Standardization of cleaning practices in a growing food supplement wholesaler

A STUDY ON CLEANING PROCESSES, THEIR AMBIGUITY AND THE HYGIENIC RISKS INVOLVED

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This report is destined for Company X and the examiners of the University of Twente.

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Preface

Dear reader,

You are about to read my thesis called *Standardization of cleaning practices in a growing food supplement wholesaler*. This thesis is the product of my work at Company X, where I have worked for the last few months. The goal of this research was to improve the processes and standardization within the capsuling and mixing department of the production in Company X. I found it very interesting to get to know this company both on an organizational level as well as on a very operational level, through working as an operator in the capsuling and mixing department myself. I learned a lot and gained interesting experience. I hope my research will help Company X to further improve the quality in their production and that it will aid in the growth the company is going through.

I would like to thank everyone at Company X for their guidance and involvement in my project, and for making me feel welcome at the company. I also want to thank my supervisors from the UT, for guiding me and giving very useful and critical feedback. I would like to thank Wouter van Heeswijk, my main supervisor, for making time for me and guiding me in the right direction, especially at the beginning of this research. I would like to thank both Wouter van Heeswijk and Leo van der Wegen, my second supervisor, for always giving very critical and supportive feedback and for the pleasant communication, even now that all communication needs to take place online. This all has helped to take my thesis to a higher level.

I hope you enjoy reading this thesis.

Elise Potters, October 2020

Management summary

Company X is a rapidly growing business which specializes in the production and packaging of food supplements. It is important to keep the quality high and to keep improving. This research was motivated by the fact that there are discrepancies in the way processes are executed, especially in the capsuling and mixing department of the production facility. In this department, such discrepancies mostly cause problems for the hygiene. The capsuling and mixing department only processes powder supplements, and powder gets into the air and on surfaces easily. The surfaces, parts and machines therefore easily get contaminated with powder so cleaning is very important. Improper cleaning gives the risk of (cross) contamination. The goal of this research is to find out the degree of variation of cleanliness standards, to establish one standard of cleanliness and to improve the cleaning and cleanliness within the capsuling and mixing department of Company X. The main research question to reach this goal is:

What should Company X do to improve the cleaning processes within the mixing and capsuling department, with the goal of achieving one standard of cleanliness and department-wide familiarity of this standard?

We answer the research question by using the Practical Risk Analysis for Safety Management (Kinney and Wiruth, 1976) and a sensitivity analysis.

The Practical Risk Analysis for Safety Management

In this thesis, we work with the Practical Risk Analysis for Safety Management (Kinney and Wiruth, 1976) to assess risks in the cleaning methods and cleanliness. This method defines three factors to make up a total risk score by multiplying the factors. The total risk score is used to determine what the risk situation is, as shown in Table A. These factors are the factor for possible consequence, the likelihood factor and the exposure factor. The factors are determined for certain hazards. In this research, we focus on the cleaning and cleanliness hazards within the capsuling and mixing department of Company X.

Table A The risk situations and their scores according to the risk analysis theory

Risk situation	Risk score
Very high risk; consider discontinuing operation	> 400
High risk; immediate correction required	200 to 400
Substantial risk; correction needed	70 to 200
Possible risk; attention indicated	20 to 70
Risk, perhaps acceptable	< 20

In an existing risk analysis, Company X has defined several hazards within their production, of which we use seven for this research. Additionally, we define ten problematic situations that cause these hazards. For example, one of these situations is 'The degree of personal coverage'. This problematic situation causes, among others, the hazard 'Contamination through polluted clothing'. Like this, we define how all ten problematic situations influence the hazards. The result is 37 combinations of problematic situations and hazards which we call sub-problematic situations.

We define a KPI for each of the ten problematic situations. These KPIs are deconstructed to find the KPI values of the 37 sub-problematic situations. We determine likelihood scores for all sub-problematic situations, by defining a scale of likelihood factors for each possible KPI value. We assess which likelihood factor belongs to each interval of possible KPI values. The actual KPI values are known through observation and measuring the KPIs. Therefore, we know the KPI values and we can look in what interval these KPI values belong. This results in a likelihood score for each sub-problematic situation. The product of this likelihood score and the exposure factor and factor of possible consequence that were defined earlier, gives the risk factor for each sub-problematic situation. The risk factors are assessed according to the Practical Risk Analysis for Safety Management where the risk situation for each risk score interval is determined, according to Table A.

The result is that three of the sub-problematic situations have a risk situation that is 'high risk' or 'very high risk'. The situation with a very high risk involves switching of operators to different cabins. The risk in this situation is that operators cross-contaminate products because they switch from working with one product to working with another product. The situations with a high risk involve the method of storing clean parts and the method of cleaning parts. When a part is not stored correctly, it is likely to be contaminated by powder in the air which risks cross-contamination when that part is used again. This risk is also present when a part is not cleaned properly. There are several other situations that either have a risk situation of 'substantial risk', 'possible risk' or 'acceptable risk'.

Sensitivity analysis

The goal of the sensitivity analysis is to discover how improvements in the problematic situations influence the risk factors. We want to know what type of solution is needed for each sub-problematic situation in order to bring the risk situation to a level of 'acceptable risk'. Intuitively, a high risk situation needs a large improvement to become an 'acceptable risk' situation. Although this is often true, this is not always the case. It could be that the risk is high, but only with a small improvement the risk gets to an acceptable level or that the risk is low but the improvement to get to an acceptable level of risk is large. This is important to know, so that solutions can be generated in the most accurate way. We find that the most drastic changes need to be made for the control of cleaning and cleanliness and for the storage of parts.

Solutions

To improve the cleaning and cleanliness we advise Company X to do the following.

1. Invest in setting up a clear and concise cleaning handbook for the capsuling and mixing department.
2. Improve the layout of the capsuling and mixing department in the short term, by moving the stored parts to the hallway and providing gloves and face covers in a better way.
3. Start checking the cleaning and cleanliness in a structured manner.
4. Improve education and communication through internal and/or external trainings and monthly meetings with the capsuling and mixing operators.
5. Organize the capsuling and mixing department in the new production location in such a way that efficient and effective cleaning is ensured. The most important points to look at are materials that are easy to clean and structures that hinder the spread of powder.

We advise Company X to implement these solutions and to evaluate the KPIs in half a year, to see whether the KPIs improved by implementing the solutions.

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1. Problem identification and methods

This research was conducted for Company X, a contract manufacturer and packager of nutritional supplements. We will research the standardization of cleaning processes within the capsuling and mixing department in the production. This chapter explains the background and problem approach. Section 1.1 describes the background and motivation of the research, Section 1.2 describes the main problems, Section 1.3 explains several theories from literature relevant to this thesis and Section 1.4 describes the problem approach.

1.1. Background

This section explains the necessary background information of Company X, and the factors that motivated this research.

1.1.1. Company X

Company X is a rapidly expanding contract manufacturer and packager of nutritional supplements. The company offers a lot of services, such as mixing raw materials, capsuling, tablet pressing, producing soft-gels, blistering capsules, tablets and soft-gels and also filling and packaging. A simplified production process diagram is shown in Figure 1.1.

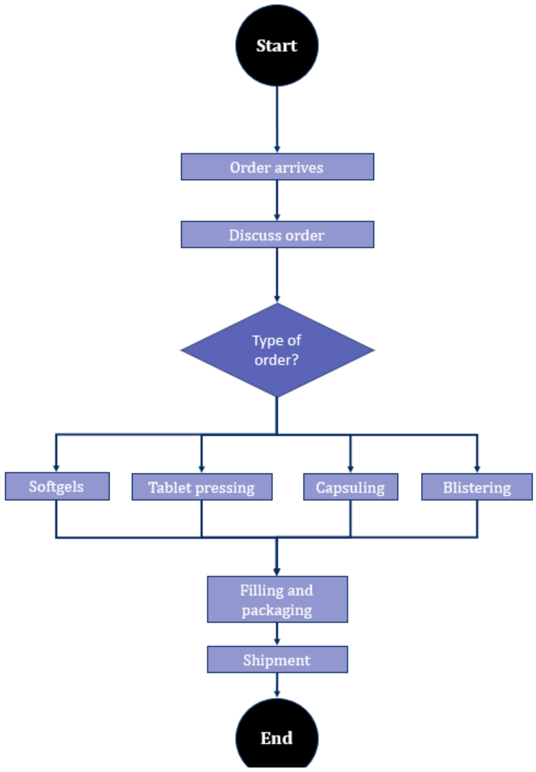

Figure 1.1 Simplified production process at Company X

The goal of Company X is to shoulder the burden of production and packaging for their clients. Company X aims for short lead times with the best possible quality.

Company X has a lot of different clients who want different types of products. This means that products are often produced simultaneously, in batches. There is no continuous production since the products that are produced are different every day. Company X is growing rapidly because of rising demand.

1.1.2. Research motive

Company X is a relatively small business which is currently rapidly growing. It is important to keep improving and to keep the quality high. Company X has a Higher Level IFS Food certification since 2015. IFS stands for International Featured Standard. It is a Global Food Safety Initiative (GSFI). This standard is recognized for auditing food manufacturers, and a certification like this is necessary to operate. The standard concerns food processing companies and food packaging companies. The company is checked for food safety and quality, amongst other things. There are various requirements, organized in these topics:

- Senior management responsibility
- Quality and food safety management system
- Resource management
- Planning and production process
- Measurements, analysis, improvements
- Food Defence

For this thesis, we will not look at the specific requirements from the IFS. However, it is always good to keep improving and this is also what the IFS encourages. The IFS certification is an extra incentive to keep improving the quality, which complements the main research incentive that will be discussed in the next sections.

To verify and extend the certificate, Company X undergoes a yearly IFS audit. The last audit was recently and it was passed, with one clear point of improvement. This improvement was the ambiguity in the cleaning processes, especially in the capsuling and mixing department. There is a lot of tacit knowledge among the operators in the production, but documented processes are lacking. New operators are trained by experienced operators who teach from experiences. This can cause discrepancies in the way processes are excecuted. For Company X, this causes the most problems at the capsuling and mixing department. At this department, powder is mixed and processed into capsules. Powder has the disadvantage that it gets into the air easily and therefore it is hard to clean. It is recognized that the cleaning processes at this department need to be improved. Operators clean in different ways and not always in the right way. Improper cleaning risks contamination which is undesirable and possibly dangerous. Cross contamination is a high risk for Company X since they have a lot of orders from different clients with completely different products. These products are produced simultaneously so it is very important that strict guidelines are followed to prevent contamination. Because of this, the focus of this research is put on the cleaning procedures and the ambiguity of these within the mixing and capsuling department.

1.2. Problem statement

In order to conduct research we need to set a goal. To set a goal, it is important to know what problems there are and how these problems are related. This section explains these problems. We collected information about the situation in Section 1.1. We visualised this in a problem cluster. This problem cluster is displayed in Figure 1.2. The problem cluster helps to find out the cause or causes of the main problems and in this way, these main problems can be solved systematically (Heerkens and Van Winden, 2017).

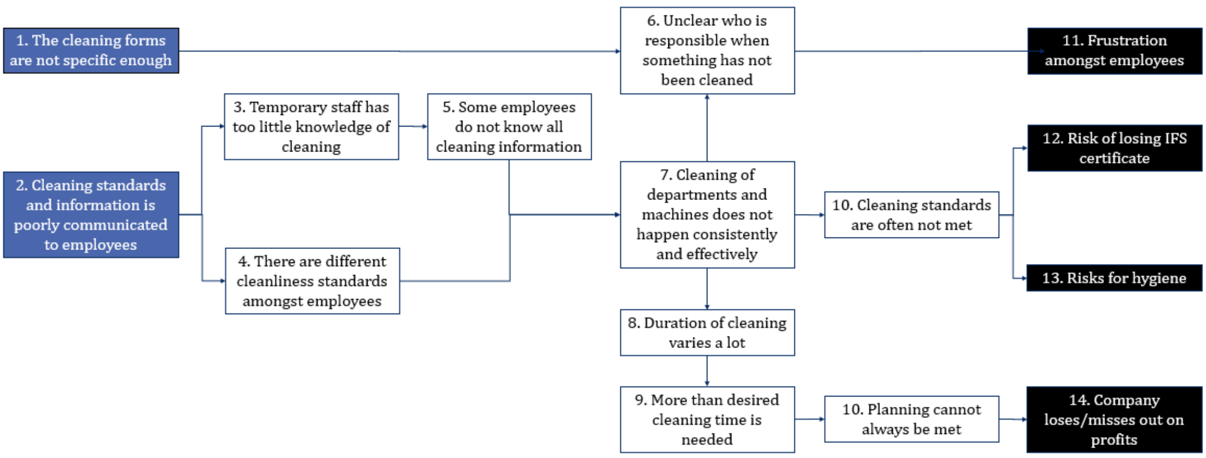

Figure 1.2 Problem cluster of the cleaning situation within capsuling and mixing

The problem cluster shows the relationships between the different problems within the mixing and capsuling department. The cluster helps us to find out what the aim of this research should be. We have identified four resulting problems (black boxes) and two core problems (blue boxes). All resulting problems are in some way influenced by the two core problems which shows that all problems have several causes. We therefore choose to tackle both core problems in this research. However, we see that problem 1 is a simpler problem since it only concerns the cleaning forms.

Cleaning forms are the forms on the doors of the cabin that are filled in with a name, as to check whether the cabin has been cleaned properly. The goal of this is that it is clear who was responsible for the cleaning, so when the cabin is not properly cleaned, other operators know who to address. However, the forms are very general so when a specific thing was not done, it is hard to trace who exactly was responsible. Since this problem is quite simple to solve, this thesis will focus more on problem 2. This problem is the root cause for all problems in cleaning. The problem is very process-related since it concerns the flow of information and the process of communication. The quality of these processes directly influences the hygiene. Therefore, we will solve problem 2 with thorough analysis. Problem 1 will be considered briefly while generating solutions at the end of this thesis.

The risks for hygiene, so problem 13 in the cluster, will be the main subject of this thesis, since this is the main concern posed by Company X. In the problem cluster, other action problems include a low employee satisfaction, the risk of losing the IFS certificate and the possible loss of profits. These problems are considered less important but will be taken into account as well.

With the hygiene as focus, the main problem statement of this research can be described as follows. Company X has unclear and hardly documented cleaning procedures within the mixing and capsuling department and the standards of cleanness vary amongst employees. Therefore, the cleaning often does not happen adequately and the cleaning times vary too much. The degree of visibility and varying of standards is hardly known. Together with the operators and the management of Company X, the following goals are established, limited to the capsuling and mixing department of the production:

1. The degree of variation of cleanliness standards amongst employees are known.
2. There is one standard of cleanliness which is documented and therefore visible and familiar for everyone.
3. The points and steps where the cleaning does not happen adequately (often), so where the cleaning deviates from the standard, are known.

This explanation of problems and goals leads to the following research question:

What should Company X do to improve the cleaning processes within the mixing and capsuling department, with the goal of achieving one standard of cleanliness and department-wide familiarity of this standard?

1.3. Theoretical framework

Within this theoretical framework, several theories will be demonstrated in two parts. The first part is a methodological theory about observation strategies. This is an important theory for the collection of data within this research. The second part demonstrates several risk analysis methods. Alternatives are discussed and a choice of risk analysis method is made. The theoretical framework supports the approach of this thesis, by underpinning the methods that are used.

1.3.1. Observation strategies

According to Cooper and Schindler (2014), simple observations can be used in the exploratory stage of a study. However, when the study becomes more descriptive and detailed, a systematic observation is needed. There are four classifications of observation studies. The first is a completely unstructured research in a natural setting. This is used to generate hypotheses. The second is an unstructured research in a laboratory. The third is a structured observation in a natural setting. This is generally used to test hypotheses and an observation checklist is used. The fourth is a completely structured research conducted in a laboratory. It is used to test hypotheses and an observation checklist is used.

To conduct observations of the problems within the capsuling and mixing department, the third classification of observation will be used. This type of observation takes place in a natural setting, which is the production setting, and takes advantage of an observational instrument such as a checklist or other type of form. In the observation for this research, we will use an observation form to note all relevant cleaning acts and practices in a structured manner. It is important to specify the observation content, both the major variables and the variables that may affect them. In the case of this thesis, we will not test a hypothesis, but rather measure current values of variables. The variables have to be operationalized. With this thesis, the variables are operationalized in terms of what parts are cleaned, what exact steps are taken and what hygiene measures are taken. Observation can be at either a factual level or an inferential level. On the factual level, facts are stated such as a specific act, duration, order number. On the inferential level more subjective aspects are measured such as effectiveness, credibility, status. The observations in this thesis are done on a factual level because specific acts are observed.

It is important to define what a separate unit of observation entails. This could be one act in production, but the thoughts, actions and dialogue leading to this act could also be one unit of observation. Furthermore, time could be important in the observation. For example, some things only happen one day of the week or on specific times of the day. Also, the place of the observation is of importance. This can influence the acts that are recorded. For this research, we defined several units of observation, for the different situations that are observed. Mostly, we observe production acts. These units of observations are further defined in Chapter 3.

To conclude, for this research we will set up a checklist with all the variables we want to measure operationalized. Then the observation will be as consistent as possible. Using the checklist, we will obtain all the information needed.

1.3.2. Risk analysis methods

We considered several methods of risk analysis for this research through a literature research on risk analysis methods. We eventually chose three methods to elaborate on, and from those we chose the Practical Risk Analysis for Safety Management (Kinney and Wiruth, 1976) to use for this thesis. Therefore, the MORT method and the FMEA method are explained only concisely. We explain the choice between the three methods at the end of this section.

1.3.2.1. Management Oversight and Risk Tree

The Management Oversight and Risk Tree (MORT) method (Knox & Eiger, 1992) is a risk analysis tool for detailed analysis of causes of risks and problems. (International Crisis Management Association, n.d.) We make a ‘tree’ in which the risks are positioned. An example of such a tree can be seen in Figure 1.3. The top event is the ‘loss’. This is the undesired outcome such as an accident in the workplace. Underneath this event, there are two options under which the types of events leading to the loss are classified, which are ‘Assumed Risks’ and ‘Oversight’. An assumed risk is a risk that is accepted to be there, where as an oversight is something that can be tackled. Under this, many more causal factors, which are denoted “LTA” (Less Than Adequate) can be seen in order to get to the root of the problem or problems. This system is complex and looks beyond immediate causes since it explores all sides of the problem systematically.

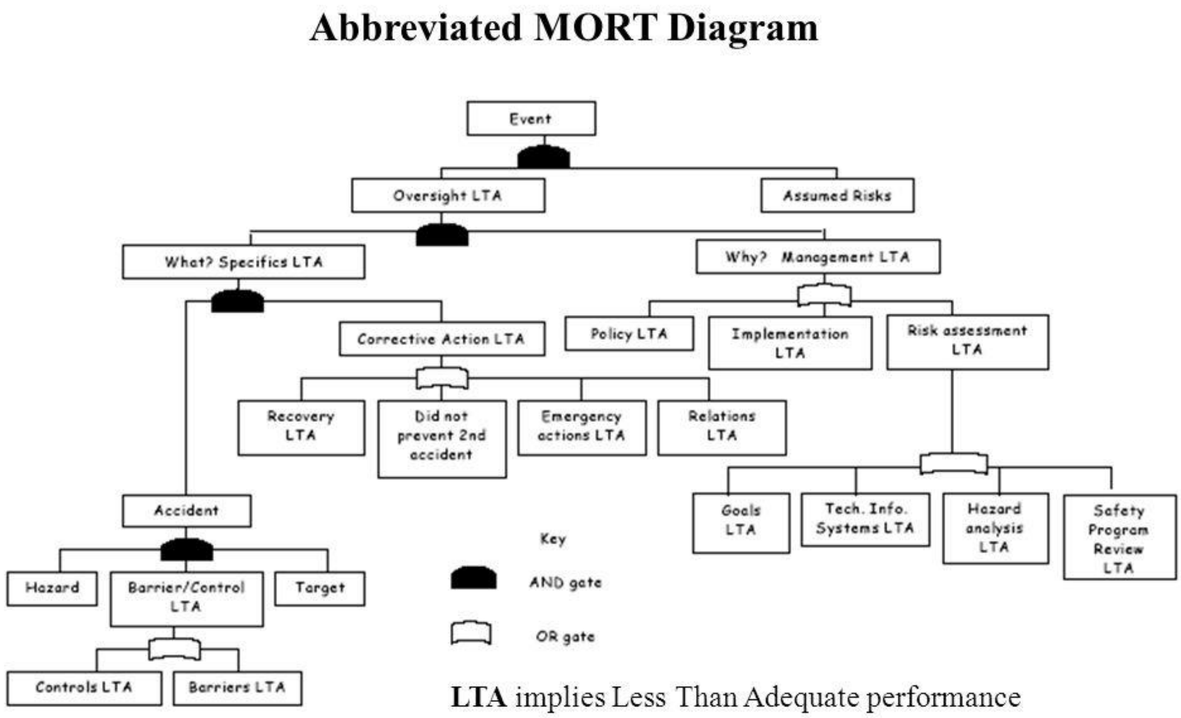

Figure 1.3. Example of a MORT diagram (Bishop et al., 2003)

The key strength of the MORT risk analysis method is that it is very thorough. Many causes for problems can be found. Also, it is easy to find quantifiable results. However, the MORT risk analysis method is very complicated. It is advised to know the method thoroughly to use it adequately.

