PEOPLE'S DEMOCRATIC REBUPLIC OF ALGERIA

MINISTRY OF HIGHER EDUCATION AND SCIENTIFIC RESEARCH

The Higher School of Commerce

Thesis Submitted in Fulfilment of the Requirement for the Degree of LMD Doctorate in Management Sciences

Management of Organisations

Concretisation of the Preventive Management of Risks theory in multiple cases studies in the Algerian context

Elaborated by:

Miss. MAAMIR Safa

Board of Examiners

MERHOUN Malek	Professor-HSC	Chairman
DERGHOUM Mahfoud	Professor-HSC	Supervisor
HAMMOUTENE Ali	Professor-HSC	Examiner
ZEROUTI Messaoud	Professor-HNSM	Examiner
TOUMI AMARA Djamila	Associate professor **A**- HNSM	Examiner
BOUKERCH Yahia	Associate professor **A**- HSC	Examiner

Academic year: 2023/2024

Dedications

To my father "May God have mercy on him" & my beloved mother

I dedicate my thesis

Acknowledgements

My deepest gratitude goes to my supervisor ***Pr. DERGHOUM Mahfoud*** for placing his trust and confidence in my abilities to complete this thesis. It has been an honor to have him as my supervisor.

My appreciation extends to my father (May God have mercy on him) who was the best father ever, his absence is felt at this moment of achievement. My mother also deserves my gratefulness for her encouragement and her presence in my life and her sincere love.

I would like to thank ***Pr. Tari Mohamed larbi*** for his support and PhD ***Redda khadidja*** for her precious piece of advice and orientations.

I am indebted to all my sisters and brothers for their encouragement and support.

I would like to thank the members of the jury **, Pr. MERHOUN Malek, Pr.DERGHOUM Mahfoud, Pr.HAMMOUTENE Ali, Pr. ZEROUTI Messaoud, Dr.TOUMI AMARA Djamila, Dr. BOUKERCH Yahia**

My due acknowledgement are also to all the teachers at the Higher School of Commerce, particularly, **Pr. ADMANE Merizek, Pr. LAHRACHE Tahar, Pr. BELAIDI Abdelaziz, Dr. MAABOUT Zakaria.**

I would like to express my thanks to all the staff members of The Higher National School of Management, HNSM, where I completed my master's degree. Thank you for offering me the appropriate atmosphere for learning.

I would also like to think my former lecturers at The Higher National School of Management,

Pr.TOUMI	***Pr.MESSAID***	***Pr.FERROUKHI***	***Pr.MEZHOUDA***	***Pr.AZZOUZ***
Dr.YAHIAOUI	***Dr.SLIMANI***	***Dr.MEHDEB***	***Pr.CHOHRA***	***Dr.MENSOUR***
Pr. ZEROUTI	***Dr.BOUCHETARA***	***Dr.AMOKRANE***	***Dr.BENDAOUD***	***Dr.MADAGH***
Dr.ABID	***Dr.LAOURARI***	***Dr.OUSSEDIK***		

Very special words go to my best friends that I consider sisters : ***Asma , Sara Aouetta, Hadjar , Hind , Sarah and Fatma Zohra*** , thank you for being there for me .

I would like to thank the staff members of Higher School of Commerce, particularly, Ainas Mohamed, Nedjari Nouzha and Fethi Roubahie for their help and patience.

I offer my thanks to the staff members of Colaital, Sosémie and Frater-Razes.

Abstract

The present study aims at concretising the preventive management of risks theory through the application of the the knowledge –based process of the integrated management of Risks and Business Processes (K-PIMRBP), which is the process structuring the theory, to multiple case studies in the Algerian context. It aims also at providing practical implications of this abstract model and explaining its contribution in preventing from the operational risks in the enterprises studied.

In order to reach the objectives of the study, we applied the K-PIMRBP to three production companies in which the operational risks have a significant impact. The present study involved three phases, in the first phase we conducted interviews with responsible persons in the enterprises studied to understand the context of the study, reveal the operational risks classes in each enterprise and formulate the hypotheses of the study. In the second phase, we applied the process of the preventive management of risks to the enterprises and we generated the diagrams of risk management, which constituted the knowledge in the present study, which were shared with the employees and then stored in files. In the third phase, we tested the hypotheses to reveal the effectiveness of the K-PIMRBP in preventing from the operational risks.

In the present study, we opted for pragmatism paradigm and we adopted mixed methods. The main practical implications of the study constitute of the two main contributions of the preventive management of risks, which depend on the degree of the enterprise maturity in terms of quality management, where in high quality management enterprises this process contributes in raising employees' awareness on risks, which leads to risk prevention. While in the case of poor quality management enterprises, this process contributes in training employees on risks in order to prevent from them.

Keywords: risk, prevention, management, K-PIMRBP, Algerian context.

الملخص

تهدف هذه الدراسة الى تجسيد نظرية الإدارة التحوطية من خلال تطبيق K-PIMRBP الذي ينظم النظرية، في عدة حالات في السياق الجزائري. يهدف أيضا الى تقديم نتائج عملية لهذا النموذج النظري وتفسير مساهمته في التحوط من المخاطر التشغيلية في التي تمت دراستها.

من اجل تحقيق اهداف الدراسة، قمنا بتطبيق النموذج K-PIMRBP في ثلاث مؤسسات إنتاجية أين للمخاطر التشغيلية أثر كبير. هذه الدراسة تضم ثلاث مراحل، في المرحلة الأولى أجرينا مقابلات مع مسؤولين في المؤسسات التي درسناها من اجل فهم سياق الدراسة، الكشف عن المخاطر التشغيلية التي تهدد كل مؤسسة وتكوين فرضيات الدراسة. في المرحلة الثانية قمنا بتطبيق النموذج المنظم لنظرية الإدارة التحوطية في المؤسسات، للحصول على المخططات إدارة المخاطر والتي تمثل المعرفة في هذه الدراسة والتي قمنا بمشاركتها مع العمال ثم قمنا بحفظها في ملفات. في المرحلة الثالثة قمنا باختبار الفرضيات لاختبار فعالية K-PIMRBP في التحوط من المخاطر التشغيلية.

في هذه الدراسة قمنا باعتماد النمط البراغماتي وتبنينا المنهج المختلط. اهم النتائج العملية التي توصلت اليها دراستنا تتمثل في المساهمتين الاساسيتين لإدارة التحوط من المخاطر، والتي تتعلق بدرجة نضج المؤسسة من ناحية إدارة الجودة، اين في المؤسسات التي تضم نظام جودة عالي المستوى يساهم هذا النموذج في رفع مستوى وعي العمال حول المخاطر والذي يؤدي الي التحوط من المخاطر بينما في المؤسسات التي تضم نظام جودة متدني المستوى يساهم هذا النموذج في تكوين العمال حول المخاطر من اجل التحوط منها.

الكلمات المفتاحية: المخطر، التحوط، الادارة، K-PIMRBP ، السياق الجزائري

List of tables

List of figures

Abbreviations

AMA	Advanced Measurement Approach	**OBS**	Observations
AVE	Average variance extracted	**OHA**	Operating Hazard Analysis
BAT	Bon à trier	**ONIL**	Office National interprofessionnel du lait et des produits laitiers
BIA	Basic indicator approach	**OR**	Operational risk
BP	Business process	**PE**	Probability of event
BPF	Bonnes pratiques de fabrication	**PhD**	Doctor of philosophy
BPM	Business process management	**PMO**	Pasteurised Milk Ordinance
CAPA	Corrective action preventive action	**PPM**	Packaged pasteurised milk
CCP	Critical Control Points	**PrHA**	Preliminary hazard analysis
CGMP	Current Good manufacturing practices	**R**	Risk
CIP	Cleaning in place	**R2**	Coefficient of determinant
COSO	Committee of Sponsoring Organisations	**R-BPM**	Risk aware business process management
CR	Composite reliability	**SPA**	Société par action
EI	the exposure indicator	**3SF**	Super fin
E.G	Example	**TSA**	Standardized approach
ERM	Enterprise risk management	**US**	United states
ETA	Event-tree analysis	**VaR**	value-at-risk
F^2	Effect size	**Q2**	Predictive relevance
FDA	Federal drug administration	**QA**	Quality assurance
FMEA	Failure modes and effects analysis	**QHSE**	Quality hygiene security environment
FSMA	Food safety modernisation act		
FTA	Fault-tree analysis		
GI	Gross income		
GOF	Goodness of fit		
H	Hypothesis		
HACCP	Hazard Critical Control Points		
HARPC	Hazard Analysis and Risk-Based Preventive Controls		
HAZOP	Hazard and operability study		
ICT	Information and communication technology		
ISO	the International Organisation for Standardisation		
IKMP	Integrated knowledge management process		
KMP	Knowledge management process		
K-PIMRBP	knowledge-based process of the integrated management of risks and business processes		
KM	Knowledge management		
LGE	Loss given the event		

Table of contents

Introduction:

From risk management to preventive management of risks theory:

The emergence of risk management traces back to 1100s, it was firstly introduced into the roman market, during this era sellers used to write contracts to buyers which were called lettres de faire , that was the promise to deliver the products. In the 1990s, the modern risk management was emerged (Crockford, 1982), with the establishment of Basel I which set the minimum capital standards for Banks to promote financial stability (Van Roy, 2005) .In 2004,Basel committee created the Basel II, then in 2010 the Basel III was established (Crockford, 1982) . Many other standards and norms for risk management were implemented namely: ISO 31000:2009 and COSO: 2004 …etc.

Risk management was introduced in stages , the first phase was characterised by the emergence of various norms for risk management, hence, the risk management during this period of time is qualified to be called the normative approach. According to Suriadi et al (2014) the risk management should be linked to business process management (BPM) to momentarily monitor and mitigate emerged risk to ensure a proper termination of processes ; this was the idea behind the emergence the risk-aware business process management(R-BPM) which is the second stage of risk management development. R-BPM is the result of the integration of the risk management with the business process management to increase the risk-awareness of the business processes of an enterprise (Lamine, E, et al., 2020). Various studies contributed to the development of this science including the study of (Zur Muehlen & Ho, 2005) who integrated in their study, risk management into BPM lifecycle and then they analysed the risks within BPM project, however they did not provide neither strategies for mitigating risks nor a framework to integrate risk management into BPM. Then Rosemann & Zur Muehlen (2005) made a progress in that area , by identifying the best process configuration for risk minimisation through the integration of risks in business activities . However, we notice that the authors did not apply any explicit conceptual framework for risk management, including the frameworks provided by ISO and COSO…etc. Thus, the results of this study can just be considered as the first step in integrating risk management into BPM.

To fill this gap, (Sienou, 2009)and (Lamine, E, et al., 2020) developed the BPRIM process, which structures the R-BPM approach.

Based on the forgoing, the normative approach to risk management has provided processes and methods for managing risk effectively in organisations. While the R-BPM has contributed to

managing risk individually and immediately in each activity, in order to preserve the created value.

In the previous two approaches , risk management is conducted after the occurrence of risks; hence, (Madagh & Chedri maamar, 2017) went to the next level in managing risk by anticipating it before its occurrence and emphasised the importance of the implementation of the preventive management of risks in organisation ,but this study discussed only the concept of preventive management of risks and it did neither give a clear definition of the concept nor a process that structures the discipline. (Neef, 2005)conducted another research on the prevention of risks in which he argued that knowledge risk management leads to the prevention of risks. Knowledge risk management is another approach to risk management which seeks to improve the quality of risk management (Haltiwanger, Landaeta, & Pinto, 2010), but it still constitutes the first step towards the foundation of a strong theory of the preventive management of risks (MAAMIR & DERGHOUM, 2021).

In 2021, MAAMIR & DERGHOUM (2021) developed the preventive management of risks theory and the K-PIMRBP process which structures the theory. The theory was developed based on the previous studies, and it was the result of the integration of a knowledge management process with a risk management process. This study has a strong theoretical implication but it does not have any practical implication.

Hence, we seek through this thesis to fill in the gap in the literature by concretising the theory of preventive management of risks in the context of the Algerian enterprises. Since there are different risks threatening the enterprises, we are going to focus in the present study on the operational risk, because it happens in any enterprises regardless of its size and nature, which will facilitate the achievement of the main objective of the study since we can apply the theory in any enterprise. Besides that, K-PIMRBP focuses on the operational level of the enterprise.

In order to attain the objectives of the present study we are going to answer the following question:

« How well does the K-PIMRBP model serve to prevent from the operational risk in three enterprises in the Algerian context? »

Secondary questions:

- What are the outcomes of the K-PIMRBP process?

- How do the outcomes of the K-PIMRBP process contribute to the prevention of operational risks?
- What are the changes that the K-PIMRBP process bring to the enterprise?
- How can these changes lead to the prevention of risks?

Objective of the study:

The main objective of the study is the concretisation of the preventive management of risks theory by applying the K-PIMRBP in real case studies in the Algerian context, to obtain practical impactions, which explain the contribution of this process in preventing from the operational risks.

To achieve the main objective of the study we will opt for pragmatism paradigm in which the focus in on answering the main research question and we will adopt mixed methods.

The present study includes three stages:

- In the first study, we will adopt qualitative approach to collect qualitative data , hence we will conduct interviews with responsible persons to reveal the main operational risks in each enterprise and disclose how to prevent from them and then we will formulate the hypotheses of the study;
- In the second phase, we will apply the K-PIMRBP and generate the risk management outcomes, which will be then shared with the employees and stored in files;
- In the third phase, we will test the hypotheses of the study to assess the effectiveness of the K-PIMRBP in preventing from the operational risks.

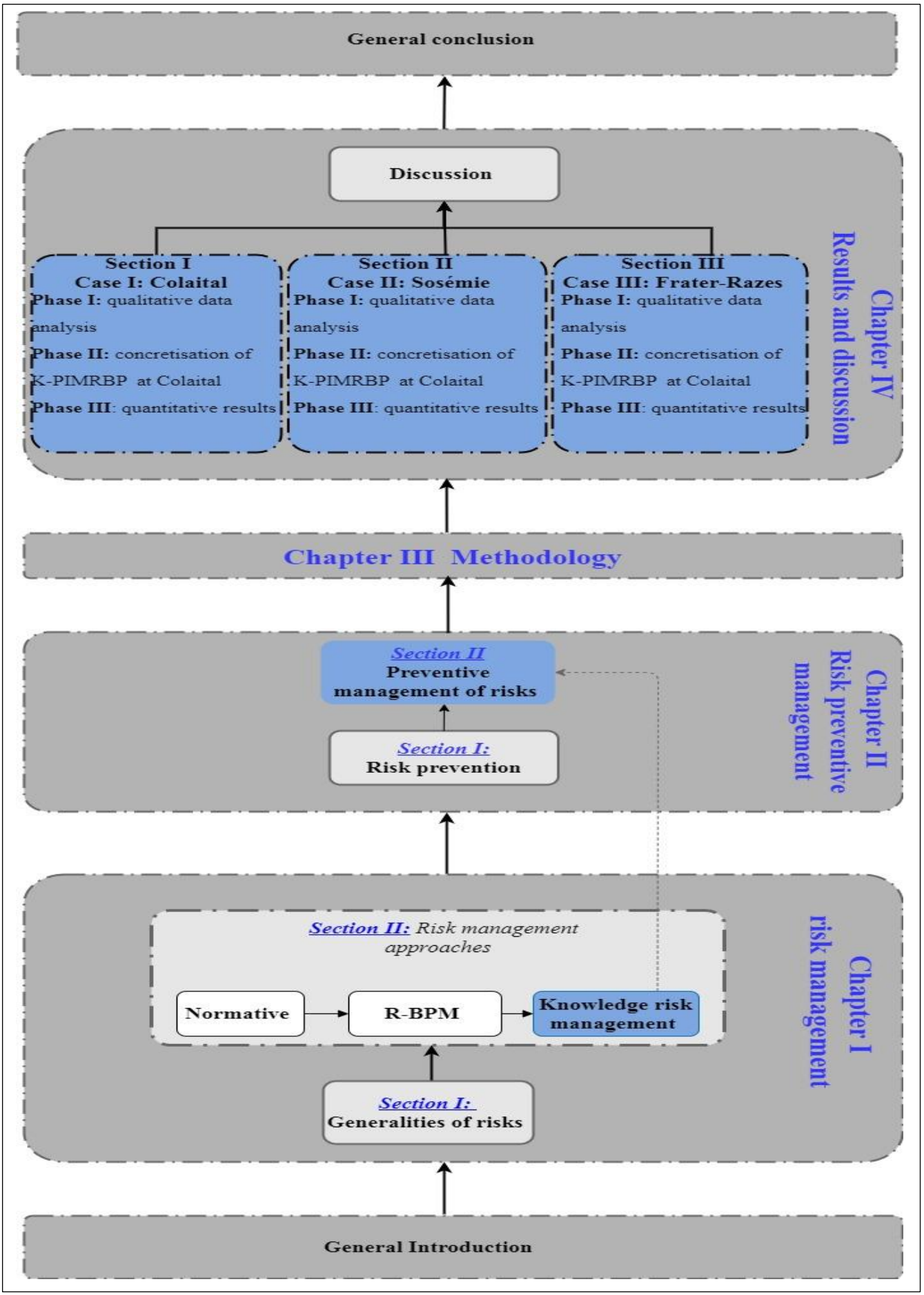
We will apply the present study in production companies in the Algerian context, because the significance of the operational risks is very important.

The present thesis is organised as follows:

Two theoretical chapters, which includes the conceptual framework:

- The first chapter, involves two sections, in the first section we will discuss the concepts around the risks and in the second section we will present the three approaches of the risk management that we found in the literature;
- The second chapter involves, two section which provide a discussion about the difference between risk prevention and preventive management of risks

- The third chapter involves three sections, which outlines the methodology adopted in the present study;
- The fourth chapter presents the results of the empirical study and the conclusion.


General conclusion
Discussion
Section I
Case I: Colaital
Phase I: qualitative data analysis
Phase II: concretisation of K-PIMRBP at Colaital
Phase III: quantitative results
Section II
Case II: Sosémie
Phase I: qualitative data analysis
Phase II: concretisation of K-PIMRBP at Colaital
Phase III: quantitative results
Section III
Case III: Frater-Razes
Phase I: qualitative data analysis
Phase II: concretisation of K-PIMRBP at Colaital
Phase III: quantitative results
Chapter IV
Results and discussion
Chapter III Methodology
Section II
Preventive management of risks
Section I:
Risk prevention
Chapter II
Risk preventive management
Section II: Risk management approaches
Normative
R-BPM
Knowledge risk management
Section I:
Generalities of risks
Chapter I
risk management
General Introduction

Chapter I:

Risk Management

Introduction

The aim of the present thesis is to shed light on preventive management of risks, which is based on the risk management. Hence, we devoted this chapter to discuss the main concepts around the risk management, which help the reader of the present thesis to understand better the preventive management of risks which will be discussed in chapter two and therefore understand the empirical results of the present study.

This chapter involves two main sections, in the first section we discuss the main concepts related to risks and their classification and then we display the three risk management approaches, namely: normative approach, risk-aware business process management (R-BPM) and knowledge risk management

Section I: Generalities of risks

In this section, we discuss the concepts related to risks

I.1 Enterprise Risks

In the literature of risk management, there are many definitions of risks. Some definitions of enterprise risks are set out in Table 01.

Table n° 01: definitions of risk

	Definition
(ISO31000, 2018)	*« Effect of uncertainty on objectives. Note that an effect may be Positive, negative, or a deviation from the expected. Also, risk is often described by an event, a change in circumstances or a Consequence. »*
(Hopkin, 2018)	*« Event with the ability to impact (inhibit, enhance or cause doubt about) the mission, strategy, projects, routine operations, objectives, core processes, key dependencies and / or the delivery of stakeholder expectations. »*
(COSO, 2004)	*« The possibility that an event will occur and adversely affect the achievement of objectives »*
(Drennan, 2014)	The chance of the occurrence of something that will have an impact on objectives; often specified as an event or set of circumstances and their (both positive and negative) consequences.

Source: elaborated by the author based on the literature

It is argued that risks are described as probable events (Hopkin, 2018), which may have positive or negative impact or unexpected events that may affect a part or the whole organisation.

I.2 Risk classifications

I. 2.1 Classification based on the nature of risk outcomes

Risks may have negative, positive or uncertain effects. There are three types of risks: hazard (or pure) risk, control (or uncertainty) risk, opportunity (or speculative) risk (Hopkin, 2018) This classification is based on the nature of the risk effect .Each one of them has a different impact on the organisation (see table 02).

Table n°02: Risk types

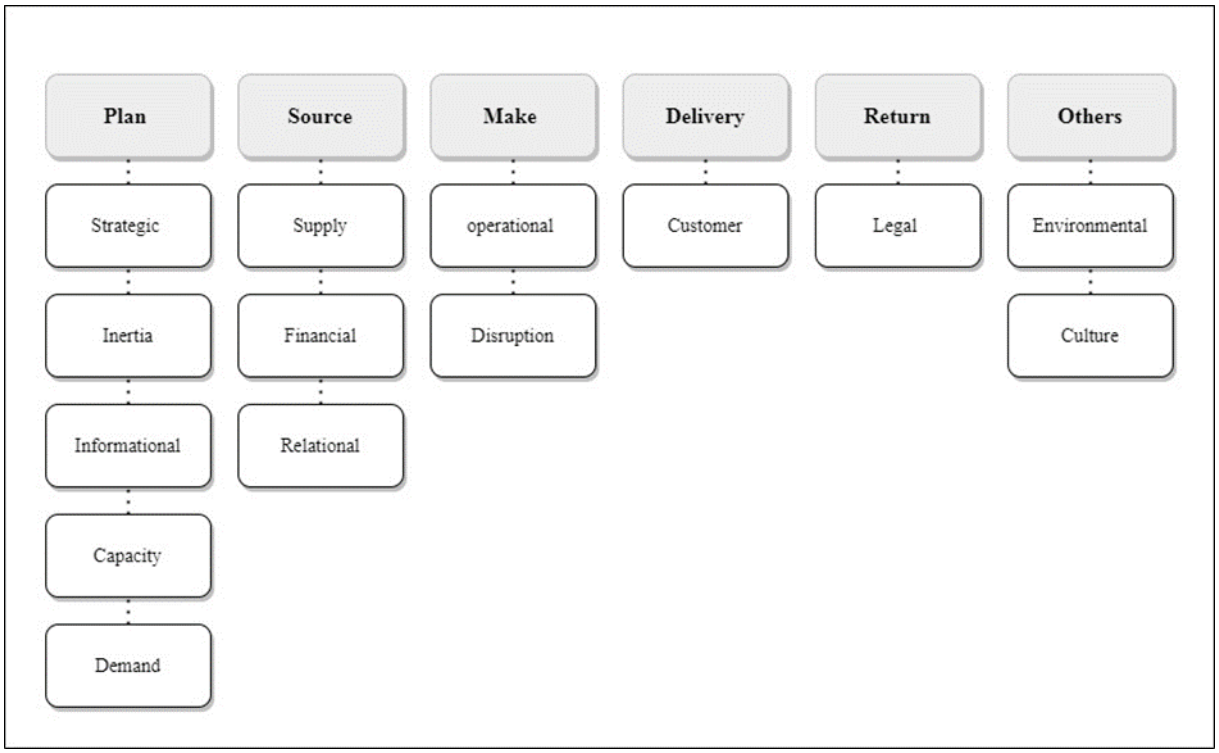
Risk type	Definition
Hazard (Insurable or Pure) risks	Risks that have a negative impact. Examples: risks of product contamination, theft, employee injury or explosion, etc.
Control (or uncertainty) risks	Risks that have uncertain consequences. These risks are associated with project management wherein the profit, the budget and the delivery of the project with the specifications stipulated are uncertain.
opportunity (or speculative) risks	Risks that may have a positive impact, which are considered as opportunity. Example: investments or the launch of a new product or service, which provide a positive financial return to the business.

Source: Adapted from (Hopkin, 2018); (Drennan, 2014)

I.2.2 Classification of risks

The literature of supply chain discusses the risks associated with each activity within the supply chain, which involve the different risks threatening the company.

Figure 02: Classification of risks in supply chain



Source: (Rangal, Oliveira , & Leite , 2014)

Figure 02 outlines the five activities within the supply chain: plan, source, make, delivery, return and others, each activity is exposed to enormous risks. The present study covers only the internal environment of the enterprises, and excludes the external environment, including the other parts of the supply chain that involve the suppliers and clients of the enterprises. Moreover, the focus in our study is on the operational level of enterprises, hence we will study the operational and disruption risks related to "Make" process or production activities, which refers to the process of transforming the raw materials into products (Cohen & Roussel, 2005). Because the purpose of the thesis is to contribute to preserving the value created in the business processes, which constitute the operational level of enterprises through the preventive management of risks.

In the next sub-sequence, we will discuss in depth the concept of operational risk.

I.2.3 Operational risks classification in non-financial enterprises

Although the operational risk literature focuses more on examining the effect of this risk on the financial institutions, this sort of risk is threating the other organisations and the financial institutions alike. The particularity of the financial institutions is the quantification of the level of operational risk, which should be covered by a part of the institution capital (Hopkin, 2018).

The literature of operational risk provided different definitions of this concept; in the present study, we use the definition of Basel II. Although it concerns the financial institutions, it can be used in the case of non-financial institutions, because it is exhaustive and widely accepted definition (Assienin & Ouattara, 2016).

Operational risk is defined: « *as the risk of loss resulting from inadequate or failed internal processes, people and systems or from external events. This definition includes legal risk, but excludes strategic and reputational risk* » (BASEL, 2006)

According to this definition, the operational risk is the result of deficiencies in the internal process, systems and people or it may occur from external factors. It involves different risks and excludes strategic and reputational risks.

The operational and disruption risks are the consequence of events that disrupt the production process within the focal enterprise, interruptions in materials flow or company's facilities failure that cause production deficit ((Rangal, Oliveira , & Leite , 2014); (Hudnurkar & et al, 2017))

Table n°03 describes the operational risks, we selected from the literature the operational risks resulted from dysfunctions in the internal processes and systems or from people inside the focal enterprise. The selection is based on the risks that we can control.

Table n° 03: operational risks

Process / Risk		Make	
	Authors	**Nature of risk**	**Definition**
Operational disruption risk	(Hudnurkar & et al, 2017) ; (Rangal, Oliveira , & Leite , 2014)	Operational	Includes all the internal factors affecting the manufacturing capability and the ability of the company to provide products and services , and issues associated with systems ,procedures , processes and people or company's facilities failures
	(Hudnurkar & et al, 2017)	Capacity	Refers to the production deficit of the company due to its limited capacities
		Design	Results from difficulties to adapt the business processes to new products or process design.
	(Rangal, Oliveira , & Leite , 2014)	Business interruption	Described by the disruption in the production or in the sale of products
		Internal controllable	Results from issues controlled by the enterprise including quality, quantity, price, costs, products, capacity, capability, problems related to the management of the company, the production and the technology used.
		Quality	Involves problems that affect the quality of products and goods which come from the non-application of quality standards
		Control	Related to the rules and procedures applied by the company to control processes
		Process	Results from issues associated with the internal activities of the company
		Forecast	Results from differences between the estimated and the actual demand
		Infrastructure support	Includes the problems associated with the infrastructure of the company

Source: Adapted from (Rangal, Oliveira , & Leite , 2014) (Hudnurkar & et al, 2017)

I.2.4 Operational risks in financial institutions

In July 1988, Basel committee established the capital accord, which refers to Basel I that fixes the minimum capital standards, which cover the bank credit risk exposure. In April 1993, the market risk has been included into Basel I, which was expanded in 1996. In 1998, the Basel committee established Basel II, which encompasses the operational risk, in 2006 the capital accord was completed by setting the capital requirement for operational risk. The regulatory capital is the amount of capital estimated by the bank to cover the operational risk exposure (Chernobai, RACHEV, & FABOZZI, 2007, p. 36).

I.2.4.1 Operational risk capital charges:

Basel II provided three approaches for measuring and calculating the operational risk capital charges, namely, the Basic Indicator Approach (BIA), the Standardized Approach, The Advanced Measurement Approaches (BASEL, 2006).

- **The Basic indicator approach (BIA)**

« *Under BIA the operational risk capital charge under the BIA is calculated as a fixed percentage of the average over the previous three years of positive annual gross income. The fixed percentage is denoted by α*» (Chernobai, RACHEV, & FABOZZI, 2007, p. 41)

$K_{BIA} = \alpha \times \frac{\sum_{j=1}^{n} GIj}{n}$

K_{BIA} : Total capital charge • Advanced Measurement Approach AMA:

GI: Gross income • Standardized approach (TSA)

n: The number of the previous three years for which GI is positive

α: The fixed percentage of positive GI (α=15%)

- **Standardized approach (TSA)**

Under this approach, the Total capital charge is calculated as the summation of the capital charges of the eight business lines of the bank, where the capital charge of each business line is calculated by multiplying the gross income of each line by β.

« GI serves as an indicator for measuring the operational risk exposure of each line; the β factor is fixed by the Basel committee connecting the level of capital required to the level of GI for each line (BASEL, 2006)

- **Advanced Measurement Approach AMA:**

According to Chernobai, (Chernobai, RACHEV, & FABOZZI, 2007), this is the most advanced approach to calculate the capital charge, which encompasses three approaches:

- **The internal Measurement Approach** in which the total capital charges is calculated as : $K_{IMA} = \sum_{j=1}^{8} \sum_{K=1}^{7} \gamma jk \times EIjk \times PEjk \times LGEjk$

γ: Parameter fixed by supervisor

EI: the exposure indicator

PE: Probability of event

LGE: Loss given the event

- **The scorecard Approach :**

« *Under which banks determine an initial level of operational risk capital (such as based on the BIA or TSA) at the firm or business line level, and then modify these amounts over time on the basis of scorecards*. » (Chernobai, RACHEV, & FABOZZI, 2007)

The capital charge is calculated as:

$K_{ScA} = \sum_{j=1}^{8} Initial\ Kj \times Rj$

R: some risk score that rescales the initial capital charge K into the new one for a given business line

- **The Loss Distribution Approach**

« *The operational capital charge is computed as the simple sum of the one-year value-at-risk (VaR) measure21 (with confidence level such as99.9%) for each business line/risk type pair »*

The capital charge is calculated as:

$K_{LDA} = \sum_{j=1}^{8} \sum_{k=1}^{7} VARjk$

Table 04 shows the seven classes of operational risk according to (BASEL, 2006)

Table n°04: operational risks types according to Basel committee

Operational risk types	Description	Examples
Internal fraud	Losses due to acts of a type intended to defraud, misappropriate property or circumvent regulations, the law or company policy, excluding diversity/ discrimination events, which involves at least one internal party.	• Unauthorised Activity • Theft and Fraud
External Fraud	Losses due to acts of a type intended to defraud, misappropriate property or circumvent the law, by a third party	• Theft and Fraud • Systems Security
Employment Practices and Workplace Safety	Losses arising from acts inconsistent with employment, health or safety laws or agreements, from payment of personal injury claims, or from diversity / discrimination events	• Employee Relations • Safe Environment • Diversity & Discrimination
Clients,Products & Business Practices	Losses arising from an unintentional or negligent failure to meet a professional obligation to specific clients (including fiduciary and suitability requirements), or from the nature or design of a product.	• Suitability, Disclosure & Fiduciary • Improper Business or Market Practices • Product Flaws • Selection, Sponsorship & Exposure • Advisory Activities
Damage to Physical Assets	Losses arising from loss or damage to physical assets from natural disaster or other events.	Disasters and other events
Business Disruption and System Failures	Losses arising from disruption of business or system failures	Systems
Execution, Delivery & Process Management	Losses from failed transaction processing or process management, from relations with trade counterparties and vendors	• Transaction Capture, Execution & Maintenance • Monitoring and Reporting • Customer Intake and Documentation • Customer / Client Account Management • Trade Counterparties • Vendors & Suppliers

Source : (BASEL, 2006)

In the first section we exposed the basic concepts of risks, and in the section we are going to discuss three approaches in risk management.

Section II: Risk management approaches

In this section, we are going to discuss three approach of risk management, namely, normative approach, risk-aware business process management and knowledge risk management.

Risk management origins

Risk management practices trace back to the 1950s. The management of insurable risks was established as the first approach to risk management, which was concerned with insurable risks. Besides the insurable risks, organisations were facing uninsurable risks, which led to the development of financial risk management, in the 1970s, to cope with this kind of risks. This system helped companies to decide whether to retain the risks within the company, or, to transfer them to the external alternatives, and the development of financial derivative products resulted in the emergence of this system. In the mid-1990s, a more holistic risk management model was developed (Dickinson, 2001).

I. Normative approach (First approach)

I.1Definition of risk management

Risk management standards provided a variety of descriptions of this concept. In seeking to examine each definition provided, we selected four criteria to make the task manageable, namely: nature, application, purpose, and risk nature.

Nature: risk management definition.

Application: level of enterprise that applies the risk management.

Purpose: the objective of risk management.

Risk nature: the nature of risk treated by the risk management.

Table n°5: comparison between risk management definitions

Author	Definition	Nature	Application	Purpose	Risk nature
(COSO, 2004)	*« Enterprise risk management is a process, effected by an entity's board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives. »*	Process	Applied to every level in the enterprise	-Detecting the events that influence the enterprise - Minimising risks effects - Reaching the established objectives	All risks
(ISO31000, 2018)	*« coordinated activities to direct and control an organization with regard to risk »*	Process	- Strategic level - Operational level - programme level - Project level	- Control and cope with risks within organisations	All risks
(BASEL, 2006)	*« Risk management generally encompasses the process of identifying risks to the bank, measuring exposures to those risks(where possible), ensuring that an effective capital planning and monitoring programme is in place , monitoring risk exposures and corresponding capital needs on an ongoing basis, taking steps to control or mitigate risk exposures and reporting to senior management and the board on the bank's risk exposures and capital positions »*	Process	It can be applied to all levels	Identify and quantify risks , allocate the necessary capital to manage risks and control risks	All risks

Source: Adapted from (ISO31000, 2018) (COSO, 2004) (BASEL, 2006)

All the standards consider the risk management as a process that includes different activities, which differs, from one other. The risk management, which was developed by Basel committee, is specific to banking sector while the risk management, which was developed, by ISO and COSO was developed to fit all organisations.

We draw the following conclusions from the three definitions of risk management:

- Risk management is a process that involves a set of steps;
- Risk management practices can be applied to all organisation's levels;
- Risk management has different purposes including: determining the events that affect the organisation, reducing the risks effects, achieving the organisation objectives, allocate the necessary resources and establish effective scenarios to cope with risks;
- Risk management practices are applied to all kinds of risks

I.2 Risk management processes

Among the plethora of Risk management processes, which was developed, we selected three processes as illustrated in the following table:

Table n° 06: comparison between risk management processes

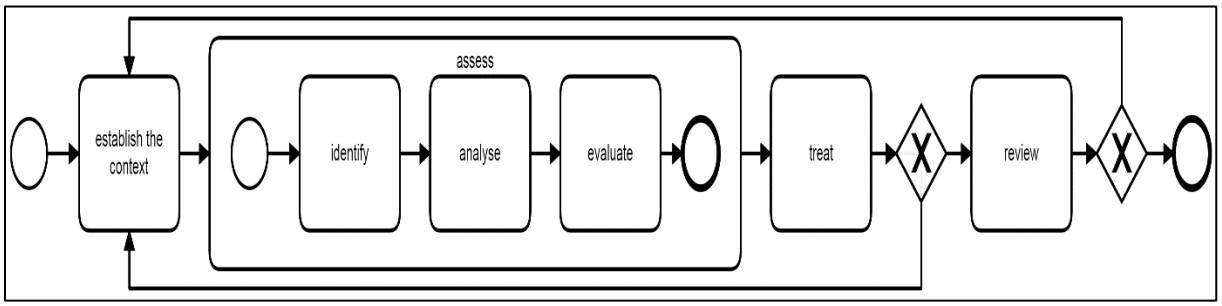
Authors	Process	Process steps	
(COSO, 2004)	COSO ERM	Internal Environment	
		Objective setting	
		Event identification	
		Risk Assessment	
		Risk Response	
		Control Activities	
		Information and communication	
		Monitoring	
(ISO31000, 2018)	Risk management process	Scope, Context , Criteria	
		Risk assessment	Risk identification
			Risk analysis
			Risk evaluation
		Risk treatment	
		Monitoring & review	
		Communication & consultation	

		Recording & reporting	
(Sienou, 2009)	risk management generic cycle	Context setting	
		Risk assessment	Risk identification
			Risk analysis
			Risk evaluation
		Risk treatment	
		Monitoring	

Source: (ISO31000, 2018) (Sienou, 2009) (COSO, 2004)

Although the risk management process , which was developed by ISO is the most commonly used process by companies to manage risks, it was criticised by Sienou (2009) who reorganised it and developed the risk management generic cycle, which we adopt in the present study (see figure n° 03).

Figure n°03: risk management generic cycle



Source: (Sienou, 2009)

In the following sub-section, we are going to describe each activity of the risk management generic cycle adopted in the present thesis.

1. Context Setting

Table **07** outlines the context setting activity:

Table n° 07: context-setting activity

Context setting	Description
	The establishment of the context consists of identifying the scope of the risk analysis application, in other words, the identification of the organisation activities that may be affected by risks (DIAS, 2017). This step includes two main components, the internal environment and the objective setting. **1. The internal environment consists** of determining the risk management philosophy and the attitude of the managers towards risk tolerance. The preconditions of this project are: - The elaboration of the organisational code of conduct, which clarifies the authorities and responsibilities of the individuals, which should be communicated to all the staff members. - The establishment of strong human resource standards to cope with employee hiring, training…etc (MOELLER, 2007). **2. Objectives settings** *« are related to the process in which the goals of the entity are defined and communicated throughout the organization»* (Lackovic, 2017).
Output	- Business processes and the activities that may be affected by risks; - The responsible and the participants in the risk management project; - The blueprint of the risk management project; - The risk management philosophy and objectives; - Risk tolerance; - The existing resources and the resources needed

Source: elaborated by the author based on the literature

2. Risk identification

Table 08 outlines the risk identification activity:

Table n°08: risk identification activity

Risk identification	Description
	The purpose of the risk identification is to determine : **1.** The nature of the potential risks in the business processes; **2.** A description of risks; **3.** Position of risks in the BPs; **4.** The characteristics of the potential risks (Sienou, 2009) In order to identify these information, it is necessary to use the current and historical information, the description of the project or service (MERNA & AL-THANI, 2005).
Outputs	- Potential risks in projects - The description of risks - The position of risks in the BPs

Source: elaborated by the author based on the literature

3. Risk analysis

Table 09 describes the risk analysis activity

Table n°09: risk analysis activity

Risk analysis	Description
	Risk analysis includes the consideration of the risk likelihood and consequences, in order to estimate the effect of risks without control, then ranking them. This step includes also the consideration of the control strategies and the estimation of their effects on the risks (BERG, 2010). There are two kinds of risk analysis approaches: qualitative risk analysis and quantitative risk analysis (MERNA & AL-THANI, 2005).
Outputs	- Risk likelihood - Severity of risk consequences - Risk ranking

Source: elaborated by the author based on the literature

3.1 Risk analysis methods

There are many methods of risk analysis, which are summarised in the following table:

Table n°10: risk analysis methods

Method	Scope
Safety/review audit	Identifies equipment conditions or operating procedures that could lead to a casualty or result in property damage or environmental impacts.
Brainstorming	Identifies risk events using facilitated sessions with stakeholders, project team members, and infrastructure support staff.
Preliminary hazard analysis (PrHA)	Identifies and prioritises hazards leading to undesirable consequences early in the life of a system. It determines recommended actions to reduce the frequency and/or consequences of the prioritised hazards. This is an inductive modelling approach.
Scenario Analysis	Descriptive models are developed to describe how the future might turn out. It can be used to identify risks by considering possible future developments and exploring their implications.
Operating Hazard Analysis (OHA)	Identifies the potential hazards in the operation of the system caused by human errors or technical failure , this technique can be used to analyse operational risk
Hazard and operability study (HAZOP)	Identifies system's deviations and their causes that can lead to undesirable consequences and determine recommended actions to reduce the frequency and/or consequences of the deviations.
Risk Matrixes	It is used to rank risks based on the probability of harm and the severity of consequences.
Checklist	Ensures that organisations apply standard practices.
What if/then	Identifies hazards, hazardous situations, or specific accident events that could result in undesirable consequences.
Failure modes and effects analysis (FMEA)	Identifies the component (equipment) failure modes and impacts on the surrounding components and the system. This is an inductive modelling approach.
Fault-tree analysis (FTA)	Identifies combinations of equipment failures and human errors that can result in an accident. This is a deductive modelling approach.

Event-tree analysis (ETA)	Identifies various sequences of events, both failures and successes that can lead to an accident. This is an inductive modelling approach.
Delphi technique	Assists in reaching the consensus of experts on a subject such as project risk while maintaining anonymity by soliciting ideas about the important project risks, which are collected and circulated to the experts for further comment. Consensus on the main project risks may be reached in a few rounds of this process.
Interviewing	Identifies risk events by interviews of experienced project managers or subject-matter experts. The interviewees identify risk events based on experience and project information.
Experience-based identification	Identifies risk events based on experience, including implicit assumptions.

Source: Adapted from (TIUSANEN, 2017); (AYYUB, 2003).

4. Risk evaluation

Risk evaluation activity is described in the following table

Table n°11: risk evaluation activity

Risk evaluation	**Description**
	Risk evaluation consists of comparing the outcomes of the risk analysis with the established risk tolerance to set the appropriate risk treatment strategy (ISO31000, 2018). Risk evaluation outcomes , help the risk manager to decide whether the risks are accepted, or, not accepted (BERG, 2010).
Outcomes	Risk evaluation matrix

Source: elaborated from the theory

5. Risk treatment

Risk treatment activity is described in the following table

Table n°12: risk treatment activity

Risk treatment	Description
	Risk treatment consists of selecting the most appropriate strategy to cope with risks ((EPSTEIN & HARDING, 2020) .According to (MERNA & AL-THANI, 2005)and (EPSTEIN & HARDING, 2020). There are four risk treatment strategies, namely: **1. Risk avoidance:** this strategy is used when the risk is significant, which refers to either the elimination of the source of risk or the avoidance of the project or business entities. **2. Risk reduction:** it is used to diminish the probability of risk occurrence and/or the severity of risk consequences if both of them are significant. **3. Risk transfer:** refers to the transfer of risks to an insurance company or if the project involves many stakeholders, they share the project risks. **4. Risk retention:** the organisation resorts to this strategy, if the risk is not identified or its impact is underestimated, then the organisation should accept the risk. This strategy is also used in the case of speculative risk.
Outputs	- Establish treatment scenarios to treat risk

Source: elaborated by the author based on the theory

6. Risk monitoring

The risk monitoring activity is described in the following table

Table n°13: risk monitoring activity

Monitoring	Description
	Risk monitoring refers to the control of the effectiveness of the risk treatment strategy. If the selected strategy did not achieve the risk treatment objectives, then the organisation should establish alternative strategy. The organisation should update the risk inventory (Sienou, 2009).
Outputs	- Updated risk inventory - Risk monitoring report

Source: elaborated by the author based on the theory

II. R-BPM approach (second approach)

II.1 Business process

The concept of business process has various definitions, amongst the definitions that we found we selected the most commonly used (see table n°14)

The analysis of the definitions in table shows that the business process is **series** (collection , set …) of interrelated(coordinated, interacting , organised) **activities** which are set off by **events** . Business processes are composed of **inputs**, which are then transformed into **outputs**

- The purpose of a business process is the creation of **added values** and/or the realisation of the **business goals.**

- The business process is executed by **actors** within an organisation, which can be interacted with other business processes that are performed by other organisations.

We propose the following definition of the concept of business process :

« Business process is series of organised and interrelated activities triggered by events. Business process transforms the inputs into outputs. The purpose of business processes are the creation of added values and / or the realisation of the business goals by actors inside an organisation. Business processes may interact with other processes executed by other organisations. »

Table n° 14 : business process definitions

Authors	Definition	Nature	Components	Purposes	Relations inside /outside the process	Context
(Sienou, 2009)	*« Le processus peut être défini comme étant une structure holistique d'activités organisées dans le temps et dans l'espèce dans le but de réaliser une finalité donnée »*	Structure	Activities	Realise a purpose	Organisation	/
(ISO9000, 2015)	*« Process ; set of interrelated or interacting activities, which transforms inputs into outputs »*	Set of activities	- Activities - Inputs - Outputs	Transform inputs into outputs	Interaction & interrelation	/
(Harmon, 2019)	*« Bounded set of activities that are undertaken in response to some initiating event to generate a valued result. Processes can be very simple or extremely complex »*	Set of activities	- Activities - Events	Generate valued results	/	/
(Hammer & Champy, 1993)	*« A business process is a collection of activities that takes one or more kinds of inputs and creates outputs that is of value for the customer »*	Collection	- Activities - Inputs - Outputs	Create valued outputs	/	/
(Weske, 2019)	*« A business process consists of a set of activities that are performed in coordination in an organizational and technical environment. These activities jointly realize a business goal. Each business process is enacted by a single organization, but it may interact with business processes performed by other organizations. »*	Set of activities	- Activities	Realise business goals	Coordination & interaction	Inside and outside the organisation
(Dumas, La Rosa, Mendling, & Reijer, 2013)	*« Business process encompasses a number of events and activities. Events correspond to things that happen atomically, meaning that they have no duration... This event may trigger the execution of series of activities… a typical process involves decision points,.. A process also involves a number of actors. Physical objects and immaterial objects. the execution of a process leads to one or several outcomes. »*	/	- Events - Activities - Decision - Actors - Physical objects - Immaterial objects - Outcomes	Create outcomes	/	/

Source: elaborated by the author based on the theory

II.2 Business process management

According to (Dumas, La Rosa, Mendling, & Reijer, 2013): *« Business Process Management (BPM) is the art and science of overseeing how work is performed in an organization to ensure consistent outcomes and to take advantage of improvement opportunities. »* we can distil from this definition that the main purpose of the BPM is the improvement of the quality of the business outcomes.

BPM is not a recent science, it went through many steps over the years, and table provides the evolution of the business process management **from 1900s to 1990s**

Table n°15: evolution of BPM 1900-1990

Phases	Description
1900s	During this period, Frederick Taylor established the task-oriented manufacturing. The focus was on the execution of specific tasks for the purpose of maximising the profits and minimising the costs.
1960s -1980s	This period was characterised by the technology development, which triggered the adoption of process orientation by the Japanese companies, which were concerned with quality improvement. Few years later, American business began adopting process approach. The focus was on the cross-functional team rather than the corporate mission.
1980s-1990s	The emergence of just-in-time supply chain created the need for understanding the enterprise processes. During this period, the company was viewed as a system and the business process management is the discipline that manages this system.

Source: Adapted from (Lusk, Paley, & Spanyi, 2005)

II.3 Business process management process :

According to (Sienou, 2009), Business process management is a piloting process. We found in the literature many different BPM processes we selected five of them, each process involves different activities. The analysis of these processes is provided in table

Table n°16: comparison between the BPs' steps in different definitions

Authors / BP Steps	(van der Aalst, 2004)	(Netjes, Reijers, & van der Aalst, 2006)	(Houy, Fettke, & Loos, 2010)	(Zur Muehlen & Ho, 2005)	(Sienou, 2009)
BPs steps			Strategy development	Specification of objectives and analysis of environment	Prepare
	Diagnosis	Diagnosis			
	process design	design	Definition and modeling	Design	Design
	System Configuration	configuration			
			Implementation	Implementation	Implementation
	process enactment	execution	Execution		
		Control	Monitoring and controlling	Monitoring	Control
				Evaluation	Evaluate
			Optimization and improvement		

Source: elaborated by the author based on the theory

In the present study, we adopt the cycle developed by (Sienou, 2009), which constitutes one of the components of the model (K-PIMRBP), which we are going to apply in the present study. A deep discussion about this model will be provided in chapter II.

The process developed by (Sienou, 2009) involves the following steps:

1) **Prepare:** Consists of setting the objectives of the process management and the mission of business processes. It involves also the establishment of the blueprint for the realisation of the objectives.
2) **Design (business process modeling):** Business process modelling refers to the representation of all or a part of a business process to create a model of the behaviours needed to provide product and/or service to the consumer (Aldin & De Cesare, 2009).

This phase involves three main elements:

- **Discover:** this stage provides information about the context studied (the enterprise, business processes etc.)

- **Model:** this phase provides graphical representations of the business processes and the activities of an enterprise.
- **Analyse the processes**: examine the business processes.

3) **Implementation:** the execution of the business processes by means of change management and technology.
4) **Control** : review and monitor the business processes.
5) **Evaluate :** assess the needs to improve the current business processes.

II.4 Risk-aware business process management (R-BPM)

For many years ago, business process management and risk management were considered as separated disciplines. Recent researches provided an interesting discussion about the interdependencies between these two disciplines, which resulted in the emergence of risk-aware BPM field of study. R-BPM increases the risk-awareness of the business processes of an enterprise (Lamine, E, et al., 2020).

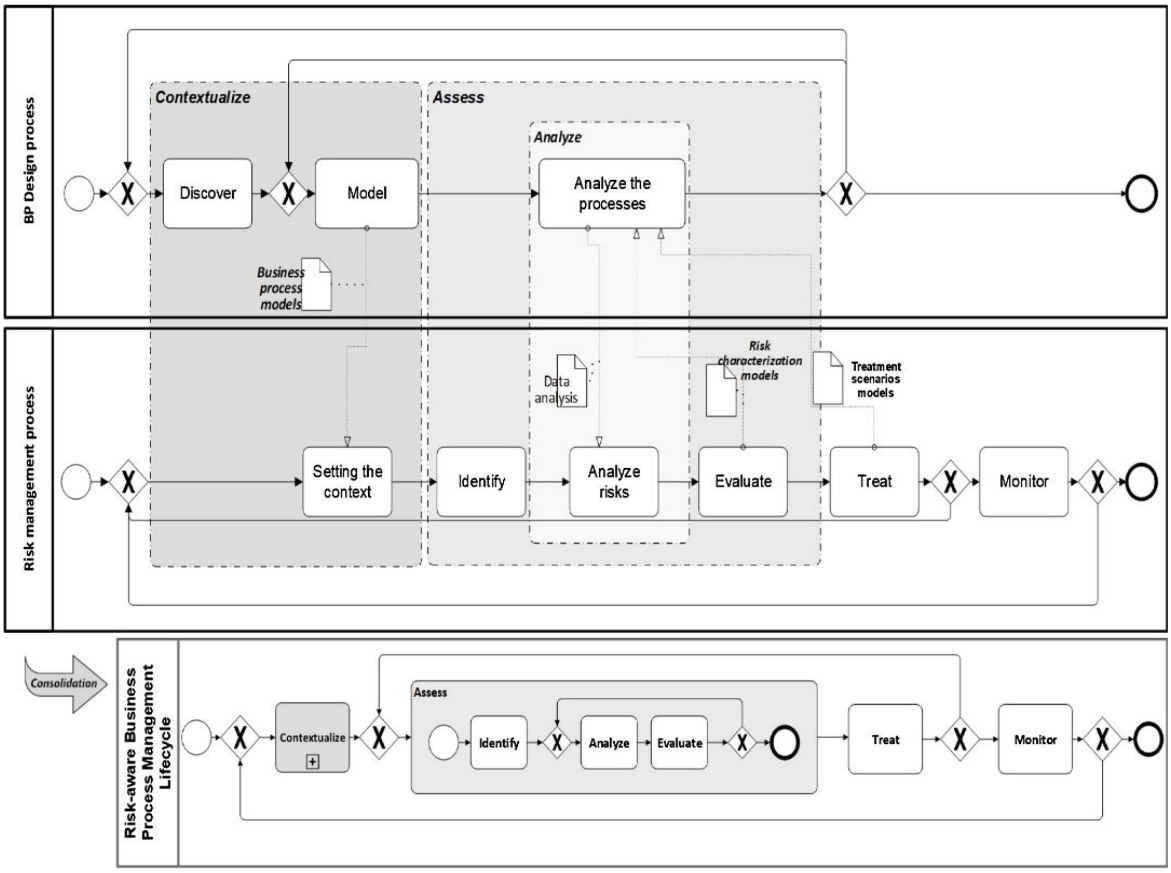
Several studies enabled the emergence of this new field of study ((Suriadi, Weib, Winkelmann, Ter Hofstede, & Adams, M, 2014); (Cope, Kuster, Etzweiler, Deleris, & Ray, 2010) (Zur Muehlen & Ho, 2005) ; (Rosemann & Zur Muehlen, 2005)).

In the latest study on R-BPM developed by Lamine et al (2020) , they coupled the BPM process and ERM process which resulted in the development of the BPRIM process which is the process that enables the R-BPM , in other words, this process structures the R-BPM research field.

The BPRIM process integrates steps of the second phase of BPM process, which is “design or business process modelling” with the steps of ERM (see figure 4).

The design phase involves three main steps: discover, model, analyse the processes (Sienou, 2009).

Figure n°04: BPRIM process



Source : (Lamine, E, et al., 2020)

According to (Lamine, E, et al., 2020), BPRIM process includes the following steps:

Contextualise: the purpose of this step is to set up the context of R-BPM, which consists of the establishment of both the context of risk management and business process management.

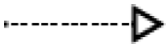
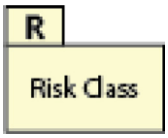
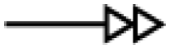
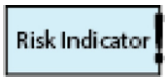
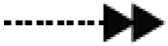
Assess: this phrase consists of studying jointly the risk and processes. The joint study of risk and processes resulted in the identification, analysis and evaluation of risks within the business processes. The outcomes of this phase are risk assessment in form of diagrams

Treat: this phase comprises the determination of treatment scenarios. These treatment alternatives are integrated in the business process models.

Monitor: this phase consists of verifying whether the treatment alternatives have been implemented as planned and checking the effectiveness of these alternatives.

Figure shows the **BPRIM** language

Figure n°05:BPRIM language

BPRIM object types			**BPRIM relation types**		
1		Characteristics of the system affecting the cause or the consequence of risk.	1  8		**Influence** relation of a factor on an event. Inter-event influence relation.
2		The state in which a risk event may lead the system.	4  6		Representation of the **belonging** of the risk to a risk class. The direction indicates the class of risk.
3		The value exposed to risk.	4  4		Representation of the risk **aggregation** relationship.
4		The possibility of a situation affecting an asset.	4  4		Representation of the risk **generalization** relationship. The direction indicates the general risk.
5		Activities planned or executed in order to face a risk.	8  2		**Causality** relation between an event and a risk situation.
6		Construct that represents a class including a breakdown structure of risks.	2  3		**Impact** relation between risk situation and asset.
7		Construct that represents a risk indicator.	4 7		**Association** which could outline relationship between risk and risk manager, or between risk and risk indicator.
8		Construct that represents a non-risky related event.	4  *		**Affect** association which outlines that a given risk acts on a given business process concepts (process, activity, and object).
9		Organizational unit that is involved in risk assessment.	3  9		**Interest** relation between a stakeholder and an asset.
10		AND operator, OR Operator and XOR Operator.	4  5		**Treatment** relation between risk and risk treatment measure.

Source: (Lamine, E, et al., 2020)

III. Knowledge risk management (Third approach)

III.1 Data, information and knowledge

For an extended period of time, the concept of knowledge has attracted significant attention. Greek philosophers including Plato and Aristotle were concerned with the following question: what is knowledge? Which led them to develop the epistemology, the theory of knowledge (Bolisani & Bratianu, 2018) .

Plato defined knowledge as : « *verified ,true belief*» (Hjørland & Hartel, 2003). The belief must be correct and justified to be called knowledge (Hunt, 2003).

Some researchers use the term data, information and knowledge interchangeably, in reality, each one of them has a different meaning (Stenmark, 2001).

There is consensus among researchers that data are kind of symbols (Ackoff, 1989); (Liew, 2007) others define data in terms of information and vice versa and define knowledge in terms of information and data (Chaffey & Wood, 2005, p. 21). According to (Stenmark, 2001)information could be also obtained from knowledge while data could be obtained from information . (Liew, 2007) states that information is a meaningful message while knowledge is the know-how , know what and know why. (Ackoff, 1989) argues that we get information by answering questions beginning with who, what, when, where, and how many.

III.2 Knowledge in organisational context

Japanese companies have succeeded to compete with giants in all domains and become pioneer in different fields, they are gaining competitive advantages through continuous innovations based on knowledge creation. The knowledge is the key factor of the success of the Japanese companies (Nonaka & Takeuchi, 1995).

The table below shows the types of knowledge within an organisation

Table n° 17: the types of knowledge within an organisation

Authors	Types of knowledge	Definitions
(De Long & Fahey, 2000)	**Human knowledge**	It consists of the knowledge acquired by an individual, which allows him to do a particular task or job.
	Social knowledge	Collective knowledge created and shared among members of a group.
	Structural knowledge	Knowledge implemented in the system, routines and processes of the organisation.
(Prusak, 2009, p. 23)	**Individual knowledge**	To know how to communicate and resolve problems.
	Group knowledge	To have particular methods to arrange and organise things.
	Organization knowledge	To know how to harmonise group and to convey knowledge to the rest of the members of the organisation.
	Network knowledge	To know how to collaborate and how to vend and purchase.
(Nonaka & Takeuchi, 1995)	**Individual knowledge (human knowledge)**	Tacit knowledge
		Explicit knowledge
	Group knowledge	It is the development of the individual knowledge through discussion experience sharing within the group.
	Organizational knowledge	Start from the individual knowledge in which an individual takes the initiative to create new knowledge which then be developed in the group level.

Source: elaborated by the author based on theory

III.3 Knowledge management process

In 1986, Knowledge management was introduced, for the first time, in Europe Management Conference (Allameh & Zare, 2011).

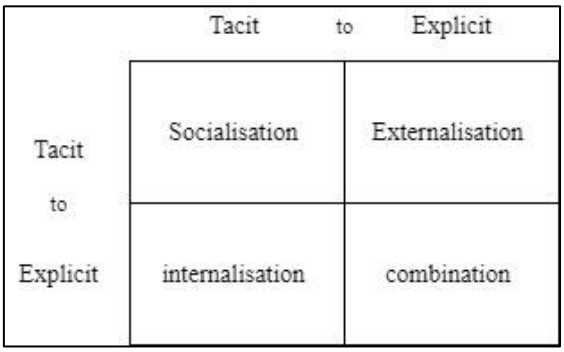
(Nonaka & Takeuchi, 1995), consider knowledge creation process and knowledge management process alike , Knowledge creation is based on tacit knowledge which is created and accumulated at the individual level then it is increased through knowledge conversion until it becomes clearer.

There are various KM processes developed by researchers, we selected five processes as follows:

(Nonaka & Takeuchi, 1995), Knowledge creation model includes the following parts:

1. **Socialisation:** This phase consists of converting tacit knowledge to tacit knowledge from the individual level to group level through knowledge sharing.
2. **Externalisation:** it refers to the process of articulating and converting the tacit knowledge to explicit knowledge in the form of concepts. The figurative language, such as metaphor and analogy are used to create concepts.
3. **Internalisation:** it consists of converting explicit knowledge to tacit knowledge.
4. **Combination:** It refers to the combination of existing and new explicit knowledge to create knowledge system specific to the organisation (see figure 6).

Figure n°06: Knowledge creation (Nonaka & Takeuchi)



Source: (Nonaka & Takeuchi, 1995)

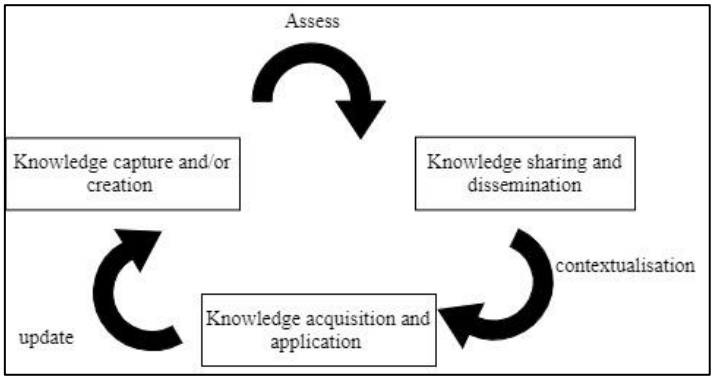
(Dalkir, 2005), developed the integrated model of knowledge management, which includes three major stages: Knowledge capture and/or creation, Knowledge sharing and dissemination, Knowledge acquisition and application (see figure 7).

1. **Knowledge capture:** refers to the identification of the codification of the existing knowledge and the know-how inside and outside the organisation;
2. **Knowledge creation:** refers to the development of new knowledge and Know-how.

The knowledge captured and/or created is followed by the assessment of the value of the existing or the new knowledge, which is then assimilated and shared;

3. **Contextualisation:** it refers to the following steps:
    - Associate the knowledge with the persons who know about the content.
    - Acquisition: it refers to the identification of the content qualities.
    - Application: it refers to the integration of the content within the business processes of the organisation. .
4. **Update:** The user contributes to the validation of the update of the content

Figure n°07: knowledge creation (Dalkir)

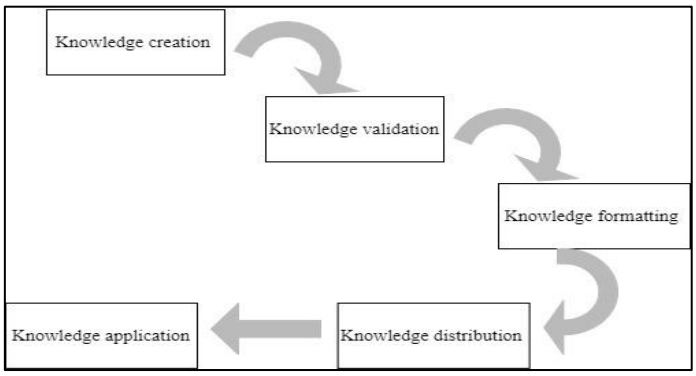


Source: (Dalkir, 2005).

According to (Bhatt, 2001), Knowledge management is considered as a process that includes five phases (see figure 8):

1. **Knowledge creation:** It refers to the reconfiguration, recombination and interaction of knowledge to create new meanings and realities;
2. **Knowledge validation:** it refers to the evaluation of knowledge effectiveness and the continuous monitoring of the existing knowledge to fit the potential or existing organisational environment;
3. **Knowledge presentation:** Methods by which knowledge is showed to the users and members of the organisation;
4. **Knowledge distribution:** it consists of sharing knowledge all over the organisation through people, technologies and techniques;
5. **Knowledge application**: it refers to the use of the knowledge developed in the organisation in its processes, services and products;

Figure n°8: knowledge creation (Bhatt)



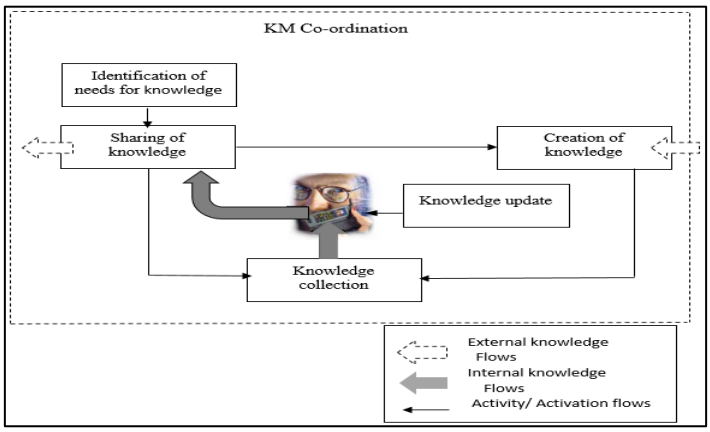
Source: (Bhatt, 2001)

According to (kucza, Knowledge management process model, 2001), KM process includes two main parts: the co-ordination processes, which involve the management tasks associated with KM. While the operational processes represent the processes of elaborating KM. We focus our attention on operational processes, which provide the practical steps of KM.

According to (kucza, 2001), the elements of KM process are:

1. **Identification of needs for Knowledge:** it consists of determining the knowledge needed;
2. **Sharing knowledge:** it includes "knowledge pull" which refers to the use of the existing knowledge in the system by the workers who need it, and "Knowledge push" which consists of providing knowledge for those who need it;
3. **Knowledge creation**: it refers to the creation of the missing knowledge;
4. **Knowledge collection and storage:** it consists of collecting new knowledge in databases or in human minds;
5. **Update:** reviewing existing knowledge;

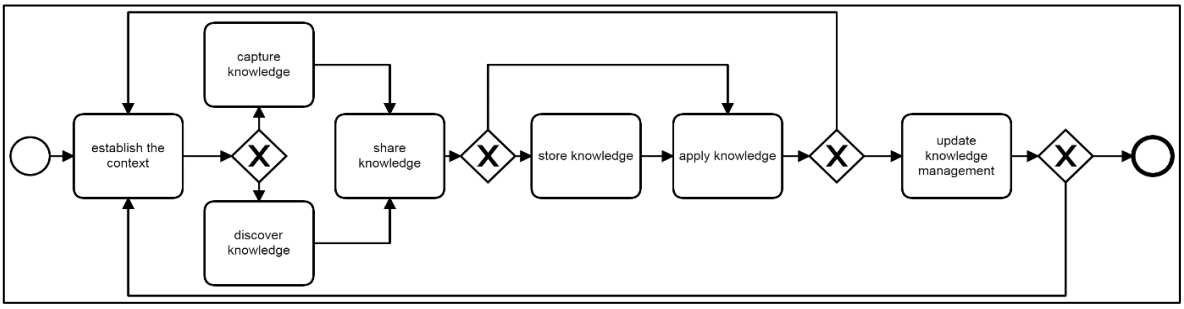
Figure n°09: knowledge creation (kucza)



Source: (kucza, 2001)

(MAAMIR & DERGHOUM, 2021), examined the four previous models then they created an integrated knowledge management process as shown in figure 10.

Figure n°10: IKMP



Source: (MAAMIR & DERGHOUM, 2021)

In the present study we are going to adopt MAAMIR's model , because it is a holistic model that includes all the steps mentioned in the literature for managing knowledge.

Establish the context: this step consists of setting the objectives of the KM and determining the actors involved in the KMP. It involves also the identification of the existing and missing knowledge. (Probst et al , 2000 mentioned by (RaudeliÅ & DavidaviÄ ienÄ, 2018).

Knowledge capture: The main role of this step is to accumulate the existing tacit and explicit knowledge from outside or inside the organisation ((Fernandez & Sabherwal, 2010).The identification of knowledge is supported by knowledge modelling and mapping technologies (Maier & Hadrich, 2011).

Knowledge sharing: «

The *exchange of knowledge between and among individuals, and within and among teams, organizational units, and organizations. This exchange may be focused or unfocused, but it usually does not have a clear a priori single objective* » (King, 2011).

Knowledge discovery

It consists of creating new explicit knowledge by synthesising, communicating, integrating and systematising of different bodies of explicit knowledge, or reconfiguring, categorising and contextualising the existing explicit knowledge to create new knowledge; or creating new tacit knowledge by synthesising the tacit knowledge existing in the individual's minds (Fernandez & Sabherwal, 2010).

Knowledge storage

It is the organisational memory (Jasimuddin, 2005), which is defined as: « It *is consisted of unordered information and concepts, which exist in the culture of the organization or in the individual's minds, and which may be described by databases. It consists also of ordered information and concepts which may be described by computerized files »* (Jennex & Olfman, 2003).

Knowledge use

It is the knowledge application, which is **«** *an integration of knowledge to organization process or activities such as directives, organizational routines, and self-contained task teams »* (Assegaff & Hussin, 2012) .

KM update

Bring up to date the KM if new knowledge is created or modified or if there is any change in the business processes (kucza, 2001).

III.4 Knowledge Risk Management:

The literature of Knowledge Risk Management provides two completely different definitions of this concept. The first definition defines the knowledge Risk management as the management of only the knowledge risks ((Durst, Zięba, & Helio, Knowledge risk management in organizations, 2018); (Durst, Bruns, & Henschel, 2018) , (DURST, Susanne et FERENHOF, & Helio, 2016); (Ferraris, 2019). Knowledge risk is defined as «*a measure of the probability*

and severity of adverse effects of any activities engaging or related somehow to knowledge that can affect the functioning of an organization on any level » (Zieba & Durst, 2018, p. 256).

Knowledge risks include ,but not limited to, Knowledge loss, Knowledge leakage , Knowledge spill over, Knowledge outsourcing risks, Knowledge waste, Knowledge hiding, Knowledge hoarding, Risks related to unlearning, Risks related to forgetting (Durst, Zięba, & Helio, 2018).

While in the second definition, the Knowledge risk management is concerned with different kinds of risks and not only the knowledge risks. In this current Knowledge management is incorporated with risk management for enhancing the outcomes of this latter ((Neef, 2005); (Haltiwanger, Landaeta, & Pinto, 2010); (Massingham, 2010); (Jafari, Rezaeenour, Mazdeh, & Hooshmandi, 2011); (Alhawari, Karadsheh, Talet, & Mansour, 2012).

According to (Massingham, 2010), in this current, Knowledge management is incorporated with risk management for many reasons, including but not limited to:

- Knowledge can assist risk identification, risk quantification, and risk response;
- Knowledge management can improve risk management by transferring knowledge

to decision makers, improving accessibility of knowledge, incorporating knowledge in controls and systems, to inhibit financial risks.

According to (Neef, 2005), the incorporation of these two disciplines resulted in the emergence of the prevention of risks. The study of (MAAMIR & DERGHOUM, 2021) is an extent of the study of Neef, in which they justified the integration of these two disciplines to create the preventive management of risks theory and the process structuring the theory. The preventive management of risks theory is based on knowledge risk management approach, in other words the components of KRM constitutes the pillars of this theory. This theory will be discussed in more detail in the second chapter.

Conclusion of the chapter

In this chapter, we defined the basic concepts related to risk then we presented the three approaches of risk management to highlight the contributions and the limitations of each approach in risk management and in the end we presented the third approach, which is the basis of the preventive management of risks as we discussed above.

Chapter II:
Risk preventive management

Chapter II : risk preventive management

Introduction

The concept of prevention, particularly in food industry has received considerable attention since 1923 along with the development of the Pasteurised Milk Ordinance (PMO) , which is a set of standards developed by the U. S. Food & drug administration (FDA) for Grade "A" milk production and processing. From then the risk prevention literature has provided different systems, approaches and actions to eliminate the causes of risks up until 2021 when Maamir & Derghoum developed the preventive management of risks process, which is called K-PIMRBP. The purpose of this chapter is to distinguish between the risk prevention and the preventive management of risks, by displaying in the first section the different risk prevention systems found in the literature, and then in the second section we describe the elements of the preventive management of risks

Section I: Risk Prevention

In this section, we show different risk prevention systems and then we will compare between them.

I. Corrective action and preventive action: CAPA

Businesses are striving to develop and implement actions to prevent from potential problems that affect their financial performance. The establishment of preventive actions becomes a regulatory requirement expected by quality systems including International Organization for Standardization (ISO) and U. S. Food & drug administration (FDA), which ensures that the products are in conformity with the quality standards, which is critical for the customer satisfaction (Baldwin).

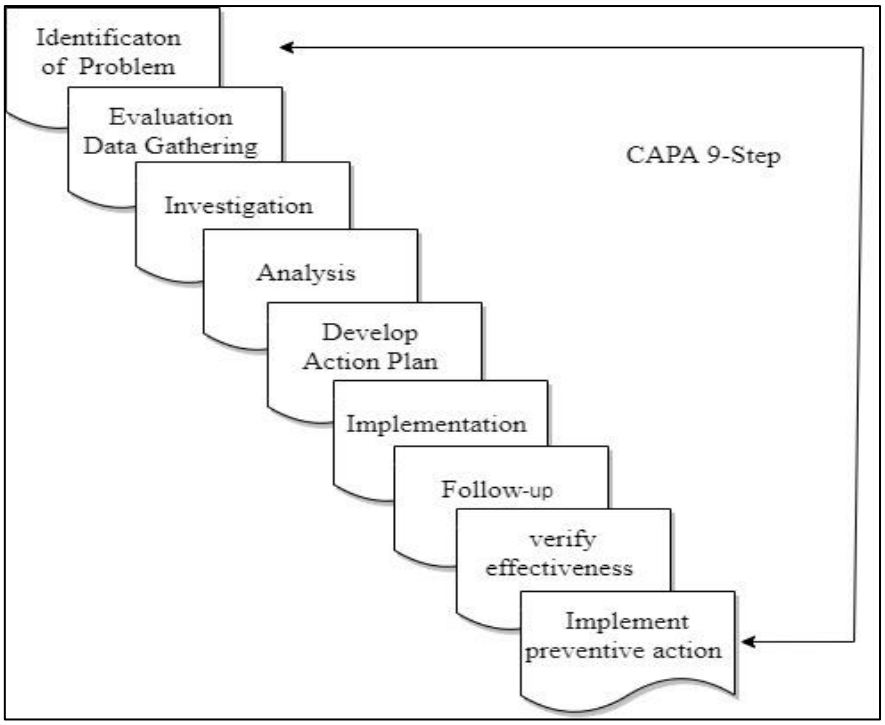
Corrective action and preventive action (CAPA) is one of the concepts of Current Good manufacturing practices CGMP developed by FDA , which aims at identifying , analysing , correcting , and subsequently preventing problems. CGMP and quality system call for documenting corrective action that is reactive tool, which is implemented after the occurrence of problems while the preventive action is a proactive tool, which is implemented before the occurrence of problems to prevent from the recurrence of potential risks (FDA, 2006).

Corrective actions and preventive actions are not alike. According to (ISO9000, 2015) Corrective action is : « *Action to eliminate the cause of a nonconformity and to prevent recurrence …there can be more than one cause for a nonconformity »* while *« Action to*

eliminate the cause of a potential non-conformity or other potential undesirable situation …there can be more than one cause of non-conformity »

Figure 11 shows the steps of CAPA which is composed of 9 steps as follows:

Figure n°11: CAPA steps



Source: (Rodriguez, 2007)

CAPA steps are described in the following subsection:

1. Identification of the problem:

CAPA process is triggered by the existence of problems. This step consists of determining the situation, when the problem occurred, the responsible and all the other details associated with the problem (Rodriguez, 2007).

2. Gather and analyse data:

The data that describe the problem are gathered from the following sources: « *Internal Audits, Customer feedback, Annual product reviews and Output of management reviews …etc. »* (Tashi, Mbuya, & Gangadharappa, 2016). The third step consists of analysing the data using risk assessment tool, namely : matrix, which describes the frequency and the impact of the risk (Kavina, Charmy, Chirag, & Manan, 2019).

3. Perform root cause analysis:

This step refers to the identification of the causes of the problem by using a systematic approach there are many tools that can be used in this step including : Brainstorming , Process mapping value stream mapping , Bar chart/Pie chart , Pareto chart and Fishbone (Ishikawa) diagram (Kavina, Charmy, Chirag, & Manan, 2019).

4. Develop and implement action plan:

After identifying the root causes of the problem, an action plan is developed to specify the actions that will be done, the responsible for the execution of the plan , how and where it will be accomplished. Once the action plan is developed, it should be executed and all the intended actions should be completed (Rodriguez, 2007).

5. Follow-up:

All the actions executed must be documented so an independent investigation is conducted to confirm that they have been executed as planned (Rodriguez, 2007).

6. Verify the effectiveness of Action Plan and Confirm Preventive Action

We verify that the action plan is effective in eliminating the causes of the problem. Once we confirm the effectiveness of the action plan, we use it as a preventive action in other systems or in the same system to avoid the recurrence of the problem (Rodriguez, 2007).

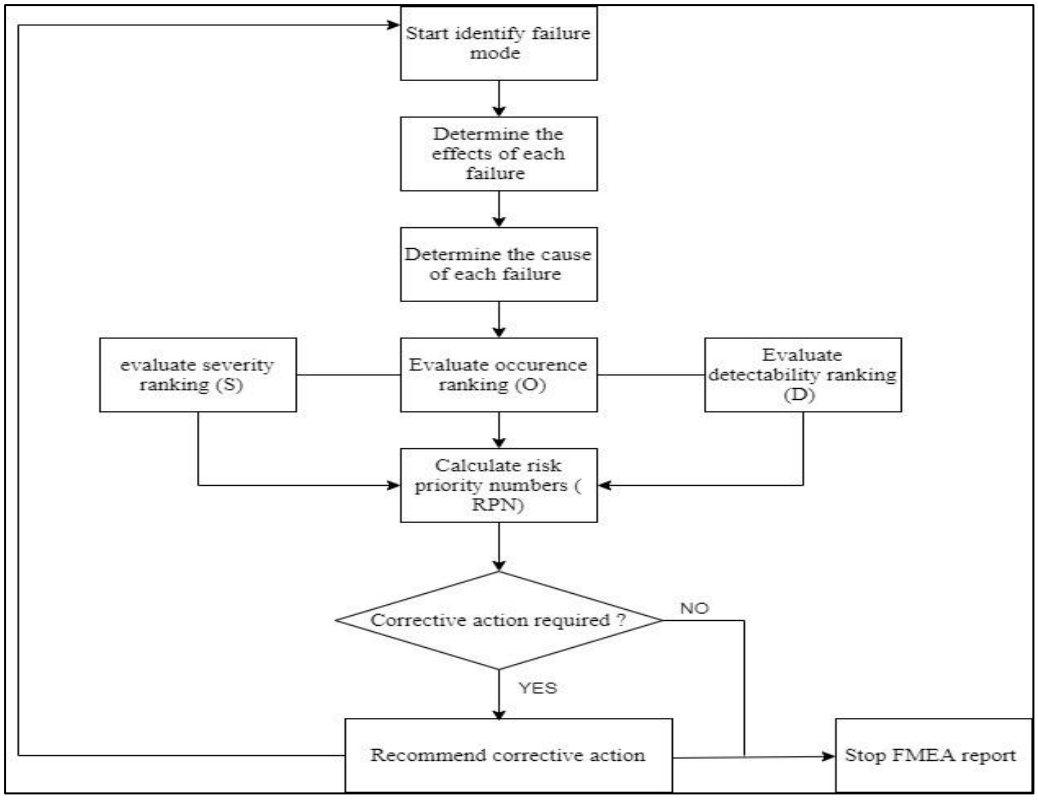
II. Failure Mode and Effect Analysis FMEA methodology

The FMEA is a proactive risk prevention technique used in the prevention of errors, failures and accidents ((McDermott , Mikulak , & Beauregard, 1996); (Chiozza & Ponzetti, 2009); (Ho & Liao, 2011); (Wang, Liu, Qin , & Liu, 2019)).

