analyze, improve, and control (ANTONY & BANUELAS, 2002).

As the focus of Lean is to improve process flow and reduce waste and variability and Six Sigma will mainly concentrate on improving the processes by identifying problems and using data to identify and

eliminate the root causes of these problems, a combination of these two initiatives, named L&SSi, can be even more effective (TIMANS et al., 2014). It combines both problem solving models to address the root causes of deficient performance. Lean Six Sigma merges Six Sigma's ability to control processes with Leans' ability to improve process speed together and provides this way an option for organizations to increase their potential for improvement (BHUIYAN & BAGHEL, 2005).

Both models enable the use of a wide variety of methods. What kind of methods will be used in the end depends on the process and what the wish for improvement is. There are several methods that can help to focus most efficiently on continuous improvement. These can be broken down to three distinct steps: the assessment of processes, the improvement of the process, and the monitoring of the improvements made. The different methods that can be used for these three areas are displayed in figure 2 and include interactive methods as well as methods for graphical representation, statistical evaluation or documentation and verification (COSTA et al., 2018). To be working efficiently on continuous improvement as an action it is important to use different methods from the different process steps. This will secure that all different aspects are covered and the changes due to continuous improvement will work on a long-term basis.

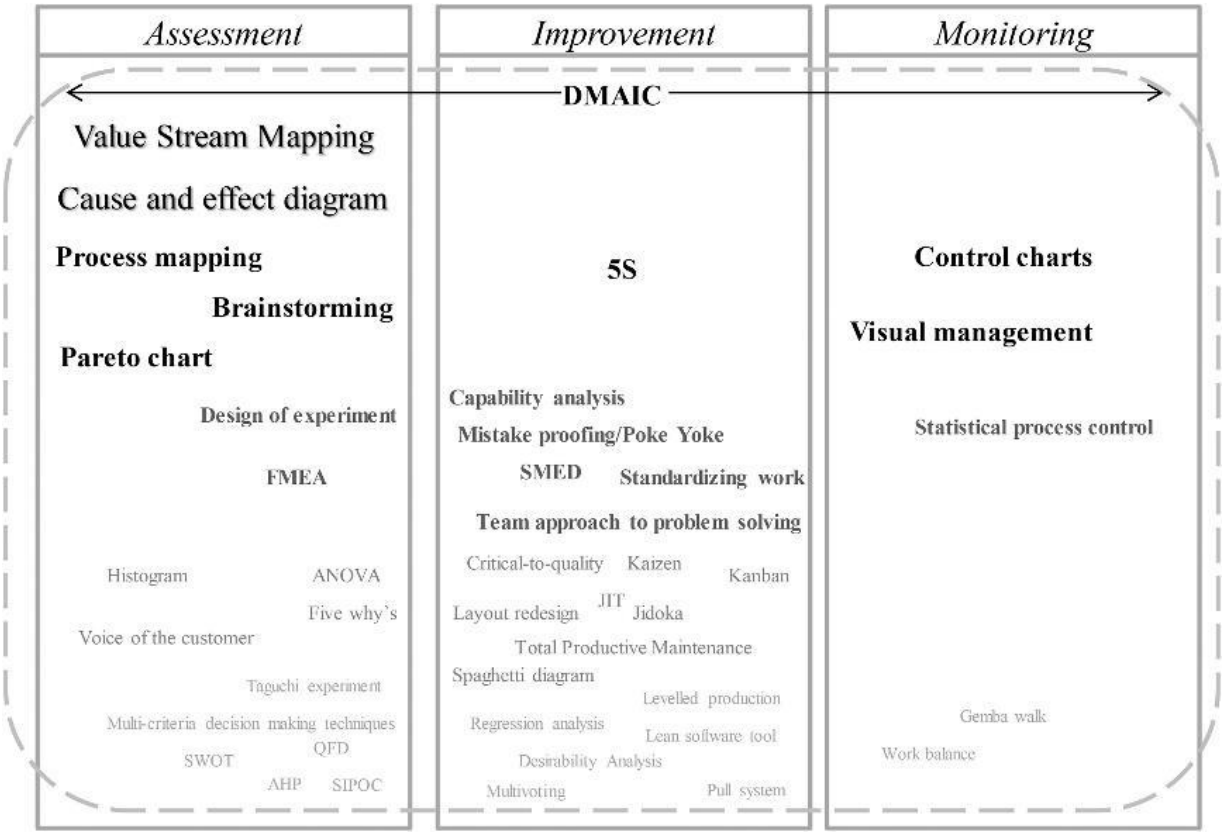

Figure 2 Tools and methods for continuous improvement classification (COSTA et al., 2018)

Some of these methods can also be applied cross-sectoral, for example the PDCA method, which stands for plan, do, check, and act or the DMAIC method, which stands for define, measure, analyze, improve, and control are used for Six Sigma to accomplish the following topics: defining the opportunities, measuring the performance, analyzing the opportunities, improving the performance, and controlling the performance (MITTAL et al., 2023).
The benefits of L&SSi as a combination of Lean and Six Sigma have been proven by several studies. Though there is still a lack of literature on how to implement these initiatives and models in the food industry. A particular challenge here is to measure and transfer the success of a program in the food industry (COSTA et al., 2018).

4. MANAGEMENT OF RAW MATERIALS AT NESTLÉ

Raw material management is a critical aspect of ensuring food safety, as it ensures that the ingredients used in food production are safe and suitable for consumption. Managing raw materials involves identifying potential hazards in the supply chain, sourcing materials from reliable suppliers, and verifying the quality and safety of each batch of raw materials. The failure of managing raw materials effectively can lead to a possible contamination of the final product, potentially causing quality defects (e.g., spoilage), and damaging the reputation of the company.
Regulatory bodies require food companies to implement robust raw material management practices to ensure food safety and quality. Therefore, effective raw material management is crucial for the food industry to ensure that the product is safe, of high quality, and meets customer expectations. Important aspects as for example the traceability of food is specified and defined in the previously presented laws and regulations.
As mentioned before, the management and release of raw material is done by the Site QA at NPTC Food Singen. For this there will be differentiation between raw materials for trials and for commercial production. The release criteria are all based on general risk assessments and are different depending on the raw material. However, since the safety of the food is always paramount, these are always chosen in such a way that a potential risk is reduced to its minimum (ZHANG, 2022). How exactly the process for the handling of raw materials at the NPTC takes place is explained more detailed in the chapter “Representation of the previous state at NPTC Singen” under “1. How are raw materials managed at NPTC?”.

4.1. Systems, Applications, and Products in data processing (SAP)

SAP, or Systems, Applications, and Products in data processing, is a German multinational software corporation that specializes in enterprise resource planning (ERP) software. The theoretical background to SAP lies in the field of business process management (BPM) and ERP systems.
ERP systems are designed to integrate and manage various business processes and functions within an organization (e.g., finance, human resources, supply chain management, sales, and customer relationship management). One of the key theoretical frameworks that underpins SAP is the concept of business process reengineering (BPR). This involves the radical redesign of business processes to achieve significant improvements in performance, efficiency, and effectiveness. SAP's ERP software is built on the idea of streamlining and optimizing business processes through automation and integration. Another theoretical aspect of SAP is the use of data modeling and database management systems. SAP utilizes a relational database management system (RDBMS) to store and manage data. This provides a structured and efficient way to organize and retrieve data.
Overall, the theoretical background to SAP encompasses concepts from BPM, BPR, data modeling, and database management. These provide the base for the design, development, and implementation of SAP's ERP software, enabling organizations to streamline their operations and improve their overall efficiency and productivity (HÖLZER & SCHRAMM, 2009).

4.2. Nestlé Trial Management System (NesTMS)

The Nestlé Trial Management System (NesTMS) is an internal software which is used in Nestlé R&D locations instead of SAP. The system is used for different internal activities and tasks such as (NPTC Singen[10]):

- Managing the materials availability in R&Ds as well as creation of new temporarily used materials
- Managing the creation and execution of trials
- Validation & approval of trials
- Product releases
- Creation of simple workflows and how to manage them
- Creating analysis requests (chemical, physical, microbiological) and assigning them to samples
- Creating dispatch-orders for shipping of samples
- Improving the traceability of a trial in both directions “bottom up and top down”

Almost every employee is working with NesTMS and needs therefore an access, including project managers, kitchen, pilot plant, purchasing, quality assurance, labs, logistics and packaging. An overview which department is involved in which NesTMS area and operation is displayed in figure 3.

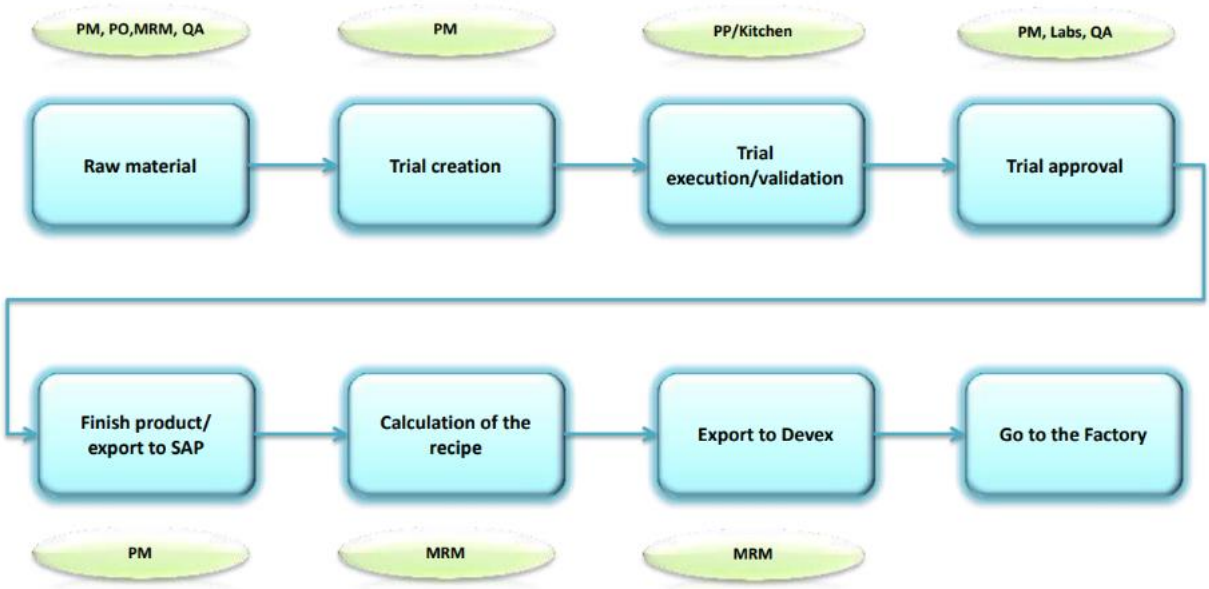

Figure 3 Involved departments in the NesTMS process (NPTC Singen[10])

For the trial management planned trials can be divided into:

- Technical Trials: just for technical purposes (e.g., testing machines and improving processes)
- Consumer-Test Trials: used for consumer-tests (the project manager needs to assure that the materials used comply with the conditions rules)
- Kitchen Trials: created by the kitchen chef and executed by the kitchen team (the materials used are from the kitchen warehouse)

How the creation of a trial group or collection works with NesTMS works in detail is displayed in figure 4 in form of a flowchart.

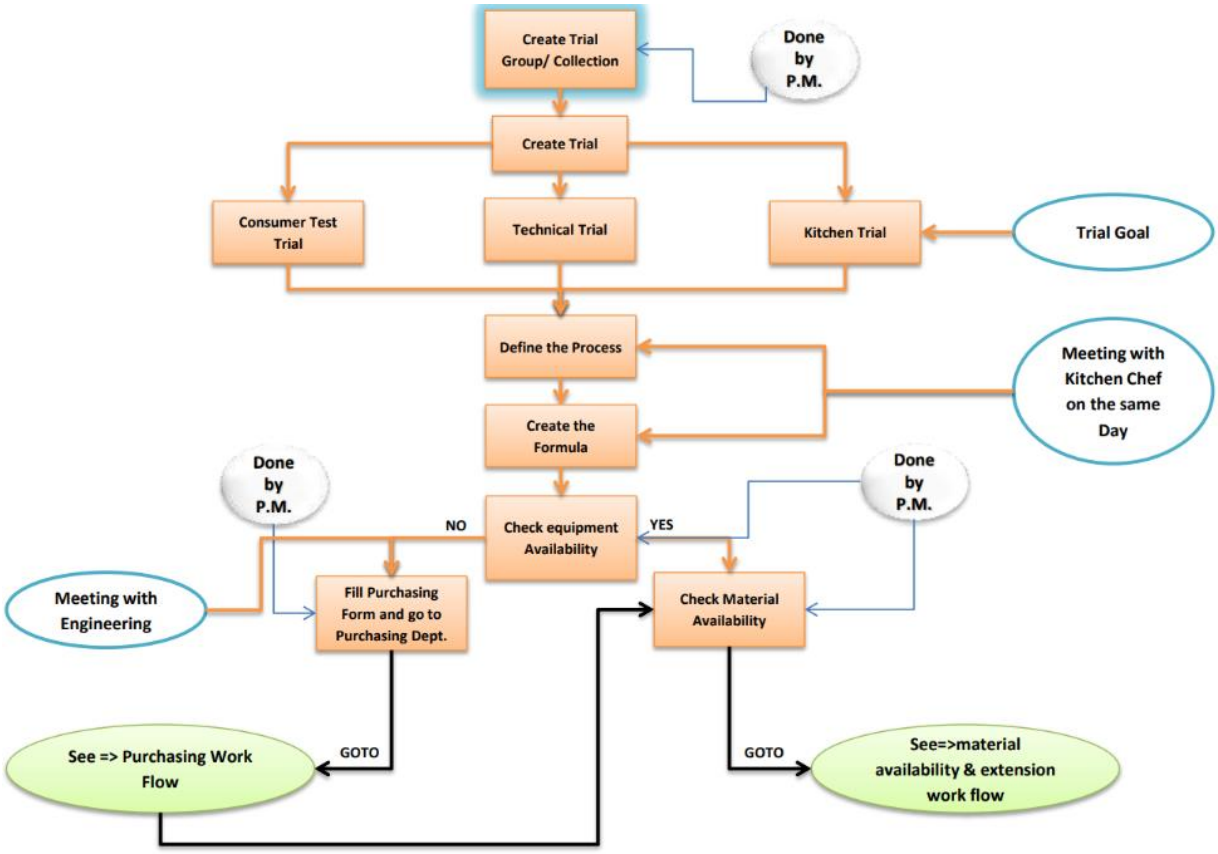

Figure 4 Creation of trial groups or collections in NesTMS (NPTC Singen[10])

The workflow for Test Product Release (TPR) begins also in NesTMS. At the same time when the validation of a trial in the pilot plant is going on, the project manager can create the TPR for the trial in NesTMS. For this the project manager needs to create the samples, assign the right analysis to them, and test and identify the samples with labels. TPR is only done for trials with the goal consumer test. How the creation of TPR with NesTMS works in detail is displayed in figure 5 also in form of a flowchart.

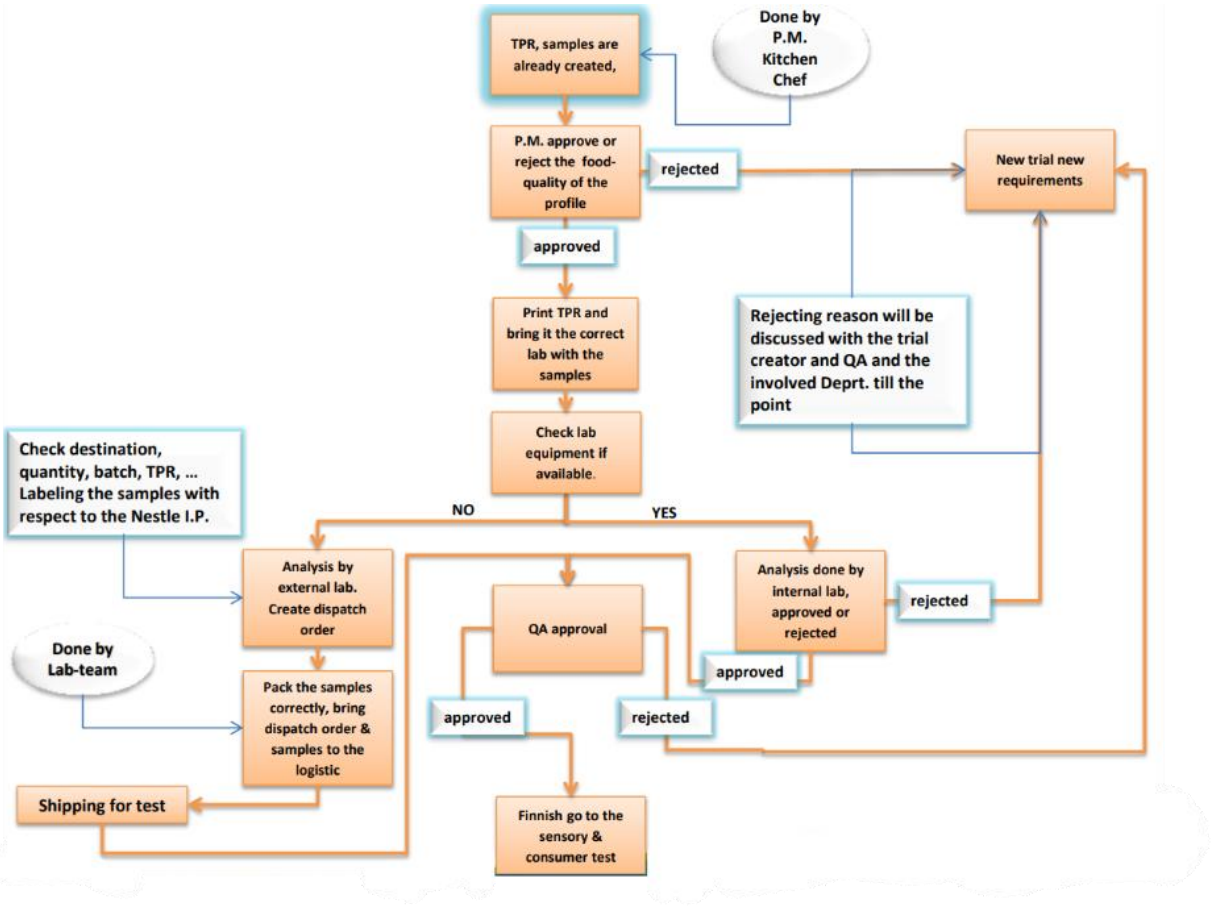

Figure 5 Working of Test Product Release (TPR) in NesTMS (NPTC Singen[10])

5. COMMERCIAL PRODUCTION AT NPTC SINGEN AND QUALITY MONTOING

The Nestlé Product Technology Center (NPTC) is a world-leading research and development facility focused on producing innovative and high-quality food products and developing new technologies and processes. At NPTC Food Singen, it is important to understand the commercial production of food and address the challenges of a growing global population. Therefore, commercial productions on a small scale are done at NPTC for test and learn phases. A team of experts translates research into practical solutions, aiming to deliver products that meet consumers' needs while addressing global health and nutritional challenges. The goal is to leverage cutting-edge technology and scientific expertise to develop sustainable food production systems and reduce environmental impact. The commitment to transparency, safety, and quality ensures that the delivered products meet the highest standards for healthy and nutritious food. Also, being dedicated improving the quality of life for individuals and

communities by providing innovative and sustainable food solutions is very important. If the test and learn phases at NPTC are successful, the commercial productions on larger scales will be outsourced to a factory.