1.3.2.2. Failure Mode and Effects Analysis (FMEA)

The Failure Mode and Effect Analysis (FMEA) method is a risk management tool for identifying possible failures, solving known errors, analysing causes and effects of known failures and reducing the most relevant failures by proposing control measures (Guiñón et al., 2020). First, we make a description of the functions of a process and analyse what can go wrong within the process. Then, the possible consequences of these mistakes are estimated and scaled. Next, the causes of the mistakes are assessed and the frequency of these causes are estimated and scaled. Lastly, the detection possibilities, so the chances the mistakes are detected in time, are assessed and also scaled. Finally, the RPN (Risk Priority Number) is calculated: RPN = S (severity) x F (frequency) x D (detection chance). The higher the RPN, the more important improvement is (Management Impact, 2016). The strengths of the FMEA method are that it is relatively simple to use and that it clearly indicates possible failures. However, a weakness could be that the FMEA method uses the detection chance as one of the parameters. This is a disadvantage when the goal is to prevent mistakes. It therefore depends on the type of research and usage of this method whether the detection parameter is a weakness or a strength.

1.3.2.3. Practical Risk Analysis for Safety Management

The Practical Risk Analysis for Safety Management (Kinney and Wiruth, 1976) is distinguished by its three parameters: the factor for the possible consequence, the likelihood of a hazardous event and the exposure factor. This risk analysis method was originally developed for safety considerations of a program of explosive blast effects. However, the risk analysis method has been proven to be useful for many types of risk assessment.

The factor for the possible consequence indicates how serious the consequence is, i.e. the severity. A consequence can be 'catastrophic' at its worst, where the estimated damage is many fatalities. The consequence is the mildest at the 'noticeable' level, with a minor injury. For instance, the consequence of an explosion in a large building is catastrophic because many deaths and injuries can be expected.

The likelihood of a hazardous event means the chance of the event happening. A likelihood is at its biggest when the event might well be expected. The likelihood is the smallest when it is virtually impossible that the event takes place. For example, if a ladder is not secured and is standing on a wobbly surface, a falling accident might well be expected.

The exposure factor within this risk analysis method is the factor of how often a potentially hazardous event takes place. The exposure factor is the largest when this type of event occurs continuously. The exposure factor is smallest when such an event is very rare, or it happens yearly or less than yearly. For example, when a person uses a ladder only once a year, there is only exposure to a ladder falling accident once a year, so very rarely.

These factors have weights assigned to them, according to Table 1.4 to 1.6.

Table 1.4 The factors for possible consequences according to the risk analysis theory

Factor for possible consequence (C)	Weight
Catastrophe (many fatalities, or >$\$10^7$ damage)	100
Disaster (few fatalities, or >10^6 damage)	40
Very serious (fatality, or > 10^5 damage)	15
Serious (serious injury, or >$\$10^4$ damage)	7
Important (disability, or >$\$10^3$ damage)	3
Noticeable (minor first aid incident, or $100 damage)	1

Table 1.5 the factors for likelihood of a hazardous event according to the risk analysis theory

Factor for likelihood of a hazardous event (L)	Weight
Might well be expected	10
Quite possible	6
Unusual but possible	3
Only remotely possible	1
Conceivable but very unlikely	0.5
Practically impossible	0.2
Virtually impossible	0.1

Table 1.6 The exposure factors according to the risk analysis theory

Exposure factor (E)	Weight
Continuous	10
Frequent (daily)	6
Occasional (weekly)	3
Unusual (monthly)	2
Rare (a few per year)	1
Very rare (yearly)	0.5

The assessment of the weights of the three factors can be done in different ways, adapting to the circumstances. However, Kinney and Wiruth states that a safety program should be based on factual information and informed judgment, rather than subjectivity and intuition. For the factor for possible consequence, it could be that a team of safety experts look at different situations, map all the possible consequences and add weights based on expertise and experience. For the likelihood factor, investigation in the form of observation and time measurement could be done with certain situations in order to see how often a hazardous event takes place. This measurement is preferably taken as often as possible over a representative amount of time, such as a few months or a year, depending on the situation. For the exposure factor, the same type of investigation can be done, now measuring the time that a potentially hazardous event takes place.

The risk score is the product of the three factor weights. The formula for the risk score is shown below. C is the factor for possible consequence, L is the factor for likelihood of a hazardous event and E is the exposure factor.

$$Risk\ Factor = C * L * E$$

The risk score gives a risk situation. Kinney and Wiruth defines a risk situation for all possible risk score intervals. These situations are given in Table 1.7.

Table 1.7 The risk situations and their scores according to the risk analysis theory

Risk situation	Risk score
Very high risk; consider discontinuing operation	> 400
High risk; immediate correction required	200 to 400
Substantial risk; correction needed	70 to 200
Possible risk; attention indicated	20 to 70
Risk, perhaps acceptable	< 20

1.3.2.4. Choice of risk analysis method

From the three risk analysis methods described, the Practical Risk Analysis Method for Safety Management by Kinney and Wiruth is chosen to be used for this thesis. This is because firstly, the MORT method contains aspects that are not needed for this research. Also, since it is a complicated method for risk analysis, it requires much in-depth research into the method and it is advised not to use this method unless the researcher knows everything about the method. The choice between the FMEA method and the Kinney and Wiruth method is more difficult, but the choice is based on one of the three risk assessment factors of the Kinney and Wiruth method that is preferred over the factors in the FMEA method. The detection chance factor in the FMEA method is not so relevant for this study and that is why this method is eliminated. Detection of a mistake, for example when a part is not clean according to the standard, is useful since it is an extra step to prevent contamination. However, for this thesis we will be looking mostly at the cleaning practices. We have noticed frustration amongst employees when something is insufficiently cleaned and they have to clean it since the extra cleaning costs valuable time and the appreciation amongst colleagues deteriorates. Adding a detection parameter will not solve these problems, because detection is part of the problem.

Since the FMEA method and the MORT method have shown to be unsuitable, we explore the Kinney and Wiruth method. The main difference between the Kinney and Wiruth method and the FMEA method is that the Kinney and Wiruth method has an exposure factor and a likelihood factor, whereas the FMEA method has only a frequency factor. They both have a severity factor. We deem this exposure factor to be very useful. This factor shows when a hazardous event can potentially take place. If a machine runs a high-risk operation but this only happens once a year, then the risk is also lower. A frequency or likelihood factor does not take this into account.

Therefore, because of the unnecessary detection chance factor in the FMEA method and the useful exposure factor in the Kinney and Wiruth method, we choose to use the Kinney and Wiruth method in this thesis.

Typically, the Kinney and Wiruth risk analysis is used for identifying risks and hazards within a workplace. Hazards are often expressed in possible injuries and deaths. Since this research is about the cleaning practices and the hygiene within a department, a 'hazard' initially does not appear to be the correct word to describe a risk. Illnesses or deaths could occur when a product is contaminated, for example with an allergen, but this is highly unlikely. It would be more likely that contamination causes a mild (allergic) reaction, a bad review, risk of losing quality certificates, returning of products, et cetera. Still, the Kinney and Wiruth risk analysis method has shown to be widely applicable. For instance, Gul & Celik (2018) conducted a Fine-Kinney based risk assessment for rail transportation systems. The Fine-Kinney method is derived from the Kinney and Wiruth risk method and is very similar. Gul & Celik listed many possible hazards, a lot of which are not directly seem to be dangerous for humans such as waste disposal. For this reason, we have decided to use the Kinney and Wiruth method in this research.

1.4. Problem approach

In order to go through all the research steps and to answer the main research question, the following research questions are set up. When these are answered, the main question 'What should Company X do to improve the cleaning processes within the mixing and capsuling department, with the goal of achieving one standard of cleanliness and department-wide familiarity of this standard?' can be answered. The first two research questions are answered in Chapter 2.

1. What does the current situation in the capsuling and mixing department look like?

We will conduct an exploratory research as to what the current process looks like. We will provide process maps and explain how the department works.

2. What hazards currently lie in the capsuling and mixing department, and what are the factors of these hazards according to the Kinney and Wiruth method?

We will assess the cleaning and cleanliness risks within the capsuling and mixing department. We will define all important and relevant hazards. These hazards all need three factors for risk assessment to compute the total risk score according to the Kinney and Wiruth method. These factors are the factor for possible consequence, the likelihood factor and the exposure factor. We will explain how to find these factors for each hazard.

The next three research questions are answered in Chapter 3.

3. What problematic situations influence the hazards found?

Since the hazards are not concrete actions, and therefore cannot be easily or directly influenced, we will define problematic situations that influence the hazards that are found. The problematic situations are found through exploratory observations and conversations with operators and management. By looking at the situation from several angles we will define problematic situations that are measurable and have a high influence on the hazard that we defined earlier.

4. What KPIs are needed to assess the problematic situations?

We will define KPIs for each problematic situation, to quantify the problematic situations. In this way, the data can be converted into KPIs that can be used for the risk model.

5. What data needs to be collected, how will this be collected and what are the data results?

We will explain which data needs to be collected and why this data needs to be collected. The method of data collection will be explained and will be in line with the data collection methods mentioned in Section 1.3. The data will be summarized into the KPI values and this is shown.

The next two research questions are answered in Chapter 4.

6. **How can the risk scores be computed from the KPI values?**

We will explain how the risk scores translate into the likelihood factors in the Kinney and Wiruth risk method. With careful assessment and deliberation with all parties involved, an educated estimation is made of what KPI value translates to which likelihood factor. This, together with the exposure factor and factor for possible consequence determined earlier, computes the total risk score.

7. **What conclusions can we draw from the determined risk scores?**

We draw conclusions about which practices pose the most risk for Company X, in terms of hygiene and cleanliness.

The following research question is answered in Chapter 5.

8. **How can a sensitivity analysis model be set up to assess the influence of the problematic situations on the risk levels?**

We set up a sensitivity analysis in order to see how the KPIs influence the risk factors. Intervals of possible KPI values are used to see what KPI level gives which risk factor. This shows how the KPI levels can improve and what KPI improvements are worth the improvement.

The final research question is answered in Chapter 6.

9. **What are solutions to close the gap between the current situation and the desired level of cleanliness, cleaning method visibility and cleaning times, and how can these solutions be implemented?**

From all the data collected, the risk analysis and the sensitivity analysis, conclusions are drawn. We prioritize between problems since we know the most influential and hazardous problems now. Both long term and short term solutions and implementation strategies are required.

1.5. Conclusion

This research was motivated by the risk of contamination within the capsuling and mixing department, and by the IFS certification which requires solid cleaning processes. Currently, there is ambiguity of the cleaning practices and the cleanliness standards in the department. Therefore, the following research goals are established:

- The degree of variation of cleanliness standards amongst employees are known.
- There is one standard of cleanliness which is documented and therefore visible and familiar for everyone.
- The points and steps where the cleaning does not happen adequately (often), so where the cleaning deviates from the standard, are known.

When these goals are reached, the main research question of this thesis will be answered:

What should Company X do to improve the cleaning processes within the mixing and capsuling department, with the goal of achieving one standard of cleanliness and department-wide familiarity of this standard?

In order to assess the problems within the department, first an exploratory research is done by observation and unstructured interviews. Then, the Kinney and Wiruth risk analysis method is applied in order to identify and quantify the risks within the department. Lastly, we conduct a sensitivity analysis to determine which problematic situations can be solved in which way.

We will draw conclusions and invent adequate solutions. The solutions will be mostly practical and based on the most important conclusions of the risk analysis and the mathematical experiments. With knowledge from the department and consultation with management and operators, feasible solutions for communication and transparency problems are developed.

The result will be a thorough analysis of the cleaning practices and cleanliness within the capsuling and mixing department of Company X, and a list of useful solutions that will help Company X to maintain an efficient and safe production.

2. Orientation

In this chapter we will give some more in-depth information about the capsuling and mixing department of Company X. The goal of this chapter is to explain more about the capsuling and mixing department and to find critical hazards within this department. The hazards we will find concern the cleaning, cleaning practices and cleanliness. Section 2.1 answers the research question *What does the current situation in the capsuling and mixing department look like?* Section 2.2 answers the research question *What hazards currently lie in the capsuling and mixing department, and what are the factors of these hazards according to the Kinney and Wiruth method?*

2.1. The department

This thesis focuses on the capsuling and mixing department of Company X. To understand where the problems with the cleaning processes lie, it is important to gain understanding about all the processes involved in this department. The main processes of the capsuling and mixing are described in Figures 2.1 and 2.2. A simplified map of the capsuling department and the hallways around it is shown in Figure 2.3.

In order to capsule a powder, mixing has to be done first. The mixing usually consists of mixing several ingredients and some additives. The powders needed are delivered to the mixing cabins by the warehouse. The process starts when all raw materials are already in the mixing cabin. The products are scooped into separate bags and weighed up to the right amount, which can be found on the work form. When one ingredient is fully weighed and stowed away, the scoop is cleaned and dried. Then, the following ingredient is scooped and weighed. When all ingredients are scooped and weighed, an authorised person checks the weights and the ingredients are emptied into a mixing vat or the large mixer, depending on how large the order is. After mixing, the vat is brought to the designated capsuling cabin and the mixing cabin is cleaned. The process is visualised in Figure 2.1.

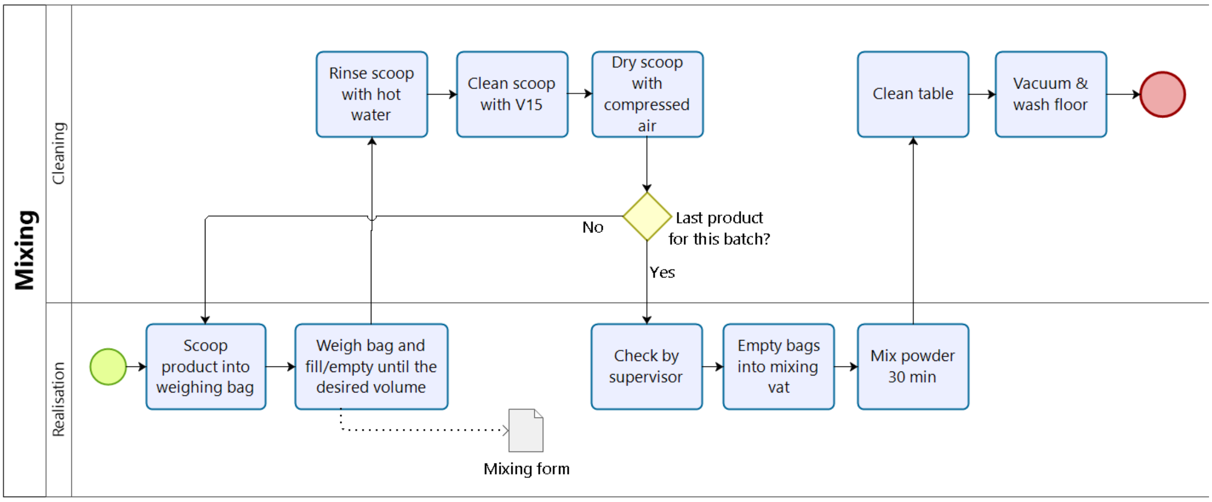

Figure 2.1 Mixing process

After the mixing, the powder is brought to the designated capsuling room. The powder is put into a funnel that guides it through the machine. Also, the adequate empty capsules are put into the machine. The machine distributes the powder across a disc that has small cylindrical sleeves. The pins in the machine are aligned with these sleeves and they press the powder. At one end of the disc, the powder transfers to another sleeve. This sleeve contains the bottoms of the capsules. The capsules are sucked into theses sleeves first and where the two discs come together, the powder is pressed into the bottom of the capsule. The disc then rotates to close the capsules with the top half. The capsules are blown out of the machine into the rocket. The rocket has bristles and polishes the capsules. The finished capsules exit the rocket into a vat lined with a plastic bag. The plastic bag is closed and boxed in the hallway. When all boxes for the work form are done, the machine, parts and cabin are cleaned. This process is visualised in Figure 2.2.

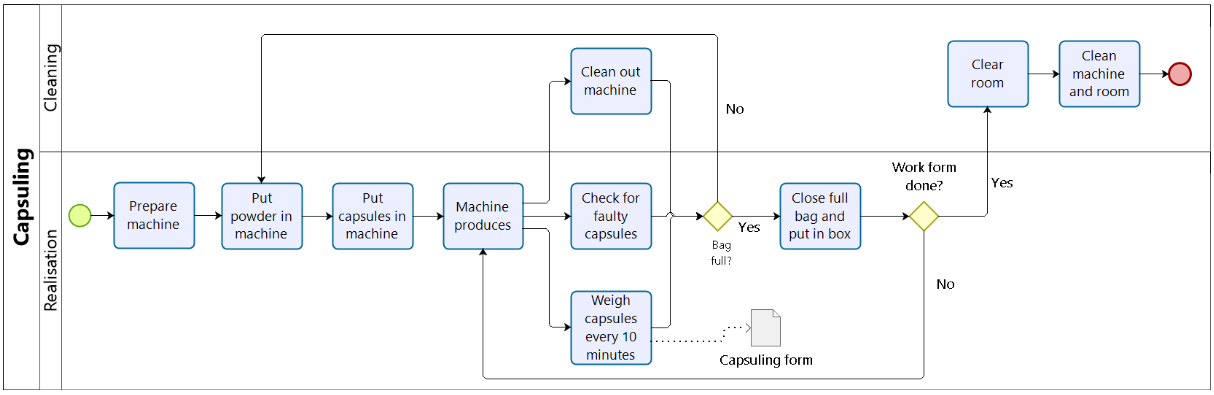

Figure 2.2 Capsuling process

Figure 2.3 shows a simplified map of the capsuling department and the hallways. The reason the hallways are shown is to show where the two cleaning stations are positioned. Cleaning happens mostly in the capsuling department. The parts that can be cleaned in the dishwasher are cleaned in the dishwasher in the hallway. The dishwasher and accompanying cleaning counter are across the general hallway.