The FMEA introduced for the first time in 1949s in the army of the united states then it was introduced to the aerospace industry. The effectiveness of this technique in the automotive industry prompted the implementation of this technique in the development and manufacture of drugs for the medication errors prevention and to the general manufacturing ((Chiozza & Ponzetti, 2009); (Scipioni et al, 2002)).

Figure 12 shows the FMEA process

Figure n°12: FMEA process



Source: (Rah, Manager, Yock, & Kim, 2016)

According to (Chiozza & Ponzetti, 2009), the FMEA process covers the following 5 steps:

1. Choosing a process to be studied

The organisation should select the sub-process to be studied from the whole process, which is identified as the most exposed to errors in the literature or in the reports of the organisation.

2. Assembling a multidisciplinary team

The organisation assigns a group of operators from different domains of study and training under a leader who guides them through the FMEA process.

3. Collecting and organising information on the process studied

Team members should draw the diagram of the AS-IS process describing the actual situation of the process studied.

4. Conducting a hazard analysis:

This step involves five activities:

- Identification of failure modes for each step;

- Determining the potential effect of each failure mode;
- Ranking the severity of failure mode effects;
- Ranking the probability and detectability of each failure mode;
- Identifying the areas of greatest concern (critical failure modes);

5. Developing and implementing actions and outcomes measures:

After identifying the root causes of the critical failures the team members should establish the corrective actions to eliminate or reduce their risks.

III . Hazard Analysis and Critical Control Point HACCP system

The HACCP was developed during the period of 1960s by the Pillsbury Company in collaboration with NASA and the US Army Laboratories at Natick to ensure the food safety for the astronauts (Wallace, Sperber, & Mortimore, 2018). Then During the 1970s the FDA integrated the HACCP principles in the food canning regulations after recognising the need for the implementation of a system to control the food manufacturing. A few years later, the implementation of HACCP system became mandatory for a variety of food processing segments in the US and in other countries including Europe, Canada, Australia and New Zealand.

HACCP principles :

Principle 1. Conduct a hazard analysis

The HACCP team starts by modelling a process flow diagram describing all the steps in the process, then the team identifies the potential hazards in each step , and determines their likelihood of occurrence and the severity and impact of hazards on consumer's health, thereby determining the preventive measure to control the hazards (Mortimore & Wallace, 2013).

Principle 2. Determine the Critical Control Points (CCPs).

In this step, the HACCP team determines the critical control points to ensure the salubraty of the products (Mortimore & Wallace, 2013). A critical control point (CCP): *« is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level*. » (Hulebak & Schlosser, Hazard analysis and critical control point (HACCP) history and conceptual overview, 2002).

Principle 3. Establish Critical limits

critical limits is defined as: *« a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate , or reduce to an acceptable level of occurrence of a food safety hazard*. » (Appendices, 1998).

Principle 4. Establish a system to monitor and control the CCP

The HACCP team should establish monitoring system to control the CCPs and make ensure that they are within their critical limits (Mortimore & Wallace, 2013).

Principle 5. Establish the corrective actions to be taken when monitoring indicates that a particular CCP is not under control

Corrective actions should be implemented to correct deviations in processes and to correct the non-compliance in the products (Hulebak & Schlosser, 2002).

Principle 6. Establish procedures for verification to confirm that the HACCP system is working correctly.

Procedures should be established to verify the effectiveness of the CCPs to control of the hazards , and to ensure that the HACCP system is working according to a plan and on schedule (Mortimore & Wallace, 2013).

Principle 7. Establish documentation concerning all procedures and records appropriate to these principles and their application

The documentation established for the HACCP system should include the following elements:

Description of the HACCP system, the HACCP plan, the validation records and the records created during the execution of the HACCP plan (Appendices, 1998).

IV. Preventive control (HARPC)

In 2015, the FDA announced the HARPC as the new food safety regulation; this system constitutes a preventive control, which helps to determine potential risks in food. The HACCP is implemented after the occurrence of hazards to fix the critical limits, while the HARPC is a proactive system, which is implemented before the occurrence of hazards to provide corrective steps (Malik, Krishnaswamy, & Mustapha, 2021).

We may draw the following observations from the above discussion:

The HARPC is included in the FDS's FSMA regulations, while the HACCP comes under the the Codex Alimentarius and guidelines given by the National Advisory Committee on Microbiological Criteria for Food, this latter covers only biological , chemical and physical hazards , besides these hazards , the HARPC covers others including : radiological hazards, natural toxins…etc.

The HACCP requires: the identification of the CCPs, the critical limits, the verification of the process controls and the review of the HACCP system once a year.

The HARPC requires the identifications of CCPs and other points and parameters, the verification of the preventive controls, the elaboration of recall , and the update of the system once every three years.

CAPA is a set of actions rather than structured system or process developed by FDA to remove the causes of non-conformity or to prevent from them, it is based on the intelligence and experience of the responsible and his team to reveal the causes of failure and suggest treatment actions.

FMEA, HACCP and HARPC are structured by a set of steps that the responsible for risk prevention and his team follow to either treat the risk or prevent from them. However, all these systems depend on the knowledge of the team responsible for risk prevention and ignore the knowledge stored in the other employees' minds, and they lack of managerial aspects that help to capture these knowledge and used them to prevent from risks. These systems could be considered as tools that help the risk manager to prevent from risk but none of them covers the operationalisation part of any system, it does not provide the steps of its implementation and it could be abstract and conceptual for junior risk manager or researchers who ignore about the organisation's environment. In other words, they do not answer the following questions: From where should we start? what kind of knowledge should we look for to prevent from risks? Who process knowledge? How can we capture knowledge? Hence, it was important to develop the preventive management of risks, which equips the risk manager with the necessary managerial aspects that help him to cope with the knowledge related to risks to prevent from them.

In the following section, we are going to discover the preventive management of risks and the K-PIMRBP, the process that structured the theory.

Section II: Preventive management of risks

In this section we will define the concept of preventive management of risks and the process which structured this theory (K-PIMRBP).

I. preventive management definition

Initially, we may consider Preventive management of risks as an umbrella term, which entails two parts: Risk prevention and management, in other words the definition of this concept should describe the risk prevention as a particular area of study in the field of management and not only as a tool or set of actions that serve to prevent risks. In order to give this concept an exhaustive definition, we will examine the different definitions of this concept in light of the previous observation, but before this, we should define separately the two terms of management and risk prevention.

- **Prevention is defined as** « *the act of stopping something bad from happening* » (TURNBULL, LEA, & PARKINSON, 2010).
- **Risk prevention** can be defined as the act of stopping risks from occurring.
- **Management:** « *Is a steering* ***influence*** *on market, production and/or resource operations in an organization and its units that may address both people and non-people issues and is exerted by multiple organizational actors through either* ***anticipatory norm-setting*** *(¼ constitutive or strategic management) or* ***situational intervention*** *(¼ operational management) with the aim of achieving the* ***unit's objectives****. To manage a unit is synonymous with "directing" or "leading" it* » (Kaehler & Grundei, 2019).

According to this definition, the management is characterised by:

Its **impact** on the internal or external environment of an organisation, which is **materialised** by the establishment of organisational norms in the **strategic or tactic levels** or the execution of operations in the **operational level** for particular **purposes.**

Materialisation: the management is an abstract term concretised by either the norms of an organisation or its operations.

Impact: the organisational norms or operations should have an impact on the internal or external environment of an organisation.

Organisational level: the management should be associated with the strategic or tactic or the operational level of an organisation.

Purpose: the management should have specific objective.

In the table 18, we provide a comparison of the different risk prevention models in order to find out which one of them describes the risk prevention as a management discipline.

Table n°18: comparison between risk prevention and preventive management of risks

Risk prevention				**Preventive management of risks**			
Domain of application	**Risk Prevention system**	**Author**	**Definition**	**Management**			**Risk Prevention**
				Materialisation	Impact	Organisational level	Purpose
Food , beverage , medical and pharmaceutical Domains	**(CAPA)**	(ISO9000, 2015)	**Corrective action** *« Action to eliminate the cause of a nonconformity and to prevent recurrence»* **Preventive action:** *« Action to eliminate the cause of a potential non-conformity or other potential undesirable situation »*	Actions	Not mentioned	Not mentioned	- Eliminate the cause of non-conformity - Prevent recurrence
Army, automotive, drug and general manufacturing	**(FMEA)**	(McDermott , Mikulak , & Beauregard, 1996); (Chiozza & Ponzetti, 2009); (Ho & Liao, 2011); (Wang, Liu, Qin , & Liu, 2019)	The FMEA is a proactive risk prevention technique used in the prevention of errors, failures and accidents	Technique	Not mentioned	Not mentioned	Prevent from errors , failures and accidents
Food supply chain	(**HACCP**)	(Appendices, 1998)	*« A systematic approach to the identification , evaluation, and control of food safety hazard »*	Approach	Not mentioned	Not mentioned	Manage the hazard

Food safety	**HARPC**	Malik, (Malik, Krishnaswamy, & Mustapha, 2021)	The new food safety regulation; this system constitutes preventive controls, which helps to determine potential risks to the food supply, which is implemented before the occurrence of hazards to provide corrective steps	System	Not mentioned	Not mentioned	- Preventive controls
All domain	**(K-PIMRBP)**	(MAAMIR & DERGHOUM, 2021)	*« Preventive management of risks is a process based on knowledge converted from the integrated management of risks and business processes outcomes, then shared and stored in the databases in form of risk prevention procedures prepared to be applied to prevent risks»*	Process	Preservation of the created value in the business processes	Operational level (business processes)	Risk prevention

Source: elaborated by the author based on the theory

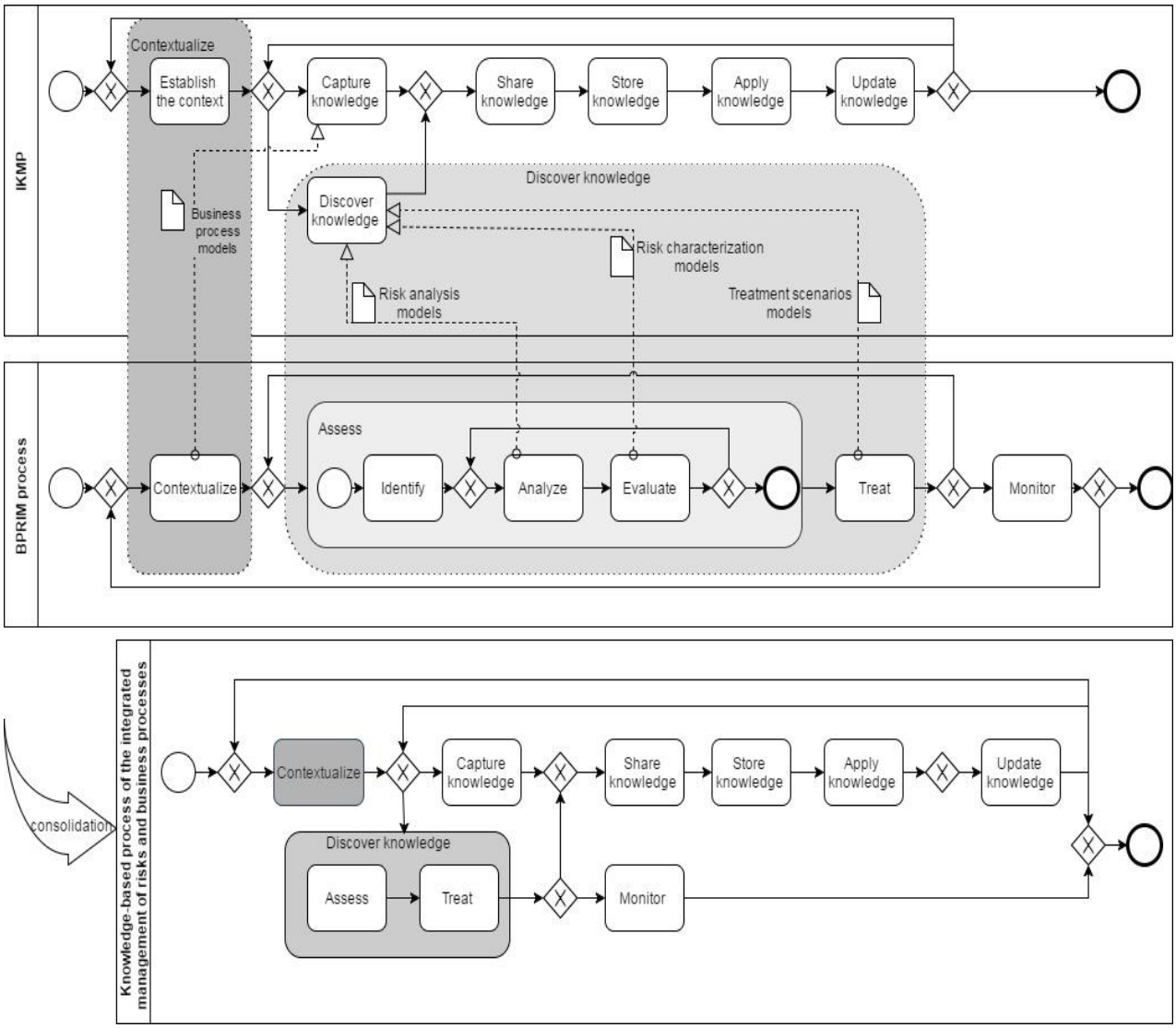
The results of the above table indicate that the preventive management of risks definition provided by Maamir and Derghoum (2021) is thorough, which describes the risk prevention as a sub-discipline in management sciences, particularly, in operational management, which is concretised by a process, which leads to risks prevention. The purpose of preventive management of risks implementation in enterprises is to preserve the created value within the business processes (MAAMIR & DERGHOUM, 2021). Thus, we will use this definition throughout the present study.

II. KNOWLEDGE –BASED PROCESS OF THE INTEGRATED MANAGEMENT OF RISKS AND BUSINESS PROCESSES (K-PIMRBP)

The purpose of the present thesis is to concretise the preventive management of risks theory in order to reveal how it contributes to the prevention of risks; hence, it is important to give an overview of the components of this process, which contributes to give the reader of this thesis a better understanding of the empirical study.

Figure 13 shows K-PIMRBP, which is the process that structures the preventive management theory and leads to the prevention of risks.

Figure n°13: K-PIMRBP



(MAAMIR & DERGHOUM, 2021)

The preventive management of risks is based on knowledge. The knowledge in the context of this theory consist of risk management outcomes in the form of BPRIM diagrams, including the risk context diagram, risk analysis diagrams…etc (MAAMIR & DERGHOUM, 2021). In line with this, (Emblemsvåg & Kjølstad, 2006) said: *« Risk analysis Here it suffices to acknowledge that this crucial step requires experience, Knowledge and creativity ».*

The K-PIMRBP includes two paths; the K-PIMRBP team should follow one of them according to the nature of risks studied. The first path includes the following steps: contextualise, capture knowledge, share knowledge, store knowledge, apply knowledge and update knowledge, this path is followed when the risk studied is an existing risk. While in the case of a new risk, the K-PIMRBP team should follow the second path, which encompasses the following steps:

contextualise, discover knowledge, if the discovered knowledge do not meet the needs to manage the risks within the business processes, the K-PIMRBP team should restart the process. While if the knowledge is sufficient, it may be shared among the workers then stored in the databases or the manuals of the enterprise in order to be applied to prevent risks. Knowledge should be updated frequently.

In the following sub-sequence, we describe the role of each activity in the K-PIMRBP as follows:

In table 19, we describe the contextualisation activity:

Table n°19: contextualisation activity

Contextualise	
Description	*« This stage aims at establishing the context of both the IKMP and BPRIM process by coupling the IKMP objectives with BPRIM process objectives. » (MAAMIR and DERGHOUM , 2021)* The objective of knowledge management consists of establishing the blueprint of the project, which depends on the nature of risks studied. In the case of actual risk, which has occurred in the business processes of an organisation, the objective of knowledge management will consist of capturing the knowledge or in the case of new risk, which does never occur in the business processes, the objective will consist of discovering or creating the knowledge. In both cases, the blueprint should determine the actors involved in the project: including the individuals who possess the knowledge and those who will work on the project. It is necessary to determine in this stage the strategy that will be adopted to prompt individuals to share their knowledge related to risks (i.e. causes, situation of risks …). The objectives of the risk-business process management includes both the objectives of risk management and business process management which consist of modelling the risk management context (i.e. modelling the organisational chart, business processes) The establishment of the context of the preventive management of risks starts by determining the nature of the risk studied, then modelling the risk management context and finally setting the blueprint for managing the

	knowledge stored or that will be created in the business processes of the enterprise for the prevention of risks. The K-PIMRBP team should be multidisciplinary and involve operators from the field of risk management and business process modelling. The team should also master the ICT tools and they should involve and collaborate with all the employees in risk prevention project.
Output	- Nature of risks studied - The objectives of knowledge management of risks : capturing or creating the knowledge - Diagrams describing the context of risk management : the units of the organisation involved and concerned by the study , business processes and their activities , actors involved in the study , the objective of the organisation and its units , the value created within the business processes Establishing the strategy for managing the knowledge within the business processes

Source: elaborated by the author

In table 20 we describe the discovery activity

Table n°20: discovery activity

Discover knowledge	
Description	**In the case of a new risk** , knowledge discovery is necessary for creating an organisational memory containing the outcomes of two steps of the BPRIM , which are risk assessment and risk treatment (MAAMIR & DERGHOUM, 2021). Lamine et al (2020) described these two steps as follows : 1. **Risk assessment:** consists of examining both risks and business processes; it involves the identification of risks in the business processes, the analysis and the evaluation of risks. the outcomes of risk assessment are in the form of diagrams 2. **risk treatment:** this step consists of integrating the treatment scenarios into the risk assessment diagrams to eliminate or reduce the effects of the risks identified,

	Risk management team should work in collaboration with business process modellers to model the diagrams of risk assessment and integrate them with the AS-IS business processes, and the TO-BE business processes which integrate the risk treatment scenarios.
Outputs	- Risks taxonomy; - Risk-extended BP diagrams ; - Risks analysis diagrams; - Risks treatment diagrams.

Source: elaborated by the author based on theory

Table 21 describes capture knowledge activity

Table n°21: capture knowledge activity

Capture knowledge
In the case of actual or **existing risk**, the K- PIMRBP team should capture the knowledge related to risk management outcomes from the organisational operators who possess these knowledge, which are developed tacitly throughout their presence in the enterprises and generated from their experience in dealing with risks that occurred in the enterprise (MAAMIR & DERGHOUM, 2021). According to (Aming'a, 2015) there is a plethora of tools and mechanisms for knowledge capture including : - Recruiting - Training - Expert systems - Brainstorming - Mentoring - Knowledge repository - Structured or unstructured interviews - Observation The nature of knowledge captured using those tools is in the form of verbatim, reports, observations, numbers, charts …etc. The K- PIMRBP team should transform this knowledge into BPRIM diagrams.
- Risks taxonomy;

- Risk-extended BP diagrams ; - Risks analysis diagrams; - Risks treatment diagrams.

Source: elaborated by the author based on theory

In table 22 we describe knowledge sharing activity

Table n°22: knowledge sharing activity

	Share knowledge
Description	Knowledge sharing activity has been already discussed in the first chapter of the present thesis, which is the same as the activity involved in the K-PIMRBP. However the nature of knowledge is different, in the preventive management process the knowledge shared is in the form of diagrams. According to (Abu-Shanab, Knight, & Haddad, 2014) ; (Chau, Maurer, & Melnik, 2003); (Mazorodze & Buckley, 2020). knowledge sharing tools include: - Communities of practice - Knowledge networks *(collaborative team members constitute a community network)* - Training - Documentation - Mentoring - Coaching - Story telling - Knowledge repositories

Source: elaborated by the author based on the theory

In table 23 we describe knowledge storage activity

Table n°23: knowledge storage activity

	Store knowledge
Description	« *Save the knowledge (preventive procedures) in the organisational knowledge repository in the form of manuals and computerised files.* » (MAAMIR & DERGHOUM, 2021).

	The K- PIMRBP team should create knowledge repository containing the BPRIM diagrams in paper and electronic format
Outcomes	- Database containing the BPRIM diagrams - Manuals containing the BPRIM diagrams

Source: elaborated by the authors based on the theory

Table 24 describes the knowledge application activity

Table n°24: Apply knowledge

	Apply knowledge
Description	The aim of this step is to incorporate K- PIMRBP diagrams/knowledge within the enterprise operations (i.e. ensure both the execution of the fabrication process and the application of K- PIMRBP diagrams/knowledge). In addition, implement the treatment scenarios to correct and prevent from risks.

Source: elaborated by the authors based on the theory

In the table we describe update knowledge activity

Table n°25: update knowledge activity

	Update knowledge /monitor
Description	Control the effectiveness of the K- PIMRBP in preventing the risks within business processes , in the case of new risks , the K-PIMRBP team should update the knowledge stored in the databases and the manuals of the enterprises and report them to the rest of employees

Source: elaborated by the authors based on the theory

Conclusion of the chapter

Risk prevention is based on knowledge (Neef, 2005), so based on this idea (MAAMIR & DERGHOUM, 2021) developed the preventive management of risks theory, which is structured by K-PIMRBP. The main contribution of this process is the management of knowledge related to risks within the organisation. Hence, we devoted these two chapters to explain this new theory and the concepts around it. The first chapter includes two sections; in the first one, we defined the risk and the concept around it, while in the second section we presented the three approaches of risk management. The second chapter involves two sections in which we provided a discussion about the difference between risk prevention and preventive management of risks.

Chapter III:
Methodology

Chapter III : Methodology

Introduction

In this chapter, we will present the methodology adopted in the present study, which involves three sections, in the first section, we will outline the research strategy and the context of the study. In the second section, we will define the paradigm adopted in this study and in the third section, we will define the methods used and the data analysis.

Section I: research strategy and context of the study

In this section, we will outline the research strategy and the context of the study.

I. Research strategy: case study

To conduct any research, it is necessary to adopt a specific strategy, which helps planning, applying and controlling the study (Cobb, 1998, p. 39). In the present study, we adopt case study strategy, which focuses on the case studied, and provide in-depth information on that case (Cobb, 1998, p. 39). According to (Yin, 2003, p. 9), the case study is used when: "*How and why question is being asked about a contemporary set of events, over which the investigator has a little or no control*." In other words, the case study strategy is used when we want to answer "How" or "what" questions and the second condition to use this strategy is the examination of actual events that we cannot manipulate or change. Those conditions suit the purpose of the thesis, in which we aim at applying the preventive management process to enterprises in order to understand "**how**" may this process serve to prevent from the operational risks in cases studied , for that we will observe events and conduct interviews to collect the data without changing or manipulating the events examined. In addition, this strategy allows us to collect information, investigate the phenomenon in-depth within its context, and therefore answer the research question.

I.1 Case study design

According to (Yin, 2003, p. 47), there are two main types of designs for the case study strategy, including single case designs and multiple case designs, in the following table we discuss the rationales for the use of each design:

Table n°26: rationales for the use of single/multiple case designs

Single case study is applied ,when it represents:	**Multiple case study is applied when :**
• A critical case to test pre-defined a theory; • A unique case when for example a study very unique , so the examination of one case will be enough; • A representative case among other cases within the same context; • A revelatory case that researchers could not examine in the past; • A longitudinal case; • Multiple case is applied, when there is a need to replicate the study in different cases	We want to replicate the results of a research in others researches. There are two types of replications namely: **literal replications** when the findings in all cases are the same and **theoretical replication** when the results of the cases are in contradiction with the a theory

Source: (Yin, 2003)

In the present thesis, we adopted multiple case study design, because the main purpose of the thesis is to obtain practical implications through the application of the preventive management process to enterprises. The K-PIMRBP is still an abstract model, which was not previously applied to real cases, so we tried through the present thesis to concretise it, which will give a better comprehension of the theoretical model and its practical outcomes. In addition, we obtained through the replication of the process in multiple case study, solid findings that illustrated the theoretical model; on the other hand, it served to understand the outcomes of K-PIMRBP to prevent from the operational risks.

We aim that the present thesis will be a reference and guidance for researchers in the field of preventive management of operational risks and practitioners in this field, hence we provided in the following chapters the steps that should be followed in the preventive management of risks.

Chapter III : Methodology

I.2 The quality of research design

The evaluation of the case study design quality is crucial, for that, four tests were determined namely: construct validity, internal validity, external validity and reliability (Yin, 2003); (Riege, 2003).

Table n°27: research design quality

Case study design tests	Corresponding design tests	Case study techniques	Phase of research in which techniques occur
Construct validity	Confirmability (corresponding to objectivity and neutrality of positivism)	- Use multiple sources of evidence - Establish chain of evidence - Have key of informants review draft case study report	Data collection Data collection Researcher's diary and report writing
Internal validity	Credibility	- Do within-case analysis, then cross-case pattern matching - Do explanation-building - Assure internal coherence of findings and concepts are systematically related	Data analysis Data analysis Data analysis
External validity	Transferability	- Use replication logic in multiple case studies - Define scope and boundaries of reasonable analytical generalisation for the research - Compare evidence with extant literature	Research design Research design Data analysis
Reliability	Dependability	-Give full account of theories and ideas - Assure congruence between research issues and features of study design - Develop and refine case study protocol - Use multiple researchers - Record observations and actions as concrete as possible - Use case study protocol - Record data, mechanically develop case study database - Assure meaningful parallelism of findings across multiple data sources - Use peer review/examination	Research design to data analysis Research design Research design Data collection Data collection Data collection Data collection Data collection Data analysis

Source: (Riege, 2003)

- **Construct validity**

Triangulation is a way of obtaining validity (Flick, 1992), so the use of different data collection methods to avoid researchers' bias (Riege, 2003). The researcher must include in the study report the verbatim of the interviews to increase the validity of the study. (Riege & Nair (1996) mentioned by (Riege, 2003)). The participants in the study should review a part of the results of the study and the researcher should take into consideration their comments in his report (Yin, 2003, p. 159).

In the present study, we adopted mixed methods, in which we used different instruments to collect data, namely, interviews, observation and questionnaire. We included verbatim notes in the qualitative results and as a part of our study the results founded were shared with the participants and we considered their comments (we will detail this point in the following chapter).

- **Internal validity**

In first phase of multiple case study analysis, it is necessary to use within-case analysis in which each case study is described individually then use cross case to compare and match the results of each case study ((Liu, Maitlis, Mills, Durepos, & Wiebe, 2010); (Riege, 2003), (Yin, 2003)). It is necessary also to include the diagrams and data analysis outcomes in the study report (Miles and Huberman mentioned by (Riege, 2003)).

In the present study, we presented the findings of each case separately then we matched between them to obtain a conclusion that leads to answer the main research question, we involved also in the empirical chapter all the diagrams generated from the findings of the study.

- **External validity**

It deals with the results generalisation, according to (Yin, 2003) the single case study should be directed by a theory, which helps to select the case that should be studied, and the results of the study will be generalised based on this theory. However, in multiple case studies, the replication logic should be adopted to generalise, or not, the findings of the study.

In the present study, we replicated the study in three enterprises of production namely: two Agri-food enterprises and one pharmaceutical enterprise , All the production companies have some operational risks in common, including, contaminations , in addition two enterprises are from the same sector, which reinforce the results of each case and therefore increase the external validity of the results.

- **Reliability**

We say that the results or a study is reliable, when another researcher follows the same steps reported during study conduction, so he arrives to the same results as the earlier study. To ensure the reliability, it is recommended to displays in the reports the protocol case study, the records and the data collected during the study, the study should be also peer reviewed.

In this chapter and chapter four, we detailed the case study protocol and we included the records and data collected.

II. Research context

K-PIMRBP could be concretised in any enterprise, but as we treat in the present study the operational risks, we judged important to apply the model in production companies, where the operational risks have a significant impact on the products.

In the following sub-section we give a brief description of the cases studied in the present study.

Case I: Colaital-SPA

Colaital is a joint stock company situated in Birkhadem; it is a subsidiary company of GIPLAIT group. It produces about 400000L/per day. It has many products namely: Lben , Packaged pasteurised milk PPM, yogurt,…etc.

In the present study, we chose to study packaged pasteurised milk PPM.

Case II: Sosémie

It is industrial commercial and production company , it produces semolina, flour, couscous and all types of pasta. It was created in 2001 and it has about 300 employees. Sosémie is Limited Liability Corporation (LLC). It is situated in Beni Mered-Blida.

Case III: Frater-Razes

The group of laboratory Frater-Razes , is a national group created by Doctor Abdelhamid Cherfaoui in 1992, it was a distribution company of pharmaceutical products. In 1994, the company has started importing pharmaceutical production , then in 1999 it has created the first industrial unit of dry form of pharmaceutical products .In 2003, it has created the injectable forms of products unit , then in 2013, it has launched a project on the development of biotechnology production. In 2020, it has started producing the first biosimilar drug

The group includes five subsidiary companies, namely:

SPA SOMEPHARM distribution, SPA PROVIVO importation, SPA LFR promotion, SPA les laboratoires FRATER-RAZES forme séche and SPA Frater-Razes form injectable.

We completed our internship in Frater-Razes forme séche (dry forme).

Section II: Paradigm

In this section, we will define the paradigm adopted in the present study

I. Paradigm

It is defined as « a basic set of beliefs that guide action » Guba 1990; mentioned by (Creswell & Poth, 2017, p. 19), so the research is directed by the paradigm. It is also, called the researchers' worldview (Mackenzie & Knipe, 2006), in other words the school of thought followed by the researchers influences the meaning of the study findings and therefore the paradigm influences the methodology and methods choice (Kivunja & Kuyini, 2017).

Table 28 shows the four main types of paradigms

Table n° 28: the four main types of paradigms

Paradigm	Positivism	Post-positivism	Pragmatism	Constructivism
Methods	Quantitative	Primarily quantitative	Quantitative+ qualitative	Qualitative
Logic	Deductive	Primarily deductive	Deductive+ inductive	Inductive
Epistemology	Objective point of view. Known and knower are dualism	Modified dualism. Findings Probably objectively "true."	Both objective and subjective points of view	Subjective points of view Known and knower are inseparable
Axiology	Inquiry is value-free	Inquiry involves value but they may be controlled	Values play a large role in interpreting results.	Inquiry is value-bound
Ontology	Naïve realism	Critical or transcendental realism	Accept external reality. Choose explanations that best produce desirable outcomes.	Relativism
Causal linkages	Real causes temporally precedent to or	There are some lawful, reasonably stable relationships among social	There may be causal relationships, but we will	All entities simultaneously shaping each other. It's

	simultaneous with effects	phenomena. These may be known imperfectly. Causes are identifiable in a probabilistic sense that change over time	never be able to pin them down	impossible to distinguish causes from effects

Source: (Tashakkori, Teddlie, & Teddlie, 1998)

According to (Tashakkori, Teddlie, & Teddlie, 1998), each paradigm is oriented towards a specific methodology. The post-positivism and positivism follow quantitative methodology because they generally investigate causal relationships between variables while constructivism follows qualitative methodology. However, for pragmatists each methodology is important and the choice of methodology relies on the nature of the research question , in other words according to this current, the paradigm should not influence the use of the methodology and the researcher should focus on ‘what works ‘ and how to answer the research question. For pragmatists we cannot reach the reality with one scientific methods and mixed methods and triangulation lead to discover knowledge (Kivunja & Kuyini, 2017).

We adopted in the present thesis the pragmatism because, on the one hand, it is the most suitable paradigm for case study strategy (Kivunja & Kuyini, 2017). On the other hand, this paradigm allows us to adopt mixed methods to answer the main research questions and attain the objectives of the thesis.

The paradigm encompasses four parts, including, ontology, epistemology, axiology and methodology (Lincoln & Guba, 1985).In this subsection we discuss these elements in the context of pragmatism since it is the paradigm adopted in the present thesis.

According to (Tashakkori, Teddlie, & Teddlie, 1998):

Ontology: it examines the nature of reality studied, pragmatists share the same opinion as positivists and post-positivists on the existence of an external reality but they disagree with them on the existence of only one explanation of that reality. For pragmatists the reality has many explanations and the researcher should choose the best interpretation of the reality.

In the present study, the purpose of the interviews conduction is to determine the operational risks in each case and reveal the potential solution to prevent from them. We focused our attention on one factor that we consider the main factor that leads to prevent from these risks, which was tested through a questionnaire in the end we provided one interpretation to the main research question.

Chapter III : Methodology

Epistemology: it examines the nature and the form of knowledge, the manner to acquire knowledge and the relationships between the researcher and the known (Kivunja & Kuyini, 2017). In the pragmatism, the standpoints are objective and subjective in the same time, because of the use of both quantitative and qualitative approaches. On the one hand, the acquirer interacts with the known in the qualitative approach while in the quantitative approach the acquirer and the known are independent (Tashakkori, Teddlie, & Teddlie, 1998).

As aforementioned, we determined from the qualitative findings, one factor that leads to risk prevention in each case from our point of view and based on the interpretation of qualitative findings, which was tested later through, a questionnaire conducted with the employees of the enterprise, which emphasises the objectivity in the results interpretation.

Axiology: it refers to the ethical considerations and values during research conduction (Kivunja & Kuyini, 2017). In pragmatism, the research is guided by the personal value of researcher from choosing the topic to the way of studying the topic, to the selection of the units studied and data analysis they also anticipate the findings of the study (Tashakkori, Teddlie, & Teddlie, 1998).

We conducted the present study with respect to scientific ethics and rigour. We chose the topic and the research question based on a literature review discussed in the previous chapter, the selection and analysis of data will be discussed in the following section. The findings interpretation were based on accurate data that will be display in the following chapter.

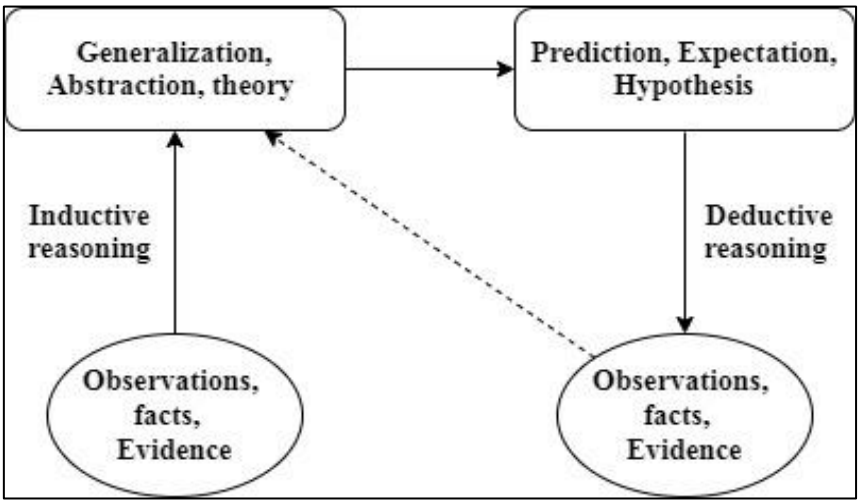
Causal linkages . On the one hand, there are causal relationships between variables , on the other hand we should accept the explanations that are congruent with the researchers' values (Tashakkori, Teddlie, & Teddlie, 1998).

We formulated a causal relationship between variables based on our interpretation of the qualitative findings.

Logic: In pragmatism, both deductive and inductive logics are accepted; the researcher can start from the construction of theoretical framework that should be experienced empirically or he can start from the observation of facts to construct then a theory (Tashakkori, Teddlie, & Teddlie, 1998).

In the present study, we adopted both inductive and deductive reasoning and we followed the same logic as represented in figure 14.

Figure n°14: inductive and deductive logic



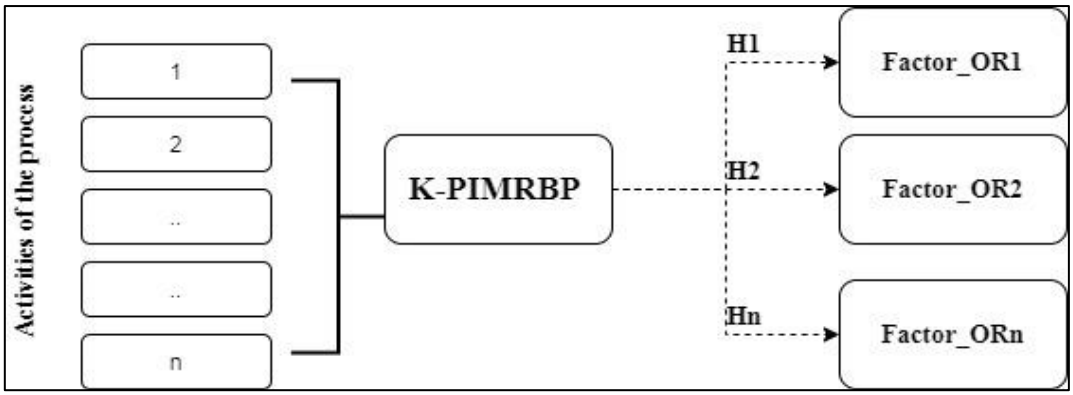
Source: (Yin, 2003)

In order to answer the main question of the study which consists of explaining the role of the preventive management process in preventing from the operational risks in enterprises. Hence, in the first phase ***"(1) inductive reasoning"*** we conducted interviews for the purpose to understand the nature of the operational risks in each case and reveal **the factor** that the enterprise should work on to prevent from the operational risks . Then based on qualitative findings we formulated hypotheses on the influence of the preventive management process **(K-PIMRBP)** ***"dependant variable"*** on that **"factor"** , we examined **the effect of that factor on each operational risk** separately which constituted the **" independent variables"**

(We will discuss deeply about **that factor**, **the operational risks** and **the independent variables** in chapter IV **)**

The figure 15 shows a model of the conceptual model for each case study

Figure n°15: a model of the conceptual model



Source: elaborated by the author

Chapter III : Methodology

In the second phase we applied the K-PIMRBP to the cases and in the third phase **(2) deductive reasoning)** we tested the hypotheses of the conceptual model to answer the main question.

Section III: Methods and data analysis

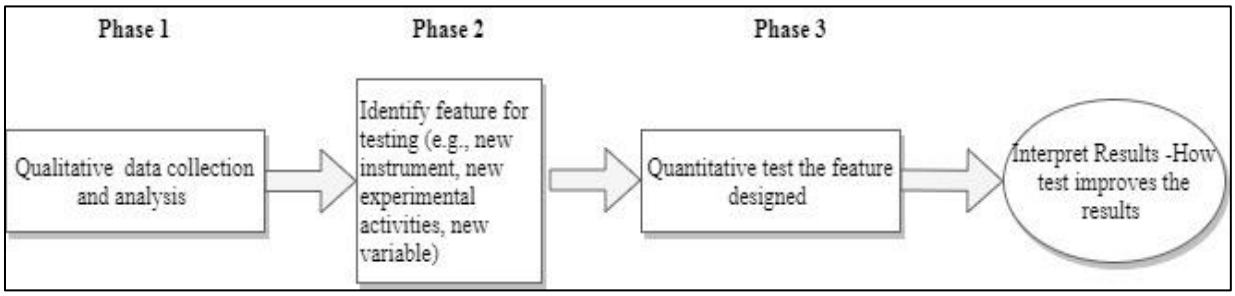
In the present section, we will expose the method adopted in the present study and the data analysis strategy.

III.1 Mixed methods

(Creswell & Creswell, 2017), determined three different designs for mixed methods, namely, Convergent design, Explanatory sequential design and Exploratory Sequential Design. In the present study we adopted Exploratory Sequential Design.

Figure 16 shows « Exploratory Sequential Design(Three-Phase Design) »

Figure n°16: Exploratory Sequential Design



Source: (Creswell & Creswell, 2017, p. 300)

Phase 1: qualitative data collection and analysis

The aim of this study is to understand the role of K-PIMRBP in preventing from operational risks. Hence, in the first phase we conducted interviews with responsible persons in the enterprises to determine the operational risks specific to each enterprise and reveal from them the main **factor that enterprises** should work on to prevent from operational risks. We did not mention neither the names nor the position of the interviewees as requested by them who asked for anonymity. In addition, the interviewees are responsible persons, they were all the time occupied with work, so the interviews were interrupted, and sometimes were postponed, therefore we did not record the time of the interviews and our focus was on the data transcription. Based on the qualitative findings we formulated the hypotheses of the study to test if the K-PIMRBP has an influence on the factor that leads to risk prevention, which was revealed in the first phase.

Phase 2 : Application of K-PIMRBP

In the second phase, we applied the K-PIMRBP in enterprises (the details of the outcomes of the application of K-PIMRBP are included in chapter four); for that, we completed three internships in three enterprises, where we passed between four to more than six months in each enterprise. The purpose of these internships was to attend to products' fabrication in the premises of the enterprises where we observed and interacted with the employees to understand every step in those processes, which allowed us to model these processes. Our presence in the premises allowed us to reveal from employees and workers the potential operational risks that may occur in the fabrication process from the reception of the raw material to the final product, in collaboration with responsible persons we assessed and we proposed treatment scenarios for those risks. We shared the diagrams of K-PIMRBP that we stored in files with workers.

Phase 3: Quantitative data collection

We were supposed after concretising K-PIMRBP and obtaining the diagrams, apply the outcomes of K-PIMRBP to the enterprises, which consists of the implementation and the use of these outcomes by the enterprises to prevent from operational risk during a period of time, and after this period we assess the effectiveness of the K-PIMRBP out in preventing from the operational risks. In other words, we re-observe the fabrication processes and premises to see if the operational risks that were determined previously were eliminated or they still exist. However, it was not possible to integrate the K-PIMRBP within enterprises' operations, hence we opted for an alternative to assess the effectiveness of the K-PIMRBP, so we conducted a questionnaire with the workers with whom we shared the outcomes of K-PIMRBP in order to evaluate if the sharing of diagrams with them positively influenced **the factor** (see figure) that lead to risk prevention or not (this step will be detailed later) .

III.2 Data collection: Triangulation

In the present study, we used instrument triangulation technique, which helped us to answer the main research question.

Interviews:

In the first phase of the study, we conducted interviews with responsible persons, as aforementioned we opted for anonymity as requested by the interviewees and we did not mention the duration of the interviews as they were cut and postponed.

Chapter III : Methodology

We prepared an interview guide (for more details about the themes and questions see chapter Four). Note that the interviews were in Arabic and French, and then we translated them into English.

Documentations:

We were allowed to consult internal documentations and take all the information necessary from them, but for confidentiality purposes, we were not allowed to include them in the thesis.

We will detail in chapter four the documents used in the present study.

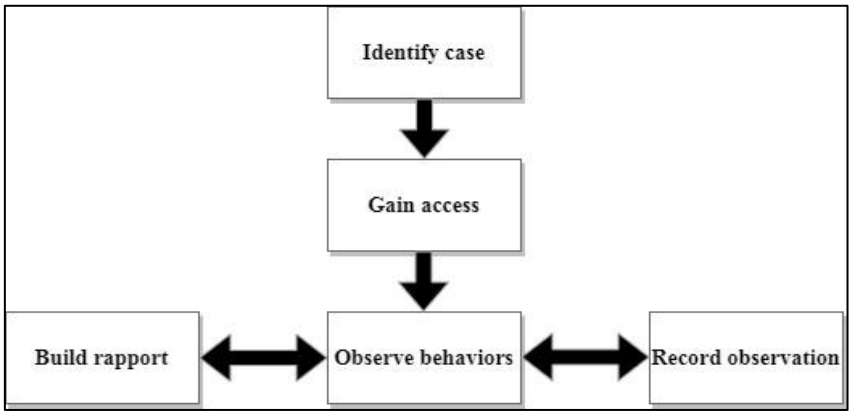
We used the following documents: HAACP, organisational charts, procedures.

Participant observation:

We used participant observation in the present study for many reasons, firstly, to understand the fabrication process of the products, secondly, to observe the internal environment where the products are produced to assess cleanliness of premises, equipment and personal hygiene , thirdly to determine with the help of workers the potential operational risks within the fabrication processes.

According to (Brancati, 2018), participant observation includes steps that the researchers should follow (see figure):

Figure n°17: participant observation steps



Source: (Brancati, 2018)

1. **Identify case:**

In the present study, we selected production companies, as we treat in the present study the operational risks so the application of this study in this kind of companies will illustrate better the model because of the significant impact of these risks on these enterprises. We focused on

the operational level where the products are produced to observe the process of fabrication and interact with the workers who are working in the premises of the enterprise to benefit from their experience.

2. Gain access

We gained access to these enterprises through agreements between the enterprises and the higher school of commerce signed by both the school director and the responsible of enterprises. By which we could enter to the enterprises observe the fabrication processes and interact with workers.

3. Building rapport

In the beginning of the internship, we were introduced as a Ph.D. student by the human resources department to the production responsible and laboratory responsible (in the case of Colaital and Sosemie) and introduced by the general director to production responsible in the case of Frater-Razes. We were then introduced by these latter to the workshop managers and line responsible who guided us during our presence in the premises and helped us while interacting with the other workers. During our presence we could build confidence with employees through our attitude , we showed respect to every one regardless his position and we listened to them carefully , we made them comfortable by asking for appointment before coming to the enterprise and when we found them busy we postponed the appointment.

4. Observe behaviour

We focused our attention during our presence in premises on supervisors and workers who are in contact with the products so they could be the source or contribute to operational risks occurrence and who acquire the tacit knowledge about the products, so they can help us to achieve the purposes of the study.

We observed their behaviours during product processing, to determine the product safety and the degree of awareness towards that.

5. Record observation

We were allowed to take photos of the fabrication process at only Sosémie and Frater-Razes, and we took note of the workers behaviours that affect the final product.

We did not include in the thesis those notes, because we judged more important to include only the conclusions extracted from them.

Chapter III : Methodology

The purpose of the participant observation is to describe fabrication process and the behaviours within the premises to reinforce the qualitative and quantitative data.

Questionnaire

The purpose of the questionnaire was to support or reject the hypotheses of the study to answer the research question of the thesis.

We elaborated for each case a questionnaire and each of them includes three parts:

- **First part:** includes questions related to personal characteristics of the respondent
- **Second part:** includes dimensions, where each one measures **(the effect of the factor that lead to risk prevention)** on **one operational risk.**
- **Third part:** Includes dimensions, where each dimension measures one activity of K-PRIMBPR (i.e., the activity of " context establishment")

Questionnaire administration

The following table shows the period of the questionnaire distribution in each case.

Table n°29: questionnaire distribution period

Colaital-SPA	5 September- 16 September 2021	Paper version
Sosémie	15juin-7july 2022	Paper version
Frater-Razes	20october-29 October 2022	Paper version

III.3 Sampling

According to (Israel, 1992), if the population is small (i.e. 200≤p), the researcher should use the consensus in which he surveys all the population.

In the present study the focus ,in the three enterprises studied, was on the operational level (i.e. premises, production workshops, production lines), in which the number of employees is less than 200 in the three enterprises and therefore we distributed the questionnaire with all the employees working in the operational level.

The respondents profile are described in the following tables:

Table 30 shows the respondents' profile at Colaital, the total number of responses is 52, in which 88.5% (46) of them are male, while the rest are female. 36.5 %(19) of respondents' reached middle school level , 23% (12) are graduated from universities, 21.2% (11) reached

secondary school and the rest primary school. 52%(27) of the respondents have worked for Colaital for more than 9 years, while 23%(12) have worked for the company for 7 to 9 years, and the rest has less than 6 years with the company. 55.7 %(29) of the workers in recombination workshops filled in the questionnaire, 28.8% (8) of the respondents are from pasteurisation and packaging workshops and 15.4% (8) are from the laboratory of the company(we included in this category, because they contributed the most in that study)

Table n°30: respondents' profile –Colaital

Population=168	**Number of responses=52**		**Response rate= 31%**
Gender	**Females**	**6**	**11.5**
	Males	**46**	**88.5**
Education level	**Primary school**	**10**	19.2
	Middle school	**19**	**36.5**
	Secondary school	**11**	**21.2**
	Tertiary education	**12**	**23**
Experience	**1-3**	**6**	**11.5**
	4-6	**7**	**13.5**
	7-9	**12**	**23**
	More than 9 years	**27**	**52**
Structure	**Quality direction**	**8**	**15.4**
	Recombination workshop	**29**	**55.7**
	Pasteurisation & packaging	**15**	**28.8**
Position	**Responsible**	**5**	**9.6**
	Engineer	**1**	**1.9**
	Technician	**5**	**9.6**
	Workshop manger	**13**	**25**
	Other	**28**	**53.8**

Source: elaborated by the authors

Table 31 shows the respondents' profile at Sosémie, the majority of them are male who constitute 98.3% (58) of the respondents, while the rest are female. 49.1% (29) of the respondents reached middle school level, followed by 33.9% (20), who reached secondary school , only 6.8% of the respondents have degrees and the rest reached primary school level. The majority of respondents worked for Sosémie for 4 to 6 years, 25.4% (15) of the respondents

worked for the company for 7 to 9, followed by 20.3% (12) of the respondents who worked for 1 to 3 and the rest for 9 or more years.

The majority of the respondents are operators who represent 40.7% (24), four line mangers and four responsible participated in our census, and the rest of the participants are either packaging agents or cleaning agents…etc.

Table n°31: respondents' profile –Sosémie

Sosémie= 66	**Number of responses= 59**	**Response rate=89.4%**	
Gender	Females	1	1.7
	Males	58	98.3
Education level	Primary school	6	10.2
	Middle school	29	49.1
	Secondary school	20	33.9
	Tertiary school	4	6.8
Experience	1-3	12	20.3
	4-6	23	39
	7-9	15	25.4
	More than 9	9	15.2
Position	Responsible	4	6.8
	Operator (fabrication unit)	24	40.7
	Packaging agent	9	15.2
	Line manager	4	6.8
	Other	18	30.5

Source: elaborated by the author

Table 32 shows the respondents' profile of Frater-Razes. The female dominate the population who constitute 75.3(49) of the respondents, while the rest are male. The majority of respondents graduated from universities and only 21.5% (14) reached secondary school level. The majority of the respondents' have been working for Frater-Razes for 3 years or less, who constitute 73.8% (48), which shows high turnover rate and the have been working there for 4 years or more. 55.4% (36) of the respondents are help operator, 27.7% (18) are operators, 6 supervisors and one responsible participated in the survey and the rest are either warehousemen or preparers.

Table n°32: respondents' profile –Frater-Razes

Population= 95 Number of responses=65 Reponses rate= 68.42%			
Gender	Females	49	75.3
	Males	16	24.7
Educational level	Primary school	0	0
	Middle school	0	0
	Secondary school	14	21.5
	Tertiary school	51	78.5
Experience	1-3	48	73.8
	4-6	10	15.4
	7-9	4	6.1
	More than 9	3	4.6
Position	Operator	18	27.7
	Help operator	36	55.4
	Preparer	2	3
	Warehouseman	2	3
	Supervisor	6	9.2
	Responsible	1	1.5

Source : elaborated by the author

Responses rate

In surveys, there is no fixed acceptable response rate (Mellahi & Harris, 2015). However, (Goyder, 1985) argues that the response rate should be above 30%.

In the presented study the response rates varied between 31% and 89.4% :

Response $rate_{COLAITAL}$ = 31%

Response $rate_{Sosémie}$ = 89.4%

Response $rate_{Frater\text{-}Razes}$ = 68.42%

III. 4 Data analysis:

Qualitative data analysis

The interviews were not recorded as requested by the interviewees, hence we transcribed the verbatim during the interviews in French and Arabic then we translated them into English. We opted for content analysis to analysis the verbatim, which allows the researcher to analyse the thoughts of the interviewees in objective and reliable manner, which includes three steps, namely, transcription, coding and treatment (ANDREANI & CONCHON, 2015).

In the present study, after transcribing and translating the verbatim in English, we eliminated the irrelevant words and phrases and we kept only the verbatim related to the topic of the study.

Then we applied close coding in which the codes (i.e. themes) are beforehand set, and then we treated manually the verbatim as discussed in chapter four.

Quantitative analysis

In order to analyse the quantitative data collected by using questionnaire, we used the PLS-SEM methods, which is the most appropriate for small sample sizes and the complex structural model involving many items (Hair , Risher, Sarstedt, & Ringle, 2019).

The samples of the present study are very small they include less than 100 units, which is normal in case studies. In addition, the structural models of the three cases are very complex (see chapter four).

Conclusion of the chapter

In this chapter, we outlined the methodology adopted in the present study, which involved three sections: in the first section, we provided a discussion about the research strategy, which is the case study, and then we outlined the context of the study in which we gave a brief description of the cases studied. In the second section, we presented the paradigm opted for this study, which is the pragmatism, and in the third section we outlined the methods and the instruments used and then we presented the data analysis strategy.

Chapter IV: results and discussion

Chapter IV : Results and discussion

In the present chapter, we will display the qualitative and quantitative findings we will also expose the outcomes of the K-PIMRBP application to Colaital, Sosémie and Frater-Razes.

The chapter includes three sections; we devoted a section to each case study.

Section I: Case I- COLAITAL SPA

Section I includes three phases, in the first phase we involved the qualitative data analysis and the conceptual model of the study, in the second we presented the outcomes of the concretisation of K-PIMRBP at COLAITAL and in the third phase we disseminated quantitative results.

Phase I: Qualitative data analysis and the conceptual model of the study

The objective of the qualitative study is to explore the context of the study, identify the major operational risks threatening the enterprise studied, reveal the major causes of risks and formulate the hypotheses on how the K-PIMRBP contributes to operational risks prevention.

The interviews guide encompasses three themes beforehand selected from the literature, which are as follows:

Table n°33: interview guide

Theme	Explanation
Theme 01: The context of the study	The aim of this theme is to understand the context of the study: the activities and products of the enterprise and select the product that will constitute the subject of the study.
Theme 02: The operational risks in production process	The aim of this theme is to determine the operational risk classes occurring in the fabrication process that will constitute the subject of the study.
Theme 03: Operational risks prevention	The aim is to determine the factor that leads to risk prevention to formulate the hypotheses of the study;

Source: elaborated by the author

We conducted the interviewees with three responsible persons of the laboratory of Colaital, we did not mention neither the duration nor the dates of the interviews because of many reasons namely:

- The interviewees did not accept to be recorded so we took notes;

- The interviews were interrupted because the interviewees were all the time busy with work.

The verbatim and a short discussion are presented in the following subsection:

a) Theme 01: The study context:

Question: would you describe the activities of Colaital ?

Colaital is a public economic enterprise created during the colonisation by a French woman it was a small dairy and by the time it is evolved and it became the Colaital of today. Colaital is one of the branches of the commercial and industrial group GIPLAIT. …It proposes different dairy products namely lben, yogurt,PPM , batter and other dairy products. … However the product that constitutes more than 90% of the company's turnover is the PPM. ….we produce about 400000 litres per day and in some occasions the quantity produced may up to 700000 litres per day … This is because we are required to meet the largest part of the PPM market need since we benefit from the largest quota of milk powder. … and you should keep in mind that the PPM is based on milk powder, which is imported from different countries by ONIL which is subsequently distributed by this organisation to the different dairy production companies in the country, for this they are adopting a quota system and as aforementioned Colaital has the largest amount of milk powder"

Colaital is a dairy company, which produces a variety of dairy products including the pasteurised packaged milk PPM that constitutes the core product of the company and therefore it will be the subject of the present study.

Question 2: What are the main phases of PPM production?

"The PPM passes by number of stages until it becomes in its final form, it includes three main phases namely: reconstitution or recombination of milk, pasteurisation and packaging. In the first phase, we reconstitute the milk by mixing the milk powder with the water to prepare the concentrated milk, which is stored in tanks of 15000 litres, which is transferred then to tanks of 30000 litres where it is diluted by adding water... Subsequently the reconstituted milk is transferred through tubes to pasteurisation, where it is heated at fixed temperature then it is cooled to kill bacterium …in the end the pasteurised milk is packaged in poletilen packages"

According the interviewee the PPM includes three stages namely: Recombination , pasteurisation and packaging ; in the present study we will study each one of them separately to identify , analyse and treat operational risks in each phase.

b) Theme 02: The operational risks in production process

In this subsection, we will discuss a part of the interviews conducted with the staff members of the enterprise, in order to introduce the types of risks highlighted by them, which constitute the subject of the study :

Question3: what are the operational risks that may occur in PPM process?

1. **Risk of Contamination: microbiological and physicochemical**

« …COLATAIL is a dairy production company. … The major risks that can threat these companies are risks of contaminations including microbiological and physicochemical contamination, these risks may occur throughout the production process of the milk. … The milk powder itself could be contaminated. …there are also many other factors that may lead to the contamination of milk… these risks could affect the product quality and safety and as consequence the consumer health… the microbiological contamination refers to the existence of bacteria in the raw materials or in the final products which can be caused by poor personal hygiene, unclean workplace and materials used …while the physicochemical contamination refers to the existence of external substances that change the constitution of the product »

According to the interviewee, Colaital as a dairy production company, is threaten by two main risks, which are: the microbiological contamination and physicochemical contamination, the milk is exposed to those risks throughout the production process , and which affect the product quality and therefore the consumer health.

2. The production decline

«…But there are other risks that have negative impacts on the objectives of the enterprise as a whole or the unites of the enterprise … these risks can prevent the enterprise from meeting the consumer expectations which are the decline in production and …the inability to control costs »

Besides the contamination risk, the interviewee highlighted two other risks, which are the production decline and the inability to control costs.

«…The production decline is originated from the damage and the breakdown of the machines…you know the production process does not stop at COLAITAL we have four groups of workers working on rotating basis 24/24h and 7/7. … The machines are overused this is why the machines often break down. … In this case, if there is standby machines we can maintain the same level of production but if there is no standby machines the production can be suspended until the repair of the machines, which can create a crisis in the market. …and you should keep in mind that the ONIL, which is the organisation responsible for the distribution of the milk powder to the producers, provides COLAITAL the largest quota of milk powder. … this is why we should satisfy more than the other producers the need in the market and as consequence we produce more than 400000 l/ per day and in some cases the production can up to 700000 in some occasions for example in Ramadan"

The interviewee emphasised the third risk, which is the production decline originated from the factory rhythm that works non-stop which lead to machinery and equipment breakdown and therefore the shortage of milk supply on the market.

3. ***Inability to control costs***

There is another risk that threatens the financial performance of the enterprise, which is the inefficient use of some products, which increases the costs and leads to additional expanses …for example the use in some cases of tap water instead of the water of well drilling. … the use of this water is not free and very expensive contrary to well drilling water. … Certainly, there are many reasons for that. …but if we want, we can find solutions to any problem. …another example we don't have liquid level sensor in the recombination phase so when we dilute the concentrated milk we can't determine precisely the quantity of water to add this is why sometimes we sell concentrated milk …"

The inability to control costs is another operational risk caused by the use of certain products or the lack of machines that generate additional costs to the enterprise.

In the present thesis, we are going to work on four operational risk classes, namely: Microbiological contamination, Physico-chemical contamination, Production decline and the inability to control costs.

Theme 03: Operational risks prevention

Question 4: How can Colaital prevent PPM production from operational risks?

"Before we talk about the operational risks prevention we should discuss about the real causes of all those risks …the human resources i mean workers particularly are the main factor of risks … because they ignore the impact of these risks on product quality and consumer health… they are unaware... They lack of training…"

Question 5: Does the new employee receive a training on risks in the workplace in the beginning of his career at COLAITAL?

"Here, we did never receive any training ... once the employee is hired, he starts immediately his job ...for the responsible, he learns what he should do from their colleagues. ... In reality, many things should be done in this regard. ... We should train them on the consequences of the poor personal hygiene on the product. ... They should understand what is a contamination and its causes and so on …because they contribute directly or indirectly to those risks…a well trained employee on risks in the workplace will prevent from risks"

Based on the interviewee verbatim we conclude that in order to prevent from operational risks, it necessary to train employees on operational risk. In other words, **the training on operational risks** is **the factor** that leads to risk prevention.

Therefore, we will try through the following study to test if the K-PIMRBP outcomes contribute **to train employees on operational risks** which leads to risk prevention, hence we formulated the following hypotheses

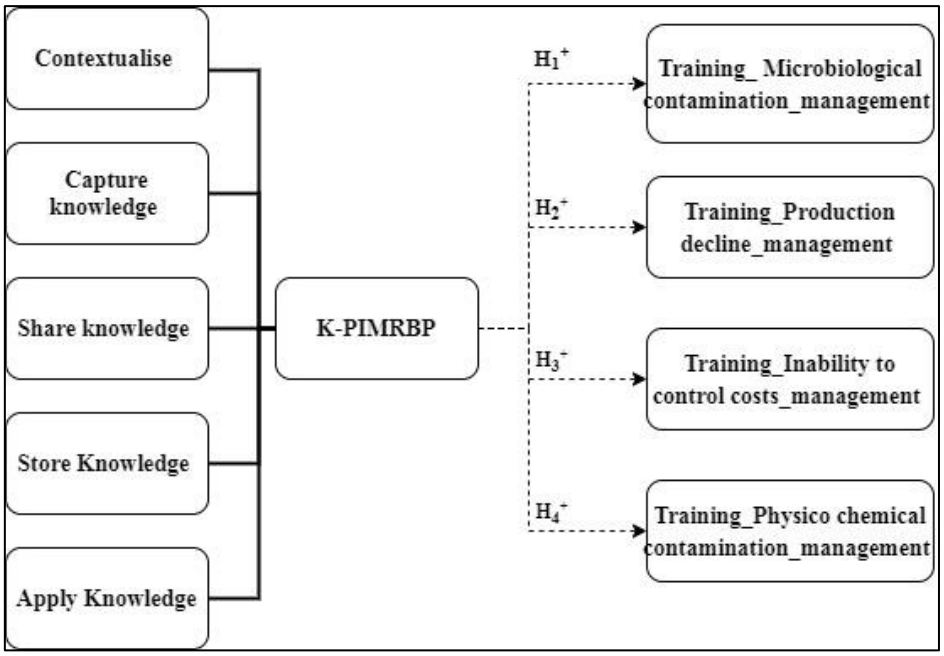
H_1: K-PIMRBP outcomes contribute to train employees on microbiological contamination management

H_2: K-PIMRBP outcomes contribute to train employees on production decline management

H_3: K-PIMRBP outcomes contribute to train employees on the inability to control costs management

H_4: K-PIMRBP outcomes contribute to train employees on Physico-chemical contamination management

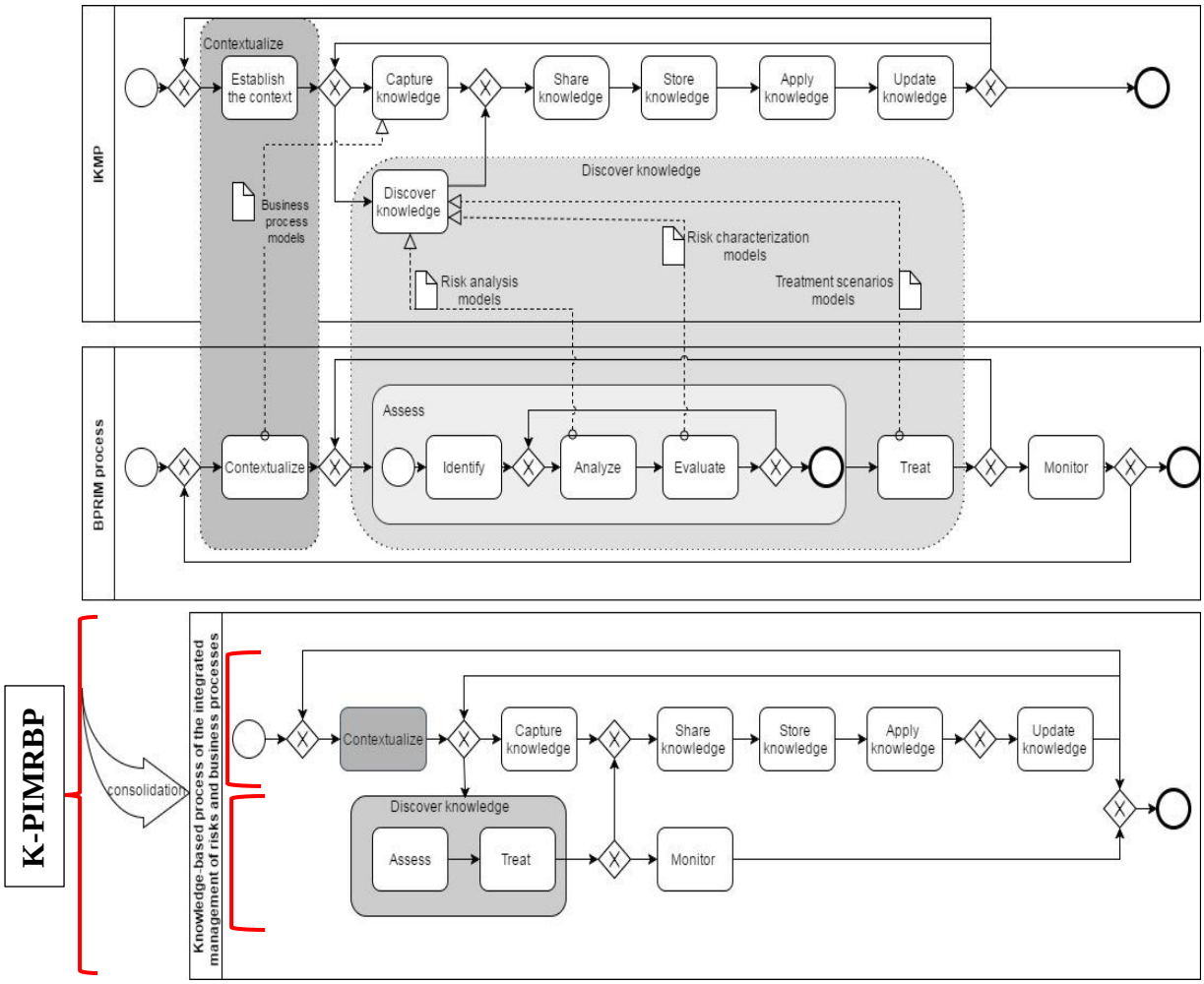
Figure n°18: conceptual model-Colaital



Phase II: The concretisation of K-PIMRBP at COLAITAL

In this section, we will show the outcomes of the K-PIMRBP application to the PPM production. As aforementioned in the previous section, the K-PIMRBP includes two sub-processes (see figure 19), in the first sub-process, if we deal with existing risks, we capture knowledge but in the second sub-process, we start by discovering knowledge when the risk is new. In our case , we studied risks known by the interviewees (staff members), so we adopted the first sub-process in which we contextualised, captured knowledge, shared knowledge , stored and then applied knowledge , we excluded from this process the knowledge update since it is the first application of the process to this enterprise.

Figure n°19: K-PIMRBP process

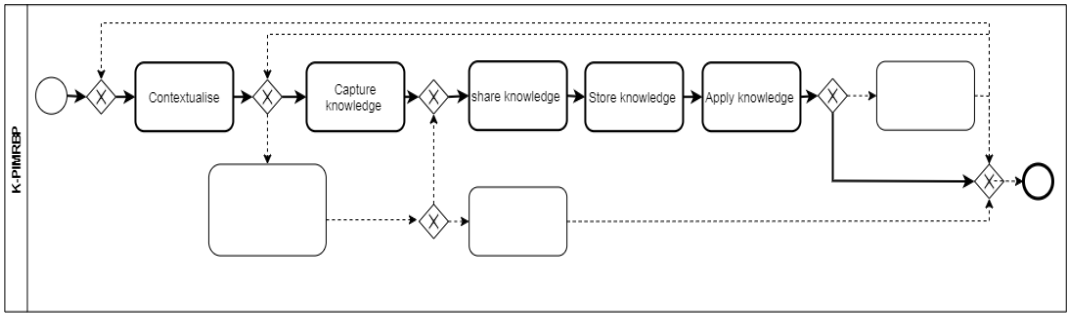


Source: (MAAMIR & DERGHOUM, 2021)

In the following sub-sections, we will show the outcomes of each activity included in the process.

Figure 20 shows the sub-process adopted in the present study.

Figure n°20: the sub-process of K-PIMRBP



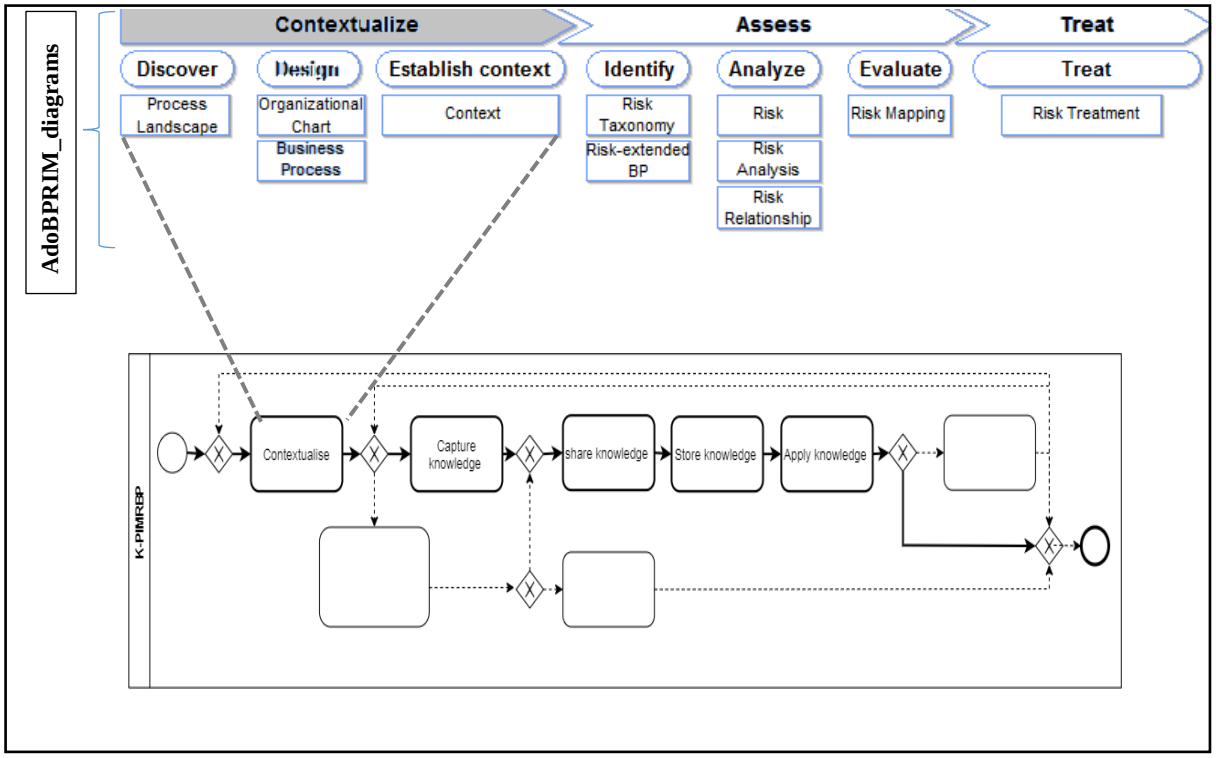
Source: (MAAMIR & DERGHOUM, 2021)

Chapter IV : Results and discussion

1. K-PIMRBP_Contextualise

The first activity in the preventive management process is the establishment of the context which gives an overview of the whole enterprise, the units included in the study , the actors and business processes constituting the subject of the study. We used the AdoBPRIM software to model the outcomes of the K-PIMRBP/contextualise which includes in the software four models (Process landscape, context, business process, organisational chart) . In the following figure we show the intersection between K-PIMRBP/contextualise--- AdoBPRIM/contextualise

Figure n°21: the intersection between K-PIMRBP/contextualise--- AdoBPRIM/contextualise



Source: Adopted from (MAAMIR & DERGHOUM, 2021)

The table below outlines the contextualisation activity

Table n°34: contextualisation activity

Activity presentation	
Contextualise	
Description	***Context:*** The aim of this activity is to model the units of the enterprise included in the study, the actors in this activity and the objectives of the units and the staff members (see figure 22) ***Business processes:*** include the activities of the PPM product (AS-IT processes) namely: reconstitution of milk, milk pasteurisation and packaging. (see Figure 23) ***Process landscape***: shows the macro view of the process of PPM production, which includes the management process, the support process, and the business processes that constitutes the subject of this study.
Interviewees/information source	In order to understand the context of the study we conducted interviews and we discussed during the internship with: • ***Laboratory staff members*** (responsible, laboratory assistants in physico-chemistry and bacteriology) • ***Production staff members*** (Production technical assistant, Workshops managers, workers)
Data (activity inputs)	***In order to establish the context we used :*** ***Documents*** (organisational chart of the enterprise) ***Verbatim*** (input) **Observation**
Knowledge (activity outputs)	***The nature of knowledge in this step are diagrams*** (context-figure / business process-figure /process landscape-figure)
Data collection tools	***Interviews: were non-directive , because the aim was to understand the context of the study and particularly PPM process to model the BPs , the questions were :*** - What are the steps of milk production? - What are the unites that contribute to PPM production? - Could you describe each step in that process? - What are the materials and utensils used in that process? ***observation :*** We attended and observed the PPM process ***and documentary research (organisational chart)***
modelling toolkit	***AdoBPRIM***

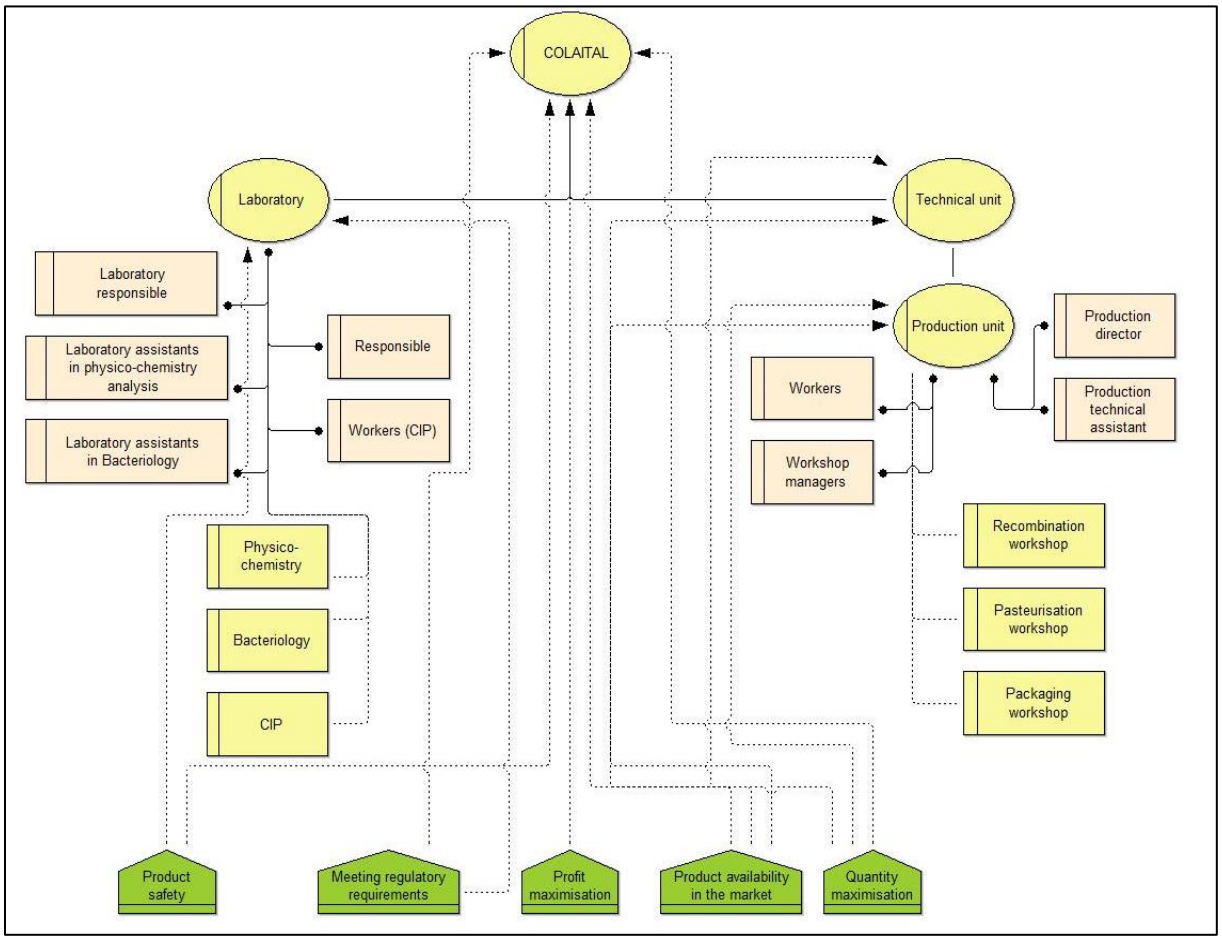
Source: elaborated by the author

Chapter IV : Results and discussion

Figure 22 shows the context diagram of the part of COLAITAL that constitutes the subject of the study and which includes two unites namely: Production unit , attached to technical unit, which includes three workshops (recombination, pasteurisation and packaging) in which the PPM is produced , this unit is directed by a production responsible and a production technical assistant , and each workshop has a team constituted of a workshop manager and workers.

The laboratory is responsible for Physico-chemical and bacterilogical control and cleaning (CIP) of workshops. The laboratory has a responsible and assistants , there is also a responsible and workers for the cleaning. Colaital has four main objectives namely: product availability in the market and quantity maximisation for which the production unit is responsible , and product safety and meeting regulatory requirements which is the responsibility of the laboratory.

