# EVALUATION OF PROCESS WATER QUALITY FOR THE PRODUCTION OF DRY FOODSTUFFS

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August 10, 2020, Eexterveenschekanaal
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# Evaluation of process water quality for the production of dry foodstuffs

Bachelor thesis

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# Preface and Acknowledgements

Before you lies my bachelor thesis report ‘Evaluation of process water quality for the production of dry foodstuffs’. This thesis was written as a graduation paper for the International Food Business program at the Aeres University of Applied Sciences.

Over the course of the past four years in this program I have learned a lot about all the processes concerned with the food supply chain, from marketing to consumer safety. Through my minors food safety management and food supply chain management, I have created a personal focus on what I find most interesting; management of processes in a safe and cost-efficient method. For my final thesis I had a deep desire to conduct a research on a question coming from the industry. Using my network, I was able to get in contact with the potato processing company Avebe.

After having received feedback on the initial thesis, the following aspects of the report have been changed: the research on Operation Excellence has been expanded, this has resulted in additions to the introduction, methodology, results, discussion of results, and the conclusions and recommendations. The chapters results, discussion of results, and the conclusions and recommendations also have been improved on different subjects.

I would like to thank the following people for their help in coaching me and providing me with constructive feedback. I would like to thank the following people in particular:

- My thesis coach Cynthia Akkermans, for all her time and effort in coaching me through the thesis writing process.
- My company coach Mandy Michauk, for her help during the chaos caused by the corona virus, and for providing very constructive feedback.
- My father and fiancé, for keeping me motivated and focused, and for letting me bounce some ideas off of you.

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# Summary

In the food industry water is commonly used in production. The legislation on water quality is focused on drinking water. The question arises:

**How should European producers of dry bulk food ingredients approach their decisions on process water quality considering production efficiency and the food safety for the consumers of the final product?**

This question was answered through identifying the 10 most relevant contaminants in both food production and water, the extent to which these parameters can divert from the European directive 98/83 without compromising the food safety of the product, through identifying and qualifying the risks of different approaches. Finally, the benefits in Operation Excellence of implementing a Process Water Quality Plan were researched.

The extent to which microbiological parameters can divert was found to be limited.

The ten most relevant contaminants are; arsenic, benzo(a)pyrene, cadmium, cyanide, lead, manganese, mercury, nickel, PAH, and aluminium. Research found that no diversion to the set parameters is legal due to the As Low As Reasonably Attainable principle set by the European Council. Diversion from the analysis frequency was found to be legally allowed if safety of the final product can be assured.

Through a risk analysis two safe approaches two process water quality have been found; the current parameters and analysis frequency, and a new approach where the analysis frequency is reduced according to the risks associated with the contaminants. A reduction in the analysis frequency of 2.12% was found from the current approach to the new approach.

The Operation Excellence benefits are increased efficiency, increased control, and indicating a future plan toward World Class. The Process Water Quality Plan might also be useful in increasing employee involvement.

European producers of dry bulk ingredients should approach their decision on process water quality by setting their analysis frequency of contaminants based on a risk analysis. Based on this risk analysis the frequency of analysis can be reduced according to the risk score. The data collected to this point should be summarized in a Process Water Quality Plan, which can be implemented by a company. The implementation of this plan has been found to have Operation Excellence benefits.

The recommendations for producers of dry food ingredients are to; implement the analysis frequencies as found in this research, to determine analysis frequencies for contaminants not researched in this thesis, to monitor any implemented changes, and conduct a periodic re-evaluation of the process water quality monitoring.