Monitoring the quality is also essential for ensuring food safety as it involves regular checks and evaluations of the product to ensure that it meets quality and safety standards. The monitoring of quality is a prolonged process that begins with the raw materials and continues throughout the production process and to the finished product. This process includes visual inspection, testing of the product for possible hazards, and sensory evaluation. Effective quality monitoring allows food manufacturers to detect and address potential problems before the product is released into the market, reducing the risk of contamination, and safeguarding the health of the consumer. Quality monitoring is also crucial in ensuring that the product meets customer expectations, providing an essential competitive advantage in a crowded market. Effective quality monitoring is a key component of food safety management and enables companies to reduce risks while protecting their brand reputation. As the monitoring of quality can be complex, due to the different areas that can affect the quality and many different parties that can have an influence on this, it is important to have a lean way for the documentation throughout the process. At NPTC this is handled with the Quality Monitoring Schemes (QMS) which covers and documents all important aspects during a commercial production. How this is done exactly will be explained more detailed in the chapter “Representation of the previous state at NPTC Singen” under “2. How is the quality monitored during commercial production?”.

APPLIED METHODS

The following chapter aims to describe the different methods used to develop and optimize the processes for raw material handling and quality monitoring for commercial production.

1. CONTINUOUS IMPROVEMENT FOR RAW MATERIAL MANAGEMENT

The desire for optimization of this process came with the realization during past commercial productions that the entire process was not very lean and smooth and that the responsibilities were not precisely defined. Therefore, there were time delays and misunderstandings within the process, what highlighted the need for optimization and continuous improvement even more.

For working on process improvement, the continuous improvement cycle, shown in figure 6, can build the base for every measure planned. This cycle consists of four different steps, which form an infinitive loop of the process. The first process step is to identify the momentary disturbances and future possibilities for the process, to have an understanding where room for improvement is, and what should be the root cause to focus on. For the second step the planning will be done on how the previously identified points can be improved and how the process can be optimized in total. Afterwards as the third step it comes to implementing and executing the developed improvement measures to the process and if necessary doing an additional testing phase before these measures will be fully integrated. Then, in form of the fourth and last step, an assessment of the changes and how effective they are in their implementation should happen. If possible, a quantitative assessment should be made and a comparison of before and after should be conducted. As the name already suggests, this is a never-ending process, as various aspects (e.g., digitalization, restructuring within the company, gaining new insights) are constantly changing, allowing processes to be optimized increasingly. Continuous improvement can be really challenging especially when it comes to a practical implementation. Without a structured, continuous approach to process improvement, it is difficult to keep momentum moving. To facilitate its implementation, various methods can be used for the cycle. These can either cover only one of the areas or the entire process. Which methods were used and how they were implemented exactly is described in the following sections (MITTAL et al., 2023). For the search for suitable literature,

Figure 6 The continuous improvement cycle (Business Process Improvement Guide | Planview)

the platform Science Direct was mainly used, which has a variety of e.g., books, essays, or reviews on the subject.

1.1. First steps for continuous improvement and getting an impression of the situation on site

Continuous improvement can be broken down to several steps. Many of these are in the pre-phase where the process first needs to be identified, mapped, and analyzed before the actual working on continuous improvement can begin. In the following subchapters these first steps will be explained and described how these were implemented for the work of this thesis (LYNN).

1.1.1 Identifying the process and the people involved

After seeking through various literature to get an overall understanding on what continuous improvement is and what is important to be successful with it, as a first step a cross-functional working group between the different involved departments was created to take a closer look at every possible angle of the process and to work on continuous improvement. For this it was necessary to find a sponsor who was willing to support the aim of the project.
Together with this a screening of various documents related to the process happened and a closer look on how each step throughout the process is defined was done. This was done by reading different standard operating procedures (SOPs) and other internal documents (e.g., standards and forms) and talking to representatives of the various departments involved. It was also observed how efficient the communication between the different involved parties was and what the consequences would be if this communication is not running effortless and smooth.
The results of this first investigation showing an overview of the process and how it worked with the involved parties is deposited in the appendix I.

1.1.2 Mapping the process and setting up a platform

After getting a first impression of the process the process mapping started by identifying and documenting the start, the different steps in between, and the end of the process via brainstorming. This was also done by involving other people and therefore the created cross-functional working group was used to get all departments and different sides together. To gather the different parties together and to have an organized brainstorming and process mapping a facilitator was introduced for this activity. The involved parties of the working group consisted of Site QA, Logistics, Project Management,

Pilot Plant and Weighing. For being consequent and focused on the task this group of people met once per week to keep track about all new developments regarding the process. For the documentation a "SharePoint" as well as the interactive platform "mural" was used together with a training on how to use it.

The existing process was then documented and illustrated in form of a flow chart via "mural". During this activity, the different parties discussed their different sights of the process so that it could be investigated with every detail and the work every department invests is taken into consideration (NPTC SINGEN[6]). To map and visualize the process it was indispensable to define the various steps involved in the process and to outline who is working on each of these steps and where handoffs take place between the departments.

It was important to understand the existing process and where it breaks down, before implementing any changes that will make an impact. The goal was to first get an accurate picture of the process as it is and starting to think about how this process can be optimized (LLOYD & SOLAK, 2003). The identified and mapped process is explained in detail in the chapter "Representation of the previous state at NPTC Singen" under "1. How are raw materials managed at NPTC?".

1.1.3 Analyzing the process

The next step for continuous improvement was analyzing the process further in detail. To identify the problems that come with this process the created "mural" document was extended. This started by doing more investigations and identifying the different aspects that could affect the process (e.g., the ordering process or sampling process) and was documented by creating a fishbone diagram and doing a cause-and-effect analysis, which is shown in figure 7. To understand the causes of the problem in a deeper sense and to find the underlying cause of it, the "5 Whys" method was used to identify for example the cause why the raw material ordering process is so complicated and its impact on this. This was also examined in the "mural" document (NPTC SINGEN[6]).

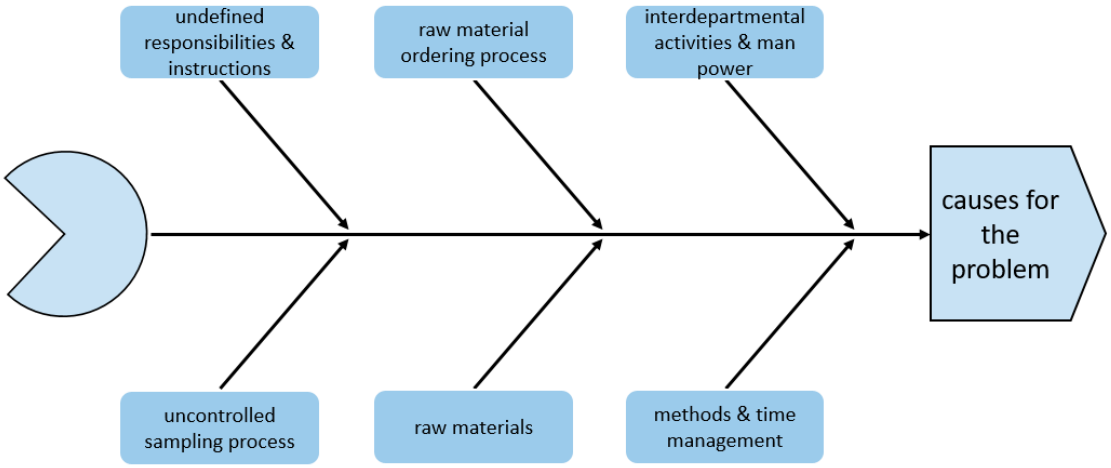

Figure 7 Cause identification to improve the process (CI Raw Material release NPTC Singen | mural)

After breaking up the process and investigating this more in detail, it was important to identify the things which were working and not working and where the process is inefficient. Also, it was significant to know if the people involved get frustrated at some point, because the process was not running smoothly, to highlight what was needed to make the process leaner. For investigating the problems of the process in detail and getting to the core of it the following questions were used, while talking about the process:

- What is working about this process? What is not working?
- Where does the work get stuck? Are there any recurring bottlenecks or blockers in the process?
- What issues are getting the team members frustrated?
- What do the issues of this process prevent to accomplish?
- What must be done to make this process work?

In addition to this and to get a distinct perspective, different measures were taken. One was that the release of raw materials was compared with other Nestlé sites (e.g., Maggi factory Singen, R&D Kemptthal and R&D Orbe). This aimed to check how strict they were when it comes to raw material handling and whether they maintain a more efficient process.
For this Maggi factory was visited twice. Once to visit the raw material receipt of the factory and the other time to visit the factory's' sample management. After getting an impression on how the factory is managing these processes, there was another exchange with the Nestlé sites of Konolfingen and Orbe about how their processes work. The corresponding documents are stored on the "SharePoint" and provide a detailed insight into the handling of the processes and the comparison between the different sites (NPTC SINGEN[7]).

Another action that was done to analyze the process further in detail, was visiting every process involved department and having a closer look on their work in detail. This was particularly important to understand the entire process and to know how much work of the different parties is needed to get the process working. Until this moment it was never clear how the process was working in detail. Before every department just knew what they were doing but not what the other departments were doing. These observations are also deposited in the chapter “Representation of the previous state at NPTC Singen” under “1. How are raw materials managed at NPTC?”. By using different methods for gathering information and looking with different perspectives at the process, it was analyzed in its full complexity which was mandatory to continue with the next step of continuous improvement.

1.2. Working on continuous improvement for raw material management

Continuing with the steps in the implementation phase the process needs to be redesigned, implemented, communicated, and monitored. In the following subchapters these steps will be explained, describing how these were implemented for the work of this thesis (LYNN). To implement the continuous improvement measures the PDCA cycle was applied as a cross-sectoral method. This method consists of four separate phases (GARZA-REYES et al., 2018):

- **Plan** the new process
- **Do** the required work and try it in practice
- **Check** the results and measure the efficiency
- **Act** or adjust the new process if it is not working properly

1.2.1 Redesigning the process

First, the process needed to be redesigned, for this the insights made before for this process and the identified problems are used, to revise the process. Proposals for changes needed to be suggested and afterwards all the involved people worked together to implement this new process. This needed a few attempts, because often a suggestion for the redesigned process was declined by one or more parties because they felt disadvantaged by the proposal or thought that it was not feasible. Redesigning the process builds the first step in the PDCA cycle and contains the planning step, where the process will be revised due to the existing problems and wishes for improvement (GARZA-REYES et al., 2018).

1.2.2 Implementing and communicating the changes

After the process has been redesigned the recent changes needed to be implemented and communicated. This started with a pilot and testing phase of eight weeks to verify that the process is also working in practice and not only in theory. Following this testing phase, a presentation was held in which all improvements made were communicated to the employees and the progress made so far was presented. Then for communicating the changes furthermore all relevant documents that relate to the process needed to be revised and published. Afterwards to implement the changes completely it was important to organize and put on some trainings sessions that everyone gets to know the new process in detail and knows how to collaborate with it. Implementing and communicating the changes has been the second step for the PDCA cycle, which was all about converting the planned actions into practice (GARZA-REYES et al., 2018).

1.2.3 Monitoring the results and measuring the improvement

To measure how successful the improvement was and if any of the changes have led to an improvement the quantity has been measured. For this the Key-Performance-Indicators (KPIs) needed to be identified on how to measure the impact of the made improvement (e.g., shorter release time and adequate CoAs). These KPIs were as followed:

- Comparing the numbers of how many adequate CoAs are gathered to how many analyses needed to be done
- Investigating the changes of the average release times for batches before and after the new process has been introduced (further differentiation between batches for trials, com. prod., and kitchen)
- Comparing the numbers of trials that needed to be rescheduled due to unreleased raw materials before and after the new process has been introduced

This was important to review if the new process was working as expected and if any occurring problems needed to be fixed (MCCUE, 2007). All data relating to the release of raw materials in the period between March 2023 and August 2023 were collected in an excel sheet and later evaluated (NPTC SINGEN[8]).
Monitoring the results and measuring the improvement was dealing with the third and fourth step of the PDCA cycle. The third step for checking was done by measuring the improvement and how effective the new process was. The fourth and last step which was all about acting has happened in form of smaller adjustments of the process (GARZA-REYES et al., 2018).

2. OPTIMIZING THE QMS DOCUMENT FOR COMMERCIAL PRODUCTION

When it comes to the Quality Monitoring Schemes (QMS) for commercial production, it was noticeable that various work steps were documented several times and that the individual process instructions were not easily and clearly accessible for controlling. Root cause for this was that there are several documents used while planning a commercial production (e.g., QMS document, raw material tracking list or the HACCP document).

To address this issue in a methodical way, an overview of the existing documents was first obtained. In addition, discussions were held with various participants in the process (e.g., quality assurance, pilot plant and product development) to clearly define what is important and should be dealt with in the QMS document. Once this was done, the aim was to work out where it was best to store which of the information so that access and handling is as efficient as possible for all parties and the document is as detailed as necessary and as short as possible. For the future use of the QMS document suggestions have been made how to improve the usage and what would make the work smoother and more lean for all participants.

REPRESENTATION OF THE PREVIOUS STATE AT NPTC SINGEN

In this chapter the situation from before the changes for improvement were made at NPTC is explained and how the process for raw material management and quality monitoring during commercial production is structured.

1. HOW ARE RAW MATERIALS MANAGED AT NPTC?

In figure 8 it is shown how the raw material management process has been managed at NPTC and what was the base for the continuous improvement measures. In the following sections, the individual process steps are described and already identified weak points are presented. This is structured into the responsibilities and work of the different departments. The process starts with the logistics and on how to order raw materials and ends with the work of the Site QA and releasing of the raw materials.