Figure n°22: the context diagram



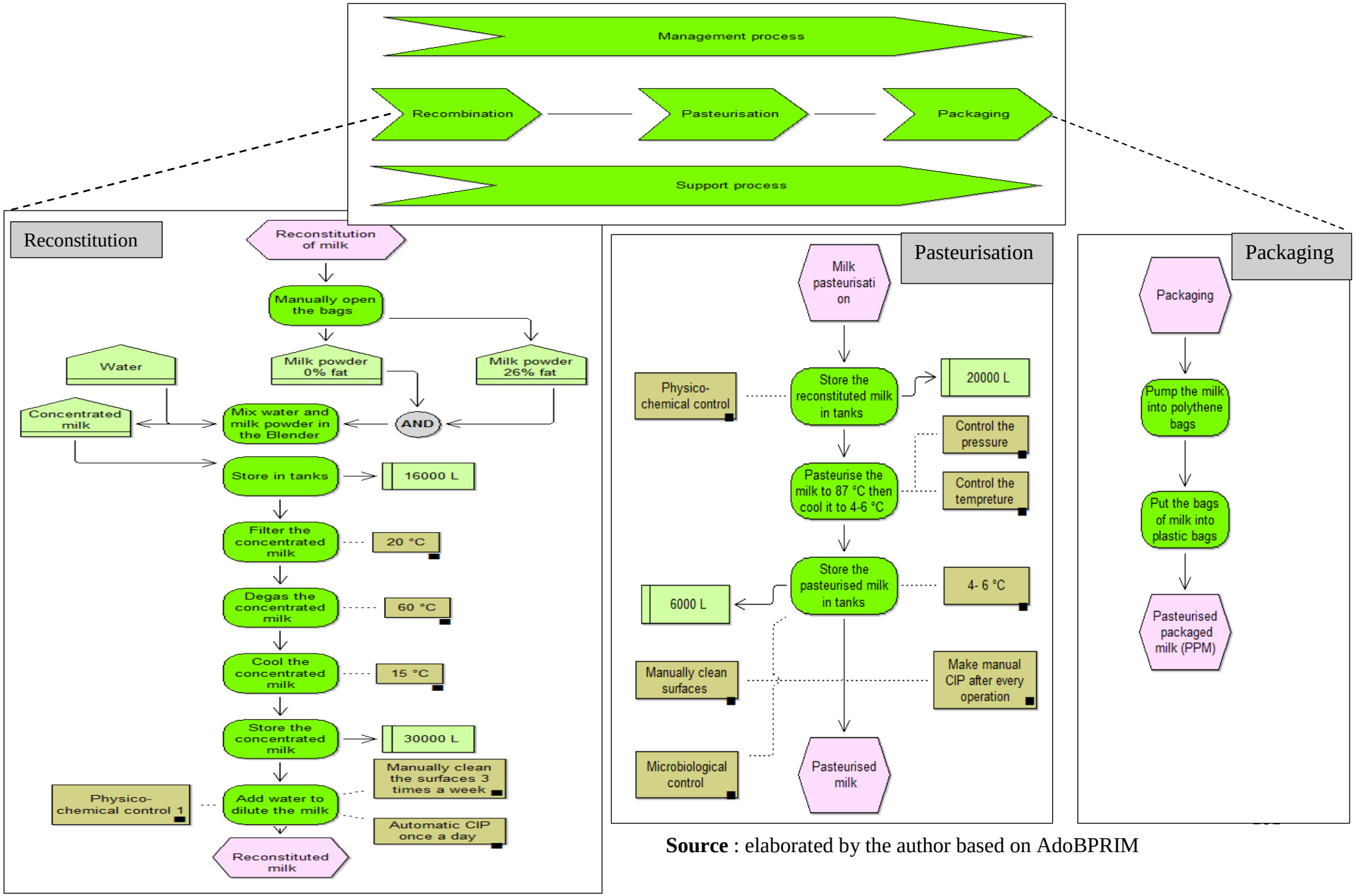
Source:elaborated by the author based on AdoBPRIM software

Chapter IV : Results and discussion

Figure 23 shows the Process landscape of COLAITAL , in the present study we focus on the operational level of the enterprise , in other words , the business processes which involve three BPs namely : recombination , pasteurisation and packaging.

Business processes : The PPM production starts by the reconstitution of the powdered milk, which is mixed with the water to constitute the concentrated milk this process includes many activities as shown in figure 23 .Secondly the concentrated milk passes by the pasteurisation activity to eliminate the bacterial load **(**see figure 23) finally the pasteurised milk is packaged for the selling.

Figure n° 23: process landscape and



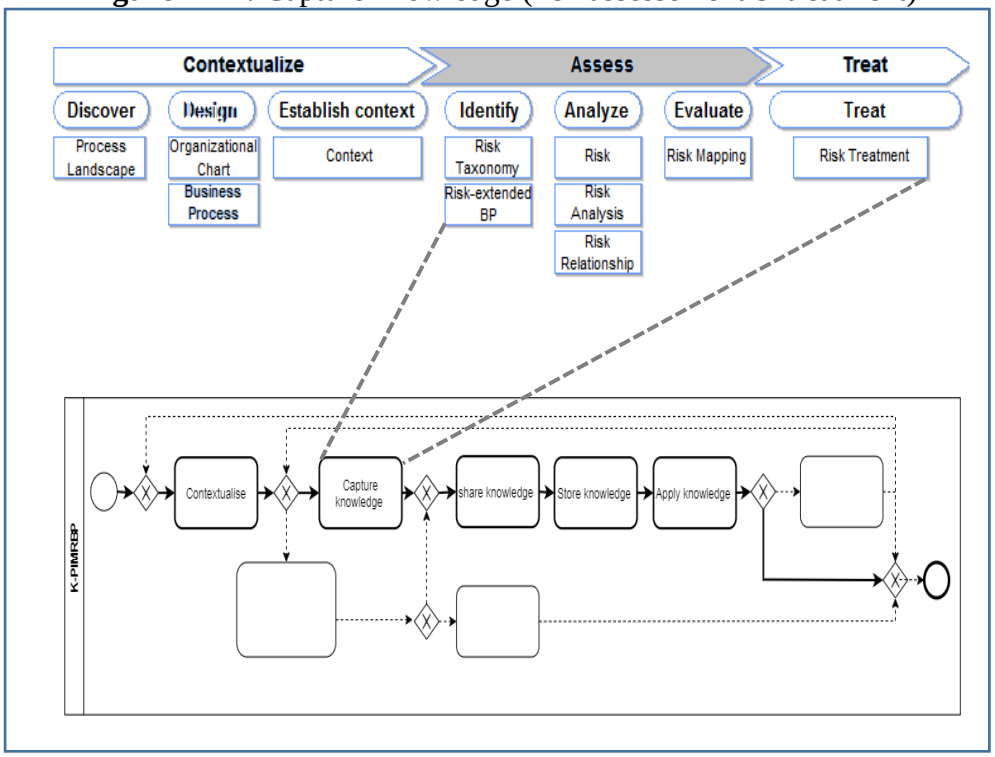
Source : elaborated by the author based on AdoBPRIM

Chapter IV : Results and discussion

2. K-PIMRBP _ Capture knowledge

In the present study, we mean by Knowledge the risk management outcomes in form of diagrams. So, **capture knowledge activity** refers to the collection of the outcomes of the risks assessement (identification, analysis and evaluation) and risks treatment as shown in the figure n° 24.

Figure n°24: Capture knowledge (risk assessement & treatment)



Source: adapted from (MAAMIR & DERGHOUM, 2021)

The table below outlines "**capture knowledge**" activity :

Table n°35: Capture knowledge activity

Activity presentation	
Capture knowledge	
Description	**1. Risk identification:** the aim of this activity is to determine the opertional risks throughout the PPM process, this activity involves two sub-activities namely : **1.a) The risk taxonomy** (figure 25): In this activity we classified the potential and the actual operational risks into four classes of risks identified from the qualitative data analysis (figure25). **1.b) Risks-extended BP diagrams:** In this activity we place the risks in the business processes in order to show the position of risks. **2. Risk analysis:** The aim is to determine the **risk causes , risk situation, risk likelihood for this we applied qualititative estimation as follows :** **0:** not defined **1:** very improbable **2:** very unlikely **3:** unlikely **4:** possible/likely **5:** very likely to certain **And risks severity :** **0:** not defined **1:** minor **2:** significant **3:** major **4:** critical **5:** catastrophic **The impact of the risk on values:** degrades, worsens, cancels or increases the value created in the enterprise. **3. Risk evaluation:** the risk may be acceptable , acceptable under control or unacceptable ; the risk evaluation is visualised in the risk matrix **figure 26**

	Risk Treatment: the aim of this activity is to provide treatment scenarios to treat the risks . Table 38
Interviewees/information source	In order to assess the risk (**capture knowledge**: identify, analyse and evaluate risks) we conducted non-directive interviews with: ***Laboratory staff members*** (responsible, laboratory assistants in physico-chemistry and bacteriology) ***Production staff members*** (Production technical assistant, Workshops managers, workers)
Data (activity inputs)	***Documents (HACCP)*** ***Verbatim (input)*** ***Observation***
Knowledge (activity outputs)	***The nature of knowledge in this step are diagrams (risk taxonomy, Risks-extended BP diagrams and risk matrix)***
Data collection tools	***Interviews:*** were non-directive ,because the aim was to determine the operational risks in each BP and the position of risks in the BPs and evaluate the risks : What are the operational risks (problems, errors …) that occur in each step in the BPs? What are the causes of these risks? How may this risk affect the product? How often the risk occur ? What is the severity of these risks? ***observation : We observed the process of PPM production and documentary research (HACCP)***
Modelling toolkit	***AdoBPRIM***

Source: elaborated by the author

a. Assessement-*identification* : In this activity we identify the operational risks reported by the interviwees (the staff members) and observed by the researcher during our presence in the workshops. Figure 25 shows the risk taxonomy as follows:

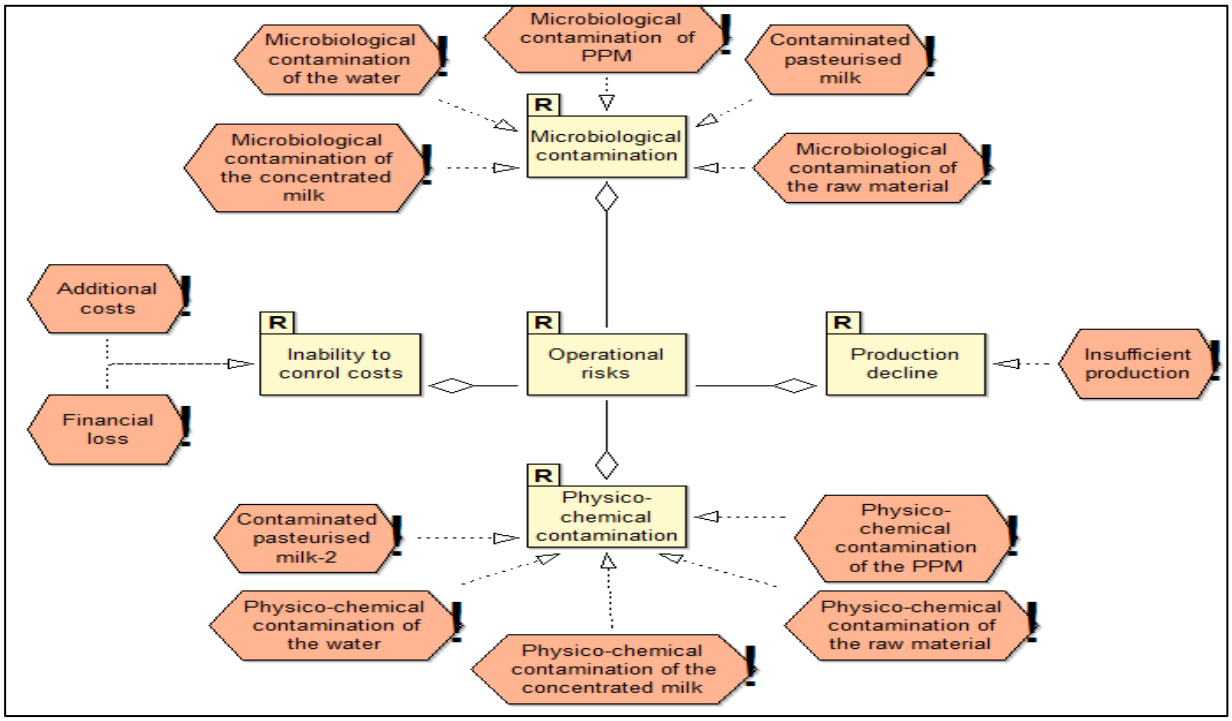
a.1 Risk taxonomy:

PPC process is exposed to four main operational risks classes wherein each class involves many operational risks as discussed in the qualitative section namely : (1) **Microbiological contamination class** : "*Microbiological contamination refers to the non-intended or accidental*

introduction of infectious material like bacteria, yeast, mould, fungi, virus, prions, protozoa or their toxins and by-products" (Ghiglione, Martin-Laurent, & Pesce, 2016). This risk occurs throughout the PPM process, in the beginning of recombination process when the water and/or the raw material are contaminated or in the end of this process. The pasteurised milk could be also contaminated.

(2) Physico-chemical contamination: physical contamination includes the covering material, insects, and rodent droppings while heavy metals and pesticides cause chemical contamination (Kamala & Kumar, 2018). It could occur at any stage in the production, in the water , raw materials and in the concentrated milk it can also exist in the pasteurised milk or in the PPM.
(3) Inability to control costs: it involves two risks namely additional costs and financial losses
(4) Production decline includes one risk is the insufficient production

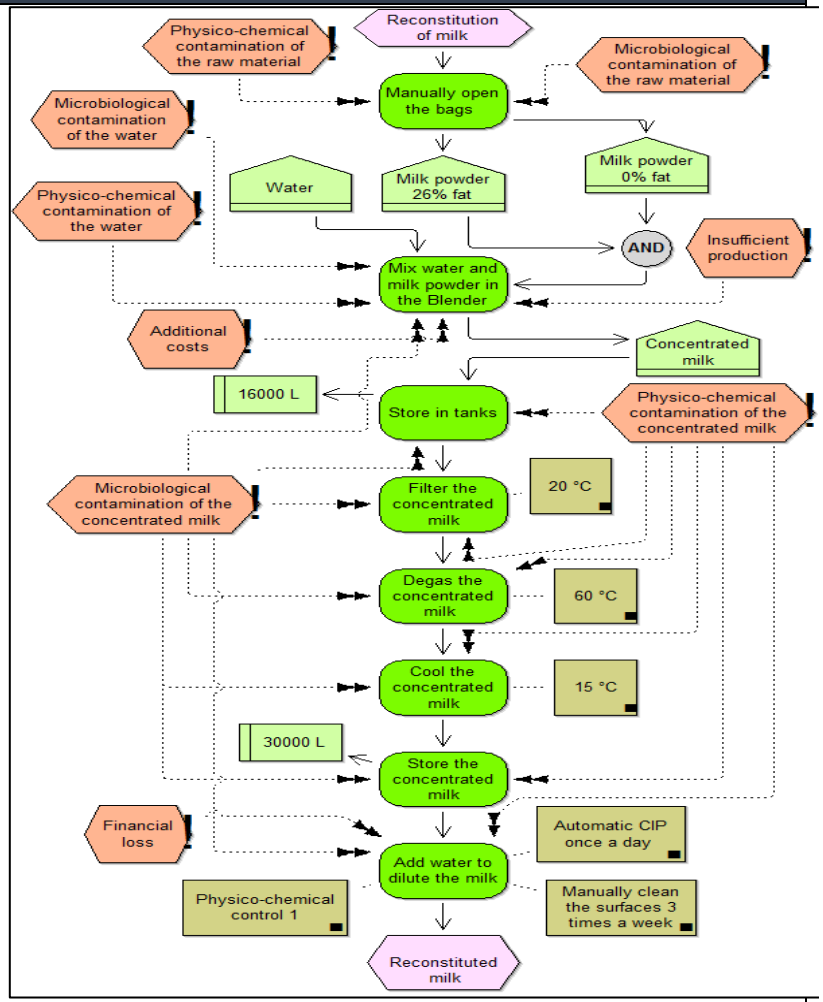
Figure n°25 risk taxonomy

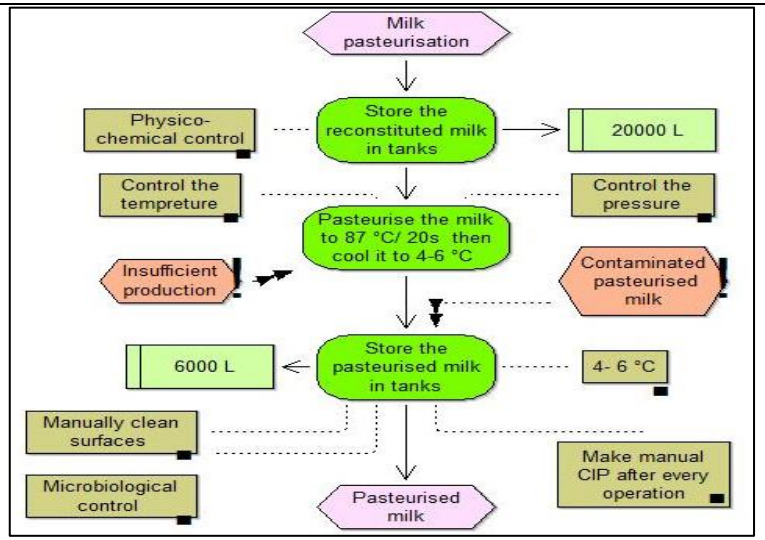
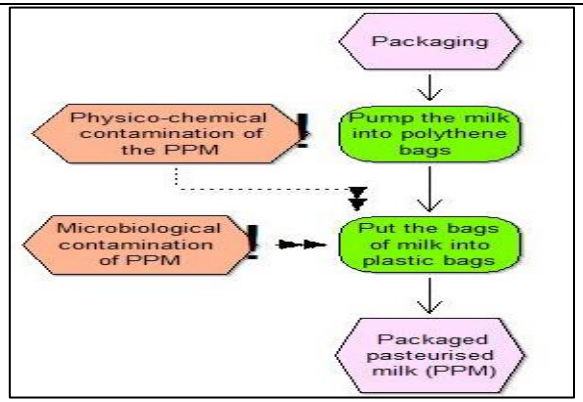


Source: Source: elaborated by the author based on AdoBPRIM software

a.2) Risk-extended BP: Table 36 indicates the operational risks in business processes (reconstituted, pasteurisation and packaging) of PPM process.

Table n°36: Risk-extended BPs (Colaital)

BP	OPR	Comments	Risks-extended BP diagrams
Reconstitution (Risk-extended to BP)	**Contamination of the water :**	In the dairy production, we should use treated water (process water) for the milk production and utility; but at COLAITAL they generally use non-treated water and in some cases they use even tap water for the milk production which may contain bacteria or any microorganism or any physico-chemical contaminants (sand, insects, pesticides…etc). While the treated water is used for utility(industrial boiler & cooling system) because the water treatment station is small and it cannot satisfy the need.	
	Contamination of raw material:	Powdered milk can contain microbiological contaminants or any physico-chemical contaminants from the supplier or it can become contaminated inside the factory because of the storage poor conditions.	
	Contamination of the concentrated milk:	The concentrated milk could become contaminated during the reconstitution with microbiological or physico-chemical contaminants.	

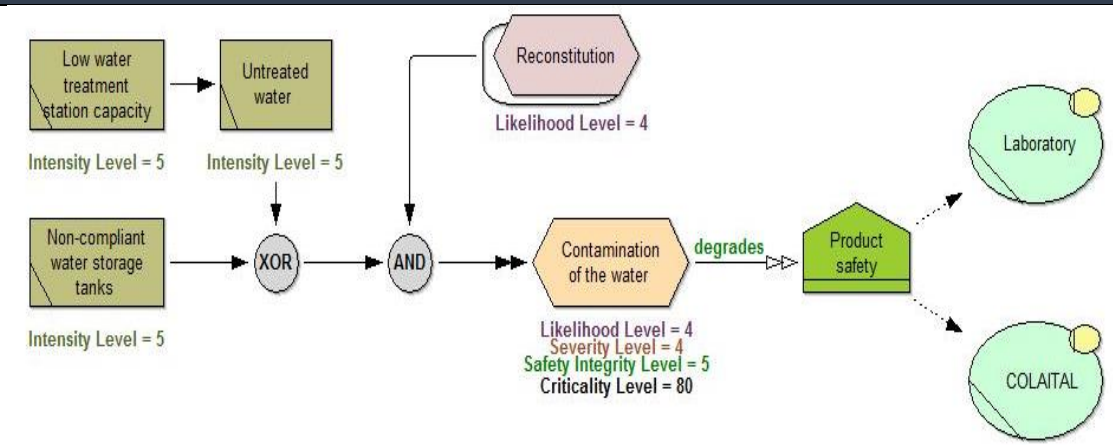
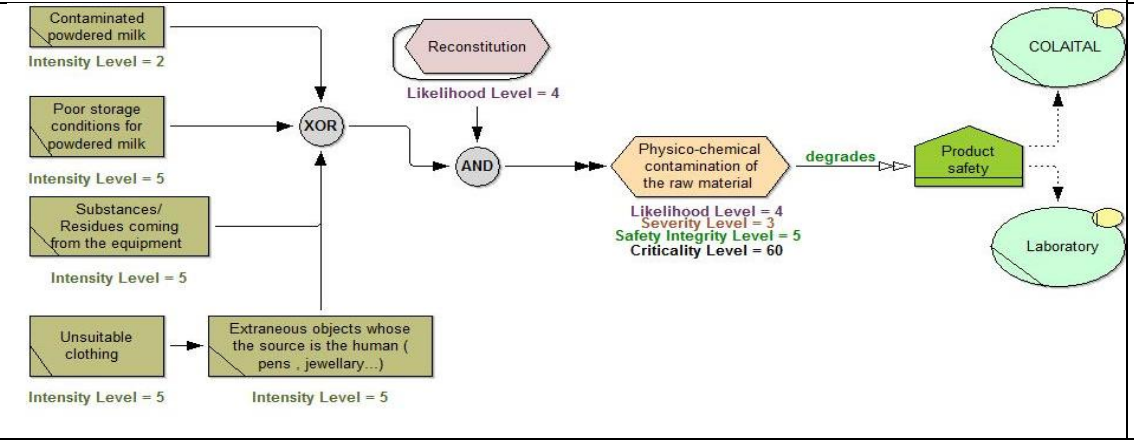
	Insufficient production:	The inability to reach the optimal production volume.	
	Financial loss:	The lack of materials or the ineffective use of products may generate financial losses to the enterprise.	
Pasteurisation	**Contaminated pasteurised milk**	Milk pasteurisation failure due to the existence of specific bacteria after the pasteurisation.	
	Insufficient production capacity	The incapability to reach an optimal production capacity.	
Packaging	**contamination of the PPM**	The existence of physico-chemical contaminants or microbiological contaminants.	

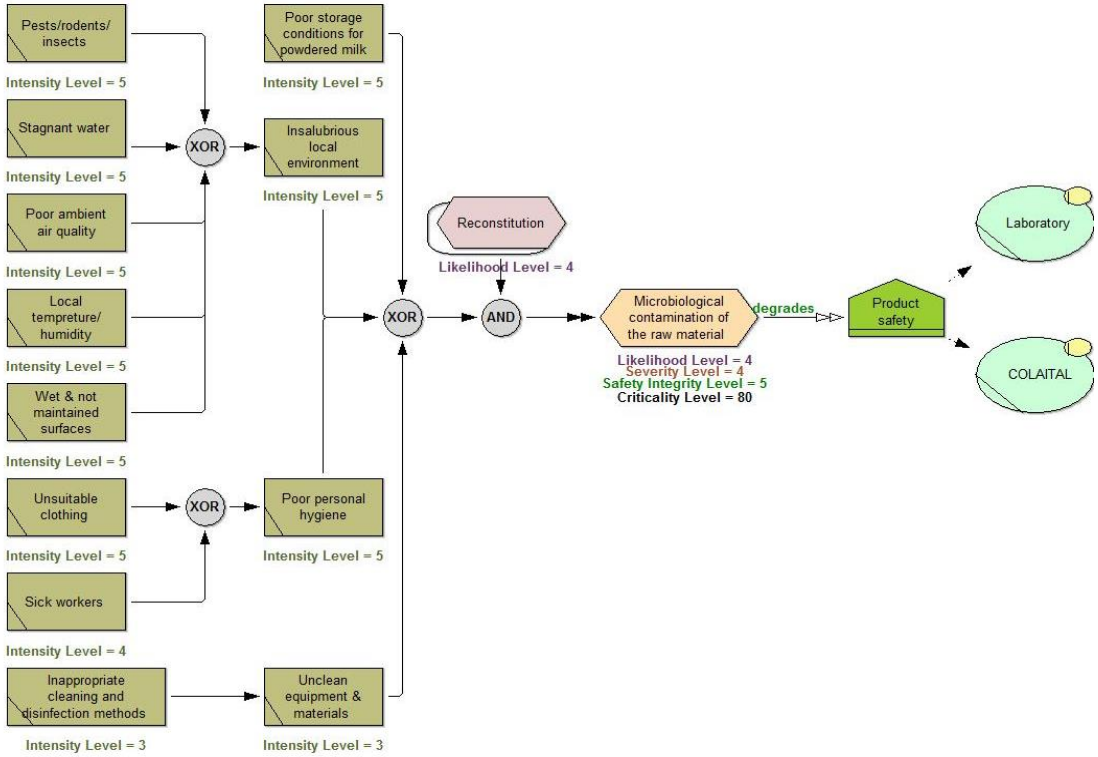
Source : elaborated by the author based on AdoBPRIM

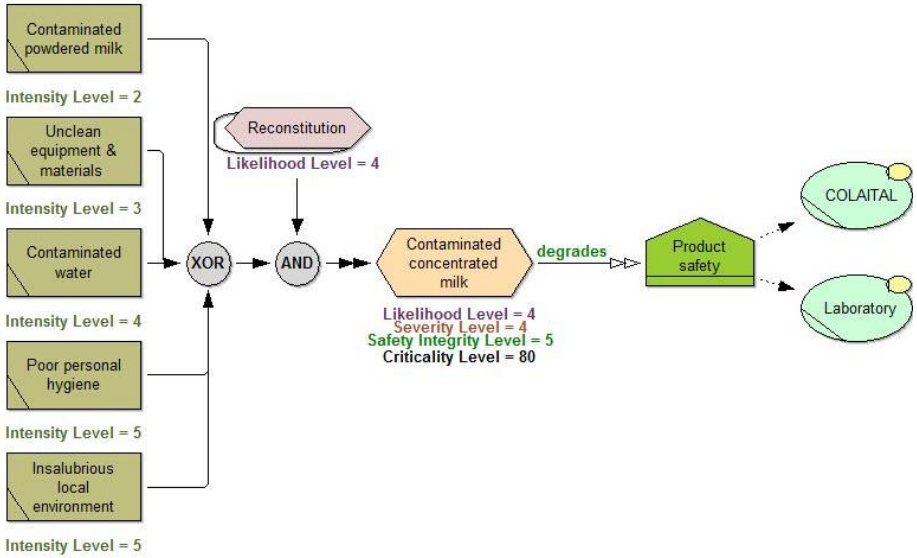
a.3) Assessment - Risk analysis***:***

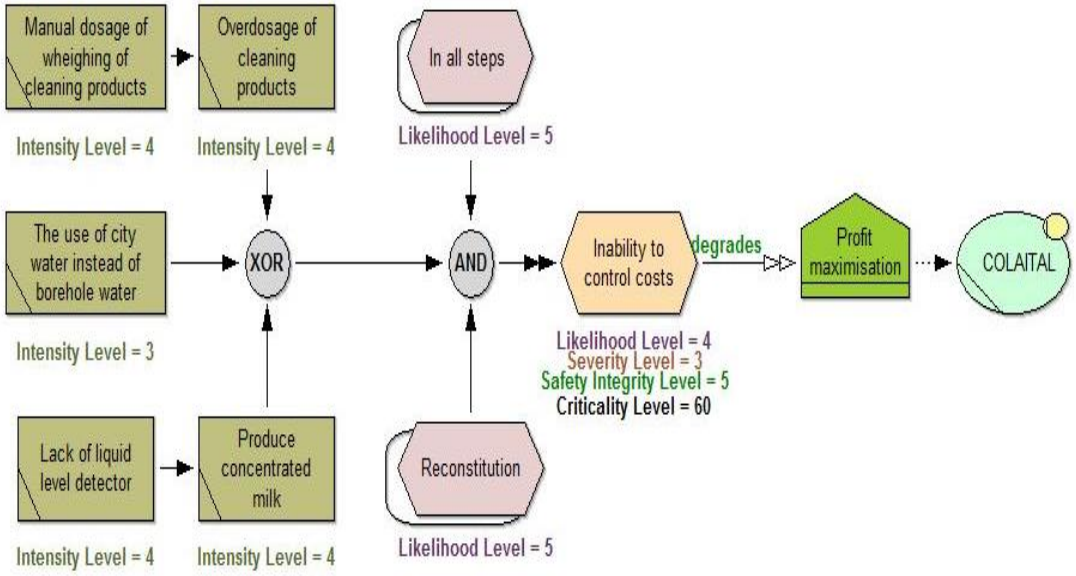
Each risk has enormous causes and has impact on the enterprise objectives, in the following table we display the risk analysis of the risks determined:

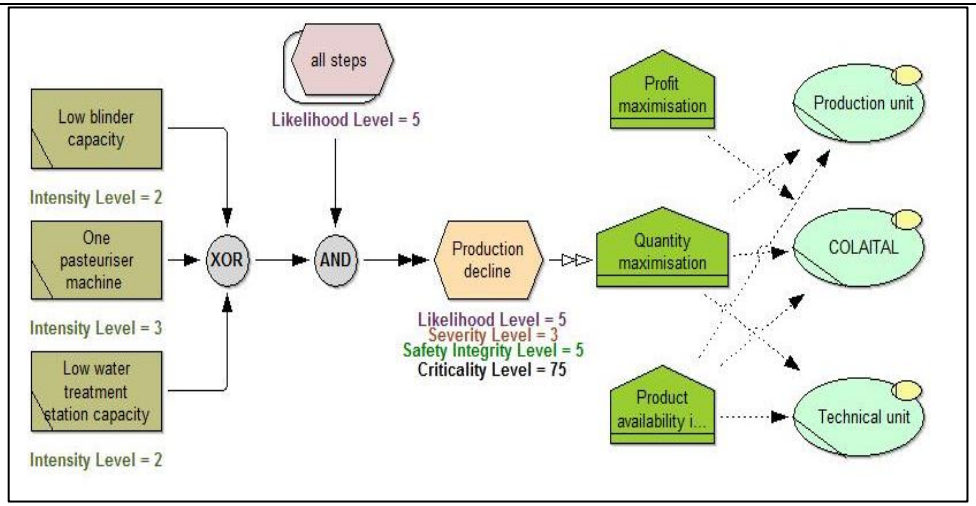
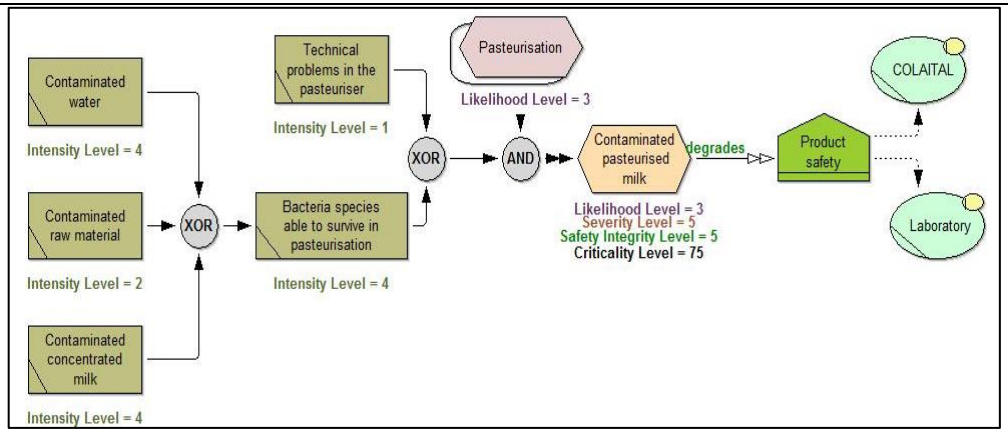
Table n°37: Risk analysis diagrams (Colaital)

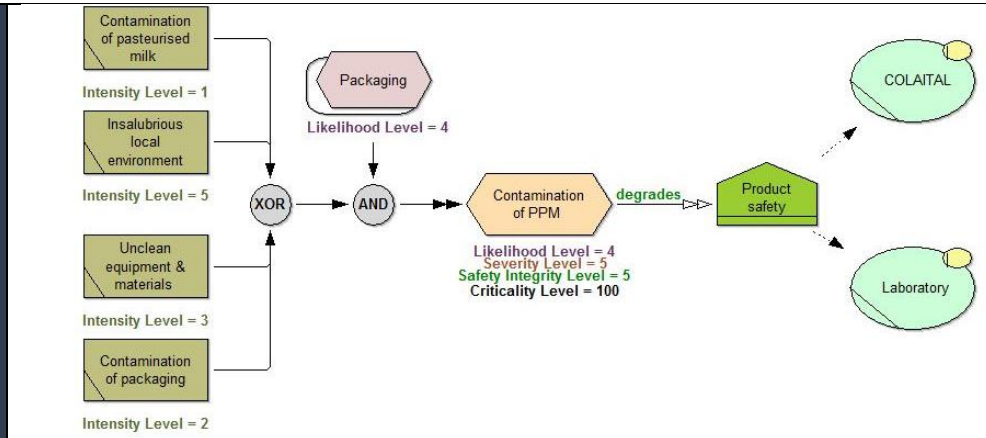
OPR	Risk analysis diagrams	Comments
Contamination of water		The causes of the contamination of water are : ° The use of untreated water because of the low capacity of water treatment station; ° Non-compliant water storage tanks. this risk occurs in the reconstitution phase , which is critical because it degrades the product safety for which the laboratory and Colaital are responsible , for more details see the risk analysis diagram
Physico-chemical contamination of the raw materials		The causes of physico-chemical contamination of the raw materials (powder, water) used in the reconstitution are: ° Supplier may supply contaminated powdered milk containing physico-chemical contaminants; ° The poor storage conditions (humidity, temperature…etc) ; ° The residues coming from the equipment;

		° We noticed that workers or the vistors wear unsuitable clothing in the workplace (they do not wear hairnets, gloves , footwears…etc) which may be the source of contamination. This risk can possibly occur in the enterprise, which is a critical risk because it degrades the product safety for which the laboratory and Colaital are responsible.
Microbiological contamination of the raw materials		The causes of microbiological contamination of the raw materials (powder, water) used in the reconstitution are: ° During our internship in Colatail we noticed the presence of pests, rodents and insects in the workshops, there is also stagnant water because the surfaces are not maintained, we noticed also the poor ambient air quality in workplace where the local temperature and humidity are not appropriate for dairy production, all that make the local environment of the workplace insalubrious; ° As discussed previously, there is a serious personal hygiene issues of workers in the workplace; ° Inappropriate cleaning and disinfection methods (there is no strict cleaning plan);

		° Poor storage conditions. This risk can possibly occur in the enterprise, which is a critical risk because it degrades the product safety for which the laboratory and Colaital are responsible.
Contaminated concentrated milk		The concentrated milk (reconstituted milk) can be contaminated due to several factors namely: ° Contaminated powdered milk; ° Unclean equipment and materials; ° Contaminated water; ° Poor personal hygiene; ° Insalubrious local environment. This risk can possibly occur which is critical risk because it degrades the product safety for which the laboratory and Colaital are responsible.

Inability to control costs		Colaital suffers from the inability to control costs due to several factors : ° In some cases , for the equipment and surfaces they may overdose the cleaning and disinfection products when they manually measure them, which incur additional costs; ° As previously discussed, in the reconstitution step they use the tap water which is not free while the well drilling water is free which incurs additional costs to the enterprise; ° The production of concentrated milk because of the lack of liquid level sensor; This risk can possibly occur which is a critical risk because it affects the profitability of the enterprise.

Production decline		The causes of the production decline : ° Low equipment capacity which slows down the production process and therefore the quantity produced per day; ° Small water treatment station; ° Lack of equipment. This risk can very possibly occur which is a major risk and it affects the profitability of the enterprise, the quantity produced and the product availability in the market.
Contaminated pasteurised milk		The milk after pasteurisation may still contaminated if it contains bacteria species able to survive in pasteurisation , or if there is technical problem in the pasteuriser It is unlikely that this risk occurs but it is critical because it affects the product safety

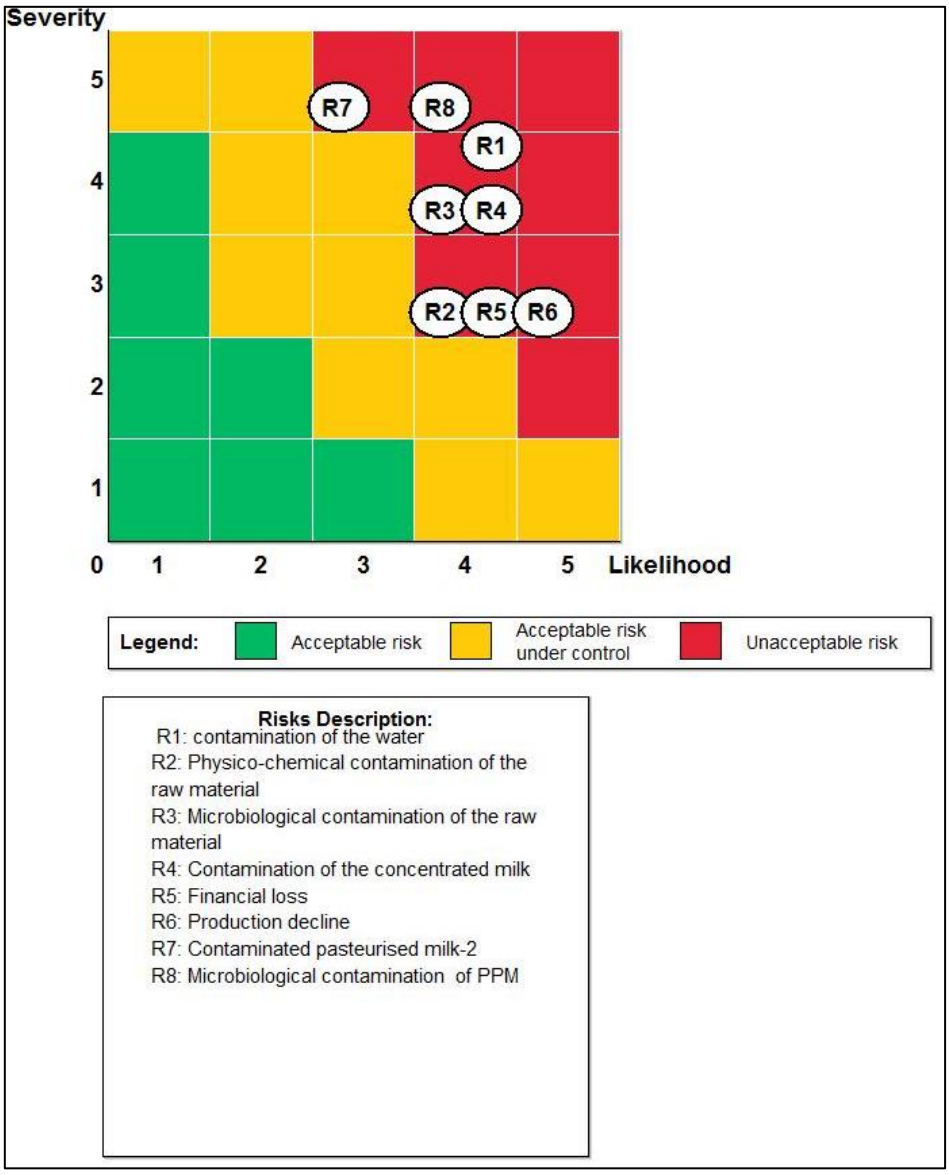
Contamination of PPM		The causes of PPM contamination are: ° The contamination of the pasteurised milk ° Insalubrious local environment, unclean equipment and materials ° They may use contaminated packaging (polythene) because they do not control the conformity of the packaging in the enterprise This risk may possibly occur but it is critical risk because it affects the final product safety, which is delivered to the consumer.

Source: elaborated by the author based on AdoBPRIM software

a.4) Assessment -*Risk evaluation/matrix:*

Figure 37 outlines the risk matrix

Figure n°37: risk matrix



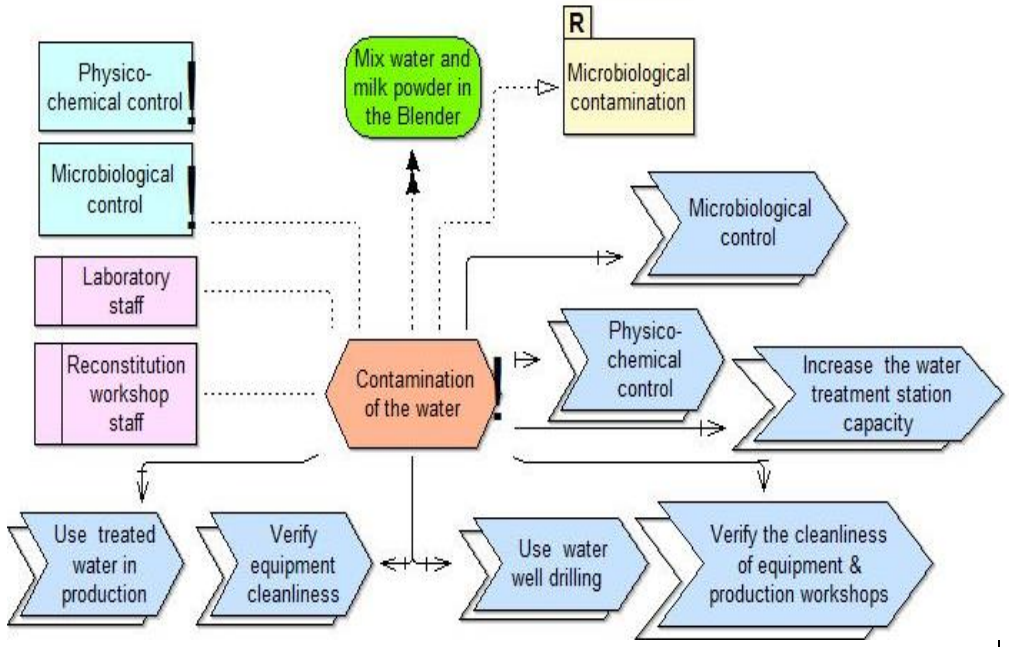
Source: elaborated by the author based on AdoBPRIM software

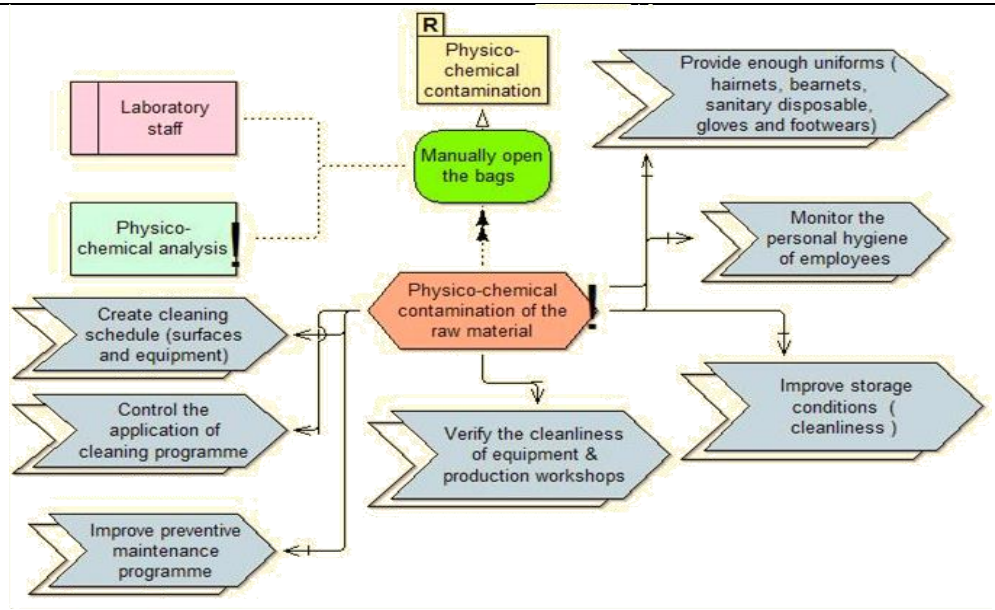
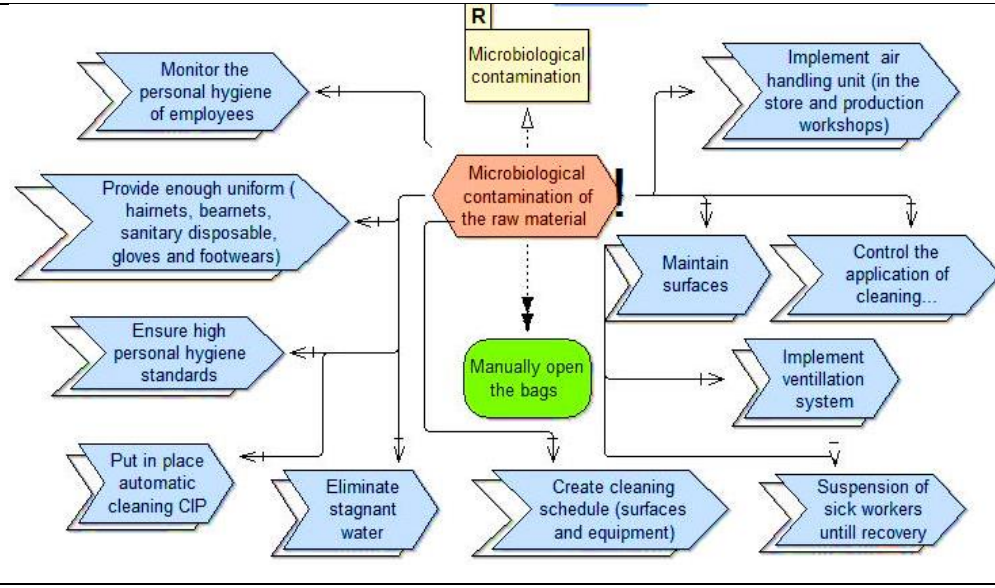
According to risk matrix all the operational risks detected are unacceptable risk and should be treated

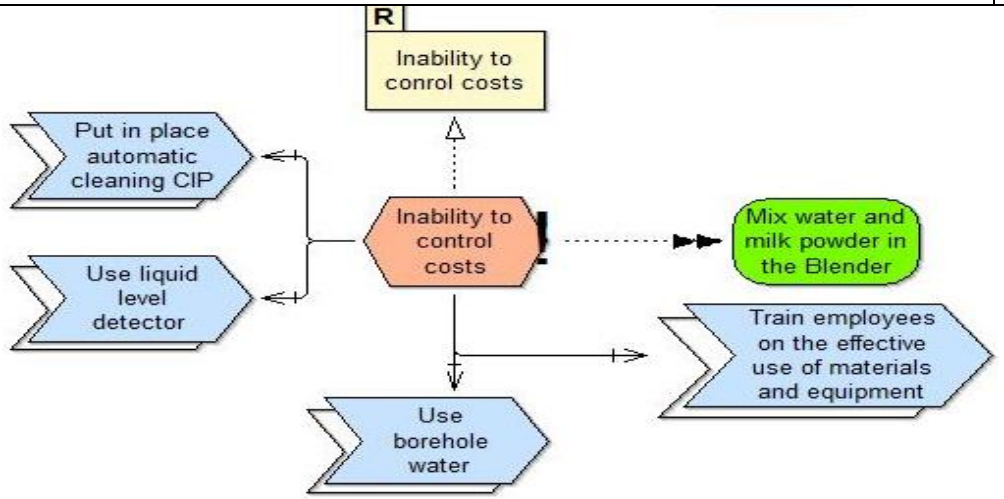
b) Risk treatment

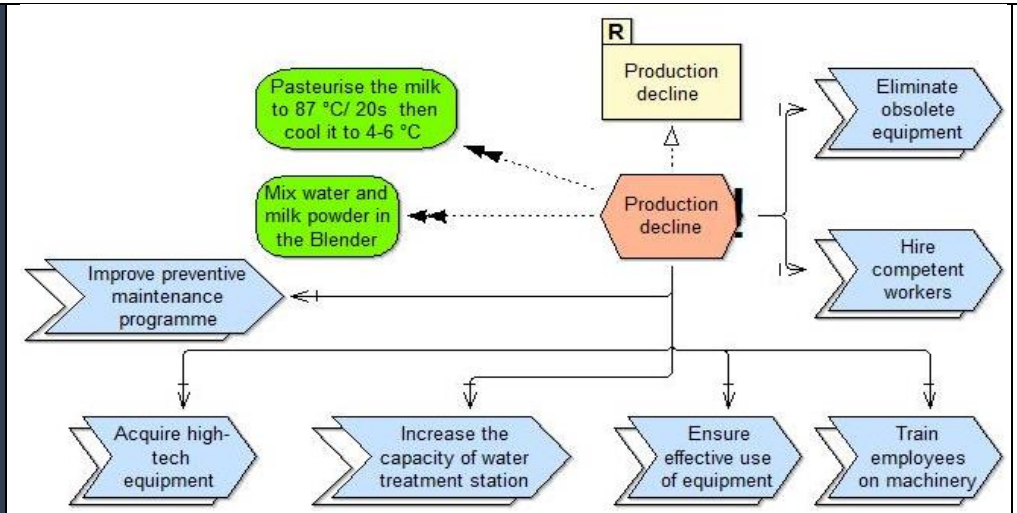
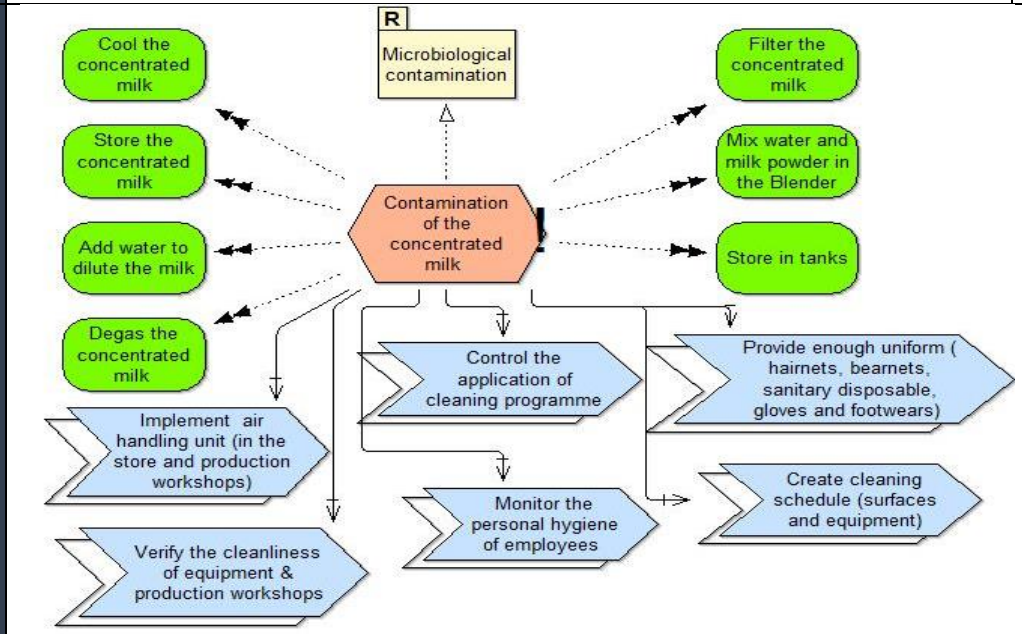
In the following table, we suggest scenarios to treat the operational risks

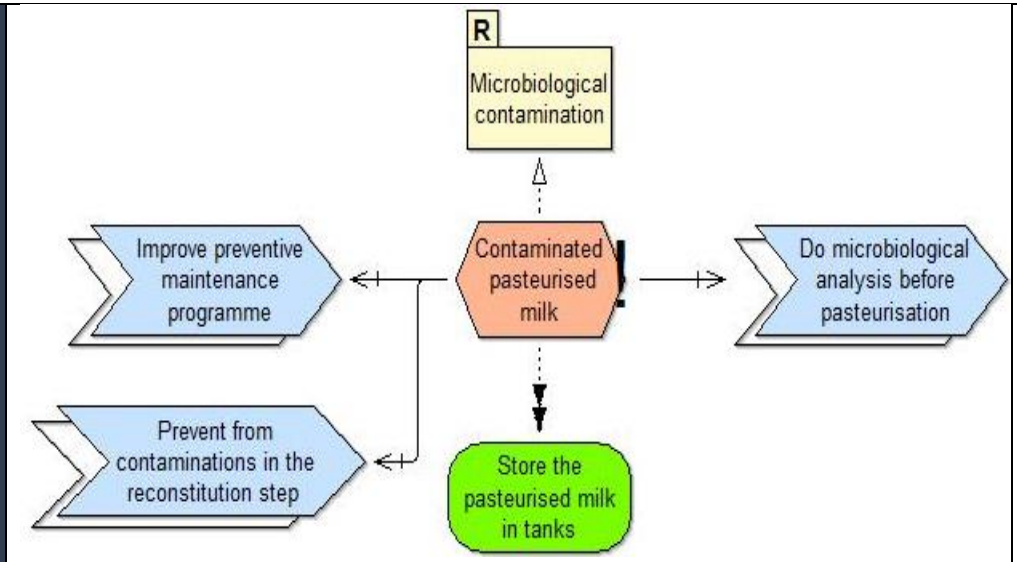
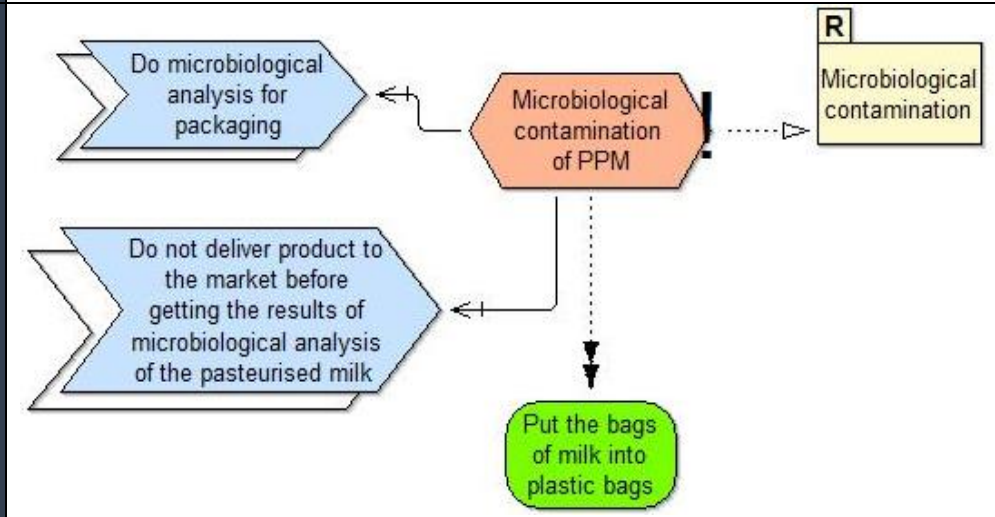
Table n° 38 : risk treatment diagrams

OR	risk treatment diagrams	Comments
Contamination of water		To prevent from water contamination, it is necessary : ◦ To use water well drilling instead of tap water because it is controllable and the well drilling is frequently treated; ◦ To do microbiological and physico-chemical control for water before the production; ◦ To use only treated water in the production; ◦ To verify the cleanliness of workshops and equipment; ◦ To increase the capacity of the water treatment station to satisfy the need of the production and utility;

Physico-chemical contamination of the raw materials		To prevent from physico-chemical contamination of raw material, it is necessary to : ° Provide enough uniforms in workshops to workers and the visitors; ° Monitor the personal hygiene of workers; ° Improve storage conditions and cleanliness; ° Verify the cleanliness of equipment and workshops; ° Improve preventive maintenance programme; ° Create and control the application of cleaning plan for the surfaces and the equipment.
Microbiological contamination of the raw material		To prevent from microbiological contamination of the raw materials, it is necessary : ° To provide enough uniforms in workshops to workers or the visitors; ° To monitor the personal hygiene of workers; ° To suspend sick workers until recovery; ° To create and control the application of cleaning plan for the surfaces and the equipment; ° To maintain surfaces to eliminate stagnant water;

		° To implement air handling in workshops and in the store for ambient air quality; ° To implement ventilation system in workshops and in the store; ° To put in place CIP to ensure the appropriate cleaning for equipment.
Inability to control costs		To reduce additional costs it is necessary to: ° Train employees on the effective use of materials (cleaning products) to raise their awareness on the additional costs incurred from that; ° Put in place CIP to avoid wasting products; ° Use liquid level detector when diluting milk; ° Use water well drilling.

Production decline		To increase the production, it is necessary to: ° Eliminate obsolete equipment; ° Use high-tech equipment ; ° Train workers on the effective use of the new equipment; ° Improve preventive maintenance programme; ° Hire competent workers.
Contamination of the concentrated milk		To prevent from contamination of the concentrated milk, it is necessary to: ° Provide enough uniforms in workshops to the workers and the visitors; ° Monitor the personal hygiene of workers; ° Verify the cleanliness of equipment and production workshops ; ° Create and control the application of cleaning plan; ° Implement air handling unit for an ambient air quality in the premises.

Contaminated pasteurised milk		To prevent from contamination of pasteurised milk, it is necessary to: ° Prevent from all contaminants, particularly the bacteria able to survive in pasteurisation , in the reconstitution step by applying what we suggested previously; ° Do microbiological analysis before pasteurisation and eliminating the quantity that contains that sort of bacteria; ° Improve preventive maintenance programme for the pasteuriser.
Microbiological contamination of the PPM		To prevent from the microbiological contamination of PPM, it is necessary : ° Although the rapid microbial test delivers results after 24h, it is necessary to not deliver the milk to the market before getting the results of the test of the pasteurised milk , to avoid the risk of delivering contaminated pasteurised milk; ° Do microbiological analysis for packaging , to avoid the contamination of pasteurised milk by the contaminated packaging.

Source : elaborated by the author based on AdoBPRIM software

3. Share Knowledge

As we indicated previously, the knowledge in the context of this study refers to the diagrams of K-PIMRBP. As one of the activities of this process, we shared the diagrams with laboratory responsible persons and we explained to them the contents of these diagrams and the objective of our study. We shared also the diagrams with workshops managers and we explained to them the content of them, who shared with the workers these diagrams.

We were supposed to organise workshops to explain the contents of the diagrams to all the staff members, who are working in the premises of the enterprise, but we were not allowed, so we opted for an alternative that we explained previously.

4. Knowledge storage

The diagrams are stored in files in paper version. In the future they can store them in the electronic data bases of the enterprise.

5. Knowledge application

As we indicated in chapter three, we were supposed after sharing the diagrams with the workers, to return to the enterprise after a period and re-analyse the operational risks in the workplace to assess the effectiveness of the K-PIMRBP outcomes in preventing from these risks, but it was not possible. Therefore, we opted for an alternative, which is the elaboration of a questionnaire to assess whether the outcomes of K-PIMRBP contributed to train the workers on operational risk management (microbiological contamination, production decline, inability to control costs and physico-chemical contamination), or not.

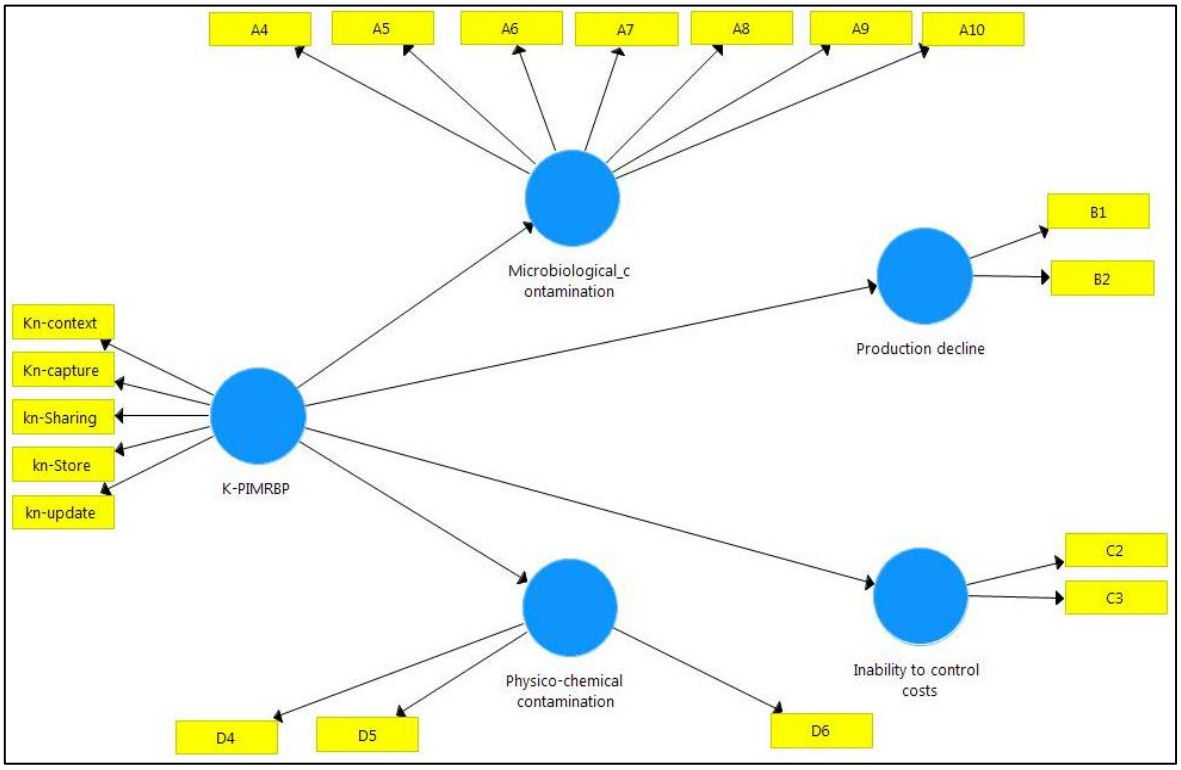
Chapter IV : Results and discussion

Phase III. Quantitative results

In the present sub-section we present the results of the quantitative study (see annexe A).

The Validation of measurement model includes: assessment of measurement model and assessment of structural model (Hair, Hult, Ringle, & Sarstedt, 2017, p. 130)

Figure n° 27: measurement model



Source: Outcome of SmartPLS3

1. Assessment of the measurement model

It is measured by convergent validity and discriminant validity (Hair, Hult, Ringle, & Sarstedt, 2017, p. 130),

1.1Convergent validity

The convergent validity is measured by the outer loadings, which should be more than 0.7, or between 0.4 and 0.7 under the condition that the retention of the item increases the composite reliability CE or the average variance extracted AVE (Hair, Hult, Ringle, & Sarstedt, 2017). We delated from the model the following items which did not meet the conditions mentioned before (A11,B3,B4,B5,B6,B7,B8,C1,C4,C5,D1,D2,D3).The table shows that CR of the

variables are higher than 0.7 as suggested by (Hair, Bill , Barry, & Rolph, 2006) while the AVR of the variables are higher than 0.5 (Fornell & Larcker, 1981).

Table n°39: convergent validity outcomes

Constructs	Items	Outer Loading	AVE	CR
Microbiological contamination	**A1**	**0.834**	**0.826**	**0.979**
	A2	**0.850**		
	A3	**0.938**		
	A4	**0.744**		
	A5	**0.964**		
	A6	**0.965**		
	A7	**0.934**		
	A8	**0.946**		
	A9	**0.929**		
	A10	**0.956**		
Production decline	**B1**	**0.937**	**0.679**	**0.806**
	B2	**0.693**		
Inability to control costs	**C2**	**0.864**	**0.752**	**0.858**
	C3	**0.870**		
Physico_chemical contamination	**D4**	**0.762**	**0.703**	**0.876**
	D5	**0.897**		
	D6	**0.852**		
K-PIMRBP	**Context**	**0.796**	**0.599**	**0.881**
	Kn_Capture	**0.889**		
	Kn_Sharing	**0.687**		
	Kn_Store	**0.736**		
	Kn_update	**0.745**		

Source: outcome of SmartPLS3

1.2. Discriminant validity

The discriminant validity is acceptable when the square root of the AVEs in the diagonal of the matrix are higher than the non-diagnal elements of the matrix (Fornell & Larcker, 1981). The table shows that the value of the elements in the diagonal are higher than the value of the elements in the non diagonal, so the discriminant validety of the model is accepted.

Table n°40: discriminant validity outcomes

	Inability to control costs	K-PIMRBP	Microbiological contamination	Physico-chemical contamination	Production decline
Inability to control costs	**0.867**				
K-PIMRBP	0.489	**0.774**			
Microbiological contamination	0.121	0.311	**0.909**		
Physico-chemical contamination	0.344	0.656	0.153	**0.839**	
Production decline	0.403	0.569	0.260	0.632	**0.824**

Source: the outcome of SmartPLS

2. Assessment of structural model

2.1 Path coefficient of the research Hypotheses

The table shows that the hypotheses 1, 2, 3 and 4 are supported

Table n°41: Path coefficient of the research Hypotheses

	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values	OBS
K-PIMRBP -> Inability to control costs_	0,489	0,522	0,113	4,345	**0,000**	**H3 is Supported**
K-PIMRBP -> Microbiological contamination	0,311	0,410	0,110	2,831	**0,005**	**H1 is Supported**
K-PIMRBP -> Physico_chemical contamination	0,656	0,676	0,070	9,351	**0,000**	**H4 is Supported**
K-PIMRBP -> Production decline_	0,569	0,598	0,084	6,817	**0,000**	**H2 is Supported**

Source: outcomes of SmartPLS3

2.2 Coefficient of determinant R2 ,the effect size $\mathbf{f^2}$

$\mathbf{R^2}$ measures the predictive power of the model, which should be higher than 0.1 (Falk & Miller, 1992); the results below show that the models are acceptable

Table n°42: Coefficient of determinant R2

	R^2
Inability to control costs	0.239
Microbiological contamination	0.1
Physico-chemical contamination	0.430
Production decline	0.324

Source: outcomes of SmartPLS3

f^2 measures the effect size of the independent variables on the dependant variables (Hair, Hult, Ringle, & Sarstedt, 2017) **.** According to (Cohen J. , 1988) , $f^2 > 0.35$ (the effect size is large), $0.15 > f^2 > 0.35$ (the effect size is medium), $0.02 > f^2 > 0.15$ (the effect size is small). The results of the present study are shown in the following table

Table n°43: effect size f^2

	f^2	**Results**
Inability to control costs	**0.315**	**Medium**
Microbiological contamination	**0.107**	**Small**
Physico-chemical contamination	**0.753**	**Large**
Production decline	**0.480**	**Large**

Q^2 measures the predictive relevance of the model (Hair, Hult, Ringle, & Sarstedt, 2017) According to (Chin , 2010), Q^2 above 0 means that the model has a predictive relevance. The results of the study are shown in the following table

Table n°44: the predictive relevance of the models Q^2

	Q^2
Inability to control costs	**0.155**
Microbiological contamination	**0.017**
Physico-chemical contamination	**0.287**
Production decline	**0.181**

The table 45 shows that all the models have predictive relevance.

Goodness of fit of the model GOF

According to (Wetzels, Odekerken-schroder, & Van oppen, 2009), tolerance intervals are (less than 0.1 = no fit; 0.1-0.25= small fit, 0.25-0.36= medium fit, greater than 0.36= large).

$$\mathbf{GOF=}\sqrt{(\overline{\boldsymbol{R^2}}\ \mathbf{x}\ \overline{\boldsymbol{AvE^2}}}\qquad\qquad \mathbf{GOF = 0.2}$$

From the result of GOF we conclude that goodness of fit the model is medium.

In the first section, we presented the results of the application of K-PIMRBP to Colaital, the study included three phases. In the first step we conducted interviews and analysed the qualitative findings from which we summarised the operational risks at Colaital into four classes namely : microbiological, physico-chemical , production decline and inability to control costs and we formulated the hypotheses of the study . In the second step we applied the K-PIMRBP to Colaital, and in the third step presented the quantitative findings, which indicated positive influence of the outcomes of this process on the prevention from the operational risks.

The results of the study are shown in the following table.

Table n°45: The results of the study(Colaital)

H1	K-PIMRBP outcomes contribute to train employees on microbiological contamination management	**Supported**
H2	K-PIMRBP outcomes contribute to train employees on production decline management	**Supported**
H3	K-PIMRBP outcomes contribute to train employees on the inability to control costs management	**Supported**
H4	K-PIMRBP outcomes contribute to train employees on Physico-chemical contamination management	**Supported**

Source: elaborated by the author

Chapter IV : Results and discussion

Section II : case Sosémie

In the second chapter, we will present the qualitative and quantitative findings we will also expose the outcomes of the K-PIMRBP application to Sosémie.

Phase I. Qualitative data analysis and the conceptual frame of the study (Sosémie)

The objective of the qualitative study is to explore the context of the study, identify the major operational risks in the short pasta –making process, reveal the major causes of risks and formulate the hypotheses on how the K-PIMRBP contributes to operational risks prevention.

The interviews guide encompasses three themes beforehand selected from the literature, which are as follows:

Table n°46: interviews guide

Theme	Explanation
Theme 01: The context of the study	The aim of this theme is to understand the context of the study: the activities and products of the enterprise and select the product that will constitute the subject of the study.
Theme 02: The operational risks in production process	The aim of this theme is to determine the operational risk classes occurring in the fabrication process that will constitute the subject of the study.
Theme 03: Operational risks prevention	The aim is to determine the factor that leads to risk prevention to formulate the hypotheses of the study;

Source: elaborated by the author

Theme 01: The study context

Question: can you describe the activities of Sosémie ?

" *Production at Sosémie entails two units …. the first unit is called "mill unit" where we do the first transformation of durum wheat and the soft wheat. …you should keep in mind that the semolina is made from durum wheat while the flour is made from soft wheat. … flour is sold as it while a part of semolina is sold as it and the other part passes by the second transformation in the second unit which is called " pasta and couscous unit " wherein we produce different kinds of pasta (long and short pasta) and couscous from semolina* ***"***

According to the interviewee Sosémie has two main activities namely : the first transformation of durum wheat to semolina and the transformation of soft wheat to four ,and the second transformation of semolina to pasta and couscous .In the present study we will examine the short pasta-making process.

Question 2: What are the main phases of short pasta-making process ?

"The short pasta and long pasta pass by the same process .... the pasta in general is made from thin semolina ... in the unit of pasta and couscous we receive thin semolina which is then mixed with water to prepare the dough then it is injected into a mould to give it a shape, after that we dry the shaped dough in the pre-dryer to dry the outside surface then we dry its inside surface in the dryer then we cool it ...we package the pasta to get the final product which is then stored and prepared for sale"

The short pasta-making process encompasses five activities namely: dough preparation, moulding, drying , cooling and packaging

Theme 02: The operational risks in production process

In this subsection, we will discuss a part of the interviews conducted with the staff members of the enterprise, in order to introduce the types of risks highlighted by them, which constitute the subject of the study

Question3: What are the operational risks that may occur in short pasta-making process ?

"*The process is full of risks from the reception of semolina to the final product ...we start from the raw material (semolina). ... as we discussed the pasta is made from thin semolina for that, after the " milling " it is transferred to " transfer unit" where it is sieved to eliminate particularly the 3SF and classify semolina into three types (thin semolina , medium and thick) after that the thin semolina is transferred to 'pasta and couscous unit" for the second transformation. .. if the thin semolina is not well sieved and contains medium semolina, white spot will appear in the final product...if the raw material contains 3SF, the final product will contains black spots which we consider as defects of the physical appearance of the pasta ... contaminations are also one of the main problems. ..we have also wastes throughout the process (in moulding , drying....) ...breakdown of the equipment and so on ....all those problems have negative effects on*

the quality of the product or even on the process of fabrication… one problem can stop all the process in one second…"

According to the interviewee , there are four classes of operational risks namely: production of wastes, contaminations, appearance defects and deficiency of equipment

Theme 03: Operational risks prevention

How can you prevent from those risks? Is it important to train workers on operational risk management to prevent from risks?

" *as you may notice during your visit to the premises, the poor quality in the workplace …the poor personal hygiene… we do not wear (hairnets, footwear…) ….because there is a lack of strict control, the workers lack of awareness and the responsible persons are not engaged in quality improvement …because it costs them a lot of money. …equipment breakdown because of the lack of preventive maintenance. ...so it is important to train workers on good manufacturing practices. …yes. … This will raise their awareness on the importance of quality in workplace. ..They will also understand the effect of wastes on the profitability… so yes it is important to involve workers in quality improvement for that it is important to train them on quality importance and impact of risks on quality of the product and therefore the reputation of the enterprise …."*

Based on the interviewee verbatim, we conclude that in order to prevent from operational risks it is important to train employees on operational risks management to raise the workers/employees' awareness on the effect of operational risks on product quality.

Therefore, we will try through the following study to test if the K-PIMRBP outcomes contribute to train employees on operational risks which leads to risk prevention, hence we formulated the following hypotheses

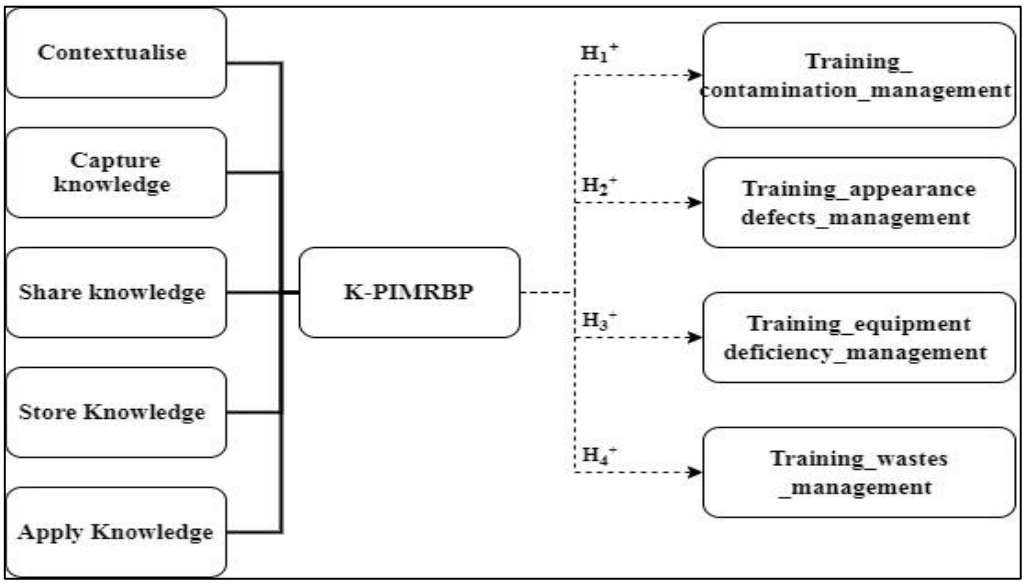
H1: K-PIMRBP outcomes contribute to train employees on contaminations management

H2: K-PIMRBP outcomes contribute to train employees on appearance defects management

H3: K-PIMRBP outcomes contribute to train employees on equipment deficiency management

H4: K-PIMRBP outcomes contribute to train employees on wastes management

Figure n°28: Conceptual framework (Sosémie)



Source: elaborated by the author

Phase II: The concretisation of K-PIMRBP at Sosémie:

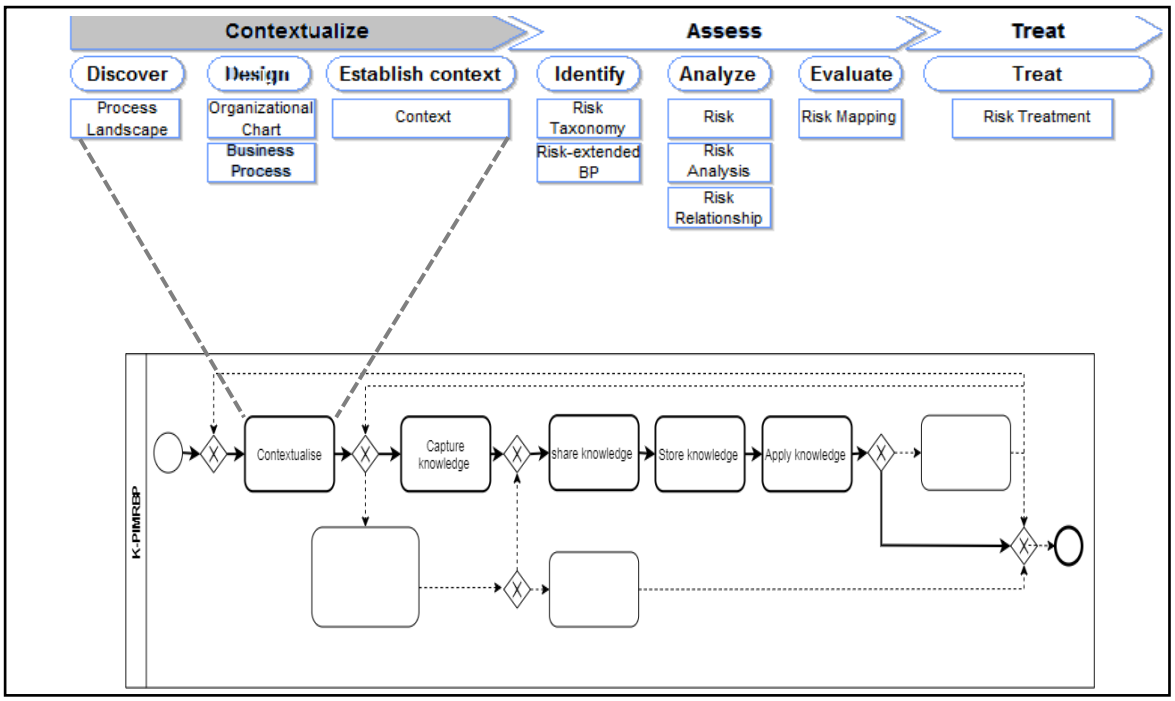
In this subsection, we will present the outcomes of the application of the K-PIMRBP for that we will follow the same steps as in the case of Colaital.