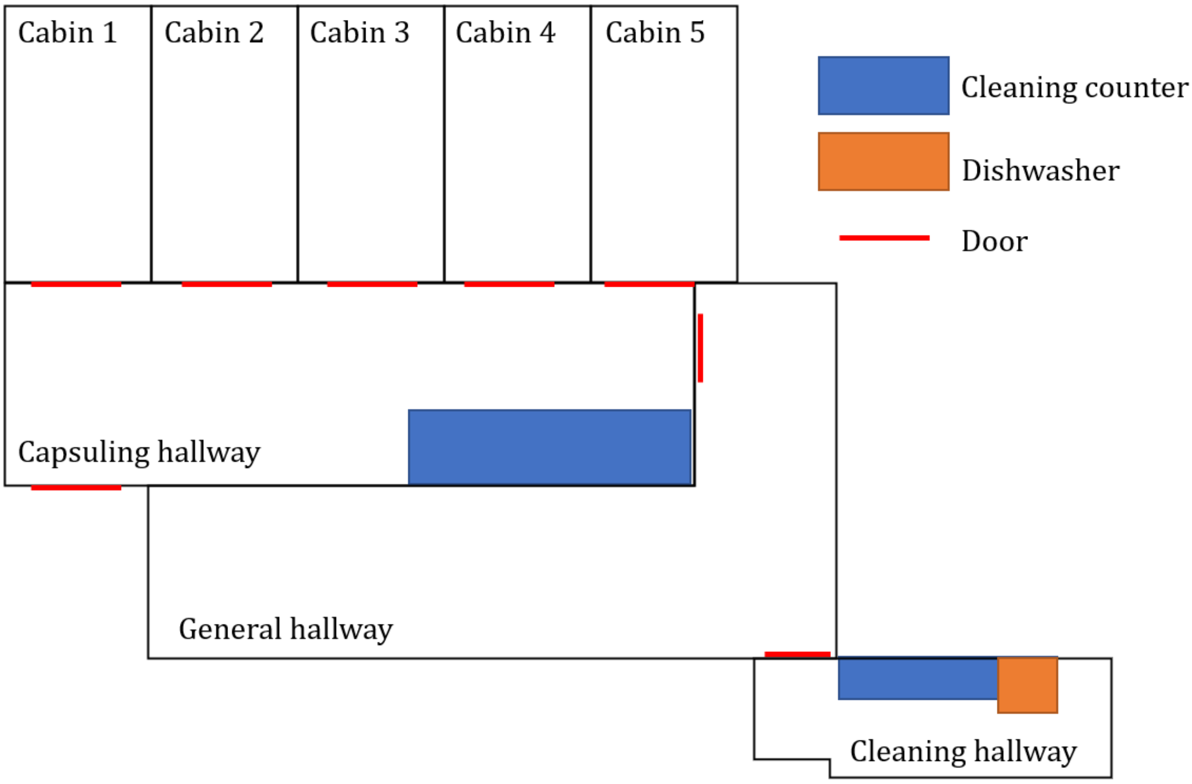

Figure 2.3 Simplified map of the capsuling department and cleaning stations

2.2. Hazards and risk assessment explanation

This section explains the hazards we will focus on in this thesis. Like many manufacturers, Company X has an elaborate quality manual including risk assessment of the production. After careful consideration of all the risk steps we decided that for this thesis, seven points from this already existing risk analysis manual are important. We will refer to this already existing quality manual as 'the manual' from here on.

The seven points from the manual we chose to use all concern contamination, whether it is cross-contamination from different products or contamination from elsewhere. The problematic situations can be directly linked to one or several of these points. In the manual, the points are scored on severity and likelihood. Company X uses a very similar scale for scoring as in the Kinney and Wiruth method. Only the exposure factor is missing. In this chapter, we will define the exposure factor and factor for possible consequence. The factor for likelihood requires additional analysis and will be explained further in Chapter 4.

2.2.1. Factor for possible consequence

We decide to directly adopt the values of 'severity' from the manual as the factors for possible consequence in this research since Company X has assessed these carefully with a consultancy agency. The severity of a possible consequence hardly changes over time. An opinion of how severe an event is can change, but this hardly happens, especially when the manual is carefully constructed with all parties involved.

The hazards with their factors for possible consequence, or 'severity scores' as indicated in the manual, can be found in Table 2.4. The numeric values are not from the manual. However, since the factor descriptions are practically equal to the factors from the Kinney and Wiruth method, we decide to adopt the corresponding numeric values from the Kinney and Wiruth method. An elaborate explanation of these values can be found in Section 1.3.

Table 2.4 Production hygiene hazards as assessed by Company X – Severity scores

Hazard number	Hazard	Factor for possible consequence (from the manual)	Value
A	A hair gets into the product	Noticeable	1
B	Allergen transfers from person eating in canteen	Disaster	40
C	Contamination through polluted clothing	Important	3
D	Contamination with previous or other product	Serious	7
E	Contamination with allergens from previous or other product	Very serious	15
F	Contamination from pallets	Serious	7
G	Contamination with wood splinters from pallets	Very serious	15

2.2.2. Factor for likelihood of a hazardous event

The factor for likelihood of a hazardous event is the chance of the event happening, as also described in Chapter 1. This is the most important factor in this research, since this is the factor that is the most unknown. In Table 2.5, the likelihood scores as assessed in the manual from Company X are shown. We provide this table to give an indication of how Company X assessed the likelihood scores.

Table 2.5 Production hygiene hazards as assessed by Company X – Likelihood scores

Number	Likelihood factor (according to the manual)	Value	Remarks (from the manual)
A	Practically impossible	0.2	There have never been any complaints

B	Virtually impossible	0.1	No risk seen by the Allergen Consultancy
C	Practically impossible	0.2	Daily clean clothes, not pathogen sensitive
D	Only remotely possible	1	Seems to happen once a year, and it is possible when the machine is not cleaned well
E	Conceivable but very unlikely	0.5	This gets checked with the cleaning check
F	Practically impossible	0.2	No direct contact with the pallets
G	Practically impossible	0.2	No direct contact with the pallets. Also, the splinter would not get into the product.

In Section 2.2.1 we state we directly adopt the 'severity' values from the manual as the factors for possible consequence for the hazards chosen. We do not choose to do this for the factor for likelihood. This is because the likelihood can differ greatly over time. Company X specifically expressed concern about the risks of (cross-)contamination. The current factors of likelihood do not reflect the company's concern about the cleanliness of the department. We will generate the current factors for likelihood for the hazards defined in Chapter 4. This will be done through structured observations and thorough analysis.

2.2.3. Exposure factor

The exposure factor describes how often a potentially hazardous situation takes place. We want to determine this for each hazard. Computing the exposure factors is simple since it is a matter of how often the hazard has the possibility to occur. For each hazard, we will describe the situation and assign a factor according to the Kinney and Wiruth method. Table 2.6 shows these factors.

Table 2.6 Exposure factor values

Exposure factor	Weight
Continuous	10
Frequent (daily)	6
Occasional (weekly)	3
Unusual (monthly)	2
Rare (a few per year)	1
Very rare (yearly)	0.5

The exposure factor is the time a potentially hazardous event takes place. Within the production of the capsuling and mixing department, many of the hazards are continuously possible. Only when there is no production, the hazards are not possible. Therefore, we define continuous within production as the total production time, so from 7 AM to 10 PM, so 15 hours per day in stead of 24 hours. Two of the hazards are not continuously possible because they concern allergens, and allergens are only processed approximately weekly. This gives the results in Table 2.7.

Table 2.7 Exposure factor for the hazards

Hazard number	Hazard	Exposure factor	Value
A	A hair gets into the product	Continuous	10
B	Allergen transfers from person eating in canteen	Unusual	2

C	Contamination through polluted clothing	Continuous	10
D	Contamination with previous or other product	Continuous	10
E	Contamination with allergens from previous or other product	Occasional	3
F	Contamination from pallets	Continuous	10
G	Contamination with wood splinters from pallets	Continuous	10

We see from Table 2.7 that most hazards have the maximum exposure factor, but two do not. The first is the allergens transferring from a person eating in the canteen onto a product. We estimate that a person eats something with listed allergens about once a week. Hence, the score of 3. The second is contamination with allergens from previous or other products. Allergen or risk products are only produced in the capsuling and mixing department about once a week. So also here, an exposure factor value of 3 counts.

2.3. Conclusion

This chapter provides a clear view of what the capsuling and mixing department currently looks like. Seven cleaning and cleanliness hazards are found and scored on two of the three parameters of the Kinney and Wiruth risk analysis method. These scores will be used in the upcoming chapters, to compute the risk scores for each hazard. The third parameter of the Kinney and Wiruth risk analysis method will be defined thoroughly in the next two chapters.

3. Problematic situations

Now that we have background knowledge of the department and the risk analysis method we will use, we can start to identify problems. After identifying the most important problems within the cleaning situation of the capsuling and mixing department, we will investigate the ideal situation of these problematic situations. This can be done through consultation with operators and management. The reason that we measure problematic situations and not the hazards in this chapter, is that it is impossible to measure the actual hazards within the scope of this research. We need data to find the likelihood factor of each of the hazards from Chapter 2, but measuring the hazards is hardly possible since the information that would be needed is not available. Therefore, we define problematic situations that all closely relate to at least one of the hazards from Chapter 2, and are measurable within the scope of these research.

Section 3.1 answers the research questions *What problematic situations influence the hazards found?* and *What KPIs are needed to assess the problematic situations?* Sections 3.2, 3.3 and 3.4 answer the research question *What data needs to be collected, how will this be collected and what are the data results?*

3.1. Problems

By working alongside the operators, observing all operations and cleaning processes, and conducting unstructured interviews with both operators and management, key problems were found. These problems concern practices within the capsuling department that all have to do with cleaning and/or cleanliness. We iterated a list of problems with the goal of establishing a list of all important problematic situations that both the managers and the operators agreed on. The result is the following list of ten problematic situations.

1. *The degree of structured control*

The first problematic situation is the degree of control. We notice that the cleanliness of the cleaned machine parts and cabin sections is hardly ever checked. Often, parts are checked for cleanliness only when they are used again. When the parts are not clean, the operator that sees this can never know whose responsibility this was, and therefore it is hard to solve. Also, the operator has to clean it again which costs valuable time. Therefore, control during the cleaning is desired. We have not observed structured control, meaning that sometimes, a colleague might check if a part is clean by coincidence, but there is no schedule or agreement for this.

2. *The degree of simultaneous cleaning*

Simultaneous cleaning is the cleaning of parts and appliances of different cabins (therefore, different product residue on the parts) at the same station, risking cross-contamination during cleaning. Simultaneous cleaning is a likely issue to occur, since there are only two cleaning stations, while there are three capsuling cabins and two mixing cabins. Also, one of the two cleaning stations has a dishwasher, and therefore to clean the parts and appliances of one cabin, often both cleaning stations are used. Eventually, every product has to be equally clean so at first sight simultaneous cleaning should not matter that much. However, every product is different and some products are harder to clean than others. When one method and cleaning agent is used for one cabin, this might work for those parts and appliances, but the product from the other cabin could be more persistent and harder to remove. When these parts and appliances are cleaned simultaneously, residue could go unnoticed easily.

3. *The intensity of switching to other cabins*

Capsuling is a complex operation and not every operator has the same knowledge. Therefore, operators need to help each other when there is a problem. Although helping each other is encouraged, it does pose hygienic threats. When operators switch from cabin to cabin, there is a risk of cross-contamination. Handling two different machines can cause powder to transfer from the gloves or clothes.

4. The time a door is open

We have observed open doors in the capsuling and mixing department. Opening cabin doors is necessary when helping others, discarding waste, putting away a finished product and taking breaks. However, at all times, the door should directly be closed after passing through. The result of neglecting to do so could be that powder from the cabin gets into the hallway and contaminates clean products. Also, outside air could get into the cabin and therefore contaminate the product.

5. The method of storing parts

Even when cleaning practices are adequate, parts and appliances can get contaminated. This happens when the parts and appliances are stored incorrectly. Powder inevitably gets into the air and descends onto everything in the cabin and hallway. Some parts are stored inside a plastic bag to prevent contamination, but many parts are not. This could go unnoticed, highly risking cross-contamination. Additionally, if it is noticed, the cross-contamination risk is much smaller but the extra cleaning costs unnecessary time.

6. The method of cleaning for the hallway

The hallway of the capsuling department is often visibly contaminated with several powders. Mostly yellow residue is visible. This shows that there is a significant amount of powder in the air, that can contaminate clean parts. Also, it is visually unappealing and slightly unprofessional. The method of cleaning is ambiguous. There is hardly any standard and operators clean the hallway in different ways.

7. The degree of personal coverage

Personal coverage is important for the health of operators and for the purity of the product. It is noticed that some forms of personal coverage are not always worn. This endangers the product and the operators.

8. The method of cleaning for detachable parts

The detachable parts are parts of the machine that can be removed and other appliances, like scoops, sieves, bins and brushes. These parts are cleaned in the dishwasher or in the sink. Contamination is possible when the cleaning does not happen adequately. Inadequate cleaning seems to happen regularly. There is no consensus about how the parts should be cleaned. Different operators clean in different ways.

9. The method of cleaning for undetachable parts

The undetachable parts of the machine are the parts of the machine that cannot be removed and therefore have to be cleaned inside the cabin. Improper cleaning seems to happen regularly. There is no consensus about how the machine should be cleaned. Different operators clean in different ways.

10. The method of cleaning for the cabins

The production cabin is to be cleaned after each batch to prevent cross-contamination. Improper cleaning seems to happen regularly. There is no consensus about how the cabins should be cleaned. Different operators clean in different ways.

3.2. Ideal situation

The problematic situations described in Section 3.1 all have some form of an ideal situation. We will call this the norm level. The norm levels are described in the same sequence as the problematic situations. Some have a reference to an appendix, since the norm levels can be very specific.

1. *The degree of structured control*

There should be some form of control of the cleaning. Structured control means that the control is arranged beforehand. This can be done in several ways but the result should be that every part, machine and cabin is checked for cleanliness by someone other than the operator who cleaned it.

2. *The degree of simultaneous cleaning*

No parts should be cleaned simultaneously. Simultaneous cleaning is when parts from different cabins, so with product residue from different batches, are cleaned at the same station at the same time.

3. *The intensity of switching to other cabins*

An operator is assigned to one cabin each shift. Operators should only switch to rooms when this is necessary, like when the operators from the other cabin really cannot solve a problem themselves. When operators need to switch to another cabin, shoe protectors and gloves need to be changed, and changed again when returning to their original cabin.

4. *The time a door is left open*

Doors should only be opened when necessary and closed behind the operator at all times. A door left open is not acceptable. Necessary moments to open a door are to help another operator, to take a scheduled break and to store away a finished product.

5. *The method of storing parts*

Parts need to be stored in a way such that they cannot be contaminated with powder from the air. The preferred way to do this is storing parts in clean, closed cupboards outside of the capsuling and mixing department. When this is not possible and a part has to be stored within the capsuling department where there is a lot of powder in the air, the part has to be packed in a plastic bag to prevent contamination from the powder in the air.

6. *The method of cleaning for the hallway*

There are eight steps that have to be taken at the end of each shift, to clean the hallway, as to preventing cross-contamination and keeping the hallway looking professional.

1. All dishes should be done
2. All parts are stored away either to the cabin where they will soon be used or their righteous place in one of the cupboards
3. All towels are placed in the laundry bins
4. The sink and countertop are empty, cleaned with cleaning agent 'V15' and disinfected with disinfectant 'Nedalco'.
5. Garbage is disposed of correctly
6. Tools and forms are stored away
7. The floor is cleaned with the scrubbing machine
8. The corners of the floor are cleaned with a towel and/or sponge

7. *The degree of personal coverage*

There are several forms of personal coverage. Some are always worn and some are worn in some cases. Here follows a list of the personal coverage forms to be worn and when they have to be worn.

1. A hair cover is always worn in production.
2. Operators never wear their own clothing, only production clothing provided by Company X.
3. Shoe covers are worn at all times in production and replaced when switching between rooms and/or departments.

4. Beard and arm hair covers are worn in production when needed. These covers are needed with heavy arm hair and with beards.
5. Orange gloves are worn at all times at the capsuling and mixing department. When the glove is contaminated with another product, or is dirty, ripped or broken, the gloves are replaced immediately.
6. A full face cover is always worn while producing in the capsuling and mixing department.
7. Dust masks are worn when visiting a capsuling or mixing cabin, or shortly helping in a capsuling or mixing cabin.
8. Earplugs are worn in the cabin whilst producing.

8. The method of cleaning for detachable parts

Detachable parts generally have to be cleaned at the sink or in the dishwasher, and disinfected with disinfectant 'Nedalco'. However, different parts are cleaned in different manners. We have set up a method of cleaning for each detachable part. This can be found in Appendix A.

9. The method of cleaning for undetachable parts

Undetachable parts generally have to be cleaned with small amounts of hot water, soap and disinfected with disinfectant 'Nedalco'. However, different parts are cleaned in different manners. We have set up a method of cleaning for each undetachable part. This can be found in Appendix A.

10. The method of cleaning for the cabins

The cleaning of the cabins consist of three or four parts. The floor, the walls, the windows and the ceiling. These are cleaned in different ways, found in Appendix A.

3.3. Data collection methods

In this section, we will explain the data that needs to be collected, the methods of collecting data, the data collected and the way this data will be used for the upcoming risk analysis. In order to collect the correct data, it is important to understand what we want to measure exactly. For this research, the goal is to find out where the risks lie within the cleaning process, measure these risks and to come up with solutions. In Chapter 2 we described some problematic situations of the cleaning. We want to measure these situations in order to assess the risks further on in this research. It is important to collect data that is as quantifiable as possible so that the risk assessment is as thorough and accurate as possible. Therefore, we made an observation form that is directly in line with the problematic cleaning situations as seen in Sections 3.1 and 3.2. This observation form is specific and will allow us to observe in a structured manner. It can be found in Appendix A. An explanation of each observation unit follows. The percentages are all designed in such a way that the value of 100% signifies the best possible value, and 0% signifies the worst possible value.