# 1. Introduction

In food production one of the most common ingredients or processing agents used is water. Since water is such a common product, the processes behind this ingredient are often overlooked or not given priority over other, more complex ingredients (M. Michauk, personal communication, February 11, 2020). In food production the first and foremost goal is to create products which are safe for human consumption in both short- and long-term use (European parliament and council, 2002). On the other hand, food processing companies need to make a profit in order to have a continuing business. How much profit a company can make depends on revenue and the costs. Revenue is the money received from customers for the final products, and the costs are the prices the company pays for its ingredients and processes (Business Victoria, 2020). The price of water as an ingredient is influenced by the incoming water quality, as this influences the degree of treatment processes required for the water, and the frequency and amount of analysis on the water, because performing an analysis costs money. It can also be that the company uses pure drinking water, as delivered by an external company. This would result in a higher cost for the water but lower costs on analyzing the water.

For food companies producing dry bulk ingredients, the decision-making process on the quality of water to be used as a processing agent is very difficult and legislation is not strictly decisive. Due to the low availability of detailed research on water quality for dry food production, decision making is difficult and requires a lot of resources from a company to assess the possible risks and benefits, which would be required to make a grounded decision. Therefore, this research on the process water quality will be conducted for companies producing dry bulk ingredients to give more clarity about the quality of process water used.

## 1.1 Sustainability and water usage in food production

Sustainability is an increasing worldwide concern: an increasing number of people from several countries are concerned about the amount of pollution, climate change and environmental damage (Globe Scan, 2019). As the concern rises, companies have an increasing need and desire to enhance sustainability within their operations. Sustainability consists of three pillars as described by many scientists (Purvis, Mao, and Robinson, 2019). The three pillars are described as; social, environmental and economic. Sustainability in the food production sector has been linked to food security. Food security has been defined by the Rome Declaration on World Food Security (1996) with three basic dimensions; availability, accessibility and utilization. According to Berry, et. Al. (2015) sustainability should be taken into consideration when assessing the long-term dimension of food security. In the decision about the water quality needed in food production, all three sustainability factors are important.

In the environmental pillar the focus lies on reducing carbon footprints, reducing waste and water use, and reducing the overall impact on the environment. If sustainability is about being able to continue business, the environment must be saved in order to be able to continue business (Purvis, Mao, and Robinson, 2019). In context of the environment the waste water which is discharged into the environment, should have a low impact and enable aquatic life to continue. This is legally required by the Dutch law on environment; *Wet Milieubeheer* (Rijkswaterstaat, Ministerie van Infrastructuur en Waterstaat, 2020). Also, the intensity of water treatment required is of influence for the environment. Processing energy is used by machines which clean the water, and waste is created as cleaning agents are added. The cleaning agents which are added have their own supply chain, and therefore also their own carbon footprint.

The social pillar is all about the people a company works with, how are people treated and paid. If people are not treated right, business is very hard to be conducted, therefore it is a pillar of sustainability (Purvis, Mao, and Robinson, 2019). Another aspect of the social pillar is the perception society has about a certain business. In the societal context of this research it is important that the food produced will be safe for consumption now, and also safe considering long time exposure.

An example that the quality of food products has a societal impact is the case of the American restaurant chain Chi-Chi, which found itself having to pay over 30 million euros after many people got food poisoning from eating at their restaurant (Kok, 2005). After Chi-Chi had paid these huge fees, they had to face their bad reputation among consumers. The absence of societies trusts in the safety of their products again cost the company a lot of money; no trust lead to no business (Kok, 2005). Therefore, the quality of water is important, because it can influence the safety of the dry bulk ingredients.

Finally, the most overlooked pillar of sustainability; economic. If a company has very little impact on the environment and treats its people perfectly but the company doesn't make any profit, the company will soon be closed and will no longer be able to contribute to the economy (Purvis, Mao, and Robinson, 2019). In the economic pillar sustainability is found in a combination of costs and benefits. If the water ensures a safe product which consumers will continue to use, the company will continue and will make a profit. The processing and analyzing of the water on the other hand, costs the company money. In the water processing it is very important to be efficient. Being efficient means that the company does things right. In terms of water processing this means that the water should be processed using the method which has the best results, while also being the best cost option.  Sustainability will be ensured if a balance between the three pillars is found.