1. K-PIMRBP - Contextualise

The first activity in the preventive management process is the establishment of the context which gives an overview of the whole enterprise, the units included in the study , the actors and business processes constituting the subject of the study. We used the AdoBPRIM software to model the outcomes of the K-PIMRBP/contextualise which includes in the software four models (Process landscape, context, business process, organisational chart) .

The following figure shows the intersection between K-PIMRBP/contextualise---AdoBPRIM/contextualise

Figure n°29: the intersection between K-PIMRBP/contextualise--- AdoBPRIM/contextualise



Source: elaborated by the author

The table below outlines the contextualisation activity

Table n°47: contextualisation activity

Activity presentation	
Contextualise	
Description	***Context:*** The aim of this activity is to model the units of the enterprise included in the study, the actors in this activity and the objectives of the units and the staff members (see figure 30) ***Business processes:*** include the activities of the short pasta-making process (AS-IT processes) namely: dough preparation, moulding, drying, cooling and packaging. (see Figure) ***Process landscape***: shows the macro view of the process of short pasta-making process, which includes the management process, the support process ,and the business processes that constitutes the subject of this study.
Interviewees/information source	In order to understand the context of the study we conducted non-directive interviews and we discussed during the internship with:

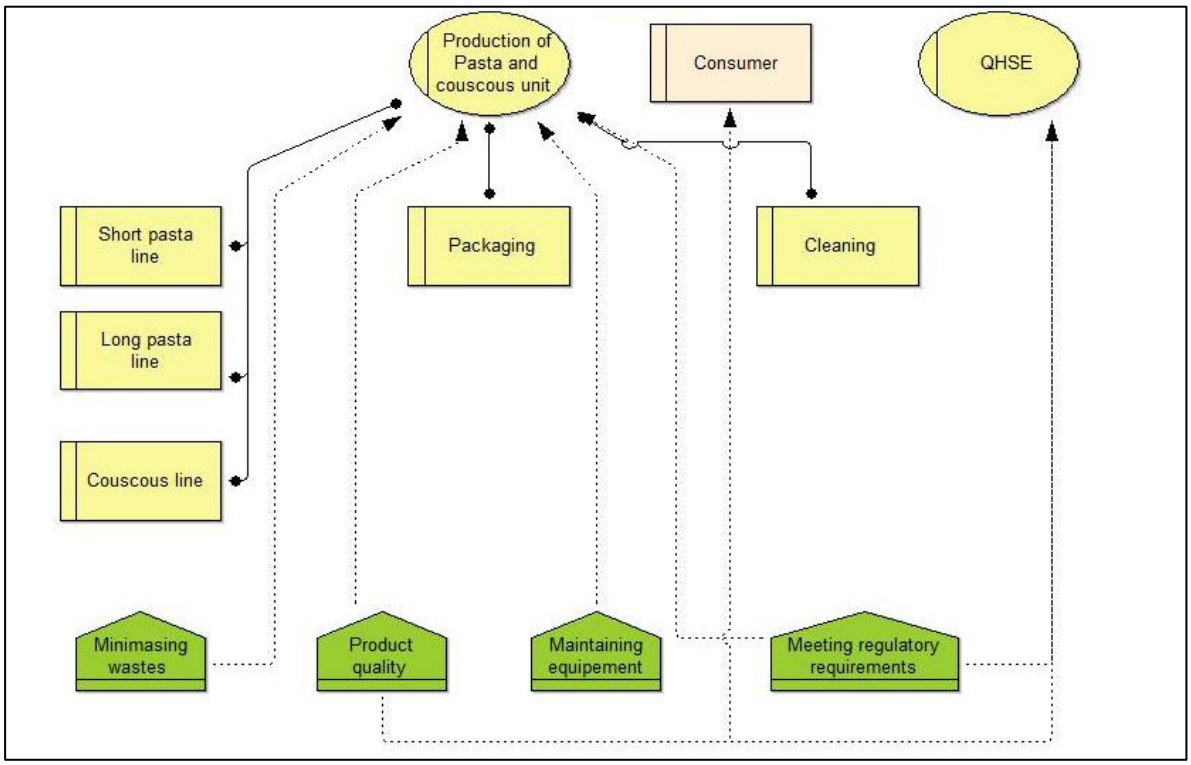
	• ***QHSE/Laboratory staff members*** (responsible, laboratory assistants in physico-chemistry and bacteriology) • ***Production staff members*** (Production responsible, line managers, workers)
Data (activity inputs)	***In order to establish the context we used :*** ***Documents*** (organisational chart of the Enterprise) ***Verbatim*** (input) **Observation**
Knowledge (activity outputs)	***The nature of knowledge in this step are diagrams*** (context-figure / business process-figure /process landscape-figure)
Data collection tools	***Interviews: were non-directive , because the aim was to understand the context of the study and particularly short pasta making process to model the BPs , the questions were :*** - What are the steps of short pasta-making process? - What are the units that contribute to short pasta-making process? - Can you describe each step in that process? - What are the materials and utensils used in that process? ***observation :*** We observed and attended to the short pasta-making process ***and documentary research (organisational chart)***
modelling toolkit	***AdoBPRIM***

Source: elaborated by the author

Figure shows the context diagram of the part of Sosémie that constitutes the subject of the study, which includes two units namely: Production of pasta and couscous unit, which entails three lines including (short pasta line, long pasta lines and couscous line), this unit is directed by the production responsible, and each line has a line manager and operators. Production unit should ensure product quality, maintain equipment, minimise as much as possible wastes, and meet the regulatory requirements.

QHSE responsible is in the same time the laboratory responsible. QHSE should ensure product quality and meet the regulatory requirement.

Figure n°30: the context diagram

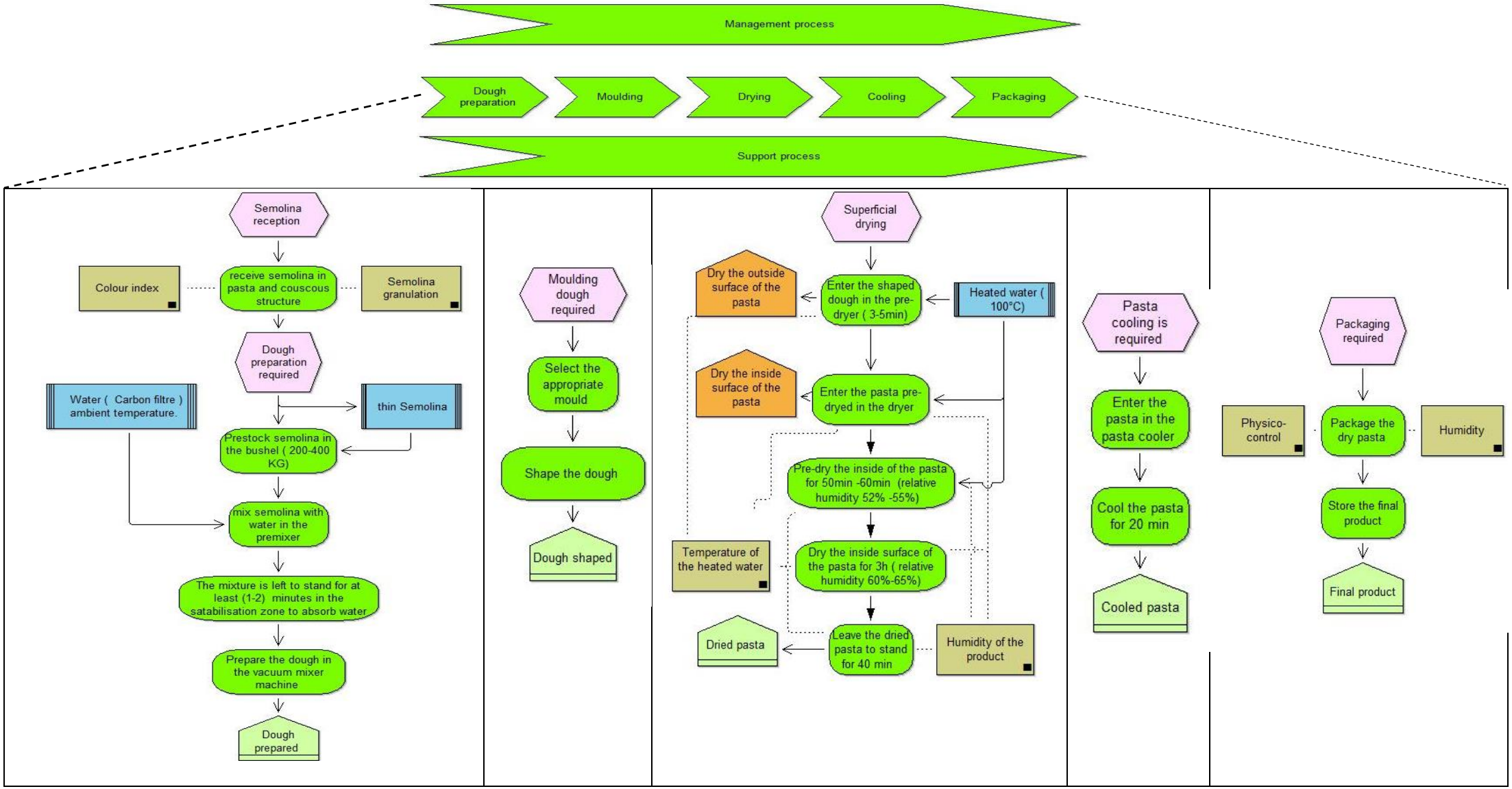


Source: elaborated by the author based on AdoBPRIM software

Figure 31 shows the Process landscape of sosémie , in the present study we focus on the operational level of the enterprise , in other words , we examine the business processes which involve five BPs namely : dough preparation , moulding, drying, cooling and packaging.

Business processes: The short pasta –making starts by preparing the dough , then it is shaped in the moulding step , the shaped pasta is then dried then it is cooled , and finally the dried pasta is packaged and stored , for more details about the business processes see figure 32.

Figure n°31: process landscape and BPs



Source: elaborated by the author based on AdoBPRIM software

Chapter IV : Results and discussion

For a better comprehension of the business processes of short pasta making, we will show in the following subsection, photos taken during our internship at Sosémie of the business process namely: Semolina transfer (raw materials, dough preparation, moulding, drying, cooling, packaging and storage).

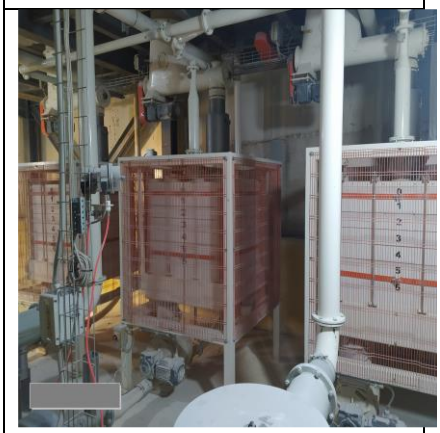
1. Semolina transfer:

In the transfer unit, the semolina is classified into three types (thin, medium and thick) and all additions and 3SF are eliminated to be then transferred to ‘pasta and couscous unit” where the semolina passes by the second transformation.

Figure n° 32: photos of semolina transfer at Sosémie

Silo

3SF filters



Refuse filters (7 sieves)

Scales

Source: taken by the author

2. Dough preparation

In the preparation step, the semolina is mixed with water to prepare the dough ‘see annexe” which is then entered to stabilisation zone and after that it is entered to the vacuum mixer for a better absorption of water and to get a homogenous mix.

Figure n° 33 : dough preparation activity at Sosémie

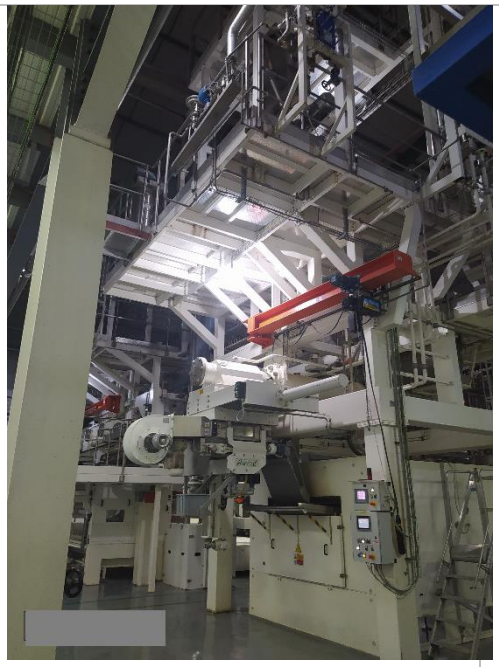
Source: taken by the author

3. Moulding step

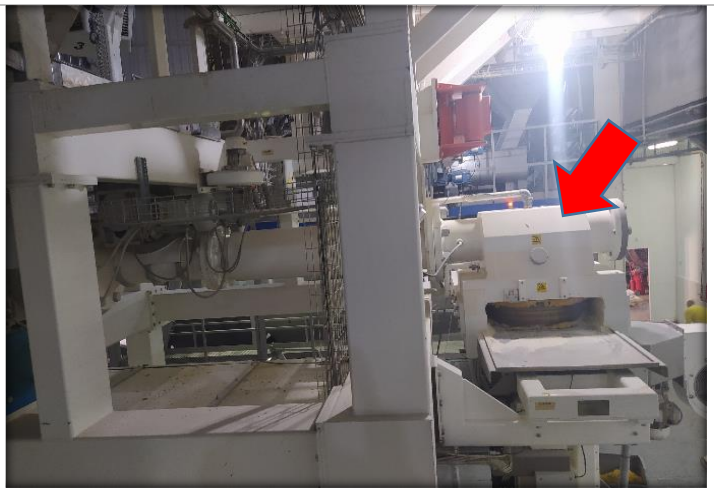
The figure 34 shows the moulding step

Figure n°34: Photos taken of the moulding step

Moulding



Moulding zone



Cutting unit

(Moulds) Pasta dies

Pasta

Source: taken by the author

4. Drying:

Photos show the drying process, this process involves two sub-processes, in the first phase the pasta is entered in the pre-dryer to dry the outside of the pasta then it entered to the dryer to dry the inside of the pasta

Figure n°35: photos of drying step at Sosémie

Pre-drying	 **Pre-dryer**	 **Pre-drying entry**  **Pre-drying exit**
Drying	 **dryer**	 **Drying exit**

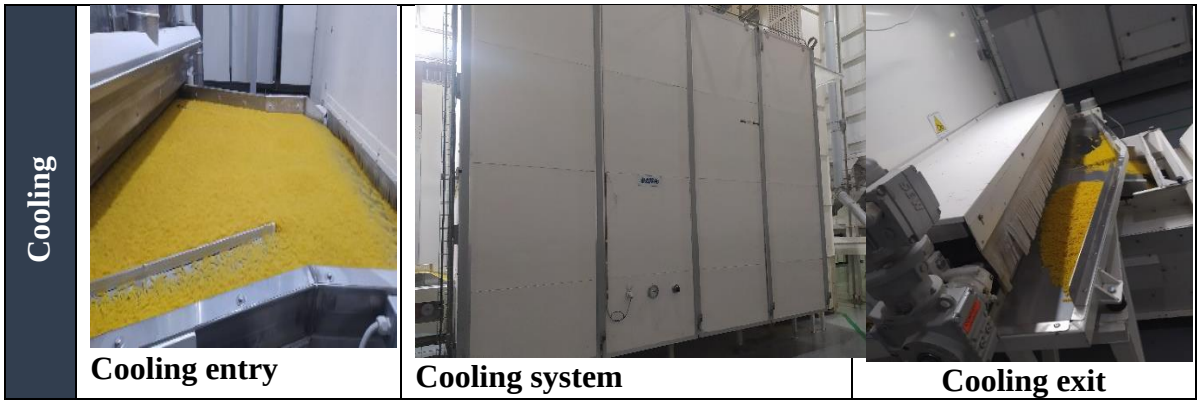
Source: taken by the author

Chapter IV : Results and discussion

5. Cooling

Figure 36 shows cooling system

Figure n°36: photos of cooling step at Sosémie



Source: taken by the author

6. Packaging:

Figure 37 shows the steps of packaging. After sieving and weighing the pasta, it is packed into plastic bags then into cardboard boxes.

Figure n°37: photos of packaging step

Source: taken by the author

Chapter IV : Results and discussion

7. Storage

Figure 38 shows the stores of Sosémie

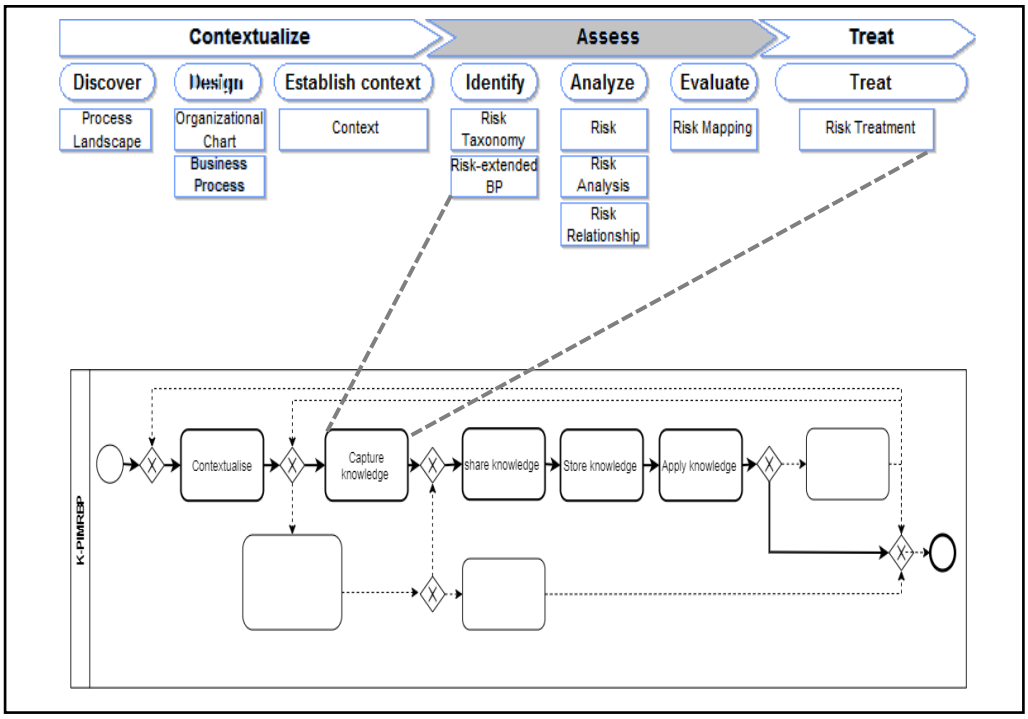
Figure n° 38: photos of the stores at Sosémie

Source: taken by the author

2. K-PIMRBP / Capture knowledge

In the present study, we mean by Knowledge the risk management outcomes in form of diagrams. So the , capture knowledge activity refers to the collection of the outcomes of the risks assessement (identification, analysis and evaluation) and risks treatment as shown in the

Figure n° 39: Capture knowledge (risk assessment & treatment)



Source: elaborated by the author

The table below outlines "**capture knowledge**" activity

Table n°48: capture knowledge

Activity presentation	
Capture knowledge	
Description	**1. Risk identification:** the aim of this activity is to determine the opertional risks throughout the short pasta-making process, this activity involves two sub-activities namely : **1.a) The risk taxonomy** (figure 40): In this activity we classified the potential and the actual operational risks into four classes of risks identified from the qualitative data analysis (see figure 40). **1.b) Risks-extended BP diagrams:** In this activity we place the risks in the business processes in order to show the position of risks. **2. Risk analysis:** The aim is to determine the **risk causes , risk situation, risk likelihood for this we applied qualititative estimation as follows :** **0:** not defined **1:** very improbable **2:** very unlikely **3:** unlikely **4:** possible/likely **5:** very likely to certain **And risks severity :** **0:** not defined **1:** minor **2:** significant **3:** major **4:** critical **5:** catastrophic **The impact of the risk on values:** degrades, worsens, cancels or increases the value created in the enterprise. **3. Risk evaluation:** the risk may be acceptable , acceptable under control or unacceptable ; the risk evaluation is visualised in the risk matrix **figure 41**

	Risk Treatment: the aim of this activity is to provide treatment scenarios to treat the risks (see table 51)
Interviewees/information source	In order to assess the risk (**capture knowledge**: identify, analyse and evaluate risks) we conducted non-directive interviews with: ***Laboratory staff members*** (responsible, laboratory assistants in physico-chemistry and bacteriology) ***Production staff members*** (Production technical assistant, Workshops managers, workers)
Data (activity inputs)	***Verbatim (input)***
Knowledge (activity outputs)	***The nature of knowledge in this step are diagrams (risk taxonomy, Risks-extended BP diagrams and risk matrix)***
Data collection tools	***Interviews:*** were non-directive ,because the aim was to determine the operational risks in each BP and the position of risks in the BPs and evaluate the risks : What are the operational risks (problems, errors …) to which the BPs are exposed? What are the causes of these risks? How can these risks affect the product? How often this risk occur? What is the severity of this risk? ***observation :*** during our internship at Sosémie we observed and attended to short pasta making process
Modelling toolkit	***AdoBPRIM***

Source: elaborated by the author

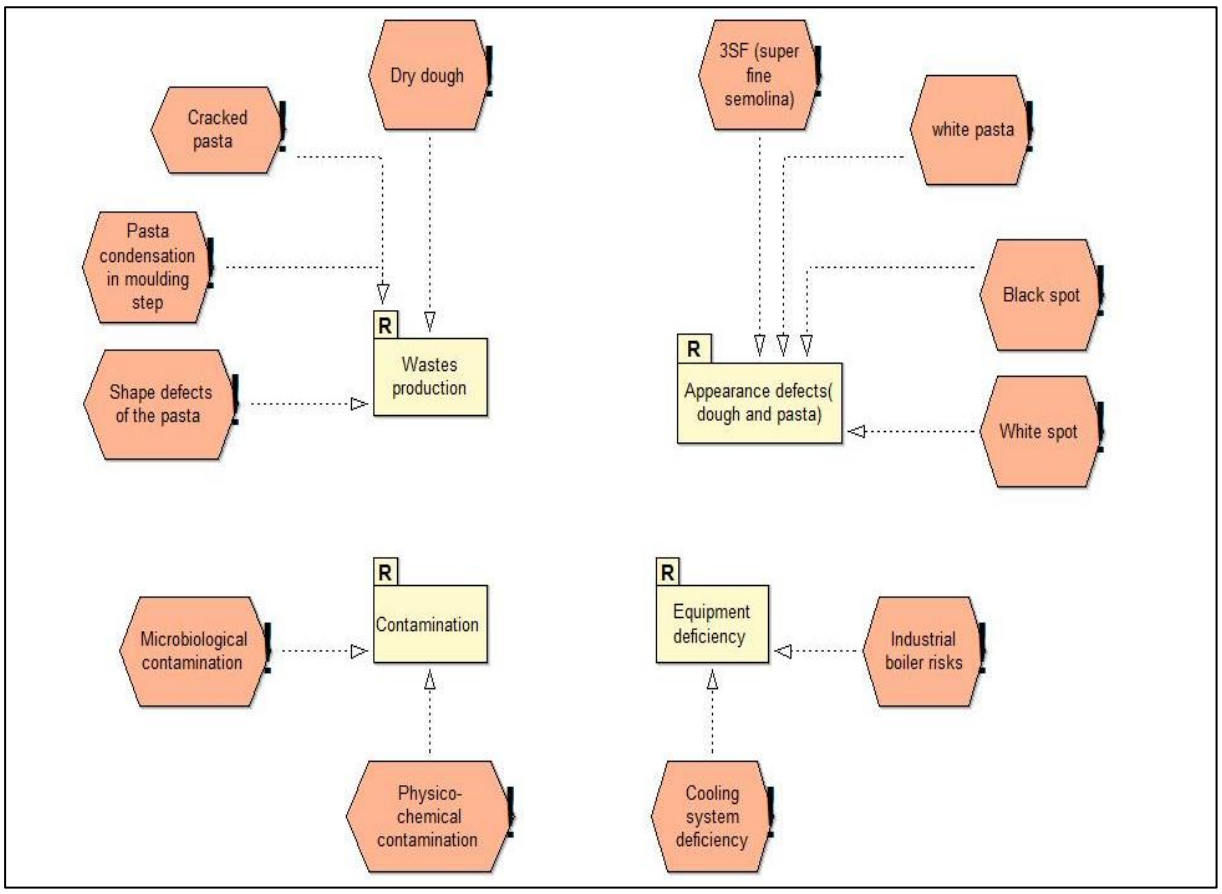
a.Assessement-*identification* : In this activity we identify the operational risks reported by the interviwees (the staff members) and observed by the researcher during our presence in the workshops. Figure 40 shows the risk taxonomy as follows:

a.1 Risk taxonomy:

Short pasta-making process is exposed to four main operational risks classes wherein each class involves many operational risks as discussed in the qualitative section namely: (1) contamination class (**2)** Appearance defects (**3)** Wastes production (**4)** equipment deficiency

Figure 40 shows the taxonomy of risks

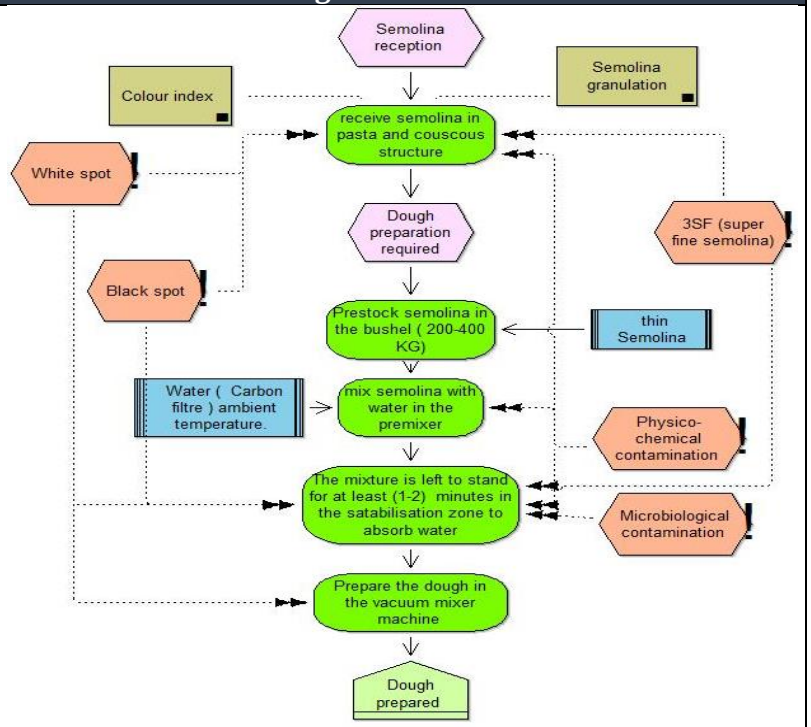
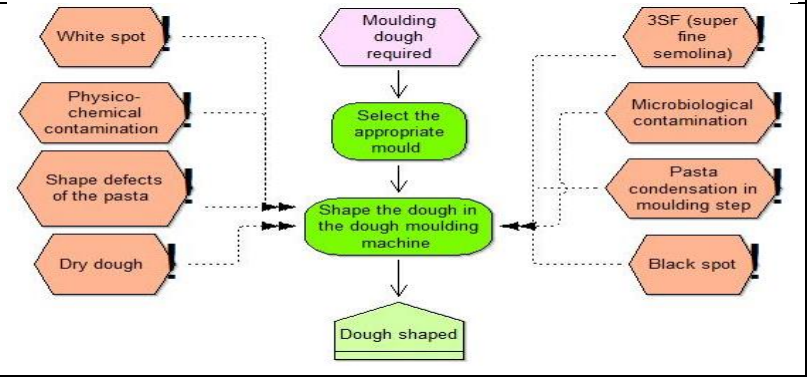
Figure n°40: taxonomy risk (Sosémie)

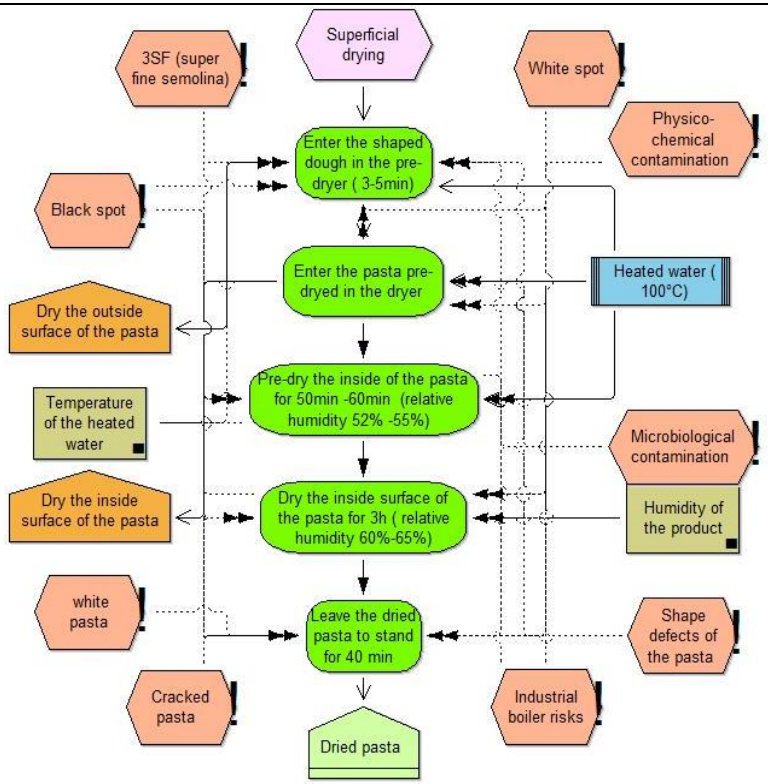


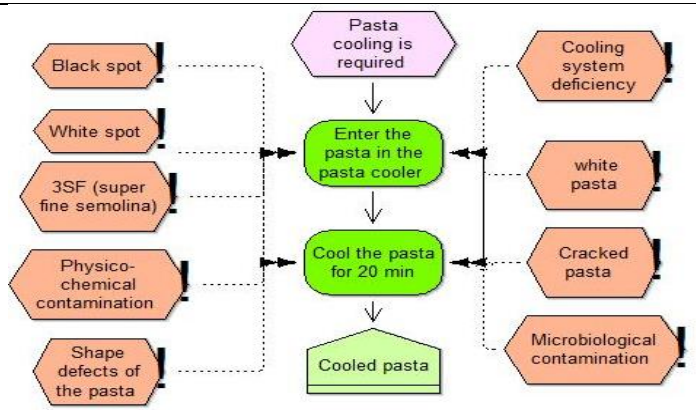
Source: elaborated by the author based on AdoBPRIM software

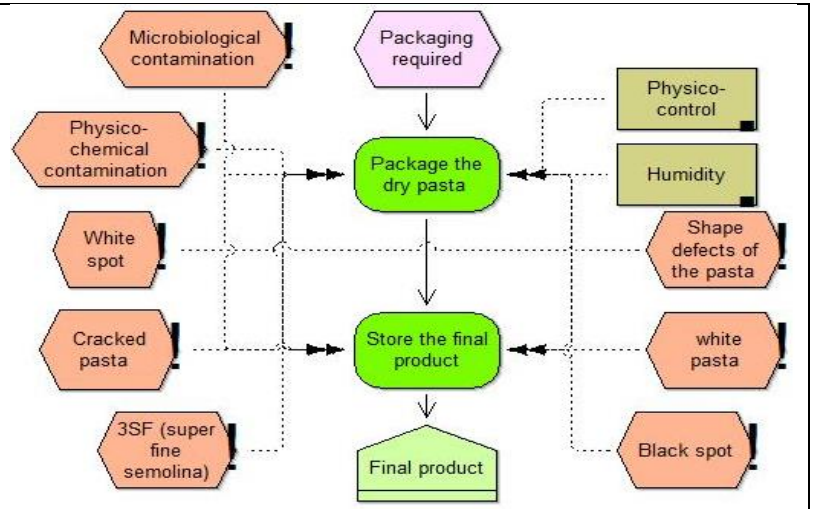
a.2) Risk-extended BP: Table indicates the operational risks in business processes (reconstituted, pasteurisation and packaging) of PPM process

Table n° 49: Risks-extended BP diagrams

BPs	OPR	Comments	Risks-extended BP diagrams
Dough preparation	**Physico-chemical contamination**	The transferred semolina ,from the milling to pasta and couscous unit, may contain microorganisms (insects, debris…), so it should pass by "the transfer unit" where they eliminate these microorganisms but it may still some contaminants that cause physico-chemical contamination	
	Microbiological contamination	The semolina can be exposed to microbiological contamination if there is mould on semolina	
	White spot	White spot is an appearance defect that may appear in the dough and the pasta	
	Black spot	Black spot is an appearance defect that may appear in the dough and the pasta	
	3SF	Very thin semolina that should be removed from semolina by using filters that contain sieves. The presence of 3SF in the semolina is the source of the white spot on the dough and the pasta.	
Extrusion (moulding)	**White spot**	If the white spots appear on the dough, it will continue to appear in the whole process	
	3SF	If the raw material "semolina" contains 3SF, the dough and pasta will also contain it.	
	Black spot	If the black spots appear on the dough, it will continue to appear in the whole process	
	Shape defects of the pasta	The unevenness of the pasta in size, which is produced in the moulding (extrusion) step.	

	Condensation in the moulding step	The condensation of dough may occur during extrusion (moulding) step, the dough sticks in the mould (dies)	
	Dry dough	It refers to the under-hydration of the dough , when there is limited amounts of water in the dough	
	Microbiological contamination	The presence of microbiological contaminants(bacteria …)in the dough	
	Physico-chemical contaminations	The presence of physico-chemical contaminants in the dough	
Drying step	**3SF**	If the raw material "semolina" contains 3SF, the pasta in drying step will also contain it.	
	White spot	If the white spots appear on the dough, it will appear on the pasta in drying step	
	Black spot	If the black spots appear on the dough, it will appear on the pasta in drying step	
	White pasta	Opaque pasta product is one of the physical appearance defects of the pasta, it may appear in drying process in packaging and/or store.	
	Shape defect of the pasta	This defect is produced in moulding step and continue to appear in drying step	
	Cracked pasta	The cracks in pasta during or after drying	
	Industrial boiler risks	For pasta drying , we use heated water from the industrial boiler , if it is misadjusted this will affect the water temperature and therefore the drying process	
	Microbiological contamination	The presence of microbiological contaminants(moulds) after drying, if the pasta is not well dried , in the other words , the moisture percent was not reduced	
	Physico-chemical contaminations	The presence of physico-chemical contaminants in the pasta	

Cooling	**Black spot**	If the black spots appear on the dough in preparation step, it will appear on the pasta in cooling step	
	White spot	If the white spots appear on the dough in preparation step, it will appear on the pasta in cooling step	
	3SF	If the raw material "semolina" contains 3SF, the pasta in cooling step will also contain it.	
	White pasta	Opaque pasta product is one of the physical appearance defects of the pasta, it may appear in drying process in packaging and/or store.	
	Cracked pasta	The crack in the pasta may began to appear in the drying step or in the cooling step	
	Shape defects of the pasta	This defect is produced in moulding step and continue to appear in drying step	
	Cooling system deficiency	Is a system used after drying step to lower the temperature of the dried pasta before packaging to avoid the development of moulds in packaging, so the system failure will interrupt the whole process.	
	Microbiological contamination	Is originated from the development of moulds	
	Physico-chemical contamination	The presence of physico-chemical contaminants in the pasta	
Packaging	**3SF**	If the raw material "semolina" contains 3SF, it will appear in the final product.	
	Black spot	If the black spots appear on the dough in preparation step, it will appear on the final product	
	White spot	If the white spots appear on the dough in preparation step, it will appear on the final product	
	White pasta	Opaque pasta product is one of the physical appearance defects of the pasta, it may appear in the final product	

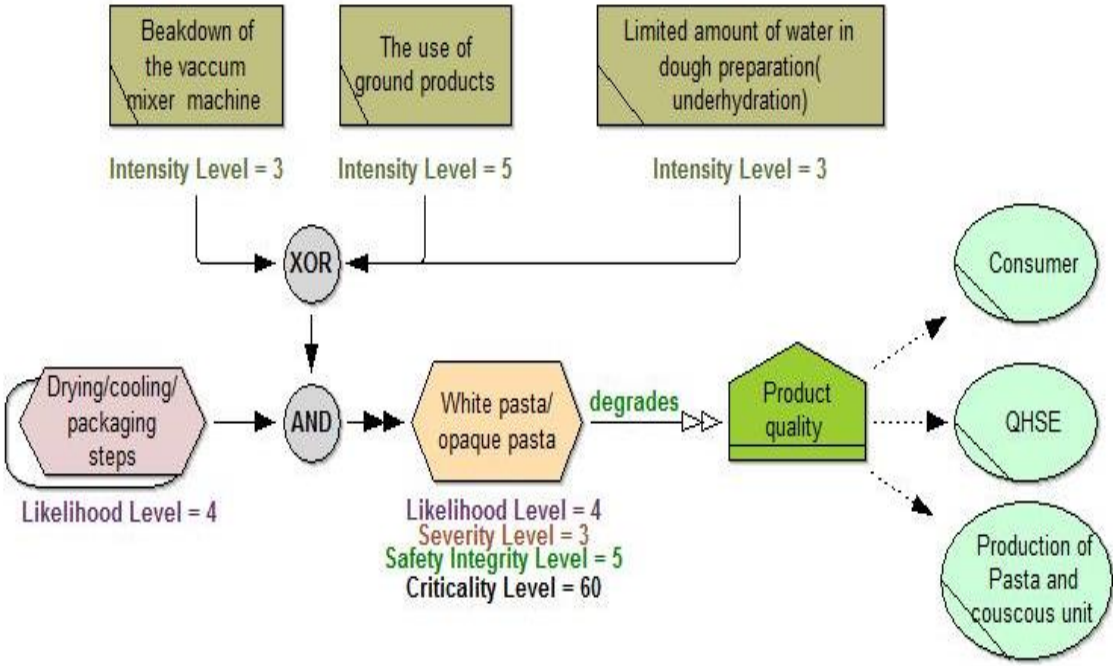
	Shape defects of the pasta	This defect is produced in moulding step and continue to appear in drying step	
	Cracked pasta	The crack in the pasta may began to appear in the drying step or in the cooling step	
	Microbiological contamination	The development of moulds on final products	
	Physico-chemical contamination	The presence of physico-chemical contaminants	

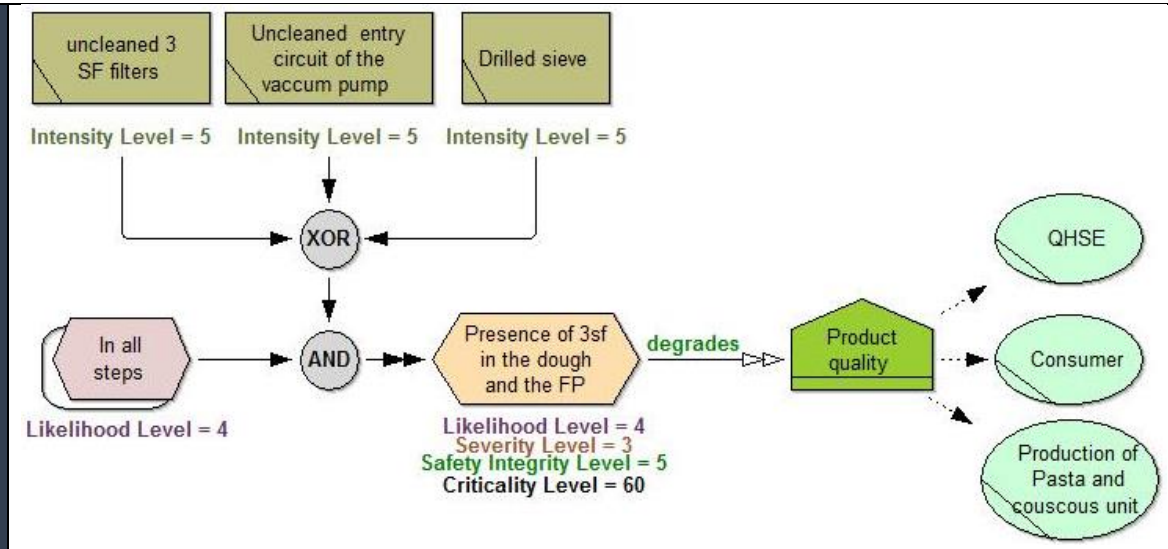
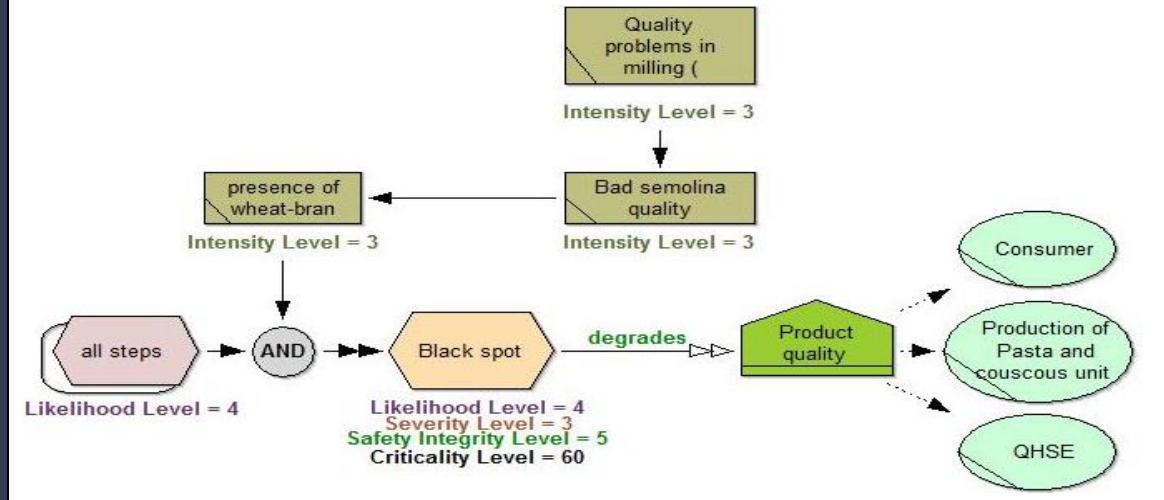
Source: elaborated by the author based on AdoBPRIM software

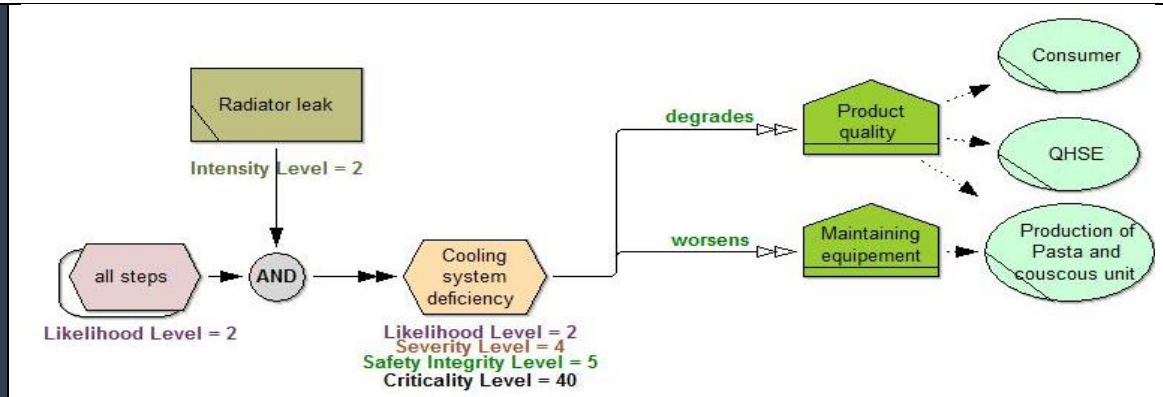
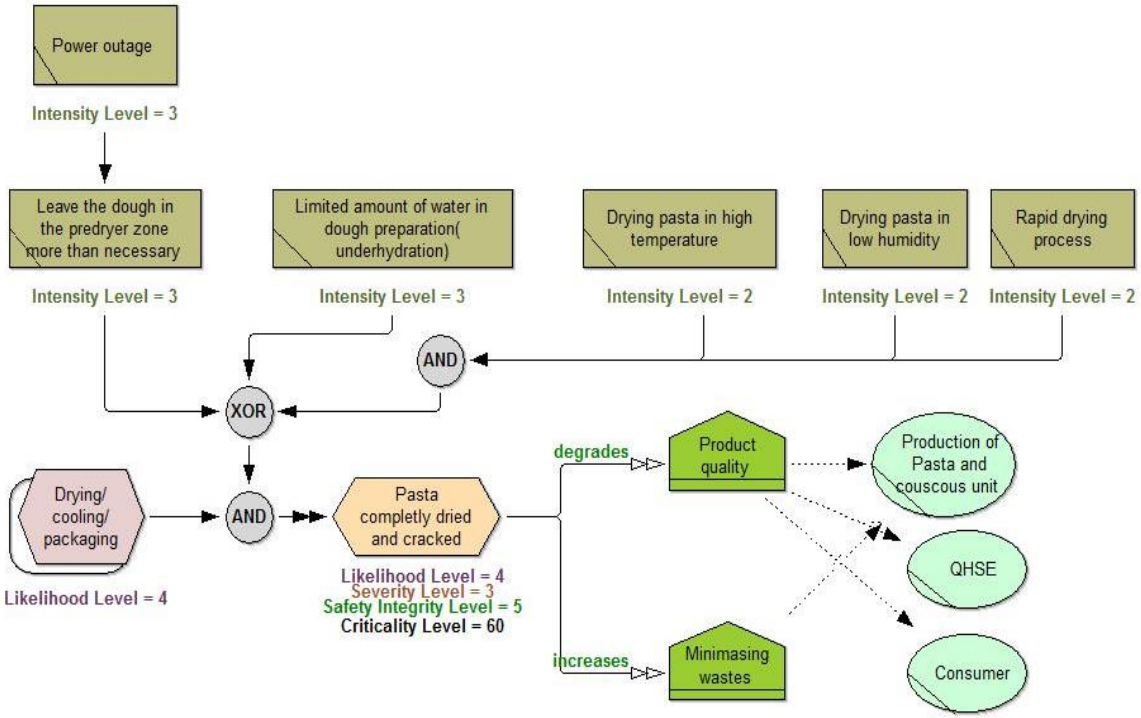
a.3) Assessment - Risk analysis:

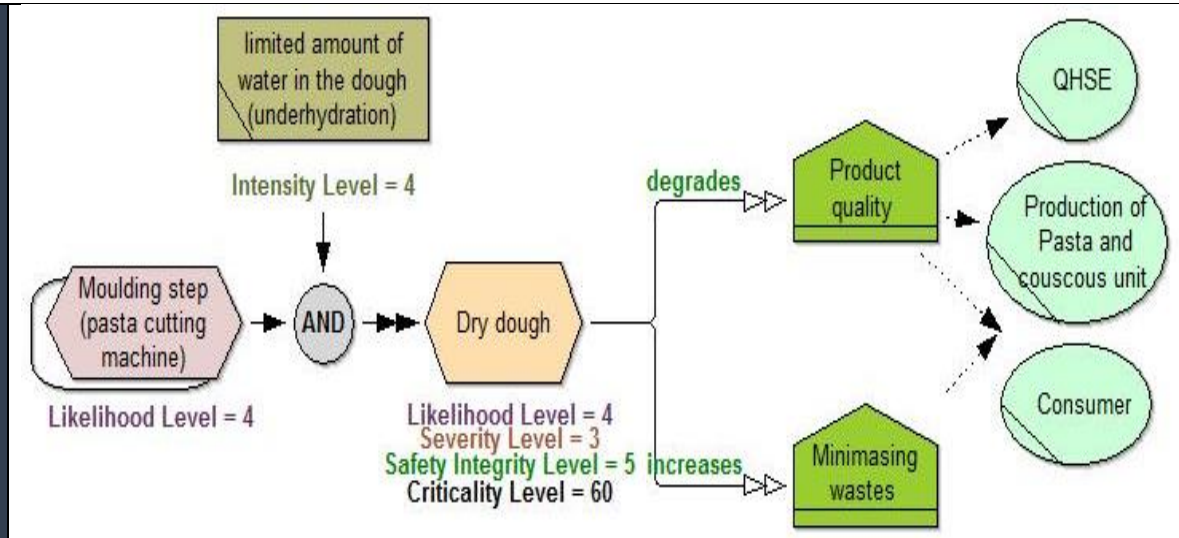
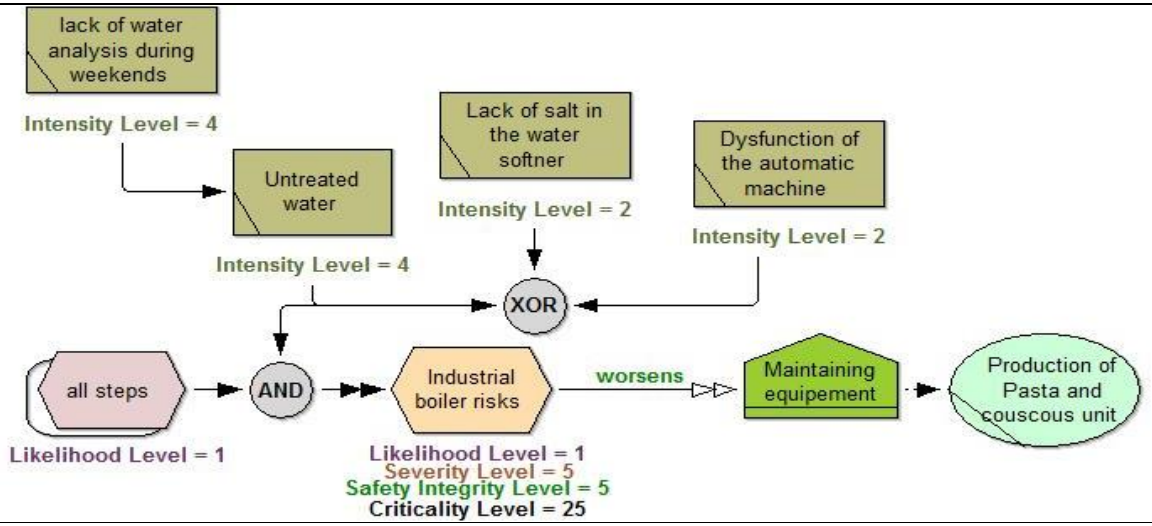
Each risk has enormous causes and has impact on the enterprise objectives, in the following table we display the risk analysis of the risks determined:

Table n°50: risk analysis diagrams (Sosémie)

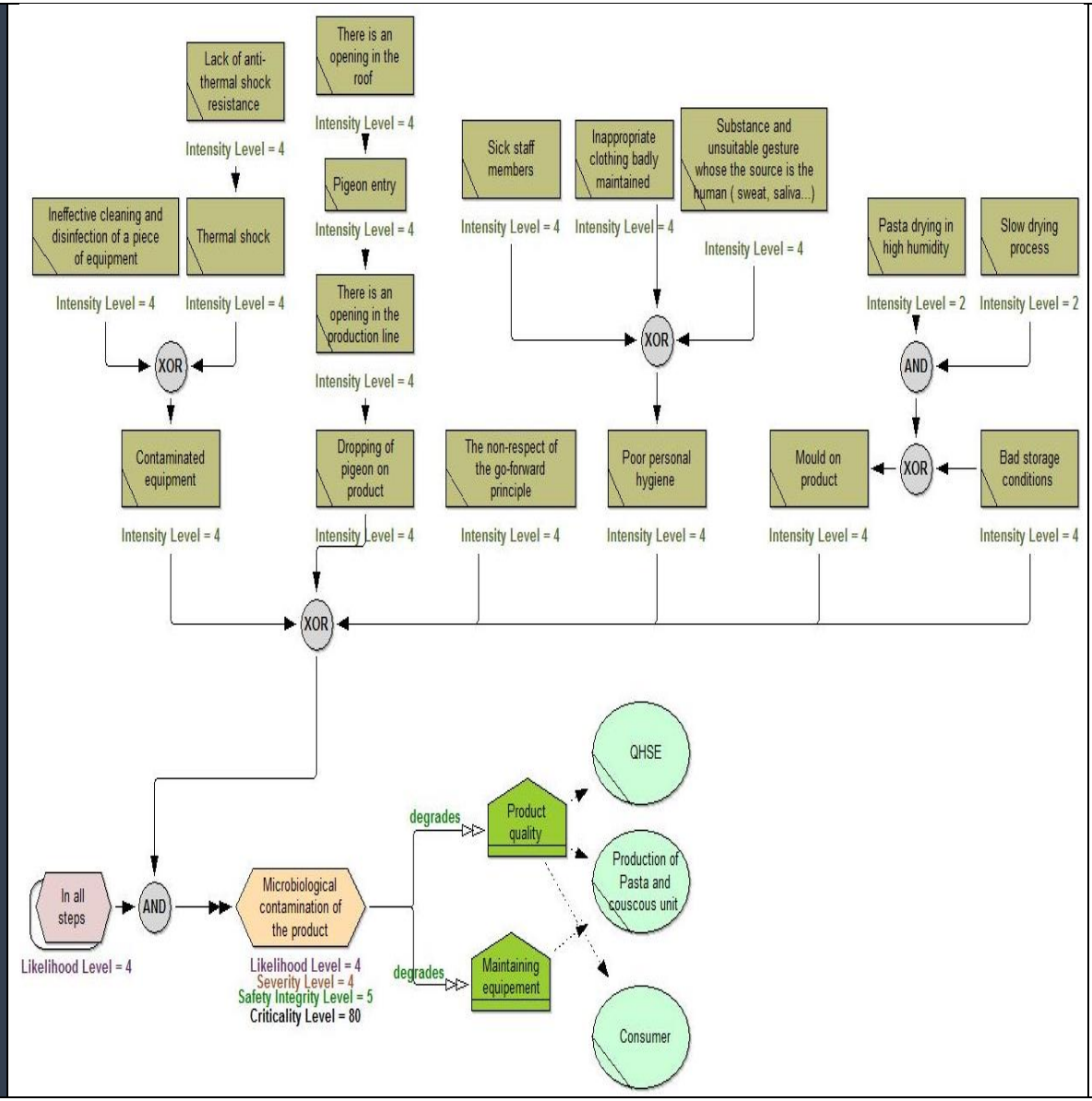
OPR	Risk analysis diagrams	Comments
Opaque pasta		Opaque pasta product is an appearance defect which is originated from: ◦ The use of ground products which is mixed with semolina and water during dough preparation; ◦ Breakdown of the vacuum mixer machine prevents the mixture from absorbing the water equally, which produces non-homogeneous mix, the air also will not be removed from the mixed which will allow the development of air bubbles on the dough and on the pasta; ◦ The under-hydration in preparation step; This risk can possibly occur which is a major risk because it affects the visual quality of the product ,for which QHSE and production units are responsible, which influences also the consumers' perception

3SF		The 3SF is very thin semolina , which is the source of the presence of small spot on the pasta, hence it should be removed from semolina before preparation . The sources of the presence of 3SF are: ° Sieves of 3SF filers are drilled in "transfer unit" ° Unclean 3SF filters in production unit; ° Unclean entry of the vacuum pump; so the 3SF are not removed of the mixture; This risk can possibly occur which is a major risk because it affects the visual quality of the product ,for which QHSE and production units are responsible, which influences the consumers perception
Black spot		Black spots is an appearance defect which is originated from: The presence of wheat-bran in the semolina, which should be eliminated during milling. This risk can possibly occur which is a major risk because it affects the visual quality of the product ,for which QHSE and production units are responsible, which influences the consumers perception

Cooling system deficiency		Cooling system failure is caused by the radiator leak This risk can very unlikely happen, it is a critical risk because it interrupts all the process.
Cracked pasta		Cracks in the pasta are originated from : ° Rapid drying process in high temperature and in low humidity , ° Under-hydration of dough ° Leaving the pasta in the pre-dryer for more than 5min, in case of power outage, so cracks will appear in the pasta This risk can possibly occur which is a major risk because it affects the visual quality of the product, for which QHSE and production units are responsible, which influences the consumers' perception. If the cracks appear in the pre-drying , they should be thrown which increases the quantity of wastes.

Dry dough		The dry dough in extrusion (moulding step) is originated from: ° Under-hydration of the mixture during preparation This risk can possibly occur which is a major risk because it affects the quality of the product because it is the cause of opaque pasta product, for which QHSE and production units are responsible, which influences the consumers' perception. If the dough is too dry it should be removed from the extruder
Industrial boiler risks		Industrial boiler provides heated water to dry pasta, its failure is originated from : ° The use of untreated water , particularly in weekends because the laboratory is closed; ° The lack of salt in the water softener ; ° The dysfunction of automatic machine associated with the boiler. The industrial boiler is considered as a bomb , its explosion is a catastrophic risk , for which the production unit is responsible and its failure will interrupt the pasta-making process

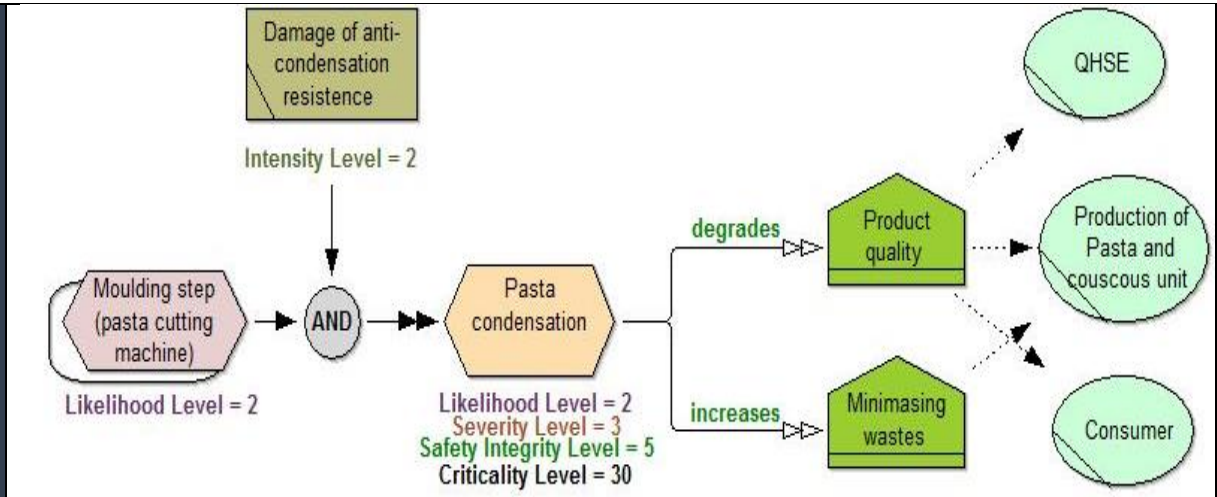
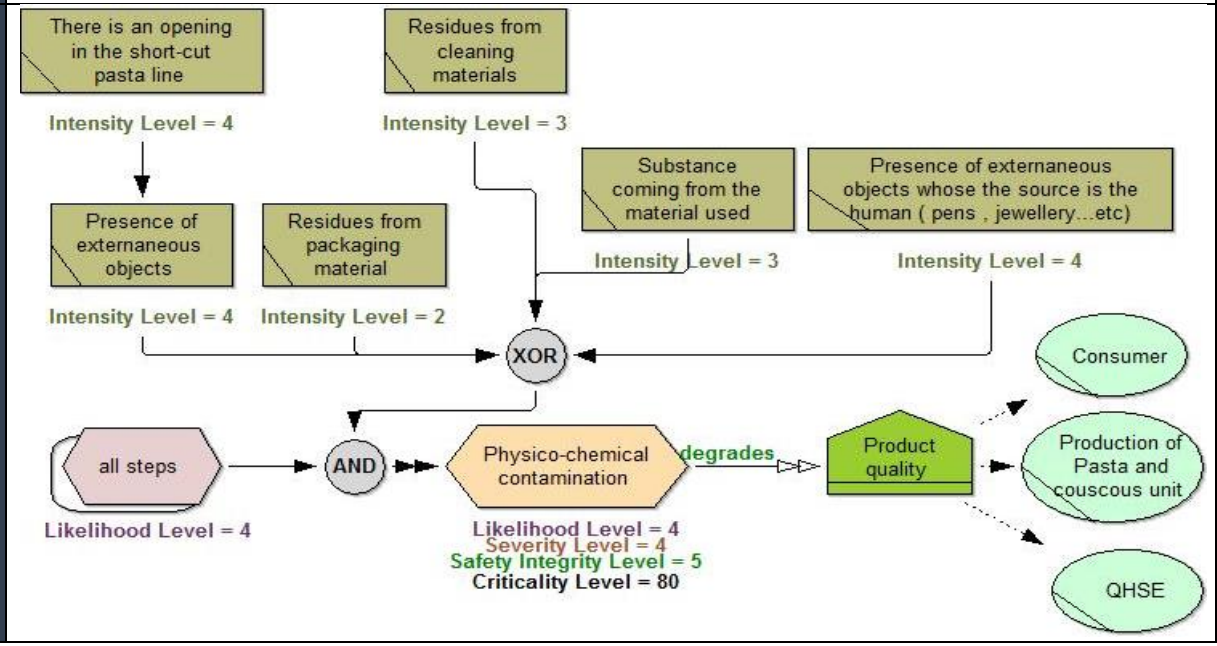
Microbiological contamination

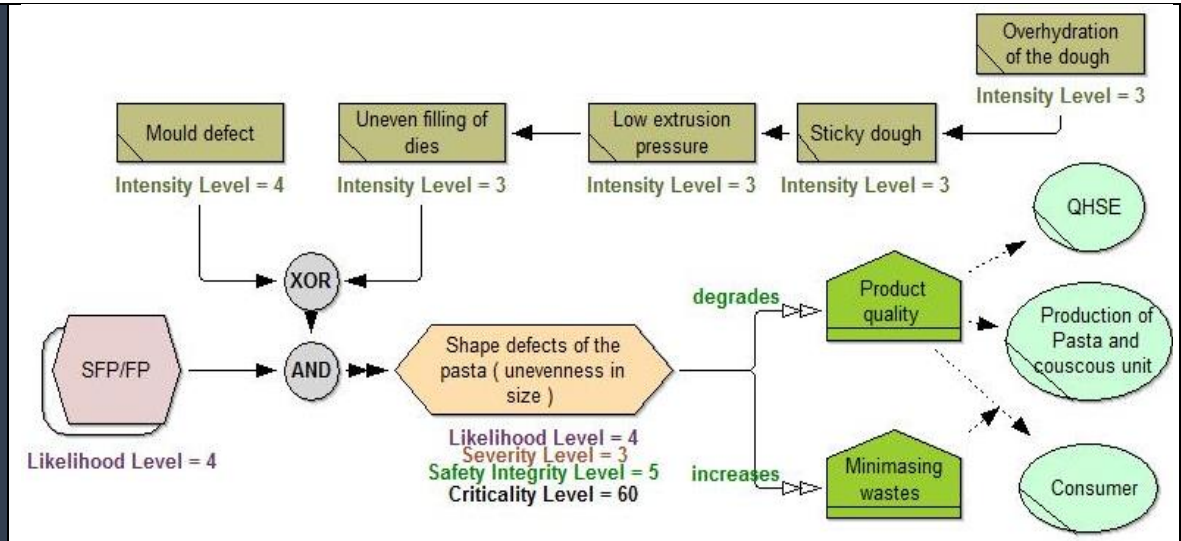
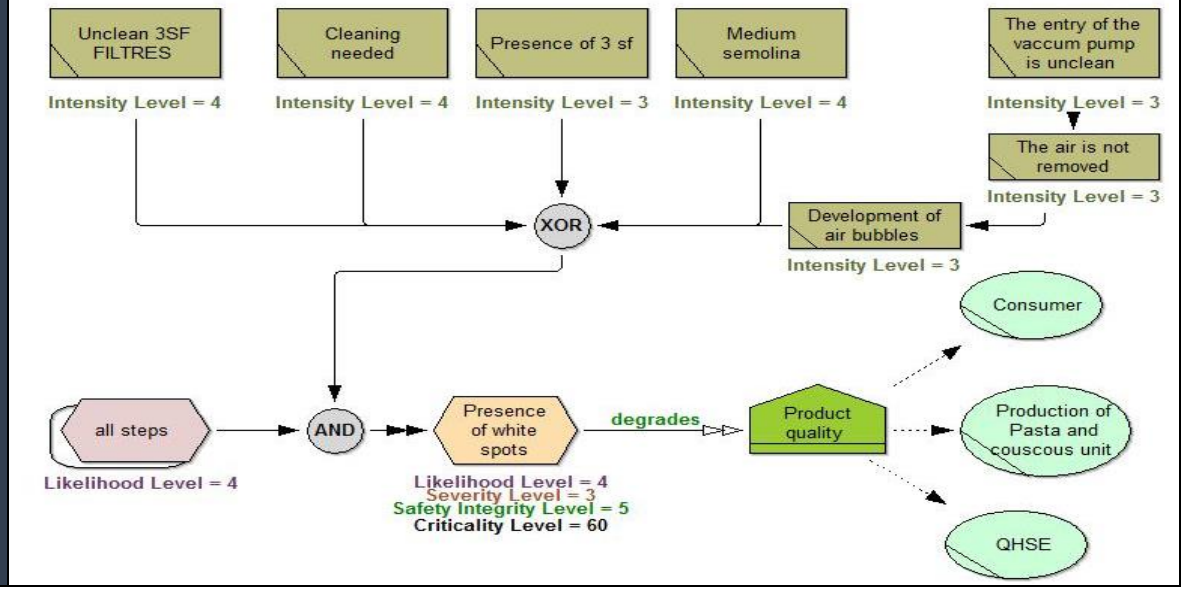


All the pasta-making process is exposed to microbiological contamination(micro-organisms), from semolina to the final product which is originated from :

- Contaminated equipment ;
- The non-respect of go-forward principle, the contact of the product with wastes;
- Bad drying and bad storage conditions lead to the development of moulds on the products;
- Poor personal hygiene;
- Dropping of pigeon on product.

This risk can possibly occur in the enterprise, which is a critical risk because it degrades the product quality and safety for which QHSE and production units are responsible, which influences the consumers' perception.

Pasta condensation		The cause of pasta condensation in moulding step is: The damage of the anti-condensation resistance which provides hot air to avoid the pasta condensation This risk can very unlikely happen , but it is still a major risk because it affects the product quality , for which QHSE and production units are responsible, which influences the consumers' perception, and in some cases it should be removed completely from the extruder which increases the wastes.
Physico-chemical contamination		All the pasta-making process is exposed to physico-chemical contamination(micro-organisms), from semolina to the final product which is originated from : ° Presence of extraneous objects, because there is an opening in the line ° Residues from cleaning materials ° Residues from packaging materials ° Substance coming from equipment and materials used (debris) ° Presence of extraneous objects whose the source is the human This risk can possibly occur in the enterprise, which is a critical risk because it degrades the product quality and safety for which QHSE and production units are responsible, which influences the consumers' perception.

Shape defects of the pasta		The shape of the pasta can be uneven in size because of : ° Mould defect, in which the dies are uneven ° Uneven filling of the dies, if the dough is overhydrated which lowers the extrusion pressure This risk can possibly occur in the enterprise, which is a major risk because it degrades the visual quality of the product for which QHSE and production units are responsible, which influences the consumers' perception
White spot		The presence of white spots on the dough and the pasta is originated from: ° Presence of 3SF in the semolina; ° Presence of medium semolina with the thin semolina ; ° Unclean 3SF filters; ° Unclean entry of vacuum pump , so the air is not removed from the mixture of semolina and water which allows the development of air bubbles. This risk can possibly occur in the enterprise, which is a major risk because it degrades the visual quality of the product for which QHSE and production units are responsible, which influences the consumers' perception

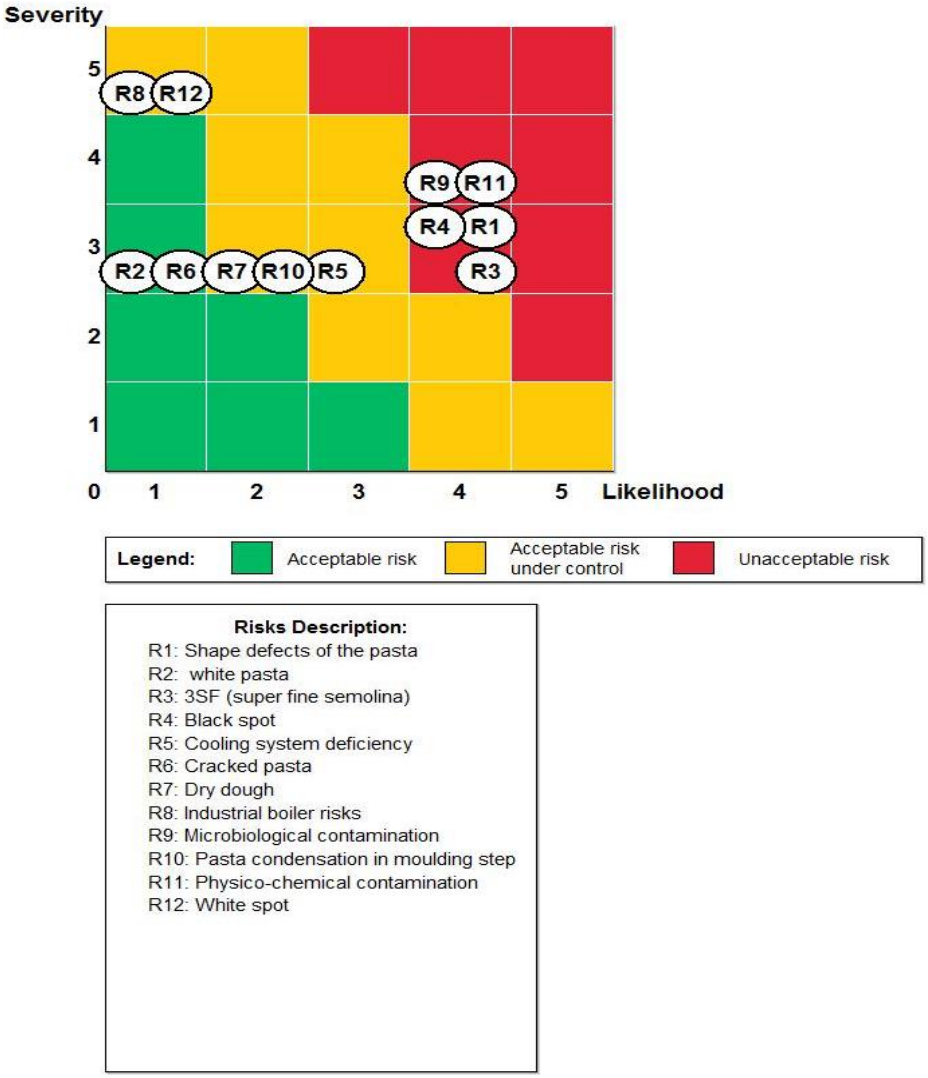
Source: elaborated by the author based on AdoBPRIM software

Chapter IV : Results and discussion

a.4) Assessment -Risk evaluation/matrix

Figure shows the risk evaluation matrix

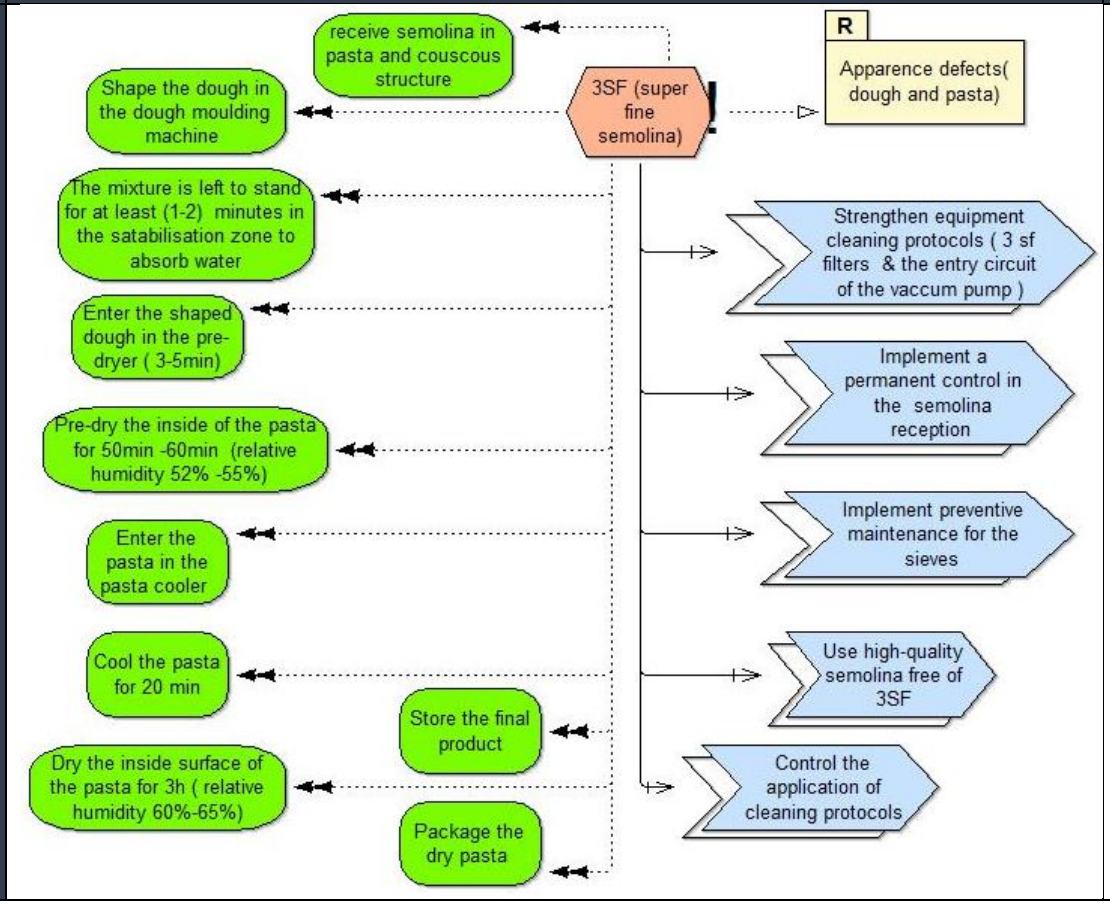
Figure n°41 : risk matrix (Sosémie)

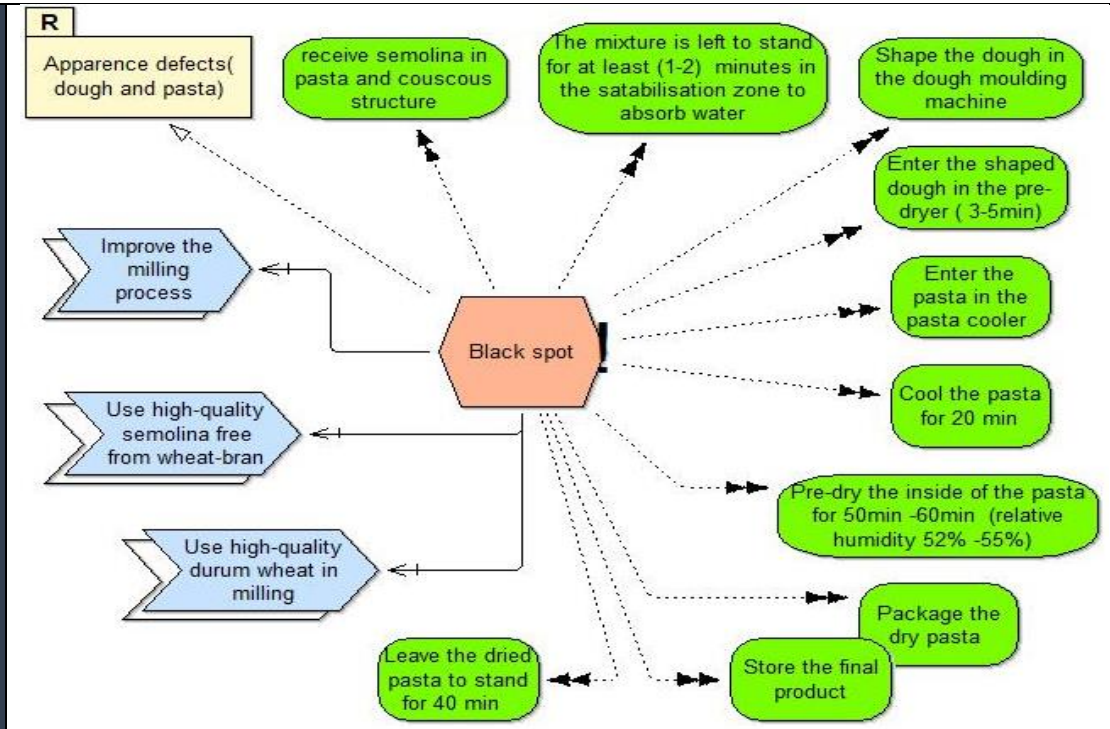
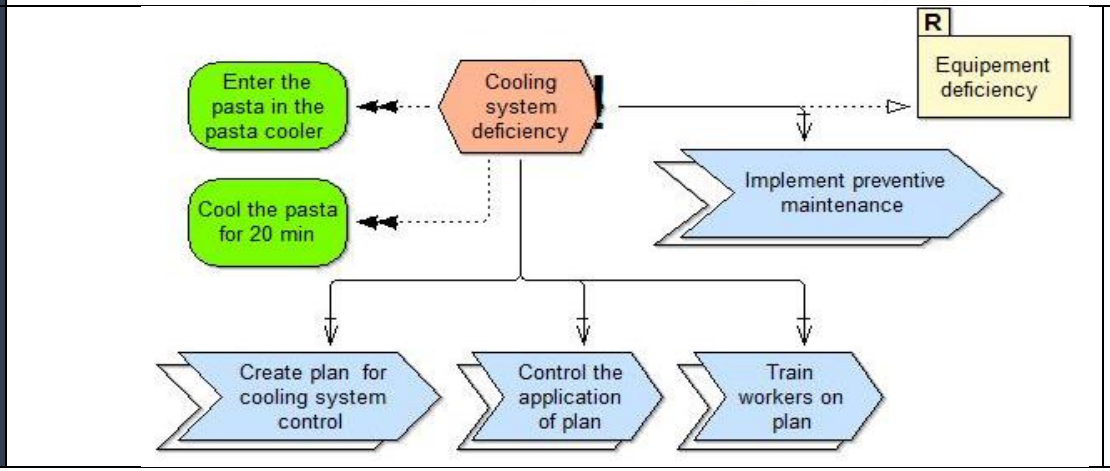


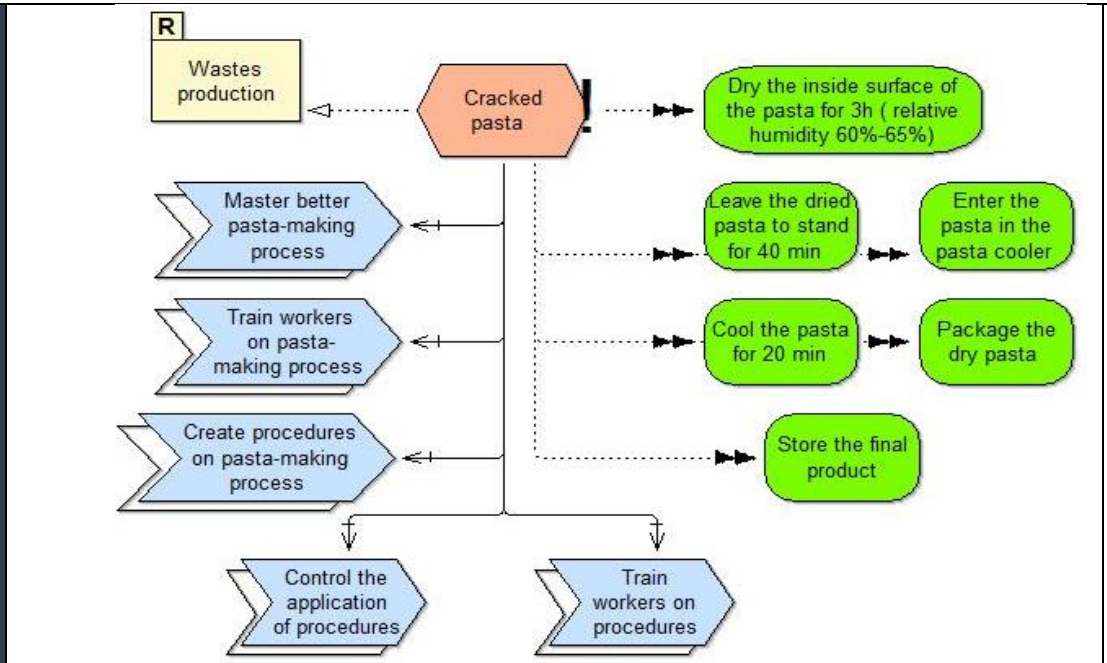
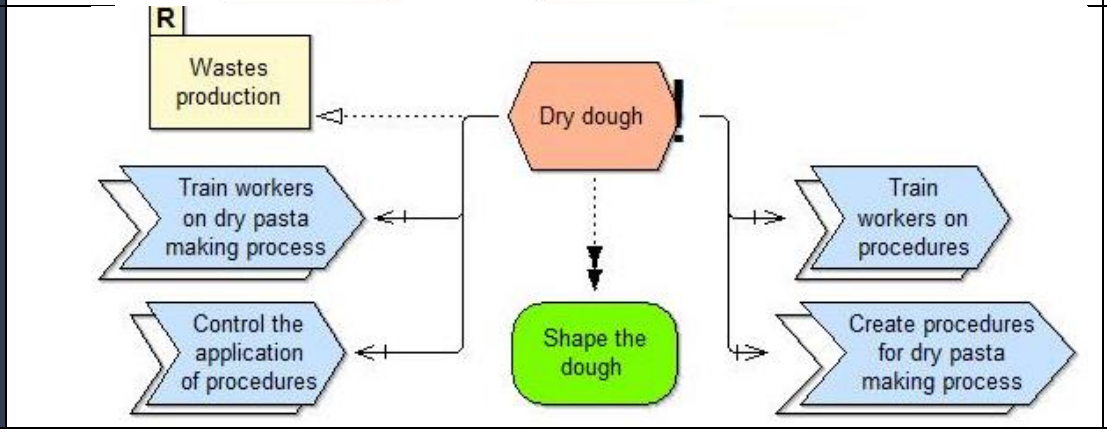
Source: elaborated by the author based on AdoBPRIM software

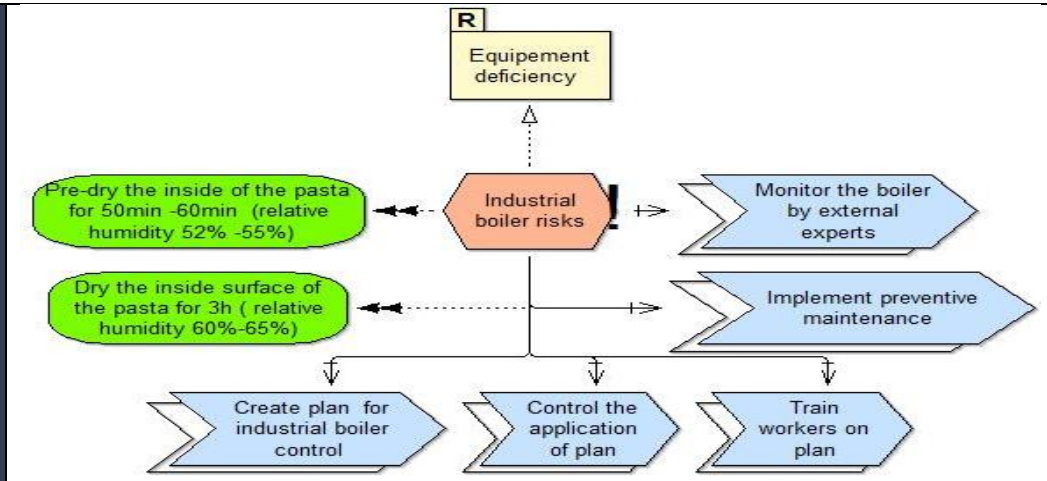
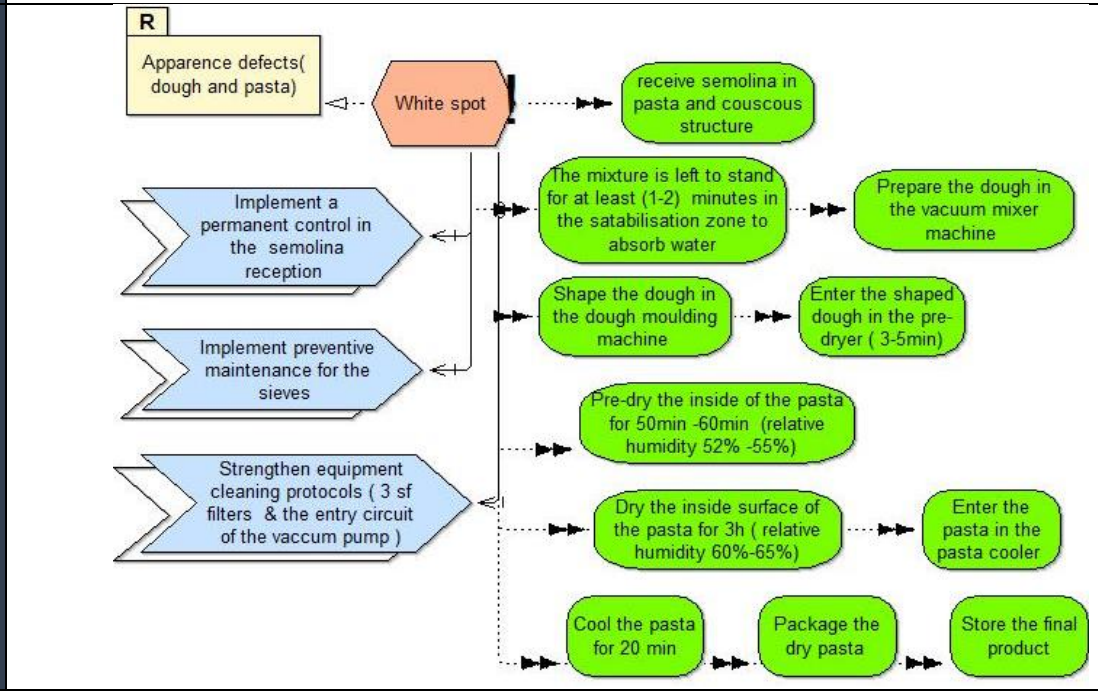
According to the risk matrix, the white pasta and the cracked pasta are acceptable risk, while cooling system deficiency, dry dough, industrial boiler risks, pasta condensation in moulding step and white spot are acceptable under control. Shape defects of the pasta, 3SF , black spot, microbiological contamination and physico-chemical contamination are unacceptable risks. In the following subsection, we will present the scenarios to treat the risks.