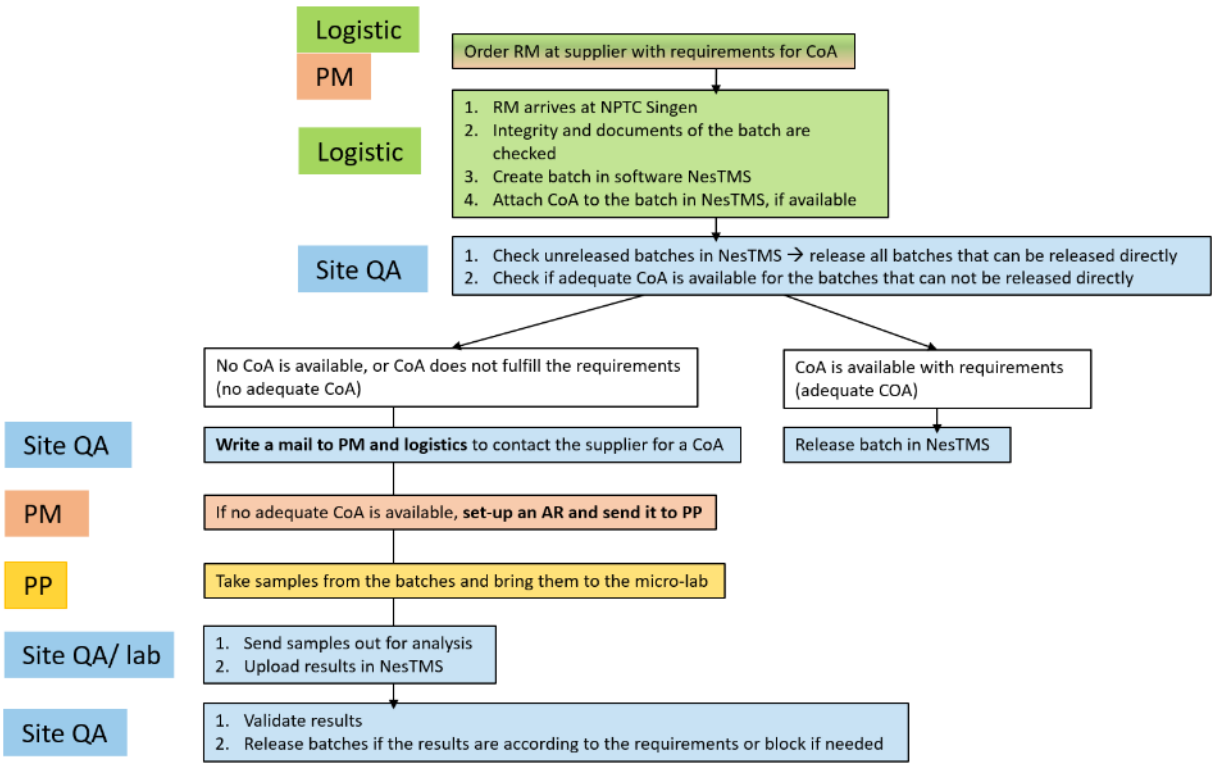

Figure 8 The old raw material management process (own depiction 2023)

As there are different kinds of raw materials used at NPTC Singen and sometimes the process steps can change a little bit depending on the intended use of the materials the following sections will be further subdivided into raw materials for trials, commercial production and kitchen.

1.1. Way of working at the logistics

The logistics is the first step every incoming raw material must go through, and it builds the first step of the releasing process for raw materials at NPTC.

1.1.1 Process of ordering raw materials

The ordering process of raw materials at NPTC can happen in two ways. It can either be done by the logistics or the project manager can order the raw materials directly by themselves. For this purpose, the condition must be fulfilled that the material has already been created in NesTMS. If this is not the case, the form “F-QA-004 Checklist for RA of New RM + Creation Form” must first be filled out and the material must be created in NesTMS. For new raw material creations NPTC separates between Research and Development (RD), Supplementary Data Repository (SDR) and Master Data Repository (MDR) materials. The creation form for new raw materials is deposited in the appendix II.
If the logistic is responsible for ordering the raw material, the responsible project manager needs to fill out the document “F-PP-037 GLOBE Material Order Form” before, containing the following information: material number, globe material name, quantity, unit, project number, cost center, desired delivery date, material contains component of sesame and/or peanuts, material needed for commercial samples, contains component of animal origin, and contains unwanted ingredients.
The project manager can also name a preferred vendor for the raw material but in the end the logistics will decide where to order the material, contact the supplier, and order the raw material. After selecting and contacting the vendor the logistics will add information on the price per kg, the currency, hazardous substance, MDR/SDR extension required, and storage condition. The template of the form is attached in the appendix III. The ordering process will be then done via GLOBE / SAP, where all materials are deposited. For the ordering procedure the logistics will separate between raw materials for trials or kitchen and for commercial production after they received the ordering form, because for raw materials that will be used in a commercial production more parameters on a CoA will be requested. Besides this there are no other deviations within the ordering process for different kinds of trial and production raw materials.
With the order of a raw material, it will be asked for an adequate CoA, as long as the order is done at suppliers where a CoA would be needed. An adequate CoA means that the supplier provides a

certificate of analysis (CoA) with defined requirements and information such as material name, lot number, analysis parameters, analysis unit and analysis method.
All new ordered raw materials will be afterwards transferred manually to the “Raw Material Order tracking list” where all ordered raw materials are listed and will be updated on the various stages. This list includes all raw materials for trials, commercial production, and kitchen, containing all information concerning the material and the vendor as well as the purchase order and all dates within the ordering and receiving process. As the last step in this list the created batch number will be added and deposited (NPTC SINGEN[4]).
If the project manager orders raw materials without the logistics, he will contact the supplier directly for example per mail. The ordered raw materials, usually only smaller sample amounts, then end up separately from the standard raw materials as a package next to the logistics and do not always get a batch creation afterwards. This depends if the raw materials will be used for trials. If so, they need to get a batch creation and release before they can be used for a trial. The project managers get informed when their orders have been received and can collect them from the logistics or request for a batch creation if needed.

1.1.2 Raw material receipt and creating a batch

The incoming raw materials ordered by the logistics are divided into three different categories: ambient stable, chilled, and frozen. On a monthly basis there are about 250 to 300 small containers up to 25 kg of incoming raw materials and in addition batches with larger amounts as well as the ordered raw materials for commercial production. Referring is this process to the “SOP-PP-014 Goods receipt” (GROSS, 2018).
For every incoming raw material, a visual inspection takes place before the raw material will be accepted. During this inspection, the raw material will be checked for any external contamination or non-conformities. In addition, for chilled and frozen raw materials a temperature measurement takes place to verify that an uninterrupted cold chain is warranted. After accepting the raw material, it will be stored next to the raw material receipt or in the cooling chambers of the logistics before it will be transferred to the storage area after creating a batch.
An employee of the logistics will verify if the delivery order is conform with the original order and that the existing raw material is the correct one. In detail this means that the employee will check the following points:

- Is the delivered quantity the same amount that was ordered?
- Does each unit belong to the specified lot number?
- Has every unit the same best-before date?
- Is a material specification available? Either as an attachment to the delivery order or as a note signing that the raw material corresponds to a certain specification.

The logistics is working with SAP and NesTMS. SAP is used for the ordering process, while NesTMS will be used for creating the batch and any internal actions concerning the materials. If there are any deviations (e.g., a different quantity than it was ordered by the supplier) the logistics employee must contact an SAP specialist, who is able to change the batch data stored in SAP. And if any further information is missing, like a best before date, the supplier must be contacted.
The creation of a new batch is the same process whether the raw material is for trials, commercial production, or kitchen. For creating a new batch in NesTMS, the tab “Material handling” and then “Goods Receipt” is selected. Afterwards the purchase order number is entered, and the different order items will be displayed. For each of these order items a batch for the corresponding material is created. While creating a batch where will be done another cross-checking step if all the information is correct and conform with the order. The information about the batch that will be stored in NesTMS are the following and an example how this is presented is shown in figure 9:

- Name of the raw material [1]
- Project manager as the responsible [2]
- Vendor and vendor ID [3]
- Material ID [4]
- Date of the batch creation as the production date [5]
- Best-before date as expiry date [6]
- Lot number as vendor batch ID [7]

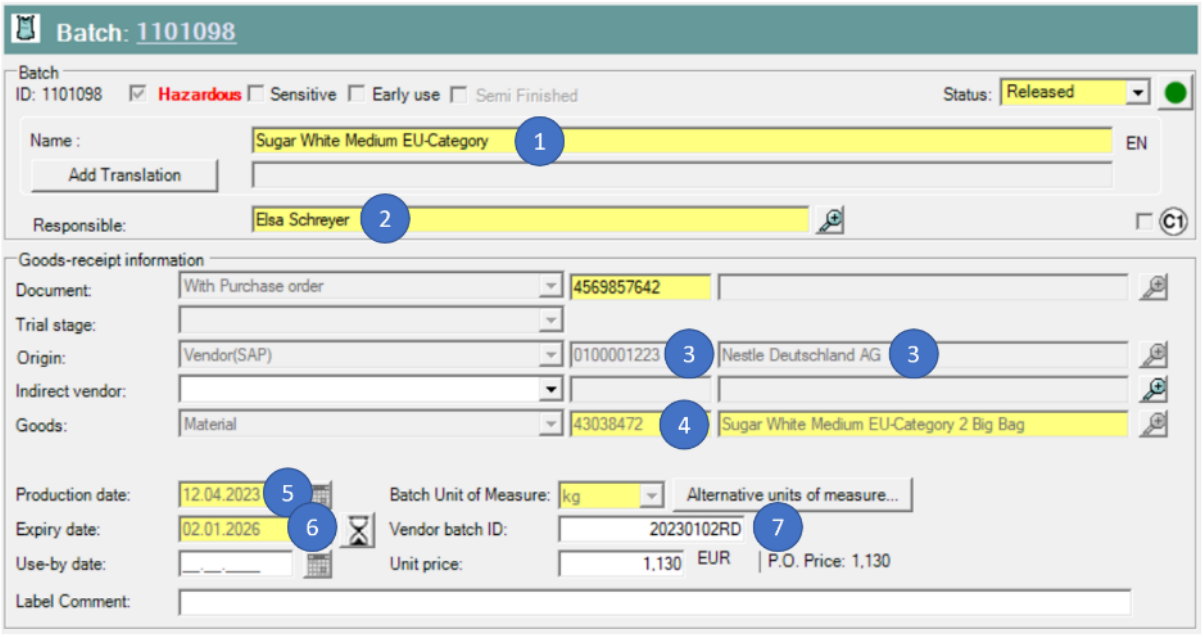

Figure 9 Example of how a batch is illustrated in NesTMS (NesTMS 2023)

After creating the batch, a stock movement for the batch will be created linked with the information about the quantity of the batch and where it is stored. If for the batch a certificate of analysis (CoA) is available, it will be attached in NesTMS to the batch or there will be a comment left in NesTMS, if a CoA has already been requested. After creating the batch and when all the information in SAP matches with the information deposited in NesTMS, the entry in SAP will be deleted automatically if the order was done with purchase order by the logistics. If the order was done without purchase order by a project manager directly, the entry in SAP must be deleted manually, because the entry in NesTMS is not directly linked to the order in SAP and therefore the deletion in SAP is not happening automatically.
As the final step of the batch creation labels containing information of the batch number and material will be printed and applied onto each of the units, guaranteeing that the traceability of the batch is secured at any time. All the order documents will be filed in a folder afterwards.

Trials

While creating a batch for the place of storing there are two feasible options for ambient stable batches used for trials. Either the batch will be booked directly at the right storage place, or it will be first booked with a place holder. This could be the case for example for an ambient stable material used for trials which will be stored in the storage U-111. For this the place holder can be the storage bin A1, and the actual storage place will be assigned later in the process when it is decided where the material shall be stored exactly. Chilled and frozen batches will be assigned directly to the correct storage locations,

as their number is way smaller and their handling thus easier. For raw materials ordered for trials there are defined storages with the desired temperatures and batches will be assigned directly to the appropriate warehouse and storing areas.

Commercial Production

For the commercial production at NPTC the process for creating a batch is completely the same as for trials and kitchen. The only additional measure that is taken, is that in the batch name the identifier "<< com.Prod. >>", as shown in figure 10, will be used. This makes a clear distinction between raw materials for trials or kitchen and raw materials for commercial production. Batches ordered for commercial production will get different storage locations assigned than batches that were ordered for trials. The reason for this is that the handling of raw materials used for commercial production should be done as precise as possible and therefore any risk that comes with other raw materials (e.g., cross-contaminations) should be minimized due to the food safety.

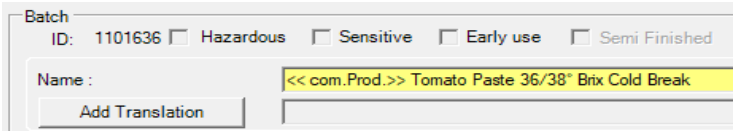

Figure 10 Identification of a batch that will be used for commercial production (NesTMS 2023)

Kitchen

Raw materials that have been ordered by the kitchen for kitchen trials will be placed aside and after the batch creation these materials will be collected by an employee of the kitchen.

1.1.3 Identified problems at the logistics

There are a few problem areas that were identified while having a closer look at the way of working at the logistics. The identified problems are the following:

- Batches for raw materials were not directly created after the arrival of the raw materials
- Batch creations for the project managers are done even though the material is physically not available or the amount of the material is not confirmed
- Not all employees of the logistics know what a CoA is for and why it is important or what they need to request for in a CoA
- Not enough space in the logistics, as the number of raw materials ordered, and their amounts increased

These can be used to develop further improvement measures and to achieve an optimization within the release and management process.

1.2. Way of working at the warehouse and weighing area

The warehouse is the next station after receiving the raw materials and creating a batch at the logistics. After creating a batch for every incoming raw material, the entire batch will be transferred to the storing area. The raw materials will be used for different purposes such as trials. For these recipes will be created and need to be weighed out.

1.2.1 Storing of raw materials

Depending on the intended use of the raw materials (trial, commercial production, or kitchen) the storage location changes. The main warehouse is in the basement of NPTC and is used for the trial raw materials as these make the majority of the incoming batches and come often with large quantities. At any time while a batch is at NPTC, all stock movements are registered in NesTMS, so that it is always transparent where the batch is stored and how much quantity is available.

Trials

In the basement the employee who is responsible for the storage and weighing will store the material in the designated storage area and if necessary, he will change the storage place in NesTMS. If more quantity of the same material is already stored at a certain location, the newly arrived goods will also be booked there. It can also happen that different raw materials are stored at the same storage bin, as there are not enough storage locations, and the available space should be used as efficiently as possible. The storage bins do not have a specific assignment, which means that the materials are stored where there is space and not, for example, alphabetically or according to the product category. Once a week, the batches with expired best-before dates are sorted out and will be disposed. Most of them will be donated for example to the food bank, who will get information before what kind of materials will expire and can be donated. The donation can only take place for common raw materials as for example salt. More particular or hazardous materials for example flavors will not be donated.

Commercial Production

The batches for commercial production will not be stored in the warehouse together with the batches for trials as there would be a higher risk for cross-contaminations. Since the food safety is ranked way higher for commercial production as for trials, the potential risk for a batch should be held as low as possible and therefore the batches are stored separately due to allergen management. In the past years, these batches have been stored in containers outside NPTC. For this year there have only been two planned commercial productions at NPTC and for these the raw materials are stored in the robot room in the pilot plant.

Kitchen

The batches that have been ordered for the kitchen will be collected after their batch creation and transferred to the kitchen warehouse or to one of the cupboards of the chefs. To these storing locations only the employees of the kitchen have access and the raw materials will be only used for kitchen trials.

1.2.2 Weighing of raw materials

On a daily basis, different recipes for trials are surrendered. And additionally, if an upcoming commercial production is planned the recipes for these also need to be weighed out. Most important when it comes to weighing out raw materials is that, all stock movements are documented and the available stock of the materials is up to date.

Trials

The recipes for trials have different amounts of raw materials listed and these will be weighed out and stored together until they are picked up. Specified raw materials needed for the recipe are already listed with their batch number and will be collected from the storage. Basic raw materials that are used at regular intervals, for example salt, sugar, or raps oil, will have no deposited batch number. For these materials the batch currently in use will be used during the weighing process. This means that there is already an open batch of the material and this one will be used until it is empty and will then be replaced by another batch. Normally these basic raw materials are not ordered by the project managers for their trials, because huge amounts already exist in the storage and will be used up gradually.
After all the needed raw materials are gathered from their storage places the code on the recipe will be scanned and the automatic sequence of the weighing of the individual raw materials takes place. Gradually, each of these raw materials is displayed on the scale and can be weighed out after scanning the batch. Sometimes there will be small deviations like a change of the batch number or a different raw material. If this is the case the changes need to be done manually by the employee. The used scales have a direct connection to NesTMS, so that the withdrawn quantities are noted as stock movements in the batch and are booked out directly.

Commercial Production

Similar to the storing process the weighing of raw materials that are for commercial production will be done in a separate area due to allergen management, but the weighing process is happening in the same way as for trials. Additionally, the responsible employee will use other equipment than for weighing out normal raw materials to avoid a cross-contamination of the batch and he will also change his working clothes to a fresh unworn set before starting the weighing process. Only raw materials that

have been ordered for commercial production and labeled accordingly can be used for this. The weighing of raw materials used for commercial productions is conducted in the robot room.

Kitchen

The weighing of raw materials for kitchen trials is happening usually in the kitchen directly, because the recipes for kitchen trials are smaller in scale and no large quantities of raw materials are therefore needed. There are a few exceptions when materials are needed from the large warehouse in the basement. For these cases the weighing process happens the same way as for trials.

1.2.3 Identified problems at the warehouse and weighing area

There are a few problem areas that were identified while having a closer look at the way of working at the warehouse. The identified problems are the following:

- When a person needs an amount of raw material at short notice, they sometimes get it by themselves and often the amount of a raw material is not booked out in NesTMS
- Batches are not stored back at the indicated storage bin, or an incorrect quantity is deposited in NesTMS
- People are asking for raw materials that have not been released or even arrived at NPTC

These can be used to develop further improvement measures and to achieve an optimization within the release and management process.

1.3. Releasing process for raw materials (Site QA)

The process of releasing raw materials is the responsibility of the Site QA team. The release process of raw materials takes place via NesTMS. Referring is this to the “SOP-QA-004 Release of raw materials” (ZHANG, 2022). How the release of raw materials functions in detail is explained in the following subchapters.

1.3.1 Release criteria for raw materials

In general, the release criteria differ between raw materials for trials and for commercial production. For raw materials used for trials in the pilot plant and kitchen it is limited to microbiologic analysis. The release process for raw materials used for commercial production is more extensive.

Trials

The release of raw materials for trials delivered from suppliers is based on risk assessments performed at NPTC. Incoming raw materials at NPTC are divided into three categories:

- ambient stable
- chilled
- frozen

For these categories are specific microbiological parameters prescribed that need to be checked before the batch can be released. What kind of microbiological analyses are needed for each category is displayed in table 1.