Considering these factors, the question rises what the desired quality of the water should be. The safest option might be desired from society perspective, but material costs for water treatments and analysis should be reduced to a minimum in order to remain profitable. For food producing companies with their own water processing facilities this question is very relevant. First and foremost, they need to produce food products which are safe for human consumption. As the water is used as a processing agent during the production process, the water should be of a quality fit for this purpose. On the other hand, every additional processing step, and analysis to confirm that the processing step has been sufficient, leads to additional costs. A company could choose different strategies in this decision, each strategy has its own risks and rewards. Should a company choose to aim for the highest possible quality of the water used, the costs of production would increase with the increase of water treatment, and the customer perception on the quality of the business and its products would be projected to be high too. High customer satisfaction would result in re-purchases, and thus continuity for the business. Another extreme strategy could be to aim for the lowest amount of water processing in order to minimize production costs. With the lower costs the profit would be higher. On the other hand, cost reduction on water quality might lead to food safety incidents, and perhaps even bankruptcy. Another risk would be that the food safety authorities find out about this negligence in production, and could issue the company a large fine, which would again decrease profit.

Quality systems are put in place by companies in order to guide the company to follow its set direction and strategic decisions. The general case strategies as described in the paragraph above, would be put in a quality system in order to implement this strategy. Different quality systems are used to focus on different subjects, e.g. ISO 9001 is focused on quality, and HACCP is focused on food safety (Kafetzopoulos & Gotzamani, 2013).

For many years' companies producing dry foodstuffs have followed the general drinking water regulation. Because of this they have been using drinking water in their production. The quality of drinking water needs to be validated through analysis confirming the water is within the set parameters. The regulation 98/83/EC states how the drinking water should be analyzed and at what interval (European Council, 1998). Conducting these analyses is a costly operation (M. Michauk, personal communication, March 3, 2020). It might be interesting for food production companies to lower the standards of the quality of the process water used, and to reduce the amount of analysis performed on this water, as this would save production costs and thus increase profit. Re-evaluation of the quality manual in general in a dry foodstuffs production company has led to the request of research on this topic.

## 1.2 Processing dry bulk ingredients

Food processors which use a lot of water are for instance producers of starch, sugar, proteins and fibers in powdered form. They isolate specific ingredients from raw materials (e.g. potatoes, corn, sugar beets). These products can be referred to as bulk ingredients, as they are produced and sold in mostly large quantities. Another important characteristic these products have, is that these products are identified as dry products. Dry food in this research will be defined as products which have a water activity, water activity (Aw) value, below 0.85. The definition of dry under the Aw value of 0.85 is taken from comparable researches on low-water activity foods as described by Beuchat et al. (2013).

The specific product, which will be used to benchmark to, in this research is potato starch with a water content between 70mg/g and 80mg/g. Based on research by Witczak, T. et al. (2016) this water content in potato starch translates to an Aw value between 0.1 and 0.2 as is shown in figure 1 on the right. As this research should be applicable to the entire industry, I have taken products with Aw value under 0.85 into consideration. This demarcation of water activity in products will be used to include or exclude data in the literature research.

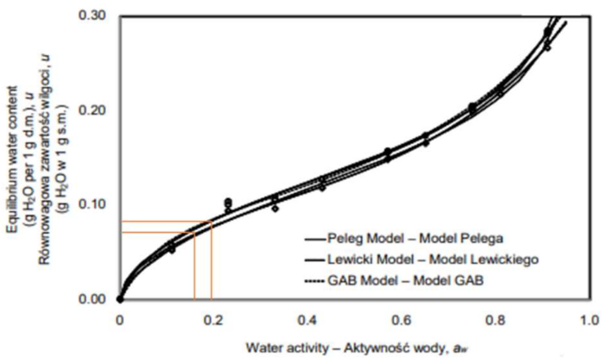


**FIGURE 1 RELATIONSHIP BETWEEN WATER CONTENT AND WATER ACTIVITY (WITCZAK, T. ET AL., 2016)**

The general flow of processing potatoes into starch, protamylasse (thickened potato juice), protein, and fibers is shown in figure 2 on the next page. The most important information from this flowchart for this research are the process steps where process water is added to the process, and where the water is removed from the process. In general, the amount of water used to process one ton (1000 kg) of potatoes is 1.16m$^3$ . Calculating back from the final product the amount of water used is; 5,8m$^3$ water to produce one ton of starch (B. Gerrits, Personal Communication, March 31, 2020).