1. The degree of structured control

To assess the level of structured control, we will write down the time intervals when cleaning and paying attention to the structured control. We keep tally of the times another operator, the quality manager or the production manager is deliberately called or asked to check the cleanliness and/or cleaning method of one or several parts. The result will be a percentage of parts not structurally checked, of the total parts cleaned in that time interval. KPI_1 measures the degree of structured control.

$$KPI_1 = \frac{Number\ of\ parts\ controlled\ on\ cleaning}{Number\ of\ parts\ observed} \times 100\%$$

2. The degree of simultaneous cleaning

Measuring the degree of simultaneous cleaning is simple. When observing the cleaning of parts and appliances, we note whether parts from only one cabin are cleaned, so with one type of residue, or from two or three cabins. This results in a percentage of non-simultaneous cleaning of the total times parts and appliances are cleaned.

$$KPI_2 = \left(1 - \frac{Number\ of\ times\ batches\ of\ parts\ are\ cleaned\ simultaneously}{Number\ of\ times\ a\ batch\ of\ parts\ is\ cleaned\ in\ total}\right) \times\ 100\%$$

3. The intensity of switching to other cabins

We measure the intensity of switching to other cabins by observing one operator at a time for a certain amount of time. We will note when an operator switches to another cabin. Changing of gloves is also important, but this will be assessed at the situation 'The degree of personal coverage'. The result is a number of switches during a certain amount of time. From this, we get a number of switches per hour. The KPI will be a percentage of how many switches there are with respect to the 'maximum' amount of switches per hour. We set the maximum switches per hour to 3, since the maximum we observed was 2.5 switches per hour. We believe that operators will not switch more than 3 times per hour, realistically. A low percentage signifies that an operator switches the most times and a high percentage signifies that an operator switches the least times, (close to) zero times.

$$KPI_3 = \left(1 - \frac{Number\ of\ switches\ to\ another\ room}{Number\ of\ hours\ the\ operator\ is\ observed * 3}\right) \times\ 100\%$$

4. The time a door is left open

In the orientation phase we noticed that doors are often left open. We want to measure the time intervals where this happens by observing an operator a certain amount of time and noting the time a door opens and closes again. This does not concern a time when the door is closed directly behind the operator. In this way, the result is a percentage of time the door was closed, of the total time measured.

$$KPI_4 = \left(1 - \frac{Time\ a\ door\ is\ open}{Total\ time\ the\ door\ is\ observed}\right) \times\ 100\%$$

5. The method of storing parts

In the observation phase, mostly the discs in the cupboard in the hallway were seen as a problem. Other parts are stored elsewhere. Discs are used for all capsuling operations and come in direct contact with the product. We will therefore measure the times when the discs in the cupboard are covered with a plastic bag, to prevent contamination from the air. We will assess this three times per shift, at the beginning, middle and end of the shift to get an accurate depiction of how the parts are stored. We will note down the total number of parts that are covered in a bag, and the total number of parts in the cupboard at that time. This results in a percentage of total observed discs stored in a bag, with respect to the total number of discs observed.

$$KPI_5 = \frac{The\ number\ of\ parts\ that\ are\ bagged}{The\ total\ number\ of\ parts\ in\ the\ closet\ observed} \times\ 100\%$$

6. The method of cleaning for the hallway

It is hard to measure how clean something is. Swab and air tests do exist but are expensive and we can only draw a very limited conclusion from them. Therefore, we will adhere to a few standards for the hallway at the end of each shift. The hallway is inevitably contaminated during production. However, cross-contamination can be limited when the hallway is sufficiently cleaned in between shifts. We defined 8 standards that have to be met after each shift. We will observe whether this has been done after each shift. The result is a percentage of standards met with respect to the total times the standards are observed.

$$KPI_6 = \frac{Number\ of\ standards\ met}{8} \times 100\%$$

7. The degree of personal coverage

We want to measure how often each type of personal coverage is worn and how often it is not worn. We will observe operators when they are producing and note down what they are and are not wearing. The result is a percentage of times that a certain personal coverage was not worn, with respect to the total times personal coverage should have been worn.

$$KPI_7 = \frac{Number\ of\ times\ a\ certain\ coverage\ is\ worn}{Total\ times\ that\ coverage\ is\ observed} \times 100\%$$

8. The method of cleaning for detachable parts

It is hard to measure whether a part is actually clean. Swabs exist but are expensive, and the entire part then has to be swabbed. Therefore, we set up a cleaning norm. This is a list of all parts and appliances used within capsuling and mixing. When following these norms, parts and appliances should generally be 100% clean. Therefore, we will measure the method of cleaning by measuring the steps followed. We will observe the cleaning of the parts and appliances and fill in a '1' when a step is followed and a '0' when a step is skipped. A '0.5' can be filled in when a step is partially skipped or when another method is used (for example, a different cleaning agent). In this way, the result will be a percentage of steps adequately followed.

$$KPI_8 = \frac{Sum\ of\ scores}{Number\ of\ detachable\ parts\ scored} \times 100\%$$

9. The method of cleaning for undetachable parts

The scoring works the same as with the method of cleaning the detachable parts. There are several aspects to cleaning the undetachable parts of the machine and these require certain steps. The steps are measured with a '1', '0' or '0.5'. The result is a percentage of steps that are adequately followed.

$$KPI_9 = \frac{Sum\ of\ scores}{Number\ of\ undetachable\ parts\ scored} \times 100\%$$

10. The method of cleaning for the cabins

The cleaning of the cabins is scored in the same way as the cleaning of the parts, with a '1', '0' or '0,5'.

$$KPI_{10} = \frac{Sum\ of\ scores}{Number\ of\ sections\ scored} \times 100\%$$

The data will be collected through observing the operators within the capsuling and mixing department. We use observation forms that can be found in Appendix B. These observation forms measure what we want to find to calculate the KPIs. The results from the observation forms will tell us the cleaning times and how well the cleaning practices adhere to the norm. We assume the KPIs have reliable values that we can base the risk analysis on since we got a representative sample.

3.4. KPI results

We collected data over a course of two months, measuring production 10 shifts and one partial shift. This data is the input for the KPI formulas as stated in Section 3.3. Table 3.1 shows the KPI values of all problematic situations.

Table 3.1 KPI value results

KPI number	Problematic situation	KPI value
1	The degree of structured control	9.8%
2	The degree of simultaneous cleaning	91.7%
3	The intensity of switching to other cabins	54.4%
4	The time a door is left open	81.2%
5	The method of storing parts	14.5%
6	The method of cleaning for the hallway	29.0%
7	The degree of personal coverage	69.1%
8	The method of cleaning for detachable parts	70.0%
9	The method of cleaning for undetachable parts	64.6%
10	The method of cleaning for the cabins	86.1%

In Table 3.1, we see that problematic situation 2, the degree of simultaneous cleaning, performs best with a value of 91.7%. This means that only about 1 out of 10 times, parts from different orders are cleaned simultaneously. Problematic situation 1, the degree of structured control, has the lowest value, which is 9.8%. This signifies that only about 10% of parts are checked after cleaning, which can prevent unclean parts from being used.

These values give an image of what the situation is like currently. When a value is 100%, this means the problematic situation is at its optimal value, which is the ideal situation as defined in Section 3.2. When a value is 0%, it means the problematic situation is at a minimal value. To draw conclusions about the risks of the problematic situations, we need to know how the problematic situations influence the hazards exactly. This is discovered in the next chapter.

3.5. Conclusion

We identified ten main problems concerning the cleaning processes and the cleanliness of the mixing and capsuling department, all related to at least one of the hazards from Chapter 2. These problems have been given a norm value, which show what the situation should be like. We assigned KPIs to each problematic situation, corresponding with the ideal situation of that problematic situation. The results of the data are summarized into these KPIs. The KPI values will be used to compute the likelihood factors for the risk analysis.

4. Risk analysis and results

In this chapter, the risk analysis will be explained and conducted. The goal of this chapter is to assess what problems have the most impact on the hygiene level of the capsuling and mixing department. Sections 4.1 answers the research question *How can the risk scores be computed from the KPI values?* Sections 4.2 and 4.3 answer the research question *What conclusions can we draw from the determined risk scores?*

4.1. Relation of KPIs to problematic situations

To draw conclusions about what needs to be improved within the capsuling and mixing department in terms of cleaning, we have to combine the hazards defined in Chapter 2 with the problematic situations defined in Chapter 3. As explained in Chapter 3, we combine the hazards with the problematic situations because actually measuring hazards is hardly possible. For example, measuring whether a beard hair transfers to a product, or an allergen transfers to a different product is hard. Swab tests to test for contamination do exist but are expensive and could only be used by sampling, since swabbing all products and all surfaces is practically impossible. On the other hand, stating that a problematic situation is a hazard is also not favourable. It is hard to say what effect a problematic situation has since the consequences are not directly clear. For these reasons, we use a combination of pre-defined hazards from the manual of Company X and a list of problematic situations defined in Chapter 3 of this thesis. The ten problematic situations are all linked to one or more of the seven hazards. These connections can be seen in Table 4.1, and Table 4.2 shows what hazard number belongs to which hazard.

Table 4.1. Problematic situations linked to pre-defined hazards

Problematic situation number	Problematic situation	Hazard number
1	The degree of structured control	D, E
2	The degree of simultaneous cleaning	D, E
3	The intensity of switching to other cabins	D, E
4	The time a door is left open	D, E
5	The method of storing parts	D, E
6	The method of cleaning for the hallway	D, E
7	The degree of personal coverage	A, B, C, D, E, F, G
8	The method of cleaning for detachable parts	D, E
9	The method of cleaning for undetachable parts	D, E
10	The method of cleaning for the cabins	D, E

Table 4.2 shows the hazards again, to clarify what these are.

Table 4.2 Hazard numbers and the corresponding hazard

Hazard number	Hazard
A	A hair gets into the product
B	Allergen transfers from person eating in canteen
C	Contamination through polluted clothing
D	Contamination with previous or other product
E	Contamination with allergens from previous or other product

F	Contamination from pallets
G	Contamination with wood splinters from pallets

The connections between the problematic situations and the hazards are important because they show what hazard is influenced by which problematic situation. Every problematic situation influences multiple hazards, mostly hazards D and E. For example, problematic situation 8 is the degree of cleaning of detachable parts. This problematic situation influences hazard D, the contamination of parts from previous products, and also hazard E, the contamination with allergens from previous products. However, problematic situation 8 does not, or does hardly, influence the other hazards. Contamination with a hair or polluted clothing, for example, happens during production and is (almost) never a product of insufficient cleaning.

The goal is to know the risk for each individual hazard, which is the product of a likelihood factor (L), factor for possible consequence (C) and exposure factor (E). We know the factor for possible consequence and the exposure factor, but we still need to determine the likelihood factor for each individual hazard. Since all problematic situations influence at least two hazards, we need to split the problematic situations in some way. This is possible, because we have the information we need. For example, we know for each observation whether it concerns an risk (allergen) product or a non-risk (allergen) product. Also, for problematic situation 7, we can distinguish between the part of problematic situation 7 that influences hazard A, or hazard B, et cetera. For example, since hazard A is the hazard that a human hair gets into the product, only the hair coverage part of problematic situation 7 is relevant in that case. This type of split can be made for each combination of KPI and hazard, so that we have an accurate depiction of which exact KPI influences which hazard in what way.

Table 4.3 shows these divisions. We work with combinations between hazards and problematic situations from here on, and therefore these have been given a code consisting of both numerical and alphabetical values, corresponding with their hazard and problematic situation number. There are three types of codes. The first is the simple code, used for problematic situations 2 until 7 and 10. For example, code D2 stands for the combination of hazard D (contamination with previous or other product) and problematic situation 2 (the degree of simultaneous cleaning), creating the sub-problematic situation “the degree of simultaneous cleaning not including risk (allergen) batches”.

The second type of code is the code for problematic situations 8 and 9. For example, code D8X stands for the combination of hazard D and problematic situation 8 (the method of cleaning for detachable parts). The X stands for the parts within this problematic situation that are in direct contact with the product. The other option is a Y, this indicates that the parts are not in direct contact with the product. This distinction is made because the cleanliness of a part that is in direct contact with the product has more impact on the possible cross-contamination than the cleanliness of a part that is not in direct contact with the product.

The third type of code is the code for problematic situation 1, the degree of structured control. This problematic situation influences hazards D and E in combination with problematic situations 8, 9 and 10, the methods of cleaning. This is because the control and the method of cleaning together have an influence on hazard D or E. They cannot be seen separately, because when the cleaning is sub-optimal but the control is good, the control will ensure that the part or cabin section is cleaned again, properly. Therefore, for each sub-problematic situation of hazards 8, 9 and 10 a sub-problematic situation for the control of these situations is made. For example, D19Y is the control of the method of cleaning for undetachable parts not in direct contact with product, not including risk (allergen) batches. D means that this sub-problematic situation influences hazard D, 1 means that it concerns the control, 9 means that it concerns undetachable parts and Y means that it concerns parts not in direct contact with the product.

The codes for the sub-problematic situations, as seen in Table 4.3, will from here on be used to refer to its combination of sub problematic situation and a hazard.

Table 4.3. Problematic situations linked to the existing hazards

Problematic situation reference number	Problematic situation and sub-situation	Hazard number that is influenced
1	The degree of structured control	D, E
D18X	The degree of structured control for problematic sub-situation D8X	D
D18Y	The degree of structured control for problematic sub-situation D8Y	D
E18X	The degree of structured control for problematic sub-situation E8X	E
E18Y	The degree of structured control for problematic sub-situation E8Y	E
D19X	The degree of structured control for problematic sub-situation D9X	D
D19Y	The degree of structured control for problematic sub-situation D9Y	D
E19X	The degree of structured control for problematic sub-situation E9X	E
E19Y	The degree of structured control for problematic sub-situation E9Y	E
D110	The degree of structured control for problematic sub-situation D10	D
E110	The degree of structured control for problematic sub-situation E10	E
2	The degree of simultaneous cleaning	D, E
D2	The degree of simultaneous cleaning not including risk (allergen) batches	D
E2	The degree of simultaneous cleaning including risk (allergen) batches	E
3	The intensity of switching to other cabins	D, E
D3	The intensity of switching not including risk (allergen) batches	D
E3	The intensity of switching including risk (allergen) batches	E
4	The time a door is left open	D, E
D4	The time a door is left open not including risk (allergen) batches	D
E4	The time a door is left open including risk (allergen) batches	E
5	The method of storing parts	D, E
D5	The method of storing part not including risk (allergen) batches	D
E5	The method of storing part including risk (allergen) batches	E
6	The method of cleaning for the hallway	D, E

D6	The method of cleaning for the hallway not including risk (allergen) batches	D
E6	The method of cleaning for the hallway including risk (allergen) batches	E
7	The degree of personal coverage	A, B, C, D, E, F, G
A7	The degree of wearing hair covers	A
B7	The degree of wearing face covers	B
C7	The degree of wearing adequate clothing	C
D7	The degree of adequately wearing gloves not including risk (allergen) batches	D
E7	The degree of adequately wearing gloves including risk (allergen) batches	E
F7	The degree of adequately wearing gloves	F
G7	The degree of adequately wearing gloves	G
8	The method of cleaning for detachable parts	D, E
D8X	The method of cleaning for detachable parts in direct contact with product, not including risk (allergen) batches	D
D8Y	The method of cleaning for detachable parts not in direct contact with product, not including risk (allergen) batches	D
E8X	The method of cleaning for detachable parts in direct contact with product, including risk (allergen) batches	E
E8Y	The method of cleaning for detachable parts not in direct contact with product, including risk (allergen) batches	E
9	The method of cleaning for undetachable parts	D, E
D9X	The method of cleaning for undetachable parts in direct contact with product, not including risk (allergen) batches	D
D9Y	The method of cleaning for undetachable parts not in direct contact with product, not including risk (allergen) batches	D
E9X	The method of cleaning for undetachable parts in direct contact with product, including risk (allergen) batches	E
E9Y	The method of cleaning for undetachable parts not in direct contact with product, including risk (allergen) batches	E
10	The method of cleaning for the cabins	D, E
D10	The method of cleaning for the cabins, not including risk (allergen) batches	D
E10	The method of cleaning for the cabins, including risk (allergen) batches	E

The KPIs defined in Chapter 3 can be used to compute the values for the sub-KPIs as defined in Table 4.3. To compute these sub-KPI values, the input is specified, but the same formula for a sub-KPI is used as for its corresponding parent KPI. For example, the KPI for problem 4 is stated below.

$$KPI_4 = \left(1 - \frac{Time\ a\ door\ is\ open}{Total\ time\ the\ door\ is\ observed}\right) \times 100\%$$

To compute the sub KPI for E4, so for the part of problematic situation 'the time a door is open' that only causes hazard E, and not hazard D, we will only use the data from the times a risk product was produced, since hazard E concerns contamination from risk products. We do this because we want to know whether when different hazards are at risk, operators handle the situation in a different way. For example, it would be logical that allergen products are handled with more care than non-allergen products. This would naturally decrease the likelihood of contamination of a product with an allergen.

The KPI formula for sub KPI E4 would then be:

$$KPI_{E4} = (1 - \frac{Time\ a\ door\ is\ open\ only\ for\ measurements\ of\ risk\ batches}{Total\ time\ the\ door\ is\ observed\ during\ production\ of\ risk\ batches}) \times 100\%$$

This type of specification is also done for the other sub KPIs. The results of the KPIs and sub-KPIs are shown in Table 4.4.

Table 4.4 KPIs of sub problematic situations

Problematic situation reference code	KPI value
1	9.8%
D18X	2.9%
D18Y	3.9%
E18X	12.5%
E18Y	10.6%
D19X	33.3%
D19Y	21.4%
E19X	23.8%
E19Y	57.1%
D110	33.3%
E110	34.8%
2	91.7%
D2	88.9%
E2	100.0%
3	54.4%
D3	49.7%
E3	64.1%
4	81.2%
D4	78.8%
E4	84.9%
5	14.5%
D5	17.4%
E5	7.5%
6	29.0%
D6	40.9%
E6	17.0%
7	69.1%
A7	69.7%
B7	68.2%
C7	63.6%
D7	68.8%

E7	66.7%
F7	68.2%
G7	68.2%
8	70.0%
D8X	70.9%
D8Y	67.3%
E8X	72.8%
E8Y	70.7%
9	64.6%
D9X	88.9%
D9Y	56.5%
E9X	100.0%
E9Y	54.6%
10	86.1%
D10	95.8%
E10	66.7%

It is important to note that decomposing the KPIs in this way gives us fewer datapoints, which makes the results less accurate. However, within the scope of this research it is hardly possible to collect more data. The sub-KPIs do give an indication of what the situation is currently like which is already very useful. Also, it is advised to measure the KPIs more often in the future. This remark is further discussed in Chapter 7.

With the specified values of the sub-KPIs, we can compute the likelihood values for each sub-problematic situation. We need to know what the value of the sub-KPI means for the influence of that sub-problematic situation on the corresponding hazard. For example, a sub-KPI value for A7 of 69.7% means that the degree of wearing hair covers is fairly good. About two-thirds of the needed hair covers are worn, in general. We can convert this value into a likelihood factor. The likelihood factors as defined in the Kinney and Wiruth, also shown in Chapter 1, are shown in Table 4.5 again.

Table 4.5 Factor for likelihood of a hazardous event (Kinney and Wiruth)

Factor for likelihood of a hazardous event	Weight
Might well be expected	10
Quite possible	6
Unusual but possible	3
Only remotely possible	1
Conceivable but very unlikely	0.5
Practically impossible	0.2
Virtually impossible	0.1

For each sub-KPI value, we will assess what likelihood factor from the Kinney and Wiruth method belongs with this value. For example, for our example of the value 69.7 for A7, we say that the likelihood of a hair getting into a product, through the problematic situation that hair covers are or are not properly worn, is *conceivable but unlikely*. This means that A7 with a value of 69.7% has a likelihood factor of 0.5. This is an educated estimation, consulted with experienced operators and management. This group of employees have experience within the capsuling and mixing department of Company X and have an idea of what practice causes what hazard. Also, they have knowledge about complaints, and for this example we know that only once, a product was sent back because there was a hair in it.

We set up matrices with intervals of sub-KPI values to make the estimation of the likelihood factors more reliable. For each interval of KPI values, we assign a likelihood factor from Table 4.5. Estimating with a matrix is more reliable than estimating only based on the current KPI value, since the operator or manager filling in the table has to think about all the scenarios. The best and worst cases are filled in first, so that the person filling in the matrix knows between which values they are. Then, the remaining intervals are filled in. With this type of educated estimation, all the likelihood values were computed for each sub-KPI value. The matrix of likelihood factors for all sub-problematic situations except for situations 1, 8, 9 and 10 can be seen in Table 4.6.

Table 4.6 Likelihood factors assigned to each KPI – Hazard combination except problems 1, 8, 9 and 10

Code	0% - 10%	10% - 30%	30% - 50%	50% - 70%	70% - 90%	90% - 100%
A7	3	1	1	0.5	0.2	0.2
B7	3	1	1	1	0.2	0.2
C7	3	3	1	1	0.2	0.2
D2	10	6	6	3	0.2	0.1
D3	10	6	6	3	0.2	0.1
D4	6	6	6	3	1	0.2
D5	3	3	1	1	0.5	0.2
D6	1	0.5	0.2	0.1	0.1	0.1
D7	3	3	1	0.5	0.2	0.1
E2	6	6	3	1	0.5	0.2
E3	10	6	6	3	0.2	0.1
E4	6	6	6	3	0.2	0.1
E5	3	3	1	1	0.5	0.2
E6	1	0.5	0.2	0.1	0.1	0.1
E7	1	0.5	0.2	0.2	0.1	0.1
F7	1	1	0.5	0.2	0.1	0.1
G7	1	1	0.5	0.2	0.1	0.1

Table 4.6 does not show KPIs 1, 8, 9 and 10. This is because problematic situation 1, the degree of structured control, is directly connected to the methods of cleaning. The combination of the degree of control and the method of cleaning ultimately determines the likelihood of the corresponding hazard. For example, a sub-KPI value for D9X of 88.9% means that the non-risk (allergen) undetachable parts that are in direct contact with the product are cleaned in a close to ideal manner. The cleaning is checked with a value of D19X of 33.3%, which means these parts are checked one third of the time. We estimate, with the same estimation method as with Table 4.6, that this combination of the KPIs gives a value of 1 for the likelihood factor, which means a likelihood of *only remotely possible*. The matrices for KPI combinations 1 with KPIs 8, 9 and 10 can be found in Tables 4.8, 4.9 and 4.10.