Table 1 Microbiological analysis requirements for raw materials for trials (ZHANG, 2022)

RAW MATERIAL CATEGORY	MICROBIOLOGICAL PARAMETERS NEEDED FOR RELEASE
AMBIENT STABLE	- absence of *Salmonella* in at least 25 g
CHILLED	- absence of *Salmonella* in at least 25 g - absence of *Listeria monocytogenes* in at least 25 g
FROZEN	- absence of *Salmonella* in at least 25 g - absence of *Listeria monocytogenes* in at least 25 g

For ambient stable materials, a testing for absence of *Salmonella* in at least 25 g is required while for chilled and frozen materials a testing for absence of *Salmonella* and *Listeria monocytogenes* in at least 25 g is required. This information can either be already given by providing an adequate CoA from the supplier or the required analysis needs to be done by setting up an analysis request (AR), taking samples, and sending the samples out for analysis. In addition, there are a few exceptions depending on the kind of raw material and the supplier they come from. Many of the incoming raw materials can be released directly without any analysis. This refers to all incoming batches that come from another Nestlé site, as Nestlé factories and companies that belong to Nestlé (e.g., “Sofinol”). This is feasible as the raw materials have already been released and therefore approved by Nestlé. Similar to raw materials coming from Nestlé sites the raw materials coming from one of the “5 key flavor houses” will

be also released immediately based on a performed risk assessment. These are built up of the following suppliers:

- International Flavors & Fragrances (IFF)
- Givaudan International
- V. Mane Fils
- Symrise AG
- Firmenich SA.

Reason for the direct release are general company statements of the suppliers that assure the batches have been evaluated before they are send out. Raw materials that are marked with the letters “RD” either in the batch name or in the material number can also be released directly since they are prototypes or samples from suppliers and their intended use is just for internal purposes (e.g., internal tastings or technical trials). It is not allowed for an intended use outside of NPTC for example a consumer test. This is the same with materials that have a “CS” in their batch name, which means that they are commercial materials and come from commercial suppliers e.g., supermarkets or butchers. As these raw materials already have been on the commercial market there is no need for further release requirements.

Another exception for raw material release are aseptically filled raw materials. These will be released with the condition that when they will be used a raw material monitoring will be done. For vegetable oils no microbiological parameters are needed but they need to provide a CoA with a peroxide value lower than 1,0 meq 0_2 / kg and with a free fatty acid’s percentage of less than 0,1 %. Otherwise, the material needs to be analyzed for these parameters. There are a few vegetable oils that, have higher or also lower limits. But for the most common ones, as for example raps or sunflower oil the regular limits are valid. Chemical raw materials are also not analyzed for microbiological parameters, but they need to provide a food grade certificate that states the material can be used for the food production.

The last material category are packaging materials, and their release is based on the following flow chart (shown in figure 11). For these materials, the Site QA will just release

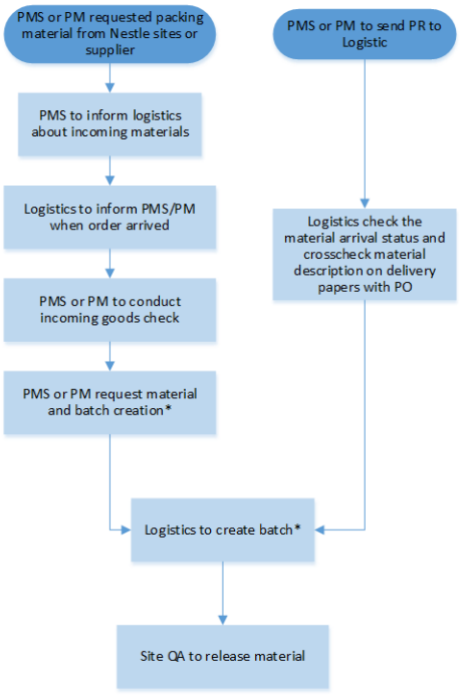

Figure 11 Releasing packaging material for trials (ZHANG, 2022)

the batches because the logistics or the project manager together with a packaging specialist already crosschecked everything necessary concerning the packaging material.

Commercial Production

The releasing criteria for raw material used for commercial production are stricter and more complex than for trials. For materials that come from Nestlé factories or other Nestlé sites no microbiological and chemical analysis are needed, however a valid major allergen declaration (MAD) form is required. The MAD shall not be older than three years and fully accurately completed by the supplier. Commercially available raw materials (e.g., from supermarkets) cannot be applied for commercial production because of missing information from the producers.

For each other raw material, the project manager fills out the excel table for raw materials for commercial production that contains all relevant information for the release and is stored in the "ManCom SharePoint" (NPTC SINGEN[5]). The compiling of information by the project manager needs to be started when the recipe development is finalized, and the commercial production is planned. Afterwards quality and packaging specialists judge the information received and fill in information under their responsibility in the excel sheet. If all release requirements are fulfilled and the different involved parties have given their approval (e.g., chemical, physical and microbiological lab) for release the Site QA team can release the batch. The release criteria differentiate for every ordered raw material, as it has an influence for example what kind of raw material it is or from which country they come from.

Also, the release for packaging materials is different for commercial production than for trials. In figure 12 it is shown, how the release process for packaging material for commercial productions is managed. For this also the compliance for the material must be tracked in the excel sheet and batches will be not released until all the requirements are fulfilled and confirmed by the responsible persons and packaging specialist.

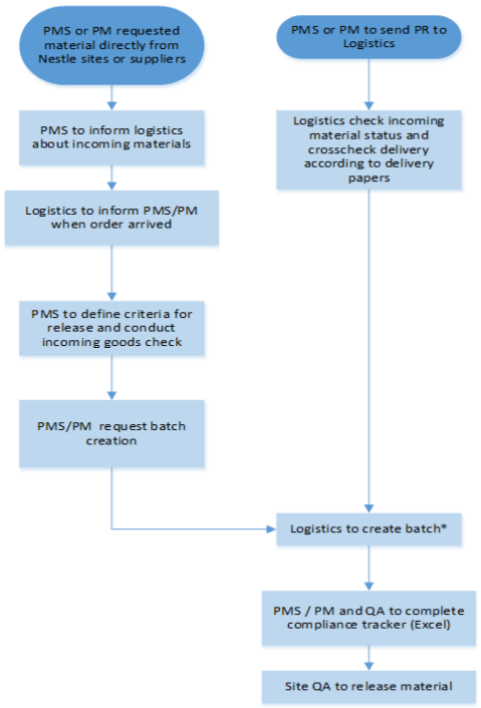

Figure 12 Releasing packaging material for commercial production (ZHANG, 2022)

Kitchen

The release criteria for batches ordered by the kitchen and used for kitchen trials are the same as for trials. Additional to this there are some special cases for the kitchen when they order a raw material

with a low shelf life and an analysis for micro parameters would be needed, for example yoghurt. For these special raw materials an “early use” in NesTMS will be done, the analysis will be organized, and a soon as the results arrive and are within limits the batch will be released.

1.3.2 Execution of the release procedure

For the execution of the release procedure the Site QA filters and checks for all batches that have as origin “vendor (SAP)” and as status “unreleased” in the NesTMS system. After clicking on “search” and opening all new appearing batches, they check, if the release criteria are fulfilled as above-mentioned. How the search function for batches in NesTMS works is shown in figure 13.

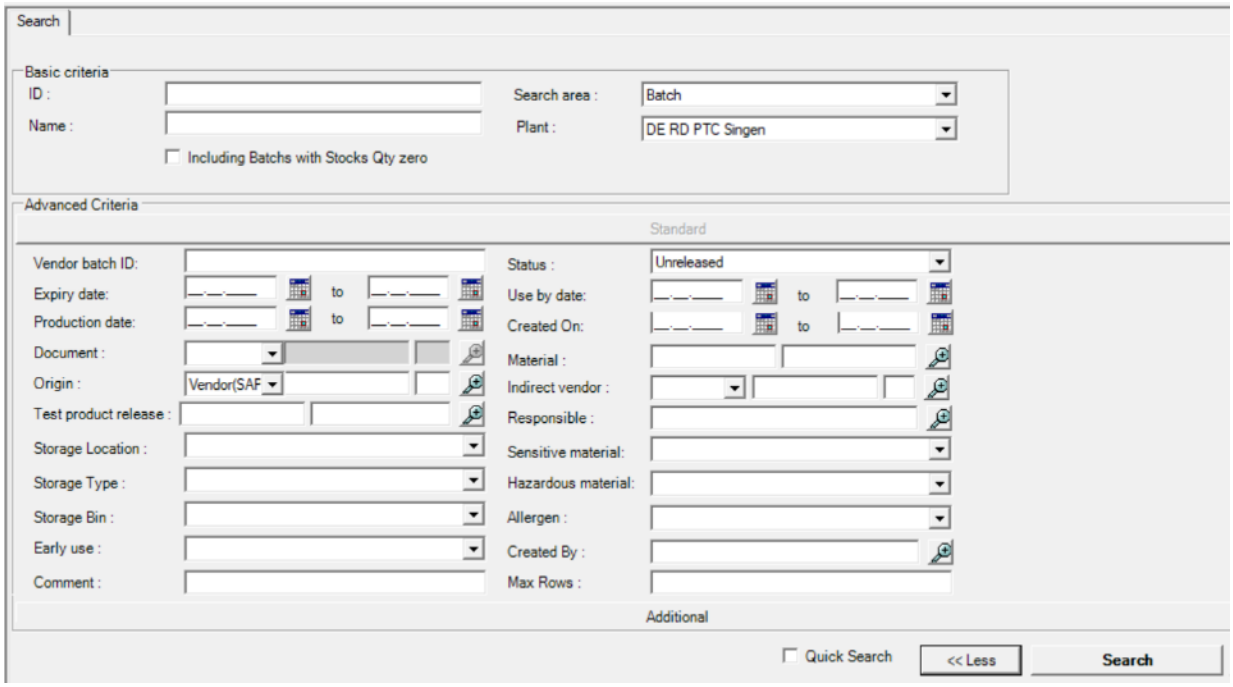

Figure 13 Search function in NesTMS for unreleased batches (NesTMS 2023)

Trials

If it is a raw material for trials and it cannot be released directly, Site QA checks if the batch has a CoA attached and if yes and the CoA provides the needed release criteria the batch can be released. When the attached CoA is not adequate, or no CoA is available the employee of the Site QA contacts the responsible person for the batch (e.g., the project manager) to organize the CoA or to organize a sampling and create an analysis request (AR). The taken samples are then send out to an external lab and after receiving the analysis results the Site QA team uploads, validates and releases the results and the batch afterwards.

Commercial Production

Raw materials for commercial production are also released by the Site QA when all the requested information is complete, and all the release relevant criteria are within the defined limits. When it is applicable and the shelf-life allows it, the raw material for commercial production should be delivered to NPTC as soon as possible before the production to ensure in-time release. Visual and sensorial inspections of the raw materials before their application must be performed by the responsible person for the ingredients. The detailed process on how to release raw materials for commercial production is deposited in the "SOP-QA-004 Release of raw materials" (ZHANG, 2022).

Kitchen

For raw materials that have been ordered for the kitchen the release procedure is the same as for trials. The only deviation is that if no adequate CoA is available as the responsible not the project manager but instead an employee of the kitchen will be contacted to either organize an adequate CoA or a sampling.

1.3.3 Identified problems during the release process of raw materials

There are a few problem areas that were identified while having a closer look at the way of working for the releasing procedure. The identified problems are the following:

- There are for example old unreleased batches in NesTMS from years ago
- Project managers are not consequent in organizing the analysis of raw materials and then they need the release as fast as possible
- A lot back and forth between Site QA, logistics, vendor, and project manager, because of requesting a CoA
- Release process is often undefined about who has which responsibilities and due to this, actions are managed on last minute (e.g., release and weighing out for trials or commercial production)

These can be used to develop further improvement measures and to achieve an optimization within the release and management process.

2. HOW IS THE QUALITY MONITORED DURING COMMERCIAL PRODUCTION?

For the quality monitoring at NPTC primarily the Quality Monitoring Schemes (QMS) document is used. Additional to this document there are other supporting and supplementary documents that are processed by a large number of people. For example, the excel table for raw materials for commercial production that contains all relevant information for the release and is stored in the "ManCom SharePoint" (NPTC SINGEN[5]) . The QMS document, together with the HACCP concept and the associated documents, is considered as the basis for important projects such as commercial productions. For the work on the QMS document have been two documents from past productions of the projects "Starfish" and "Panacea" used. Excerpts from these documents are deposited in the appendix IV as a reference on how the QMS documents looks like and for a better understanding of the process. For overview purposes the QMS document is divided into three different clusters:

- QMS team
- QMS raw materials
- QMS process

The first section is all about the QMS team and lists all relevant people and their functions who are involved in the project, e.g., project manager, Site QA, packaging specialist, product developer, pilot plant supervisor or microbiologist. Selecting a QMS team is the first step that needs to be done, before starting with the work on QMS. The main QMS team for every project such as commercial productions must primarily consist of the areas project management, quality assurance, and production and can depending on other areas such as packaging, logistics, engineering, sensory, or lab be expanded. The participation may for some functions be required only on need basis.
Section number two is all about the raw materials and packaging and lists different inspection stages or types together with information as inspection point, inspector, inspection characteristic, CCP / oPRP / CP, sampling frequency, inspection method, specification / evaluation, corrective actions, and check results. Inspection stages for raw materials can be for example for the following types:

- Raw materials
- Packaging materials
- Label artwork
- Primary packaging

The third and last section is about the QMS process and builds the largest of the three sections. This part is further divided into the different process steps and has again the same checkpoints that list different inspection stages or types together with information as inspection point, inspector, inspection characteristic, CCP / oPRP / CP, sampling frequency, inspection method, specification / evaluation, corrective actions, and check results. The various process steps may include, for example, the following points with different types of inspections:

- Raw material weighing
    - weighing tools
    - raw materials
- Wet mixing
    - equipment
    - semi-finished product
- Filling
    - equipment
    - semi-finished product
    - finished product
- Finished product

For all kinds of different inspections, it is vacant what different procedures, e.g., visual checks, weighing, calibration, or sensory are listed and how many procedures are done for an inspection type. Under finished product for example different inspections can be listed, as all the different analysis parameters such as pH value, water activity, viscosity, sensory, or different micro parameters.
The types of inspections also vary, as different process steps are carried out in different projects and therefore the checkpoints within the QMS document also change. The two projects "Starfish" and "Panacea" were similar product categories with an ambient stable paste as the end product, therefore the two QMS documents are similar in terms of their structure and checkpoints.

WORKING ON CONTINUOUS IMPROVEMENT

This chapter discusses which problems could be identified and how they were addressed in order to create an optimization for the process and lead to a continuous improvement.

1. PROBLEM AREAS AND POTENTIAL IMPROVEMENT FOR RAW MATERIAL MANAGEMENT

With the cross-functional working group and all involved departments the key points for an all-round improvement for everyone have been identified. To get an impression on how complex the process is and to break it down it was important to investigate every detail and first get to the root cause before thinking about practical solutions. This was all about identifying, mapping, and analyzing the process (NPTC SINGEN[6]).

The identified problem areas and planned solutions to minimize or eliminate these problems are deposited in the following table 2. This summary is primarily intended to provide a better overview and directly groups and categorizes the various problems.

Table 2 Identified problems and suggestions for improvement of the raw material release process

	IDENTIFIED PROBLEMS TO WORK ON	SUGGESTION FOR IMPROVEMENT
GENERALLY CROSS-DEPARTMENTAL	people are working in a bubble, without informing about what the other colleagues are doing → work is done twice or not at all	making the process more transparent and showing its complexity; training sessions to raise awareness
	often no existing suitable backup, as the person who is normally responsible has not informed others about their work, or colleagues are not trained to backup	planning of backups (first and second backup); training sessions
COMPLETE RM RELEASE PROCESS	full process with all its steps and responsibilities is not documented → release and weighing can happen under pressure and last minute	mapping the process and defining responsibilities
	lots of mails between different parties as responsibilities are not defined; unnecessary back and forth	defining responsibilities and revising the SOP; reducing numbers of involved parties
LOGISTICS	batch creation is not happening right away	should be happening right away and on the same day the raw material arrives
	lack of space as the amount of RMs is continuously increasing	reconstruction measures for the logistic → planned for 2024
WEIGHING AND PP	lack of space as the amount of RMs is continuously increasing	reconstruction measures for the storage
	PMs often get RMs by themselves, without booking out the taken amount or bringing the RM back → traceability is no longer given	locking the different storage rooms so just a few people have access and can move RMs
	materials are often not stored in the indicated storage place in NesTMS	everything that gets a batch should be stored in the storage or in the private shelves
	PMs are asking for RMs that have not been released or even arrived till this moment	RMs should be released or send out for analysis as fast as possible after the batch has been created
SITE QA	unreleased batches in the NesTMS system from years ago	discard all batches older than 2023
	often weeks go by before an AR is set up and the analysis takes place → long time before the RM gets released	defining responsibilities and process to optimize the time management

Subsequently, the continuous improvement measures were derived and could be implemented in the newly developed process. These identified problems served as a basis and the associated suggestions as an orientation in which direction the improvement measures should go. How far the implementation of these was possible so far and if so, how successful they are, will be described more in detail in the next chapter.