As can be found in figure 2 on the next page, water is added to the process at five different steps. In the one of the steps where water is added, a part of the water used is re-used from a downstream process step; washing of potatoes. The removal of water from the process is found in six different processing steps. Five out of the six times, the removal of water is the final step in producing a dry bulk ingredient.

The process waste water is thoroughly cleaned at the processing site. However, this cleaning process of water lies outside the scope of this research, as this water is cleaned to a degree where no adverse effects are found if the water is pumped back into the local ecosystem, and thus not cleaned for the production or processing of food materials.

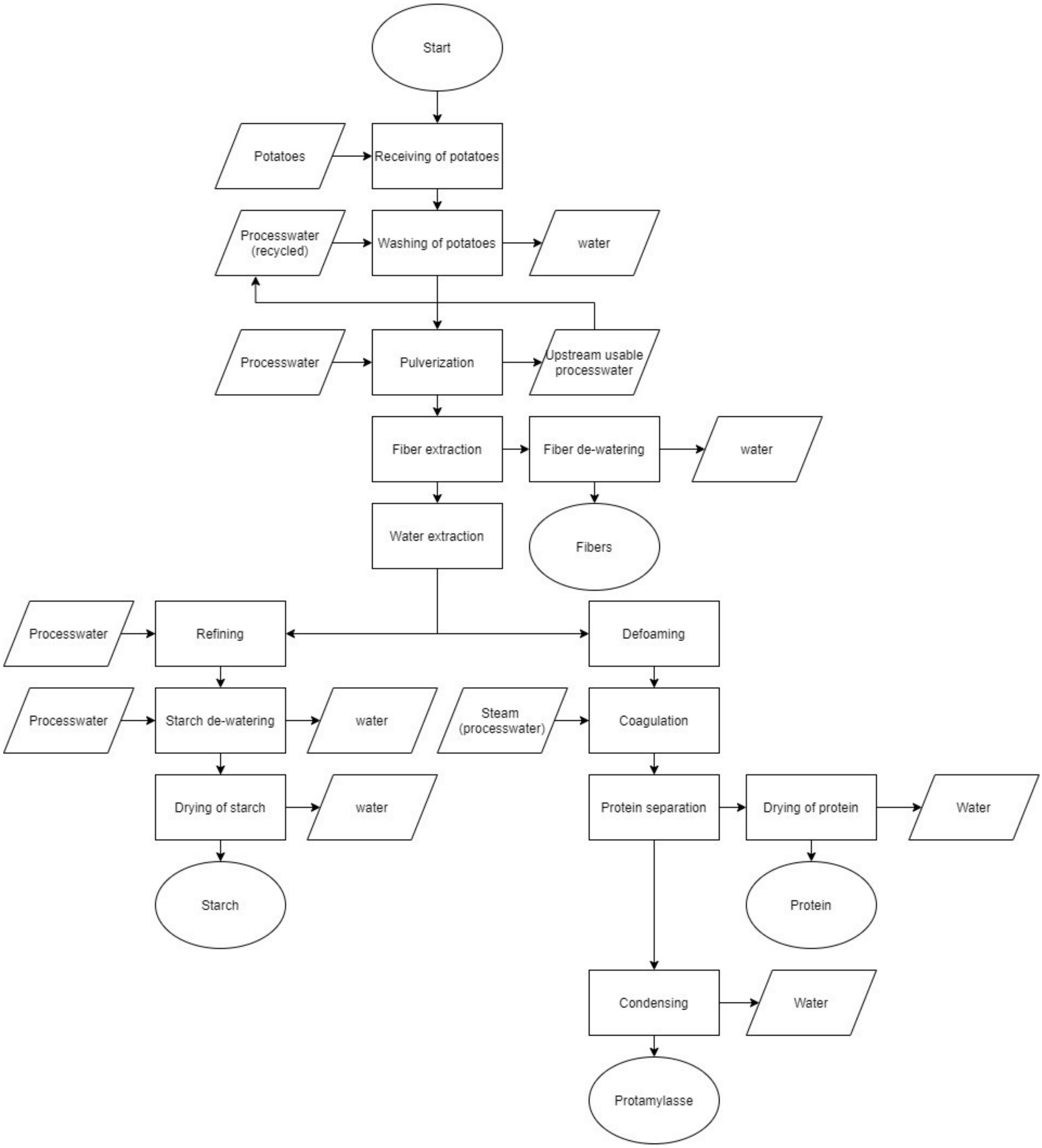


**FIGURE 2 FLOWCHART POTATO STARCH PRODUCTION PROCESS (M. MALLEE, PERSONAL COMMUNICATION, FEBRUARY 24, 2020)**

## 1.3 European legislation on water in food production

Legislation on water quality is aimed at ensuring safety for consumers of the drinking water. The World Health Organization's guidelines state that safe drinking water should not represent significant risk to health over a lifetime of consumption (2017). Looking at research on contamination of drinking water, an average daily consumption of 2 liters is typically considered (Mohammadi, Yousefi, Mahvi, 2017).

European legislation connected to processing water in food production is found in two subjects; food safety, as regulated by 315/93 EC (European Council, 1993) and 178/2002/EC (European Council, 2002), and drinking water which is regulated by 98/83/EC (European Council, 1998).

In 1993 the council regulation No 315/93/EC '*Laying down Community procedures for contaminants in food'* came into force (European Council, 1993). This regulation enforces a principle now known as ALARA (as low as reasonably achievable). This principle states that, even though a contaminant is found to be only potentially dangerous above a certain level, it is the producer's responsibility to still reduce the level of the contaminant to the lowest level which is reasonably achievable if good practices are followed.