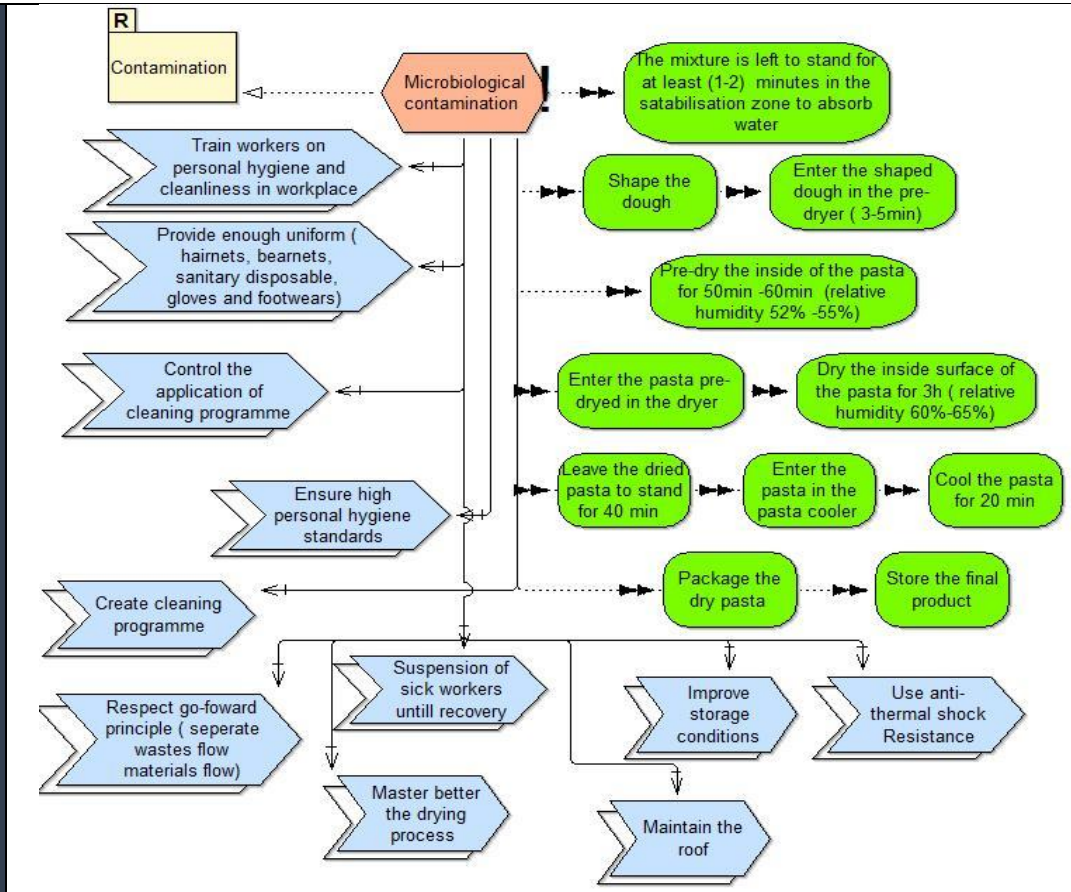
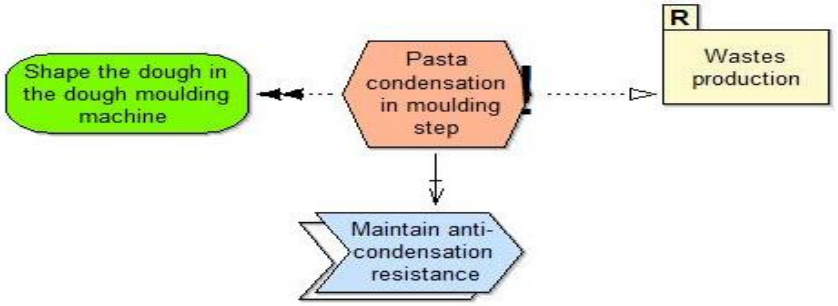
Table n° 51: risk treatment diagrams (Sosémie)

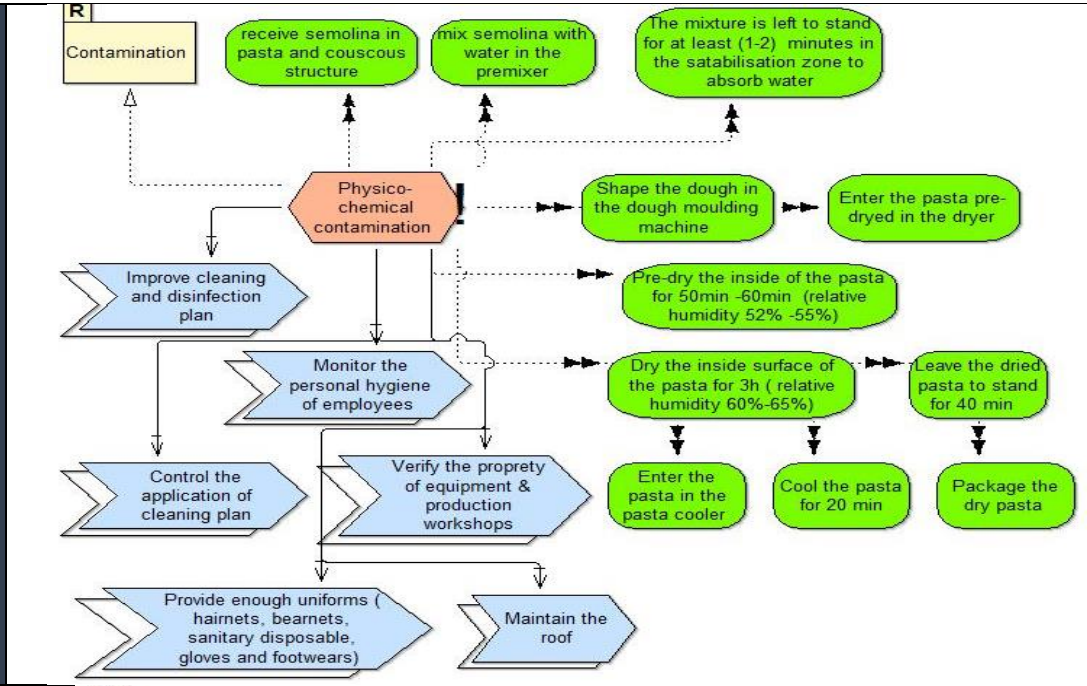
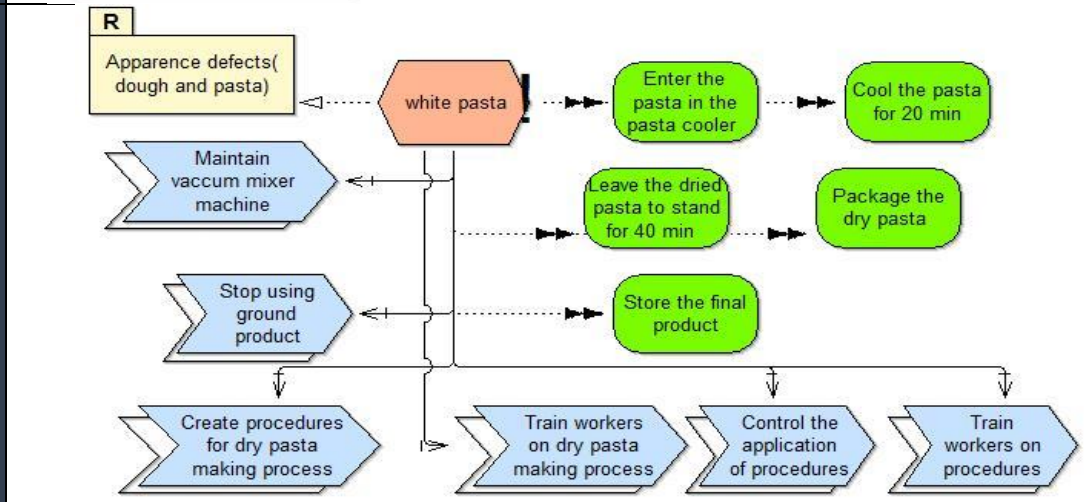
OR	Risk treatment diagrams	Comments
3SF		To reduce 3SF from semolina and product it is necessary to: ◦ Before preparation , make sure to use only high-quality semolina free from 3SF; ◦ Implement preventive maintenance for sieves in "transfer unit"; ◦ Implement a permanent control in the semolina reception " transfer unit" to control the operation of semolina sieving; ◦ Strengthen equipment cleaning plan; ◦ Control the application of cleaning plan of the equipment (SSF filters…).

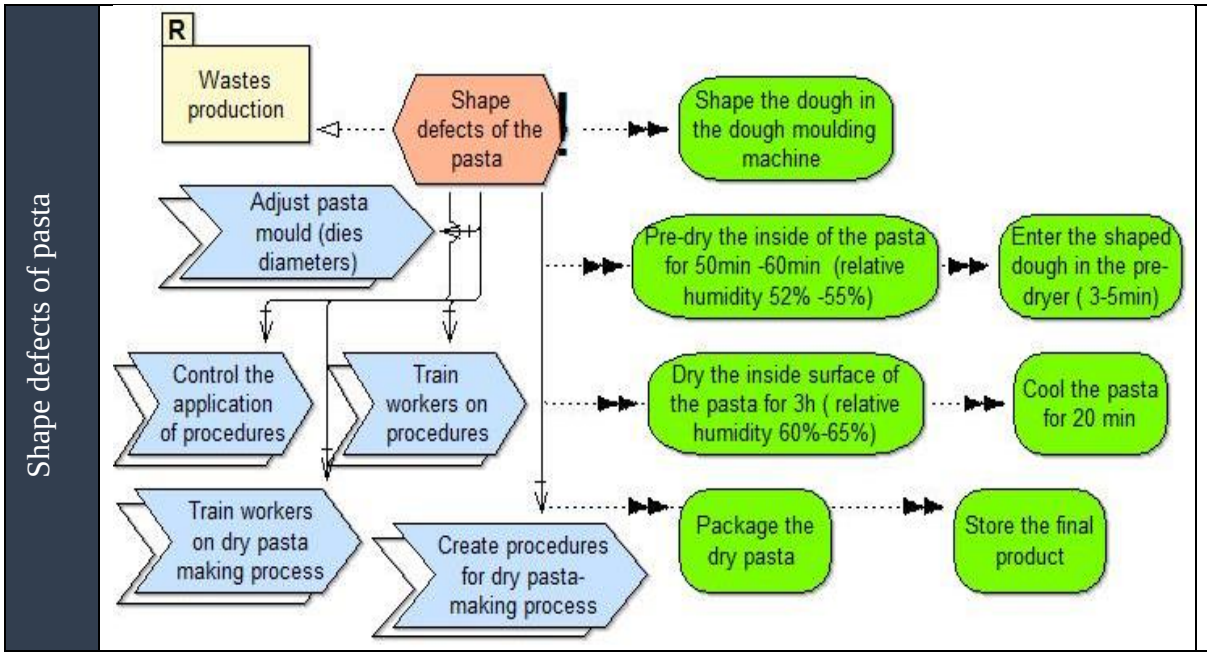
Black spot		To prevent from black spots it is necessary to: ◦ Use high-quality of durum wheat in milling; ◦ Improve the quality of milling process outcomes; ◦ Use in the pasta-making only high-quality semolina.
Cooling system deficiency		To prevent from cooling system failure, it is necessary to: ◦ Implement preventive maintenance and create plan for cooling system ; ◦ Train workers on the control plan; ◦ Control the application of the plan.

Cracked pasta		To prevent from Cracks on pasta: ◦ The staff should master the pasta making process, so they should receive training on pasta making process; ◦ it is necessary to create procedures for pasta making process; ◦ It is necessary to train workers on the procedures; ◦ It is necessary to control the application of procedures.
Dry dough		To prevent from dry dough: ◦ The staff should master the pasta making process, so they should receive training on pasta making process; ◦ It is necessary to create procedures for pasta making process; ◦ It is necessary to train workers on the procedures and control the application of procedures.

Industrial boiler risks		To prevent from industrial boiler risks, it is necessary to: ° Monitor the boiler by external experts from time to time; ° Implement preventive maintenance; ° Create plan for industrial boiler control; ° Train workers on plan of control; ° Control the application of plan; ° Do the water treatment control every day.
White spot		To prevent from white spots on pasta, it is necessary: ° Before preparation , to make sure to use only thin semolina free from medium semolina; ° Implement preventive maintenance for sieves in “transfer unit”; ° Implement a permanent control in the semolina reception “ transfer unit” to control the operation of semolina sieving; ° Strengthen equipment cleaning plan; ° Control the application of cleaning plan of the equipment (3SF filters…).

Microbiological contamination		To prevent from microbiological contamination it is necessary to: ° Provide enough uniforms in workshops to workers and the visitors; ° Train workers on personal hygiene; ° Monitor the personal hygiene of workers; ° Suspend sick workers until recovery; ° Create and control the application of cleaning plan for the surfaces and the equipment; ° Maintain surfaces to eliminate stagnant water; ° Master the drying process and improve storage conditions ° Respect go-forward principle (wastes/products) ° Maintain the roof
Pasta condensation		To prevent from pasta condensation it is necessary to: Maintain the anti-condensation resistance

Physico-chemical contamination		To prevent from physico-chemical contamination of raw material, it is necessary to : ◦ Provide enough uniforms in workshops to workers and the visitors ◦ Monitor the personal hygiene ◦ Improve cleaning and disinfection plan ◦ Verify the cleanliness of equipment and workshops ◦ Control the application of cleaning plan for the surfaces and the equipment ◦ Maintain roof
White pasta		To produce even in size pasta it is necessary to : ◦ Adjust pasta mould (dies diameters) ◦ The staff should master the pasta making process, so they should receive trains on pasta making process ◦ Create procedures for pasta making process ◦ Train workers on the procedures ◦ Control the application of procedures



To prevent from shape defects, it is necessary to:

- Adjust pasta mould(dies diameters);
- Create procedures for dry pasta making process;
- Train workers on procedures;
- Train workers on dry pasta making process
- Control the application of procedures

Source: elaborated by the author based on AdoBPRIM software

3. Share Knowledge

As we did in the case of Colaital , we shared the diagrams with the four managers of lines we explained to them the contents of these diagrams and the objective of our study. In their turn, each manager shared the diagrams with his team and explained to them the contents of the diagrams.

As previously indicated, we were supposed to organise workshops to explain the contents of the diagrams with all the staff members working in the premises of the enterprise, but we were not allowed so we opted for an alternative that we explained previously.

4. Knowledge storage

The diagrams are stored in files in paper version. In the future, they can be stored in the data bases of the enterprise.

5. Knowledge application

As we indicated in chapter three, we were supposed after sharing the diagrams with the workers, to return to the enterprise after a period and re-analyse the operational risks in the workplace to assess the effectiveness of the K-PIMRBP outcomes in preventing from these risks, but it was not possible. Therefore, we opted for an alternative, which is the elaboration of a questionnaire to assess whether the outcomes of K-PIMRBP contributed to train the workers on operational risk management (Contaminations, appearance defects, wastes production and deficiency equipment).

Chapter IV : Results and discussion

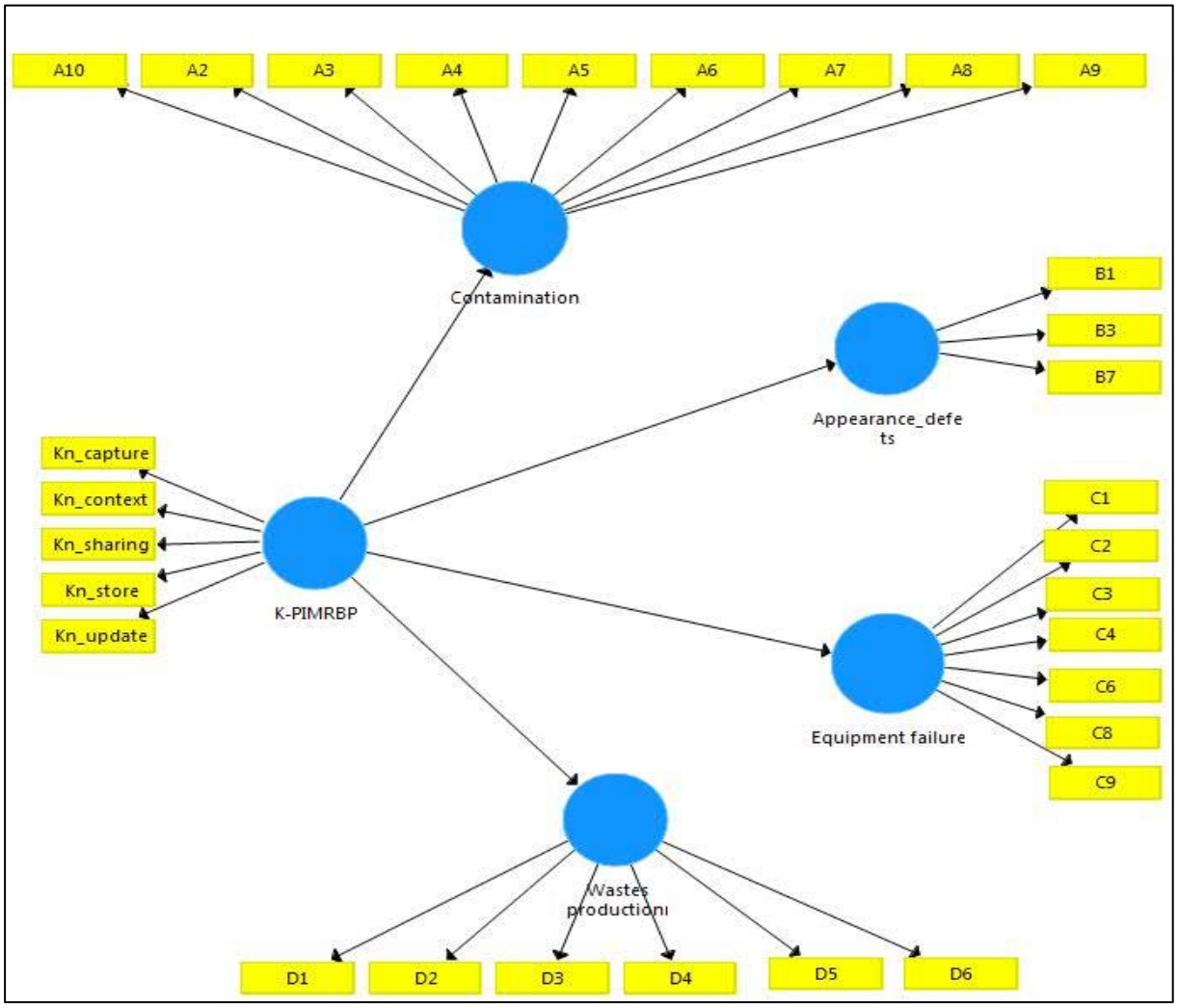
Phase III: Quantitative results

In the present sub-section we present the results of the quantitative study (see annexe B). The Validation of measurement model includes: assessment of measurement model and assessment of structural model (Hair, Hult, Ringle, & Sarstedt, 2017, p. 130).

1. Assessment of the measurement model

It is measured by convergent validity and discriminant validity (Hair, Hult, Ringle, & Sarstedt, 2017, p. 130)

Figure n°42: measurement model



Source: outcomes of SmartPLS

1.1 Convergent validity

The convergent validity is measured by the outer loadings, which should be more than 0.7, or between 0.4 and 0.7 under the condition that the retention of the item increases the composite reliability CR or the average variance extracted AVE (Hair, Hult, Ringle, & Sarstedt, 2017, p.

137). We delated from the model the following items which did not meet the conditions mentioned before (A1, B2, B4, B5, B6, C5, C7).

The table 52 shows that CR of the variables are higher than 0.7 as suggested by (Hair, Bill , Barry, & Rolph, 2006)while the AVR of the variables are higher than 0.5 (Fornell & Larcker, 1981) .

Table n°52: convergent validity outcomes

	Appearance _defects	Contaminations	Equipment failure	K-PIMRBP	Wastes production	AVE	CR
A10		**0,873**				**0,810**	**0,974**
A2		**0,913**					
A3		**0,957**					
A4		**0,924**					
A5		**0,913**					
A6		**0,976**					
A7		**0,770**					
A8		**0,944**					
A9		**0,808**					
B1	**0,705**					**0,687**	**0,867**
B3	**0,871**						
B7	**0,898**						
C1			**0,716**			**0,596**	**0,911**
C2			**0,825**				
C3			**0,891**				
C4			**0,729**				
C6			**0,719**				
C8			**0,751**				
C9			**0,758**				
D1					**0,830**	**0,778**	**0,954**
D2					**0,885**		
D3					**0,932**		
D4					**0,915**		
D5					**0,900**		
D6					**0,824**		
Kn_capture				**0,735**		**0,661**	**0,907**
Kn_context				**0,881**			
Kn_sharing				**0,800**			
Kn_store				**0,792**			
Kn_update				**0,850**			

Source: outcomes of SmartPLS3

1.2. Discriminant validity

The discriminant validity is acceptable when the square root of the AVEs in the diagonal of the matrix are higher than the non-diagonal elements of the matrix (Fornell & Larcker, 1981). The table shows that the value of the elements in the diagonal are higher than the value of the elements in the non-diagonal, so the discriminant validity of the model is acceptable.

Table n°53: discriminant validity outcomes

	Appearance_defects	**Contaminations**	**Equipment failure**	**K-PIMRBP**	**Wastes production**
Appearance_defects	**0,829**				
Contaminations	0,844	**0,900**			
Equipment failure	0,788	0,880	**0,772**		
K-PIMRBP	0,418	0,367	0,363	**0,813**	
Wastes production	0,442	0,537	0,444	0,498	**0,882**

Source: outcomes of SmartPLS3

2. Assessment of structural model

2.1 Path coefficient of the research Hypotheses

The table 54 shows that the hypotheses 1, 2, 3 and 4 are supported

Table n°54: Path coefficient of the research Hypotheses

	Original Sample (O)	**Sample Mean (M)**	**Standard Deviation (STDEV)**	**T Statistics (|O/STDEV|)**	**P Values**	**OBS**
K-PIMRBP -> Appearance_ defects	0,418	0,442	0,058	7,243	**0,000**	**H2 is Supported**
K-PIMRBP -> contaminations	0,367	0,389	0,066	5,601	**0,000**	**H1 is Supported**
K-PIMRBP -> equipment failure	0,363	0,403	0,103	3,523	**0,000**	**H3 Supported**
K-PIMRBP -> wastes production	0,498	0,504	0,080	6,259	**0,000**	**H4 Supported**

Source: outcomes of SmartPLS3

2.2 Coefficient of determinant R2 , effect size f^2 , predictive relevance of the model Q^2 , goodness of fit GOF

R^2 measures the predictive power of the model, which should be higher than 0.1 (Falk & Miller, 1992); The results below show that the values of all the models are higher than 0.1, which means that all the models are accepted.

Table n° 55 : Coefficient of determinant R2

	R^2
Appearance_ defects	0.175
Contaminations	0.135
Equipment failure	0.132
Wastes production	0.248

Source: outcomes of SmartPLS3

f^2 measures the effect size of the independent variables on the dependant variables (Hair, Hult, Ringle, & Sarstedt, 2017, p. 210) **.** According to (Cohen J. , 1988), $f^2 > 0.35$ (The effect size is large), $0.15 > f^2 > 0.35$ (the effect size is medium), $0.02 > f^2 > 0.15$ (the effect size is small). The results of the present study are shown in the following table

Table n°56: effect size f2

	f^2
Appearance_ defects	0.212
Contaminations	0.156
Equipment failure	0.152
Wastes production	0.330

Source: outcomes of SmartPLS3

Q^2 measures the predictive relevance of the model (Hair, Hult, Ringle, & Sarstedt, 2017) According to (Chin , 2010), Q^2 above 0 means that the model has a predictive relevance. The results of the study are shown in the following table

Table n°57: the predictive relevance of the models Q2

	Q^2
Appearance_ defects	0.101
Contaminations	0.092
Equipment failure	0.051
Wastes production	0.185

Source: outcomes of SmartPLS3

The table 57 shows that the four models have predictive relevance.

Chapter IV : Results and discussion

Goodness of fit of the model GOF

According to (Wetzels, Odekerken-schroder, & Van oppen, 2009) tolerance intervals are (less than 0.1 = no fit; 0.1-0.25= small fit, 0.25-0.36= medium fit, greater than 0.36= large).

$$\textbf{GOF}= \sqrt{(\overline{R^2} \times \overline{AvE^2}} \quad ; \quad \textbf{GOF = 0.124}$$

From the result of GOF we conclude that goodness of fit the model is small.

In the first section, we presented the results of the application of K-PIMRBP to Sosémie, the study included three phases. In the first step we conducted interviews and analysed the qualitative findings from which we summarised the operational risks at Sosémie into four classes namely : (1) contamination class (2) Appearance defects (3) Wastes production (4) equipment deficiency and we formulated the hypotheses of the study . In the second step, we applied the K-PIMRBP to Sosémie, and in the third step we presented the quantitative findings, which reinforced the results of the case of Colaital and indicated positive influence of the outcomes of this process on the prevention from the operational risks.

The results of the study are shown in the following table.

Table n°58: The results of the study(Sosémie)

H1	K-PIMRBP outcomes contribute to train employees on contaminations management	**Supported**
H2	K-PIMRBP outcomes contribute to train employees on appearance defects management	**Supported**
H3	K-PIMRBP outcomes contribute to train employees on equipment deficiency management	**Supported**
H4	K-PIMRBP outcomes contribute to train employees on wastes management	**Supported**

Source: elaborated by the author

Chapter IV : Results and discussion

Section III: Case study 3- Frater-Razes

In this section, we are going to present the findings of the application of K-PIMRBP to Frater-Razes.

Phase I: Qualitative data analysis and the conceptual model of the study

The objective of the qualitative study is to explore the context of the study, identify the major operational risks threatening the enterprise studied, reveal the major causes of risks and formulate the hypotheses on how the K-PIMRBP contributes to operational risks prevention.

The interviews guide encompasses three themes beforehand selected from the literature, which are as follows:

Table n° 59: The interviews guide

Theme	Explanation
Theme 01: The context of the study	The aim of this theme is to understand the context of the study: the activities and products of the enterprise and select the product that will constitute the subject of the study.
Theme 02: The operational risks in production process	The aim of this theme is to determine the operational risk classes occurring in the fabrication process that will constitute the subject of the study.
Theme 03: Operational risks prevention	The aim is to determine the factor that leads to risk prevention to formulate the hypotheses of the study;

Source: elaborated by the author

The verbatim and a short discussion are presented in the following subsection:

Theme 01: The context of the study

Question 01: can you describe the activities of frater-Razes-dry form?

"Frater-razes laboratory is a group which encompasses five enterprises, in frater-Razers dry which is one of the enterprises of the group, form we fabricate pills"

Frater-Razes-dry form is one of the branches of the group Frater-Razes, it produces pills .In the present study we are going to study ***SPASMOODYL 80mg.***

Question 02: What are the main phases of the SPASMOODYL 80mg fabrication?

"*It is a drug available in pill form… it is prescribed for spasmodic pain …it involves five steps namely: weighting, sieving, preparation, compression, and packaging. … in*

the first step the preparer weights the quantity of the active substance and the excipients mentioned in the procedures then he sieves the materials ,in the third step he mixes the materials to prepare the ***formulation*** *after that it is compressed and then packaged."*

The fabrication of *SPASMOODYL* 80mg involves five steps namely: weighting, sieving, preparation, compression and packaging.

Theme 02: The operational risks in production process

Question 03: What are the operational risks to which the fabrication process of SPASMOODYL 80mg is exposed?

"*Drugs are exposed to contamination, particularly the cross-contamination, throughout the fabrication process from the material reception to batch release …contaminations in general affects the drug's effectiveness and it may also have negative effects on the patients' health …this is why we pay great attention to the environment quality to avoid contaminations. … Product quality in pharmaceutical enterprises is a broad word; it involves the effectiveness and safety visual appearance of the product. … the pill of SPASMOODYL should be white free from spots … we control the defects of all materials involved in the fabrication process from the raw material , to packaging articles to the final products. …the equipment failure and the tooling wear interrupt the fabrication process. .. Many actors should contribute to resolve the problems"*

Question 4: During our presence in the enterprise, we noticed the large quantity of wastes, what can you say about this?

"*Yes we have different kinds of wastes including: ordinary wastes and pharmaceutical wastes …but we have a specific treatment for the pharmaceutical wastes including pills of the control , blisters …yes they are large in quantity … but it is a part of the pharmaceutical fabrication we cannot avoid it!"*

Question 05: Another problem that we noticed, which is the slow circulation of batch in which you use the paper version, which implies the batch liberation delay, what you can say about that?

" Yes there are so many other factors that contribute to batch liberation delay not only the slow circulation of batch… and yes using paper version of documents is a serious problem…"

Why do not you use electronic version of documents and e-batch?

"Putting in place electronic system for documentation and using e-batch ….is a good idea but it is a big project that necessitates an important budget; it is a big investment …."

Based on the verbatim bellow we can classify the operational risks to which the process of drug fabrication in general and SPASMOODYL 80mg in particular, is exposed into six classes: Contaminations, equipment deficiency, wastes production, delay in batch liberation, materials defects and risks caused by human.

In your opinion what is the main cause of these risks? Do you think that employees (operators , supervisors…) contribute to the occurrence of these risks ? And How?

" *it is difficult to give one main cause of these risks but yes the employees I mean the operators contribute directly to the occurrence of risks…I tell you an anecdote. ... one time an operator hold a bag of material and put it immediately in the bin without verifying the valve which was unfortunately open , so the materials fell on the ground and for fear of punishment he took the fallen materials and put them again in the bin. …after that we found that the materials failed the microbial and physicochemical test which is very rare. …then we initiated an investigation and we reviewed the camera recording and we knew what happened !! due to this I organised a meeting with all the employees ' operators, supervisors. …" to raise their awareness on the quality importance and therefore the product quality and patients' health ….you should keep in mind that all the employees without exception are well trained on the importance of quality in the workplace but from time to time we should remind them and raise their awareness as aforementioned. …"*

According to the interviewee, all the employees receive a training on the quality in the workplace during the **introductory period**, but they still contribute to operational risks occurrence in the enterprise, because the awareness raising is a permanent activity , responsible should from time to time raise their awareness in this regard.

Therefore, we will try through the following study to test if the K-PIMRBP outcomes contribute **to raise employees' awareness on operational risks,** which leads to risk prevention, hence we formulated the following hypotheses

H_1: K-PIMRBP outcomes contribute to raise employees' awareness on contamination management

H_2: K-PIMRBP outcomes contribute to equipment failure to raise employees' awareness on Human Risk Management

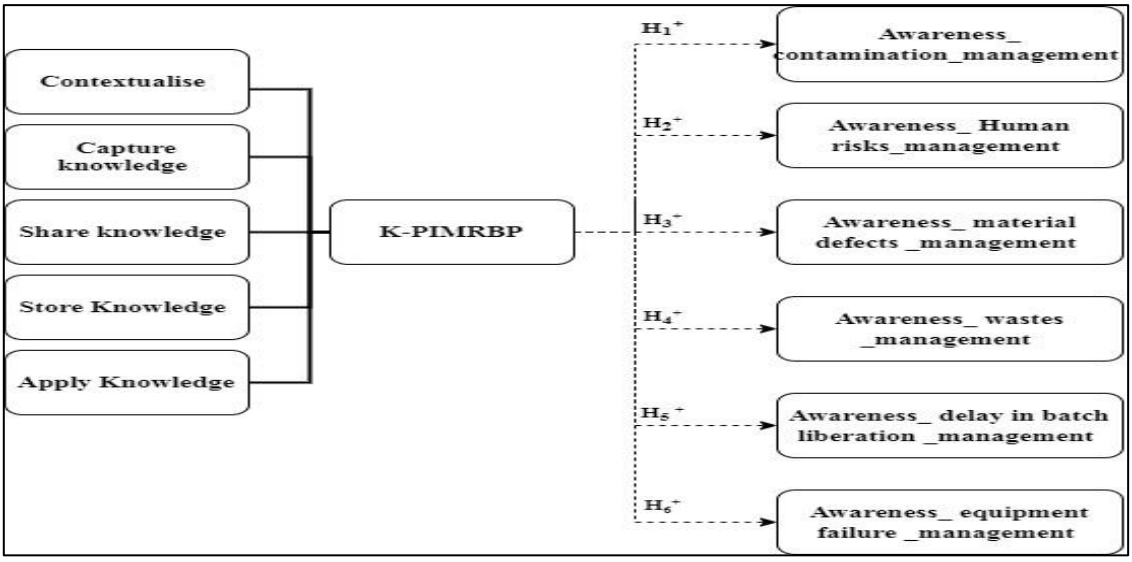
H_3: K-PIMRBP outcomes contribute to raise employees' awareness on materials defects management

H_4: K-PIMRBP outcomes contribute to raise employees' awareness on wastes management

H_5: K-PIMRBP outcomes contribute to raise employees' awareness on delay in batch liberation management

H_6: K-PIMRBP outcomes contribute to raise employees' awareness on equipment failure management

Figure n°43: conceptual model (Frater-Razes)



Source: elaborated by the author

Phase II: The concretisation of K-PIMRBP at Frater-Razes

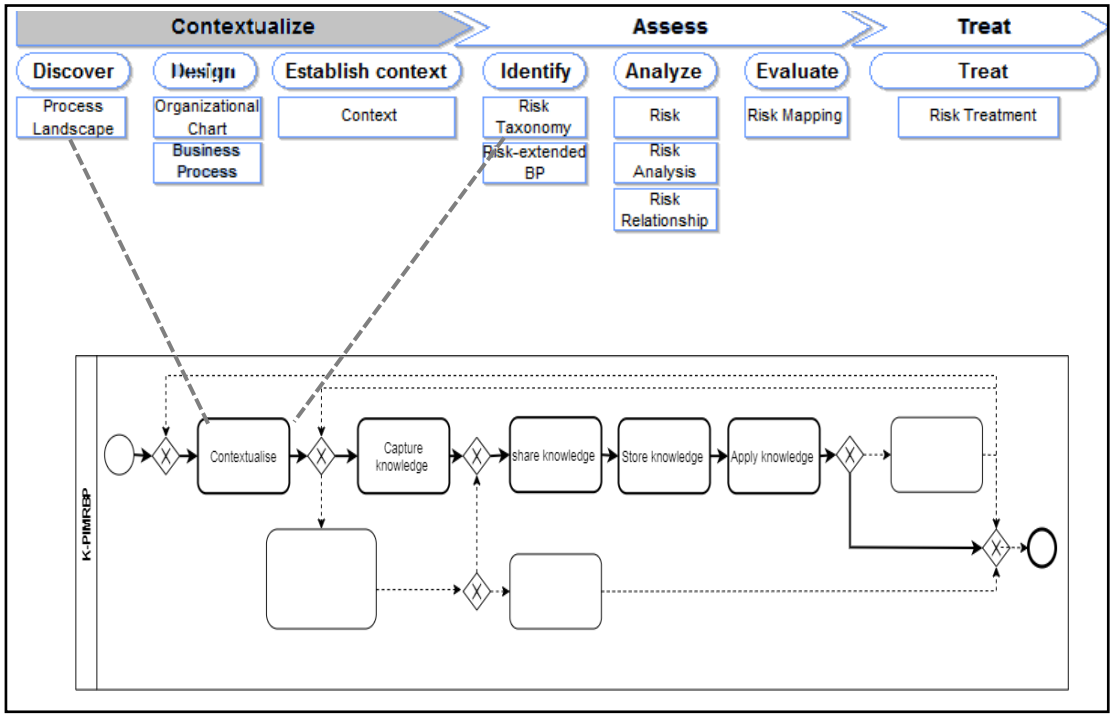
In this subsection, we will show the outcomes of the application of the K-PIMRBP at Frater-Razes, hence we will follow the same steps applied to the previous case studies.

1. K-PIMRBP_Contextualise

The first activity in the preventive management process is the establishment of the context which gives an overview of the whole enterprise, the units included in the study , the actors and

business processes constituting the subject of the study. We used the AdoBPRIM software to model the outcomes of the K-PIMRBP/contextualise which includes in the software four models (Process landscape, context, business process, organisational chart) . In the following figure we show the intersection between K-PIMRBP/contextualise--- AdoBPRIM/contextualise

Figure n°44: intersection between K-PIMRBP/contextualise--- AdoBPRIM/contextualise



Source: elaborated by the author

Table 60 shows the outcomes of contextualisation activity

Table n°60: contextualise activity

Activity presentation	
Contextualise	
Description	***Context:*** involves the enterprise units, actors and the objectives of the units (see figure 45) ***Business processes:*** include the activities of the fabrication process of the SPASMOODYL 80mg (AS-IT processes) namely: Weighing, sieving, preparation, compression and packaging. ***Process landscape***: shows the macro view of the fabrication process of the SPASMOODYL 80mg , which includes the management process, the support process ,and the business processes that constitutes the subject of this study.

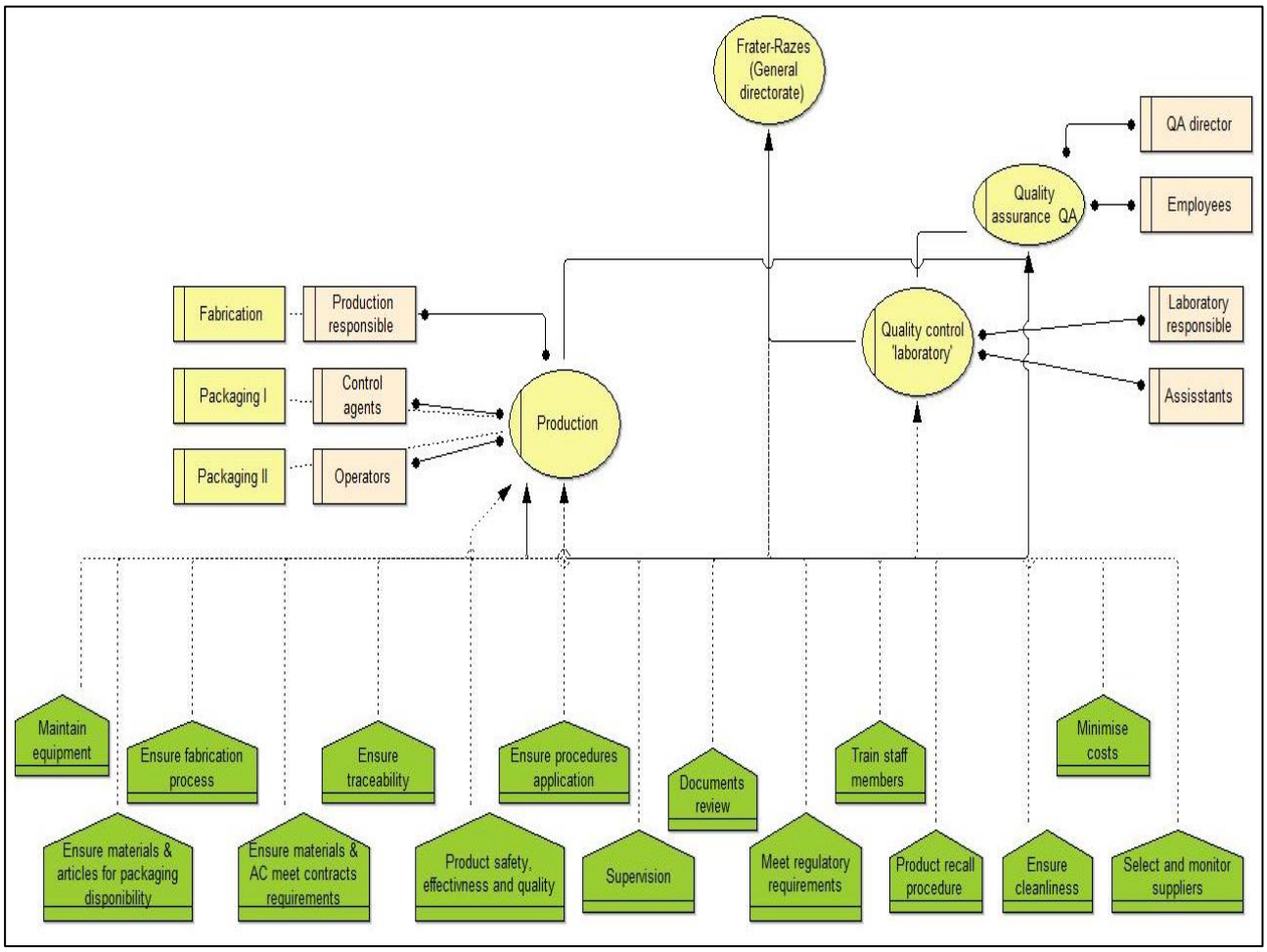
Interviewees/information source	We conducted interviews and we discussed during the internship with : • ***Production staff members*** (Production responsible, supervisors)
Data (activity inputs)	***In order to establish the context we used :*** ***Documents*** (Procedures of **SPASMOODYL 80mg**) ***Verbatim*** (input) ***Observation***
Knowledge (activity outputs)	***The nature of knowledge in this step are diagrams*** (context-figure / business process-figure /process landscape-figure)
Data collection tools	***Interviews: were non-directive , because the aim was to understand the context of the study and particularly to model the BPs , the questions were :*** - What are the steps of the fabrication process of the SPASMOODYL 80mg ? - What are the units that contribute to SPASMOODYL 80mg fabrication? - Could you describe each step in that process? - What are the materials and utensils used in that process? ***observation :*** We observed and attended to fabrication process of the SPASMOODYL 80mg ***and documentary research (organisational chart)***
modelling toolkit	***AdoBPRIM***

Source: elaborated by the author

Figure 45 shows the context diagram of the study; we included in the diagram only the units that constitute the subject of the study, namely: assurance quality unit, which is responsible for the documents review, creation and application of procedure, ensuring product safety and effectiveness, ensuring traceability…etc. Production unit, which entails three main sub-units (fabrication, compression and packaging), this unit is directed by the production responsible. Production unit should ensure product quality and fabrication process… etc.

The laboratory controls the quality of materials, Articles and the products; the following figure gives more details.

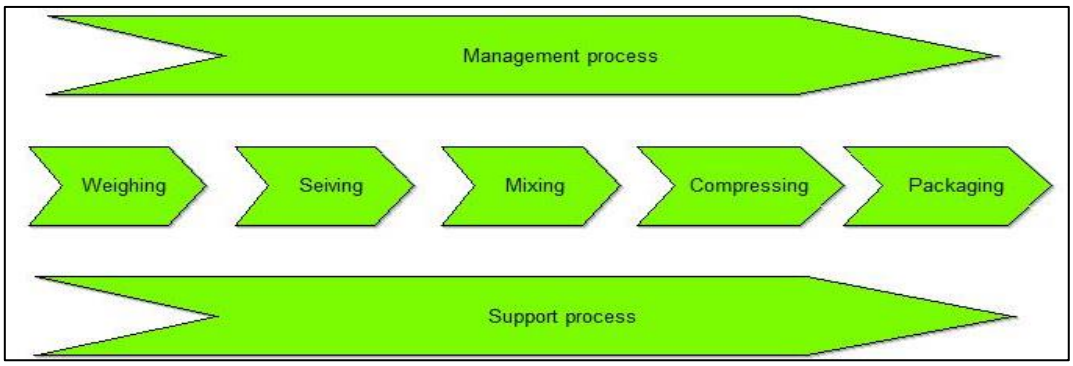
Figure n°45: the context diagram of the study



Source: outcome of AdoBPRIM software

Figure 46 shows the Process landscape of Frater-Razes, in the present study we focus on the operational level of the enterprise, which includes five BPs namely: weighing, sieving, mixing, compressing and packaging.

Figure n°46: process landscape (Frater-Razes)



Source: outcome of AdoBPRIM

Chapter IV : Results and discussion

Business processes: In the following subsection, we outline the five activities of fabrication process of SPASMOODYL 80mg and we associated with each step photos taken during our internship:

1. Weighing:

In the first step, preparer should wear an appropriate clothing, then he should verify the presence of the necessary documents and materials, he should also ensure the absence of documents of the precedent batch to avoid cross-contamination (see figure for more details). After preparing the local, the preparer starts weighing the quantities of the active substance and excipient as mentioned in the procedure, he should calculate the net and the gross weights of materials. The figure and photos show weighing activity.

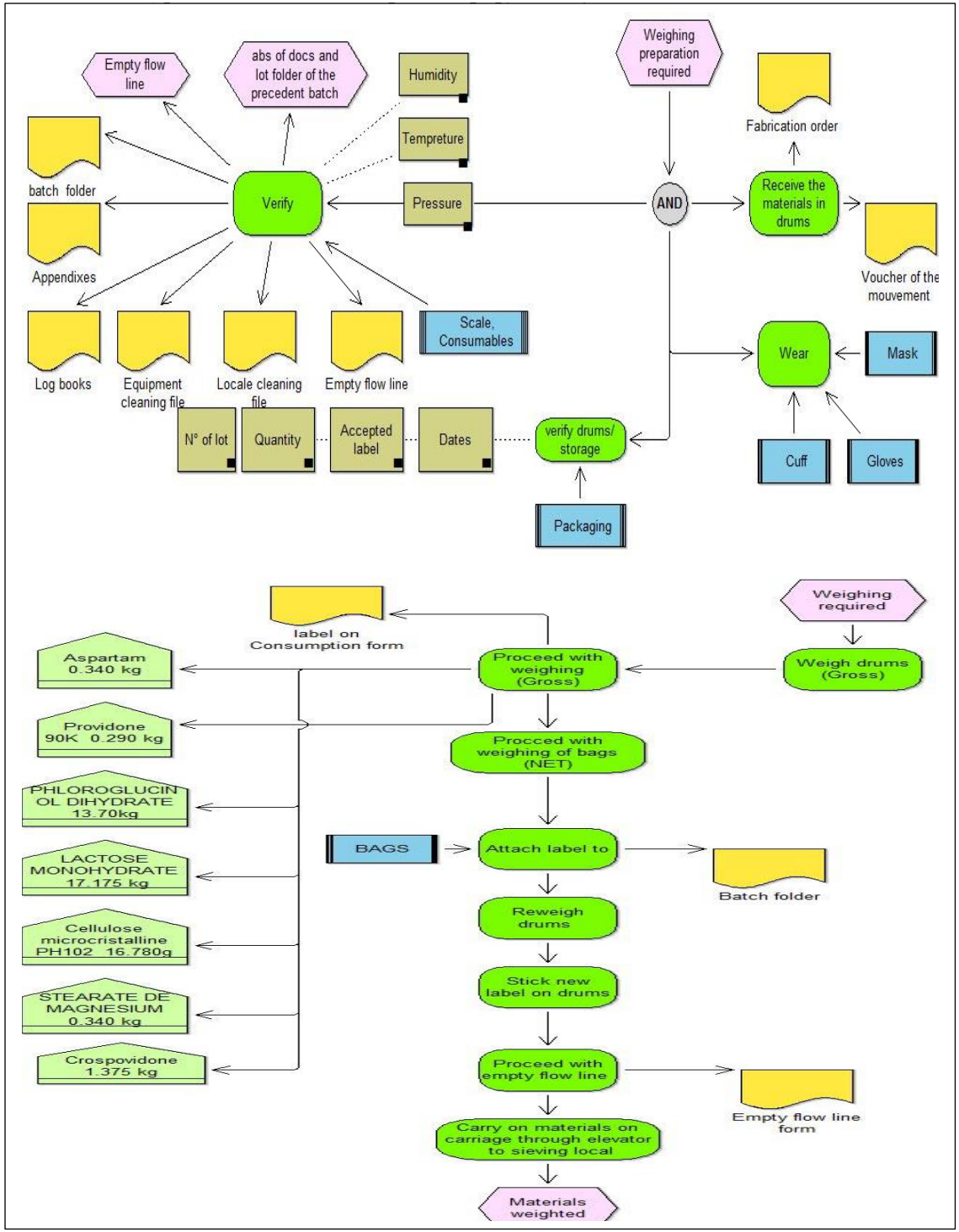


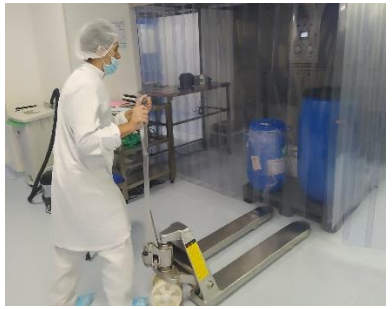
Figure n° 47 : weighing activity

Weighing activity

Weighing

Drum contains bags of materials

Empty flow line



Transfer the weighed materials to sieving local

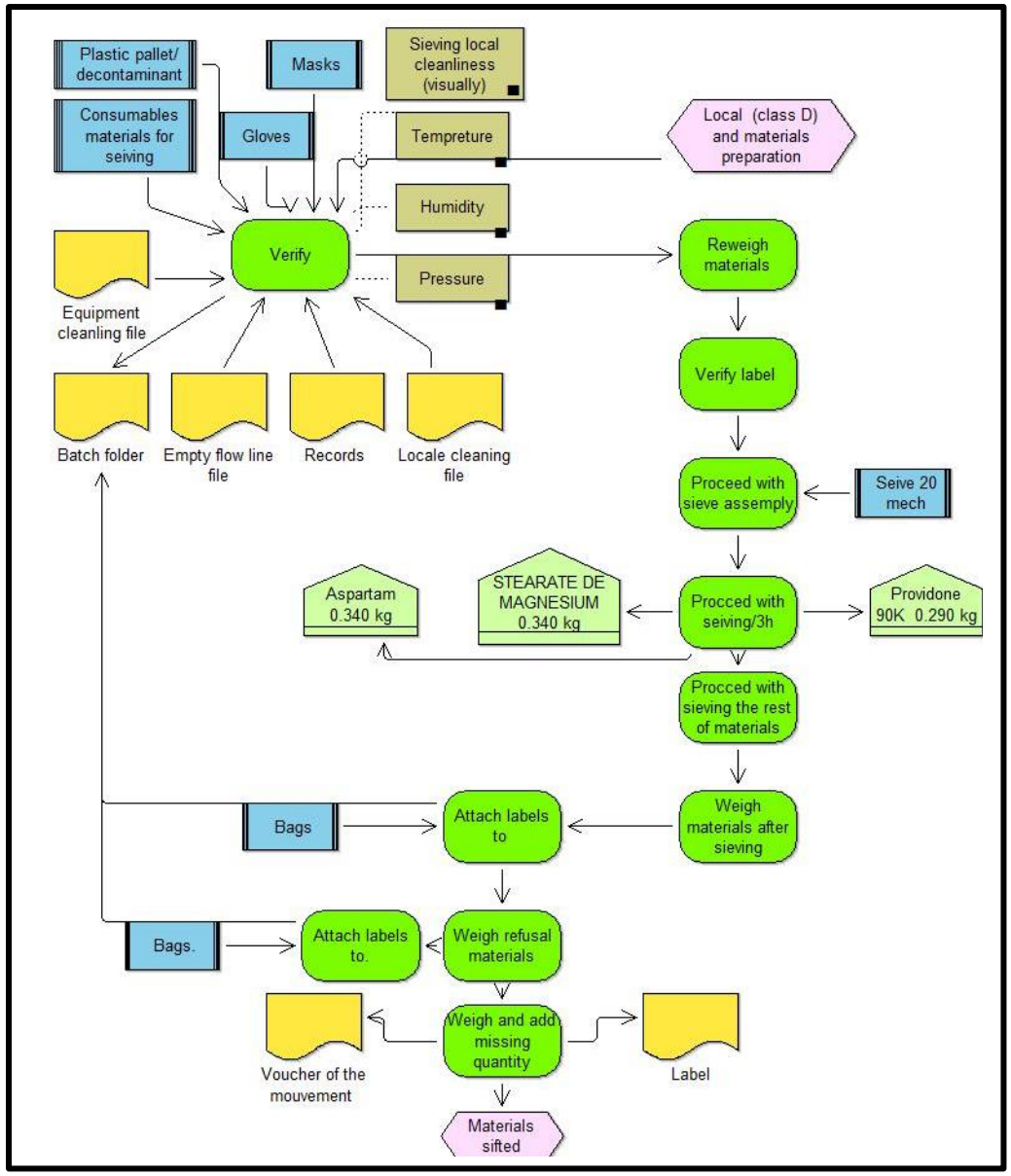
Source: photos taken by the author; diagram is the outcome of AdoBPRIM

2. Sieving

After weighing the materials, the preparer uses the elevator of materials to transport the materials to sieving local , so the materials flow and people flow do not coincide to avoid cross contamination,. Before sieving the materials, the preparer with agent from assurance quality re-weigh the materials and verify the presence of all the materials and documents necessary. The preparer starts sieving after signing the permission of "activity beginning" by assurance quality agent. The preparer should follow the procedures of sieving.

Figure 48 shows the sieving activity.

Figure n°48: the sieving activity.



Weighing materials before sieving

Sieving

Materials for sieving

Emptying the refusal materials in bags

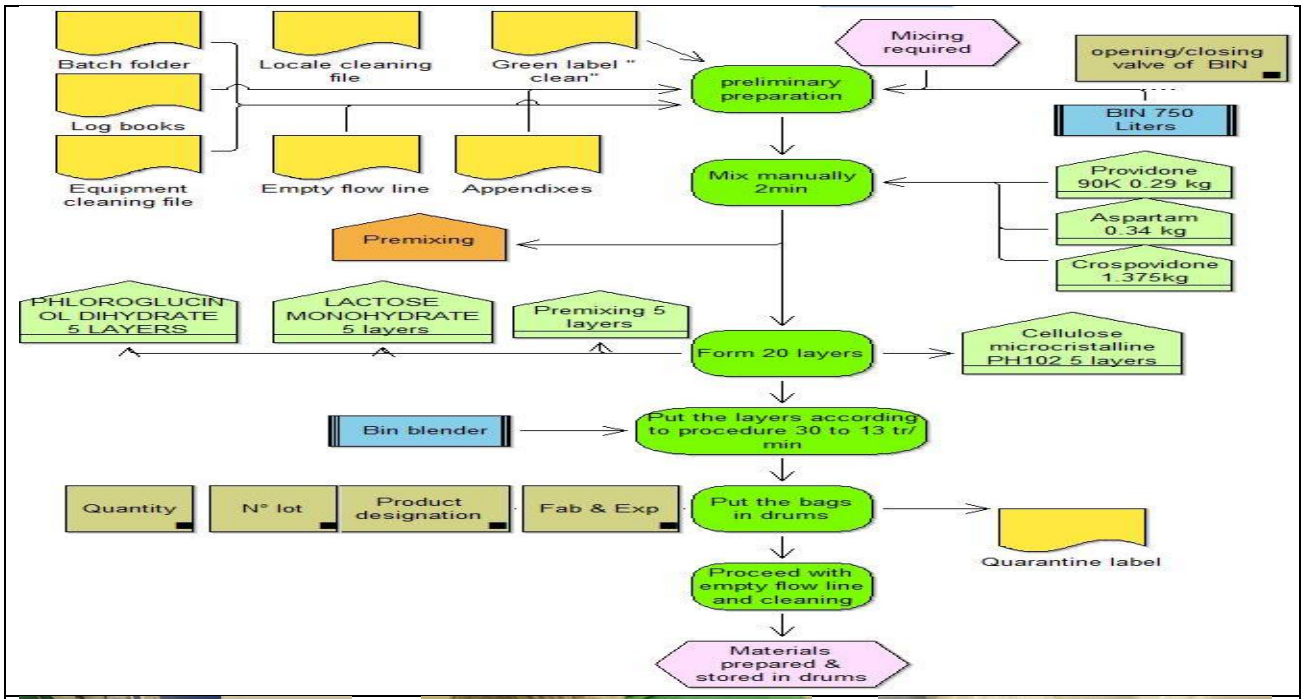
Sieved materials

Source: photos taken by the author; diagram is the outcome of AdoBPRIM

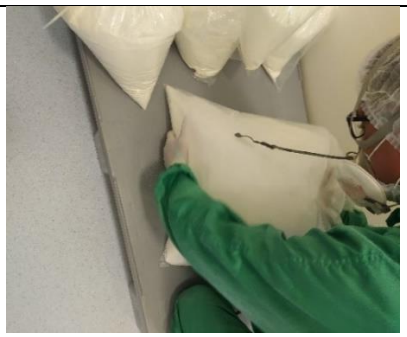
3. Premixing/mixing:

After weighing the materials, the preparer proceeds with the pre-mixing of the materials in sieving local as indicated in the procedure then mixing the materials in the bin in preparation locale.

Figure n°49: premixing/mixing activity







Pre-mixing



mixing step

Source: photos taken by the author; diagram is the outcome of AdoBPRIM

4. Compressing:

The architecture of pharmaceutical enterprise is particular, where the locales of each activity (sieving and compression) includes one SAS for materials flow, which is a small room where they store drums of materials and wastes . Another SAS for the staff, which is another small room from which the staff members enter to the locale of sieving or compression, these separations are preventive measures to avoid cross-contamination.

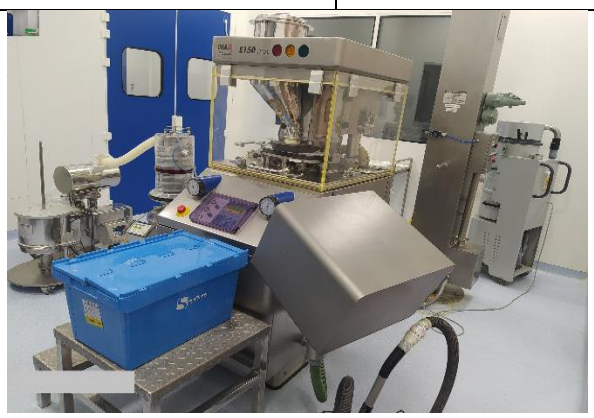
Photos below show the architecture of compression locale

Figure n°50: the architecture of compression locale

SAS (SAS for staff, SAS for materials and compression locale)

SAS for materials

SAS for staff



Compression locale

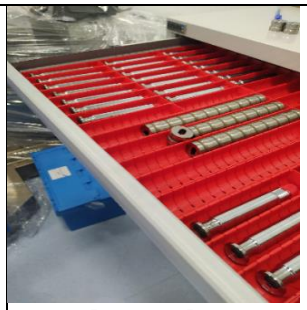
Source: taken by the author

The aim of compressing activity is to transform the mix of the powder (active substance and excipient) into pills, but before proceeding with compression, the operator should verify the availability of materials and documents.

Photos below show the equipment and tooling used in the compression.

Figure n°51: the equipment and tooling used in the compression.

Tablet machine



Punches & dies

Scale

External vacuum

Hopper

Source: taken by the author

Photos below show the quality control materials, where they test the friability, hardness, mass uniformity, the average mass and the thickness of the pills

Figure n° 52: quality control materials

Quality control materials

Thermo hygrometer

Caliper

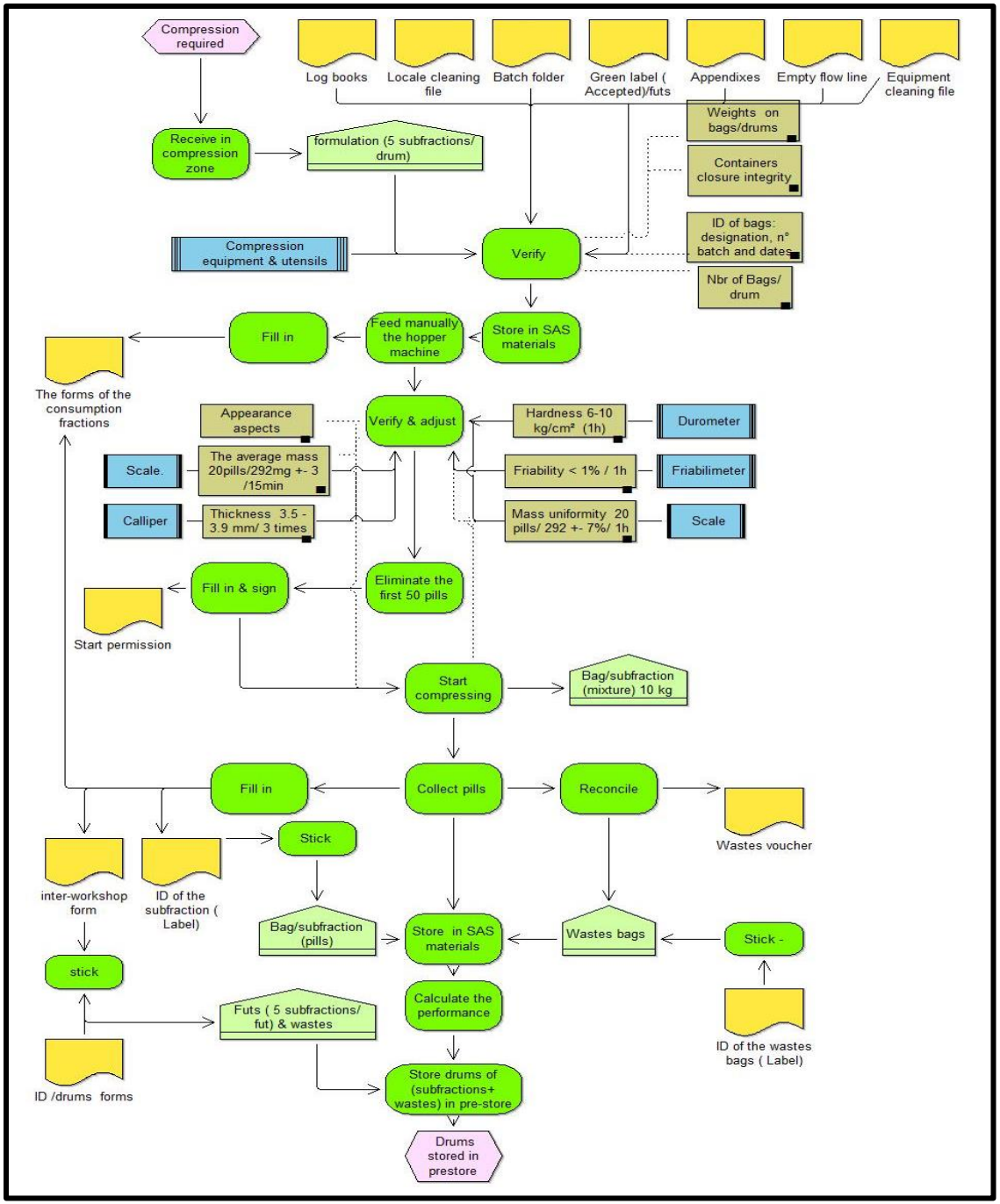
Durometer

Friabilimeter

Source: taken by the author

Figure below provides the details of compression step from verification of documents and materials to pills collecting.

Figure n°53 : compression activity



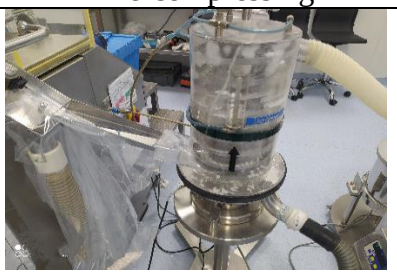
Blue case contains 1 sub-fraction of mix of powder

Feeding the hopper

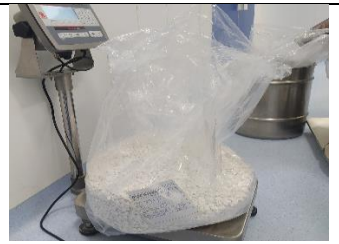
Dies filling

Pre-compressing

Scraper of pills



Dust collector



Weighing pills

Collecting of pills

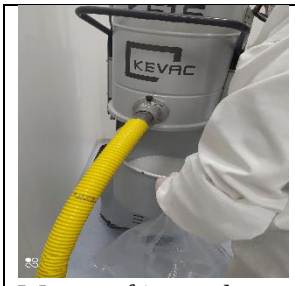
Source: photos taken by the author; diagram is the outcome of AdoBPRIM

Chapter IV : Results and discussion

4.1 Reconciliation (wastes collection)

The reconciliation is a main step in compression, in which all wastes are collected, weighted and stored in the drum. Photos below show the reconciliation activity

Figure n°54: reconciliation activity



Wastes of internal vaccum


Wastes of external vaccum


Wastes of control


Metal detector wastes


Wastes of the end of batch


weighing

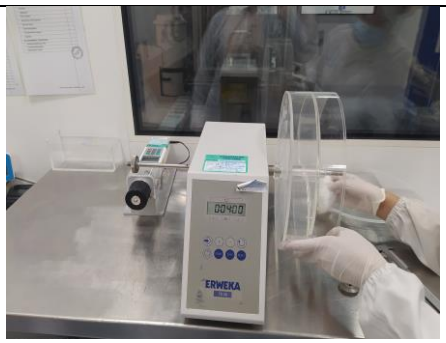

Drum for wastes

Source: taken by the author

4.2. Empty flow line/intermediate (in the end of a lot) and storage

Empty flow line is one of the most important step in the pharmaceutical fabrication, which constitutes of eliminating documents and the rest of products of the precedent batch. Photos below show the activity of the empty flow line.