2. PROBLEM AREAS AND POTENTIAL IMPROVEMENT FOR MONITORING QUALITY DURING COMMERCIAL PRODUCTION

Similar to the part for continuous improvement for the raw material management process the identified problem areas and planned solutions to minimize or eliminate these problems have been also investigated for the improvement of the QMS document and are deposited in the following table 3. This summary is primarily intended to provide a better overview and directly groups and categorizes the various problems.

Table 3 Identified problems and suggestions for improvement of the QMS document

	IDENTIFIED PROBLEMS TO WORK ON	**SUGGESTION FOR IMPROVEMENT**
NESTMS	data on how trials or productions are done is nowhere kept → no QMS documentation in NesTMS	QMS shall be integrated in NesTMS (e.g., used equipment) → no more excel sheet or way smaller, as most will be linked directly to the trials and production
QMS SHEET	many information is doubled and unstructured → red thread not clearly visible	list of all possible inspection types and checkpoints
	different documents are used (e.g., QMS document, RM tracking list, net content release form)	unification of information, maybe even some kind of template would be useful
	time line for QMS is not really given → related information is discussed or disseminated too late, resulting in time constraints towards the end	determination of strict time management and when each step has to be taken
	the QMS document is long and can be confusing	shortening of the QMS document and working with color coding

These identified problems served as a basis and the associated suggestions as an orientation in which direction the improvement measures should go. The plans for an implementation of these instructions will be described more in detail in the next chapter.

To finalize the work on continuous improvement it was essential to start implementing the developed actions and to plan when this should happen. For this it was mainly important to document the whole progress and have defined steps how to reach the final goal and break this up into smaller actions and working fields.

1. IMPLEMENTING CONTINUOUS IMPROVEMENT MEASURES FOR RAW MATERIAL MANAGEMENT

To make the release process of raw materials leaner and smoother an improvement for the existing process was developed and tested for a period of eight weeks. After this testing phase first results were evaluated, and the decision was made if the process delivered the expected improvement. After this testing phase further measures were taken which either formed a corresponding supplement to the process or expanded it further. In the following sections these measures are divided into those which are already implemented or still ongoing and planned. This focuses mostly on the new developed process for the release of raw materials and additional improvement factors which were indicated while working with the new process. All relevant documents around the work for the new process is stored in the SharePoint of the working group (NPTC SINGEN[9]).

1.1. The new process for raw material release and measuring its efficiency

The processes for raw material management differ for trials, commercial production, and kitchen. In comparison to the old process for raw material release shown before in figure 8 the developed new processes for raw material management are now more efficient and the time till the batches are released is significant shorter, especially when it comes to analyzing for release.

Trials

In figure 14 it is displayed as a flowchart how the new process for raw materials used for trials is working. The main difference is that the project manager is no longer involved in the process after ordering the raw material. This new process functions as followed.

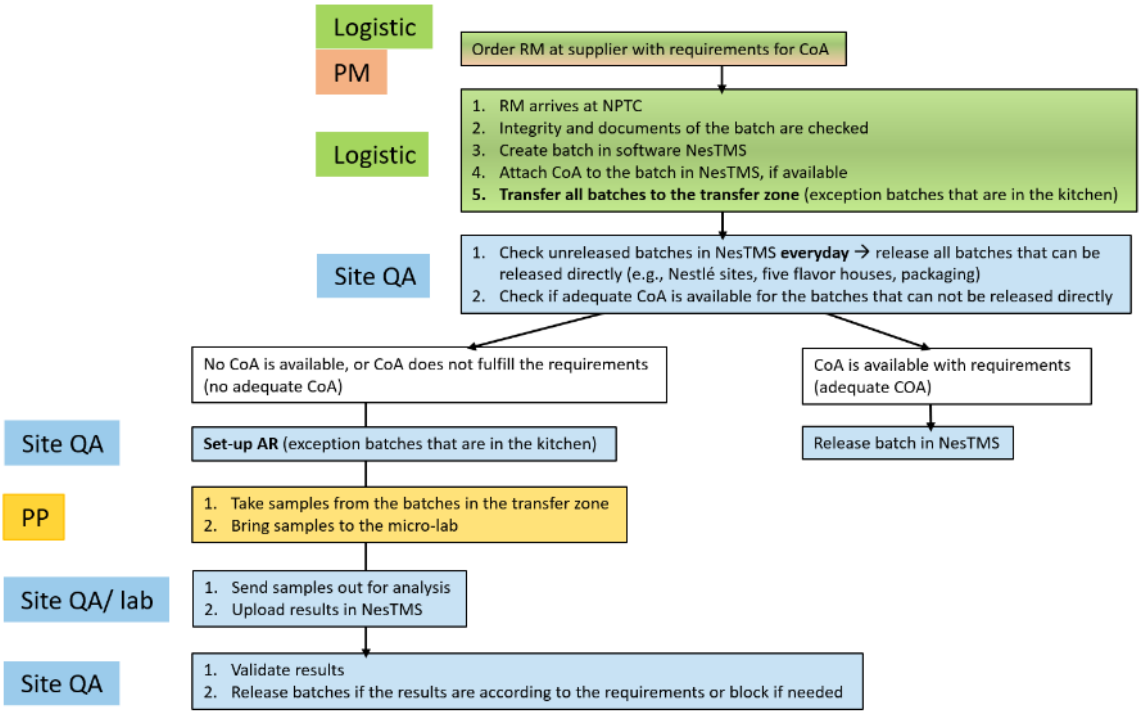

Figure 14 The new raw material management process for trials and kitchen (own depiction 2023)

It all starts by ordering the desired raw materials by the supplier, which is done either by the logistics or by the responsible project manager. If the material comes from a supplier a CoA would be needed. The CoA shall be then requested directly e.g., via the supplier letter or by the project managers. The supplier letter has also been revised in the context of the development of the new process and has been split up into two letters, one for trial and kitchen raw materials and one for commercial production raw materials. These contain all information what data the supplier should provide including the material name, lot number, expiry date, shelf life, material specification, CoA parameters and temperature if it is a chilled or frozen raw material. The letter for raw materials ordered for trials or kitchen is deposited in the appendix V. After the order was done and the material arrives at NPTC the logistics checks the integrity of the material and all concerning documents. If this is all conform the batch number can be created, and a CoA will be attached in NesTMS if one is available. Till this moment the process has not changed compared to the old version.

One of the biggest changes with the new process is the new storing areas in form of the transfer zones. These serve as transition zones before the batches are transferred to the actual warehouse. There are three new transfer zones. The transfer zone for ambient raw materials is in the basement next to the weighing area and the transfer zones for chilled and frozen raw materials are in the logistics in the cooling chambers. Pictures of the new introduced transfer zones are deposited in the appendix VII. All incoming batches will be kept in the transfer zones until they are released.

After the batches are created and stored in the transfer zones a responsible person from Site QA who does the raw material release checks all new incoming batches every day. Batches that can be released directly, as explained in the chapter “Representation of the previous state at NPTC Singen” under “1.3.1 Release criteria for raw materials”, and batches that provide an adequate CoA will be released within the same day. Another one of the main changes is, that if a batch cannot provide an adequate CoA the Site QA will now set up an analysis request, before this was done by the responsible project managers. After the analysis request has been created Site QA aligns with the pilot plant on taking the sample.

In order to discuss the release of raw materials and organize sampling, a communication platform for Site QA, logistics and pilot plant was created. Additionally, all concerning information on all incoming batches is stored in an excel sheet. This includes the release status and what kind of release criteria the batch has, as well as the number of days it took till the batch was released and other additional information e.g., the supplier and storage location. All this information has been extracted from NesTMS (NPTC SINGEN[8]). After the samples are taken and brought to the sample reception of the microbiological lab, they will be sent out by Site QA to an external lab for analysis and within a few days the results will be received. The results then need to be uploaded in NesTMS and validated by the Site QA. After the validation the release of the batches can be done, and they will be transferred from the transfer zones to the indicated storage locations.

Commercial Production

A little bit different to the new process that was developed for trials is the new process for raw material batches for commercial production, which is shown in figure 15.

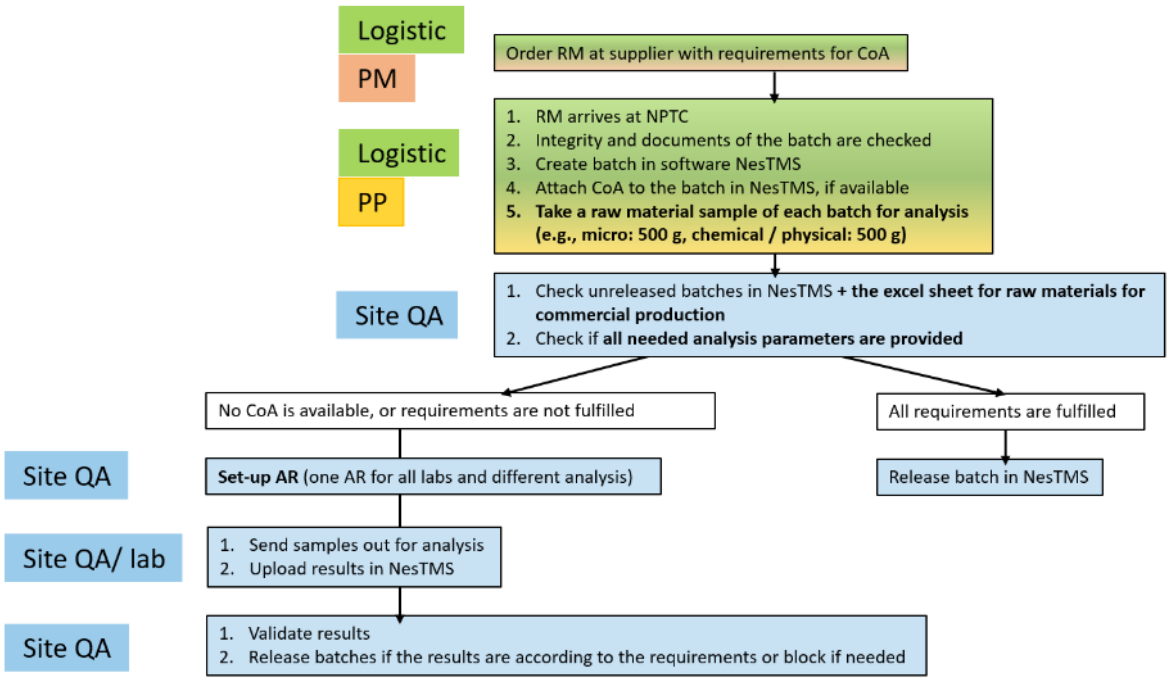

Figure 15 The new raw material management process for commercial production (own depiction 2023)

Most of the process is the same as for trials, it starts with the logistics or project managers by ordering the raw material. The supplier letter for raw materials ordered for commercial production is deposited in the appendix VI. After the raw materials arrive at NPTC the logistics checks all the concerning documents, creates a batch number in NesTMS and attaches a CoA if one is available. With the new version of NesTMS enhanced the labeling of batches for commercial production looks a little bit different than before. As an identifier a “CP” will now be put in front of the batch name and an additional blue identification mark will show up right above the batch name, as shown in figure 16.

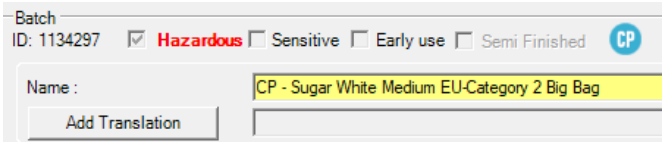

Figure 16 New identification of batches for commercial production (NesTMS enhanced 2023)

The new version of NesTMS enhanced will be introduced step by step with a new layout and additional functions. Furthermore, one of the two new main changes for commercial production is that from every batch a general sample will be taken for analysis. This will be each around 500 g for microbiological and chemical / physical lab analysis. The sample amount can differ depending what kind of analysis need to be done for the release, which is dependent on for example what kind of raw material it is and where it comes from.

The next step in the process is that Site QA checks for all unreleased batches for commercial production and they will check additionally the excel sheet for raw materials for commercial production.

If all the needed analysis parameters for release are provided and fulfilled the release can be done (NPTC SINGEN[5]). If not all the needed requirements are fulfilled the Site QA will set up one analysis request for all the needed analysis and different labs. This ensures that no analysis will be missed and the whole organization is controlled by Site QA, before there were multiple analysis requests for the same raw material. The earlier taken samples can be then used and split up for the different labs as needed. Afterwards the process is again identical to the developed process for trials and the samples will be send to the external lab and after receiving, uploading, and validating the results the batch can be released.

Kitchen

The new release process for raw materials that have been ordered for the kitchen is nearly the same as the new workflow for trials, as shown in figure 14. There are only two deviations where batches for the kitchen are managed differently.

The first one is that the batches will go directly to the kitchen from the raw material receipt without any temporary storing in one of the transfer zones. The second difference is that the Site QA will not set up an analysis request if the batch needs to be sampled for release. In this case the Site QA will contact the responsible person from the kitchen that the batch cannot be released, and they need to set up an analysis request and organize the sampling. Afterwards the process is again the same as for trials.

With the start of the new processes and to support them, additional measures were taken to have the improvement as efficient as possible. This included for example the discard of all old batches that were unreleased in the system of NesTMS and ordered in 2022 and earlier. For all batches that were ordered in 2023 and were still unreleased in the system the responsible project managers were instructed to organize the analysis for release, or the batches will be also discarded. Another action that was taken to make sure as few as possible parties have access to the raw materials was that most of the storage rooms have been locked and just a restricted number of people have the keys and therefore access to the rooms.

To identify the benefits of the new process and analyze the impact the quantity on how efficient it is was measured. For this a “picture of the moment” was documented by capturing the time till release for every single incoming batch during a six-month period. This data refers only to batches for trials and kitchens. Batches which have been ordered for commercial production are excluded here, since they require a significantly longer time for release, as the requirements are considerably more complex and, for example, chemical analyses must be carried out. The measuring of the new process was important to verify if with the new way of working the process was really optimized for a better. For this

the “time till release” was measured and this was done manually by counting the days till the status of the batch was changed to release in NesTMS. If a batch has been released on the same day it has been created, the time till release would count 1. For the counting of the days all the working days as well as the non-working days were considered. Together with the kind of release, e.g., if a batch had a direct release, provided an adequate CoA, or needs an analysis, various quantitative parameters are determined and used for the verification of the new process. The different options for this are deposited in the excel sheet for raw materials in the column “kind of release” and are explained in table 4.

Table 4 Classification of different kinds of release for raw materials used in trials

KIND OF RELEASE	MEANING OF THE TYPE OF RELEASE
DIRECT RELEASE	This includes all batches that can be released directly e.g., batches that come from Nestlé sites, 5 flavor houses, or are marked with a RD or CS. The different kinds of batches that can be released directly are further explained in the chapter ““Representation of the previous state at NPTC Singen” under “1.3.1 Release criteria for raw materials”.
PROVIDING AN ADEQUATE COA OR FGC	Batches that cannot be released directly are checked for an adequate CoA or Food Grade Certificate. If one is available and the release requirements are fulfilled, they will receive as kind of release “adequate CoA or FGC”.
USED FOR RM MONITORING	Some raw materials will be used for raw material monitoring. This could take longer for the release as more parameters need to be analyzed.
MISSING FOOD GRADE CERTIFICATE	If no Food Grade Certificate is available, the supplier needs to be contacted to get one.
SALMONELLA NEEDED (50 G)	An analysis for *Salmonella* needs to take place, when it is an ambient stable raw material, and no adequate CoA was provided.
LISTERIA AND SALMONELLA NEEDED (100 G)	An analysis for *Salmonella* and *Listeria monocytogenes* needs to take place, when it is a chilled or frozen raw material, and no adequate CoA was provided.
COA WITH SPECIAL PARAMETERS NEEDED (E.G., FFA)	If a raw material with unusual specific release criteria is given and the requirements are not fulfilled in the CoA. For example, oil batches where the values are over the limits or a CoA is missing, further investigations need to take place and there may be a delay of time.

For the quantitative determinations, only the batches for trials and kitchen over a period of 6 months were used. After approximately the first 2.5 months, the testing phase for the new process was started. Batches with an extreme deviation of the release time were not included for the calculations and analyzes. This could be for example a batch that was originally intended for commercial production but was not used and was therefore unreleased in the system for several weeks before it was downgraded for trials and released.

To measure the quantity of the new process and to have a more detailed understanding for it the total amount of batches that have been received during the time-period of 6 months was investigated. Within this period a total of 1181 batches have been created in NesTMS for trials and kitchen. Most of these batches, 967 of them, have been released directly by the before described release criteria. This means that 81,88 % of the batches ordered for trials and kitchen have had a direct release. In table 5 it is

shown how the different kinds of direct release can be split up due to their percentage in relation to the overall number of 1181 batches received which stands for a 100 %.