The directive for drinking water intended for human consumption is document 98/83/EC (European Council, 1998). In general, the main goal of this directive is to ensure consumer safety. The use of drinking water quality in production processes has preference, however, if the competent authorities can be satisfied that the quality of the water used, does not adversely affect the final product intended for consumption a lower water quality is allowed according to account consideration 7 and articles 2.1b and 3.2a.

Drinking water directive 98/83/EC states that water used in food production should be of drinking water quality, unless the competent authority can be satisfied that the quality of the water does not affect the wholesomeness of the product or the health of the consumer concerned (European Council, 1998). This legislation on process water used in food production appears to leave some room for interpretation on the required quality of the water, as long as safety is secured, and the competent authority can be convinced of this. The directive does not clearly define who the competent authority should be. The competent authority is different for each Member State, in the Netherlands the competent authority is the Dutch Food and Drug administration (NVWA). The ultimate purpose in European legislation on food production is to ensure consumer safety.

The main EU legislation on food safety is found in regulation 178/2002/EC; which lays down the general principles and requirements on food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety (European parliament and council, 2002). This regulation states the general principles of food law, and in article 5.1 this is defined as followed:

> *"Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests..."*

Through risk analysis member states shall determine whether a food product is safe for consumption or not. In this risk analysis the intended use for the product should be taken into consideration, according to articles 6.2 and 14.3 (European parliament and council, 2002). Following the decision of the European council in 2003, Member States should follow the rules as stated in the Codex Alimentarius. In the Codex Alimentarius the HACCP, Hazard Analysis of Critical Control Points, is indicated as the best risk analysis tool (Joint FAO/WHO Codex Alimentarius Commission, 2009).