Figure n°55: Empty flow line



Empty flow line activity

Source: taken by the author

5. Packaging I: it refers to primary packaging, which is the first phase in packaging, the following figure and photos provide a clear comprehension of this step

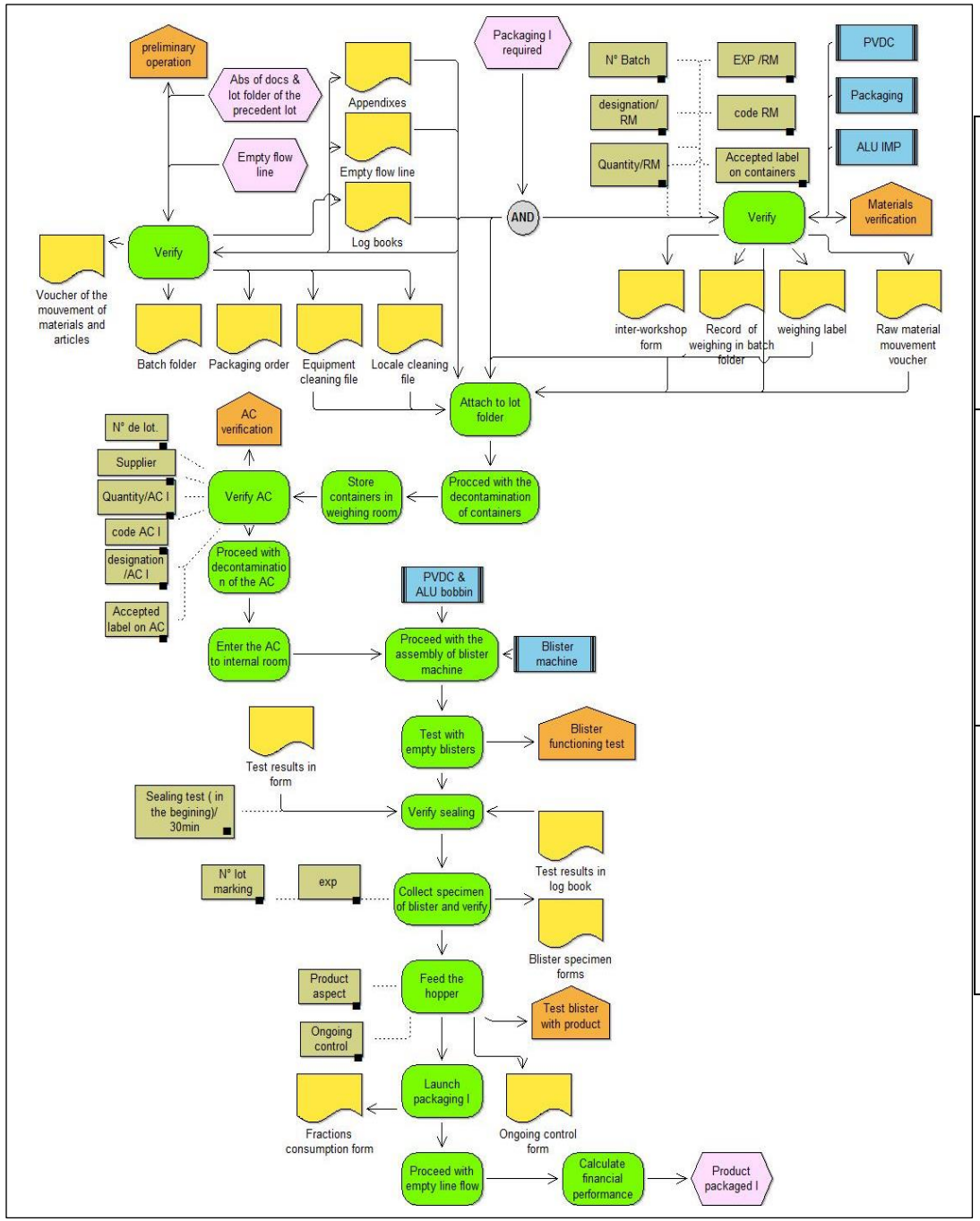


Figure n°56 : Packaging I activity

PVDC bobbin

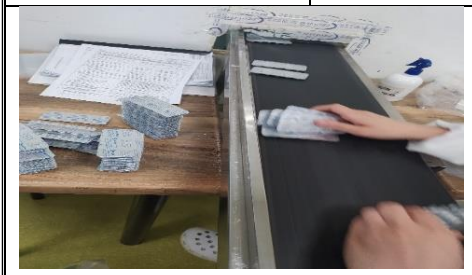
Hotplate

Blister cavity

Feeding hopper

Feeding box

sealing



Blister sorting

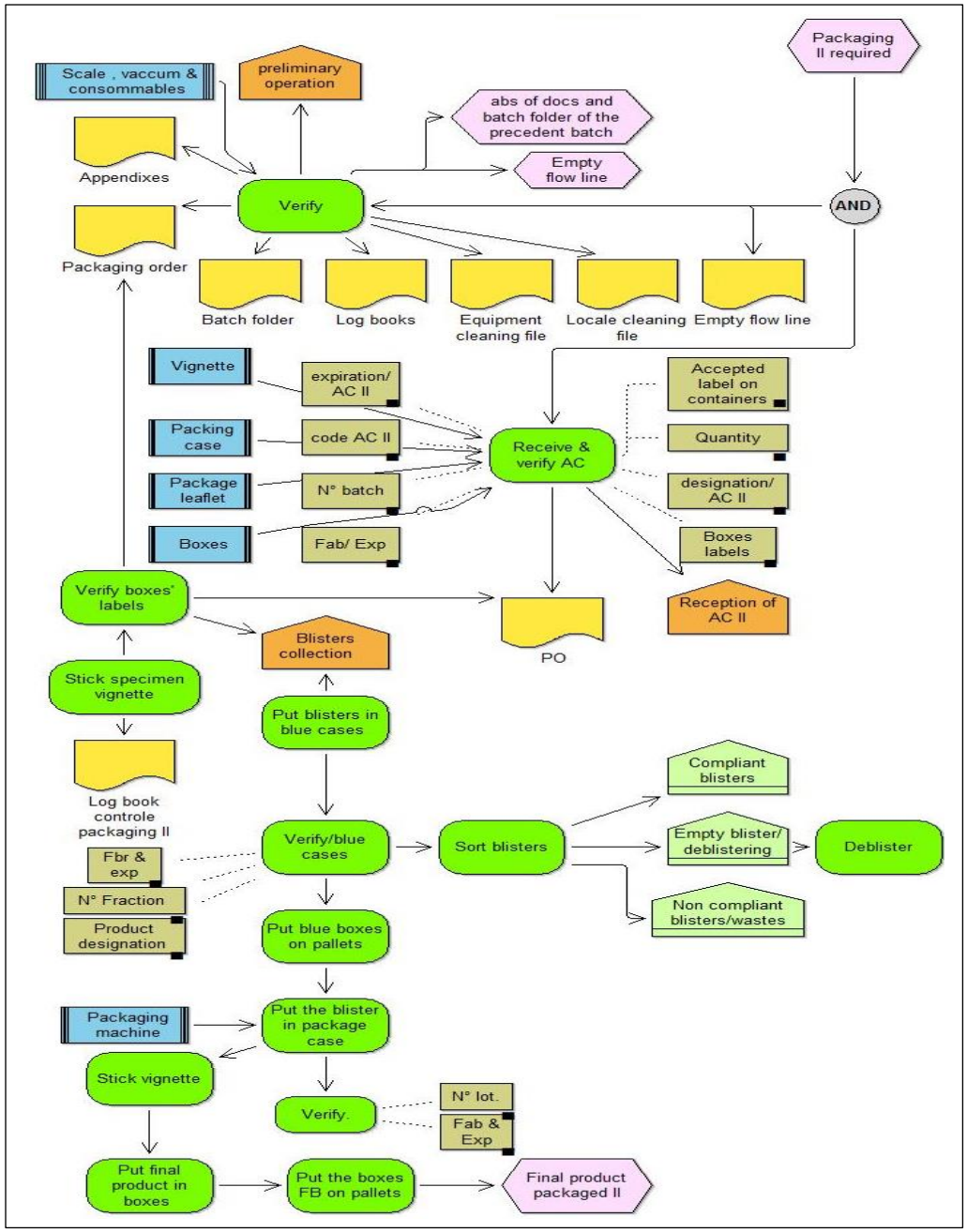
Source: photos taken by the author; diagram is the outcome of AdoBPRIM

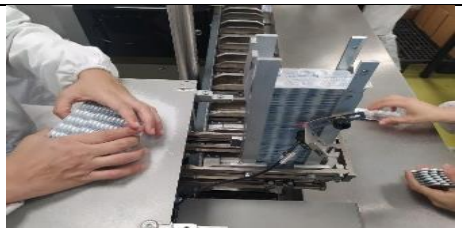
Packaging II;

It refers to the second phase of packaging , in which the blisters are put in case package.

Figure and photos provide the details of this activity .

Figure n°57 : packaging II activity





Sort blisters

Putting the blisters in packaging cases (boxes)

Putting the leaflet

Final product

Stick the vignette

Put the final boxes in boxes

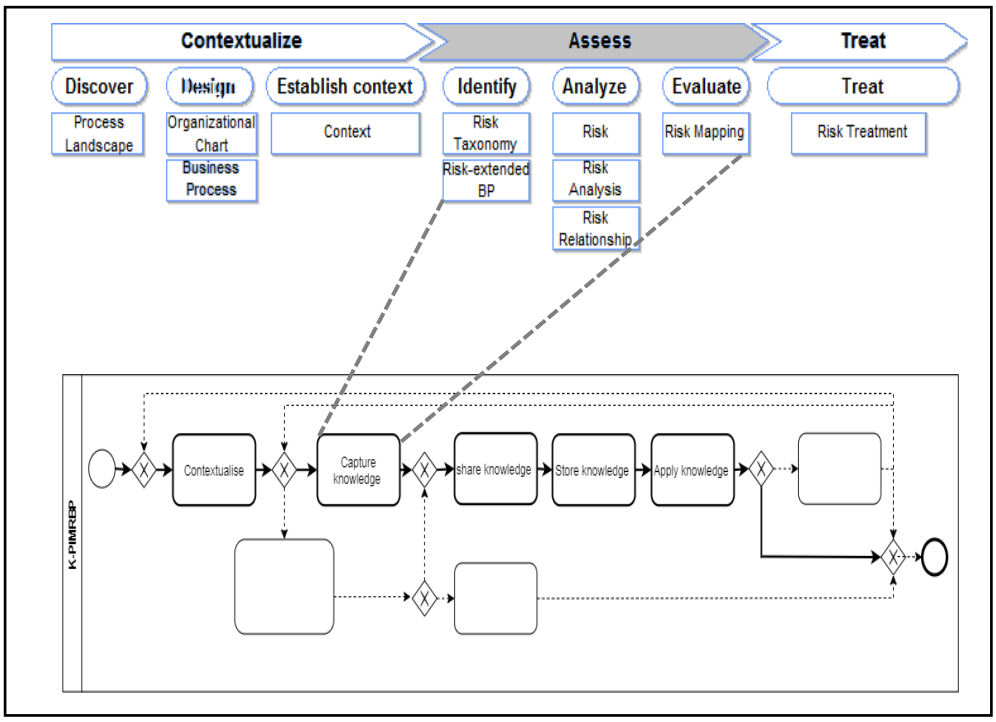
Source: photos taken by the author; diagram is the outcome of AdoBPRIM

Chapter IV : Results and discussion

2. K-PIMRBP / Capture knowledge

In the present study, we mean by Knowledge the risk management outcomes in form of diagrams. Capture knowledge activity refers to the collection of the outcomes of the risks assessement (identification, analysis and evaluation) and risks treatment as shown in the figure 58.

Figure n°58: capture knowledge



Source:elaborated by the author

The table below outlines "**capture knowledge**" activity

Table n°61: capture knowledge

Activity presentation	
Capture knowledge	
Description	**1. Risk identification: in this step we will determine** the operational risks in the fabrication process of SPASMOODYL 80mg , this activity involves two sub-activities namely : **1.a) The risk taxonomy** (figure59): In this activity we classified the potential and the actual operational risks into six classes of risks identified from the qualitative data analysis (figure 59). **1.b) Risks-extended BP diagrams:** In this activity we place the risks in the business processes in order to show the position of risks. **2. Risk analysis:** The aim is to determine the **risk causes , risk situation, risk likelihood for this we applied qualititative estimation as follows :** **0:** not defined **1:** very improbable **2:** very unlikely **3:** unlikely **4:** possible/likely **5:** very likely to certain **And risks severity :** **0:** not defined **1:** minor **2:** significant **3:** major **4:** critical **5:** catastrophic **The impact of the risk on values:** degrades, worsens, cancels or increases the value created in the enterprise.

	3. Risk evaluation: the risk may be acceptable , acceptable under control or unacceptable ; the risk evaluation is visualised in the risk matrix **figure** **Risk Treatment:** the aim of this activity is to provide treatment scenarios to treat the risks . figure
Interviewees/information source	In order to assess the risk (**capture knowledge**: identify, analyse and evaluate risks) we conducted interviews with: ***Production staff members*** (Production responsible ,supervisors)
Data (activity inputs)	***Verbatim (input)***
Knowledge (activity outputs)	***The nature of knowledge in this step are diagrams (risk taxonomy, Risks-extended BP diagrams and risk matrix)***
Data collection tools	***Interviews:*** were non-directive ,because the aim was to determine the operational risks in each BP and the position of risks in the BPs and evaluate the risks : What are the operational risks (problems, errors …) to which the BPs are exposed? What are the causes of these risks? How can these risks affect the created value? How often this risk occur? What is the severity of this risk? ***observation :*** during our internship at Frater-Razes we observed and attended to fabrication process of SPSMOODYL 80 mg
Modelling toolkit	**AdoBPRIM**

Source: elaborated by the author

a. Assessement-*identification* :

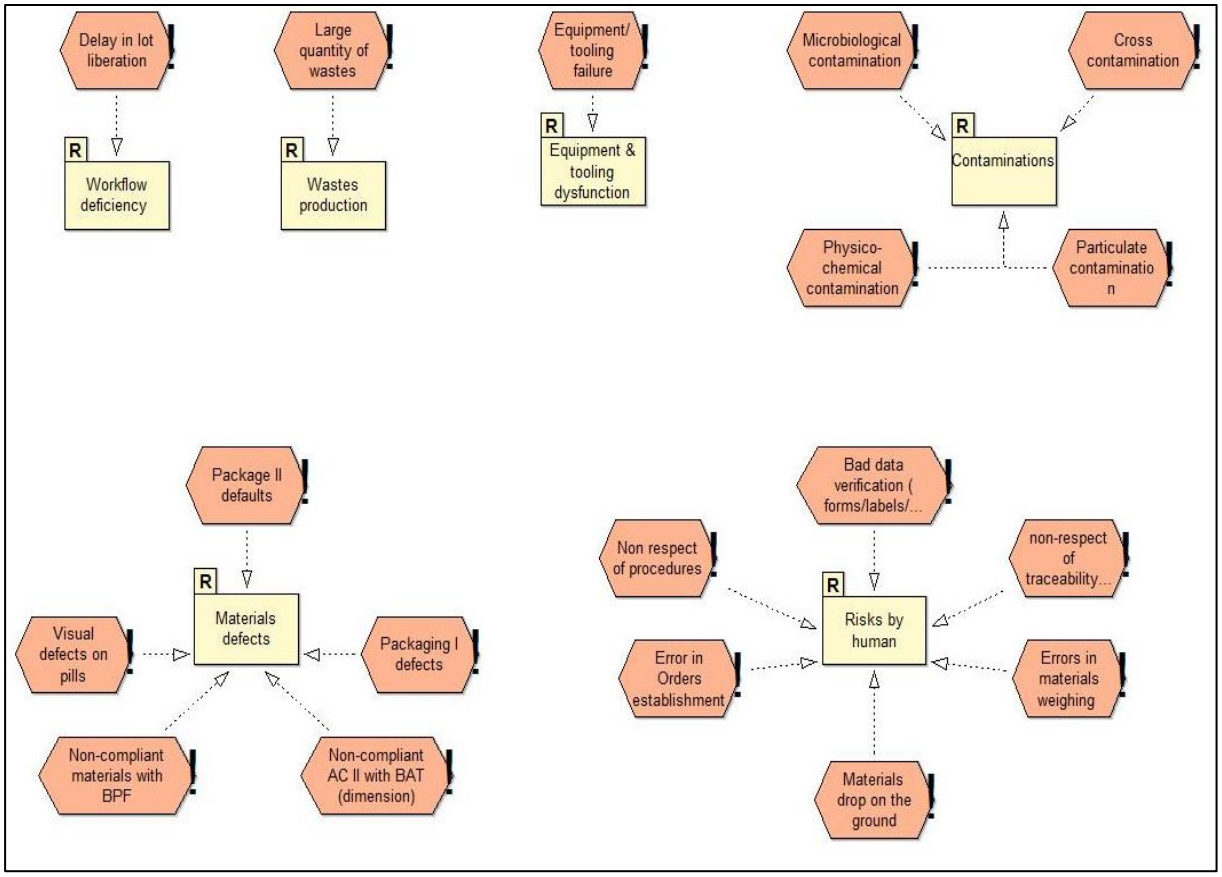
In this activity we identify the operational risks reported by the interviwees (the staff members) and observed by the researcher during our presence in the workshops. Figure 59 shows the risk taxonomy as follows:

Chapter IV : Results and discussion

a.1 Risk taxonomy:

Short pasta-making process is exposed to four main operational risks classes wherein each class involves many operational risks as discussed in the qualitative section namely: (1) contamination class (**2)** materials defects (**3)** Wastes production (**4)** equipment and tooling deficiency**(5)** workflow deficiency **(6)** risks caused by human

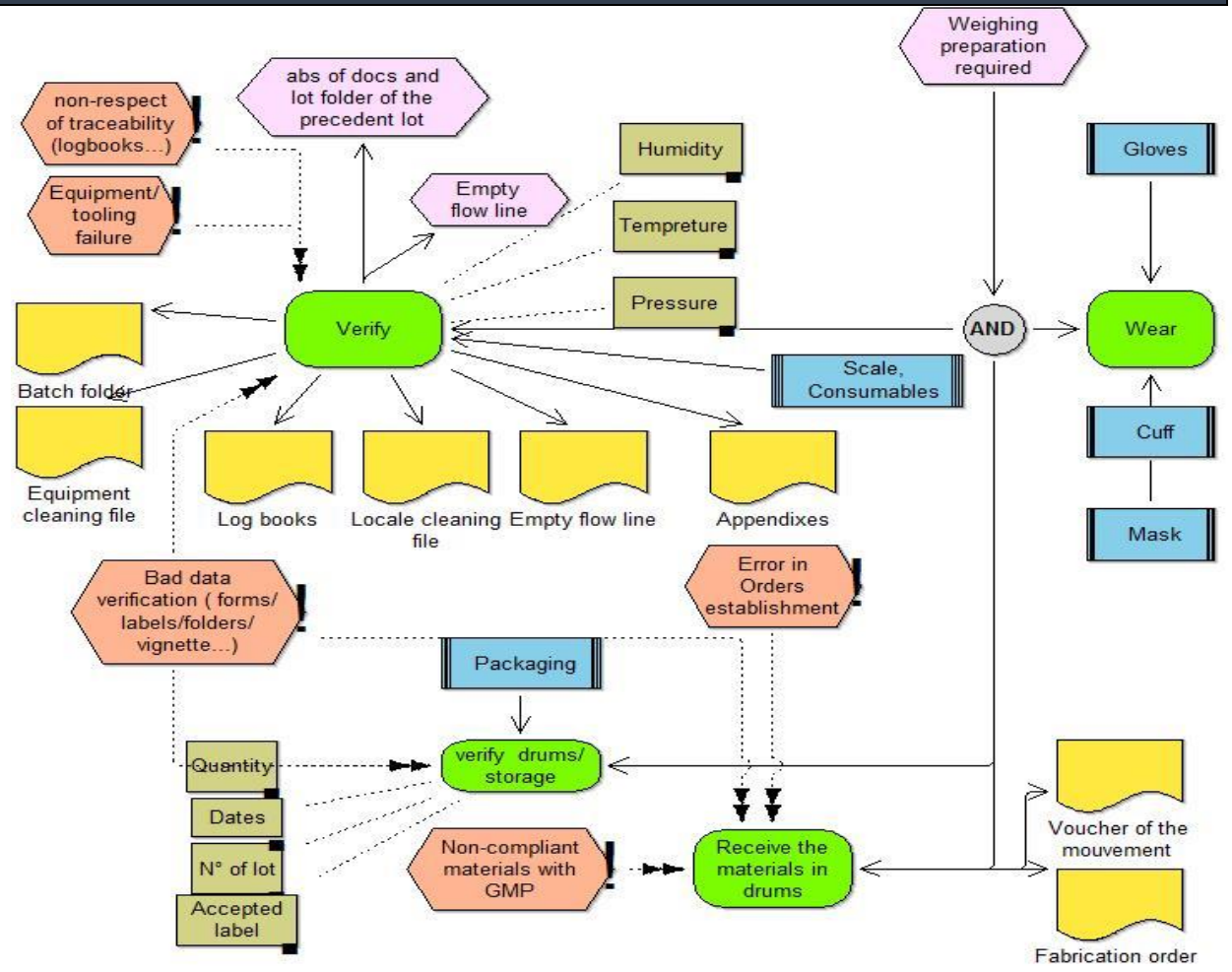
Figure n°59: risk taxonomy (Frater-Razes)

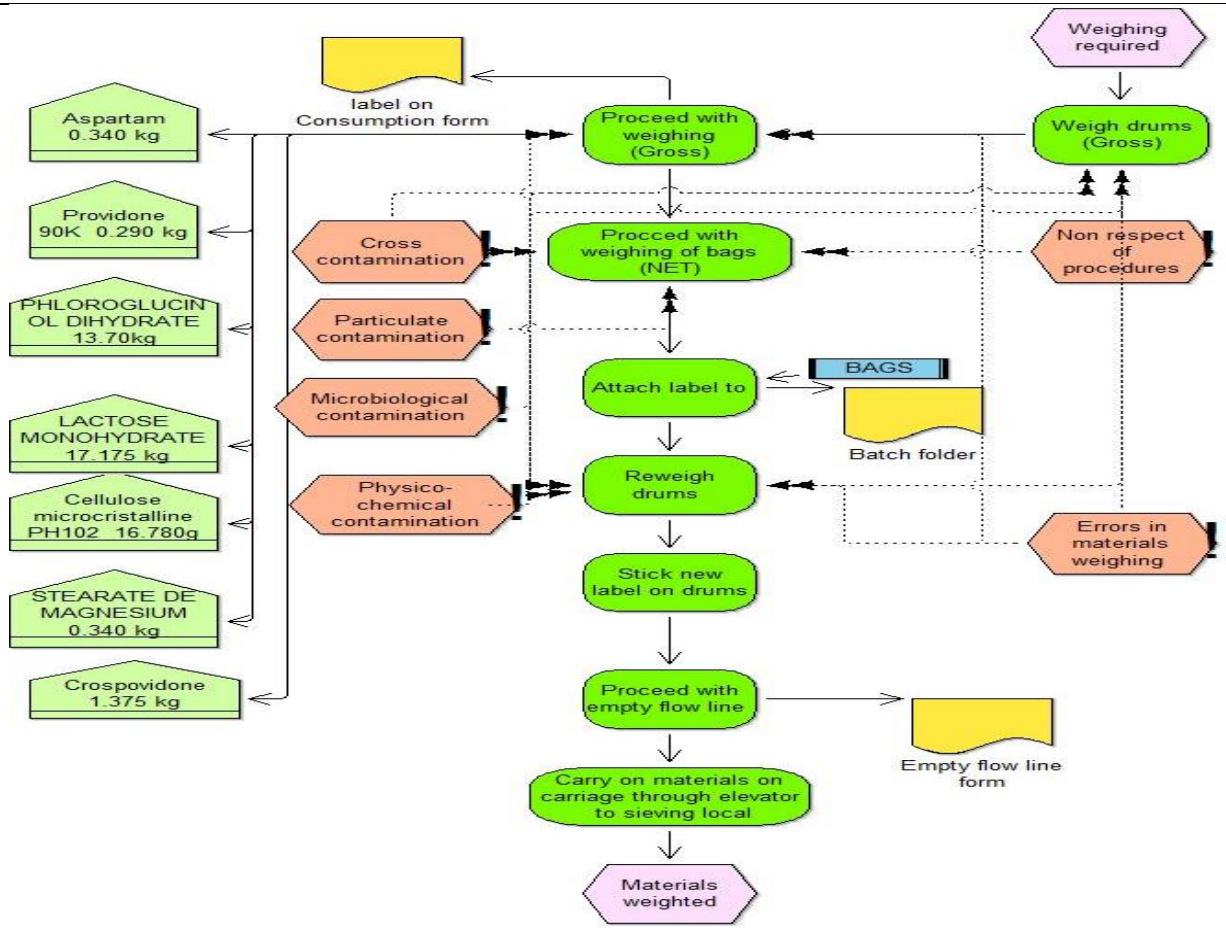


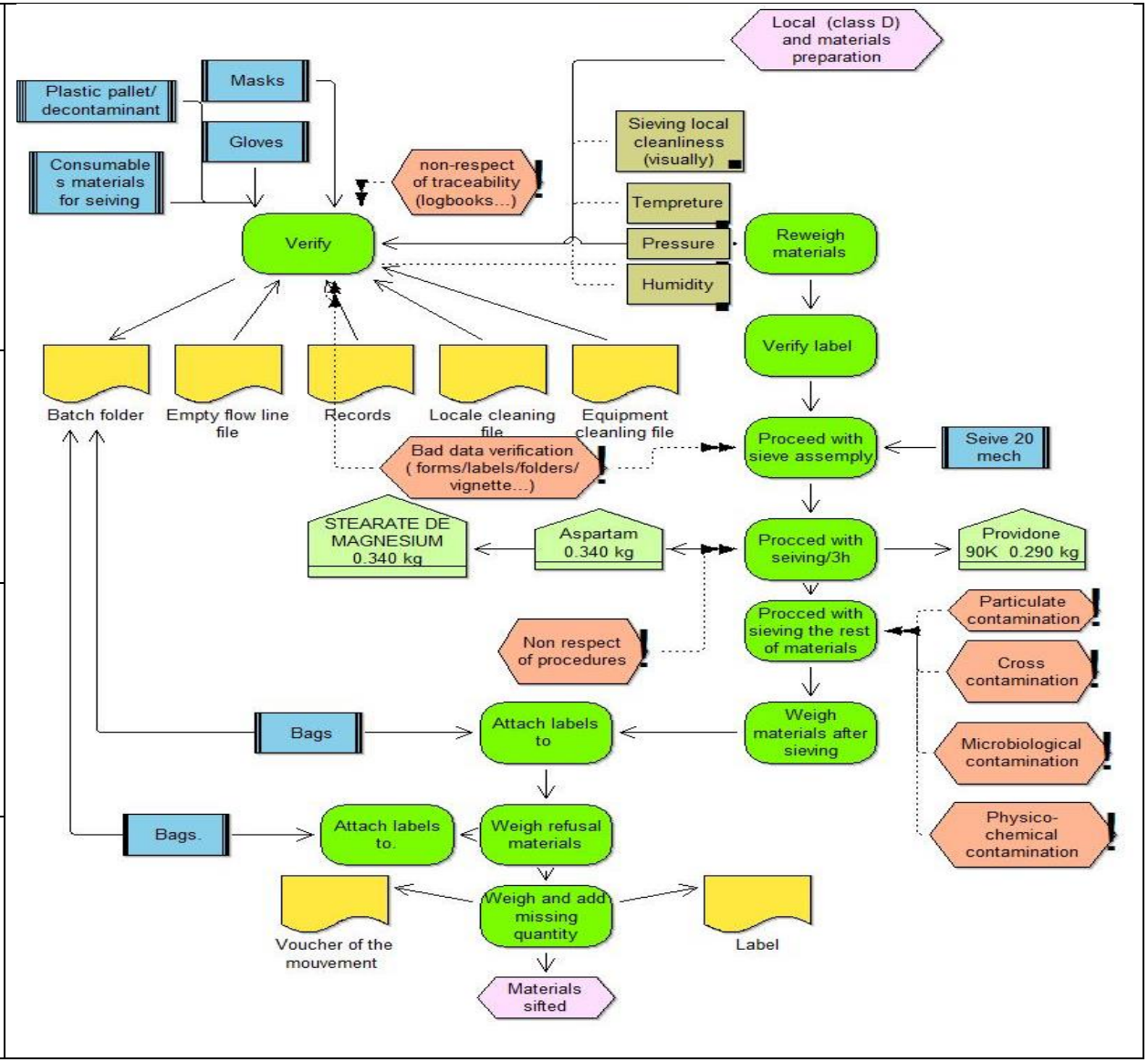
Source: outcome of AdoBPRIM

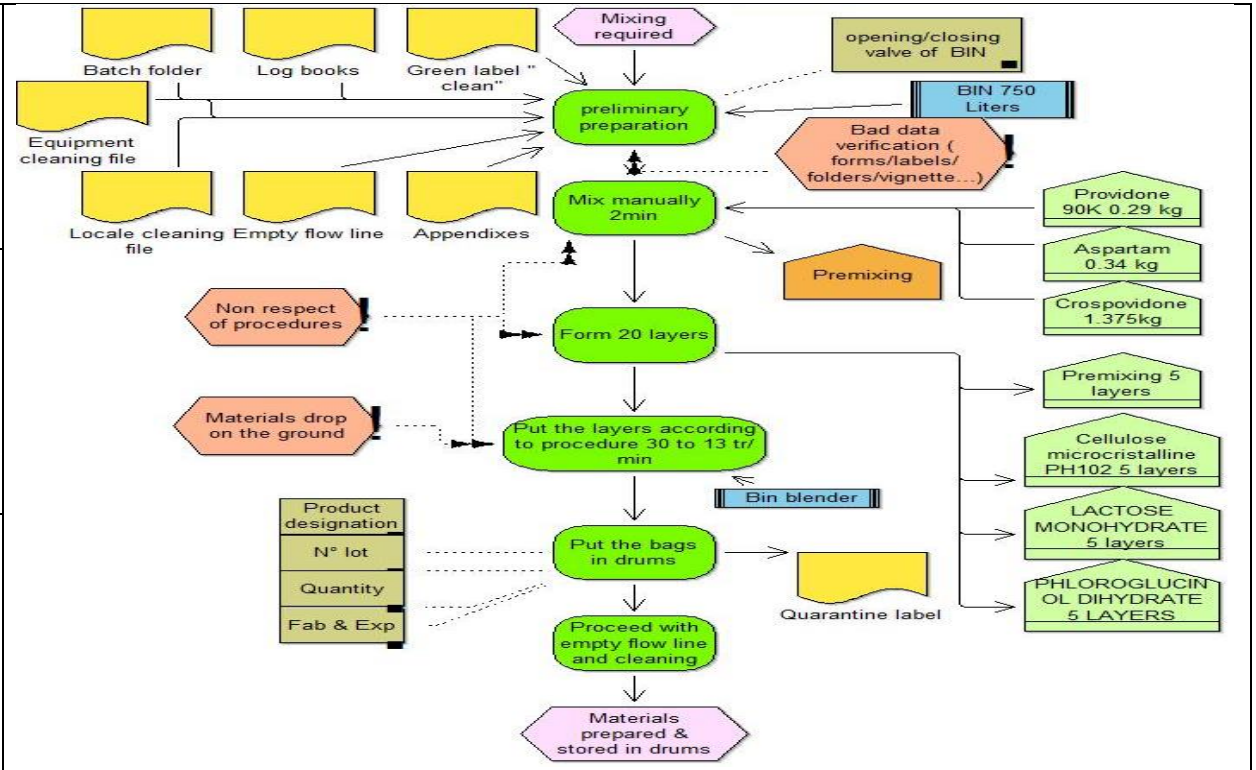
a.2) Risk-extended BP: Table indicates the operational risks in business processes (weighing,sieving, mixing, packaging I and packaging II) of the fabrication of SPASMOODYL 80mg.

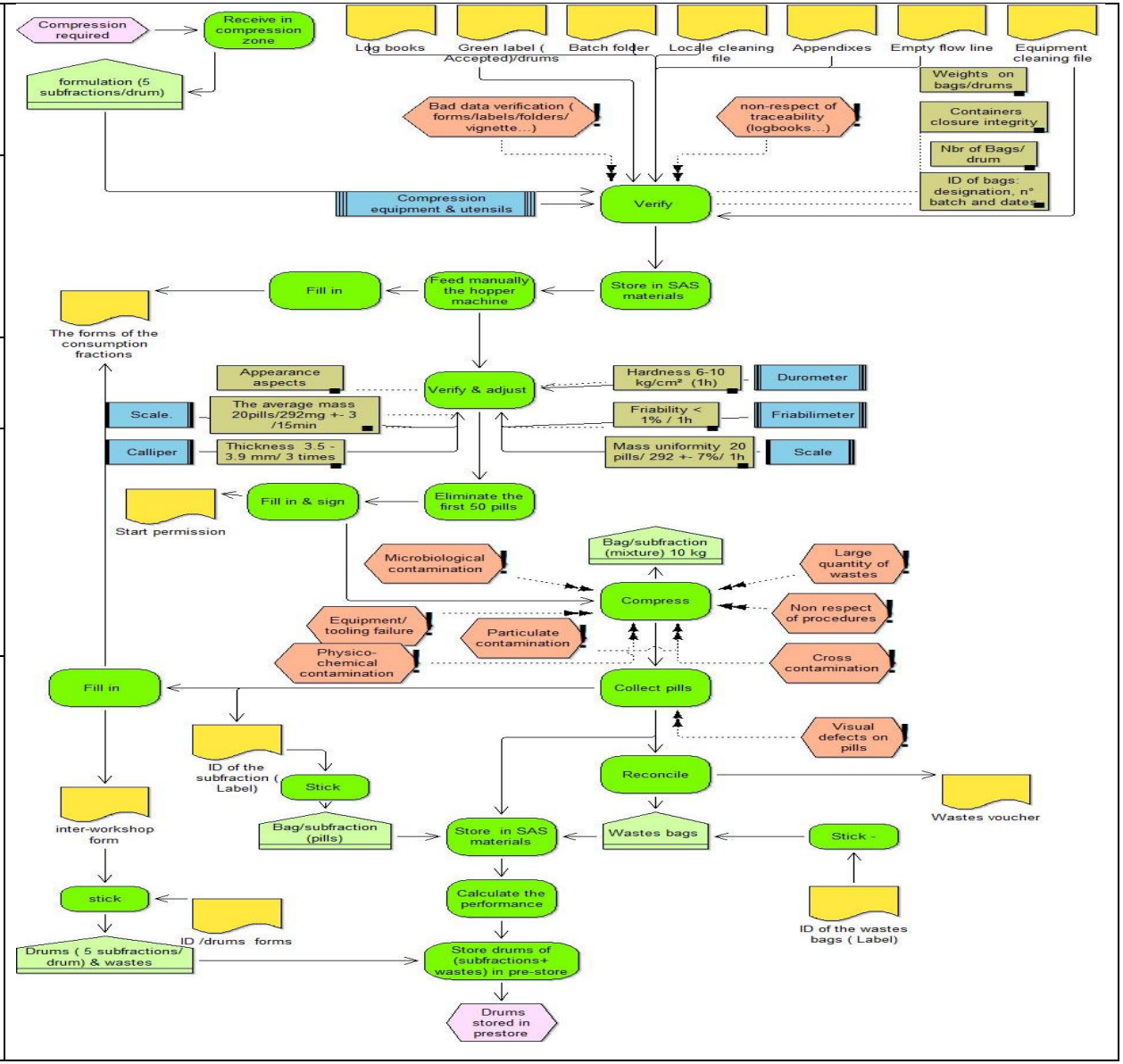
Table n°62 : Risk-extended BPs

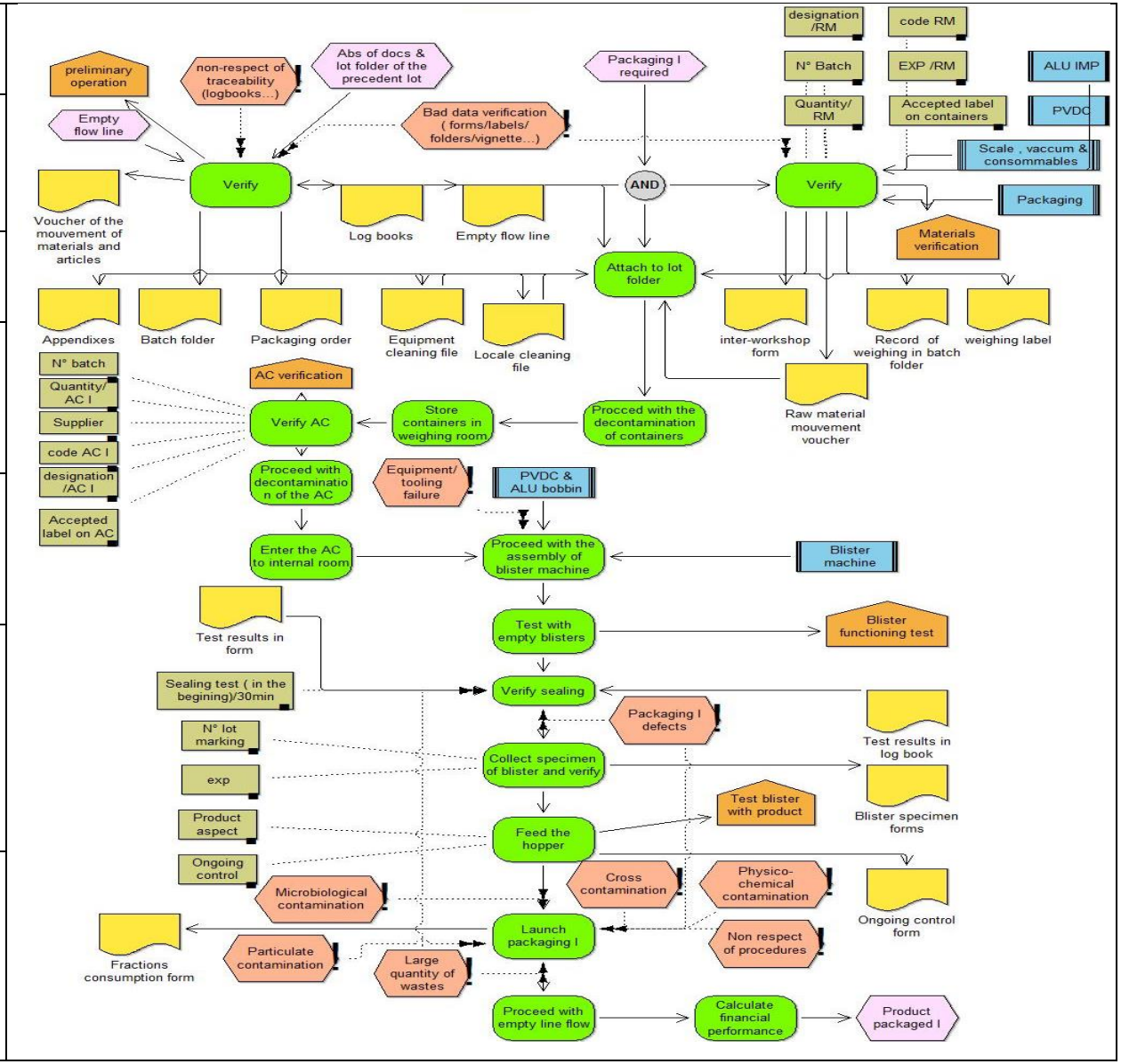
BPs	OR	Comments	Risks-extended BP diagrams
Pre-weighing	**Bad data verification**	Labelling is a requirement in pharmaceutical enterprises, by which the drug process is organised. In weighing step, labels are stuck on drums and bags of materials (green labels, which indicate that the materials were controlled by laboratory and white labels contain information about materials). There is a potential risk of bad data verification by the preparer or supervisor, mislabelling and errors of data on forms…etc. That create confusion between materials.	
	Non-respect of traceability	Besides weighing materials, the preparer should also fill the log books and batch folder, who may forget to ensure traceability by forgetting to fill in the form.	
	Error in order establishment	There is a potential risk that production responsible or technical responsible make errors in order establishment (N° batch…)	
	Equipment/ tooling failure	It refers to the use of uncalibrated scale. Frater-Razes has a service, which verifies periodically the qualification of equipment, there is a potential risk that this qualification expires and the service does not notice that.	

	Non-compliant materials with GMP	There is potential risk that the enterprise receives non-compliant materials with GMP from supplier.	
Weighing	**Contaminations**	Materials are exposed to all types of contaminations in this step (cross contamination, particulate contamination, microbiological contamination and physico-chemical contamination)	
	Errors in weighing	There is a potential risk that preparer makes errors in weighing materials	
	Non-respect of procedures	There is a potential risk that the preparer makes errors in the procedure of weighing (i.e., forget a step)	

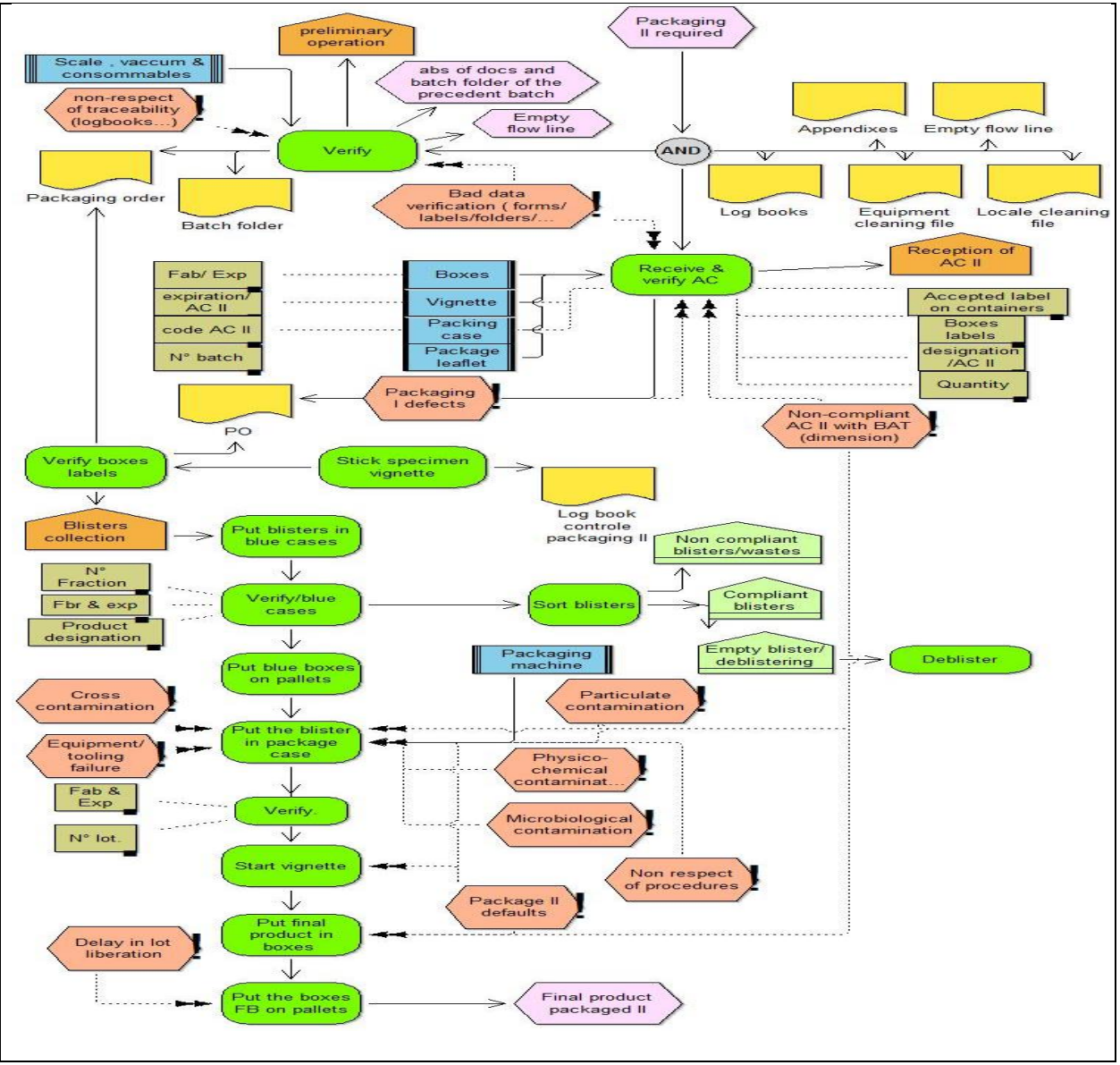
Sieving	Non-respect of traceability	In sieving step , preparer should fill the log books and batch folder to ensure traceability , but there is a potential risk that the preparer does not fill the forms on time and therefore he does not ensure traceability	
	Bad data verification	There is a potential risk of bad verification of data on labels which creates confusion between the bags of materials , or bad verification of data in forms and folders	
	Non-respect of procedures	There is a potential risk that the preparer makes errors in the application procedure of sieving (e.g. forget a step)	
	Contamination	The sieving activity is exposed to all types of contaminations	

Mixing	**Bad data verification**	As any step in drug fabrication process, there are files and forms to fill, there is a potential risk of missing data or data errors originated from a bad data verification.	
	Non respect of procedures	There is a procedures for SPASMOODYL preparation, in which the step of mixing materials and the duration of mixing…etc. are detailed, but there is a potential risk that the preparer misses a step or makes an error in the procedure application.	
	Materials drop on the ground	Some materials are very thin , so there is a potential risk that they slip from the preparer hand and drop on the ground	
Compression	**Bad data verification**	In the compression step, there is a potential risk of bad verification of data on files and folders	
	Non-respect of traceability	There is a potential risk that the operator/control agent misses to fill the forms on time, which leads to lack of product traceability.	

	Non respect of procedure	The enterprise created a procedure for compressing activity ,but there is a potential risk that the operator makes an error in its application	
	Equipment and tooling failure	One of the main operational risks in fabrication process is equipment breakdown and tooling wear, which interrupt and stop all the process.	
	Contaminations	The product in this step is exposed to all types of risks	
	Large quantity of wastes	The compression step, incurs a large quantity of pharmaceutical wastes including (adjustment wastes in the beginning of compression step which consists of adjusting the compressing machine according to the parameters set; control wastes...etc.)	
	Visual defects on pills	SPASMOODYL is white round pill , so any deviation from these characteristics are considered as defects (spots, color deviation) . The pills should met five parameters (friability, weight, hardness, thickness) ,if not ,then visual defects will appear on the pills	

Packaging I	Contaminations	The product is exposed to all kinds of contaminations in this step	
	Large quantity of wastes	The blister packaging incurs a large quantity of pharmaceutical wastes including the blister pack wastes	
	Bad data verification	There is a potential risk of bad verification of data on files and folders	
	Non respect of procedure	The operator may make mistakes in the application of blister packaging process	
	Non-respect of traceability	Operators may miss to fill the log book and files of batch folder which lead to lack of traceability	
	Package I defects	Is the blister packaging process, in this step we use articles (Aluminium, PVDC) which may be of bad quality , there are also other risks that occur during this process including (bad sealing, bad marking and incomplete blisters)	
	Equipment and tooling failure	Blister machine may breakdown and tooling may wear with over usage	

Packaging II	**Non-compliant ACII with BAT**	Articles may not be compliant with BAT information (number of the articles , the products characteristics),including the dimension and the cardboard colour of the package case
	Bad data verification	There is a potential risk of bad verification of data on the articles of packaging received by the supplier including : the information on leaflet or on the vignette
	Non-respect of traceability	The operators/supervisor may miss to fill in the files and forms on time which lead to the lack of traceability
	Non-respect of procedures	The operators may make mistakes in the application of packaging procedures
	Packaging I defects	The Packaging defects that were not detected during this step, they will appear in the second phase of packaging particularly the bad marking of (dates and N° of batch)
	Contaminations	Although the blister pack , the product is still exposed to all types of contaminations



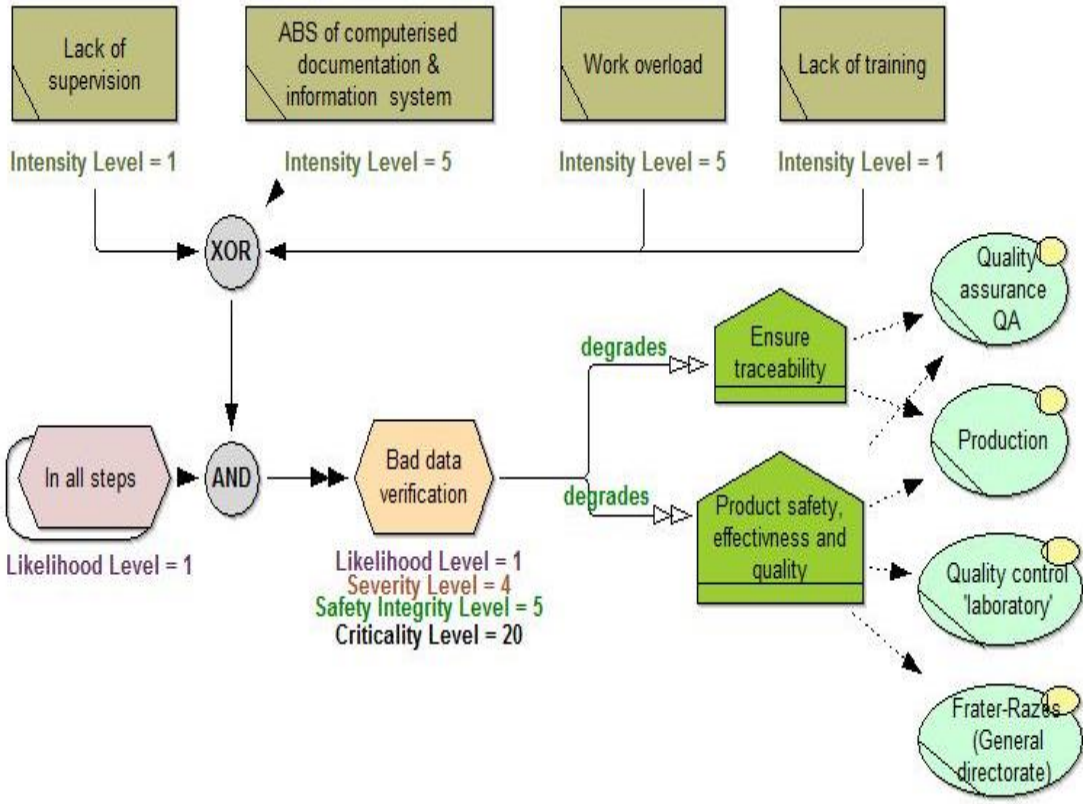
	Equipment and tooling failure	The case packing system or its parts may breakdown or it may need adjustment	
	Packaging II defects	In the second phase of packaging, many defects may appear namely: the bad marking on packaging case (date and N° batch), packaging case damage, bad printing of information on vignette.	
	Delay in batch liberation	In pharmaceutical enterprise , before starting the fabrication of any batch of product, responsible estimated the date of its liberation, but that is a potential risk of delay in liberation because of many reasons that will be detailed in the following part of this section	

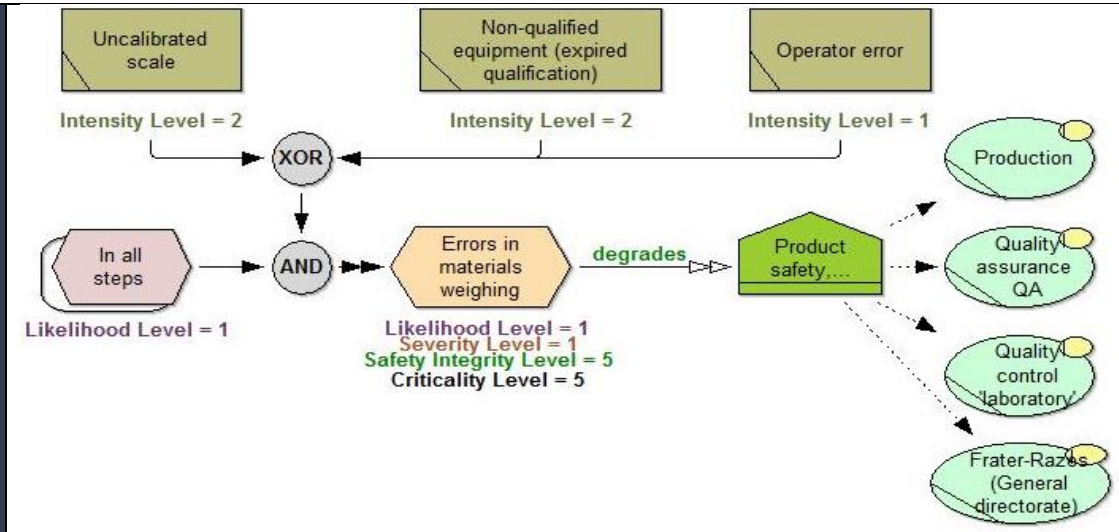
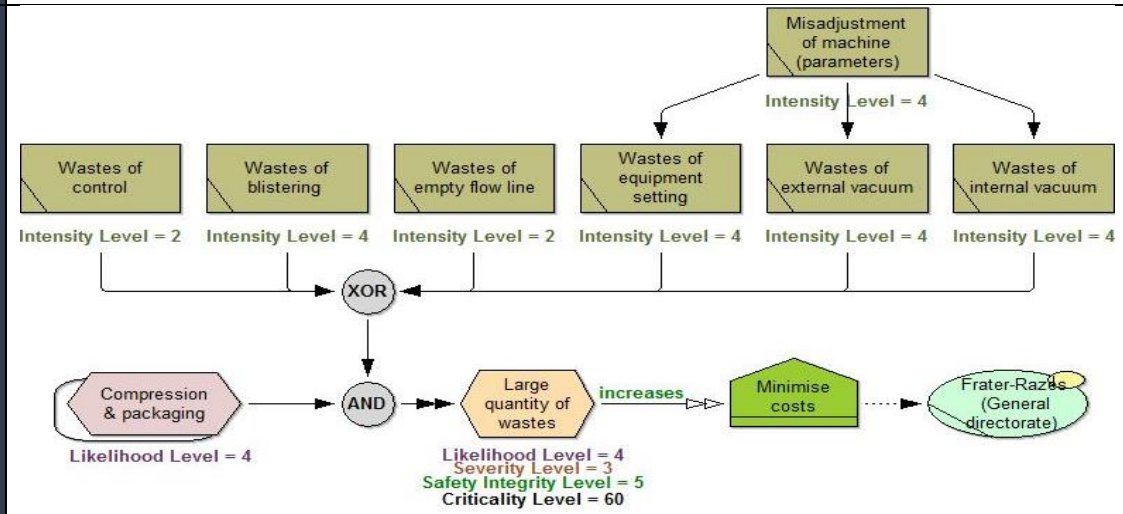
Source: elaborated by the author

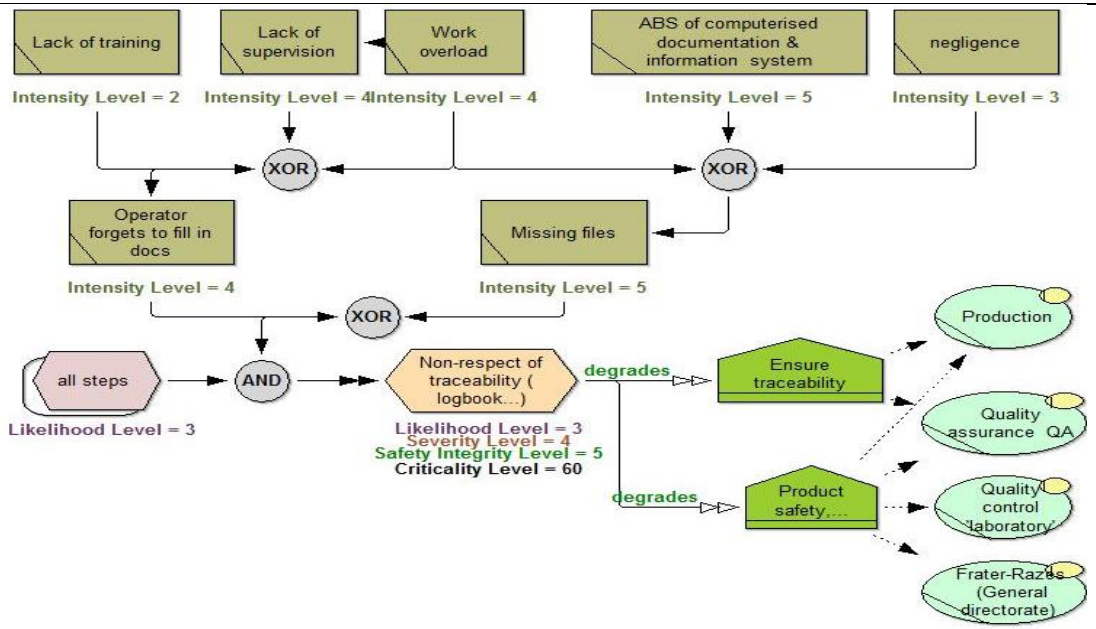
a.3) Assessment - Risk analysis:

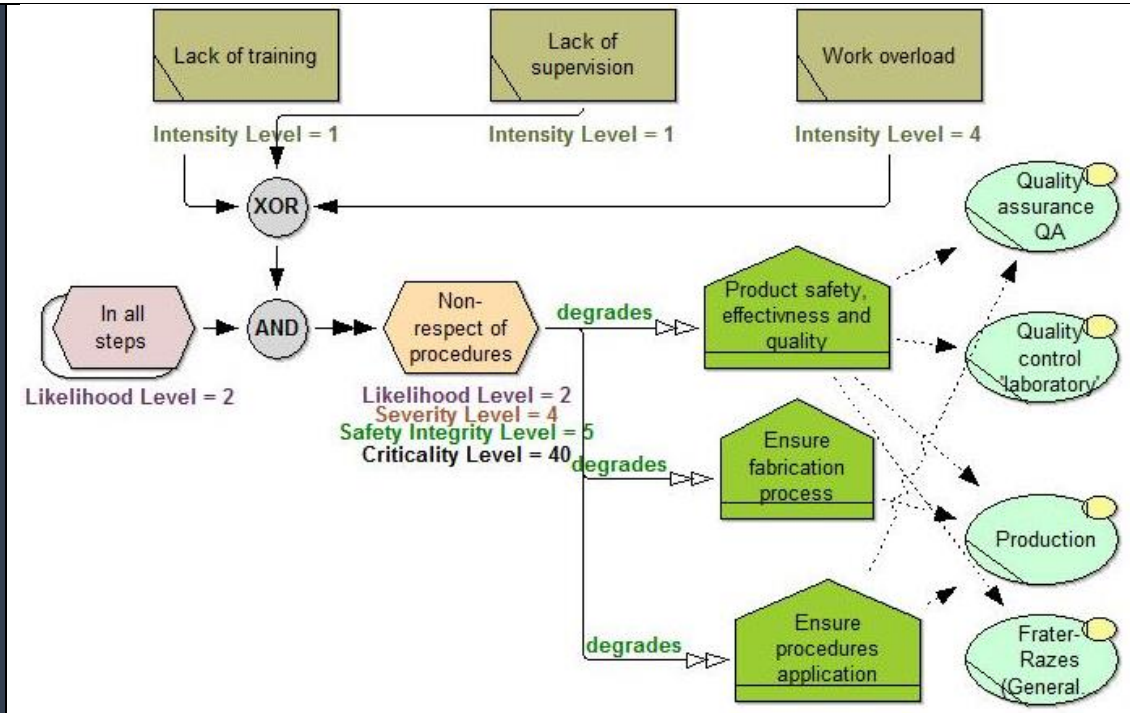
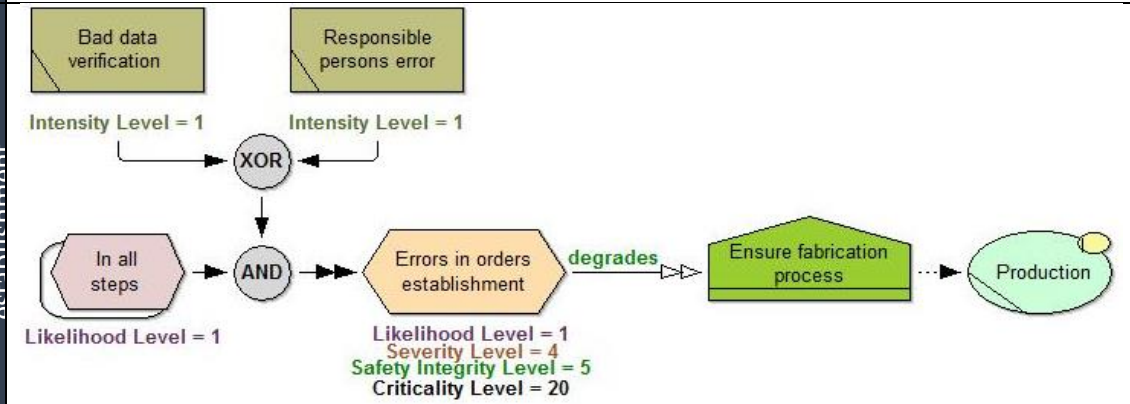
In the following sub-section we will display the risk analysis diagrams

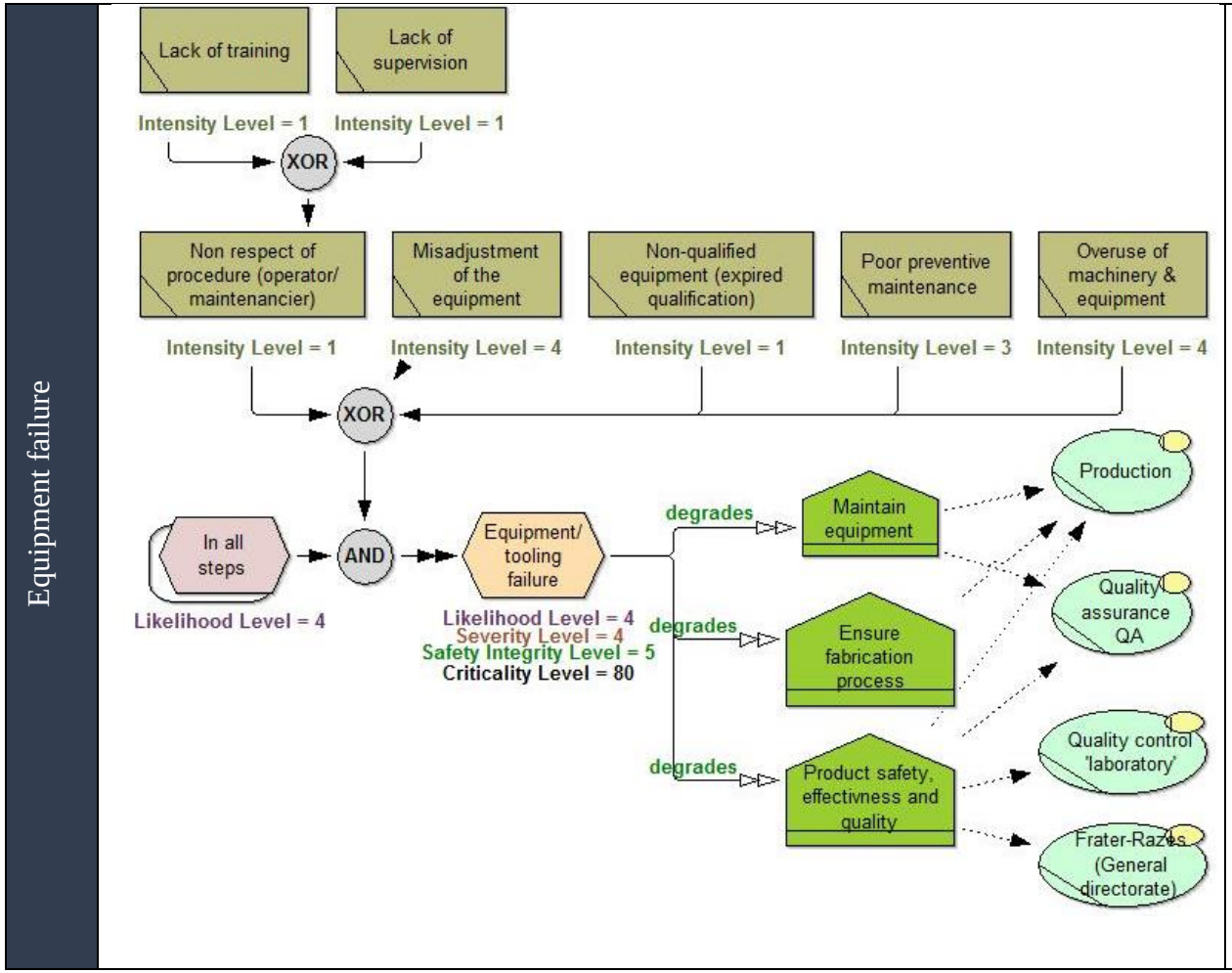
Table n°63: risk analysis diagrams

OR	Risk analysis diagrams	Comments
Bad data verification		The bad verification of data on files, log book and blister pack (dates and N° of batch) and information (dates and N° of batch) on vignette , packaging case and leaflet are caused by: ° Lack of supervision and control of operators by the supervisors ° Lack of training , particularly , for new employees ° Work overload ° Absence of computerised system, which replaces the paper version of documents, in which the employees fill in the electronic forms. This risk is very improbable , which is a critical risk because it affects the product safety, effectiveness and quality for which all the structures of Frater-Razes are responsible and which leads also to lack of traceability

Errors in materials weighing		There is a potential weighing errors because of: ° The use of uncalibrated scale; ° The use of non-qualified equipment; ° Operator error, particularly, if the operator is new or he lacks of training or because of work overload. This risk is very improbable, which is a minor risk because it is rectifiable error, but if it is not corrected it affects the product safety, effectiveness and quality for which all the structures of Frater-Razes are responsible.
Large quantity of wastes		The large quantity of wastes of compressing and packaging steps could be originated from: ° The control of the product; ° The empty flow line activity; ° The blistering ; ° Equipment setting; ° Internal and external vacuum. This risk may possibly occur, which is a major risk because it incurs the company additional costs.

Non-respect of traceability		The operator who forgets to fill in forms on time or when files are missing from batch folder, cause the lack of traceability. It is unlikely that this risk happens at Frater-Razes, but it is a critical risk because if there is a lack of traceability we cannot track the product, which affects the product safety, effectiveness and quality, for which all the structures are responsible.

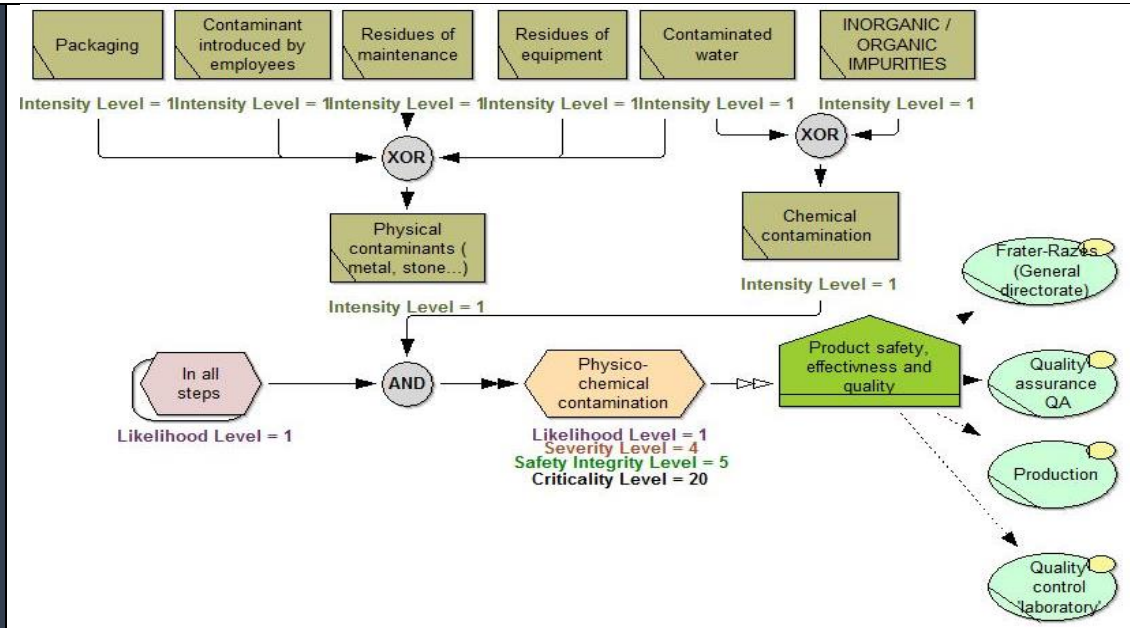
Non-respect of procedures		Non-respect of procedures is originated from the lack of supervision, the lack of training for employees and the work overload, if the procedures are not applied as indicated, fabrication process may not generate the expected results, which affects the product safety, effectiveness and quality, hence it is a critical risk. However, It is very unlikely that this risk happens at Frater-Razes.
Errors in orders establishment		The responsible persons (technical and production responsible) may make errors in orders establishment of the fabrication and packaging activities, because of the bad verification of data on the orders. It is a critical risk because it may interrupt the whole process of fabrication. However, it is very unlikely that this risk happens at Frater-Razes.

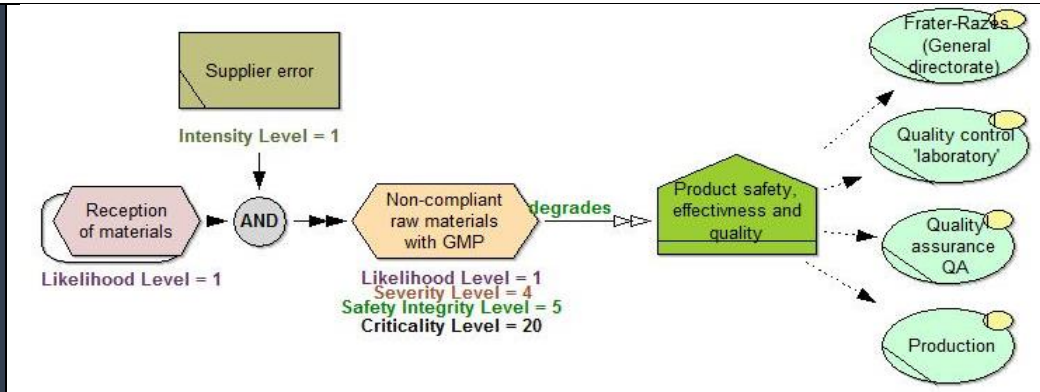


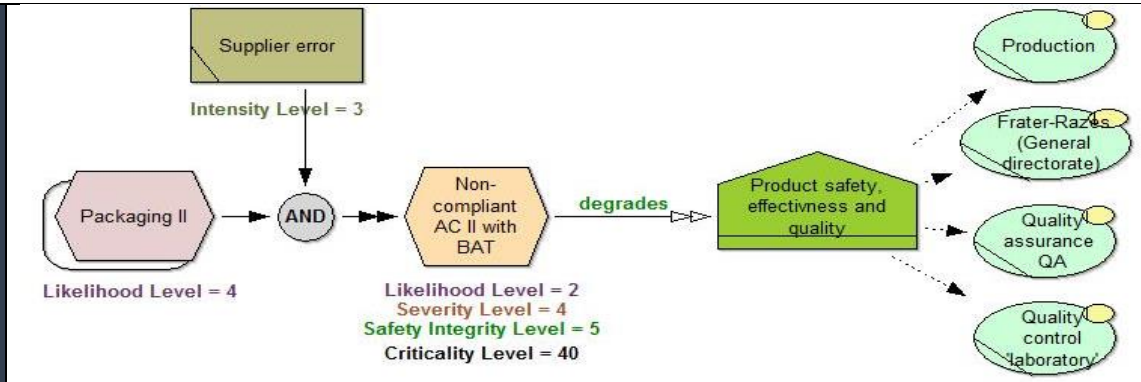
Equipment failure is caused by:

- The overuse of machinery and equipment;
- The use of non-qualified equipment;
- The misadjustment of the equipment and the non-respect of procedures of the equipment use. At Frater-Razes, in the beginning of an operation, the operator should adjust the equipment, but if he does not follow the procedure that may lead to equipment failure;
- Poor preventive management.

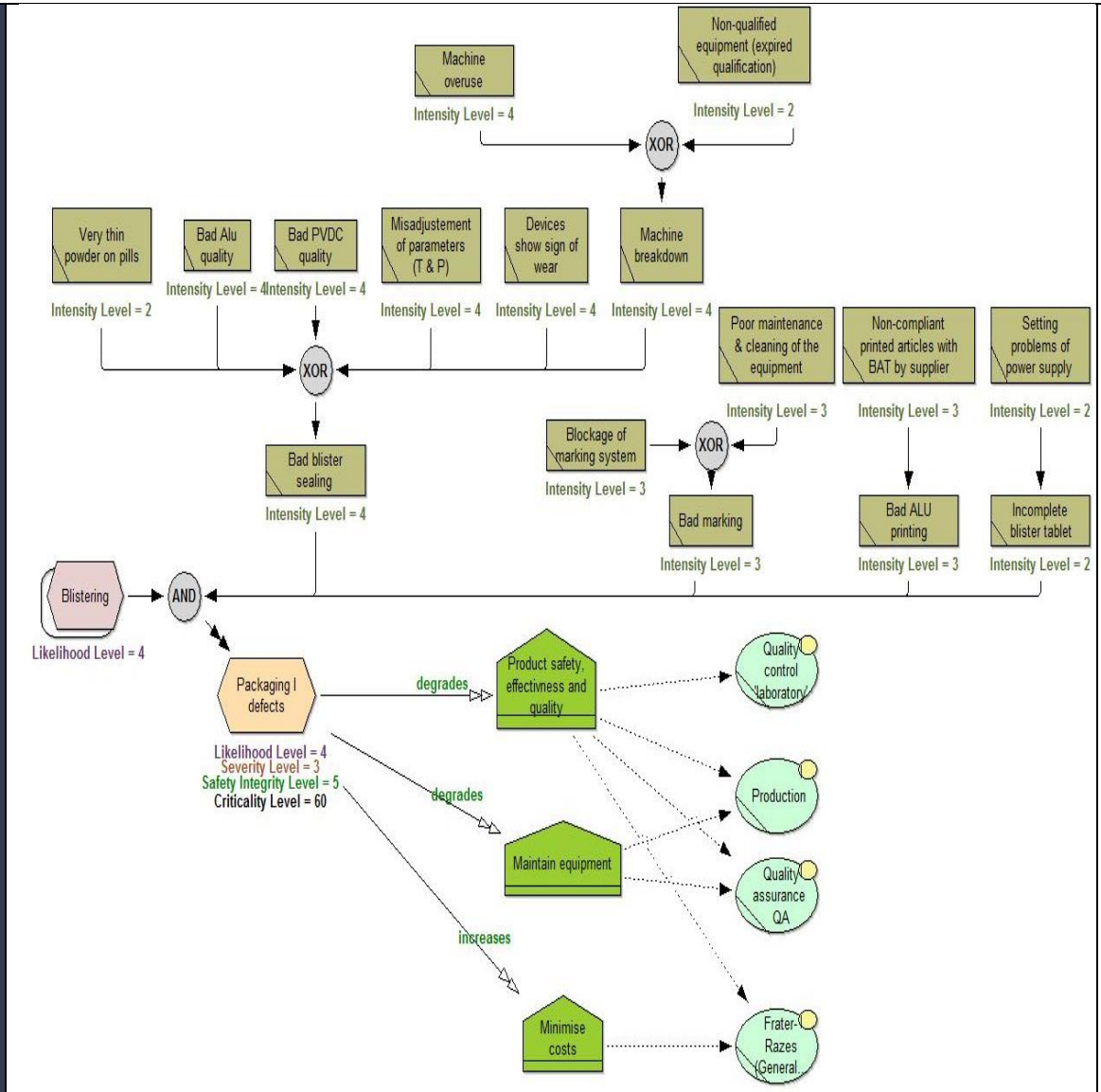
This risk is a critical risk because it interrupts the fabrication process and it may affect the product safety, effectiveness and quality for which all the structures of Frater-Razes are responsible. It is a frequent risk threatening the production company, where their activities are performed by means of equipment, so it may possibly occur at Frater-Razes.

Physico-chemical contamination		Physico-chemical contamination is caused by: ° The existence of Physical contaminants, namely: contaminated water, residues of the equipment, contaminants introduced by the human and contaminated packaging; ° The existence of chemical. This risk is a critical risk because it affects the product safety, effectiveness and quality for which all the structures of the enterprise are responsible. However, it is very improbable to occur at Frater-Razes, because they pay great attention the quality of the workplace.

Non-compliant raw materials with GMP		The supplier may send non-compliant raw materials with GMP. At Frater-Razes, all the materials received from the supplier are controlled by the laboratory, so if the raw material is not compliant with the GMP, the laboratory will reveal that, and the materials will be returned to the supplier. Hence, it is very improbable to enter to the store of the enterprise, but it is a critical risk because it affects the product safety, effectiveness and quality for which all the structures of the enterprise are responsible.

Non-compliant AC II with BAT		The BAT of the packaging articles includes the dimension, the information that should be on the articles, the characteristics of the articles. The supplier may provide non-complaint articles with the BAT. However, it is very unlikely that the non-compliant articles enter to the store of the enterprise, because all the received articles from the suppliers pass by the laboratory that refuse the non-compliant articles. This risk is critical because it affects the quality of the product for which all the structures of the enterprise are responsible.

Packaging I defects



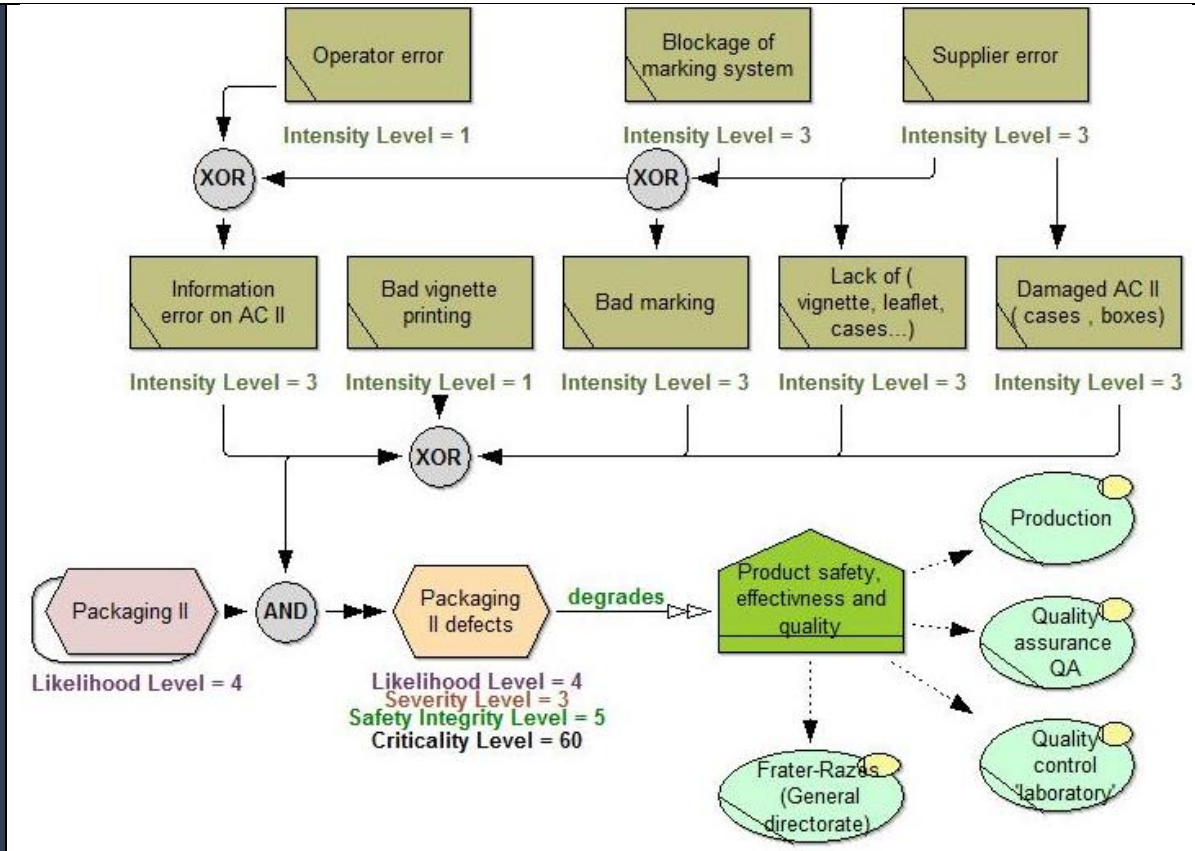
The defects in the primary packaging articles are originated from:

- The blockage of the marking system leads to bad marking of the information (e.g. dates and N° BATCH) on the items of packaging on the items of packaging;
- Bad blister sealing;
- The bad printing of the information on the aluminium;
- Incomplete blister tablet.

For more details, see the diagram analysis of this risk. This risk may affect the product quality, it increases the quantity of wastes, which incurs additional costs to the enterprise and may breakdown the equipment if the item is not compliant. Hence, it is a major risk. It may possibly occur at Frater-Razes.

All the structures of Frater-Razes are responsible for this risk.