Table 4.7 shows the matrix for the combination of problematic situation 1 and partly problematic situations 8 and 9. Specifically, it shows the combination values of D8X with D18X, E8X with E18X, D9X with D19X and E9X with E19X. The matrix can be used to find the likelihood values for each of the four KPI combinations. For example, the KPI value for E9X is 100.0% and the KPI value for E19X is 23.8%. We look at the top row to find the column corresponding to E9X = 100.0% (the last column, 90%-100%) and find the row corresponding to E19X = 23.8% (the third row, 20%-30%). This gives a likelihood for the E9X-E19X combination of 0.5.

These four combinations of KPI values are shown in one table, because the contamination likelihood of products, both with risk and non-risk products, is assumed to be the same for all parts that are in direct contact with the product. This assumption is made because firstly, all surfaces on parts that are in direct contact with the product, touch the product approximately the same amount of time. Secondly, allergen products have not shown to attach more or less to a machine part. The difficulty to clean a product is slightly different per type of powder product, but this does not depend on whether the product contains an allergen or not.

Table 4.7 KPI 1/8/9 matrix values for parts in direct contact with product

KPI value D18X, E18X, D19X, E19X ↓	KPI value D8X, E8X, D9X, E9X 0% - 10%	10%- 20%	20% - 30%	30% - 40%	40% - 50%	50% - 60%	60% - 70%	70% - 80%	80% - 90%	90% - 100%
0% - 10%	10	10	10	10	10	6	3	3	1	1
10% - 20%	10	10	10	6	6	3	3	3	1	0.5
20% -30%	10	10	6	6	6	3	3	3	1	0.5
30% - 40%	10	10	6	6	6	3	3	3	1	0.5
40% - 50%	10	10	6	6	3	3	3	1	1	0.5
50% - 60%	10	6	6	6	3	3	3	1	1	0.5
60% - 70%	10	6	6	3	3	3	1	1	0.5	0.2
70% - 80%	6	6	3	3	3	1	1	0.5	0.2	0.1
80% - 90%	3	3	1	1	0.5	0.5	0.2	0.2	0.1	0.1
90% - 100%	1	1	0.5	0.2	0.2	0.1	0.1	0.1	0.1	0.1

Table 4.8 shows the matrix for the combination of problematic situation 1 and partly problematic situations 8 and 9. Specifically, it shows the combination values of D8Y with D18Y, E8Y with E18Y, D9Y with D19Y and E9Y with E19Y. The matrix can be used to find the likelihood values for these four KPIs in the same way this is explained for Table 4.7. The same assumption is made for this matrix as well, but instead, Table 4.8 concerns only the parts that are not in direct contact with the product.

Table 4.8 KPI 1/8/9 matrix values for parts not in direct contact with product

KPI value D18Y, E18Y, D19Y, E19Y ↓	KPI value D8Y, E8Y, D9Y, E9Y 0% - 10%	10%- 20%	20% - 30%	30% - 40%	40% - 50%	50% - 60%	60% - 70%	70% - 80%	80% - 90%	90% - 100%
0% - 10%	6	6	6	6	6	3	1	1	0.5	0.5
10% - 20%	6	6	6	3	3	1	1	1	0.5	0.1
20% -30%	6	6	3	3	3	1	1	1	0.5	0.1
30% - 40%	6	6	3	3	3	1	1	1	0.5	0.1
40% - 50%	6	6	3	3	1	1	1	0.5	0.5	0.1
50% - 60%	6	3	3	3	1	1	1	0.5	0.5	0.1
60% - 70%	6	3	3	3	1	1	0.5	0.2	0.2	0.1
70% - 80%	3	3	1	1	1	0.5	0.2	0.1	0.1	0.1
80% - 90%	1	1	0.5	0.5	0.2	0.2	0.1	0.1	0.1	0.1
90% - 100%	0.5	0.5	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1

Table 4.9 shows the matrix for the combination of problematic situation 1 and problematic situation 10. Specifically, it shows the combination values of D10 and D110 and E10 and E110. The matrix can be used to find the likelihood values for these two KPI combinations in the same way this is explained for Tables 4.7 and 4.8. The same type of assumption is made for this table as

well, which is that the level of cleanliness in of the cabin has the same influence on contamination of non-risk products as on contamination of risk products. Therefore, the matrix is used for both hazards D and E.

Table 4.9 KPI 1/10 matrix for cabin cleaning

KPI value D110, E110 ↓	KPI value D10, E10 0% - 10%	10%- 20%	20% - 30%	30% - 40%	40% - 50%	50% - 60%	60% - 70%	70% - 80%	80% - 90%	90% - 100%
0% - 10%	6	6	6	6	6	3	1	1	0.5	0.5
10% - 20%	6	6	6	3	3	1	1	1	0.5	0.1
20% -30%	6	6	3	3	3	1	1	1	0.5	0.1
30% - 40%	6	6	3	3	3	1	1	1	0.5	0.1
40% - 50%	6	6	3	3	1	1	1	0.5	0.5	0.1
50% - 60%	6	3	3	3	1	1	1	0.5	0.5	0.1
60% - 70%	6	3	3	3	1	1	0.5	0.2	0.2	0.1
70% - 80%	3	3	1	1	1	0.5	0.2	0.1	0.1	0.1
80% - 90%	1	1	0.5	0.5	0.2	0.2	0.1	0.1	0.1	0.1
90% - 100%	0.5	0.5	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1

This section defined the likelihood factors (L) for each sub-KPI, so for every sub-problematic situation and hazard combination. With these likelihood factors and the exposure factors and factors for possible consequence as defined in Chapter 2, we can define the total risk factors according to the Kinney and Wiruth method, in the next section.

4.2. Results

Section 4.1 discussed the methods of how to compute the likelihood factor for each sub-problematic situation. This section shows these likelihood factors, which are the results of the matrices and the KPI values. The result is a risk factor for each combination of hazard and problematic situation. To compute the risk factors, we need the factor for possible consequence (C) and the exposure factor (E) from Chapter 2, and the likelihood factors (L) determined from the matrices. The risk factor is the product of these three factors, as stated in the formula below.

$$Risk\ Factor = C * L * E$$

The three factors and the risk factor for each code are shown in Table 4.10.

Table 4.10 Risk factors per hazard – KPI combination

Code	Factor for possible consequence (C)	Exposure factor (E)	Likelihood factor (L)	Risk factor	Risk situation
A7	1	10	0.5	**5**	Acceptable risk
B7	40	2	1	**80**	Substantial risk
C7	3	10	1	**30**	Possible risk
D2	7	10	0.2	**14**	Acceptable risk
D3	7	10	6	**420**	Very high risk
D4	7	10	1	**70**	Substantial risk
D5	7	10	3	**210**	High risk
D6	7	10	0.2	**14**	Acceptable risk
D7	7	10	0.5	**35**	Possible risk
D8X/D18X	7	10	3	**210**	High risk

D8Y/D18Y	7	10	1	**70**	Substantial risk
D9X/D19X	7	10	1	**70**	Substantial risk
D9Y/D19Y	7	10	1	**70**	Substantial risk
D10/D110	7	10	0.1	**7**	Acceptable risk
E2	15	3	0.2	**9**	Acceptable risk
E3	15	3	3	**135**	Substantial risk
E4	15	3	0.2	**9**	Acceptable risk
E5	15	3	3	**135**	Substantial risk
E6	15	3	0.5	**22.5**	Possible risk
E7	15	3	0.2	**9**	Acceptable risk
E8X/E18X	15	3	3	**135**	Substantial risk
E8Y/E18Y	15	3	1	**45**	Possible risk
E9X/E19X	15	3	0.5	**22.5**	Possible risk
E9Y/E19Y	15	3	1	**45**	Possible risk
E10/E110	15	3	1	**45**	Possible risk
F7	7	10	0.2	**14**	Acceptable risk
G7	15	10	0.2	**30**	Possible risk

The hazard KPI combinations are assessed with a risk score and its corresponding risk situation. The risk situations are from the Kinney and Wiruth risk analysis method and are stated in Table 4.11.

Table 4.11 Risk situation corresponding to each risk score interval

Risk situation	Risk score
Very high risk; consider discontinuing operation	> 400
High risk; immediate correction required	200 to 400
Substantial risk; correction needed	70 to 200
Possible risk; attention indicated	20 to 70
Risk, perhaps acceptable	< 20

Most hazard KPI combinations have a risk value of 'possible risk'. However, a good amount of hazard and KPI combinations have a value of substantial risk or higher. Some even have a value of very high risk. We will highlight all high risks.

The first high risk is the only very high risk found in this table. It concerns code D3, the combination of hazard D (contamination with previous or other product) with problematic situation 3 (the intensity of switching to other cabins). This means that the risk of cross-contamination of non-risk products through switching to other cabins is very high. It is important to note, however, that the risk can be reduced by wearing adequate personal protection, mainly gloves. This has also been observed, through hazard 7. D7, the degree of adequately wearing gloves not including risk (allergen) batches, has a value of 35, or *possible risk.* This is not very high and it can therefore be expected that the risk of D3 is not actually this high. Still, it is important to note that apparently the intensity of switching is alarming. There are two more high risk values. The first of these is D5, the combination of hazard D (contamination with previous or other product) with problematic situation 5 (the method of storing parts). This means that the current method of storing parts forms a risk for contamination, as the storing method subjects the stored parts to contamination from the polluted air. The other high risk factor is D8X/D18X, which is the combination of hazard D and the method of cleaning for detachable parts in direct contact with the product and the control of this situation. This means that the current cleaning practices for detachable parts not including risk products and the control of these cleaning practices are below standard. Measures have to be taken to ensure the cleanliness of the parts and to limit cross-contamination.

Chapter 5 will show to what extent each combination of hazard and problematic situation needs to be improved to come to a desired level of risk.

4.3. Conclusion

We combined the hazards from the manual from Company X with problematic situations that were measured in the production setting. This results in risk scores for each combination of problematic situation and hazards. The results vary a lot and measures need to be taken in order to lower the risks to more acceptable levels. This will be explored in Chapter 5.

5. Sensitivity analysis

In this chapter we will conduct a sensitivity analysis. The goal of this chapter is to find out to what extent the problematic situations must be altered and improved to come to an acceptable risk factor level. The research question that is answered in this chapter is: *How can a sensitivity analysis model be set up to assess the influence of the problematic situations on the risk levels?*

5.1. Methods

In Chapter 4, we only assess the KPI values of the current situation. Since we want to improve the KPIs so that they give a more desired level of risk, we have to assess all possible outcomes for each hazard and problematic situation combination. To do this, we conduct a sensitivity analysis. For this sensitivity analysis, we use the values of the matrices used for the computation of the likelihood factors (L) of the hazards, which are the values in Tables 4.6 to 4.9. Additionally, each hazard has an exposure factor (E) and a factor for possible consequence (C), as defined in Chapter 2. The sensitivity analysis values can be found in Appendix C.

In Appendix C, we can see all possible risk factor values and the current risk factor value and KPI percentage value next to it. From this, we can determine to what extent the percentage needs to improve. We will assess this per hazard and problematic situation combination. We identify the gap between the current and desired situation by addressing the current KPI value and the KPI value that is needed to get to the desired risk factor. The desired risk factor is lower than 20, since this gives a risk situation of *acceptable risk*. We clarify what type of improvement is needed. The type of improvement depends on the desired KPI percentage increase. We will classify each needed improvement as either *not drastic*, *somewhat drastic*, *drastic* or *very drastic* and as *low priority, moderate priority* and *high priority*. The choice for classification is determined by the needed increase in the KPI. A low required increase, until 20%, does not require a drastic improvement. A moderate required increase, until 50%, requires a somewhat drastic improvement. A high required increase, from 50% to 100%, requires a drastic improvement. A very high required increase, everything from 100%, requires a very drastic improvement. Additionally, situations with an *acceptable risk* or *possible* risk have a low priority for improvement. Situations with a *substantial risk* have a moderate priority for improvement. Situations with a *high risk* or *very high risk* have a high priority for improvement. Assigning these two indicators will give a clear overview of prioritization so that Company X will know which problem should be tackled first. Also, the severity of the needed improvement indicates what type of solution there should be. Both indicators help with finding solutions in the next chapter.

5.2. Sensitivity analysis results per hazard

In this section, the methods from Section 5.1 are executed and the results from the sensitivity analysis in Appendix C are explained.

5.2.1. Hazard A - A hair gets into the product

There is one problematic situation that potentially causes hazard A, which is problematic situation 7. Problematic situation 7 is the degree of personal coverage and the sub-problematic situation for this hazard is the degree of wearing hair covers. The risk factor for A7 is 5, which gives a risk situation of *acceptable risk.* This means that the degree of personal coverage, in specific, the degree in which hair covers are worn, is a low risk situation. This hazard has a low improvement priority and the needed improvement is not drastic.

5.2.2. Hazard B – Allergen transfers from person eating in canteen

There is one problematic situation that potentially causes hazard B, which is problem 7, like for hazard A. The sub-problematic situation for this hazard is the degree of wearing face covers. The risk factor for B7 is 80, which gives a risk situation of *substantial risk*. This gives this situation a moderate improvement priority. The KPI value for B7 is 68.2%. We want to lower the risk to a level of *acceptable risk*, so to a risk factor lower than 20. In the sensitivity analysis table in Appendix C, we can see that the next KPI percentage interval already gives a risk factor of only 16 which is good enough to improve this risk level. The next KPI percentage interval starts at 70%. Therefore, the KPI B7 has to increase with at least 2.7%, to a value of 70%. Therefore, the situation requires a solution that is not drastic.

5.2.3. Hazard C – Contamination through polluted clothing

Hazard C is caused by one problematic situation, which is problematic situation 7, like with hazards A and B. The sub-problematic situation that causes hazard C is the degree of wearing adequate clothing. The risk factor belonging to this combination is C7 with a value of 30, which belongs to a risk situation of *possible risk*. C7 has a KPI percentage of 63.6% and the sensitivity analysis shows that the KPI percentage should be at least 70% to have a risk situation of *acceptable risk*. This means that the KPI has to improve with at least 10.1%. Therefore, the situation requires a solution that is not drastic. The priority of finding a solution is low, since the current risk situation is *possible risk* which is the second lowest level of risk.

5.2.4. Hazard D – Contamination with previous or other product

Hazard D is caused by all problematic situations. We will assess the situation for each problematic situation.

1. The degree of structured control

We will assess this situation at situations 8, 9 and 10 since we will draw conclusions about the combination of the control and the cleaning.

2. The degree of simultaneous cleaning

This hazard and problematic situation combination belongs to code D2. D2 has a KPI value of 88.9% and a risk factor of 14. A risk factor of 14 gives a risk situation of *acceptable risk*. This means that no improvement is needed and any possible improvement has a low priority.

3. The intensity of switching to other cabins

This hazard and problematic situation combination belongs to code D3. D3 has a KPI value of 49.7% and a risk factor of 420. A risk factor of 420 gives a risk situation of *very high risk*. The advice from Kinney and Wiruth is to consider discontinuing the operation. However, we cannot be sure that this risk is actually this high. The reason for this is also stated in Section 4.3, namely that the adequate wearing and replacing of gloves also aids in reducing the risk of cross-contamination whilst switching to other cabins. With the current value, a KPI improvement to at least 70% would be needed, an increase of at least 40.9%. This is an increase under 50%, so the improvement would be somewhat drastic. This is said with the recommendation to keep in mind that the level of personal protection, mostly wearing and adequately replacing of gloves, is important when switching to other cabins. When no solution is found for the need to switch to other cabins, personal protection needs to be ensured. The improvement priority of this situation is high.

4. The time a door is left open

This hazard and problematic situation combination belongs to code D4. D4 has a KPI value of 78.8% and a risk factor of 70. A risk factor of 70 means a risk situation of *substantial risk*. This means that the improvement for this situation has a moderate priority. The minimal value for the KPI to be at a risk situation of *acceptable risk* is 90%. This requires a KPI increase of at least 14.3%. This does not require a drastic improvement.

5. The method of storing parts

This hazard and problematic situation combination belongs to code D5. D5 has a KPI value of 17.4% and a risk factor of 210. A risk factor of 210 means the risk situation is *high risk*. According to Kinney and Wiruth, immediate correction is required. This gives this situation a high improvement priority. According to the sensitivity analysis, the minimum KPI value for a risk situation of *acceptable risk* is 90%. This means that a KPI improvement of minimal 417.3% is needed. This is an extremely high improvement of the KPI. This means that a very drastic improvement is needed.

6. The method of cleaning for the hallway

This hazard and problematic situation belongs to code D6. D6 has a KPI value of 40.9% and a risk factor of 14. A risk factor of 14 means the risk situation is *acceptable risk*. This gives the situation a very low improvement priority since the risk situation is already at a desired level. Improvements can be made, but are not necessary.

7. The degree of personal coverage

This hazard and problematic situation belongs to code D7. D7 has a KPI value of 68.8% and a risk factor of 35. A risk factor of 35 means the risk situation is *possible risk*. This gives this situation a low improvement priority, since a *possible risk* is the second lowest risk situation there is. To reach an *acceptable risk* situation, KPI D7 needs to be improved to at least 70%. This means that the KPI has to increase with at least 1.8%. This is a very small increase which means that a non drastic improvement is needed.

8. The method of cleaning for detachable parts

The codes belonging to this problematic situation and hazard combination are D18X, D18Y, D8X and D8Y. D18X and D8X concern the parts that are in direct contact with the product and D18Y and D8Y concern the parts that are not in direct contact with the product. We will first look at the sensitivity analysis for the cleaning of the parts in direct contact with the product and then at the analysis for the cleaning of the parts not in direct contact with the product.

D18X has a KPI value of 2.9% and D8X has a KPI value of 70.9%. This gives a risk factor of 210, which makes this a risk situation of *high risk*. According to Kinney and Wiruth, this means that immediate correction is required. This gives this situation a high improvement priority. The desired KPI increase is different than with the preceding KPIs, because this situation concerns two KPI values of which the combination determines the risk factor. We will give the intervals of improvement that are needed. In the sensitivity analysis, we can see that KPI D18X has to increase to at least 60% to get to a risk factor of 14, which gives an *acceptable risk*. In this situation, KPI D8X has to increase to at least 90%. KPI D8X can also increase to at least 80% but then KPI D18X must increase to at least 70%. If KPI D8X stays the same, or at least 70%, KPI D18X must increase to at least 80%. All of these situations require a large increase of KPI D18X and a smaller increase of KPI D8X. The minimal increase of KPI D18X lies between 1989.0% and 2658.7%. The minimal increase of KPI D8X lies between 0% and 27.0%. This means that the improvement for KPI D18X needs to be very drastic. The needed improvement for KPI D8X is not drastic.

D18Y has a KPI value of 3.9% and D8Y has a KPI value of 67.3%. This gives a risk factor of 70, which makes this a risk situation of *substantial risk*. Therefore, this situation has a moderate improvement priority. The desired KPI increase depends on the combination of the two KPIs. We can see from the sensitivity analysis that KPI D18Y has to increase to at least 10% to get a risk factor of 7, which would mean an *acceptable risk* situation. In this case, KPI D8Y has to increase to at least 90%. The other possibilities are that KPI D18Y is at least 60% and KPI D8Y at least 70%, or KPI D18Y is at least 70% and KPI D8Y at least 60%, the last possibility being the current situation for KPI D8Y. The minimal increase for KPI D18Y lies between 156.5% and 1694.9%. The minimal increase for KPI D8Y lies between 0% and 33.8%. This means that the improvement for D18Y needs to be very drastic and the improvement for KPI D8Y does not have to be drastic.