In chapters 4 and 5 the Codex Alimentarius (2009) gets more specific on water quality required for production of foodstuffs. In chapter 4.4.1 water supply it is stated that potable water is required whenever necessary to ensure safety and suitability of food. Chapter 5 gets more specific as it states in 5.5.1 water in contact with food; "*Only potable water should be used in food handling and processing, with the following exceptions: … and; in certain food processes, …, provided this does not constitute a hazard to the safety and suitability of food."* (Joint FAO/WHO Codex Alimentarius Commission, 2009).

Looking at how the European Commission has regulated maximum levels for certain contaminants in food, regulation 1181/2006/EC is the first document to look at. The fourth consideration states that maximum levels of contaminants should be set at a strict level which is reasonably achievable, and for contaminants which are considered to be genotoxic carcinogens the maximum levels should be set at a level which is as low as reasonably achievable, this value is to be benchmarked with the rest of the industry. In article 2 the regulation states that the food business operator shall be able to provide, and justify, the contaminants level in products which are either diluted, dried or processed, whenever the competent authority carries out an official control (European parliament and Council, 2006).

## 1.4 Contaminants in drinking water

The European council has created an extensive list of microbiological and chemical contaminants which should be controlled in drinking water. This list has been created based on research conducted by the World Health Organization (World Health Organization regional office for Europe, 2017). In the research both the potential health risk, and the occurrence of the contaminant in water were taken into consideration.

Table one on the next page lists the contaminants which have been identified in directive 98/83/EC as being the contaminants in drinking water which should be controlled. In the first column the contaminant is given, in the next column the parameter set by the European Council is given. The last column gives the analysis frequency required for a company which uses 9000 $m^3$ of water per year. The data from this table will be used to compare data specific for food parameters to. The purpose of this table is to set the framework on what parameters will be relevant for this research.

TABLE 1 POSSIBLE CONTAMINANTS AND SAFE PARAMETERS OF WATER (EUROPEAN COUNCIL, 1998)

| **Contaminant** | **Water quality parameter** | **Analysis Frequency (per year)** |
|---|---|---|
| *Escherichia Coli* (E. coli) | 0/ 100 ml[1] | 31 |
| Enterococci | 0/ 100 ml | 31 |
| Acrylamide | 0,10 µg/l | 3 |
| Antimony | 5,0 µg/l | 3 |
| Arsenic | 10 µg/l | 3 |
| Benzene | 1,0 µg/l | 3 |
| Benzo(a)pyrene | 0,010 µg/l | 3 |
| Boron | 1,0 mg/l | 3 |
| Bromate | 10 µg/l | 3 |
| Cadmium | 5,0 µg/l | 3 |
| Chromium | 50 µg/l | 3 |
| Copper | 2,0 mg/l | 3 |
| Cyanide | 50 µg/l | 3 |
| 1,2-dichloroethane | 3,0 µg/l | 3 |
| Epichlorohydrin | 0,10 µg/l | 3 |
| Fluoride | 1,5 mg/l | 3 |
| Lead | 10 µg/l | 3 |
| Mercury | 1,0 µg/l | 3 |
| Nickel | 20 µg/l | 3 |
| Nitrate | 50 mg/l | 3 |
| Nitrite | 0,50 mg/l | 3 |
| Pesticides | 0,10 µg/l | 3 |
| Pesticides – Total | 0,50 µg/l | 3 |
| Polycyclic aromatic hydrocarbons | 0,10 µg/l | 3 |
| Selenium | 10 µg/l | 3 |
| Tetrachloroethane and trichloroethane | 10 µg/l | 3 |
| Trihalomethanes – Total | 100 µg/l | 3 |
| Vinyl chloride | 0,50 µg/l | 3 |
| Aluminum | 200 µg/l | 3 |
| Ammonium | 0,50 mg/l | 3 |
| Chloride | 250 mg/l | 3 |
| *Clostridium Perfringens* (including spores) | 0/ 100 ml | 31 |
| Color | Acceptable to consumers and no abnormal change | 31 |
| Conductivity | 2500 µS $cm^{-1}$ at 20˚C | 31 |
| Hydrogen ion concentration | =/> 6,5 and =/< 9,5 | 31 |
| Iron | 200 µg/l | 31 |
| Manganese | 50 µg/l | 3 |
| Odor | Acceptable to consumers and no abnormal change | 31 |
| Oxidisability | 5,0 mg/l $O_2$ | 3 |
| Sulphate | 250 mg/l | 3 |
| Sodium | 200 mg/l | 3 |
| Taste | Acceptable to consumers and no abnormal change | 31 |
| Colony count at 22˚C | No abnormal change | 31 |
| Coliform bacteria | 0 /100 ml | 31 |
| Turbidity | Acceptable to consumers and no abnormal change | 31 |