Table 5 Number of direct releases compared to all incoming batches

	NUMBER OF ALL INCOMING BATCHES	NUMBER OF DIRECT RELEASES			
		batches from Nestlé sites	RD batches that are not Nestlé	batches from the 5 flavor houses that are not RD material	other batches (e.g., packaging, CS material, vinegar etc.)
MONTH 1	226	128	29	28	11
MONTH 2	143	70	21	27	6
MONTH 3	108	63	7	11	4
MONTH 4	241	128	27	31	21
MONTH 5	199	95	26	18	15
MONTH 6	264	116	27	45	13
IN TOTAL	**1181**	**600**	**137**	**160**	**70**
%	**100,00**	**50,80**	**11,60**	**13,55**	**5,93**

1.1.1 Comparison of direct releases, batches with an adequate CoA, and batches that needed to be analyzed

To investigate the release process further it was important to compare the number of direct releases to the number of batches that provided an adequate CoA or needed to be analyzed. These results are displayed in table 6. Of the 1181 batches that arrived during the measuring period and serve as a reference 967 batches have been direct releases, 114 batches have provided an adequate CoA, and 78 batches needed to be analyzed before they could be released. This means that 81,88 % of the batches were released directly and 16,26 % were batches with adequate CoAs or were analyzed for microbiological parameters. The missing 1,86 % were batches with special release criteria as for example aseptically filled raw materials or chemical materials that were missing a food grade certificate. Additionally, a comparison of the numbers of batches that provided an adequate CoA and batches which needed to be analyzed was made. Both kinds of release were less than 10,0 % in total with the adequate CoAs at 9,65 % and needed analyses at 6,60 %.

Table 6 Number of direct releases compared to batches that provided an adequate CoA or needed to be analyzed

	DIRECT RELEASE	ADEQUATE COA OR FGC	ANALYSIS NEEDED	ADEQUATE COA AND ANALYSIS NEEDED TOGETHER
MONTH 1	196	18	9	27
MONTH 2	124	14	4	18
MONTH 3	85	14	7	21
MONTH 4	207	8	22	30
MONTH 5	154	22	14	36
MONTH 6	201	38	22	60
IN TOTAL	**967**	**114**	**78**	**192**
%	**81,88**	**9,65**	**6,60**	**16,26**

1.1.2 Has the average release time been reduced after introducing the new process?

For measuring the quantity of the release and to get a “picture of the moment” the average release times of every single batch have been documented. As a comparison there was a differentiation between batches that are released directly or provide adequate CoAs to batches that needed to be sampled and analyzed. To calculate the average release times the mean values of the corresponding groupings were calculated. This was carried out for the periods before the implementation of the new process happened and after the introduction of the new process, so that the results could be used to determine to what extent the new process has led to an improvement. These results are displayed in table 7. Before the new process was introduced the average release time for batches that have been released directly or provided an adequate CoA or food grade certificate was at 1,44 days and the average for batches that needed to be analyzed was at 22,11 days. After the new process has been introduced the time for direct releases and adequate documents was at 1,23 days and for analysis at 10,79 days.

Table 7 Groupings of the average release times in days for raw materials before and with the new process

	BEFORE THE NEW PROCESS		**WITH THE NEW PROCESS**	
	direct release and adequate CoA or FGC (days)	analyses in total (days)	direct release and adequate CoA or FGC (days)	analyses in total (days)
MONTH 1	1,81	17,08		
MONTH 2	1,41	28,50		
MONTH 3	1,09	20,75	1,54	14,67
MONTH 4			1,13	10,37
MONTH 5			1,06	10,33
MONTH 6			1,19	7,79
IN TOTAL	**1,44**	**22,11**	**1,23**	**10,79**

The grey fields are periods when measurements could not be performed because the process was in a different phase.

The batches that needed to be analyzed can be split up further into batches that were ordered for the kitchen or for trials, as shown in table 8. Especially after the new process has been introduced a massive deviation within this division can be detected. The analyses that were done for trials had an average release time of 22,47 days before and of 7,57 days after the new process has been introduced. Analyses that were done for the kitchen had an average release time of 18,38 days before and of 14,01 days after the new process has been introduced.

Table 8 Average release times in days for raw materials with analyses for trials and kitchen before and with the new process

	BEFORE THE NEW PROCESS		WITH THE NEW PROCESS	
	analyses for storage batches (days)	analyses for kitchen batches (days)	analyses for storage batches (days)	analyses for kitchen batches (days)
MONTH 1	25,40	8,75		
MONTH 2	28,50	none		
MONTH 3	13,50	28,00	7,00	22,33
MONTH 4			7,80	12,94
MONTH 5			8,90	11,75
MONTH 6			6,57	9,00
IN TOTAL	**22,47**	**18,38**	**7,57**	**14,01**

The grey fields are periods when measurements could not be performed because the process was in a different phase.

1.1.3 Has the number of trials that need to be rescheduled decreased after introducing the new process?

One factor that is inextricably linked to the release of raw materials is the performance of trials. Since only released raw materials may be used for trials, there is often a rescheduling of trials happening, if the raw materials are not available because they are not released. For this the extent to which the number of shifted trials changes with the new process due to the lack of raw materials is measured. The results for this are deposited in table 9. Again, it is divided between before the new process and with the new process. Before the new process was introduced there was a number of 101 trials planned and 20 of them, which means 19,80 %, have been rescheduled due to missing and unreleased raw materials. After the new process has been introduced the first two months have performed way better with 27 trials in total and only 2 of them needed to be rescheduled, which means only 7,41 % of the trials needed to be rescheduled. The other two months have their numbers grey deposited in the table, as these will not be considered for the process optimization assessment. The reason for this is that the values of the number for trial rescheduling is nearly 50 % and would therefore falsify the measurement. The numbers for these two months were extremely high because many raw materials were not delivered in time or damaged and therefore not registered in NesTMS. It was not because of the release process rather that the batches could not have been created.

Table 9 Numbers of trials that needed to be rescheduled before and with the new process

	BEFORE THE NEW PROCESS		WITH THE NEW PROCESS	
	total trial count	rescheduled trials due to missing RMs	total trial count	rescheduled trials due to missing RMs
MONTH 1	33,00	5,00		
MONTH 2	44,00	14,00		
MONTH 3	24,00	1,00	5,00	1,00
MONTH 4			22,00	1,00
MONTH 5			34,00	15,00
MONTH 6			48,00	22,00
IN TOTAL	**101,00**	**20,00**	**27,00**	**2,00**
%	**100,00**	**19,80**	**100,00**	**7,41**

The grey fields are periods when measurements could not be performed because the process was in a different phase.

1.2. Revising documents and trainings for the new process

In order to support the newly developed and revised process, further measures were implemented to optimize the overall picture after the testing phase was completed and the change was assessed as positive. First the supplier letter, which is send with every order to the supplier and contains all information about what is needed for the release and what should be listed in the CoA as criteria was revised. Another action that was done, was having a look on the internal “SharePoint” and checking whether all of the documents mentioned and deposited are up-to-date and accessible.

Due to the new process also, the SOP for raw material release had been revised, as the responsibilities have changed, and the transfer zones have been integrated in the process. After revising it the SOP was published and saved as an internal document that everyone is having access to (SCHWARZ, 2023).

With the revision of the new process a summary on the work done was presented in a meeting with all employees, to highlight the successful cross-functional work that was done. As the last step to implement the new process completely training sessions were held to educate the people involved in this process. For this all employees from quality management, project lead, project development, logistics, and weighing have been invited to participate and have been trained for half an hour. Additionally, the training sessions have been recorded and the recordings have been published together with the presentation slides for everybody.

1.3. Measures that are still ongoing or planned to be implemented

Not all the planned measures have been implemented yet and therefore some measures are still ongoing or have been made up as further improvement ideas connected to the new process. Some of these planned measures are listed and explained in the following subchapters.

1.3.1 Reconstruction measures for the material storage and logistics

To have the storage more organized and raw materials easier accessible a reconstruction for the storage is planned. The storing heights shall be adjusted to store more big palettes and to use the available room as efficient as possible. Before it was often the case, that many small amounts of materials have been ordered but nowadays bigger amounts of materials are ordered and therefore more space is needed for storing them. In addition, in the future it should be avoided that several materials are stored together in one storage bin. Therefore, all storage locations should be designed more generously and thus bring about a clearer arrangement. This is also intended to simplify access to the materials and to make it less difficult to extract a raw material from the storage. Additional storage space, e.g., in form of new shelfs, is also to be created, since the warehouse must be adapted to the now larger scale for trials.
Another action that will happen is the reconstruction planned for the logistics. As the logistics does not provide enough space for all the incoming raw materials it is planned to build an annex to the building or a completely new building for NPTC. This is a very complex project and the first steps have already been taken and the current planning is gradually being developed and for now planned for next year.

1.3.2 Improvement of NesTMS

Another improvement that will support an easier raw material management will be the updated version of NesTMS “NesTMS enhanced”. In addition to simpler and clearer handling, the new version is intended to add various functions. On the one hand, it should be possible to emphasize preferred suppliers in NesTMS, so that the selection of a corresponding supplier, which provides, for example, adequate CoAs, can take place directly. The required release criteria for the batch should also be able to be linked directly to NesTMS in the future. During the transfer of materials to the warehouse empty storage bins are to be displayed directly and a clearer differentiation between batches for trials and commercial production should take place, for example as shown in figure 16. And in the future, it will no longer be possible to store batches which are marked as commercial production to a storage location which is not intended for commercial production.

These are a few examples of the main innovations that will allow the new version of NesTMS to facilitate the raw materials management process and are already planned. Further optimizations by the new NesTMS will be gradually extended. The introduction of NesTMS enhanced is expected by the end of the year.

2. REVISION OF THE QMS DOCUMENT FOR COMMERCIAL PRODUCTION

Since the QMS document is an individual instrument for monitoring the quality during projects and, above all, commercial productions, no uniform standard for improvement could be determined. It was only possible to create suggestions for improvement based on the identified problems, as shown in the chapter “Working on continuous improvement” under “2. Problem areas and potential improvement for monitoring quality during commercial production”, which can be adopted for future projects. There are also new perspectives with the introduction of the new version of NesTMS, which will change the entire QMS work.

Every QMS works closely with the HACCP concept and starts by creating a QMS team. For this an overview is given in every created QMS document and there is no need for any changes. Continuing with the section for raw materials it starts where the document can get confusing and often there is no central thread that guides through the document. It happens that information appears multiple times as checkpoints with the same content and instruction or instruction types are already handled in other documents, e.g., visual checks of data for raw materials and packaging materials which is already handled in the raw material tracking list (NPTC SINGEN[5]) and are therefore not needed to be listed in the QMS document again. For this it would be helpful to have some kind of template of instruction types that need to be checked due to the sections like raw materials and that all the instructions will be listed in a structured way in the QMS document. The last section of the QMS document is the most complicate one as on the one hand very important quality aspects are there organized and on the other hand it is complicated to get a good overview over the different process stages and the associated inspection types. Here it is also often the case that checkpoints are listed twice or for example different raw materials e.g., vinegar or salt have their own checkpoints. Here it would be much more convenient to also have template for possible types and to only have one inspection for raw materials and a separate list with all the single checkpoints that need to be regarded for raw materials. It is the same with all the inspections that are listed under the process step for finished product and cite all different analysis that need to be done after producing. This is normally all listed in the corresponding analysis request and does not to be listed in detail again. It would be enough to have less checkpoints for analysis, e.g., microbiological, chemical / physical, and sensory.

A major change that would make a huge improvement for the QMS document would be a color-coding system in the document to separate the different inspections by vision and make it easy to identify

when which inspection needs to take place. A simple way to use such a system would be by color-coding them into different types of inspections:

- Inspections that take place **before** the process step
- Inspections that take place **during** the process step
- Inspections that take place **after** the process step

This way the involved people who need to work with the QMS document have it way easier to recognize what needs to be done and even if the list of instructions is long there is a clear differentiation which gives automatically a better overview over the document. This could be even more improved, as by expanding the document with time management instructions for even more efficiency.
One implementation of improvement for the quality during commercial production that already started is the usage of the new version of NesTMS “NesTMS enhanced”. With the old version of NesTMS no data on how trials are done is kept in the system. This can be really wiry when it comes to reproducing trials or productions and no information to this is documented in the system. But with first improvements it started that the QMS content gets step by step integrated into NesTMS enhanced and different parameters e.g., equipment are then deposited in the system. This would mean for the future that a excel sheet for the QMS will not be needed anymore or in a way smaller scale as most information will be linked directly to the trials and projects.

DISCUSSION AND CONCLUSION

In conclusion, this work has enabled that the desired optimization measures for continuous improvement were successfully implemented, and the practical part of this thesis can be therefore regarded as a success. For continuous improvement, it can be stated that this can be a long and often frustrating process. Especially when different departments are involved, it is difficult to find an appropriate solution that is equally effective for all parties involved, so that the changes will be adopted afterwards. Lean process improvement efforts can only be effective when every part of the organization is available and willing to change something. If not, organizations run the risk of having teams that by optimizing their own performance, sub-optimize the performance of another team, and therefore, the performance of the organization as a whole (LYNN). Especially in the NPTC many people work in a silo format, which means that people take care that their own work is running and often have no idea what the other departments do or how other work is influencing their own work and vice versa. Therefore, a process improvement is only possible when everyone is pulling together and the people are ready to compromise if necessary or open for changes. Another important aspect is that all involved parties should be at about the same level of knowledge, so that process development can be as effective as possible, and everyone knows the latest developments.
When it comes to continuous improvement it is also important to aware that this will need lots of resources, e.g., time and costs. Therefore, a sponsor is needed to offer all these resources. It must be clearly defined what is set as a goal and that this is important enough to raise the resources and to attach a certain importance to the whole process.
For continuous improvement in total in can be concluded that when everyone follows a well-tested set of steps, there are fewer errors and delays, there is less duplicated effort, and the work is done in the most effective way, reducing the need for corrective actions. Small setbacks within the process are completely normal. However, from a long-term perspective, these will not be significant and in the end what counts is that the quantitative evidence shows a significant improvement in the general situation.

For the new raw material management process, that was developed as a result for continuous improvement it can be concluded that the optimization was efficient, and that the way of working is now leaner than before. Which means that the productivity and efficiency has improved, the raw material release is faster and more structured, and that less trials need to be rescheduled. All the planned actions as explained in the chapter “Working on continuous improvement” under “1. Problem areas and potential improvement for raw material management” were implemented or are already planned to be implemented. In the following figures a few examples will be shown how this process was an improvement and how much of an impact did these improvements have. This only applies to the batches ordered for trials and kitchen. The batches for commercial production are excluded from this.

The biggest improvement by now has been the release procedure. Especially when it comes to batches that need to be analyzed for release a huge reduction of the time till release was detected. To have an overview what kind of releases are most common and how huge the amount is of batches that needed to be analyzed or provided an adequate CoA the percentages of these categories are displayed in figure 17. Most important to know is that more than 80 % of the incoming batches are direct releases as raw materials that come from Nestlé sites or one of the five flavor houses. A much smaller share own the batches that come from external suppliers and either need to provide an adequate CoA or need to be analyzed. These have a total proportion of 16,26 %, with the greater proportion (9,65 %) of batches having an adequate CoA and batches requiring analysis making up the lower proportion (6,60 %). The remaining 1,86 % are other batches that have an exceptional release for example an oil that has a CoA with parameters above the limits and will be therefore only used for technical trials.

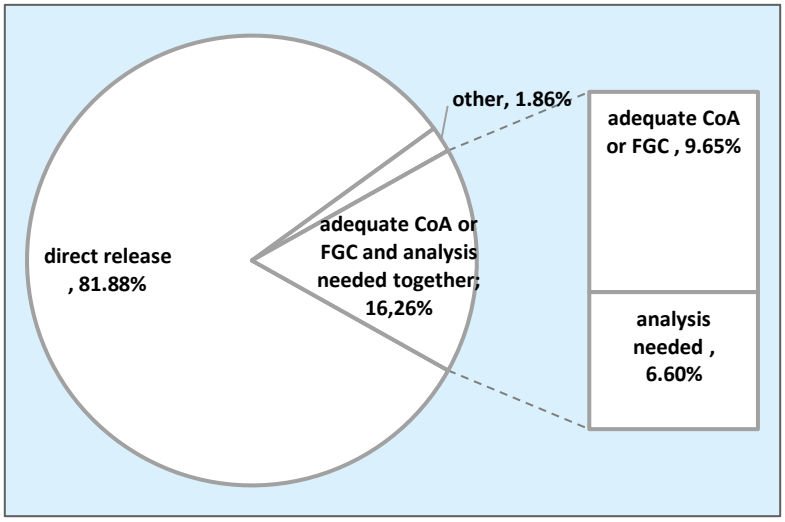

Figure 17 Percentages of the different release criteria for all incoming batches (own depiction 2023)

Figure 18 shows in detail how the average release times have changed comparing the phases before the new process and with the new process. This shows clearly that a significant improvement has occurred with the introduction of the new process.

This can be further examined using the bar chart and table 10 together. The largest improvement of 66,31 % is particularly clear detectable for analyses for storage batches. For the kitchen, the analysis improvement rate is at 23,78 %, resulting in an overall analysis improvement rate of 51,20 %. The improvement for direct release and adequate documents is less significant with only an improvement from 1,44 days to 1,23 days. Which makes

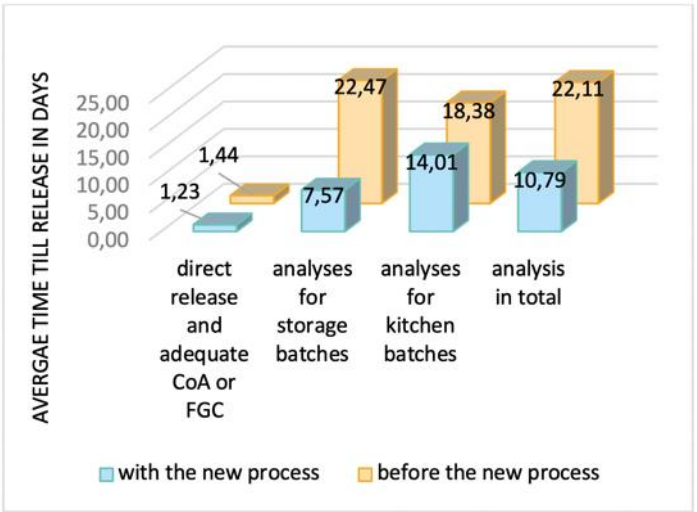

Figure 18 Average release time of different release criteria before and with the new process (own depiction 2023)

indeed 14,58 % but is still between one and two days for the average release time and makes therefore no difference in practice.