9. The method of cleaning for undetachable parts

The codes belonging to this problematic situation and hazard combination are D19X, D19Y, D9X and D9Y. D19X and D9Y concern the undetachable parts that are in direct contact with the product and D19Y and D9Y concern the parts that are not in direct contact with the product. We will assess the sensitivity analysis in the same manner as with problematic situation 8.

D19X has a KPI value of 33.3% and D9X has a KPI value of 88.9%. This gives a risk factor of 70, which means that this is a situation of *substantial risk* which gives this situation a moderate improvement priority. The desired KPI increase depends on the combination of the two KPIs. We can see from the sensitivity analysis that KPI D19X has to increase to at least 60% to get a risk factor of 14 which would mean an *acceptable risk* situation. In this case, KPI D9X has to increase to at least 90%. The other case is when KPI D9X does not improve. In this case, KPI D19X has to increase to at least 70%. The minimal increase for KPI D19X therefore lies between 80.2% and 110.3%. The minimal increase for KPI D9X lies between 0% and 1.3%. This means that the improvement for D19X needs to be drastic and the needed improvement for KPI D9X is not drastic.

D19Y has a KPI value of 21.4% and D9Y has a KPI value of 56.5%. This gives a risk factor of 70 which means that this is a situation of *substantial risk*. This gives this situation a moderate improvement priority. The desired KPI increase depends on the combination of the two KPIs. We can see from the sensitivity analysis that KPI D19Y has to be at least 10% with a KPI D9Y value of at least 90%, to get a risk factor of 7. The other possibilities are that KPI D19Y is at least 60% and KPI D9Y at least 70%, or KPI D19Y is at least 70% and KPI D9Y at least 60% or KPI D19Y is at least 80% and KPI D9Y at least 40%. The minimal increase for KPI D19Y therefore lies between 0% and 273.9%. The minimal increase for KPI D9Y lies between 0% and 59.2%. This means that the improvement for D19Y needs to be very drastic and the improvement for D9Y needs to be somewhat drastic.

10. The method of cleaning for the cabins

The codes belonging to this problematic situation and hazard combination are D110 and D10. We will assess the sensitivity analysis in the same manner as with problematic situations 8 and 9.

D110 has a KPI value of 33.3% and D10 has a KPI value of 95.8%. This gives a risk factor of 7 which means a risk situation of *acceptable risk.* This gives the situation a very low improvement priority since the risk situation is already at a desired level. Improvements can be made, but are not necessary.

5.2.5. Hazard E – Contamination with allergens from previous or other product

1. The degree of structured control

We will assess this situation at situations 8, 9 and 10 since we will draw conclusions about the combination of the control and the cleaning.

2. The degree of simultaneous cleaning

This hazard and problematic situation combination belongs to code E2. E2 has a KPI value of 100.0% and a risk factor of 9. A risk factor of 9 gives a risk situation of *acceptable risk*. This means that no improvement is needed and any possible improvement has a low priority.

3. The intensity of switching to other cabins

This hazard and problematic situation combination belongs to code E3. E3 has a KPI value of 64.1% and a risk factor of 135. A risk factor of 135 gives a risk situation of *substantial risk*. However, we cannot be sure that this risk is actually this high. The reason for this is also stated in

Section 4.3, namely that the adequate wearing and replacing of gloves also aids in reducing the risk of cross-contamination whilst switching to other cabins. With the current value, a KPI improvement to at least 70% would be needed, an increase of at least 9.3%. This would not need a drastic change in the situation. This is said with the recommendation to keep in mind that the level of personal protection, mostly wearing and adequately replacing of gloves, is important when switching to other cabins. When no solution is found for the need to switch to other cabins, personal protection needs to be ensured. The improvement priority of this situation is moderate.

4. The time a door is left open

This hazard and problematic situation combination belongs to code E4. E4 has a KPI value of 84.9% and a risk factor of 9. A risk factor of 9 gives a risk situation of *acceptable risk*. This means that no improvement is needed and any possible improvement has a low priority.

5. The method of storing parts

This hazard and problematic situation combination belongs to code E5. E5 has a KPI value of 7.5% and a risk factor of 135. A risk factor of 135 means the risk situation is *substantial risk*. This gives this situation a moderate improvement priority. According to the sensitivity analysis, the minimum KPI value for a risk situation of *acceptable risk* is 90%. This means that a KPI improvement of minimal 1100.0% is needed. This is an extremely high improvement of the KPI. This means that a very drastic improvement is needed.

6. The method of cleaning for the hallway

This hazard and problematic situation belongs to code E6. E6 has a KPI value of 17.0% and a risk factor of 22.5. A risk factor of 22.5 means the risk situation is *possible risk*. This gives the situation a low improvement priority. According to the sensitivity analysis, the minimum KPI value for a risk situation of *acceptable risk* is 30%. This means that a KPI improvement of minimal 76.5% is needed. This is a high improvement of the KPI which means a drastic improvement is needed.

7. The degree of personal coverage

This hazard and problematic situation belongs to code E7. E7 has a KPI value of 66.7% and a risk factor of 9. risk factor of 9 gives a risk situation of *acceptable risk*. This means that no improvement is needed and any possible improvement has a low priority.

8. The method of cleaning for detachable parts

The codes belonging to this problematic situation and hazard combination are E18X, E18Y, E8X and E8Y. E18X and E8X concern the parts that are in direct contact with the product and E18Y and E8Y concern the parts that are not in direct contact with the product. We will first look at the sensitivity analysis for the cleaning of the parts in direct contact with the product and then at the analysis for the cleaning of the parts not in direct contact with the product.

E18X has a KPI value of 12.5% and E8X has a KPI value of 72.8%. This gives a risk factor of 135, which makes this a risk situation of *substantial risk*. This gives this situation a moderate improvement priority. The desired KPI increase is different than with the preceding KPIs, like in Section 5.2.4, because this situation concerns two KPI values of which the combination determines the risk factor. We will give the intervals of improvement that are needed. In the sensitivity analysis, we can see that KPI E18X has to increase to at least 60% to get to a risk factor of 9, which gives an *acceptable risk*. In this situation, KPI E8X has to increase to at least 90%. KPI E18X can also increase to at least 70% but then KPI E8X must increase to at least 80%. If KPI E8X stays the same, or at least 60%, KPI E18X must increase to at least 80%. All of these situations require a large increase of KPI E18X and a smaller increase of KPI E8X. The minimal increase of KPI E18X lies between 380.0% and 540.0%. The minimal increase of KPI E8X lies between 0% and 23.7%.

This means that the improvement for KPI E18X needs to be very drastic. The needed improvement for KPI E8X is not drastic.

E18Y has a KPI value of 10.6% and E8Y has a KPI value of 70.7%. This gives a risk factor of 45, which makes this a risk situation of *possible risk*. Therefore, this situation has a low improvement priority. The desired KPI increase depends on the combination of the two KPIs. We can see from the sensitivity analysis that KPI E18Y has to be at least 10% with a KPI value for E8Y of 90% to get a risk factor of 4.5, which would mean an *acceptable risk* situation. The other possibility is that KPI E18Y is at least 60% and KPI E8Y at least 70%, which is the current situation for KPI E8Y. The minimal increase for KPI E18Y lies between 0% and 466.1%. The minimal increase for KPI E8Y lies between 0% and 27.3%. This means that the improvement for E18Y needs to be very drastic and the improvement for KPI E8Y does not have to be drastic.

9. The method of cleaning for undetachable parts

The codes belonging to this problematic situation and hazard combination are E19X, E19Y, E9X and E9Y. E19X and E9Y concern the undetachable parts that are in direct contact with the product and E19Y and E9Y concern the parts that are not in direct contact with the product. We will assess the sensitivity analysis in the same manner as with problematic situation 8.

E19X has a KPI value of 23.8% and E9X has a KPI value of 100.0%. This gives a risk factor of 22.5, which means that this is a situation of *possible risk* which gives this situation a low improvement priority. The desired KPI increase depends on the combination of the two KPIs. We can see from the sensitivity analysis that KPI E19X has to increase to at least 60% to get a risk factor of 9 which would mean an *acceptable risk* situation. In this case, KPI E9X has to be at least 90%. KPI E9X is 100.0% so this is already the case. The minimal increase for KPI E19X is therefore 152.1%. KPI E9X naturally does not have to increase. This means that the improvement for E19X needs to be very drastic and the needed improvement for KPI E9X is not drastic.

E19Y has a KPI value of 57.1% and E9Y has a KPI value of 54.6%. This gives a risk factor of 45 which means that this is a situation of *possible risk*. This gives this situation a low improvement priority. The desired KPI increase depends on the combination of the two KPIs. We can see from the sensitivity analysis that KPI E19Y has to be at least 10% with a KPI E9Y value of at least 90%, to get a risk factor of 4.5. The other possibilities are that KPI E19Y is at least 60% and KPI E9Y at least 70%, or KPI E19Y is at least 70% and KPI E9Y at least 60% or KPI E19Y is at least 80% and KPI E9Y at least 40%. The minimal increase for KPI E19Y therefore lies between 0% and 40.2%. The minimal increase for KPI E9Y lies between 0% and 64.9%. This means that the improvement for E19Y needs to be somewhat drastic and the improvement for E9Y needs to be somewhat drastic.

10 The method of cleaning for the cabins

The codes belonging to this problematic situation and hazard combination are E110 and E10. We will assess the sensitivity analysis in the same manner as with problematic situations 8 and 9.

E110 has a KPI value of 34.8% and E10 has a KPI value of 66.7%. This gives a risk factor of 45 which means that this is a situation of *possible risk*. This gives this situation a low improvement priority. The desired KPI increase depends on the combination of the two KPIs. We can see from the sensitivity analysis that KPI E110 has to be at least 10% with a KPI E10 value of at least 90%, to get a risk factor of 4.5. The other possibilities are that KPI E110 is at least 60% and KPI E10 at least 70%, or KPI E110 is at least 70% and KPI E10 at least 60%. The minimal increase for KPI E110 therefore lies between 0% and 101.2%. The minimal increase for KPI E10 lies between 0% and 35.0%. This means that the improvement for E110 needs to be drastic and the improvement for E10 does not need to be drastic.

5.2.6. Hazard F – Contamination from pallets

There is one problematic situation that potentially causes hazard F, which is problematic situation 7. Problematic situation 7 is the degree of personal coverage and the sub-problematic situation for this hazard is the degree of adequately wearing gloves. The risk factor for F7 is 14, which gives a risk situation of *acceptable risk.* This means that the degree of personal coverage, in specific, the degree of adequately wearing gloves, is a low risk situation for hazard F. This hazard has a low improvement priority and the needed improvement is not drastic.

5.2.7. Hazard G - Contamination with wood splinters from pallets

There is one problematic situation that potentially causes hazard G, which is problematic situation 7. Problematic situation 7 is the degree of personal coverage and the sub-problematic situation for this hazard is the degree of adequately wearing gloves. The risk factor for F7 is 30, which gives a risk situation of *possible risk,* which gives this situation a low improvement priority. The KPI value for G7 is 68.2%. We want to lower the risk to a level of *acceptable risk*, so to a risk factor lower than 20. In the sensitivity analysis table in Appendix C, we can see that the next KPI percentage interval already gives a risk factor of only 16 which is good enough to improve this risk level. The next KPI percentage interval starts at 70%. Therefore, the KPI G7 has to increase with at least 2.7%, to a value of 70%. This means that the improvement for G7 does not need to be drastic.

5.2.8. Summary of findings

The findings from the previous sections are summarized in Table 5.1. The column 'minimal needed increase' shows the minimal increase needed to get to the desired KPI value so that the risk factor is acceptable. The column 'needed improvement' shows how drastic the solution needs to be, and this ranges from not drastic to very drastic. Lastly, the 'priority' column shows the priority of finding a solution for that problematic situation.

Table 5.1 Needed increase and priority of each situation

Code	Risk factor	Current KPI	Minimal needed increase	Needed improvement	Priority
A7	5	69.7%	0%	Not drastic	Low
B7	80	68.2%	2.7%	Not drastic	Moderate
C7	30	63.6%	10.1%	Not drastic	Low
D2	14	88.9%	0%	Not drastic	Low
D3	420	49.7%	40.9%	Somewhat drastic	High
D4	70	78.8%	14.3%	Not drastic	Moderate
D5	210	17.4%	417.3%	Very drastic	High
D6	14	40.9%	0%	Not drastic	Low
D7	35	68.8%	1.8%	Not drastic	Low
D8X	210	70.9%	0% - 27.0%	Not drastic	High
D18X	210	2.9%	1989.0% - 2658.7%	Very drastic	High
D8Y	70	67.3%	0% - 33.8%	Not drastic	Moderate
D18Y	70	3.9%	156.6% - 1694.9%	Very drastic	Moderate
D9X	70	88.9%	0% - 1.3%	Not drastic	Moderate
D19X	70	33.3%	80.2% - 110.3%	Drastic	Moderate
D9Y	70	56.5%	0% - 59.2%	Somewhat drastic	Moderate
D19Y	70	21.4%	0% - 273.9%	Very drastic	Moderate
D10	7	95.8%	0%	Not drastic	Low

D110	7	33.3%	0%	Not drastic	Low
E2	9	100.0%	0%	Not drastic	Low
E3	135	64.1%	9.3%	Not drastic	Moderate
E4	9	84.9%	0%	Not drastic	Low
E5	135	7.5%	1100.0%	Very drastic	Moderate
E6	22.5	17.0%	76.5%	Drastic	Low
E7	9	66.7%	0%	Not drastic	Low
E8X	135	72.8%	0% - 23.7%	Not drastic	Moderate
E18X	135	12.5%	380.0% - 540.0%	Very drastic	Moderate
E8Y	45	70.7%	0% - 27.3%	Not drastic	Low
E18Y	45	10.6%	0% - 466.1%	Very drastic	Low
E9X	22.5	100.0%	0%	Not drastic	Low
E19X	22.5	23.8%	152.1%	Very drastic	Low
E9Y	45	54.6%	0% - 64.9%	Somewhat drastic	Low
E19Y	45	57.1%	0% - 40.2%	Somewhat drastic	Low
E10	45	66.7%	0% - 35.0%	Not drastic	Low
E110	45	34.8%	0% - 101.2%	Drastic	Low
F7	14	68.2%	0%	Not drastic	Low
G7	30	68.2%	2.7%	Not drastic	Low

This table is useful since the goal of this research is to improve the cleaning practices and the cleanliness within the capsuling and mixing department. We defined the problems and risks in the previous chapters, and this chapter shows how we can solve the problems. With only the risk scores from Chapter 4 we would also be able to find good solutions, but the sensitivity analysis gives more insight and therefore more information as to how to solve the problems. This is because for each problematic situation, the percentage increase is defined and the priority is determined. When the risk is high or very high, it is expected that the needed solution would be a drastic solution, and when the risk is low, that the needed solution is not drastic. However, we showed with the sensitivity analysis that this is often not the case. It could be that the risk is high, but only with a small improvement the risk gets to an acceptable level or that the risk is low but the improvement to get to an acceptable level of risk is large. Table 5.1 shows the size of the improvement, in the column for needed improvement. This will help in Chapter 6, when we generate solutions.

We see that some of the needed improvements are *very drastic* but the improvement priority is low or moderate. For example with sub-problematic situation E19X. This means that the control of the cleaning of undetachable parts in direct contact with the product, influencing hazard E, needs to improve a lot to get to an acceptable level of risk. Another example is sub-problematic situation E5. This is the storage of parts while risk products are produced. The risk situation is *substantial risk* which gives the situation a moderate improvement priority, but the needed improvement is very drastic. These types of situations are unexpected but important. Generally, drastic solutions cost the most time and money. The combination of a low improvement priority and high improvement costs makes these sub-situations the last situations Company X should invest in.

There is also one sub-situation that has a high improvement priority but a low needed improvement. This is sub-situation D8X. This is a good situation to invest in since the solution probably does not cost a lot of time and money, while the priority is high.

The other situations with a high improvement priority are already discussed in Chapter 4, since these are the situations that have a high risk factor. These sub-situations, D3, D5 and D18X need a somewhat to very drastic solution. In Chapter 6, we will define solutions for these situations first since the priority is high.

5.3. Conclusion

In this chapter, we defined the priority and the needed improvement for each problematic situation. Situations with a high priority should be tackled first, but it is also useful to tackle the non-drastic improvements first. These improvements will probably not cost too much time, effort and money, and can therefore be implemented very soon. This results in benefits for Company X in the short term. The more drastic improvements probably cost more time, money and effort and therefore these solutions will be planned more long-term. Chapter 6 shows the solutions in order of priority and divided into category of how drastic a solution is. In this way, adequate solutions for each situation are found.

6. Solutions and recommendations

In this chapter we describe solutions for the described problems. The result will be a clear plan of approach for Company X to achieve their goals for cleaning and cleanliness in the capsuling and mixing department. The solutions are formulated in three sections. The first section describes solutions for the cleaning methods. The second section finds solutions for the overall cleanliness of the department. The third section focuses on long term goals and plans. This concerns more radical changes in the department that cannot be implemented directly. The solutions all have a cost and time estimation and are mapped visually in the conclusion of this chapter, to easily show the steps Company X needs to take in order to reduce hygiene risks in the capsuling and mixing department.

6.1. High priority solutions

In this section we discuss solutions for the situations that have a high priority, from Chapter 5. There are four codes that have a high improvement priority, which are D3, D5, D8X and D18X. These situations all have a high risk or very high risk situation and therefore require immediate correction. We will first discuss the type of solution that is required and then explain more concrete parts of this solution, such as time, costs and responsibility.

6.1.1. The intensity of switching

Code D3 stands for the intensity of switching not including risk (allergen) batches. This situation influences the contamination with previous or other product (Hazard D). The risk of this situation is very high. The improvement needed is somewhat drastic, the KPI has to improve with 40.9%. We have already stated that the risk of switching is also dependent on the adequate wearing of gloves. This situation (D7) has a low risk score, of 35. This means that the wearing of gloves is already done well. An improvement that should be made is that there are gloves and a discard bin next to each cabin door. In this way, switching gloves when entering another cabin is encouraged more. For the intensity of switching, we encourage the company to invest in more operator training. When more operators know exactly how the machines work, they will need less help from one another, and therefore also walk less from cabin to cabin. This is also very necessary with the future in mind. Company X is a rapidly growing company and it is set to expand their production location. With a bigger production location, it will be harder to constantly physically help one another in the capsuling and mixing department. Operators need to be able to fix problems themselves. These solutions also cover situation E3, which is the intensity of switching including risk batches. This situation has a moderate improvement priority.

This means that firstly, we advise Company X to store gloves and discard bins next to each cabin door, so that adequate switching of gloves is encouraged. A basic solution does not cost any money, as it only requires taping the glove boxes to the doors. A more advanced solution can cost €20 to €100 depending on the type of glove boxes and discard bins. This solution can be realised easily and it has a high priority. Therefore, it should be realised within two weeks.

Secondly, we advise Company X to invest in proper training for their employees, not just the basics of the operations, but in-depth knowledge of the machine. When one operator per cabin has in-depth knowledge of the machine, switching is hardly necessary. The production manager is responsible for the training of the employees. The goal is that within three months, every cabin has one operator that has in-depth knowledge of the machine. Therefore, at least two operators need to be trained since there are currently three capsuling cabins and already one operator that has adequate in-depth knowledge. This goal can be achieved in two ways. The first is training from operators that already have in-depth knowledge of machines. These operators can educate other operators when changing over the machines. The second training approach is training from an external party. This is more costly and time-consuming, since this will likely occur outside of the work floor. The costs for these types of training range from €100 to €1500 per person, depending on the type of training. We advise Company X to start with internal training for two months and then evaluate performance. Company X evaluates whether the goal is achieved, so whether at least two operators have gained enough in-depth knowledge. When this goal is not achieved, the next step could be external training or more internal training.