Packaging II defects

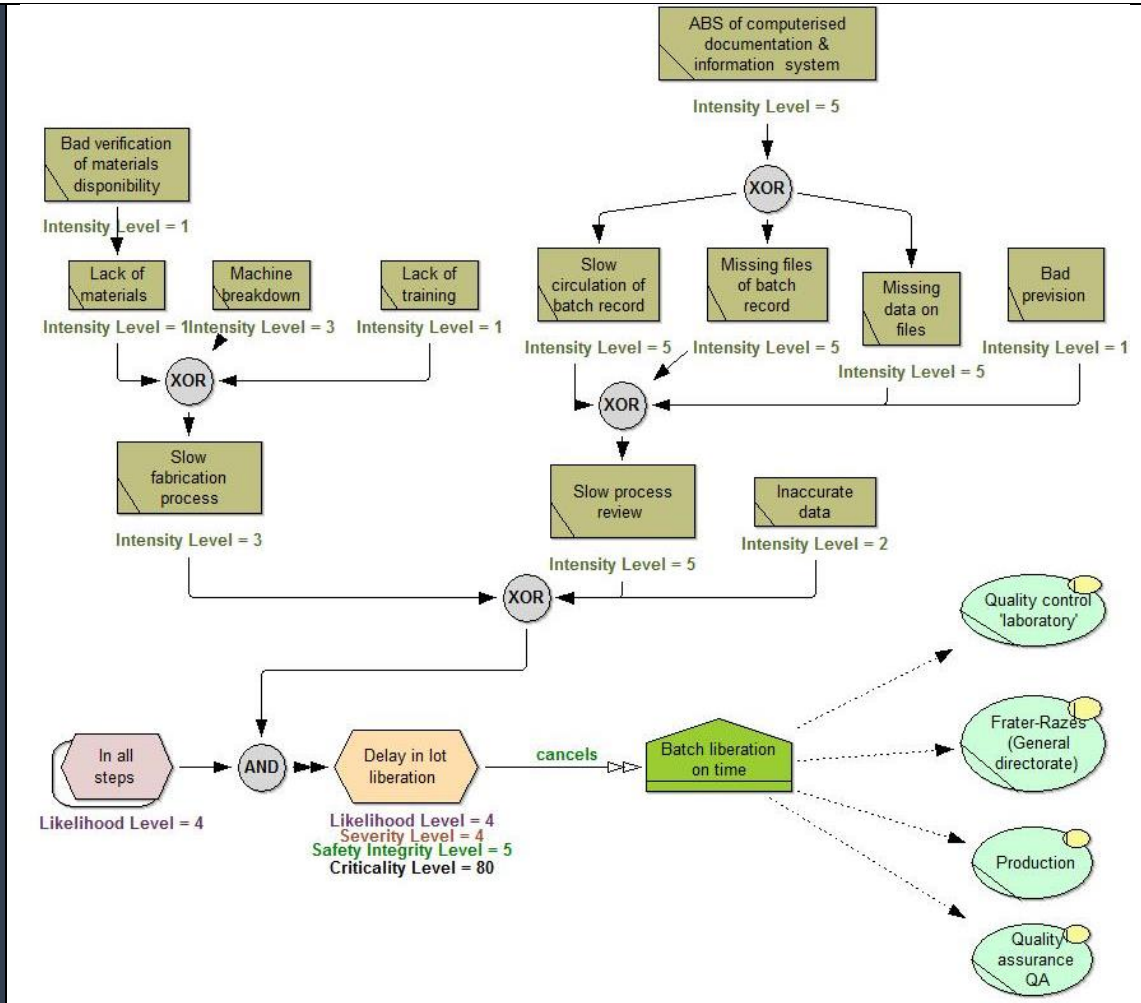


The defects of the secondary packaging articles are originated from:

- Information errors on the items
- Bad printing of the information on the vignette
- Bad marking of information on items
- Lack of items of packaging
- Damage of the articles of packaging

For more details, see the risk analysis diagram. This risk may possibly occur, which is a major risk that affects the product quality for which all the structures are responsible.

Delay in batch liberation

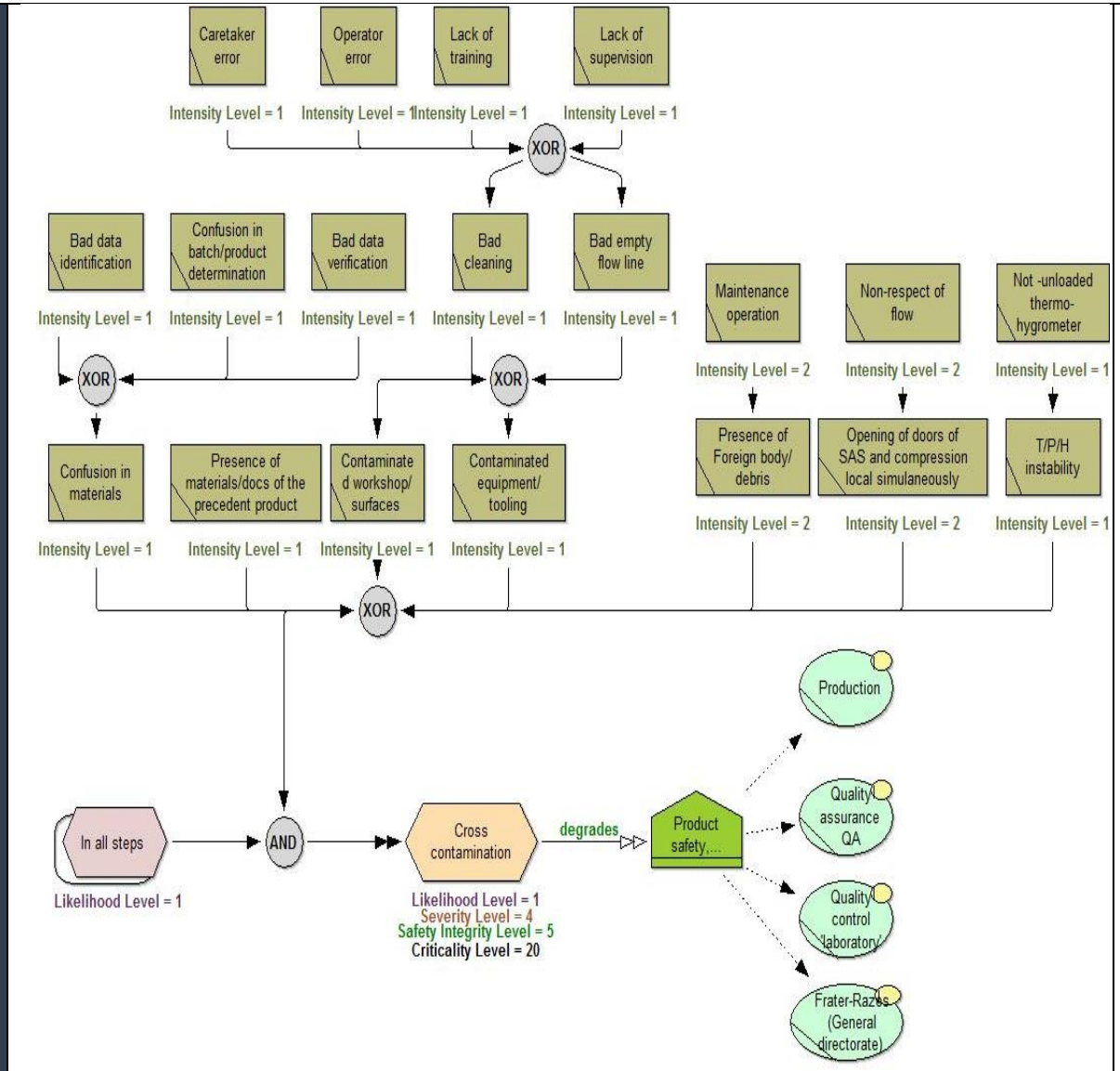


In pharmaceutical fabrication, the batch folder is essential element, which ensures the traceability of the product; the fabrication process is accompanied by the circulation of the batch folder, which is created in the beginning of the fabrication process. During our internship at Frater-Razes, we noticed the slow circulation of the batch folder, which causes the delay in liberation of the batch because they use paper version instead of electronic version.

The slow fabrication process caused by the equipment failure, which interrupts the process and delays the batch liberation.

Batch folder review may reveal inaccurate data that should be corrected, which leads to delay in batch liberation for which all the structures of the enterprise are responsible. It is a critical risk, which may possibly occur at Frater-Razes.

Cross contamination



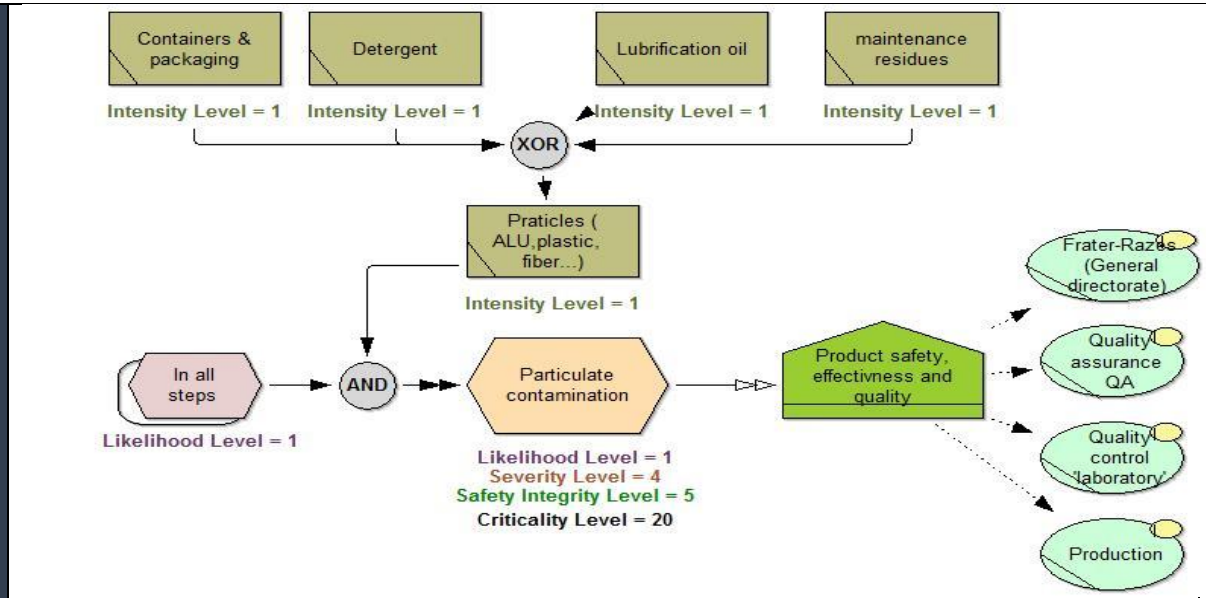
Cross contamination is caused by multiple factors , namely:

- The presence of materials and documents of the precedent product, in other words the failure of the empty flow line;
- The instability of the temperature, pressure and the humidity of the locale;
- The opening of the doors of SAS and compression of the locale in the same time;
- Presence of foreign debris;
- Contaminated equipment and tooling
- Contaminated surfaces.

For more details, see the risk analysis diagram.

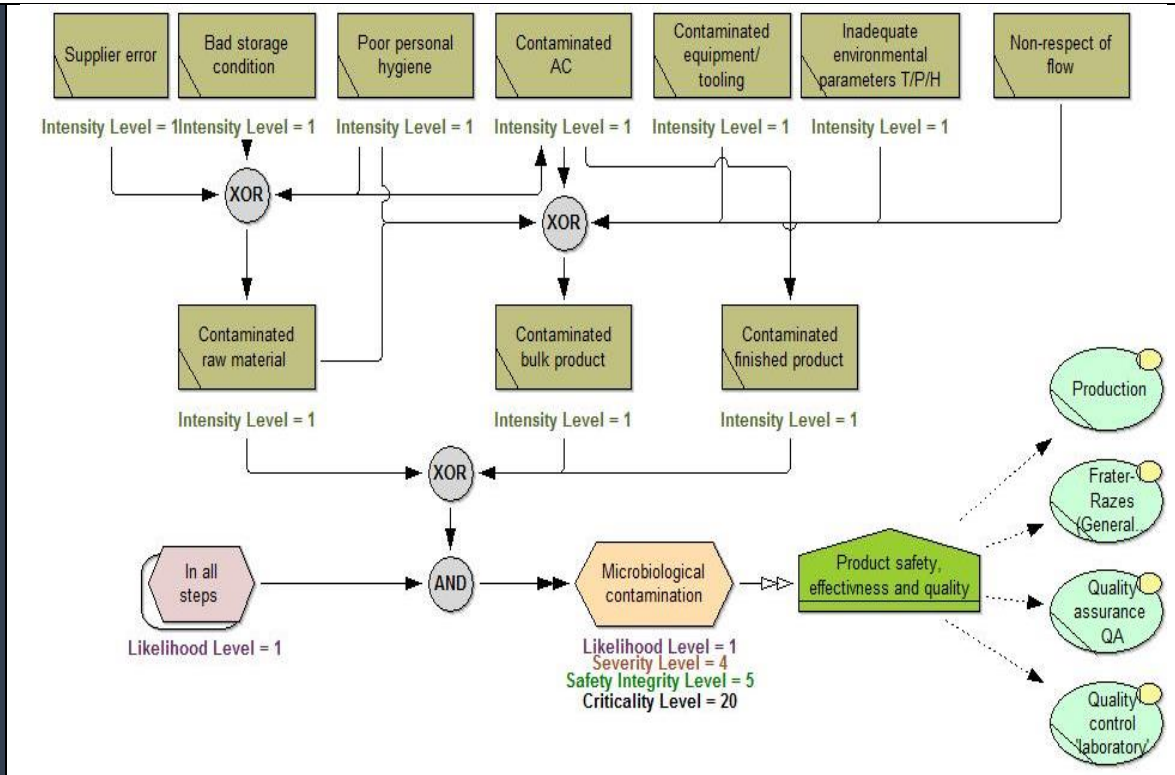
This risk is critical because it affects the product safety, effectiveness and quality for which all the structures of Frater-Razes are responsible. However, it is very improbable to happen at Frater-Razes because they give great attention to contaminations prevention.

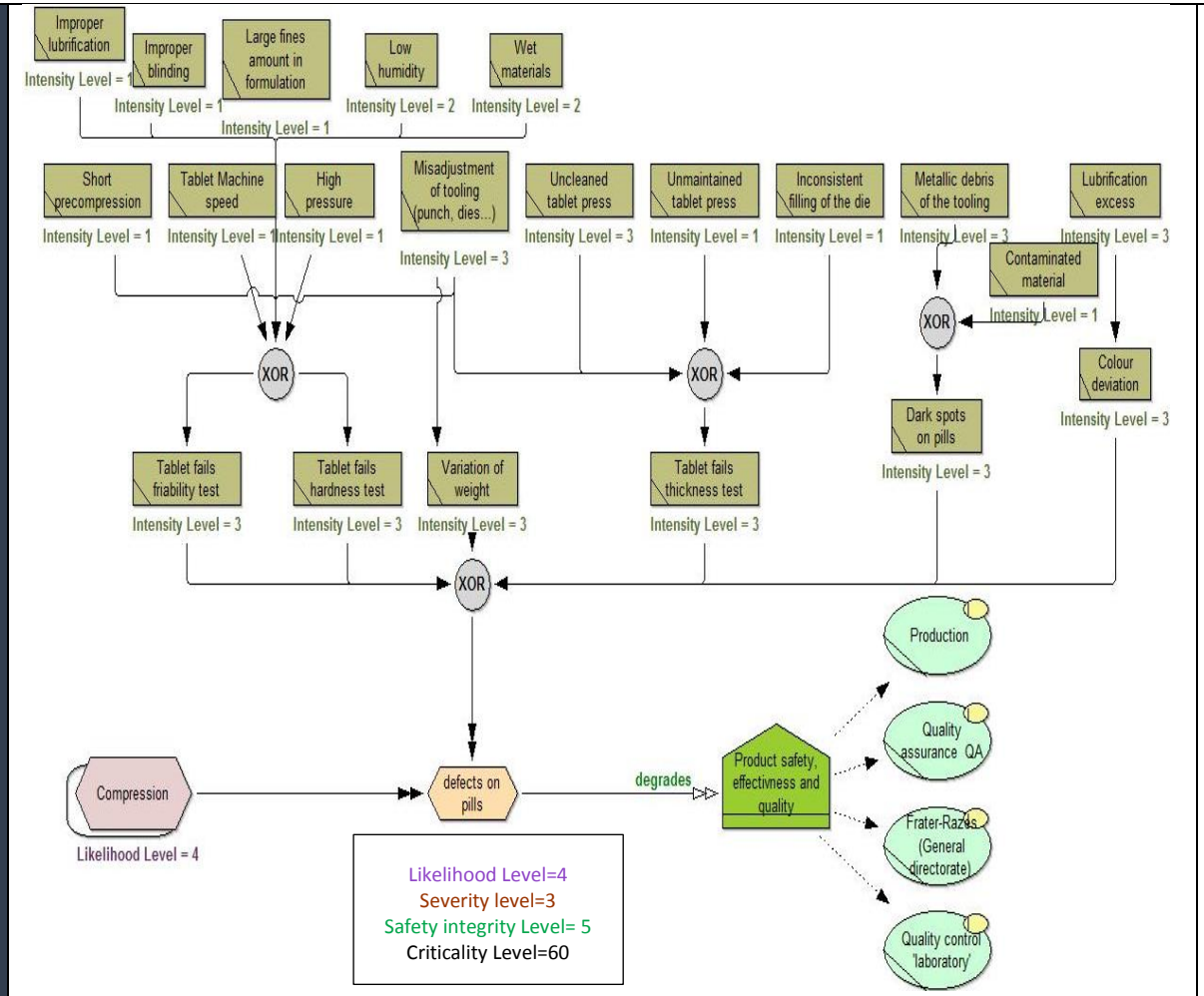
Particulate contamination

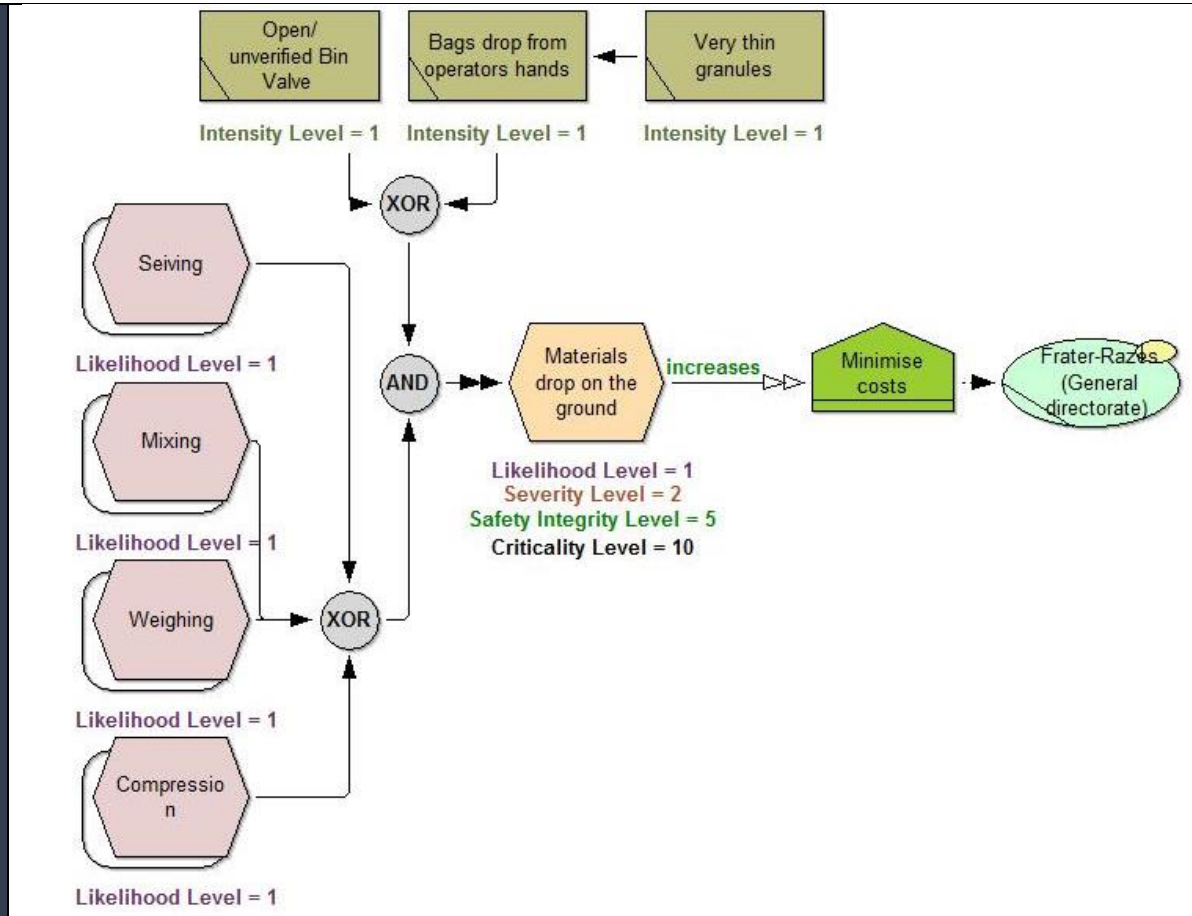


Particulate contamination is caused by the presence of small particles of plastic, fibres of clothes…etc.

This risk is critical because it affects the product safety, effectiveness and quality for which all the structures of Frater-Razes are responsible. However, it is very improbable to happen at Frater-Razes because they give great attention to contaminations prevention.

Microbiological contamination		The whole fabrication process is exposed to Microbiological contamination, from the raw material to the bulk product to the final product, which is caused by : ° The non-respect of people/material flow which should not coincide; ° Contaminated items of packaging; ° Contaminated equipment; ° Poor personal hygiene; ° Bad storage conditions; ° Inadequate environment pressure, temperature and humidity; This risk is critical because it affects the product safety, effectiveness and quality for which all the structures of Frater-Razes are responsible. However, it is very improbable to happen at Frater-Razes because they give great attention to contaminations prevention.

Visual defects on pills		Defects on pills refers to the negative results of one of more appearance controls of the pill ,in compression steps, namely: Friability test , hardness test, weight of the pills, thickness test the visual test For more details, see the risk analysis diagram. This risk is major because it affects the quality of the product for which all the structures are responsible and it may possibly occur at Frater-Razes.



Materials may drop on the ground, when the operator leaves the bin valve open or when the materials are very thin so they may drop from the operator's hands

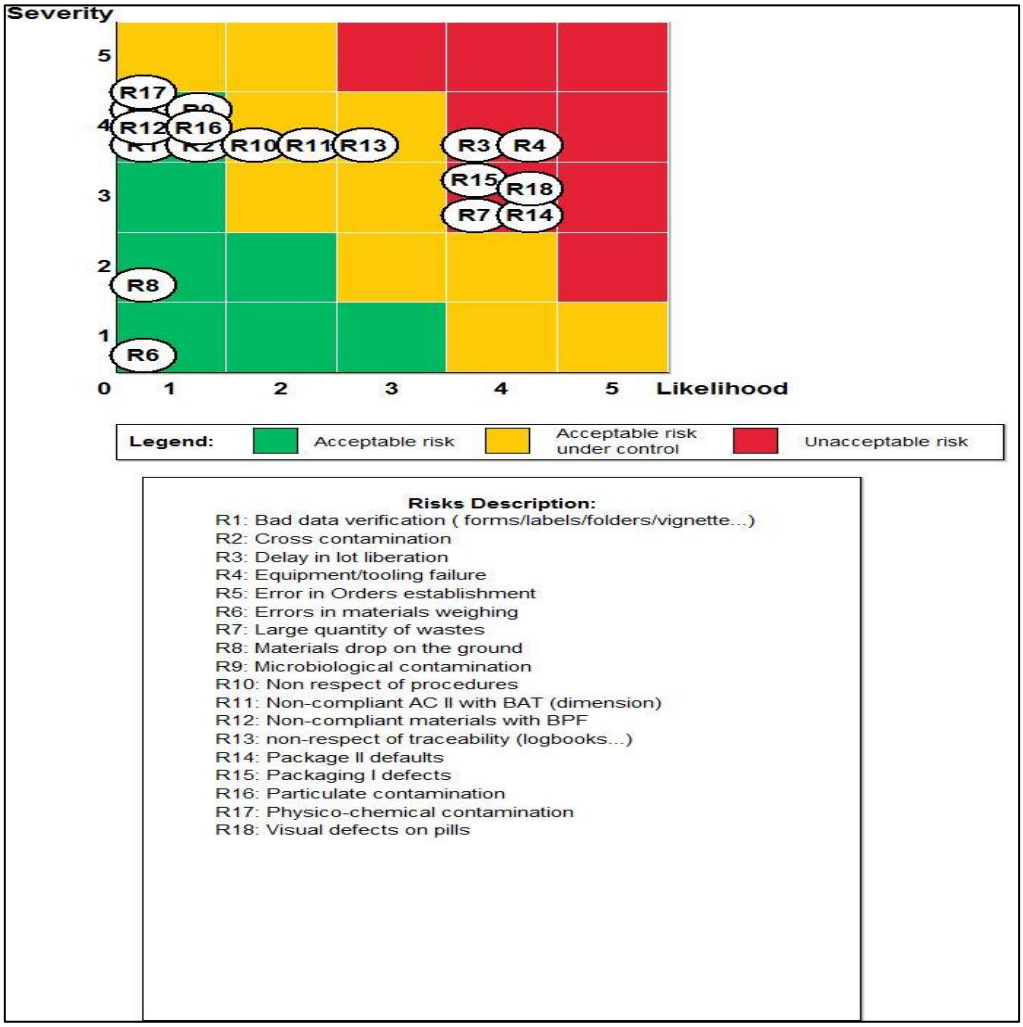
This risk is a significant, which increases the wastes and incurs additional costs because the pharmaceutical materials are very expensive. However, it is very improbable to happen because they have well trained operators.

Source : elaborated by the author

a.4) Assessment -Risk evaluation/matrix

Figure 60 shows the risk matrix

Figure n°60: risk matrix (Frater-Razes)

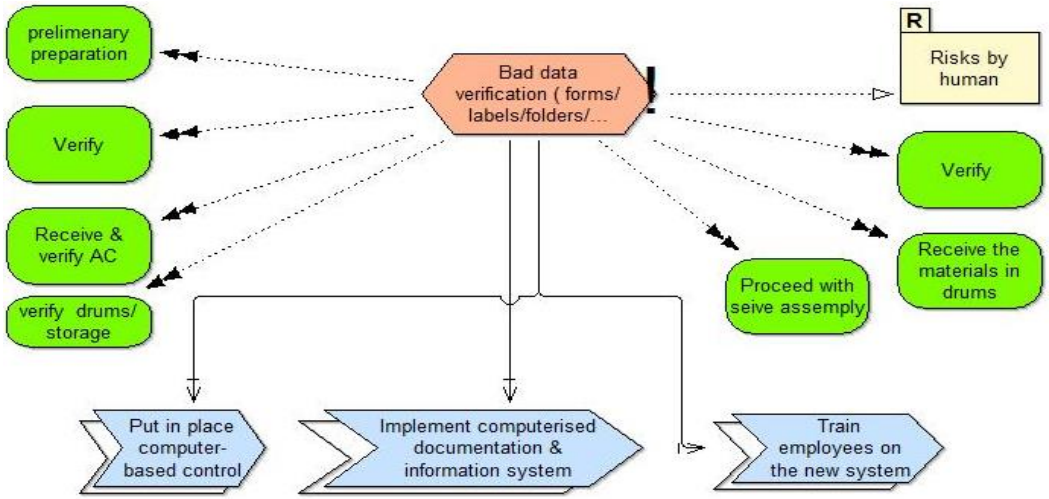
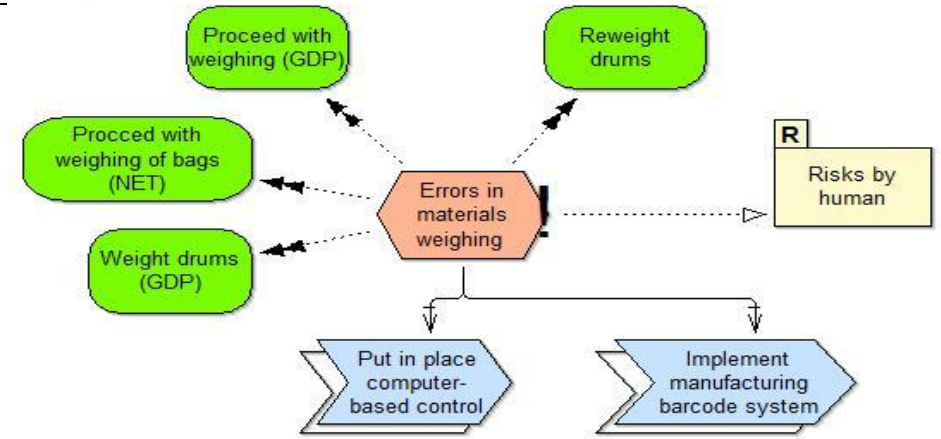


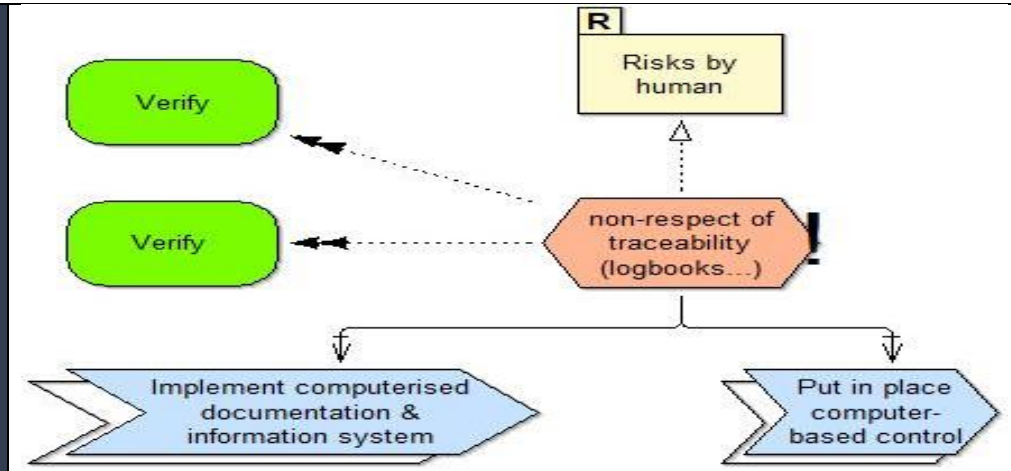
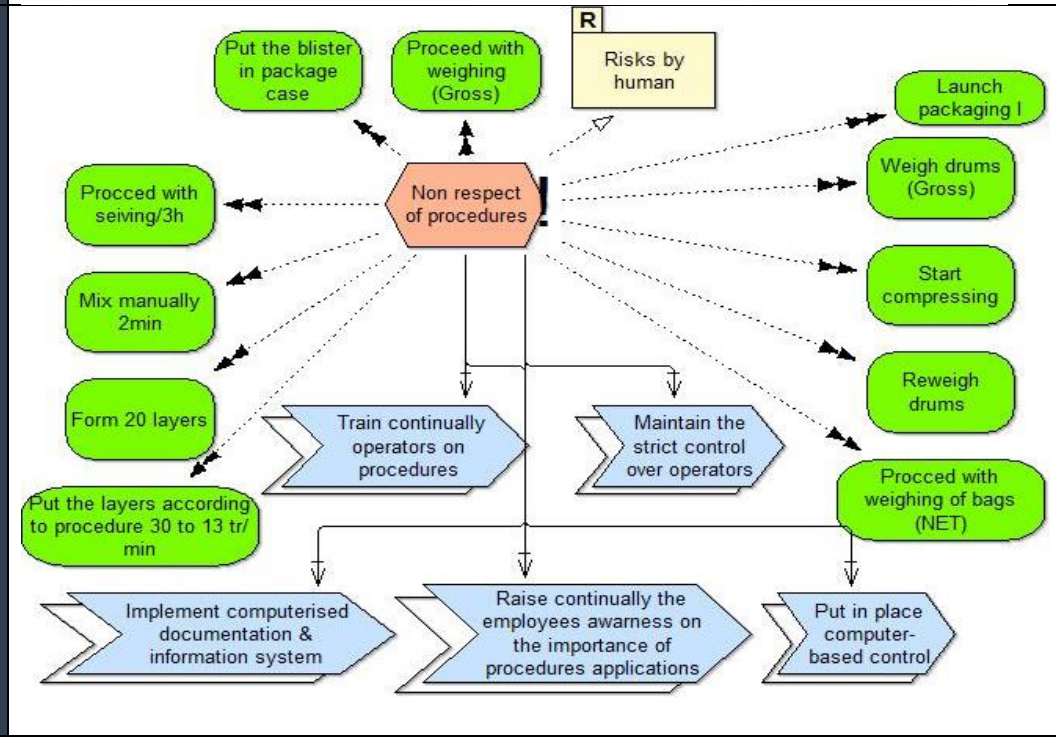
Source: outcome of AdoBPRIM

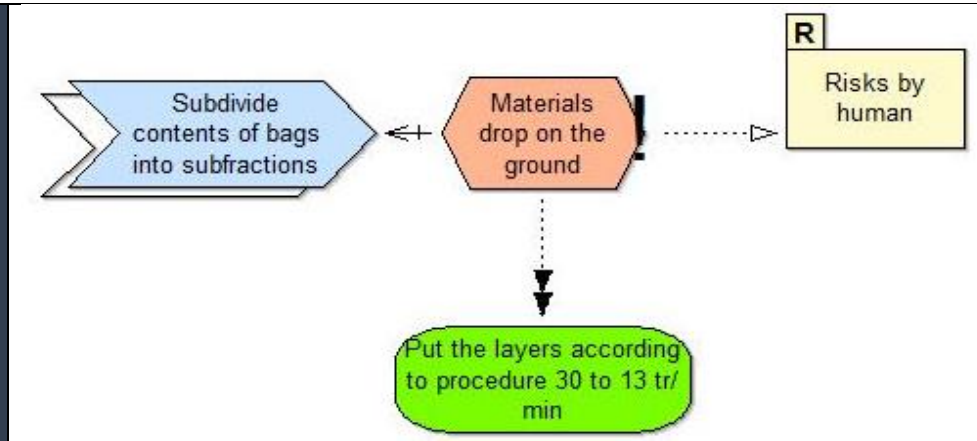
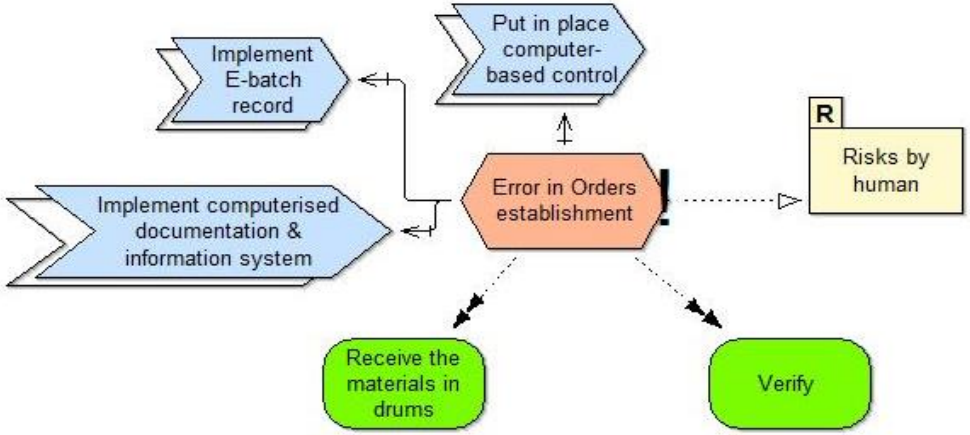
According to the risk matrix, Bad data verification, cross contamination, error in orders establishment, errors in materials weighing, materials drop on the ground, microbiological contamination, non-compliant materials with GMP, particulate contamination, physico-chemical contamination are acceptable risk because there is very little likelihood that these risks occur at Frater-Razes, particularly the contaminations. Non-respect of procedures, non-compliant of AC II with BAT and non-respect of traceability are acceptable under control while the delay in batch liberation, equipment failure, large quantity of wastes, packaging I defects, packaging II defects, and visual defects on pills are unacceptable risks, because they can possibly happen at Frater-Razes.

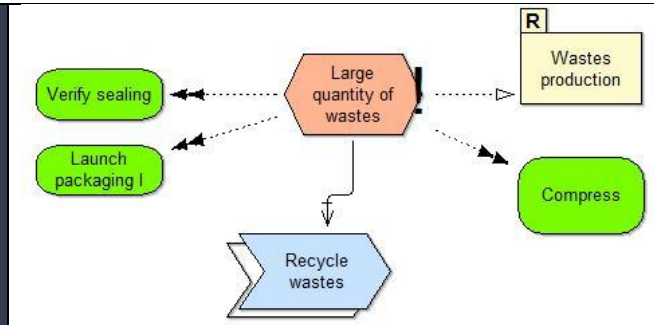
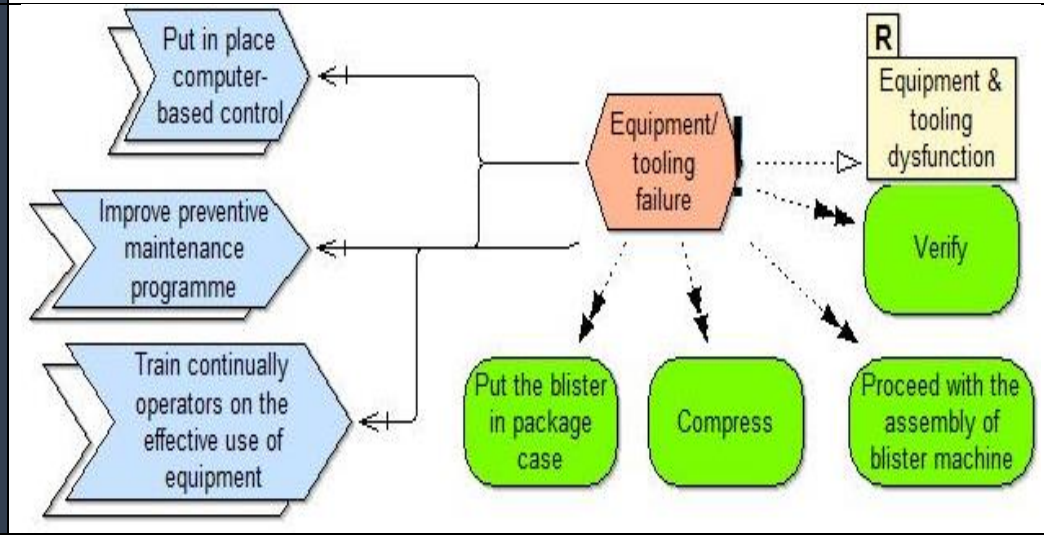
In the following subsection, we will display the scenarios to treat the risks.

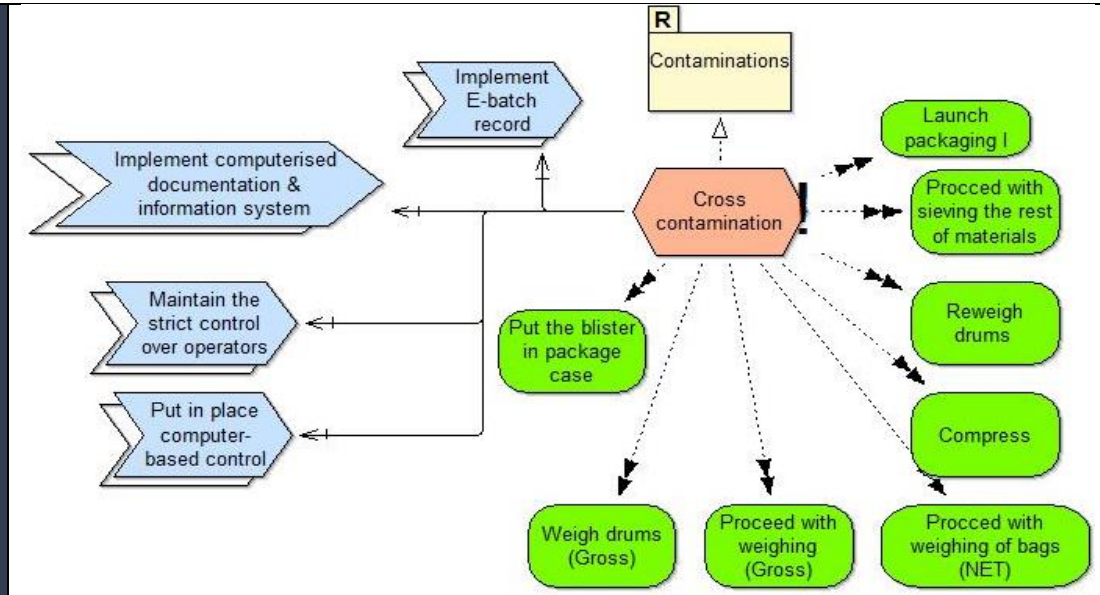
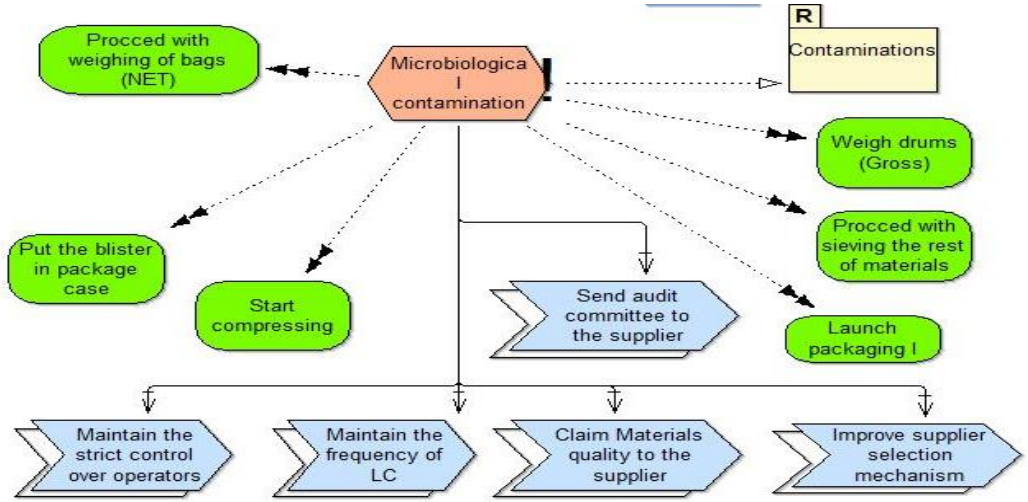
Table n°64: risk treatment diagrams

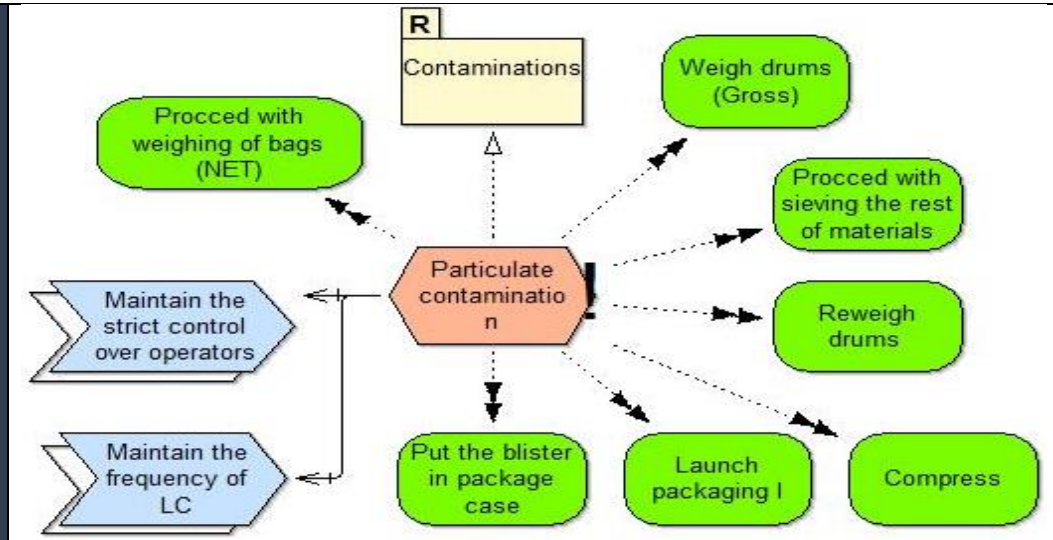
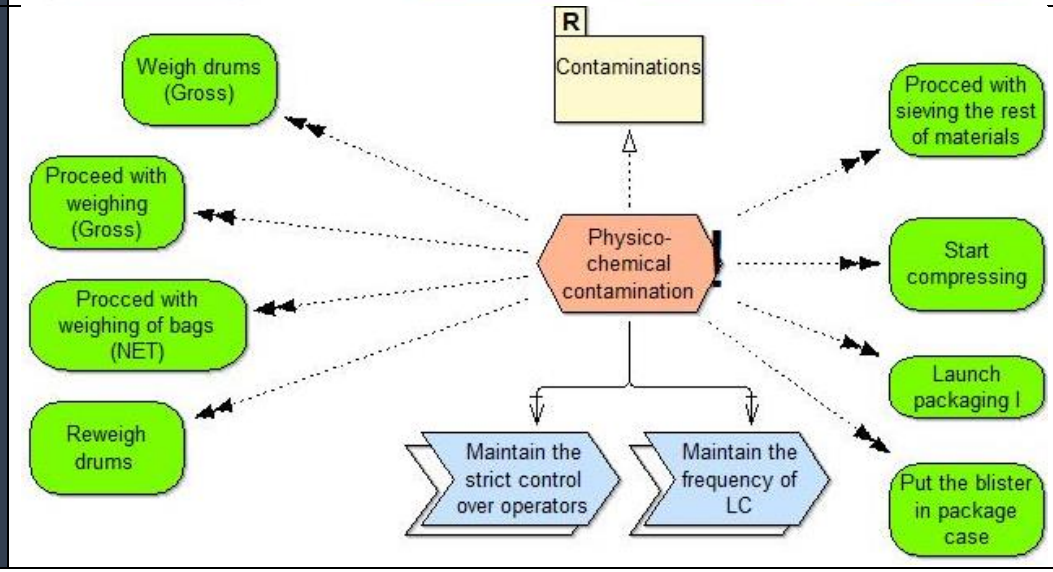
OR	Risk treatment diagrams	Comments
Bad data verification		To prevent from bad data verification, it is necessary to : ° Implement computerised documentation and information system in which the fodders and files are filled, which will minimise the errors since they will be detected automatically; ° Put in place computer-based control; ° Train employees on the new system
Errors in materials weighing		To prevent from errors in materials weighing it is necessary to use barcode system , to give an electronic identification to all the materials weighed and used in fabrication process to facilitate the track of the materials. It is important to Put in place computer-based control

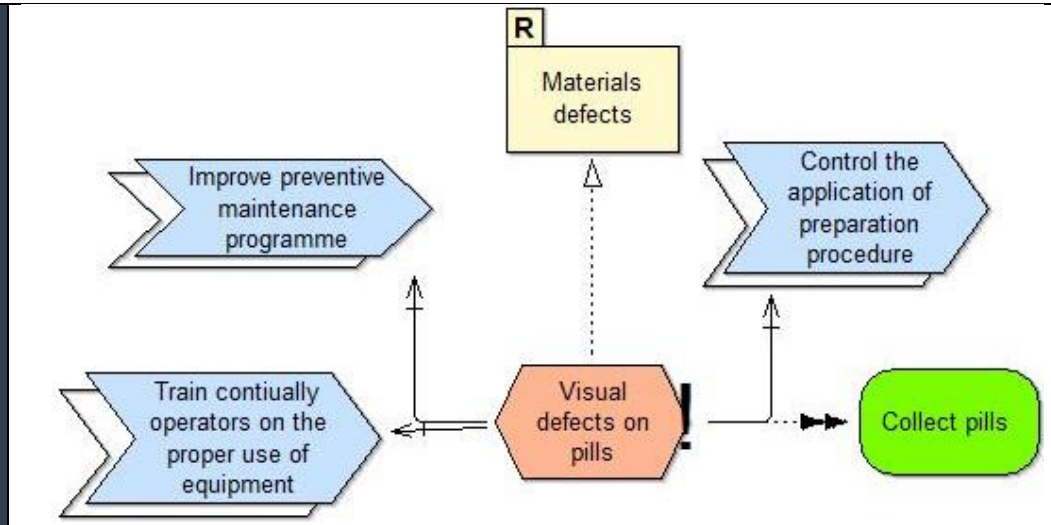
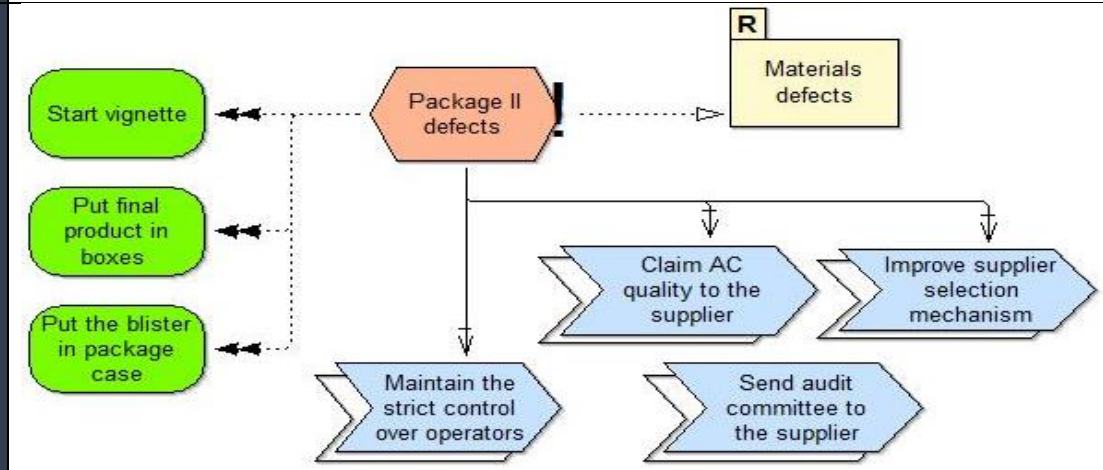
Non-respect of traceability		To prevent from non-respect of traceability, it is necessary to : ° Implement computerised documentation and information system in which the fodders and files are filled, which helps to track the product; ° Put in place computer-based control.
Non-respect of procedures		To prevent from non-respect of procedures, it is necessary to : ° Implement computerised documentation and information system in which the fodders and files are filled, which helps to track the product; ° Put in place computer-based control; ° Maintain strict control over operators; ° Train continually operators on procedures; ° Raise continually the employees awareness on the importance of procedures applications.

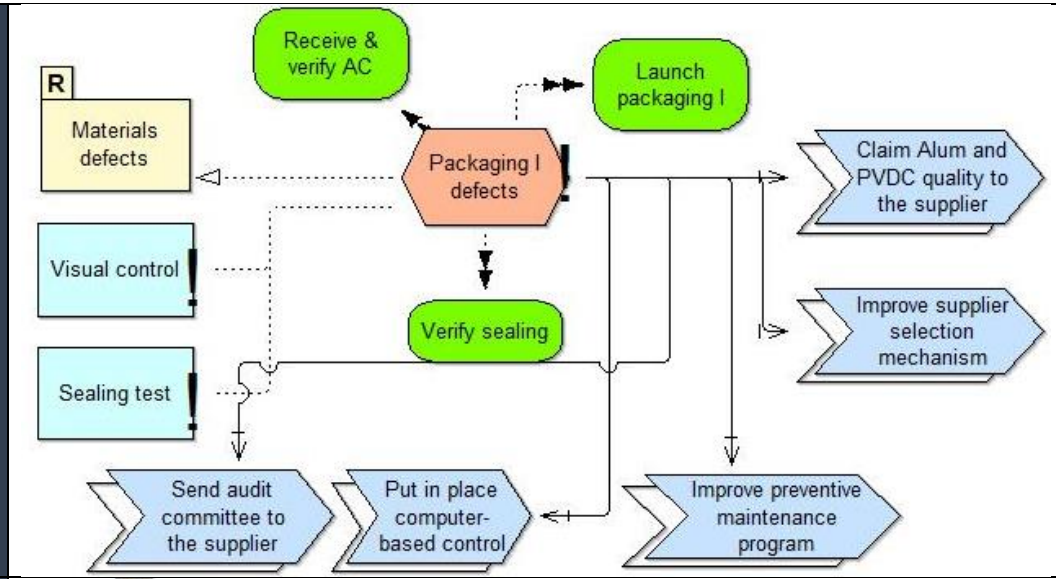
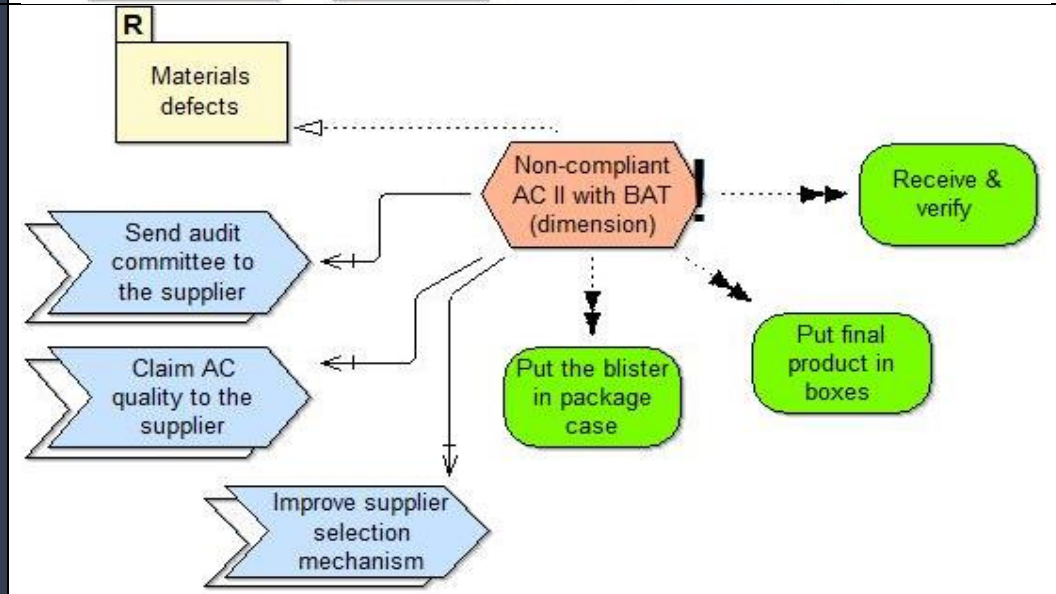
Materials drop on the ground		To prevent from materials dropping, it is necessary to subdivide the materials into small quantities and avoid to put all the materials in one bag
Errors in orders establishment		To prevent from the errors in order of fabrication or the order of packaging, it is necessary : ° To create electronic version of batch folder to detect in real time the errors ° To implement computerised documentation and information system in which the fodders and files are filled; ° To put in place computer-based control

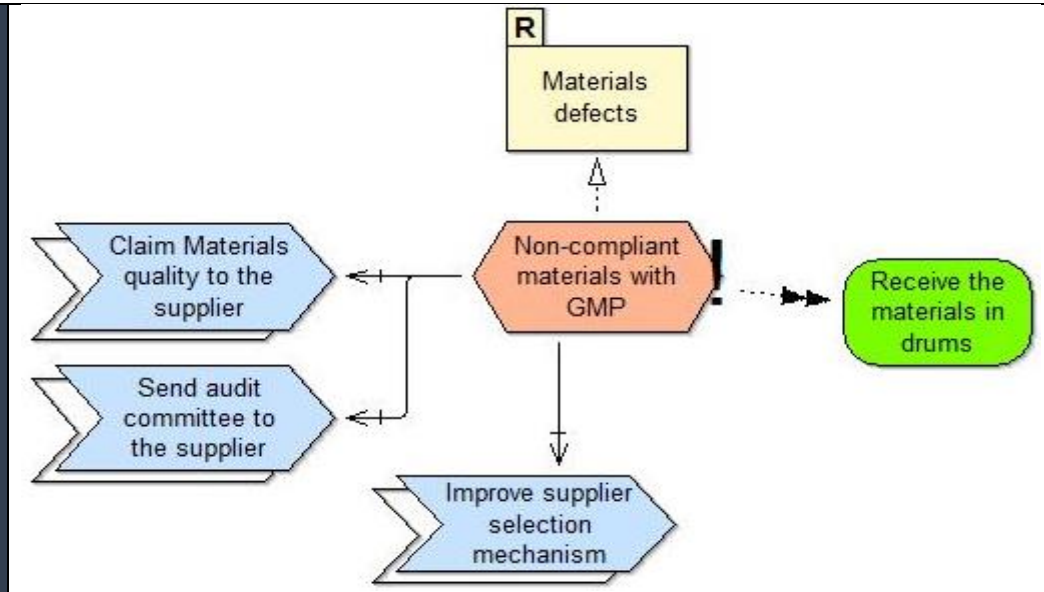
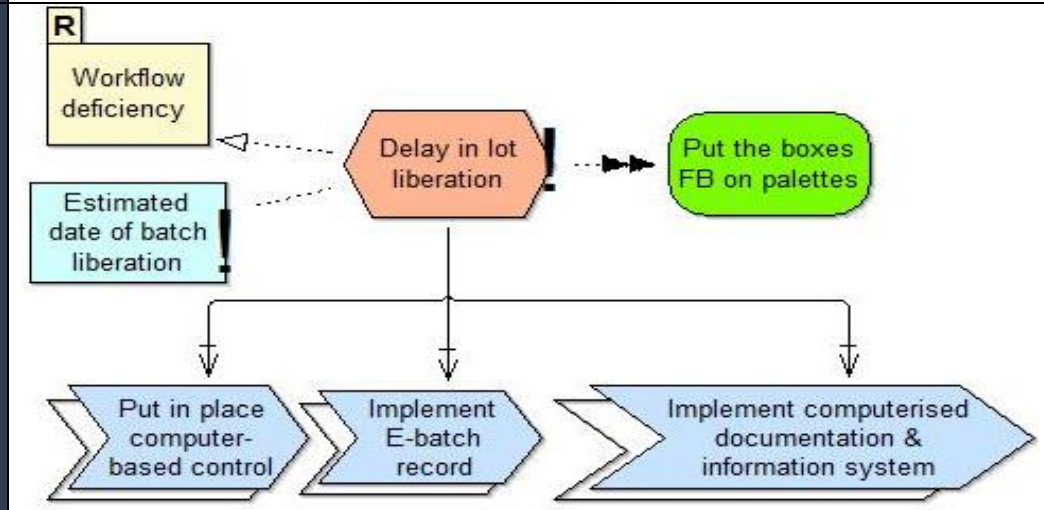
Large quantity of wastes		Frater-Razes should think of new ways to recycle the large quantity of wastes to offset the additional costs generated.
Equipment failure		To prevent from equipment failure, it essential to: Train continually the operators on the effective use of equipment Improve preventive maintenance programme Put in place computer-based control

Cross contamination		Cross contamination is acceptable risk at Frater-Razes, because they pay great attention to the prevention from this risk, hence it is necessary: ° to maintain the same level of control over operators and implement electronic batch folder; ° to implement computerised documentation and information system in which the fodders and files are filled; ° Put in place computer-based control to facilitate the detection of any errors in real time
Microbiological contamination		Microbiological contamination is acceptable risk at Frater-Razes, because they pay great attention to the prevention from this risk, hence it is necessary: ° To maintain the same level of control over operators; ° To maintain the same frequency of analysis by the laboratory ° Claim materials quality to the supplier; ° Improve suppliers selection mechanisms; ° Send audit committee to the supplier to examine the workplace quality of the supplier.

Particulate contamination		Particulate contamination is acceptable risk , at Frater-Razes, because they pay great attention to the prevention from this risk, hence it is necessary: ° To maintain the same level of control over operators; ° To maintain the same frequency of analysis by the laboratory
Physico-chemical contamination		Physico-chemical contamination is acceptable risk , at Frater-Razes, because they pay great attention to the prevention from this risk, hence it is necessary: ° To maintain the same level of control over operators; ° To maintain the same frequency of analysis by the laboratory

Visual defects on pills		To prevent from defects on pills, it is necessary to : ° Maintain the same level of control over operators; ° Train continually the operators on the effective use of equipment; ° Improve preventive maintenance programme.
Packaging II defects		To prevent from the items defects of the secondary packaging, it is necessary: ° To maintain the same level of control over operators; ° Claim materials quality to the supplier; ° Improve suppliers selection mechanisms; ° Send audit committee to the supplier to examine the workplace quality of the supplier.

Packaging I defects		To prevent from the items defects of the primary packaging, it is necessary: ° Put in place computer-based control ; ° Claim Aluminium and PVDC quality to the supplier; ° Improve suppliers selection mechanisms; ° Send audit committee to the supplier to examine the workplace quality of the supplier.
Non-compliant AC II with BAT		To prevent from the non-compliance of items of packaging with BAT, it is necessary to: ° Maintain the same level of control over operators; ° Claim materials quality to the supplier; ° Improve suppliers selection mechanisms; ° Send audit committee to the supplier to examine the workplace quality of the supplier.

Non-compliant materials with GMP		To prevent from the non-compliance of items of packaging with BAT, it is necessary to: ° To maintain the same level of control over operators; ° Claim materials quality to the supplier; ° Improve suppliers selection mechanisms ° Send audit committee to the supplier to examine the workplace quality of the supplier
Delay in batch liberation		To prevent from the delay of batch liberation, it is necessary : ° To create Electronic version of batch folder to detect in real time the errors ° To implement computerised documentation and information system in which the fodders and files are filled; ° To put in place computer-based control

Source : elaborated by the author

3. Share Knowledge

As we did in the case of Colaital , we shared the diagrams with the supervisors and we explained to them the contents of these diagrams and the objective of our study. In their turn, each supervisor shared the diagrams with his team and explained to them the contents of the diagrams.

As previously indicated, we were supposed to organise workshops to explain the contents of the diagrams with all the staff members working in the premises of the enterprise, but we were not allowed so we opted for an alternative that we explained previously.

4. Knowledge storage

The diagrams are stored in files in paper version. In the future, they can be stored in the data bases of the enterprise.

5. Knowledge application

As we indicated in the chapter three, we were supposed after sharing the diagrams with the workers, to return to the enterprise after a period and re-analyse the operational risks in the workplace to assess the effectiveness of the K-PIMRBP outcomes in preventing from these risks, but it was not possible. Therefore, we opted for an alternative, which is the elaboration of a questionnaire to assess whether the outcomes of K-PIMRBP contributed to train the workers on operational risk management ((1) contamination class (2) materials defects (3) Wastes production (4) equipment and tooling deficiency(5) workflow deficiency (6) risks caused by human.

Chapter IV : Results and discussion

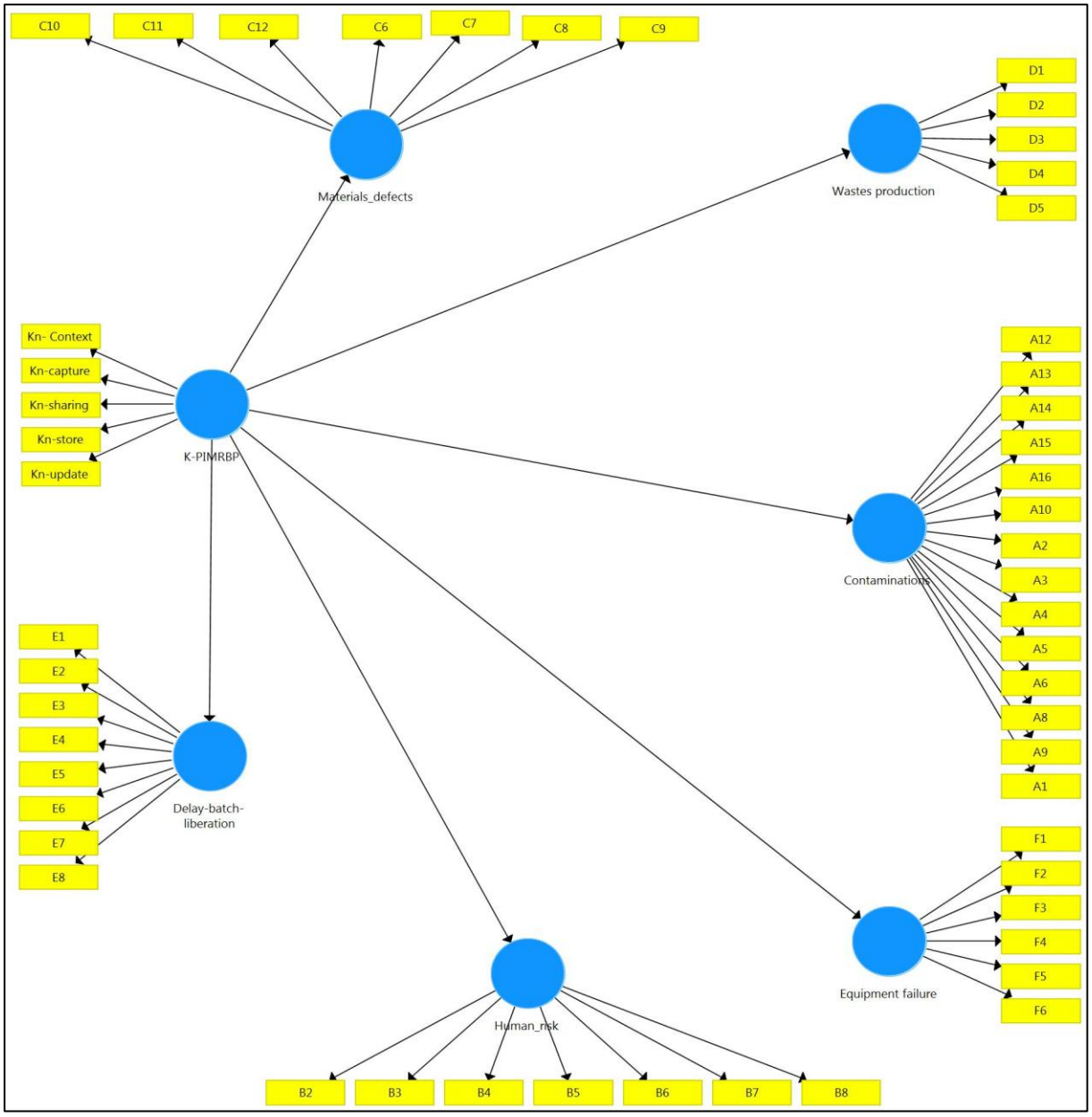
Phase III: Quantitative results

In the present sub-section we present the results of the quantitative study (see annexe C). The Validation of measurement model includes assessment of measurement model and assessment of structural model (Hair, Hult, Ringle, & Sarstedt, 2017, p. 130) .

1. Assessment of the measurement model

It is measured by convergent validity and discriminant validity (Hair, Hult, Ringle, & Sarstedt, 2017, p. 130)

Figure n° 61: Measurement model



Source: outcome of SmartPls3

Chapter IV : Results and discussion

1.1. **Convergent validity**

The convergent validity is measured by the outer loadings, which should be more than 0.7, or between 0.4 and 0.7 under the condition that the retention of the item increases the composite reliability CE or the average variance extracted AVE (Hair, Hult, Ringle, & Sarstedt, 2017, p. 137). We delated from the model the following items which did not meet the conditions mentioned before (A7,A17, B1,B9,B10, C1,C2,C3,C4,C5,C13,F7).

Table 65 shows convergent validity of the study.

Table n°65: convergent validity outcomes

	contaminations	**Delay-batch-liberation**	**Equipment failure**	**Human risk**	**K-PIMRBP**	**Materials defect**	**Wastes production**
A1	0.716						
A2	0.765						
A3	0.739						
A4	0.739						
A5	0.823						
A6	0.735						
A8	0.765						
A9	0.760						
A10	0.69						
A12	0.685						
A13	0.699						
A14	0.721						
A15	0.715						
A16	0.689						
B2				0.838			
B3				0.851			
B4				0.835			
B5				0.909			
B6				0.870			
B7				0.911			
B8				0.826			
C6						0.860	
C7						0.856	
C8						0.925	
C9						0.804	
C10						0.862	
C11						0.789	
C12						0.700	
D1							0.837
D2							0.766
D3							0.764

D4							0.881
D5							0.691
E1		0.821					
E2		0.756					
E3		0.792					
E4		0.740					
E5		0.729					
E6		0.812					
E7		0.712					
E8		0.708					
F1			0.835				
F2			0.801				
F3			0.728				
F4			0.709				
F5			0.703				
F6			0.693				
Kn-context				0.986			
Kn-capture				0.681			
Kn-sharing				0.934			
Kn-store				0.882			
Kn-update				0.974			

Source: outcomes of SmartPLS3

The table 66 shows that CR of the variables are higher than 0.7 as suggested by (Hair, Bill , Barry, & Rolph, 2006) , while the AVR of the variables are higher than 0.5 as suggested by (Fornell & Larcker, 1981).

Table n°66: CR and AVE values

	Composite Reliability	**Average Variance Extracted (AVE)**
Contaminations	0,942	0,536
Delay-batch-liberation	0,916	0,578
Equipment failure	0,883	0,558
Human_risk	0,954	0,746
K-PIMRBP	0,954	0,807
Materials_defects	0,939	0,690
Wastes production	0,892	0,625

Source: outcomes of SmartPLS3

1.2 Discriminant validity

The discriminant validity is acceptable when the square root of the AVEs in the diagonal of the matrix are higher than the non-diagnal elements of the matrix (Fornell & Larcker, 1981). The table 67 shows that the value of the elements in the diagonal are higher than the value of the elements in the non-diagonal, so the discriminant validity of the model is acceptable.

Table n°67: discriminant validity

	Contaminations	Delay-batch-liberation	Equipment	Human_ risk	K-PIMRBP	Materials_defects	Wastes production
Contaminations	0.732						
Delay-batch-liberation	0.387	0,760					
Equipment failure	0,369	0,826	0,747				
Human_risk	0,883	0,226	0,213	0,864			
K-PIMRBP	0,528	0,764	0,743	0,434	0,898		
Materials_defects	0,445	0,733	0,668	0,311	0,923	0,831	
Wastes production	0,390	0,765	0,697	0,354	0,778	0,653	0,791

Source: outcomes of SmartPLS3

2. Assessment of structural model

2.1 Path coefficient of the research Hypotheses

The table 68 shows that the hypotheses 1, 2, 3, 4, 5 and 6 are supported

Table n° 68: Path coefficient of the research Hypotheses

	Original Sample (O)	**Sample Mean (M)**	**Standard Deviation (STDEV)**	**T Statistics (|O/STDEV|)**	**P Values**	**OBS**
K-PIMRBP -> Human_ risk	0,434	0,440	0,097	4,473	**0,000**	**Supported**
K-PIMRBP -> contamination	0,528	0,543	0,073	7,283	**0,000**	**Supported**
K-PIMRBP -> equipment failure	0,743	0,745	0,082	9,045	**0,000**	**Supports**
K-PIMRBP -> Delay-batch-liberation	0,764	0,769	0,059	12,889	**0,000**	**Supports**
K-PIMRBP -> wastes production	0,778	0,779	0,062	12,501	**0,000**	**Supported**
K-PIMRBP -> Materials_defects	0,923	0,923	0,015	61,979	**0,000**	**Supported**

Source: outcomes of SmartPLS3

2.2 Coefficient of determinant R2 , effect size f^2 , predictive relevance of the model Q^2 , goodness of fit GOF

R^2 measures the predictive power of the model, which should be higher than 0.1 (Falk & Miller, 1992); The results below show that the values of all the models are higher than 0.1, which means that all the models are accepted.

Table n°69: Coefficient of determinant R2

	R^2
Contaminations	0.279
Delay-batch-liberation	0.583
Equipment failure	0.552
Human_risk	0.188
Materials defects	0.851
Wastes production	0.605

Source: outcomes of SmartPLS3

f^2 measures the effect size of the independent variables on the dependant variables (Hair, Hult, Ringle, & Sarstedt, 2017) **.** According to (Cohen J. , 1988) , $f^2 > 0.35$ (the effect size is large), $0.15 > f^2 > 0.35$ (the effect size is medium), $0.02 > f^2 > 0.15$ (the effect size is small). The results of the present study are shown in the following table .

Q^2 measures the predictive relevance of the model (Hair, Hult, Ringle, & Sarstedt, 2017) According to (Chin , 2010), Q^2 above 0 means that the model has a predictive relevance. The results of the study are shown in the following table

Table n°70: effect size f^2 and predictive relevance measurement Q^2

	f^2	**Q^2**
Contaminations	0.387	0.139
Delay-batch-liberation	1.399	0.317
Equipment failure	1.234	0.295
Human_risk	0.232	0.130
Materials defects	5.714	0.570
Wastes production	1.532	0.361

Source: outcomes of SmartPLS3

Goodness of fit of the model GOF

According to (Wetzels, Odekerken-schroder, & Van oppen, 2009) tolerance intervals are (less than 0.1 = no fit; 0.1-0.25= small fit, 0.25-0.36= medium fit, greater than 0.36= large).

$$\textbf{GOF} = \sqrt{(\overline{R^2} \times \overline{AvE^2}} \quad ; \quad \textbf{GOF = 0.36}$$

From the result of GOF we conclude that goodness of fit the model is medium.

Chapter IV : Results and discussion

In the first section, we presented the results of the application of K-PIMRBP to Frater-Razes, the study included three phases. In the first step we conducted interviews and analysed the qualitative findings from which we summarised the operational risks at Frater-Razes into six classes namely : 1) contamination class (2) materials defects (3) Wastes production (4) equipment and tooling deficiency(5) workflow deficiency (6) risks caused by human and we formulated the hypotheses of the study . In the second step, we applied the K-PIMRBP to Frater-Razes, and in the third step we presented the quantitative findings, indicated positive influence of the outcomes of this process on the prevention from the operational risks.

The results of the study are shown in the following table.

Table n°71 : The results of the study Frater-Razes

H1	H1: K-PIMRBP outcomes contribute to raise employees' awareness on contamination management	Supported
H2	H2: K-PIMRBP outcomes contribute to equipment failure to raise employees' awareness on human risk management	Supported
H3	H3: K-PIMRBP outcomes contribute to raise employees' awareness on material defects management	Supported
H4	H4: K-PIMRBP outcomes contribute to raise employees' awareness on waste management	Supported
H5	H5: K-PIMRBP outcomes contribute to raise employees' awareness on batch liberation management	Supported
H6	H6: K-PIMRBP outcomes contribute to raise employees' awareness on equipment failure management	Supported

Source: elaborated by the author

Discussion:

The aim of this study was the concretisation of the preventive management theory represented by the K-PIMRBP process, which was developed in an article published by MAAMIR & DERGHOUM in 2021, in different enterprises in the Algerian context.

We applied the present study to three production companies, to examine the ability of the process to prevent from the operational risks; this study was introduced in three stages. In the first stage, we conducted interviews with responsible persons in each enterprise, to reveal the operational risks specific to each enterprise and to understand from the interviewees how we can prevent from risks in each enterprise, which served the formulation of the hypotheses of the study. In the second phase, we generated the diagrams of the K-PIMRBP, which included the diagram that describes the context of the study, the business processes risks taxonomy, the risks-extended BP diagrams, the risk analysis diagrams and risk treatment diagrams, which constitute in the present study the knowledge captured during our presence in the enterprises. After that, we shared the diagrams with the workers, which were stored in paper version. In the third step, we elaborated questionnaires to assess the effectiveness of the K-PIMRBP to achieve the objectives of the study.

We distilled from the present study that the influence of the preventive management of risks outcomes depends on the degree of maturity of the enterprise in terms of quality management application.

The quality management is defined as :*«Quality management can include establishing quality policies and quality objectives, and processes to achieve these quality objectives through quality planning, quality assurance , quality control and quality improvement »* (ISO9000, Quality management system-Fundamentals and vocabulary, 2015)

From this definition, we can conclude that a good quality management involves the establishment of objectives, processes and policies and the achievement of these objectives through the planning, the assurance and monitoring of quality, and if these elements are absent, the quality management is considered poor. We used this definition to evaluate the degree of maturity of the enterprise studied in terms of quality management to show the contribution of K-PIMRBP in preventing from operational risks in each enterprise.

At COLAITAL, we did not find the business processes models, and the researcher who modelled all the diagrams shown in the previous chapter. Besides that, the findings of the study

showed that the assurance quality is neglected in this enterprise by the fact that there is no assurance quality structure responsible for the achievement of the quality objectives. We noticed also the widespread of causes of the microbiological and physico-chemical contaminations in the local environment, the equipment, the raw materials and the final product. Although the dairy production requires high-quality standards in the workplace, the findings of the study showed that these risks could possibly happen at Colaital, because of the lack of quality control over the employees. According to the interviewees, the main cause of the operational risks, particularly the contaminations and the poor quality management is the lack of training on risks, hence we studied the ability of K-PIMRBP to achieve this objectives. The hypotheses were supported, which indicated the effectiveness of the K-PIMRBP in training employees on risks in the workplace, which leads to prevent from them.

Sosémie is the second case studied, this enterprise also lacks of business processes models and assurance quality structure, the present study revealed the presence of the causes of the contaminations in workplace, which affects the quality of the product. The enterprise is also threatened by the risks of appearance defects, which influence the visual quality of the product.

The main cause of the poor quality in the workplace is the lack of training on risks , the employees ignore the importance of quality in preventing from risks, hence we examined the effectiveness of K-PIMRBP in training the employees by conducting a questionnaire with the employees, the results showed that hypotheses were supported.