Table 10 Improvement by the new process as percentages for different kinds of release

	DIRECT RELEASE AND ADEQUATE COA OR FGC	ANALYSES FOR STORAGE BATCHES	ANALYSES FOR KITCHEN BATCHES	ANALYSIS IN TOTAL
IMPROVEMENT BY THE NEW PROCESS	14,58 %	66,31 %	23,78 %	51,20 %

Another aspect that should be discussed is the clear difference in the average time for release by analysis between the warehouse and the kitchen, as shown in figure 19. While a significantly greater improvement could be achieved in the storage area, for the kitchen this was significantly less. However, this is not surprising, as the focus of the new process has always been on trials and commercial production. Batches that were ordered for the kitchen had almost no impact on the development of the new process and therefore the rate of change for this area was less pronounced. To improve this in a further manner in the future the kitchen needs to be instructed to set up the analysis requests and take the samples right away. At the moment it is the case, that after instructing them to take a sample often a few days go by before the sample will be taken, which results in a longer release time in NesTMS. As the process for analyzing is afterwards the same and the samples go together to the same external lab, the average release time for kitchen analyses could improve more further.

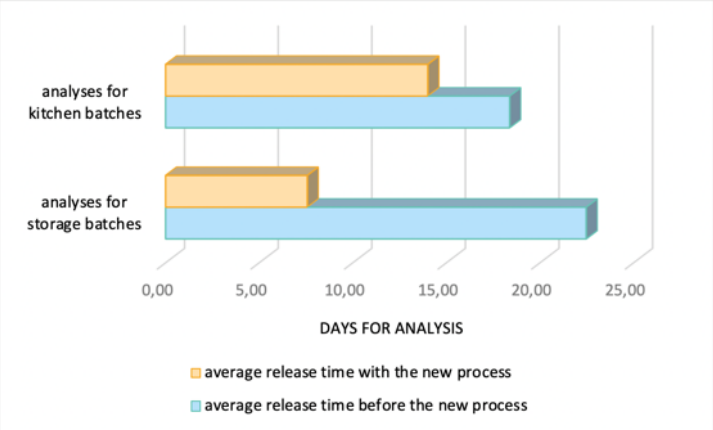

Figure 19 Comparison of the average release time of analyses for trials and for kitchen before and with the new process (own depiction 2023)

During the last quantitative measurement to determine the efficiency of the new process, the number of rescheduled trials due to missing raw materials was determined. For this the number of total trials to the number of rescheduled trials was discussed. As a result, it is visible in figure 20 that the number of rescheduled trials has not decreased significantly. But one thing that is visible is that the total trial count was way less after the new process has been introduced. This is typically normal as there are phases more trials are happening and then some where not so many trials are scheduled. Since the difference between the two measurement phases is not insignificant and there is a very large discrepancy, no correct statement can be made about the extent to which the new process has an influence on this aspect. Further observation would be necessary for this, but even then, there is a possibility that the values are still not meaningful, as it is not just the release of the raw material that can lead to a delay, but also delivery discrepancies or something similar.

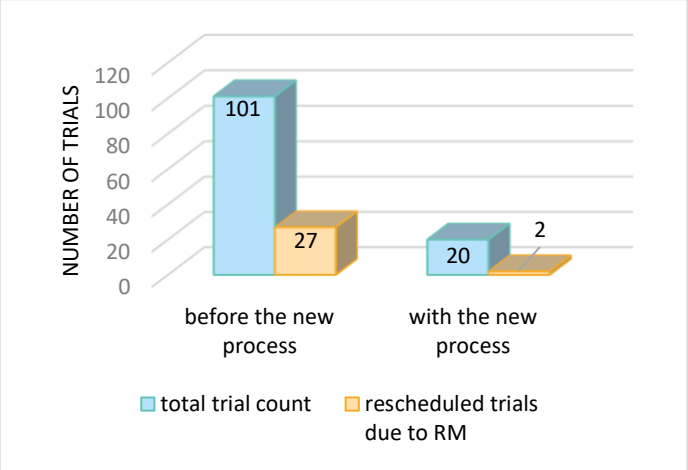

Figure 20 Total trial count and rescheduled trial count due to raw material release before and with the new process (own depiction 2023)

As the focus is on continuous improvement and the optimization for this process is not finished, there will be always room for improvement. Throughout the process everything that was still not working smoothly was documented, so that for the future it can be worked on these issues. Some of these further identified possibilities for future improvements have are already in progress. An identified improvement that would have a very significant impact on the quantity of release time would be to have less analysis in the future and more batches that deliver an adequate CoA directly. This would be particularly useful in the case of suppliers, which are frequently used and which supply a large amount of raw materials and was already started with suppliers that delivered multiple orders without any CoAs. In figure 21 it is shown in form of a flowchart what this improvement would benefit additional to the reduced release time of raw materials such as time savings by eliminating sampling, AR creations and result administration in NesTMS.

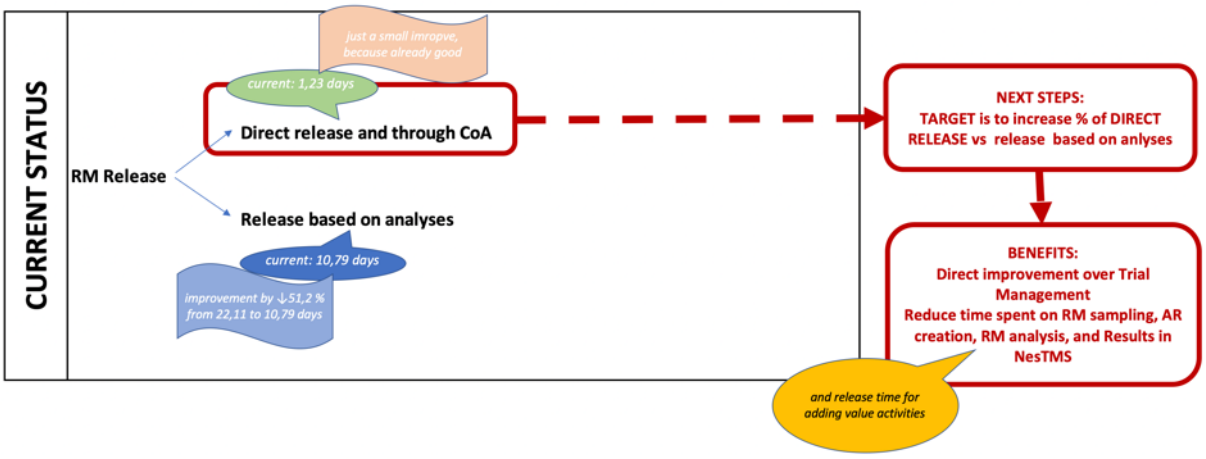

Figure 21 Future proposal to reduce the release time even further and to have time savings (own depiction 2023)

In addition to this conspicuity, another point is the analyzes in the kitchen. Here a clear difference can be seen based on the release times and can be further optimized as discussed before and shown in figure 19. Together with the planned construction measures and other smaller planned actions a further development and improvement of the process is within reach.
Overall for the new process for the management of raw materials in house it can be concluded that it has been a success and there is enough evidence to proof that the process is now way leaner and working more smoothly than before. With further planned actions and working on it continuously it will be even a greater success in the future.

When processing the QMS document, it should be noted above all that the document is merely a kind of checklist that guarantees quality monitoring. This changes depending on what kind of project or production it is, so a complete standardization of the document is not possible, as it always has to be individually adapted. However, it would be conceivable to create different templates for different product categories in order to ensure the same basic structure for future projects.
Another optimization potential is to provide the document with a color-coding system, which makes it much clearer and easier to handle. In previous versions it was often the case that points were duplicated or a clearly visible sequence of checkpoints was not entirely apparent. In addition, there are many other supplementary documents for QMS and points are therefore already included in detail there.
All involved parties working with the QMS document should also receive training on how the work can be implemented as efficiently as possible. So that in the future, duplication or, for example, the missing of signatures of the responsible persons will be minimized and working hours will be used better.

The greatest potential for optimization and improvement lies in the new NesTMS version “NesTMS enhanced”. This offers the opportunity to almost completely digitalize all QMS processes and would bring various advantages such as automation of processes, simplified processing, clearer presentation and many more. Many improvements for this are already in progress and will be gradually integrated into the system in the future. Making the handling of QMS also a case of continuous improvement, as everything is always changing a little and new potential for improvement always arises.
Finally, it should be noted that the idea of the QMS document is definitely correct and essential, especially for commercial productions. There is nothing wrong with time-consuming document management, as long as the results are correspondingly effective. Therefore, further digitization of the document and the associated work steps is definitely necessary. This would make the work much more effective and easier for everyone involved.

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APPENDIX

Appendix I: Pictures of the first process mapping for the release of raw materials
CI Raw Material release NPTC Singen • Official (mural.co)

Appendix II: F-QA-004 Checklist for RA of New RM + Creation Form
N:\Document Management System\by Department\QM - Quality Management\F

Appendix III: F-PP-037 GLOBE Material Order Form
N:\Document Management System\by Department\PP - Pilot Plant\Forms\Forms PP

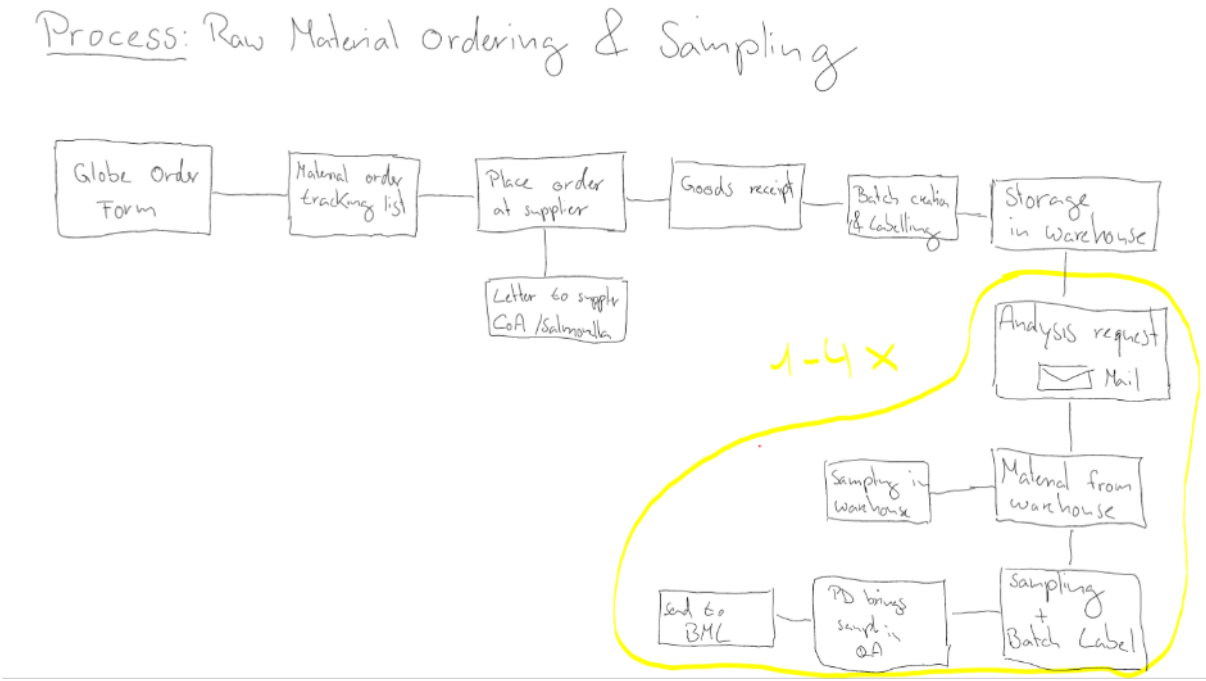
Appendix IV: Examples of a QMS document

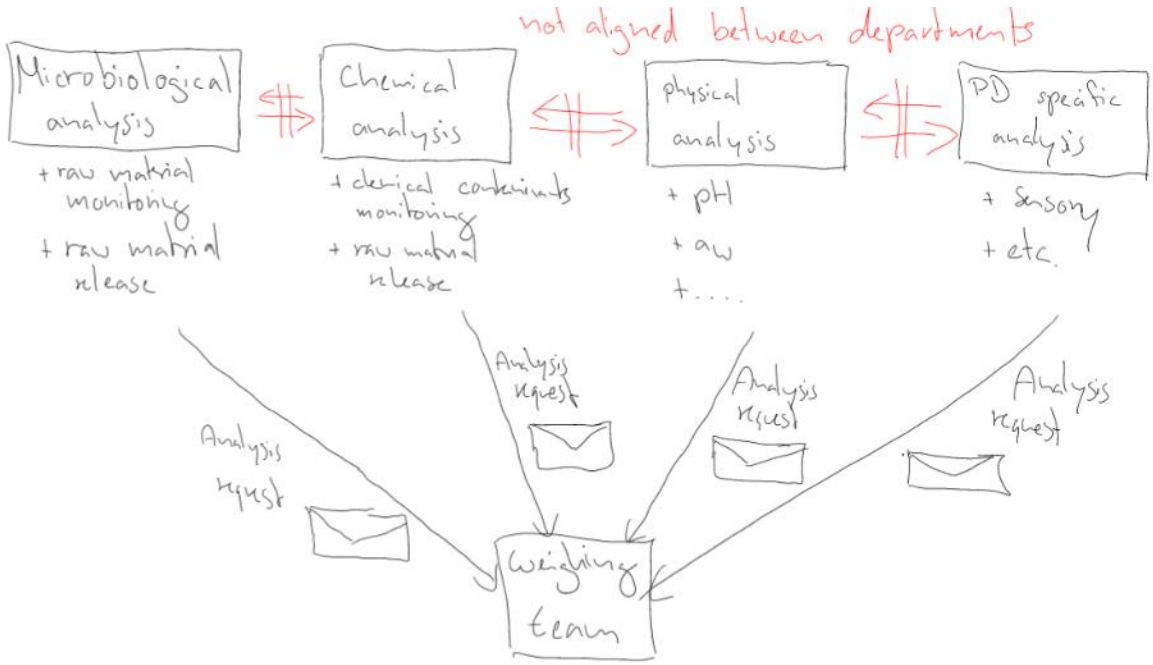
Appendix V: Supplier Letter for Raw Materials ordered for Trials and Kitchen

Appendix VI: Supplier Letter for Raw Materials ordered for Commercial Production

Appendix VII: Pictures of the transfer zones for ambient stable, chilled, and frozen raw materials

Appendix I





Appendix II

Checklist for RA of New RM + Creation form

Distribution list: all PMs, all QM, Logistics, all DK, all PP, all S &T department

Project Manager:	
Date of Request:	

Section Ia Material denotation (for extension)

Material Name	
Material Number	

Section Ib Material classification (please mark with a cross)

RD Material (samples, Mass from factory Trials)	creation			extension	
RD as SDR Material (Material are be use in Trials)	creation				
CS as SDR Material (CS Comercial sample)	creation				
SDR Material	creation			extension	
MDR Material				extension	
contains component of animal origin (K1) ?	Yes*			No	
Name of the country					
Non-EU / EU country	Non-EU			EU	
Handling of K1 Raw material/ samples underlie strict regulations!	* Please see SOP- RDSIR-004				

Section Ic - Creation of new SDR/ RD material (not required in case of SDR or MDR extension)

Material Name Proposal					
Form (e.g. Powder, liquid,...)					
Material State (e.g. Frozen, IQF, Dried, Canned, Fresh,...)					
Globe Material Group (choose from dropdown)					
Supplier (name, site, plant, country)					
Supplier Material Description					
Supplier contact (name, e-mail, phone)					
Is the Material a Hazardous Substance?	Yes		If yes, please contact Hazardous Materials Officer	No	
contains unwanted ingredients	Yes		Link: N:\NewTMS\NewTMS Documentation --> Unwanted Ingredients	No	
Comments					

Please continue and fill out the next page

Document number: F-QA-004
Checklist for RA of New RM + Creation form

Valid from: 05.04.2023 Version: 19 (01.08.2008) Issued/Revised by: Iris Schultheiss Page(1/2)

Checklist for RA of New RM + Creation form

Section II - Food Safety (to be filled by PM) (just required for SDR materials)

1. Supplier (name, site, plant, country):		
	Yes	No
2. Is the supplier specification with microbiological and chemical parameters available ?		
3. Is the supplier site approved by Nestlé ?		
4. Is the RM intended to be used for tastings ?		
5. Is the RM new to Nestlé?		