[1] The value of 0/100ml is taken from the legislation as found in Annex 1 part A of the Directive 98/83/EC, the author acknowledges that this is not a value which can be reasonably measured, it is assumed that this contaminant should be absent in a 100ml sample.

## 1.5 Operation Excellence in food businesses

Operation Excellence is all about a company making great efforts to excel in their business, and to set themselves apart from their competitors. The origins of Operation Excellence can be traced back to the works of Treacy and Wiersema (1993). In their work *"The discipline of market leaders: Choose your customers, narrow your focus, dominate your market"* (Treacy & Wiersema, 1995) they describe three core distinctive disciplines; product leadership, customer intimacy, and Operation Excellence. The term Operation Excellence is described as a strategy where a company strives to deliver a combination of quality, price, ease of purchase, and a customer service which is unique to their market, and in the industry.

Gleich & Sautter (2008) have described Operation Excellence as an enabler for oriented framework as followed: *"Operation Excellence is the development of enablers to generate competitive benefits in a dynamic environment based on the resources of an organization. The composition and expansion of enablers is the basis for continuous improvement, change, and the optimization of business processes. Therefore, Operation Excellence is the dynamic capability to realize effective and efficient core processes in the value creation chain utilizing technological, cultural and organizational factors in an integrative way and based on the respective strategy. "*

Both Treacy & Wiersema and Gleich & Sauter describe how Operation Excellence is about competitive advantages over the competition in the market and industry. A commonly accepted definition, or even a unifying theory on Operation Excellence, is currently not available, this was the conclusion of the research "Towards a theory of operational excellence" by Found, Lahy, Williams, Hu, and Mason (2018).

For the purpose of this research the framework as created by Jaeger, Matyas, and Sihn (2014) was used to indicate different aspects of Operation Excellence. Figure 3 on the next page gives their framework from the perspective of systems.

The framework gives clear indicators of a business moving from its foundation, top row, to becoming an operational oriented business, second row. A business can assess itself by looking at the different aspects; leadership, culture, strategy, organisation and people, to see how far the business as implemented operations excellence.

In culture an important indicator is the change from a focus on sustainability and long-term success to high performance, continuous improvement and working on a value stream.

In the focus of strategy important indicators are having a plan towards world class and working with a lean production system, as can be seen in figure 3. In the model of operational excellence by Naftanaila, Radu and Cioana (2013), which can be found in figure 4 on page 11, world-class performance is indicated as one of the three pillars to operational excellence.

In the model of Jaeger et al. (2014) how teams work together is important indicator of Operation Excellence, employee involvement and empowerment are part of Operation Excellence. This importance of people and people working in teams is also found in the model by Naftanaila, Radu and Cioana (2013).

Important in Operation Excellence is not only one business, but the entire value chain; from suppliers all the way to consumers. Within this value chain it is important that each link in the chain is adding business, and that the information in the chain also moves back up the chain, this is visualized in the figure by the circling arrows in the operational process.

Although this framework is a great assessment tool, it would be a misconception to think that Operation Excellence has an end point. The core of Operations Excellence is that it is an ongoing effort to improve the business (Jaeger et al. 2014).