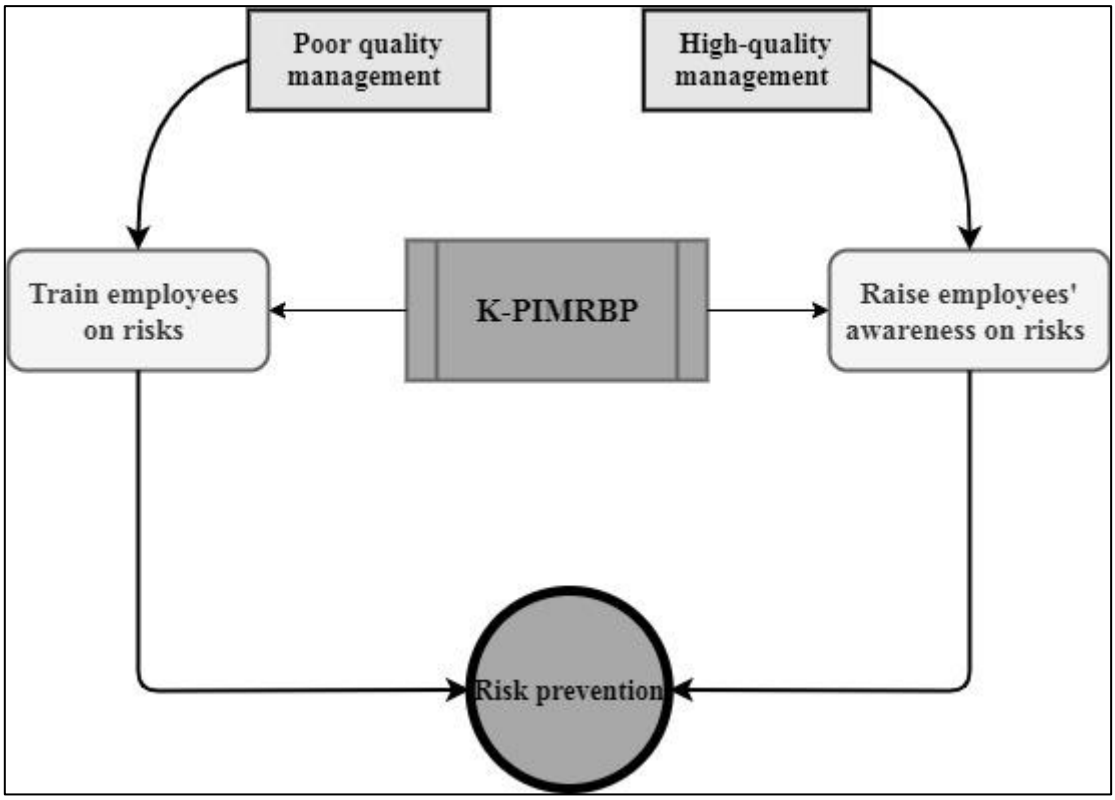
At Frater-Razes, which is a pharmaceutical enterprise, they pay great attention to quality in the workplace, cleaning and hygiene, which are ensured by assurance quality and production structures, the employees are very well trained because they receive training during the introductory period on quality management. In contrast to Agri-food industry (COLAITAL and Sosémie) where the quality management is poor, at Frater-Razes the quality management is good but there is still risks in the enterprise, the presence of these risks was justified by the need of raising employees' awareness. Hence, we examined the effectiveness of K-PIMRBP in training the employees by conducting a questionnaire with the employees, the results showed that the hypotheses were supported;

From this study we can distil that preventive management of risks depends on the degree of maturity of the enterprise in terms of quality management. In the enterprises where the quality management is poor, the K-PIMRBP, the process of preventive management of risks, serves to train employees on risks threatening the enterprise, which leads to prevent from operational

risks, since the employees who contribute directly or indirectly to fabrication of products and therefore cause the operational risks. While in High quality management enterprises like the case of pharmaceutical enterprises in which the employees, particularly the operators who execute the fabrication process are very well trained on quality and risks in the workplace, it is necessary to raise their awareness on the risks from time to time, for that the K-PIMRBP outcomes are useful.

The figure below summarises the two main contributions of the K-PIMRBP depending on the quality management degree.

Figure n°62: the two main contributions of the K-PIMRBP



Source: elaborated by the author

Conclusion of the chapter

The aim of this chapter was the presentation of the empirical findings of the study, which included three phases, namely , the first phase in which we presented the qualitative findings of the interviews conducted in three enterprise , including Colaital , Sosémie and Frater-Razes . That led to formulate the hypotheses of each study and the main conclusion that we could distil from this step was that the K-PIMRBP may contribute to prevent from operational risks, by training the employees on risks or raising the employees' awareness on risks, which depends on the degree of maturity of the enterprise in terms of quality management application. In the second phase, we applied the K-PIMRBP to the enterprises to generate the diagrams of risk management, which constituted the knowledge captured and then we shared them with the employees, which were then stored in paper versions. In the last phase, we tested the hypotheses formulated in the first phase, which were supported and that indicated the effectiveness of the K-PIMRBP in preventing from the operational risks.

General conclusion

Conclusion:

We aimed through the present study to concretise the preventive management of risks theory by applying the K-PIMRBP, which is the process that structured the theory to multiple case studies. In order to illustrate this process, which is still an abstract model and to identify its contributions in preventing from operational risks.

To achieve the objective of the study we applied the study to three production companies, where the operational risks have a significant impact on the product and the enterprise as a whole.

In order to conduct the present study we opted for pragmatism paradigm and we judged necessary to adopt mixed methods including, qualitative and quantitative methods.

The study included three phases, in the first one we conducted interviews with responsible persons in the enterprises to understand the context of the study, reveal the potential operational risks in each enterprise and identify the factor that may lead to risk prevention in order to formulate the hypotheses on how the K-PIMRBP may serve the risk prevention. In the second phase, we applied the preventive management of risks process to the enterprises and we generated the diagrams of risk management, which constituted the knowledge in the present study, which were shared with the employees and then stored in files. In the third phase we tested, the hypotheses through questionnaire distributed with the employees and the results of the quantitative findings revealed the effectiveness of the K-PIMRBP in preventing from risks.

The present study contributed in the field of preventive management of risks by:

- Clarifying the difference between risk prevention and preventive management of risks;
- Concretising the K-PIMRBP in real case studies, which helped to illustrate this abstract model ;
- Providing the researchers and practitioners in this field with a reference and guidance on how to apply the preventive management of risks to the enterprises ;
- Providing the researchers and practitioners in this field with practical implications which serve to understand this theory;
- Revealing the operational risks categories in each enterprise;
- Revealing the two main contributions of K-PIMRBP in risk prevention, which depend on the degree of the enterprise maturity in terms of quality management, where in high quality

management enterprises this process contributes in raising employees' awareness on risks, which leads to risk prevention. While in the case of poor quality management enterprises this process contributes in training employees on risks in order to prevent from them in the workplace.

Based on the findings of the study, it is recommended that:

- The three enterprises studied, integrate the K-PIMRBP outcomes in their operations;
- The enterprises studied, create new department for preventive management of risks, which ensures the application of the K-PIMRBP outcomes to the enterprises;
- The new department should be independent from the other departments and involves a multidisciplinary team and a responsible;
- The risk prevention team collaborate with all the employees who are working in the enterprise;
- The risk prevention team considers the practical implications of the present study as a guidance and a reference to prevent from risks.

As any study, the present study has limitations, which are as follows:

- As we discussed in the previous, we were not allowed to integrate the K-PIMRBP outcomes into the operations of the enterprise, hence we opted from an alternative which was the conduction of a survey to test the effectiveness of the process;
- **The restricted number of enterprises studied**: although the application of the model in three enterprises helped to answer the main research question, but we would get more relevant results if we applied it in more than three enterprises;
- **The limited number of sectors studied :** in the present study we tested the effectiveness of the K-PIMRBP in only two sectors, namely, the agri-food and pharmaceutical industries , hence but we would get more relevant results if we applied it in other sectors.

Finally, for the future researches we suggest:

- The integration of the K-PIMRBP outcomes into the operations of the enterprises, and re-conducted the same studies after a period in the same enterprises to assess the effectiveness of the process in preventing from the operational risks;
- The application of the process in different enterprises from different sectors

Bibliography

1. Abu-Shanab, E., Knight, M., & Haddad, M. (2014). Knowledge sharing practices and the learning organization: A study. *IUP Journal of Knowledge Management, 12*(2).
2. Ackoff, R. L. (1989). From data to wisdom. *16(1),* 3-9. Journal of applied systems analysis,.
3. Aldin, L., & De Cesare, S. (2009). A comparative analysis of business process modelling .
4. Alhawari, S., Karadsheh, L., Talet, A. N., & Mansour. (2012). Knowledge-based risk management framework for information technology project. *32(1),* 50-65. International Journal of Information Management.
5. Allameh, S. M., & Zare, S. M. (2011). Examining the impact of KM enablers on knowledge management processes. *3,* 1211-1223. Procedia computer science.
6. Aming'a, N. (2015). Knowledge capture and acquisition mechanisms at Kisii University. *Interdisciplinary Journal of Information, Knowledge, and Management, 10* (3), 105-116.
7. ANDREANI, J.-C., & CONCHON, F. (2015). METHODES D'ANALYSE ET D'INTERPRETATION DES ETUDES QUALITATIVES : ETAT DE L'ART EN MARKETING.
8. Appendices, V. (1998). Hazard analysis and critical control point principles and application guidelines. *Journal of Food Protection, 61*(9), 1246-1259.
9. Assegaff, S., & Hussin, A. R. (2012). Review of knowledge management systems as socio-technical system. arXiv preprint arXiv.
10. Assienin, K., & Ouattara. (2016). l'impact de la gestion des risques operationnels sur la performance des entreprises non financieres. *finance et finance internationale* .
11. AYYUB, B. (2003). Risk analysis in engineering and economics. Chapman and Hall/CRC.
12. Baldwin, R. M. (s.d.). Preventive/Corrective Actions (CAPA) Guidelines. Récupéré sur www.rmbimedical.com
13. BASEL. (2006). International Convergence of Capital Measurement and Capital Standards . Consulted : 17/02/2024, https://www.bis.org/publ/bcbs128.pdf
14. BERG, H.-P. (2010). Risk management: procedures, methods and experiences. Reliability: Theory & Applications. *17*(2), 79-95.
15. Bhatt, G. D. (2001). Knowledge management in organizations: examining the interaction between technologies , techniques , and people. *5(1),* 68-75. Journal of Knowledge Management.
16. Bolisani, E., & Bratianu, C. (2018). The elusive definition of knowledge. In Emergent knowledge strategies: Strategic thinking in knowledge management .
17. Brancati, D. (2018). *Social scientific research.* Sage.

18. Chaffey , D., & Wood, S. (2005). Business Information Management: Improving Performance Using Information Systems . FT Prentice Hall, Harlow.

19. Chau, T., Maurer, F., & Melnik, G. (2003). Knowledge sharing: Agile methods vs. tayloristic methods. In WET ICE 2003. Proceedings. Twelfth IEEE International Workshops on Enabling Technologies: Infrastructure for Collaborative Enterprises.

20. Chernobai, A. S., RACHEV, S. T., & FABOZZI, F. J. (2007). *Operational risk: a guide to Basel II capital requirements, models, and analysis.* John Wiley & Sons.

21. Chin , W. W. (2010). How to write up and report PLS analyses. Dans V. E. Vinzi, W. J. Chin , H. Henseler , & H. Wang , *Partial Least Squares: Concepts, Methods and applications* (pp. 90-655). New york: Springer.

22. Chiozza, M., & Ponzetti, C. (2009). FMEA: a model for reducing medical errors. *Clinica chimica acta,, 404*(1), 75-78.

23. Cobb, G. (1998). *Introduction to design and analysis of experiments.* New York: Springer.

24. Cohen, J. (1988). *Statistical power analysis for the behavioral sciences (2nd ed.).* Hillsdale.

25. Cohen, S., & Roussel, J. (2005). *Strategic supply chain management the five disciplines for top performance.* NEW York: McGraw-Hill.

26. Cope, E., Kuster, J., Etzweiler, D., Deleris, L., & Ray, B. (2010). Incorporating risk into business process models. *54(3)*. IBM Journal of Research and Development,.

27. COSO. (2004). Enterprise Risk Management - Integrated Framework. Committee of Sponsoring Organizations of the Treadway Commission.

28. Creswell, J. W., & Creswell, J. D. (2017). *Research design: Qualitative, quantitative, and mixed methods approaches.* Sage publications.

29. Creswell, J., & Poth, C. (2017). *Qualitative inquiry and research design: Choosing among five approaches.* Sage publications.

30. Crockford, G. N. (1982). The bibliography and history of risk management: Some preliminary observations. 169-179. Geneva Papers on Risk and Insurance.

31. Dickinson, G. (2001). Enterprise Risk Management: Its Origins and Conceptual foundation. The Geneva Papers on Risk and insurance, 26 No (3), 360_366.

32. Dalkir, k. (2005). Knowledge management in Theory and Practice. Burlington: Elsevier Butterworth-Heinemann.

33. De Long, D. W., & Fahey, L. (2000). 44. De Long, D. W., & Fahey, L. (2000). Diagnosing cultural barriers to knowledge management. *14(4)*, 113-127. Academy of Management Perspectives, 14(4), 113-127.

34. DIAS, A. (2017). A more effective audit after COSO ERM 2017 or after ISO 31000: 2009? *Revista Perspectiva Empresarial, 4*(2), 73-82.

35. Drennan, L. (2014). *Risk and crisis management in the public sector*. Routledge.

36. Dumas, M., La Rosa, M., Mendling, J., & Reijer. (2013). *Business process management.* Berlin: Springer-Verlag.

37. DURST, Susanne et FERENHOF, & Helio, A. (2016). Knowledge risk management in turbulent times.In : Competitive strategies for small and medium enterprises. 195-209. Springer, Cham.

38. Durst, S., Bruns, G., & Henschel, T. (2018). The management of knowledge risks: what do we really know?. In Global business expansion: Concepts, methodologies, tools, and applications. 258-269. IGI Global.

39. Durst, S., Zięba, M., & Helio, A. F. (2018). Knowledge risk management in organizations.

40. Emblemsvåg, J., & Kjølstad, L. (2006). Qualitative risk analysis: some problems and remedies. *Management Decision*.

41. EPSTEIN, A., & HARDING, G. (2020). Risk management chapter . In : Clinical Engineering Handbook. 335-348. Academic Press.

42. Falk, R., & Miller, N. (1992). *A primer for soft modeling.* University of Akron Press.

43. FDA. (2006). Guidance for industry: Quality systems approach to pharmaceutical cGMP regulations. Center for Biologics Evaluation and Research. US Department of Health and Human Services: Rockville, MD.

44. Fernandez, I. B., & Sabherwal, R. (2010). Knowledge management systems and processes. ME Sharpe, Inc.

45. Ferraris, A. (2019). The Risks Associated With Knowledge: Knowledge Risk Management (KRM). In Cross-Functional Knowledge Management. 130-140. Routledge.

46. Flick, U. (1992). Triangulation revisited: strategy of validation or alternative?. . *Journal for the theory of social behaviour.*

47. Fornell, C., & Larcker, D. (1981). Evaluating Structural Equation Models with unobservable variables and Measurement error. *Journal of Marketing Research, 18*, 39-50.

48. Ghiglione, J., Martin-Laurent, F., & Pesce, S. (2016). Microbial ecotoxicology: an emerging discipline facing contemporary environmental threats. *Environmental Science and Pollution Research, 23*(5), 3981-3983.

49. Goyder, J. (1985). Nonresponse effects on relationships between variables. *Public Opinion Quarterly*.

50. Hair , J. F., Risher, J. J., Sarstedt, M., & Ringle, C. M. (2019). When to use and how to report the results of PLS-SEM. *European Business review, 31*(1), 2-24.

51. Hair, J., Bill , B., Barry, B., & Rolph, A. (2006). *Multivariate Data Analysis.* Upper Saddle River: Pearson.

52. Hair, J., Hult, T., Ringle, C., & Sarstedt, M. (2017). *A Primer on Partial Least Squares Structural Equation Modeling (PLS-SEM).* SAGE Publications,Inc.

53. Haltiwanger, G., Landaeta, R., & Pinto, C. (2010). Understanding the relationship between Risk Management and Knowledge Management: a literature review and extension. *International Journal of Knowledge Management Studies, 4*(3), 281-300.

54. Hammer, M., & Champy, J. (1993). Reengineering the corporation. New York: HaperCollins.

55. Harmon, P. (2019). Business process change: a business process management guide for managers and process professionals. Morgan Kaufmann.

56. Hjørland, B., & Hartel, J. (2003). Afterword: Ontological, epistemological and sociological dimensions of domains. *30(3)*, 239-245. Knowledge Organization.

57. Ho, C., & Liao, C. (2011). The use of failure mode and effects analysis to construct an effective disposal and prevention mechanism for infectious hospital waste. *Waste management, 31*(12), 2631-2637.

58. Hopkin, P. (2018). Fundamentals of risk management: understanding, evaluating and implementing effective risk management. Kogan Page Publishers.

59. Houy, C., Fettke, P., & Loos, P. (2010). Empirical research in business process management–analysis of an emerging field of research. Business Process Management Journal.

60. Hudnurkar, & et al. (2017). Supply Chain Risk Classification Schemes: A Literature Review. *Operations and Supply Chain Management*, *10*(4).

61. Hulebak, K., & Schlosser, W. (2002). Hazard analysis and critical control point (HACCP) history and conceptual overview. *Risk analysis*, *22*(3), 547-552.

62. Hulebak, K., & Schlosser, W. (2002). Hazard analysis and critical control point (HACCP) history and conceptual overview. *Risk analysis*, *22*(3), 547-552.

63. Hunt, D. P. (2003). The concept of knowledge and how to measure it. *4 (1)*, 100-113. Journal of intellectual capital. Vol. 4 No. 1, pp. 100-113.

64. ISO31000. (2018). Risk management guidlines. Récupéré sur https://www.iso.org/obp/ui/#iso:std:iso:31000:en

65. ISO9000. (2015). Quality management system-Fundamentals and vocabulary.

66. ISO9000. (2015). Quality management systems-Fundamentals and vocabulary.

67. Israel, G. D. (1992). Determining sample size. Florida university.

68. Jafari, M., Rezaeenour, J., Mazdeh, M., & Hooshmandi, A. (2011). Development and evaluation of a knowledge risk management model for project-based organizations: A multi-stage study. *49(3)*, 309-329. Management Decision.

69. Jasimuddin, S. M. (2005). An integration of knowledge transfer and knowledge storage: an holistic approach. *18 (1)*, 37-49. Comput Sci Eng.

70. Jennex, M., & Olfman, L. (2003). Organizational Memory, Handbook on Knowledge Management.

71. Kaehler, B., & Grundei, J. (2019). *The Concept of Management: In Search of a New Definition. In HR Governance.* Springer, Cham.

72. Kamala, K., & Kumar, V. (2018). Food products and food contamination. . *In Microbial Contamination and Food Degradation* , 1-19.

73. Kavina, S., Charmy, K., Chirag, M., & Manan, S. (2019). Deviations handling and corrective actions and preventive actions: Case studies for parenteral dosage form. *Journal of Generic Medicines, 15*(4), 165-176.

74. King, W. R. (2011). Knowledge sharing. 914-923. In Encyclopedia of Knowledge Management, Second Edition. IGI Global.

75. Kivunja, C., & Kuyini, A. (2017). Understanding and applying research paradigms in educational contexts. *International Journal of higher education, 6*(5), 26-41.

76. kucza, T. (2001). Knowledge management process model. VTT Electronics, technical research center of Finland.

77. kucza, T. (2001). Knowledge management process model. VTT Electronics, technical research center of Finland.

78. Lackovic, I. D. (2017). *Enterprise risk management: A literature survey.*

79. Lamine, E, E., Thabet , R., Sienou, A., Bork, D., Fontanili, F., & Pingaud, H. (2020). BPRIM: An integrated framework for business process management and risk management. *Computer in Industry* , 1-17.

80. Liew, A. (2007). Understanding data, information, knowledge and their inter-relationships. *8(2),* 1-16. Journal of knowledge management practice, 8(2), 1-16.

81. Lincoln, Y., & Guba, E. (1985). *Naturalistic Inquiry. Thousand Oaks.* Sage.

82. Liu, F., Maitlis, S., Mills, A., Durepos, G., & Wiebe, E. (2010). *Encyclopedia of case study research.* Encycl Case Study Res.

83. Lusk, S., Paley, S., & Spanyi, A. (2005). The evolution of business process management as a professional discipline. (B. Trends, Éd.)

84. MAAMIR, S., & DERGHOUM, M. (2021). Toward preventive management of risks theory: foundation of process structuring the theory. *Management dynamics in the knowledge economy, 9*(2), 185-203.

85. Mackenzie, N., & Knipe, S. (2006). Research dilemmas: paradigms, methods and methodology. Issues In. *Educational Research, 16*, 1-15.

86. Madagh , M., & Chedri maamar, S. (2017). Les risques humains comme enjeux stratégique: Quelques éLéments de réflexion relatifs aux terrains des organisations et entreprises. *Recherches, 11*(2), 27-52.

87. Maier, R., & Hadrich, T. (2011). Knowledge management systems. In Encyclopedia of Knowledge Management, Second Edition. IGI Global.

88. Malik, S., Krishnaswamy, K., & Mustapha, A. (2021). Hazard Analysis and Risk-Based Preventive Controls (HARPC): Current Food Safety and Quality Standards for Complementary Foods. *Foods, 10*(9).

89. Massingham, P. (2010). Knowledge risk management: a framework. Journal of knowledge management.

90. Mazorodze, A., & Buckley, S. (2020). A review of knowledge transfer tools in knowledge-intensive organisations. *South African Journal of Information Management, 22*(1), 1-6.

91. McDermott , R. E., Mikulak , R., & Beauregard, M. (1996). *The basis of FMEA.* New York: Quality Resources.

92. Mellahi , K., & Harris, L. (2015). Response Rates in Business and Management Research: An Overview of Current Practice and Suggestions for Future Direction. British Journal of Management.

93. MERNA, T., & AL-THANI, F. (2005). *Corporate Risk Management: An Organisational Perspective.* John Wiley & Sons.

94. MOELLER, R. (2007). *enterprise risk management: understanding the new integrated ERM framework.* John Wiley & Sons.

95. Mortimore, S., & Wallace, C. (2013). *HACCP: A practical approach.* Springer Science & Business Media.

96. Neef, D. (2005). Managing corporate risk through better knowledge management. *The Learning Organization: An International Journal, 12*(2), 112-124.

97. Netjes, M., Reijers, H. A., & van der Aalst, W. (2006). Supporting the BPM life-cycle with FileNet. In Proceedings of the CAiSE . *6*, 497-508.

98. Nonaka , I., & Takeuchi, H. (1995). The knowledge-creating company: How Japanese companies create the dynamics of innovation . . New York: Oxford University Press.

99. Prusak, L. (2009). Knowledge in organisations. Routledge.

100. Rah, J., Manager, R., Yock, A., & Kim, G. (2016). A comparison of two prospective risk analysis methods: Traditional FMEA and a modified healthcare FMEA. *Medical physics*, 6347-6353.

101. Rangal, D., Oliveira , T., & Leite , A. (2014). Supply chain risk classification: discussion and proposal. doi: 10.1080/00207543.2014.910620

102. RaudeliÅ , J., & DavidaviÄ ienÄ, V. (2018). Knowledge management process model. *5(3)*, 542-554. Entrepreneurship and Sustainability.

103. Riege, A. (2003). Validity and reliability tests in case study research: a literature review with"hands-on" applications for each research phase",. Qualitative Market Research: An International Journal, 6 (2), 75 - 86.

104. Rodriguez, J. (2007). When Systems Fail, CAPA Validation Begins. *Journal of Validation Technology, 13*(3), 240 – 248.

105. Rosemann, M., & Zur Muehlen, M. (2005). Integrating risks in business process models. (pp. 1-10). Proceedings of the 16th Australian Conference on Information Systems(ACIS 2005).

106. Scipioni et al. (2002). Scipioni et al. FMEA methodology design, implementation and integration with HACCP system in a food company. *Food Control, 13*, 495–501.

107. Sienou, A. (2009). Proposition d'un cadre méthodologique pour filemanagement intégré des risques et des processus d'entreprise. Institut National Polytechnique de Toulouse, Toulouse.

108. Stenmark, D. (2001). The relationship between information and knowledge. *24*, 11-14. In Proceedings of IRIS.

109. Suriadi, S., Weib, B., Winkelmann, A., Ter Hofstede, & Adams, M. (2014). Current research in risk-aware business process management - overview , comparison and gap analysis. Communication of association for information.

110. Tashakkori, A., Teddlie, C., & Teddlie, C. (1998). Mixed methodology: Combining qualitative and quantitative approaches. *46*.

111. Tashi, T., Mbuya, V., & Gangadharappa, H. (2016). Corrective action and preventive actions and its importance in quality management system: A review. *International Journal of Pharmaceutical Quality Assurance, 7*(01), 1-6.

112. TIUSANEN, R. (2017). Qualitative risk analysis. Handbook of Safety Principles. 463-492.

113. TURNBULL, J., LEA, D., & PARKINSON, D. (2010). *Oxford advanced learner's dictionary.* International Student's Edition.

114. van der Aalst, W. M. (2004). Business process management: a personal view. Business Process Management Journal.

115. Van Roy, P. (2005, July). The impact of the 1988 Basel Accord on banks' capital ratios and credit risk-taking: an international study. . In EFMA 2004 Basel Meetings, Forthcoming. .

116. Wallace, C. A., Sperber, W. H., & Mortimore, S. (2018). *Food safety for the 21st century: Managing HACCP and food safety throughout the global supply chain.* John Wiley & Sons.

117. Wallace, C., Sperber, W., & Mortimore, S. (2018). *Food safety for the 21st century: Managing HACCP and food safety throughout the global supply chain.* John Wiley & Sons.

118. Wang, W., Liu, X., Qin , J., & Liu, S. (2019). An extended generalized TODIM for risk evaluation and prioritization of failure modes considering risk indicators interaction. *IISE Transactions*, *51*(11), 1236-1250.

119. Weske, M. (2019). *Business process modelling foundation. In Business Process Management.* Berlin, Heidelberg: Springer.

120. Wetzels, M., Odekerken-schroder, G., & Van oppen, C. (2009). Using PLS path modeling for assessing hierarchical construct models: guidlines and empirical illustration . MIS quarterly .

121. Yin, R. (2003). *Case study research: Design and methods.* sage.

122. Zieba, M., & Durst, S. (2018). Knowledge Risks in the Sharing Economy." In E.-M. Vatamanescuds.), Knowledge Management in the Sharing Economy. Cross-Sectoral Insights into the Future of Competitive Advantage. 253-270. Springer, Champ.

123. Zur Muehlen, M., & Ho, D. (2005). Risk management in the BPM lifecycle. *International Conference on Business Process Management. 454-466.* Spring,Berlin.

Appendices

Annexe A

Questionnaire

N° du questionnaire

Bonjour Madame, Mademoiselle, Monsieur, je m'appelle «Safa MAAMIR », je prépare une thèse de Doctorat en sciences de gestion. Dans ce cadre, je réalise une étude sur les risques.

Je vous serai très reconnaissante de me consacrer quelques minutes et répondre à mes questions. Bien entendu, nous vous garantissons l'anonymat le plus absolu quant à vos réponses.

Merci

اهلا سيدتي، انستي، سيدي. ادعى صفاء معامير، احضر أطروحة دكتوراه في علوم التسيير. في هذا الإطار انا بصدد اعداد دراسة حول المخاطر التشغيلية.

سأكون جد ممتنة إذا خصصتم بعض الدقائق من وقتكم للإجابة على هذه الأسئلة. من المؤكد اننا تضمن لكم بذلك السرية التامة في التعامل مع اجوبتكم.

شكرا

Caractéristiques personnelles الخصائص الشخصية

Q1. Genre الجنس

Femme انثى	
Homme ذكر	

Q2. Niveau d'instruction مستوى التعليمي

Non scolarisé لم التحق بالمدرسة	
Niveau primaire مستوى ابتدائي	
Niveau moyen مستوى اكمالي	
Niveau secondaire مستوى ثانوي	
Niveau supérieur مستوى جامعي	

Q3. L'ancienneté dans l'entreprise سنوات الخبرة داخل المؤسسة

Moins d'un an اقل من سنة	
1 à 3 ans سنة	
4 à 6 ans سنة	
7 à 9 ans سنة	
Plus 9 ans اكثر من تسعة سنوات	

Q4. A quelle direction appartenez-vous ? الى أي إدارة تنمي

Direction contrôle de la qualité إدارة مراقبة الجودة	
Direction de la production (D. Technique) إدارة الإنتاج	
Direction de la maintenance (D. Technique) إدارة الصيانة	
Autres. merci de préciser اخر	

Q5. Votre statut dans l'entreprise ما هو مركزك في المؤسسة

Directeur مدير	
Cadre اطار	
Ingénieur مهندس	
Technicien تقني	
Chef d'atelier رئيس ورشة عمل	
Autres	

	Contaminations microbiologiques					
Code		Trés d'accord	Accord	Indifferent	Pas d'accord	Pas du tout d'accord
A1	Il est nécessaire de mettre en place un plan pour lutter contre les nuisibles dans les ateliers de production من المهم وضع خطة لمكافحة الحشرات والحيوانات داخل ورشات الإنتاج					
A2	Il est nécessaire d'éliminer l'eau stagnée dans les surfaces des ateliers de production من المهم التخلص من المياه الراكدة من على ارضية ورشات الانتاج					
A3	Il est nécessaire de réparer ou acquérir un nouveau système de ventilation et de nouveaux appareils de mesure de température et de pression من المهم اصلاح او اقتناء نظام تهوية جديد واجهزة لقياس درجة الحرارة والضغط					
A4	Il est nécessaire d'assurer le renouvellement d'air dans les ateliers de production à l'aide d'un système de ventilation من المهم ضمان تجديد الهواء داخل ورشات الانتاج بواسطة نظام تهوية					
A5	La température et la pression de l'eau doivent être appropriées à la production laitière يجب ان تكون درجة الحرارة وضغط الماء ملائمين لإنتاج الحليب					
A6	Les travailleurs et les visiteurs doivent porter des tenues appropriées dans les ateliers de production يجب على العمال والزوار ارتداء البسة ملائمة داخل ورشات الانتاج					
A7	Les travailleurs et les visiteurs doivent porter des couvre-chaussures dans les ateliers de production يجب على العمال والزوار ارتداء اغطية احذية داخل ورشات الانتاج					
A8	Il est nécessaire d'utiliser l'eau du processus dans la production du LPC من المهم استعمال الماء المعالج في انتاج الحليب المبستر					
A9	Il est nécessaire de suspendre le personnel malade jusqu'à guérison من المهم توقيف العامل المريض عن العمل حتى يشفى					
A10	Il faut respecter les doses des produits de nettoyage et désinfection من المهم احترام قياس المواد المعالجة والتطهير					

A11	Il est nécessaire de faire le contrôle microbiologique de l'emballage dans le laboratoire de l'entreprise et former les laborantins à cette technique من المهم عمل تحليل الميكروبيولوجي للأغلفة داخل مخبر المؤسسة وتكوين المخبريين في ذلك					

	La Baisse de la production					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
B1	Il est nécessaire d'augmenter la capacité de la station de traitement des eaux من المهم رفع طاقة محطة معالجة المياه					
B2	Il est nécessaire d'acquérir et d'utiliser des équipements qui fonctionnent de manière optimale (mixeur, homogénéisateur, station de traitement des eaux…etc.) من المهم اقتناء واستعمال معدات تعمل على النحو الامثل					
B3	Il est nécessaire d'acquérir des équipements de haute technologie et qui fonctionnent de manière automatique من المهم اقتناء معدات ذات تكنولوجيا عالية وتعمل بشكل أتوماتيكي					
B4	Il est nécessaire de retirer les équipements obsolètes et inefficaces من المهم التخلص من المعدات العتيقة والغير فعالة					
B5	Il est nécessaire de ne pas surutiliser les équipements de production من المهم عدم الافراط في استعمال معدات الانتاج					
B6	Il est nécessaire de recruter des personnes qualifiées من المهم تشغيل عمال ذوي كفاءة					
B7	Il est nécessaire de former le personnel à l'utilisation du matériel et des équipements من المهم تكوين العمال حول استعمال الاجهزة والمعدات					
B8	Il est nécessaire d'assurer l'entretien du matériel et des équipements من المهم ضمان صيانة الاجهزة والمعدات					

	Les coûts supplémentaires					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
C1	Il est nécessaire d'utiliser l'eau de forage au lieu de l'eau de ville pour minimiser les coûts من المهم استعمال مياه البئر عوض مياه المدينة لتقليل التكاليف					

C2	Le dosage et le pesage manuels des produits de désinfection peuvent engendrer des pertes financières المعايرة والقياس اليدوي لمواد التنظيف والتطهير يمكن ان يخلف خسائر مادية					
C3	Il est nécessaire d'avoir un système CIP automatique من المهم استعمال نظام تنظيف CIP أتوماتيكي					
C4	Il est nécessaire d'utiliser un CIP automatique pour limiter le gaspillage des produits de désinfection من المهم استعمال نظام تنظيف أتوماتيكي للحد من الهدر في استعمال مواد التنظيف					
C5	Il est nécessaire de mettre en place un détecteur de niveau de liquide dans les tanks de recombinaison pour éviter de produire un lait concentré من المهم وضع كاشف مستوى السوائل داخل خزانات إعادة التركيب من اجل تفادي انتاج حليب مركز					

	Contaminations Physico-chimiques					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
D1	Il est nécessaire d'utiliser l'eau traité dans la production du LPC من المهم استعمال الماء المعالج في انتاج الحليب المبستر					
D2	Il est nécessaire de faire un nettoyage en profondeur de la bâche à eau من المهم تنظيف خزان الماء تنظيفا عميقا					
D3	Il est nécessaire d'éliminer l'eau stockée dans les tanks et la bâche à eau pour une durée longue من المهم التخلص من المياه المخزنة في الخزانات لمدة طويلة					
D4	Il est nécessaire de ne pas porter des bijoux où apporter des objets dans les ateliers de production من المهم عدم لبس المجوهرات او حمل اشياء داخل ورشات الانتاج					
D5	Il est nécessaire d'abandonner les toits en zinc dans les ateliers de la production du lait من المهم التخلص من أسقف الزنك داخل ورشات الانتاج					
D6	Il est nécessaire de faire le contrôle physico-chimique des doses des produits de nettoyage et désinfection dans toutes les étapes de la production du LPC (recombinaison, pasteurisation et conditionnement) من المهم عمل تحليل فيزيائي-كيميائي لمقاييس مواد التنظيف والتطهير في جميع مراحل انتاج الحليب المبستر					

	Etablissement du contexte					
		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
E1	J'ai une vision d'extérieure, globale et claire du processus de production du LPC لدي رؤية خارجية، شاملة وواضحة عن عملية انتاج الحليب المبستر					
E2	J'ai une vision claire des ateliers du processus de production du LPC لدي رؤية واضحة عن ورشات انتاج الحليب المبستر					
E3	J'ai une vision claire des activités de chaque atelier du processus de production du LPC لدي رؤية واضحة عن عمل كل ورشة من ورشات انتاج الحليب المبستر					
E4	Je vois clairement le rôle de chaque atelier dans le processus de production du LPC ارى بوضوح دور كل ورشة من ورشات انتاج الحليب المبستر					
E5	Je vois clairement les acteurs du processus de production du LPC et les parties prenantes de l'entreprise ارى بوضوح الاطراف الفاعلة في عملية انتاج الحليب المبستر واصحاب المصلحة في المؤسسة					
E6	J'ai une vision claire des objectifs et des valeurs attendues par l'entreprise, les structures et le consommateur لدي رؤية واضحة عن الاهداف والقيم المنتظرة للمؤسسة، هياكلها والمستهلك					
E7	Les diagrammes du processus de production du LPC me permettent de détecter les différents risques opérationnels potentiels dans les ateliers de production تسمح مخططات عملية انتاج الحليب المبستر باكتشاف المخاطر التشغيلية المحتملة داخل ورشات انتاج الحليب المبستر					
E8	Les diagrammes du processus de production du LPC me permettent d'identifier le personnel qui peut identifier, évaluer et proposer des scenarios de traitement de ces risques مخططات عملية انتاج الحليب المبستر تسمح بتحديد الموظف الذي يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					

	La collecte de la connaissance					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
F1	Le personnel expérimenté peut identifier, évaluer et proposer des scenarios de traitement de ces risques الموظف ذو الخبرة يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					
F2	Il est nécessaire de bénéficier de l'expérience du personnel qui peut identifier, évaluer et proposer des scenarios de traitement de ces risques من المهم الاستفادة من خبرة الموظف ذو الخبرة يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					
F3	J'ai une idée claire sur les différents risques opérationnels potentiels dans le processus de production لدي فكرة واضحة عن المخاطر التشغيلية المحتملة في عملية انتاج الحليب المبستر					
F4	J'ai une idée claire sur le positionnement exacte des risques opérationnels dans les ateliers de production لدي فكرة واضحة عن موقع المخاطر التشغيلية في ورشات الإنتاج					
F5	J'ai une idée claire sur les causes de ces risques لدي فكرة واضحة عن اسباب هذه المخاطر					
F6	J'ai une idée claire sur la fréquence d'occurrence (la probabilité d'occurrence) de ces risques لدي فكرة واضحة عن عدد مرات حدوث واحتمال حدوث هذه المخاطر					
F7	J'ai une idée claire sur la gravité de ces risques لدي فكرة واضحة عن مدى خطورة هذه المخاطر					
F8	J'ai une idée claire sur les conséquences de ces risques sur les objectifs de l'entreprise, de ces structures et du consommateur لدي فكرة واضحة عن آثر هذه المخاطر على اهداف المؤسسة، هياكلها والمستهلك					

	Le partage des connaissances					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
G1	Le partage des diagrammes de l'entreprise et des ateliers de production avec tous les membres du personnel est très important مشاركة مخططات المؤسسة وورشات الانتاج مع كل الموظفين مهم جدا					
G2	Le partage des diagrammes d'évaluation des risques avec tous les membres du personnel est très important مشاركة مخططات تقييم المخاطر مع كل الموظفين مهم جدا					
G3	Le partage des diagrammes de traitement des risques avec tous les membres du personnel est très important مشاركة مخططات معالجة المخاطر مع كل الموظفين مهم جدا					
G4	Il est nécessaire de partager avec tous les membres du personnel mes connaissances des risques potentiels dans le processus de production du LPC من المهم مشاركة كل الموظفين معرفتي المتعلقة بالمخاطر المحتملة في عملية انتاج الحليب المبستر					
G5	Il est nécessaire d'inciter les membres du personnel de partager la connaissance des risques développés avec le reste du personnel من المهم حث الموظفين على مشاركة المعرفة الخاصة بالمخاطر مع باقي الموظفين					
G6	Il est nécessaire d'organiser des réunions ou des rencontres, pour partager les connaissances avec tous les membres du personnel من المهم تنظيم اجتماعات ولقاءات من اجل مشاركة المعارف المتعلقة بالمخاطر مع باقي الموظفين					
G7	Il est nécessaire de créer un intranet dédié au partage des connaissances des risques من المهم انشاء شبكة داخلية مخصصة لمشاركة المعرفة الخاصة بالمخاطر					

	Stocker la connaissance					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
H1	Il est nécessaire de créer une base de données numérique dans l'entreprise contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم انشاء قاعدة بيانات داخل المؤسسة تحتوي مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					

H2	Il est nécessaire de donner l'accès à cette base de données à tous les membres du personnel من المهم السماح لكل الموظفين بالولوج لقاعدة البيانات					
H3	Il est nécessaire d'inciter tous les membres du personnel d'accéder à cette base de données من المهم حث جميع الموظفين على الولوج لقاعدة البيانات					
H4	Il est nécessaire d'archiver les documents contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques sur des supports papier من المهم الاحتفاظ بملفات ورقية تتضمن مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					

	Actualisation des données					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
I1	Il est nécessaire d'actualiser régulièrement la base de données numérique des diagrammes relatifs aux risques من المهم تحديث بانتظام قاعدة البيانات الرقمية للمخططات المتعلقة بالمخاطر					
I2	Il est nécessaire de réviser régulièrement les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم مراجعة بانتظام مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
I3	Il est nécessaire d'actualiser régulièrement les supports papier contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم تحديث بانتظام الملفات الورقية التي تتضمن مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
I4	Il est nécessaire d'informer tous les membres du personnel de l'actualisation des diagrammes de l'entreprise, des diagrammes des ateliers de production, et des diagrammes de l'analyse et de traitement des risques من المهم اعلام كل الموظفين بأي تحديث لمخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					

Annexe B

Questionnaire

N° du questionnaire

Bonjour Madame, Mademoiselle, Monsieur, je m'appelle «Safa MAAMIR », je prépare une thèse de Doctorat en sciences de gestion. Dans ce cadre, je réalise une étude sur les risques.

Je vous serai très reconnaissante de me consacrer quelques minutes et répondre à mes questions. Bien entendu, nous vous garantissons l'anonymat le plus absolu quant à vos réponses.

Merci

اهلا سيدتي، انستي، سيدي. ادعى صفاء معامير، احضر أطروحة دكتوراه في علوم التسيير. في هذا الإطار انا بصدد اعداد دراسة حول المخاطر التشغيلية.

سأكون جد ممتنة إذا خصصتم بعض الدقائق من وقتكم للإجابة على هذه الأسئلة. من المؤكد اننا تضمن لكم بذلك السرية التامة في التعامل مع اجوبتكم.

شكرا

Caractéristiques personnelles الخصائص الشخصية

Q1. Genre الجنس

Femme انثى	
Homme ذكر	

Q2. Niveau d'instruction مستوى التعليمي

Non scolarisé لم التحق بالمدرسة	
Niveau primaire مستوى ابتدائي	
Niveau moyen مستوى اكمالي	
Niveau secondaire مستوى ثانوي	
Niveau supérieur مستوى جامعي	

Q3. L'ancienneté dans l'entreprise سنوات الخبرة داخل المؤسسة

Moins d'un an اقل من سنة	
1 à 3 ans سنة	
4 à 6 ans سنة	
7 à 9 ans سنة	
Plus 9 ans اكثر من تسعة سنوات	

Q4. Votre statut dans l'entreprise ما هو مركزك في المؤسسة

	Contaminations					
Code		Trés d'accord موافق جدا	Accord موافق	Indifferent محايد	Pas d'accord غير موافق	Pas du tout d'accord غير موافق تماما
A1	Il est nécessaire d'acquérir le matériel nécessaire (ventilateurs, résistance) pour la prévention contre les contaminations microbiologiques dues aux chocs thermiques من المهم اقتناء المعدات الأساسية (مروحة، المقاومة) من اجل الاحتياط من التلوث الميكروبيولوجي بسبب الصدمات الحرارية					
A2	Il faut éviter que le circuit propre de la production des pâtes et couscous ne croise avec le circuit des déchets من المهم ان المسار النظيف للإنتاج للعجائن والكسكسي لا يلتقي مع مسار النفايات					
A3	Il est nécessaire de renforcer le contrôle visuel du produit fini et éliminer tous les objets et les résidus des équipements et du packaging من المهم تقوية المراقبة البصرية للمنتجات النهائية والتخلص من الاغراض ومخلفات الآلات والتغليف					
A4	Il est nécessaire de mettre en place un plan contre les pigeons et les nuisibles من المهم وضع مخطط لمكافحة الحمام الحشرات الضارة					
A5	Il est nécessaire de faire le contrôle physico-chimique des doses des produits de nettoyage et désinfection من المهم عمل تحليل فيزيائي-كيميائي لمقاييس مواد التنظيف والتطهير في جميع مراحل انتاج					
A6	Les travailleurs et les visiteurs doivent porter des tenues appropriées dans les ateliers de production يجب على العمال والزوار ارتداء البسة ملائمة داخل ورشات الانتاج					
A7	Les travailleurs et les visiteurs doivent porter des couvre-chaussures dans les ateliers de production يجب على العمال والزوار ارتداء اغطية احذية داخل ورشات الانتاج					
A8	Éviter de porter des bijoux où apporter des objets dans les ateliers de production من المهم عدم لبس المجوهرات او حمل اشياء داخل ورشات الانتاج					
A9	Il est nécessaire de suspendre le personnel malade jusqu'à guérison من المهم توقيف العامل المريض عن العمل حتى يشفى					
A10	Il est nécessaire de faire le contrôle microbiologique de l'emballage dans le laboratoire de l'entreprise et former les laborantins à cette technique من المهم عمل تحليل الميكروبيولوجي للأغلفة داخل مخبر المؤسسة وتكوين المخبريين في ذلك					

	Prévention contre les défauts dans les apparences physiques					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
B1	Il est nécessaire d'assurer une maintenance préventive des malaxeurs sous vide pour éviter de produire un produit fini sec blanc من المهم ضمان الصيانة الوقائية للخلطات الفراغية من اجل تفادي انتاج معكرونة بيضاء بالكامل					
B2	La pâte sèche doit être exempte des taches blanches issues de la présence des 3SF dans la pâte, la semoule moyenne ou l'utilisation des produits finis broyés العجائن المجففة (معكرونة) يجب ان تكون خالية من البقع البيضاء التي سببها وجود السميد الرقيق جدا جدا جدا في العجينة , السميد المتوسط و العجائن مجففة (منتوج نهائي) مسحوق					
B3	Il est nécessaire de renforcer le nettoyage des filtres 3sf من المهم تقوية عملية التنظيف لمصفيات السميد الرقيق جدا جدا جدا					
B4	Il faut mettre en place une maintenance préventive des tamis dans le transfert de la semoule من المهم وضع صيانة وقائية للمناخل في وحدة ارسال السميد					
B5	La pâte sèche doit être exempte des taches noires qui sont le résultat de la présence de particule de son dans la semoule العجائن المجففة (معكرونة) يجب ان تكون خالية من البقع السوداء التي يكون مصدرها النخالة في القمح					
B6	Il est nécessaire d'ajuster la géométrie des moules pour assurer une forme et taille identiques du produit fini من المهم تعديل قوالب العجائن من اجل ضمان شكل وحجم مماثل للمنتوج النهائي					
B7	Les défauts d'apparence physique du produit fini peuvent dégrader la qualité visuelle du produit fini de Sosémie العيوب في شكل المنتوج النهائي تنقص من الجودة المرئية لمنتوج سوسيمي					

	La prévention des risques liés aux équipements					
		Très d'accord	D'accord	Neutre	Pas d'accord	Pas du tout d'accord
C1	Il est nécessaire d'assurer le traitement des eaux pendant les weekends pour prévenir les risques liés à la chaudière et au système de refroidissement من المهم ضمان معالجة المياه في عطل نهاية الاسبوع من اجل تفادي المخاطر المتعلقة بسخان المياه ونظام التبريد					
C2	Il est nécessaire de contrôler régulièrement les chaudières et le système de refroidissement par des experts externes من المهم مراقبة بانتظام سخان المياه ونظام التبريد من طرف خبراء خارجيين					
C3	La maintenance corrective contribue à la réparation des équipements mais elle ne prévient pas les risques liés aux équipements الصيانة التصحيحية تساهم في تصليح الاجهزة ولكن لا تقي من المخاطر المتعلقة بالأجهزة					
C4	Il est nécessaire de mettre en place une maintenance préventive des équipements et matériels (capteurs, machines …etc.) dans les ateliers de productions des pâtes et couscous من المهم وضع صيانة وقائية للأجهزة والمعدات (مسجات، الات ...) داخل ورشات انتاج العجائن والكسكسي					
C5	Il est nécessaire de mettre en place un contrôle permanent dans l'unité de transfert de la semoule pour prévenir les risques dans cette unité qui peuvent endommager les équipements de l'unité de production des pâtes et couscous من المهم وضع رقابة دائمة داخل وحدات ارسال السميد من اجل منع المخاطر داخل الوحدة التي يمكن ان تتلف اجهزة وحدة انتاج العجائن والكسكسي					
C6	Le service de la maintenance doit prendre en considération les informations issues des systèmes d'alertes pour prévenir les pannes et les risques liés aux équipements خدمة الصيانة يجب ان تأخذ بعين الاعتبار المعلومات الصادرة من نظام الانذار في غرفة المراقبة من اجل منع وقوع عطب والمخاطر المتعلقة بالأجهزة					
C7	Tout le personnel de l'unité de production des pâtes et couscous est tenu de signaler les pannes et le dysfonctionnement des équipements et du matériel كل موظفي وحدة انتاج العجائن ة الكسكسي مطالب بالإبلاغ عن أي عطب او خلل في الاجهزة والمعدات					

C8	Il est nécessaire de renforcer le nettoyage des équipements pour éviter les contaminations et les pannes من المهم تقوية نظام تنظيف معدات من اجل تفادي التلوثات والاعطاب					
C9	Il est nécessaire d'acquérir le matériel nécessaire pour prévenir les chocs thermiques من المهم اقتناء المعدات الاساسية من اجل الوقاية من الصدمات الحرارية					

		Minimiser les déchets				
Code		Très d'accord	D'accord	Indifférent	Pas d'accord	Pas du tout d'accord
D1	Il est nécessaire de minimiser les déchets des pâtes et d'emballages pour éviter les pertes financières engendrées من المهم تقليل نفايات العجائن والاغلفة لتجنب الخسائر المالية الناجمة					
D2	Il est nécessaire d'ajuster la géométrie des moules pour assurer une forme et taille identiques du produit fini pour minimiser les déchets des pâtes من المهم تعديل قوالب العجائن من اجل ضمان شكل وحجم مماثل للمنتوج النهائي					
D3	Il faut former le personnel sur les bonnes manières pour sécher la pate يجب تكوين العمال حول الأساليب الجيدة في تجفيف العجين					
D4	Il faut maitriser les paramètres de séchage : la température, l'humidité يجب التحكم في معايير التجفيف: درجة الحرارة والرطوبة					
D5	Il est nécessaire de maitriser la pression d'injection de la pâte pour le moulage pour éviter de produire une pâte dure et donc minimiser les déchets des pates يجب التحكم في ضغط ضخ العجين من اجل تشكيل العجينة و ذلك لتفادي انتاج عجين صلب و التقليل من مخلفات العجين					
D6	Il est nécessaire de contrôler régulièrement les chaudières et le système de refroidissement par des experts externes من المهم مراقبة بانتظام سخان المياه ونظام التبريد من طرف خبراء خارجيين					

	Etablissement du contexte					
		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
E1	J'ai une vision d'extérieure, globale et claire du processus de production des pates courtes لدي رؤية خارجية، شاملة وواضحة عن عملية انتاج معكرونة القصيرة					
E2	J'ai une vision claire des ateliers du processus de production des pates courtes لدي رؤية واضحة عن ورشات انتاج معكرونة القصيرة					
E3	J'ai une vision claire des activités de chaque atelier du processus de production du des pates courtes لدي رؤية واضحة عن عمل كل ورشة من ورشات انتاج معكرونة القصيرة					
E4	Je vois clairement le rôle de chaque atelier dans le processus de production du des pates courtes ارى بوضوح دور كل ورشة من ورشات انتاج معكرونة القصيرة					
E5	Je vois clairement les acteurs du processus de production des pates courtes et les parties prenantes de l'entreprise ارى بوضوح الاطراف الفاعلة في عملية انتاج معكرونة القصيرة واصحاب المصلحة في المؤسسة					
E6	J'ai une vision claire des objectifs et des valeurs attendues par l'entreprise, les structures et le consommateur لدي رؤية واضحة عن الاهداف والقيم المنتظرة للمؤسسة، هياكلها والمستهلك					
E7	Les diagrammes du processus de production des pates courtes me permettent de détecter les différents risques opérationnels potentiels dans les ateliers de production تسمح مخططات عملية انتاج معكرونة القصيرة باكتشاف المخاطر التشغيلية المحتملة داخل ورشات الانتاج					
E8	Les diagrammes du processus de production des pates courtes me permettent d'identifier le personnel qui peut identifier, évaluer et proposer des scenarios de traitement de ces risques مخططات عملية انتاج معكرونة القصيرة تسمح بتحديد الموظف الذي يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					

	La collecte de la connaissance					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
F1	Le personnel expérimenté peut identifier, évaluer et proposer des scenarios de traitement de ces risques الموظف ذو الخبرة يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					
F2	Il est nécessaire de bénéficier de l'expérience du personnel qui peut identifier, évaluer et proposer des scenarios de traitement de ces risques من المهم الاستفادة من خبرة الموظف ذو الخبرة يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					
F3	J'ai une idée claire sur les différents risques opérationnels potentiels dans le processus de production لدي فكرة واضحة عن المخاطر التشغيلية المحتملة في عملية الانتاج					
F4	J'ai une idée claire sur le positionnement exacte des risques opérationnels dans les ateliers de production لدي فكرة واضحة عن موقع المخاطر التشغيلية في ورشات الإنتاج					
F5	J'ai une idée claire sur les causes de ces risques لدي فكرة واضحة عن اسباب هذه المخاطر					
F6	J'ai une idée claire sur la fréquence d'occurrence (la probabilité d'occurrence) de ces risques لدي فكرة واضحة عن عدد مرات حدوث واحتمال حدوث هذه المخاطر					
F7	J'ai une idée claire sur la gravité de ces risques لدي فكرة واضحة عن مدى خطورة هذه المخاطر					
F8	J'ai une idée claire sur les conséquences de ces risques sur les objectifs de l'entreprise, de ces structures et du consommateur لدي فكرة واضحة عن آثر هذه المخاطر على اهداف المؤسسة، هياكلها والمستهلك					

	Le partage des connaissances					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
G1	Le partage des diagrammes de l'entreprise et des ateliers de production avec tous les membres du personnel est très important مشاركة مخططات المؤسسة وورشات الانتاج مع كل الموظفين مهم جدا					
G2	Le partage des diagrammes d'évaluation des risques avec tous les membres du personnel est très important مشاركة مخططات تقييم المخاطر مع كل الموظفين مهم جدا					
G3	Le partage des diagrammes de traitement des risques avec tous les membres du personnel est très important مشاركة مخططات معالجة المخاطر مع كل الموظفين مهم جدا					
G4	Il est nécessaire de partager avec tous les membres du personnel mes connaissances des risques potentiels dans le processus de production des pates coutres من المهم مشاركة كل الموظفين معرفتي المتعلقة بالمخاطر المحتملة في عملية انتاج المكرونة القصيرة					
G5	Il est nécessaire d'inciter les membres du personnel de partager la connaissance des risques développés avec le reste du personnel من المهم حث الموظفين على مشاركة المعرفة الخاصة بالمخاطر مع باقي الموظفين					
G6	Il est nécessaire d'organiser des réunions ou des rencontres, pour partager les connaissances avec tous les membres du personnel من المهم تنظيم اجتماعات ولقاءات من اجل مشاركة المعارف المتعلقة بالمخاطر مع باقي الموظفين					
G7	Il est nécessaire de créer un intranet dédié au partage des connaissances des risques من المهم انشاء شبكة داخلية مخصصة لمشاركة المعرفة الخاصة بالمخاطر					

	Stocker la connaissance					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
H1	Il est nécessaire de créer une base de données numérique dans l'entreprise contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم انشاء قاعدة بيانات داخل المؤسسة تحتوي مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
H2	Il est nécessaire de donner l'accès à cette base de données à tous les membres du personnel من المهم السماح لكل الموظفين بالولوج لقاعدة البيانات					
H3	Il est nécessaire d'inciter tous les membres du personnel d'accéder à cette base de données من المهم حث جميع الموظفين على الولوج لقاعدة البيانات					
H4	Il est nécessaire d'archiver les documents contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques sur des supports papier من المهم الاحتفاظ بملفات ورقية تتضمن مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					

	Actualisation des données					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
I1	Il est nécessaire d'actualiser régulièrement la base de données numérique des diagrammes relatifs aux risques من المهم تحديث بانتظام قاعدة البيانات الرقمية للمخططات المتعلقة بالمخاطر					
I2	Il est nécessaire de réviser régulièrement les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم مراجعة بانتظام مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
I3	Il est nécessaire d'actualiser régulièrement les supports papier contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم تحديث بانتظام الملفات الورقية التي تتضمن مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
I4	Il est nécessaire d'informer tous les membres du personnel de l'actualisation des diagrammes de l'entreprise, des diagrammes des ateliers de production, et des diagrammes de l'analyse et de traitement des risques من المهم اعلام كل الموظفين بأي تحديث لمخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					

Annexe C

Questionnaire

N° du questionnaire

Bonjour Madame, Mademoiselle, Monsieur, je m'appelle «Safa MAAMIR », je prépare une thèse de Doctorat en sciences de gestion. Dans ce cadre, je réalise une étude sur les risques.

Je vous serai très reconnaissante de consacrer quelques minutes et répondre à ce questionnaire. Bien entendu, nous vous garantissons l'anonymat le plus absolu quant à vos réponses.

Merci

اهلا سيدتي، انستي، سيدي. ادعى صفاء معامير، احضر أطروحة دكتوراه في علوم التسيير. في هذا الإطار انا بصدد اعداد دراسة حول المخاطر التشغيلية.

سأكون جد ممتنة إذا خصصتم بعض الدقائق من وقتكم للإجابة على هذه الأسئلة. من المؤكد اننا تضمن لكم بذلك السرية التامة في التعامل مع اجوبتكم.

شكرا

Caractéristiques personnelles الخصائص الشخصية

Q1. Genre الجنس

Femme انثى	
Homme ذكر	

Q2. Niveau d'instruction مستوى التعليمي

Non scolarisé لم التحق بالمدرسة	
Niveau primaire مستوى ابتدائي	
Niveau moyen مستوى اكمالي	
Niveau secondaire مستوى ثانوي	
Niveau universitaire مستوى جامعي	

Q3. Votre expérience dans l'entreprise سنوات الخبرة داخل المؤسسة

Moins d'un an اقل من سنة	
1 à 3 ans سنة	
4 à 6 ans سنة	
7 à 9 ans سنة	
Plus 9 ans اكثر من تسعة سنوات	

Q4. Votre statut dans l'entreprise ما هو مركزك في المؤسسة

	Contaminations					
Code		Trés d'accord موافق جدا	Accord موافق	Indifferent محايد	Pas d'accord غير موافق	Pas du tout d'accord غير موافق تماما
A1	Les matières premières, les équipements et les AC sont exposés aux contaminations tout au long du processus de fabrication المواد الاولية، المعدات ومواد التغليف معرضون للتلوث خلال كل مراحل الانتاج					
A2	Le respect des règles d'hygiène est important pour lutter contre tout type de contamination احترام قواعد النظافة امر مهم من اجل المحاربة ضد كل انواع التلوث					
A3	Le respect des flux de matières et du personnel est important pour lutter contre les contaminations croisées احترام مجرى المواد والعمال امر مهم للمحاربة ضد خطر انتقال التلوث					
A4	Les matières et les articles de conditionnement doivent être conformes (contrôlés par le LCQ) pour assurer la qualité du produit يجب ان تكون مواد الانتاج ومواد التغليف مطابقة (مراقبة من المخبر) من اجل ضمان جودة المنتوج					
A5	La propreté des locaux et des équipements est importante pour lutter contre tout type de contamination نظافة قاعات الانتاج و المعدات مهمة للمحاربة ضد كل انواع التلوث					
A6	Le vide de ligne intermédiaire est nécessaire pour lutter contre les contaminations croisées quand la ligne fabrique un nouveau lot du même produit تفريغ خط الانتاج الجزئي مهم للمحاربة ضد خطر انتقال التلوث وذلك اثناء انتاج دفعة جديدة لنفس المنتج					
A7	Le vide de ligne approfondie est nécessaire lorsque la ligne fabrique un nouveau produit pour lutter contre les contaminations croisées تفريغ خط الانتاج الكامل مهم عند انتاج منتج جديد للمحاربة ضد خطر انتقال التلوث					
A8	Il est nécessaire de surveiller régulièrement (température, humidité et la pression) pour assurer un environnement adapté à la fabrication pharmaceutique من المهم المتابعة المنتظمة ل (الحرارة، الرطوبة والضغط) من اجل ضمان محيط ملائم للإنتاج الصيدلاني					
A9	Les contaminations affectent la qualité du produit fini جميع انوا ع التلوث تؤثر على جودة المنتوج					
A10	Les superviseurs et AQ doivent contrôler la bonne exécution des opérations (vides de ligne, l'application des procédures…) pour lutter contre tout type de contamination					

	المشرفون وضمان الجودة يراقبون السير الحسن للعمليات للمحاربة ضد كل انواع التلوث					
A11	Le laboratoire contrôle la qualité des matières, AC et produits finis pour lutter contre tout type de contamination المخبر يراقب جودة مواد الانتاج، مواد التغليف والمنتج النهائي					
A12	Le système des sous-fractions aide à suivre le produit et éliminer les quantités qui peuvent causer une contamination نظام التقسيمات الفرعية يساعد على متابعة المنتوج وسحب الكميات التي يمكن ان تلوث باقي الكميات					
A13	Pour éviter les défauts des AC, il est nécessaire de bien sélectionner les fournisseurs من اجل تفادي عيوب مواد التغليف يجب ان يتم انتقاء الموردون بعناية					
A14	Il est nécessaire d'auditer les fournisseurs pour assurer la qualité des matières premières et AC من المهم التدقيق مع الموردين من اجل ضمان جودة المواد الاولية ومواد التغليف					
A15	Il est nécessaire d'utiliser les étiquettes avec code à barre pour faciliter l'identification des matières et produits et éviter la confusion des matières donc éviter la contamination croisée من المهم استعمال ملصقات تحتوي الرمز الشريطي من اجل تسهيل عملية تحديد المواد والمنتجات وتجنب خلط المواد وعليه تجنب خطر انتقال التلوث					
A16	La mise en place d'un système informatisé dans lequel le personnel renseigne automatiquement les formulaires pour éviter la contamination croisée وضع نظام محوسب يقوم فيه العمال بملء بطريقة أتوماتيكية الاستمارات لتجنب خطر انتقال التلوث					
A17	Le système informatisé (dossier de lot électronique, annexes et logbook) permet de vérifier en temps réel les formulaires renseignés et contrôler les opérations النظام المحوسب يسمح بالمراجعة الانية للاستمارات المملوءة ومراقبة العمال					

	Les risques causés par le personnel					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
B1	Il peut y avoir des informations erronées sur les étiquettes, les dossiers, les ACs et même dans les OC ou OF يمكن وجود معلومات خاطئة على الملصقات الملفات أغراض التغليف والتعبئة وامر التصنيع والتغليف					
B2	Le manque de traçabilité est la conséquence de la perte des fiches et/ou d'informations نقص المعلومات وضياع الوثائق يسبب نقص اقتفاء أثر المنتجات					
B3	Les matières peuvent tomber sur terre tout au long du processus de fabrication يمكن للمواد المستعملة ان تسقط على الارض في أي مرحلة من مراحل الانتاج					
B4	Les erreurs commises par les opérateurs sont la cause de la surcharge de travail, le manque de supervision ou le manque de formation الاخطاء التي يرتكبها العمال هي نتيجة اكتظاظ العمل، نقص الاشراف او نقص التكوين					
B5	Les superviseurs et l'assurance qualité contrôlent la bonne exécution des opérations (application des procédures, la traçabilité ….) pour éviter tout type d'erreur الاشراف وضمان الجودة يراقبون التنفيذ الجيد للعمليات					
B6	Le manque de traçabilité, le non-respect des procédures et les informations erronées affectent la sécurité et la qualité des produits قلة اقتفاء أثر المنتجات، عدم احترام الاجراءات والمعلومات الخاطئة يؤثرون على امن وجودة المنتجات					
B7	Le système des sous-fractions réduit les pertes de la matière qui tombent sur terre نظام التقسيمات الفرعية يخفض خسائر المواد التي تسقط على الارض					
B8	La mise en place d'un système informatisé permet aux responsables et à l'AQ de détecter en temps réel les erreurs commises lors du renseignement des formulaires وضع نظام محوسب يسمح للمسؤولين ونظام الجودة الكشف انيا عن الأخطاء المرتكبة اثناء ملئ الاستمارات					
B9	Le système informatisé permet d'éviter les erreurs commises lors du renseignement des formulaires النظام المحوسب يسمح بتجنب الاخطاء المرتكبة اثناء ملئ الاستمارات					
B10	Il est nécessaire de former tout le personnel sur le nouveau système informatisé من المهم تكوين كل العمال في النظام المحوسب الجديد					

	Défauts des Articles de conditionnement					
		Très d'accord	D'accord	Neutre	Pas d'accord	Pas du tout d'accord
C1	La mauvaise qualité du PVDC et d'ALU et les problèmes dans la formulation sont l'origine d'un mauvais scellage الجودة الرديئة لمواد التغليف ومشاكل تركيبة الدواء هم أسباب مشاكل الغلق المحكم للدواء					
C2	Les caractères abimés du système de marquage est la cause d'un mauvais marquage الرموز التالفة لنظام التعليم هو سبب رداءة التعليم					
C3	La non-conformité des AC avec le BAT (mauvaise impression sur ALU, mauvaise qualité du carton utilisé, le non-respect des dimensions des étuis) est la responsabilité du fournisseur عدم تطابق مواد التغليف مع BAT هي مسؤولية المورد					
C4	La non-conformité des matières avec le BPF est la responsabilité du fournisseur عدم تطابق المواد مع BPF هي مسؤولية المورد					
C5	Les blisters incomplets se produisent suite au déréglage du système de l'alimentation de la blistéreuse صفائح الدواء الغير مكتملة سببه خلل في نظام التغذية في الة انتاج صفائح الدواء					
C6	Les défauts des AC affectent la qualité du produit fini العيوب التي تكون في مواد التعبئة تؤثر على جودة المنتج النهائي					
C7	Il faut établir une réclamation aux fournisseurs pour AC abimés et non-conformes يجب تقديم شكوى للموردين بشأن مواد التعبئة الغير صالحة والغير مطابقة					
C8	Il est nécessaire d'améliorer les mécanismes de sélection des fournisseurs من المهم تحسين مكنزمات انتقاء الموردين					
C9	Il faut améliorer le programme de la maintenance préventive des équipements من المهم تحسين برنامج الصيانة الوقائية للمعدات					
C10	Il est nécessaire de mettre en place un système informatisé pour contrôler l'état des équipements من المهم وضع نظام محوسب من اجل مراقبة وضعية المعدات					
C11	Il est nécessaire de maintenir le contrôle des activités des opérateurs pour éviter les défauts des AC من المهم الحفاظ على اجراءات مراقبة انشطة العمال من اجل تجنب عيوب في مواد التغليف					

C12	Le non-respect des consignes et des procédures sont les causes des défauts de l'aspect des comprimés عدم احترام الارشادات والاجراءات هي من اسباب وجود عيوب في مظهر اقراص الدواء					
C13	La formation continue est importante pour les opérateurs pour éviter les défauts d'aspect التكوين المتواصل للعمال مهم من اجل تجنب عيوب مظهر اقراص الدواء					

		Production des déchets				
Code		Très d'accord	D'accord	Indifférent	Pas d'accord	Pas du tout d'accord
D1	Il y a cinq sources de déchets : les déchets du contrôle, de la mise en blister, du vide de ligne, des aspirateurs et du réglage هناك خمس مصادر للمخلفات: مراقبة الجودة، مرحلة وضع اقراص الدواء في صفائح معدنية، تفريغ خط الانتاج ، المكانس الكهربائية و التصليح					
D2	l'étape de la compression et de la mise en blister génèrent de grandes quantités de déchets مرحلة الضغط ووضع اقراص الدواء في صفائح معدنية تنتج كمية كبيرة من المخلفات					
D3	Les déchets entrainent des coûts supplémentaires pour l'entreprise تترتب على هذه المخلفات تكاليف اضافية للمؤسسة					
D4	L'opérateur doit essayer de minimiser les déchets afin de minimiser les couts يجب على العامل محاولة تقليل المخلفات من اجل تقليل التكاليف الاضافية					
D5	Le recyclage des déchets (ACs) permet à l'entreprise de compenser les coûts engendrés إعادة تدوير مخلفات مواد التغليف والتعليب يسمح للمؤسسة بتعويض التكاليف الإضافية المترتبة					

	Retard de la libération de lot					
		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
E1	Le retard de la libération de lot est dû à la lenteur du processus de fabrication التأخر في إطلاق دفعة سببه الوتيرة البطيئة لعملية الإنتاج					

E2	Un nouvel opérateur ou un opérateur qui manque de formation peuvent ralentir le processus de fabrication et par conséquent la libération de lot العامل الجديد او العامل الذي يفتقر للتكوين يمكن ان يبطئ من وتيرة الانتاج وعليه التأخر في إطلاق دفعة					
E3	Le dysfonctionnement des équipements peut ralentir le processus de fabrication أي عطل في المعدات والاجهزة يمكن ان يبطئ من وتيرة الانتاج وعليه التأخر في إطلاق دفعة					
E4	le manque des articles de conditionnement peut ralentir le processus de fabrication نقص مواد التغليف والتعبئة يمكن ان يبطئ من وتيرة الانتاج وعليه التأخر في إطلاق دفعة					
E5	L'utilisation d'une version papier pour le dossier de lot ralentit sa circulation et sa vérification et par conséquent la libération de lot استعمال لنسخ ورقية لملف الدفعة يبطئ مساره ومراجعته وعليه التأخر في إطلاق دفعة					
E6	Les informations erronées et le manque de fiches peuvent ralentir la vérification du dossier de lot et donc la libération de lot المعلومات الخاطئة ونقص الوثائق يمكن ان يعطل مراجعة ملف الدفعة وعليه التأخر في إطلاق دفعة					
E7	La mise en place d'un système informatisé (dossier de lot électronique et annexe) permet d'éviter la perte et le manque de fiches et/ou d'informations et donc la libération de lot dans les délais وضع نظام محوسب يسمح بتجنب ضياع ونقص الوثائق و/او المعلومات وعليه اطلاق الدفعة في الوقت المحدد					
E8	La mise en place d'un système de documentation et d'information informatisé permet la vérification des formulaires renseignés et d'éviter tout type d'erreur et donc libérer le lot dans les délais وضع نظام توثيق ومعلومات محوسب يسمح بمراجعة الاستمارات وتجنب أي خطا وعليه إطلاق دفعة في وقتها الحدد					

	Le dysfonctionnement des équipements					
F1	Le non-respect des procédures et consignes peuvent endommager les équipements et outillages عدم احترام الاجراءات والارشادات يمكن ان يتلف الاجهزة والمعدات					
F2	La qualification expirée des équipements est la source de dysfonctionnement des équipements انتهاء صلاحية الأجهزة تسبب تلف الأجهزة					

F3	Le manque de maintenance préventive entraîne le dysfonctionnement des équipements نقص الصيانة الوقائية يؤدي الى تعطل الاجهزة					
F4	La surutilisation peut endommager les Équipements الافراط في استعمال الاجهزة يمكن له ان يعطل الاجهزة					
F5	Il est nécessaire de former le personnel sur le bon usage des équipements من المهم تكوين العمال حول الاستعمال الامثل للأجهزة					
F6	Il est nécessaire d'améliorer le programme de la maintenance préventive من المهم تحسين برنامج الصيانة الوقائية					
F7	Il est nécessaire de contrôler les opérateurs pour assurer l'application des procédures et consignes من المهم مراقبة انشطة العمال من اجل ضمان تطبيق الاجراءات والارشادات					

	Etablissement du contexte					
		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
G1	J'ai une vision d'extérieure, globale et claire du processus de fabrication de SPASMOODYL لدي رؤية خارجية، شاملة وواضحة عن عملية انتاج SPASMOODYL					
G2	J'ai une vision claire des ateliers de fabrication de SPASMOODYL لدي رؤية واضحة عن ورشات انتاج SPASMOODYL					
G3	J'ai une vision claire des activités de chaque atelier du processus de fabrication de SPASMOODYL لدي رؤية واضحة عن عمل كل ورشة من ورشات انتاج SPASMOODYL					
G4	Je vois clairement le rôle de chaque atelier dans le processus de fabrication de SPASMOODYL ارى بوضوح دور كل ورشة من ورشات انتاج SPASMOODYL					
G5	Je vois clairement les acteurs du processus de fabrication de SPASMOODYL et les parties prenantes de l'entreprise ارى بوضوح الاطراف الفاعلة في عملية انتاج SPASMOODYL واصحاب المصلحة في المؤسسة					

G6	J'ai une vision claire des objectifs et des valeurs attendues par l'entreprise, les structures et le consommateur لدي رؤية واضحة عن الاهداف والقيم المنتظرة للمؤسسة، هياكلها والمستهلك					
G7	Les diagrammes du processus de fabrication de SPASMOODYL me permettent de détecter les différents risques opérationnels potentiels dans les ateliers de production تسمح مخططات عملية انتاج SPASMOODYL باكتشاف المخاطر التشغيلية المحتملة داخل ورشات انتاج الحليب المبستر					
G8	Les diagrammes du processus de fabrication de SPASMOODYL me permettent d'identifier le personnel qui peut identifier, évaluer et proposer des scenarios de traitement de ces risques مخططات عملية انتاج SPASMOODYL تسمح بتحديد الموظف الذي يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					

	La collecte de la connaissance					
Code		Très d'accord	D'accord	Indifférent	Pas d'accord	Pas du tout d'accord
H1	Le personnel expérimenté peut identifier, évaluer et proposer des scénarios de traitement de ces risques الموظف ذو الخبرة يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					
H2	Il est nécessaire de bénéficier de l'expérience du personnel qui peut identifier, évaluer et proposer des scenarios de traitement de ces risques من المهم الاستفادة من خبرة الموظف ذو الخبرة الذي يمكن له تحديد، تقييم واقتراح سناريوهات لمعالجة هذه المخاطر					
H3	J'ai une idée claire sur les différents risques opérationnels potentiels dans le processus de production لدي فكرة واضحة عن المخاطر التشغيلية المحتملة في عملية انتاج أقراص الدواء					
H4	J'ai une idée claire sur le positionnement exacte des risques opérationnels dans les ateliers de production لدي فكرة واضحة عن موقع المخاطر التشغيلية في ورشات الإنتاج					
H5	J'ai une idée claire sur les causes de ces risques					

	لدي فكرة واضحة عن اسباب هذه المخاطر					
H6	J’ai une idée claire sur la fréquence d’occurrence (la probabilité d’occurrence) de ces risques لدي فكرة واضحة على عدد مرات حدوث واحتمال حدوث هذه المخاطر					
H7	J’ai une idée claire sur la gravité de ces risques لدي فكرة واضحة على مدى خطورة هذه المخاطر					
H8	J’ai une idée claire sur les conséquences de ces risques sur les l’entreprise, ces structures et les patients لدي فكرة واضحة عن آثر هذه المخاطر على اهداف المؤسسة، هياكلها والمستهلك					

	Le partage des connaissances					
Code		Très d’accord	D’accord	Indiffèrent	Pas d’accord	Pas du tout d’accord
I1	Le partage des diagrammes de l’entreprise et des programmes de production avec tous les membres du personnel est très important pour une prévention des risques مشاركة مخططات المؤسسة وورشات الانتاج مع كل الموظفين مهم جدا					
I2	Le partage des diagrammes d’évaluation des risques avec tous les membres du personnel est très important pour une prévention des risques مشاركة مخططات تقييم المخاطر مع كل الموظفين مهم جدا					
I3	Le partage des diagrammes de traitement des risques avec tous les membres du personnel est très important pour une prévention des risques مشاركة مخططات معالجة المخاطر مع كل الموظفين مهم جدا					
I4	Il est nécessaire de partager avec tous les membres du personnel mes connaissances relatives aux risques potentiels dans le processus de production pour une prévention des risques من المهم مشاركة كل الموظفين معرفتي المتعلقة بالمخاطر المحتملة في عملية انتاج					
I5	Il est nécessaire d’inciter le personnel de partager la connaissance des risques développés avec le reste du personnel pour une prévention des risques من المهم حث الموظفين على مشاركة المعرفة الخاصة بالمخاطر مع باقي الموظفين					
I6	Il est nécessaire d’organiser des réunions ou des rencontres, pour partager les					

	connaissances relatives aux risques avec tous le personnel pour une prévention des risques من المهم تنظيم اجتماعات ولقاءات من اجل مشاركة المعارف المتعلقة بالمخاطر مع باقي الموظفين					
I7	Il est nécessaire de créer un intranet dédié au partage des connaissances des risques pour une prévention des risques من المهم انشاء شبكة داخلية مخصصة لمشاركة المعرفة الخاصة بالمخاطر					

	Stocker la connaissance					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
J1	Il est nécessaire de créer une base de données numérique dans l'entreprise contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم انشاء قاعدة بيانات داخل المؤسسة تحتوي مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
J2	Il est nécessaire de donner l'accès à cette base de données à tous le personnel concerné من المهم السماح لكل الموظفين بالولوج لقاعدة البيانات					
J3	Il est nécessaire d'inciter tous le personnel d'accéder à cette base de données. من المهم حث جميع الموظفين على الولوج لقاعدة البيانات					
J4	Il est nécessaire d'archiver les documents contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques sur des supports papier من المهم الاحتفاظ بملفات ورقية تتضمن مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					

	Actualisation des données					
Code		Très d'accord	D'accord	Indiffèrent	Pas d'accord	Pas du tout d'accord
K1	Il est nécessaire d'actualiser régulièrement la base de données numérique des diagrammes relatifs aux risques من المهم تحديث بانتظام قاعدة البيانات الرقمية للمخططات المتعلقة بالمخاطر					
K2	Il est nécessaire de réviser régulièrement les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques					

	من المهم مراجعة بانتظام مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
K3	Il est nécessaire d'actualiser régulièrement les supports papier contenant les diagrammes de l'entreprise, les diagrammes des ateliers de production, et les diagrammes de l'analyse et de traitement des risques من المهم تحديث بانتظام الملفات الورقية التي تتضمن مخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					
K4	Il est nécessaire d'informer tous les membres du personnel de l'actualisation des diagrammes de l'entreprise, des diagrammes des ateliers de production, et des diagrammes de l'analyse et de traitement des risques من المهم اعلام كل الموظفين بأي تحديث لمخططات المؤسسة، مخططات ورشات الانتاج، مخططات تحليل ومعالجة المخاطر					