If questions 2 or 3 are answered with "NO", the compliance to Nestlé raw material specifications has to be approved by microbial analysis (St-51.007 or St-51.054). If both questions 4 and 5 are answered with "YES" and the RM is NOT a flavor from 5 key flavor houses, PM send chemical specialist supplier specification with chemical contaminants monitoring plan. The chemical specialist evaluates the risk for contaminants and adulteration.

Section IIIa Release Criteria - (to be filled by PM) In case of uncertainty, please discuss with Chemical Speciali

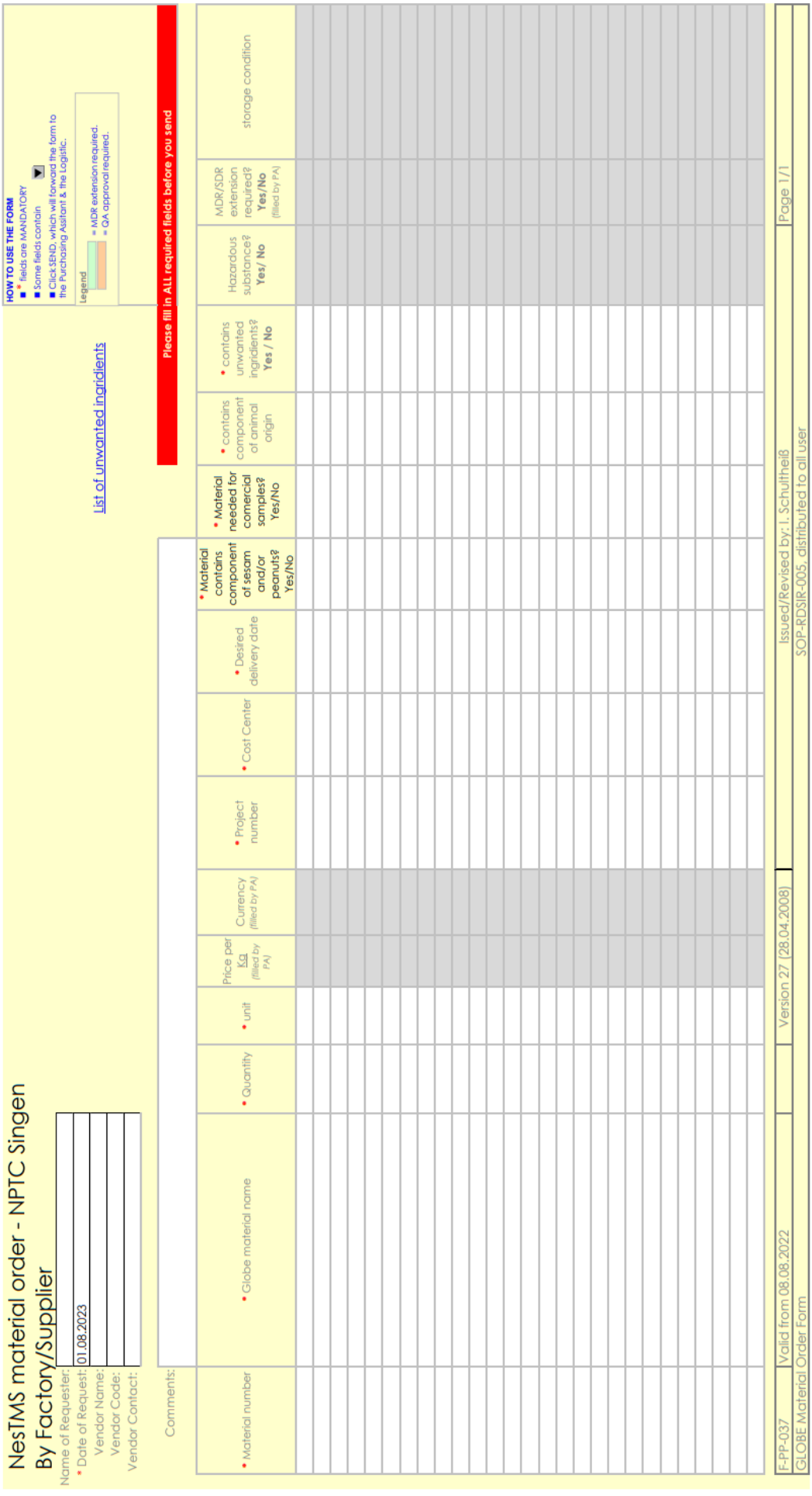
	Yes	No
6. Is the material a chemical?		
7. If yes, is it in "Food Chemical Code"? Please note: if the answer is "No", the material cannot be used!		

Section IIIb Release Criteria - In case **no** general risk assessment* is available, please contact Microbiologist to fill out

	Yes	No
8. Absence of Salmonella in 25 g have to be approved (by CoA or analysis)?		
9. Additional microbiological parameters if needed:		
10. Chemical and physical parameter if needed:		

Requestor: **QM Contact (only if needed):**
Date:

Appendix III



Appendix IV

PTC Singen | QMS documentation | Distribution: PM, QM, PP,

Quality Monitoring Scheme (QMS)
(Project - MFOO-101196 STARFISH)

QMS Team

Name	Unit	Department	Function
Edgar Kroner	NPTC Singen	Project Management	Project Manager
Jantra Daolert	NPTC Singen	QM	Quality by Design QS
Veronique le Boulicaut	NPTC Singen	QM	Site Quality
Gajanan Talwar	NPTC Singen	Packaging Department	Packaging Specialist
Pierre-Dimitri Taymans	NPTC Singen	Product Technology & Development	Product Developper
Edgar Mark	NPTC Singen	Production	PP Supervisor
Yifan Zhang	NPTC Singen	QM	Microbiologist

Reviewed By

Name	Unit	Function	Final Review Date
Veronique Le Boulicaut	NPTC Singen	QM Site Quality	11.01.23
Stefan Lißner	NPTC Singen	Site Operation Manager	11.01.23

Approved By

Name	Unit	Department	Final Approval Date
Karen Barman	NPTC Singen	Quality Manager	11.01.23

Document number: 03.2022 | Valid from: 11.01.2023 Version: 1 (11.01.2023) | Issued/Revised by: VLB

NMS Nestlé Management System for Quality & SHE

Quality Monitoring Scheme (QMS) (Project - MFOO-101196 STARFISH)

Inspection stage (type)	Inspection point	Inspected by	Inspection characteristic	CCP/OPRP/ CP/M1/M2	Sampling Frequency	Inspection Method	Specification / Evaluation	Corrective Actions
Trial number: ---------- **Date:**----------							**Pilot plant supervisor:** **Name**---------- **Signature**----------	
Raw Materials and Packaging								
Raw materials	Reception and Storage of Raw Materials	Site QA	Micro testing results or CoA	CP	Each batch	Visual check of CoA or analysis record in NesTMS	Release batch if testing results or CoA meets release criteria	Blcok the batch PM to follow up with Site QA for further actions
Packaging Materials	Reception and Storage of Packaging Materials	Site QA	CoC/DoC	CP	Each batch	Visual check of CoC/DoC	Release batch if CoC/DoC meets release criteria	Blcok the batch PM to follow up with Site QA for further actions
Label Artwork (PM3a)	Reception and Storage of Packaging Materials	Project Manager	Allergen declaration on the label	**OPRP-A-Label Reception**	Each incoming batch 5 samples per SKU	Visual check	Allergen declaration is according to the approved artwork	Block the batch Complain to the vendor and request RCA PM to follow up with Site QA for further actions
Primary Packaging (PM1)	Glass jars	Operator	Presence of foreign bodies and glass jars integrity	**OPRP-P-Glass**	Each jar before filling	Visual check of every glass jar, Rim of the glass & turning of the glass up side down	Absence of sharp and hard foreign bodies above 2mm. Glass Jars are not damaged; Rim is not damaged.	Damages and foreign bodies identified before filling. Block, notify Site Quality and PP coordinator, record here, initiate discussion with PP coordinator
Primary Packaging (PM1)	Glass jars	Site QA	Packaging Tare weight	CP	At reception	30 Glass jars are weighed per pallet. Weights are documented on net content release form	Calculate lot Tare average according to the form	Block non-compliant product (above 10% variation). Notify PP coordinator.

PTC Singen

Check results
-
NesTMS
NesTMS
Check results Ok ---------- Not ok ---------- PM Signature----------
Check results Ok ---------- Not ok ----------
Check results Ok ---------- Not ok ----------

Document number: 03.2022

NMS
Nestlé Management System for Quality & SHE

Quality Monitoring Scheme (QMS)
(Project - PANACEA - MFOO-101252)

Trial number: ----------

Date:----------

Pilot plant supervisor:

Name----------

Signature----------

Inspection stage (type)	Inspection point	Inspected by	Inspection characteristic	CCP/OPRP/ CP/M1/M2	Sampling Frequency	Inspection Method	Specification / Evaluation	Corrective Actions	Check results
Raw Materials Weighting									
Weighing tools	Tools condition	Operator	Dedicated tools, integrity and cleaning of tools	CP	Before and after production	Visual check	New or dedicated tools are used Checked for damages before and after weighing No visible product residues before use	Do not start weighing Replace the tools Damages and product residues identified before weighing: Initiate repair or replace, repeat cleaning	Check results Ok —— Not ok —— Operator sign ——
Raw materials	Visual check during weighing & dosing	Operator	Number of ingredients and quantities	CP	Each batch	Comparison of physical stock with picking list	The quantities as per recipe/picking list	Stop production Fix recipe deviations Notify PP supervisor	Check results Weighing of raw materials Ok —— Not ok —— Operator sign ——
Raw materials M9 Vegetables - Pastes M4 – Deshydrated vegetables M12 – Sugar M13 – Herbs & Spices M15 – Powder flavour	Visual check during weighing	Operator	Presence of foreign bodies	OPRP-PrVisual inspection	During Manual weighing & dosing	Visual check	Absence of sharp and hard foreign bodies	Block the batch Investigate the findings and root-cause analysis Notify the PP supervisor	Check results on Tab : Weighing of raw materials Ok —— Not ok —— Operator sign ——
M11 - Salt	Sieving	Operator	Presence of foreign bodies and sieve integrity	OPRP-PrSieving	Before and after the sieving	Visual check	No foreign bodies on the sieve Sieve size < 2 mm, properly fitted and not damaged	Stop production/block the batch Investigate the findings and root-cause analysis Notify the PP supervisor	Check results Sieve Size— Ok —— Not ok —— Operator sign ——
Raw materials (Others)	Visual check during weighing	Operator	Presence of foreign bodies	CP	During Manual weighing & dosing	Visual check	Absence of sharp and hard foreign bodies	Block the batch Investigate the findings and root-cause analysis Notify the PP supervisor	Check results Weighing of raw materials Ok —— Not ok —— Operator sign ——
Raw materials (All)	Manual weighing	Operator	Ingredient quantities in mix	CP	Each batch	Visual check on picking list	The quantities as per recipe/picking list	Do not continue the work until recipe/deviations are fixed Notify PP supervisor	Check results on Picking list Ok —— Not ok —— Operator sign ——
Raw materials M10 - Vinegar	Manual dosing	Operator	Ingredient added to the mass	OPRP-M-Dosing	Each batch	Visual check on picking list	Ingredient added to the mass	Do not continue the work until recipe/deviations are fixed Notify PP supervisor	Check results Weighing of raw materials Ok —— Not ok —— Operator sign ——
Raw materials (All the rest)	Manual dosing	Operator	Ingredient added to the mass	CP	Each batch	Visual check on picking list	Ingredient added to the mass	Do not continue the work until recipe/deviations are fixed Notify PP supervisor	Check results Weighing of raw materials Ok —— Not ok —— Operator sign ——

Appendix V

Nestlé Product Technology Centre
Lebensmittelforschung GmbH
Singen

Nestlé PTC Singen - Lange Strasse 21 - D-78224 SINGEN

Nestlé Product Technology Centre
Lebensmittelforschung GmbH
Singen

Address:
Lange Strasse 21
D-78224 Singen/Hohentwiel

Postal Address:
Postfach 671
D-78221 Singen

Phone:
Fax:

Bank:

IBAN:
BIC:

USt-ID-No:
Steuer-Nr.:

OPEN LETTER TO THE SUPPLIERS OF RAW & PACKAGING MATERIAL

YOUR REFERENCE	OUR REFERENCE	DIRECT PHONE 07731 14-	DIRECT FAX 07731 14-	DATE
	SL			01.05.2023

Dear Suppliers,

In March 2023 NPTC SINGEN was certified against ISO 22000 standard on Food Safety Management.

Based on the above standards and requirements, the following information is requested for every delivery of raw and packaging material (batch wise) to NPTC Singen:

1. **Material name, Lot number and expiry date - for ambient and frozen materials our shelf-life requirement is minimum 3 months!**

2. **The delivered batch must meet the requirements of the agreed specification. The specification is either attached to the order or is mentioned as a reference.**

3. **Certificate of Analysis (CoA) is only needed for raw materials. The CoA must include:**
   - Sales description (Verkehrsbezeichnung)
   - Name and address of the analytical lab, which performed the analyses.
   - Accreditation status of the lab (ISO 17025 accreditation or equivalent system, e.g. TGA (Therapeutic Goods Administration); the method applied must be part of accreditation scope (e.g. for *Salmonella, Listeria monocytogenes*).
   - For **ambient stable raw materials Absence of *Salmonella* in 25g** must be analysed.

- For **chilled and frozen raw materials additionally** to the analysis of Salmonella **Absence of *Listeria monocytognes* in 25g** must be analysed.

4. If not mentioned in the specification, we ask you to inform us that the material conforms to **EU/German legislation.**

In the absence of the above requested information, the material might be rejected.

For chilled and frozen products, the temperature of incoming goods will be measured for every delivery and we apply the following rules:

Chilled products:
Generally: **Target temperature is 4 – 6°C**
Deliveries will be rejected with temperatures > 8°C

Edible offal fresh: **Target temperature is 3°C**
Deliveries with temperature above will be rejected

Other meat fresh: **Target temperature is 4°C**
Deliveries with temperature above will be rejected

Frozen products:
Generally **Target temperature is -20°C**
Deliveries will be rejected with temperatures > -18°C

Thank you for your attention and collaboration allowing us to keep and improve the safety and quality standards of our products.

In case of questions, please do not hesitate to contact Stefan Lissner
[redacted]

Nestlé Product Technology Centre
Lebensmittelforschung GmbH
[redacted]
Stefan Lißner
Site Operations Manager

Appendix VI

Nestlé Product Technology Centre
Lebensmittelforschung GmbH
Singen

Nestlé PTC Singen - Lange Strasse 21 - D-78224 SINGEN

OPEN LETTER TO THE SUPPLIERS OF RAW & PACKAGING MATERIAL

Nestlé Product Technology Centre
Lebensmittelforschung GmbH
Singen

Address:
Lange Strasse 21
D-78224 Singen/Hohentwiel

Postal Address:
Postfach 671
D-78221 Singen

Phone:
Fax:

Bank:

IBAN:
BIC:

USt-ID-No:
Steuer-No:

YOUR REFERENCE	OUR REFERENCE	DIRECT PHONE 07731 14-	DIRECT FAX 07731 14-	DATE
	SL			01.05.2023

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3. **Certificate of Analysis (CoA) is only needed for raw materials. The CoA must include:**
   - Sales description (Verkehrsbezeichnung)
   - Name and address of the analytical lab, which performed the analyses.
   - Accreditation status of the lab (ISO 17025 accreditation or equivalent system, e.g. TGA (Therapeutic Goods Administration); the method applied must be part of accreditation scope (e.g. for *Salmonella, Listeria monocytogenes*).

- For **ambient stable raw materials Absence of *Salmonella* in 10 samples (each 25g)** must be analysed (pooling is possible within the same batch, if analytical pooling validation was performed).
- For **chilled and frozen raw materials additionally** to the analysis of Salmonella **Absence of *Listeria monocytognes* in 5 samples (each 25g)** must be analysed (pooling is possible within the same batch, if analytical pooling validation was performed).

4. If not mentioned in the specification, we ask you to inform us that the material conforms to **EU/German legislation.**

In the absence of the above requested information, the material might be rejected.

For chilled and frozen products, the temperature of incoming goods will be measured for every delivery and we apply the following rules:

Chilled products:

Generally:	**Target temperature is 4 – 6°C** Deliveries will be rejected with temperatures > 8°C
Edible offal fresh:	**Target temperature is 3°C** Deliveries with temperature above will be rejected
Other meat fresh:	**Target temperature is 4°C** Deliveries with temperature above will be rejected

Frozen products:

Generally	**Target temperature is -20°C** Deliveries will be rejected with temperatures > -18°C

Thank you for your attention and collaboration allowing us to keep and improve the safety and quality standards of our products.

In case of questions, please do not hesitate to contact Stefan Lissner [redacted]

Nestlé Product Technology Centre
Lebensmittelforschung GmbH
[redacted]
Stefan Lißner /
Site Operations Manager

Appendix VII

transfer zone for ambient stable raw materials for trials

transfer zone for chilled raw materials for trials

transfer zone for frozen raw materials for trials

STATUTORY DECLARATION

“I certify that I wrote this work independently without any help from others and that I only used the resources specified. Passages taken literally or figuratively from other works are identified by citing the source.”

Francesca Schwarz

„Ich versichere, dass ich die vorliegende Arbeit ohne fremde Hilfe selbständig verfasst und nur die angegebenen Hilfsmittel benutzt habe. Wörtlich oder dem Sinn nach aus anderen Werken entnommene Stellen sind unter Angabe der Quelle kenntlich gemacht.“

Francesca Schwarz