6.1.2. The method of storing parts

The next situation with a high priority is the method of storing parts not including risk (allergen) batches. The code that belongs to this is code D5. This situation influences the contamination with previous or other product (Hazard D). The risk for this situation is high, the KPI has to improve with at least 417.3%. The solution for this is drastic, but quite simple. There should not be any parts stored in the capsuling hallway. It is easy to forget to store the part inside a bag and when this is not done, powder from the air covers the entire part. Any cleaning that was done beforehand was time-wasting since the part gets contaminated. The solution is to move the cupboard to the outer hallway, where other parts are stored also. The other cupboards that are already there are used for other production departments, but another cupboard will easily fit there. This will minimize the contamination with powder from the capsuling and mixing department. This solution can be realised within one week.

6.1.3. The method of cleaning for detachable parts

The last situation with a high improvement priority is situation D8X, which is the method of cleaning for detachable parts in direct contact with product, not including risk (allergen) batches. The corresponding situation is D18X, which is the degree of structured control for problematic sub-situation D8X. We will generate solutions for these situations separately.

From the data we can see that the cleaning practices are not always followed and control is hardly ever done. It is forecasted that when both control and adherence to cleaning practices improve enough, so with 0% - 27.0% for the cleaning methods and 1989.0% - 2658.7% for the control, the risk for (cross-)contamination lowers to a more acceptable level. We defined three points of improvement for Company X with regard to the cleaning practices.

As stated at the beginning of this thesis, there is ambiguity about the supposed cleanliness and the cleaning standard. This can be improved by good and clear communication. Communication happens in multiple ways.

Firstly, it is important that management and operators have the same goals and understand each other. This lays the groundwork for good communication and problem solving, because when all parties have the same goal, problems are also tackled with the same vision in mind. To make sure operators and management are on the same track, it is very important that there are regular meetings with the parties involved. The meetings should include mentioning goals and checking whether these goals align. Also, operators and managers mention problems that arise in the department. The goal of the meeting is to understand the problems and tackle them. It is important to be understanding of one another and to keep the collective goal in mind. Management and the operators need to agree on the frequency of the meetings, preferably at least once a month. The meetings need to be scheduled well in advance. The general manager is responsible for organizing these meetings and the first meeting can be realised within one month.

Secondly, the fixed requirements of the cleaning have to be clearly documented. This is to ensure that everybody knows what, how and when to clean. The best way to do this is to make a handbook that shows the steps to clean each unit within the department. The handbook has to be readable, clear and concise. It should include basic cleaning steps as well as more in-depth cleaning steps for parts that are to be cleaned in a different way. It should also include checklists for what has to be cleaned after each shift. These checklists solve problem 1 in the problem cluster defined in Section 1.2, since the checklists can replace the current cleaning forms. The handbook will make sure that the operators know how to clean. An operator can always accidentally forget to take one step but because the knowledge is now universal, this will happen much less. Also, new operators can easily learn how to clean a certain unit by reading the manual. The production manager is responsible for making this handbook. The costs are low, €50 to €200 depending on the hours of the colleague working on the handbook. Since the steps are already known, the handbook can be made soon, the first version can be finished within one month, with two months after that to evaluate and iterate, to make the handbook perfect.

Lastly, cleaning should be a priority, more than it currently is. Cleaning is a vital part of the production process, however there is not always enough time to clean. It is important to take enough time to clean. We have roughly measured the time to clean in this thesis, however not enough to draw conclusions of how long cleaning processes really take. The management needs to consult with experienced capsuling and mixing operators about how long cleaning takes. It is important to take into account that sometimes parts are harder to clean because of different chemical compositions of the powders. Operator experience can greatly help in this. When the production manager knows the time it will take to completely clean a cabin and its belongings after a certain order, he can plan this in the schedule accordingly. This takes pressure of off the operators who then can clean in an effective and efficient way. The production manager is responsible for this solution and needs to evaluate the time to clean a cabin and its belonging over a course of four months and then plan according to the cleaning times found.

For the control, we can see that the control percentage D18X currently has a value of 2.9%. However, this should be at least 60%. This means that more than half of the machine parts and cabin parts need to be controlled, so someone needs to check whether these parts are properly cleaned. This means that a drastic solution is needed to bring the control level from almost no control to control more than half of the time. Structured control by both colleague operators as well as managers is needed. We advise that a manager, preferably the production or quality manager samples the cleaning a few times every day, by checking some parts for cleanliness as they walk by. Additionally, colleague operators on the capsuling and mixing department will check the parts more often. When a set of parts has been cleaned, or when a cabin has been cleaned, the operator who cleaned this asks a colleague to check the cleanliness. When these agreements are made and followed, the control percentage of at least 60% can be guaranteed.

To sum up, there are four solutions for the problem of the cleaning methods of the parts and the problem of control. The first is to regularly have meetings with management and the capsuling and mixing operators to establish communication and clear goals. The second is to make a clear cleaning handbook. The third is to schedule the cleaning smarter and prioritizing cleaning more. The last is to make solid agreements about checking the cleanliness of cleaned parts.

6.2. Moderate priority solutions

This section discusses solutions for two moderate priority solutions. All but two moderate priority solutions have already been discussed in Section 6.1. This is because the solution in Section 6.1.1 also is a solution to E3, the solution in Section 6.1.2 is also a solution to E5 and the solutions in Section 6.1.3 are solutions for D8Y, D18Y, D9X, D19X, D9Y, D19Y, E8X, E18X, E8Y, E18Y, E9X, E19X, E9Y and E19Y. We will generate solutions for the remaining situations, D4 and B7.

The first problematic situation that has a moderate priority is code D4, which stands for the time a door is left open not including risk (allergen) batches. The solution needed for this situation is not drastic. A simple solution would be to remind operators to close their door behind them more often. This solution can be combined with the solution in Section 6.1.3 of more communication through meetings. Explaining the risk of leaving the door open will help with this. A more elaborate solution is the concept of valves. Company X is expanding and will probably move to a new, larger production location within two years. When all cabins have double doors, where only one door at a time is opened, this will drastically minimize the contamination of the hallway or other cabins. The powder will stay inside the cabin and will transfer a little into the valve room. This is a solution with a low priority, since this can only be realised in a new production location, as there is currently no room to make valves. This solution will therefore be realised when designing the new capsuling and mixing department layout.

The other problematic situation that has a moderate priority is code B7, which stands for the degree of wearing face covers. The needed improvement is not drastic. We see that almost always, the normal face covers are worn. However, the full face cover is often not worn. It is important to distribute the normal face covers more and make operators more aware that it is preferred to wear the full face cover when producing. The distribution can happen in the same manner as with the distribution of gloves Section 6.1.1. The operators will be made more aware with reminders in the meetings that will follow from the solution in Section 6.1.3.

6.3. Low priority solutions

For the low priority solutions, we will not go into the exact situations since the situations are already at a desired level or a close to desired level. These solutions are more long-term and focus on the improvement on already good situations, rather than improving because it is necessary.

We advise Company X to think critically about the layout of their new production location. Within the capsuling and mixing department, good choices need to be made to minimize contamination and simplify cleaning. Incorporating valves as stated in Section 6.2, is a good idea to minimize contamination. Furthermore, the new location needs to have more cleaning locations to ensure better cleaning, and minimize cross-contamination through for example simultaneous cleaning. Also, the material of the cabins and hallway floors, walls and ceilings need to be re-evaluated. The material is currently porous and hard to clean. Powder easily gets onto the walls, ceiling and floor and is hard to clean, often leaving visible residue. We advise to use a strong material that is non-absorbent of water and powder, so that cleaning can happen more efficiently and effectively. The production manager is responsible for this layout. The costs will be high, but most costs are costs that already will be spent on the new production location.

We also advise Company X to re-evaluate the current ideal cleaning practices. These cleaning practices are enough to clean all parts and appliances, but it is important to keep improving. For example, dry cleaning especially for machines can be very effective. Water can be dangerous for certain appliances and in these cases, steam works faster and safer. Also, the cleaning agents should be evaluated. Some types of capsule products are hard to clean and might require a different cleaning agent than Company X is currently using. Re-evaluating the cleaning practices will cost time and effort, and perhaps an external consultant will be needed.

These are all suggestions for further improvement of the cleaning and cleaning practices of Company X. It is important to keep improving, especially when the production is expanding.

6.4. Conclusion

To conclude, there are many solutions for the situations found in the previous chapters. The most important solutions are setting up a handbook, improving education and communication and rearranging the current department when Company X moves to a new production location. We advise Company X to implement these solutions and to evaluate the KPIs in half a year, to see whether the KPIs improved by implementing the solutions. In this chapter, we assigned approximate durations and starting points for each solution. These solutions are mapped in

Figures 6.1 and 6.2. Figure 6.1 shows the short term solutions, which are the high priority and moderate priority solutions. The blue beams show the time a solution will approximately take. The dashed section is an optional solution, used for the external training. External training is only needed when the internal training did not work.

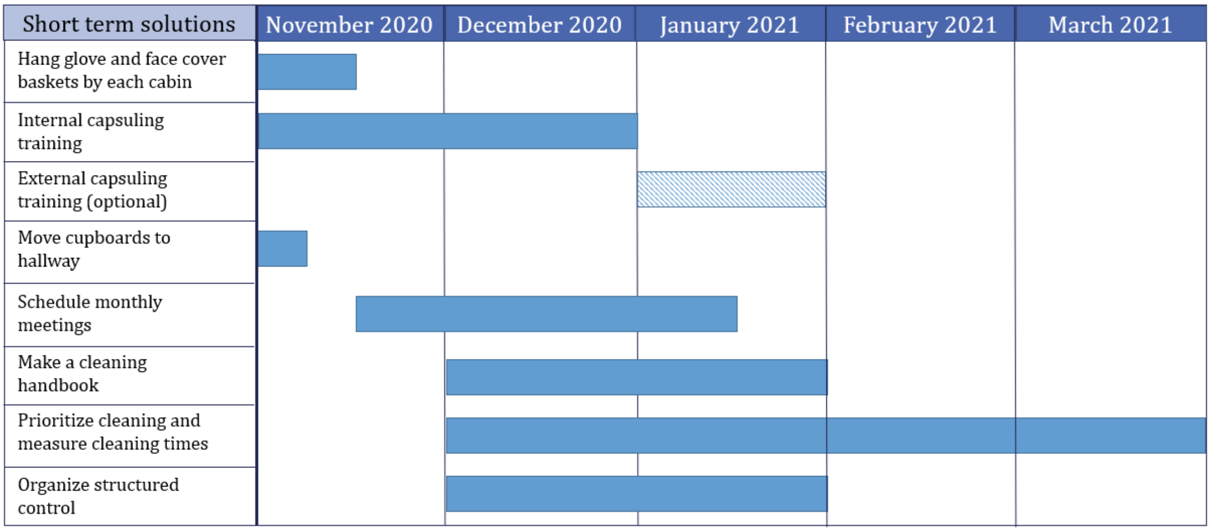

Figure 6.1. Short term solution planning

Figure 6.2 shows two long term solutions. They are partly dependent on the designing of the new location, so the time blocks are a suggestion. However, this figure gives a good view of a possible planning.

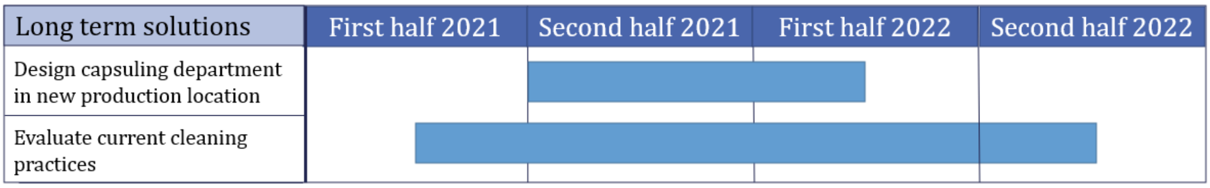

Figure 6.2. Long term solution planning

This chapter explains the most feasible solutions to the most important hygiene problems in the capsuling and mixing department. The solutions are evaluated on time and cost and a visual planning is made to aid Company X in prioritizing the solutions. This will help to implement the solutions easily and keep improving the company.

7. Conclusion and discussion

This chapter concludes the thesis *Standardization of cleaning practices in a growing food supplement wholesaler*. We summarize the most important findings and answer the main question of this thesis. Also, we discuss the scientific relevance of this research. Lastly, we recommend further research into certain aspects of this thesis.

7.1. Conclusion

This thesis is the product of the research into the problem that Company X has unclear and hardly documented cleaning procedures within the mixing and capsuling department and the standards of cleanness vary amongst employees. Because of this, the cleaning often does not happen adequately and the cleaning times vary too much. The degree of visibility and varying of standards is hardly known. We answer the following research question to solve these problems.

What should Company X do to improve the cleaning processes within the mixing and capsuling department, with the goal of achieving one standard of cleanliness and department-wide familiarity of this standard?

We defined seven hazards and ten problematic cleaning and/or cleanliness situations within the capsuling and mixing department in the production. We combined these hazards and defined a KPI for each situation. Through observation, we measured the situations. With the Kinney and Wiruth (1976) method and a sensitivity analysis, we discovered which situations pose the most risk and to what extent the situations need to be improved. Lastly, we designed adequate solutions with suggestions for implementation and we prioritized the solutions according to the outcomes in the sensitivity analysis.

The main question asks what Company X should do to improve the cleaning processes within the mixing and capsuling department with the goal of achieving one standard of cleanliness and department-wide familiarity of this standard. The answer to this question is the following. Company X should invest in better education of their operators. This needs to happen on a cleaning level, preferably with a handbook and good, structured communication. Also, more operators need to have more in-depth knowledge on the machines to minimize movement around the department. Furthermore, planning and communication should be prioritized more. Taking enough time to clean is essential for the quality of the product and the satisfaction of the operators. When looking at the foreseen growth of the company, it is vital to look at improvements in the layout of the capsuling and mixing department. It is essential to have more space for cleaning and that this space is separate from the production space, to minimize contamination. It is also interesting to look at the concept of valves with doors. When one door is opened, powder from the air does not directly get to the other room, but stays in the valve room. This concept should be used in the new production area. All solutions are clearly stated in Chapter 6.

7.2. Discussion

There are some points of discussion regarding this research. The two key points are the decomposing of data, and the computation of the likelihood scores. Firstly, we decomposed the ten KPIs from Chapter 3 to get to the sub-KPIs in Chapter 4. This is very useful since the sub-KPIs provide the information we need to compute the likelihood scores. However, decomposing means that the sample of data to compute the KPIs from becomes smaller. This makes the eventual scores less accurate. However, we did choose to do this because firstly, the scope of this research did not allow for more observation, so it was simply not possible to collect more data to compute the KPIs. Secondly, although the data could definitely be more accurate, it does what it needs to do, which is to give a clear image of what the situation is currently like. The solutions in Chapter 6 are not designed to target a specific percentage increase of each problematic situation, but rather to improve on the areas that need the most improvement. This is more qualitative than quantitative, and that is also the goal of this research. Quantifying data helps greatly in depicting the problems, but the goal is qualitative. We do advise Company X to collect more data and re-evaluate the KPIs every few months. In this way, more accurate results will be obtained.

Secondly, the computation of likelihood scores is done in a subjective manner. The Kinney and Wiruth method is already based on some subjectivity, as it relies on statements such as 'might well be expected' or 'unusual but possible'. The advantage of this is that it is easier to quantify qualitative data, but the disadvantage is that the numerical values that result are not always solid. The key is to see the values as a guideline for adequate interference. The values help greatly in identifying the hygiene risks within the capsuling and mixing department, but we do not generate solutions in a way to target the exact percentage points that a KPI should rise. The conclusion is the same as with the problem of the decomposing of KPIs. The numerical data is not completely accurate, but it does aid with the goal of this thesis which is to gain insight about the cleaning and cleanliness discrepancies and to improve the cleaning processes.

7.3. Scientific relevance

In this thesis we show how a Kinney and Wiruth risk analysis can identify and quantify risks, and generate adequate solutions using a sensitivity analysis. We show what effects the variables from the Kinney and Wiruth risk analysis method have, and how they influence certain risks. Generating solutions is often hard to do once a risk analysis is conducted. The sensitivity analysis helps greatly with this, since it shows how much a KPI needs to improve. This research is therefore useful, since it aids in the practical application of risk analyses.

7.4. Further research

We advise further research into two aspects of this thesis. Firstly, we defined ideal cleaning methods for the capsuling and mixing department of Company X. However, the cleaning methods could be improved beyond the ideal cleaning methods described in Chapter 3. The ideal cleaning methods are established from what is currently possible, but when moving to a different location, different methods might be possible. We advise Company X to keep improving their cleaning methods, as also described in Section 6.3. It is important to research what type of cleaning works for what materials and products, and to benchmark cleaning methods at competitors, or at pharmaceutical industries.

Secondly, further research on the combination of the Practical Risk Analysis for Safety Management and a sensitivity analysis is advised. In this thesis, we found this combination to be very useful. Therefore, it would be interesting to see more research using this combination. We converted all data into numerical KPIs and other numerical data within this research. For further research, it is interesting to look into data that is less quantifiable and to see whether the combination of risk analysis and sensitivity analysis is still possible.

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Appendices

Appendix A Ideal cleaning methods for parts and cabin

Figure 9.1 shows the cleaning methods for parts and cabins that were involved in the production of non-risk products.

Cleaning between normal batches (no special product such as an allergen/pro-biotic/biologic)

Num	Item	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
	Parts						
	Machine	1	2	3	4	5	6
1	Disc	Disassemble into 2 parts	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air		
2	Bronze disc	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
3	Powder slider	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
4	Capsule sleeves	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
5	Brace	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
6	Fork	Disassemble into 2 parts	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air		
7	Funnel	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
8	Helix	Disassemble into 2 parts	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air		
9	Pins	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
10	Collection bin	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
11	Screws	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
	Rocket	1	2	3	4	5	6
12	Cap	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
13	Bristle	Soak in bleach until white	Dry on rack	Disinfect with alcohol	Dry with compressed air		
14	Bottom	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
15	Capsule funnel	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
16	Back part	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
17	Belt driver	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
18	Waste collection bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
19	Screen of collector bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
20	Funnel of collector bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
	Aids						
	Small	1	2	3	4	5	6
21	Small pipe brush	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
22	Big pipe brush	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
23	Powder brush	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
24	Small strainer	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
25	Bowl	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
26	Big powder scoop	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
27	Small powder scoop	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
28	Precision scales	Damp cleaning cloth NOT TOO WET	Disinfect with damp alcohol cloth	Dry with towel			
29	Measuring cylinder	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
	Large	1	2	3	4	5	6
30	White bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
31	Table	Cleaning cloth	V15 with cloth	Rinse with hot water cloth	Dry with towel	Disinfect with alcohol	Dry with compressed air
32	Cart	Cleaning cloth	V15 with cloth	Rinse with hot water cloth	Dry with towel	Disinfect with alcohol	Dry with compressed air
33	Big strainer	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
34	Large scales	Damp cleaning cloth NOT TOO WET	Disinfect with damp alcohol cloth	Dry with towel			
35	Vacuum cleaner	Damp cleaning cloth					
	Other	1	2	3	4	5	6
36	Mixing vat metal	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
37	Powder vat plastic	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
	Cabin	1	2	3	4	5	6
38	Floor	Vacuum	Mop with bleach water				
39	Walls	Clean with cloth and bleach water					
40	Windows	Clean with cloth and glassex					
41	Ceiling	Clean with cloth and bleach water					
	Machine	1	2	3	4	5	6
42	Inside, all that comes in contact with product	Rinse with hot water + V15	Dry with towel	Disinfect with alcohol	Dry with compressed air		
43	Inside, hard to reach/mechanical part	Vacuum thoroughly					
44	Outside	Cleaning cloth with bleach water	Dry with towel				
	Rocket	Cleaning cloth	Scrub with V15	Dry with compressed air			

Figure 9.1. Ideal cleaning methods for non-risk product parts

Figure 9.2 shows the cleaning methods for parts and cabins that were involved in the production of risk products which are products that are biological or contain allergens or probiotics.

Cleaning between risk batches (allergen/pro-biotic/biologic); changes with respect to the normal cleaning are marked yellow.

Num	Item	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
	Parts						
	Machine	1	2	3	4	5	6
1	Disc	Disassemble into 2 parts	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air		
2	Bronze disc	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
3	Powder slider	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
4	Capsule sleeves	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
5	Brace	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
6	Fork	Disassemble into 2 parts	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air		
7	Funnel	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
8	Helix	Disassemble into 2 parts	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air		
9	Pins	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
10	Collection bin	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
11	Screws	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
	Rocket	1	2	3	4	5	6
12	Cap	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
13	Bristle	Soak in bleach until white	Dry on rack	Disinfect with alcohol	Dry with compressed air		
14	Bottom	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
15	Capsule funnel	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
16	Back part	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
17	Belt driver	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
18	Waste collection bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
19	Screen of collector bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
20	Funnel of collector bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
	Aids						
	Small	1	2	3	4	5	6
21	Small pipe brush	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
22	Big pipe brush	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
23	Powder brush	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
24	Small strainer	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
25	Bowl	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
26	Big powder scoop	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
27	Small powder scoop	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
28	Precision scales	Damp cleaning cloth NOT TOO WET	Disinfect with damp alcohol cloth	Dry with towel			
29	Measuring cylinder	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
	Large	1	2	3	4	5	6
30	White bin	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
31	Table	Cleaning cloth	V15 with cloth	Rinse with hot water cloth	Dry with towel	Disinfect with alcohol	Dry with compressed air
32	Cart	Cleaning cloth	V15 with cloth	Rinse with hot water cloth	Dry with towel	Disinfect with alcohol	Dry with compressed air
33	Big strainer	Clean in dishwasher	Disinfect with alcohol	Dry with compressed air			
34	Large scales	Damp cleaning cloth NOT TOO WET	Disinfect with damp alcohol cloth	Dry with towel			
35	Vacuum cleaner	Damp cleaning cloth	Disinfect with alcohol	mondje stofzuiger altijd schoonmaken en mag niet op de grond			
	Other	1	2	3	4	5	6
36	Mixing vat metal	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
37	Powder vat plastic	Rinse with hot water	Scrub with V15	Rinse with cold water	Dry with towel	Disinfect with alcohol	Dry with compressed air
	Cabin	1	2	3	4	5	6
38	Floor	Vacuum	Mop with bleach water				
39	Walls	Mop with bleach water	Dry with towel				
40	Windows	Mop with bleach water	Dry with towel				
41	Ceiling	Remove plates	Scrub with bleach	Dry with towel	Put plates back		
	Machine	1	2	3	4	5	6
42	Inside, all that comes in contact with product	Rinse with hot water + V15	Dry with towel	Disinfect with alcohol	Dry with compressed air		
43	Inside, hard to reach/mechanical part	Clean thoroughly	Disinfect thoroughly with alcohol				
44	Outside	Cleaning cloth with bleach water	Disinfect with alcohol	Dry with towel			
45	Rocket	Cleaning cloth	Scrub with V15	Dry with compressed air			

Figure 9.2. Ideal cleaning methods for risk product parts.

Appendix B Observation forms

This appendix shows the observation forms used to measure steps in the production. The first two forms are to be filled in with a 0, 0.5 or 1 in each cell or an X to indicate the product was not observed. The information can be obtained from appendix A, where the cleaning steps are described for each item. Figure 9.3 shows the observation form for detachable parts, undetachable parts and the cabin for parts involved in the production of non-risk products. Figure 9.4 shows the same observation form for parts involved in the production of risk products. It is noted behind the form whether a product was controlled on cleanliness or not, with a tick (√) or a '1'.

Cleaning between normal batches (no risk product such as an allergen/pro-biotic/biologic)							
Date							
Time							
Number	**Item**	**Step 1**	**Step 2**	**Step 3**	**Step 4**	**Step 5**	**Step 6**
	Parts						
	Machine	**1**	**2**	**3**	**4**	**5**	**6**
1	Disc						
2	Bronze disc						
3	Powder slider						
4	Capsule sleeves						
5	Brace						
6	Fork						
7	Funnel						
8	Helix						
9	Pins						
10	Collection bin						
11	Screws						
	Rocket	**1**	**2**	**3**	**4**	**5**	**6**
12	Cap						
13	Bristle						
14	Bottom						
15	Capsule funnel						
16	Back part						
17	Belt driver						
18	Waste collection bin						
19	Screen of collector bin						
20	Funnel of collector bin						
	Aids						
	Small	**1**	**2**	**3**	**4**	**5**	**6**
21	Small pipe brush						
22	Big pipe brush						
23	Powder brush						
24	Small strainer						
25	Bowl						

26	Big powder scoop						
27	Small powder scoop						
28	Precision scales						
29	Measuring cylinder						
	Large	**1**	**2**	**3**	**4**	**5**	**6**
30	White bin						
31	Table						
32	Cart						
33	Big strainer						
34	Large scales						
35	Vacuum cleaner						
	Other	1	2	3	4	5	6
36	Mixing vat metal						
37	Powder vat plastic						
	Cabin	**1**	**2**	**3**	**4**	**5**	**6**
38	Floor						
39	Walls						
40	Windows						
41	Ceiling						
	Machine	**1**	**2**	**3**	**4**	**5**	**6**
42	Inside, all that comes in contact with product						
43	Inside, hard to reach/mechanical part						
44	Outside						
45	Rocket						

Figure 9.3. Observation form non-risk product parts.

Cleaning between risk batches (allergen/pro-biotic/biologic)							
Date							
Time							
Number	**Item**	**Step 1**	**Step 2**	**Step 3**	**Step 4**	**Step 5**	**Step 6**
	Parts						
	Machine	**1**	**2**	**3**	**4**	**5**	**6**
1	Disc						
2	Bronze disc						
3	Powder slider						
4	Capsule sleeves						
5	Brace						
6	Fork						
7	Funnel						
8	Helix						
9	Pins						
10	Collection bin						
11	Screws						
	Rocket	**1**	**2**	**3**	**4**	**5**	**6**
12	Cap						
13	Bristle						
14	Bottom						
15	Capsule funnel						
16	Back part						
17	Belt driver						
18	Waste collection bin						
19	Screen of collector bin						
20	Funnel of collector bin						
	Aids						
	Small	**1**	**2**	**3**	**4**	**5**	**6**
21	Small pipe brush						
22	Big pipe brush						
23	Powder brush						
24	Small strainer						
25	Bowl						
26	Big powder scoop						
27	Small powder scoop						
28	Precision scales						
29	Measuring cylinder						
	Large	**1**	**2**	**3**	**4**	**5**	**6**
30	White bin						
31	Table						
32	Cart						

33	Big strainer						
34	Large scales						
35	Vacuum cleaner						
	Other	**1**	**2**	**3**	**4**	**5**	**6**
36	Mixing vat metal						
37	Powder vat plastic						
	Cabin	**1**	**2**	**3**	**4**	**5**	**6**
38	Floor						
39	Walls						
40	Windows						
41	Ceiling						
	Machine	**1**	**2**	**3**	**4**	**5**	**6**
42	Inside, all that comes in contact with product						
43	Inside, hard to reach/mechanical part						
44	Outside						
45	Rocket						

Figure 9.4. Observation form for risk product parts.

Figure 9.5 shows the observation form for measuring what time a door was open. The cabin and door is observed for a certain amount of time and the time of opening and closing the door is noted. This is not done when the door is closed directly behind an operator.

Opening of doors			
Date	**Cabin**	**Time opened**	**Time closed**

Figure 9.5. Observation form for noting the consecutive time a door was left open.

Figure 9.6 shows the observation form for switching between cabins. The operator is observed and every time they go to another cabin it is noted.

Switching between cabins			
Date	**Cabin origin**	**Cabin switch**	**Times (keep tally)**

Figure 9.6. Observation form for switching between cabins

Figure 9.7 shows the observation form for the personal coverage. When observing an operator we put a '1' at the items they are wearing or are not wearing but also do not have to wear and a '0' at the things they are not wearing but should wear. When a form of coverage is switched, taken off or put on, it is also noted.

Personal coverage							
Date	**Time**	**Cabin**	**Gloves**	**Face mask**	**Full face cover**	**Arm/beard hair cover when needed**	**Hair cover**

Figure 9.7. Observation form for personal coverage.

Figure 9.8 shows the observation form for the storage of parts. Two or three times per observation day, we check how many discs in the cupboard are covered and how many are not covered with plastic.

Storage of parts			
Date	**Time**	**Parts not covered**	**Parts covered**

Figure 9.8. Observation form for the storage of parts.

Figure 9.9 shows the observation form for simultaneous cleaning. Simultaneous cleaning is kept in mind during the cleaning of detachable parts. As soon as parts from a different cabin are cleaned on the counter where there are still parts from the original cabin being cleaned, or left to dry, then we speak of simultaneous cleaning. We note this down when we see it.

Simultaneous cleaning		
Date	**Time**	**Simultaneous cleaning yes/no**

Figure 9.9. Observation form for simultaneous cleaning.

Appendix C Sensitivity analysis

This appendix shows the sensitivity analysis as discussed in Chapter 5. The dark red values show the values of 'very high risk'. The red values are values for 'high risk'. The values are colour coded, to clarify the risk situation. The orange values are values for 'substantial risk'. The yellow values are values for 'possible risk'. The green values are values for 'acceptable risk'. The current risk value for each combination of hazard and problematic situation is given at the right of the hazard and is also indicated in the matrix, so that it is visible what the KPI value interval is.

These categories are determined according to the Kinney and Wiruth method, which defines risk situations for each risk factor level.

Hazard A

	0% - 10%	10% - 30%	30% - 50%	50% - 70%	70% - 90%	90% - 100%	Current value
A7	30	10	10	**5**	2	2	5

Hazard B

	0% - 10%	10% - 30%	30% - 50%	50% - 70%	70% - 90%	90% - 100%	Current value
B7	240	80	80	**80**	16	16	80

Hazard C

	0% - 10%	10% - 30%	30% - 50%	50% - 70%	70% - 90%	90% - 100%	Current value
C7	90	90	30	**30**	6	6	30

Hazard D

	0% - 10%	10% - 20%	20% - 30%	30% - 40%	40% - 50%	50% - 60%	60% - 70%	70% - 80%	80% - 90%	90% - 100%	Current value
D2	700	420	420	420	420	210	210	14	**14**	7	**14**
D3	700	420	420	420	**420**	210	210	14	14	7	**420**
D4	420	420	420	420	420	210	210	**70**	70	14	**70**
D5	210	**210**	210	70	70	70	70	35	35	14	**210**
D6	70	35	35	14	**14**	7	7	7	7	7	**14**
D7	210	210	210	70	70	35	**35**	14	14	7	**35**

D8X	0% - 10%	700	700	700	700	700	420	210	**210**	70	70	**210**
	10% - 20%	700	700	700	420	420	210	210	210	70	35	
	20% - 30%	700	700	420	420	420	210	210	210	70	35	
	30% - 40%	700	700	420	420	420	210	210	210	70	35	
	40% - 50%	700	700	420	420	210	210	210	70	70	35	
	50% - 60%	700	420	420	420	210	210	210	70	70	35	

	60% - 70%	700	420	420	210	210	210	70	70	35	14	
	70% - 80%	420	420	210	210	210	70	70	35	14	7	
	80% - 90%	210	210	70	70	35	35	14	14	7	7	
	90% - 100%	70	70	35	14	14	7	7	7	7	7	
D8Y	0% - 10%	420	420	420	420	420	210	**70**	70	35	35	70
	10% - 20%	420	420	420	210	210	70	70	70	35	7	
	20% - 30%	420	420	210	210	210	70	70	70	35	7	
	30% - 40%	420	420	210	210	210	70	70	70	35	7	
	40% - 50%	420	420	210	210	70	70	70	35	35	7	
	50% - 60%	420	210	210	210	70	70	70	35	35	7	
	60% - 70%	420	210	210	210	70	70	35	14	14	7	
	70% - 80%	210	210	70	70	70	35	14	7	7	7	
	80% - 90%	70	70	35	35	14	14	7	7	7	7	
	90% - 100%	35	35	14	14	7	7	7	7	7	7	
D9X	0% - 10%	700	700	700	700	700	420	210	210	70	70	70
	10% - 20%	700	700	700	420	420	210	210	210	70	35	
	20% - 30%	700	700	420	420	420	210	210	210	70	35	
	30% - 40%	700	700	420	420	420	210	210	210	**70**	35	
	40% - 50%	700	700	420	420	210	210	210	70	70	35	
	50% - 60%	700	420	420	420	210	210	210	70	70	35	
	60% - 70%	700	420	420	210	210	210	70	70	35	14	
	70% - 80%	420	420	210	210	210	70	70	35	14	7	
	80% - 90%	210	210	70	70	35	35	14	14	7	7	
	90% - 100%	70	70	35	14	14	7	7	7	7	7	
D9Y	0% - 10%	420	420	420	420	420	210	70	70	35	35	70
	10% - 20%	420	420	420	210	210	70	70	70	35	7	

	20% - 30%	420	420	210	210	210	**70**	70	70	35	7	
	30% - 40%	420	420	210	210	210	70	70	70	35	7	
	40% - 50%	420	420	210	210	70	70	70	35	35	7	
	50% - 60%	420	210	210	210	70	70	70	35	35	7	
	60% - 70%	420	210	210	210	70	70	35	14	14	7	
	70% - 80%	210	210	70	70	70	35	14	7	7	7	
	80% - 90%	70	70	35	35	14	14	7	7	7	7	
	90% - 100%	35	35	14	14	7	7	7	7	7	7	
D10	0% - 10%	420	420	420	420	420	210	70	70	35	35	7
	10% - 20%	420	420	420	210	210	70	70	70	35	7	
	20% - 30%	420	420	210	210	210	70	70	70	35	7	
	30% - 40%	420	420	210	210	210	70	70	70	35	**7**	
	40% - 50%	420	420	210	210	70	70	70	35	35	7	
	50% - 60%	420	210	210	210	70	70	70	35	35	7	
	60% - 70%	420	210	210	210	70	70	35	14	14	7	
	70% - 80%	210	210	70	70	70	35	14	7	7	7	
	80% - 90%	70	70	35	35	14	14	7	7	7	7	
	90% - 100%	35	35	14	14	7	7	7	7	7	7	

Hazard E

		0% - 10%	10% - 20%	20% - 30%	30% - 40%	40% - 50%	50% - 60%	60% - 70%	70% - 80%	80% - 90%	90% - 100%	Current value
E2		270	270	270	135	135	45	45	22.5	22.5	**9**	9
E3		450	270	270	270	270	135	**135**	9	9	4.5	135
E4		270	270	270	270	270	135	135	9	**9**	4.5	9
E5		**135**	135	135	45	45	45	45	22.5	22.5	9	135
E6		45	**22.5**	22.5	9	9	4.5	4.5	4.5	4.5	4.5	22.5
E7		45	22.5	22.5	9	9	9	**9**	4.5	4.5	4.5	9
E8X	0% - 10%	450	450	450	450	450	270	135	135	45	45	135

	10% - 20%	450	450	450	270	270	135	135	**135**	45	22.5	
	20% - 30%	450	450	270	270	270	135	135	135	45	22.5	
	30% - 40%	450	450	270	270	270	135	135	135	45	22.5	
	40% - 50%	450	450	270	270	135	135	135	45	45	22.5	
	50% - 60%	450	270	270	270	135	135	135	45	45	22.5	
	60% - 70%	450	270	270	135	135	135	45	45	22.5	9	
	70% - 80%	270	270	135	135	135	45	45	22.5	9	4.5	
	80% - 90%	135	135	45	45	22.5	22.5	9	9	4.5	4.5	
	90% - 100%	45	45	22.5	9	9	4.5	4.5	4.5	4.5	4.5	
E8Y	0% - 10%	270	270	270	270	270	135	45	45	22.5	22.5	45
	10% - 20%	270	270	270	135	135	45	45	**45**	22.5	4.5	
	20% - 30%	270	270	135	135	135	45	45	45	22.5	4.5	
	30% - 40%	270	270	135	135	135	45	45	45	22.5	4.5	
	40% - 50%	270	270	135	135	45	45	45	22.5	22.5	4.5	
	50% - 60%	270	135	135	135	45	45	45	22.5	22.5	4.5	
	60% - 70%	270	135	135	135	45	45	22.5	9	9	4.5	
	70% - 80%	135	135	45	45	45	22.5	9	4.5	4.5	4.5	
	80% - 90%	45	45	22.5	22.5	9	9	4.5	4.5	4.5	4.5	
	90% - 100%	22.5	22.5	9	9	4.5	4.5	4.5	4.5	4.5	4.5	
E9X	0% - 10%	450	450	450	450	450	270	135	135	45	45	22.5
	10% - 20%	450	450	450	270	270	135	135	135	45	22.5	
	20% - 30%	450	450	270	270	270	135	135	135	45	**22.5**	
	30% - 40%	450	450	270	270	270	135	135	135	45	22.5	
	40% - 50%	450	450	270	270	135	135	135	45	45	22.5	
	50% - 60%	450	270	270	270	135	135	135	45	45	22.5	
	60% - 70%	450	270	270	135	135	135	45	45	22.5	9	

	70% - 80%	270	270	135	135	135	45	45	22.5	9	4.5	
	80% - 90%	135	135	45	45	22.5	22.5	9	9	4.5	4.5	
	90% - 100%	45	45	22.5	9	9	4.5	4.5	4.5	4.5	4.5	
E9Y	0% - 10%	270	270	270	270	270	135	45	45	22.5	22.5	45
	10% - 20%	270	270	270	135	135	45	45	45	22.5	4.5	
	20% - 30%	270	270	135	135	135	45	45	45	22.5	4.5	
	30% - 40%	270	270	135	135	135	45	45	45	22.5	4.5	
	40% - 50%	270	270	135	135	45	45	45	22.5	22.5	4.5	
	50% - 60%	270	135	135	135	45	**45**	45	22.5	22.5	4.5	
	60% - 70%	270	135	135	135	45	45	22.5	9	9	4.5	
	70% - 80%	135	135	45	45	45	22.5	9	4.5	4.5	4.5	
	80% - 90%	45	45	22.5	22.5	9	9	4.5	4.5	4.5	4.5	
	90% - 100%	22.5	22.5	9	9	4.5	4.5	4.5	4.5	4.5	4.5	
E10	0% - 10%	270	270	270	270	270	135	45	45	22.5	22.5	45
	10% - 20%	270	270	270	135	135	45	45	45	22.5	4.5	
	20% - 30%	270	270	135	135	135	45	45	45	22.5	4.5	
	30% - 40%	270	270	135	135	135	45	**45**	45	22.5	4.5	
	40% - 50%	270	270	135	135	45	45	45	22.5	22.5	4.5	
	50% - 60%	270	135	135	135	45	45	45	22.5	22.5	4.5	
	60% - 70%	270	135	135	135	45	45	22.5	9	9	4.5	
	70% - 80%	135	135	45	45	45	22.5	9	4.5	4.5	4.5	
	80% - 90%	45	45	22.5	22.5	9	9	4.5	4.5	4.5	4.5	
	90% - 100%	22.5	22.5	9	9	4.5	4.5	4.5	4.5	4.5	4.5	

	Hazard F						
	0% - 10%	10% - 30%	30% - 50%	50% - 70%	70% - 90%	90% - 100%	Current value
F7	70	70	35	**14**	7	7	14

	Hazard G						
	0% - 10%	10% - 30%	30% - 50%	50% - 70%	70% - 90%	90% - 100%	Current value
G7	150	150	75	**30**	15	15	30