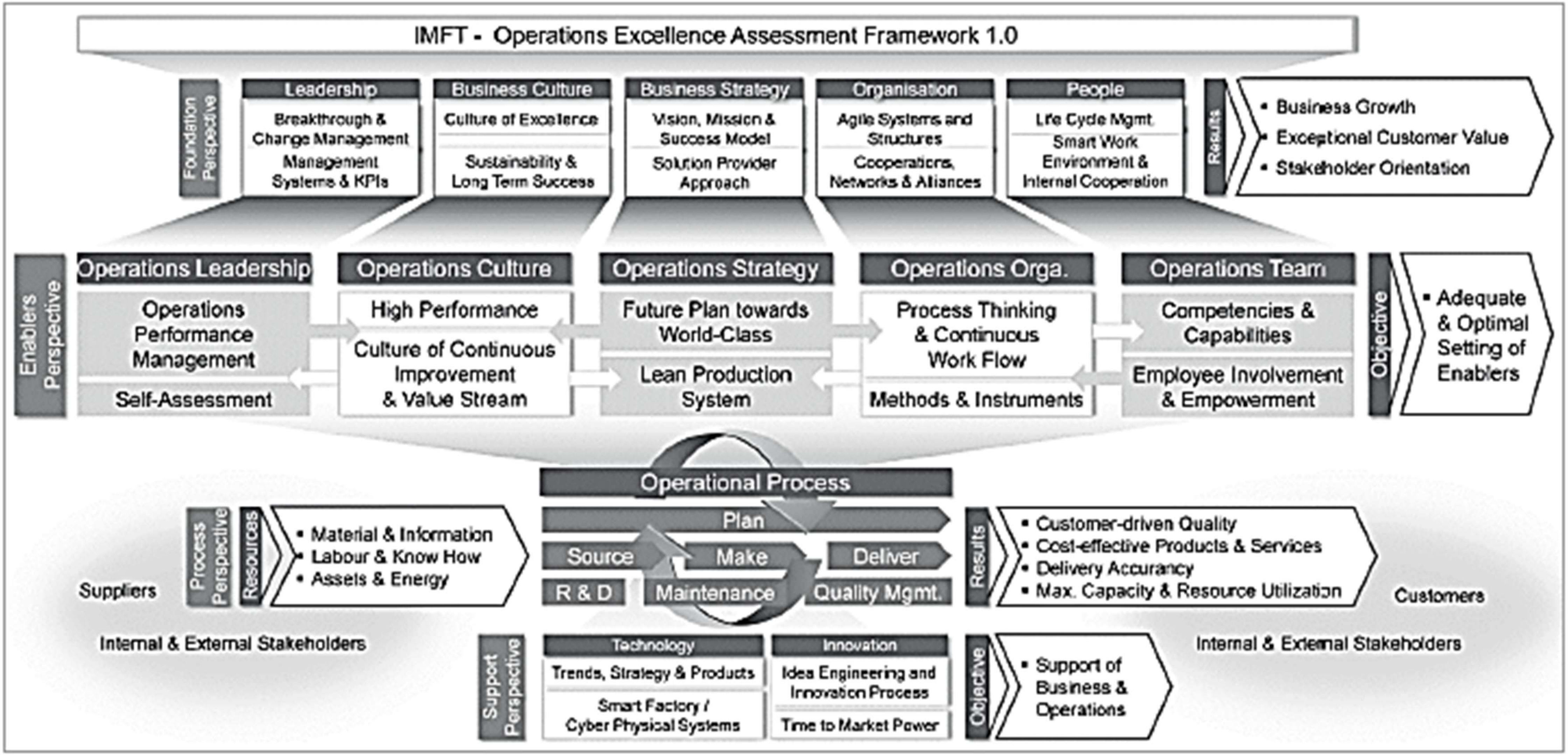


FIGURE 3 OPERATIONS EXCELLENCE FRAMEWORK (JAEGER ET AL. 2014).

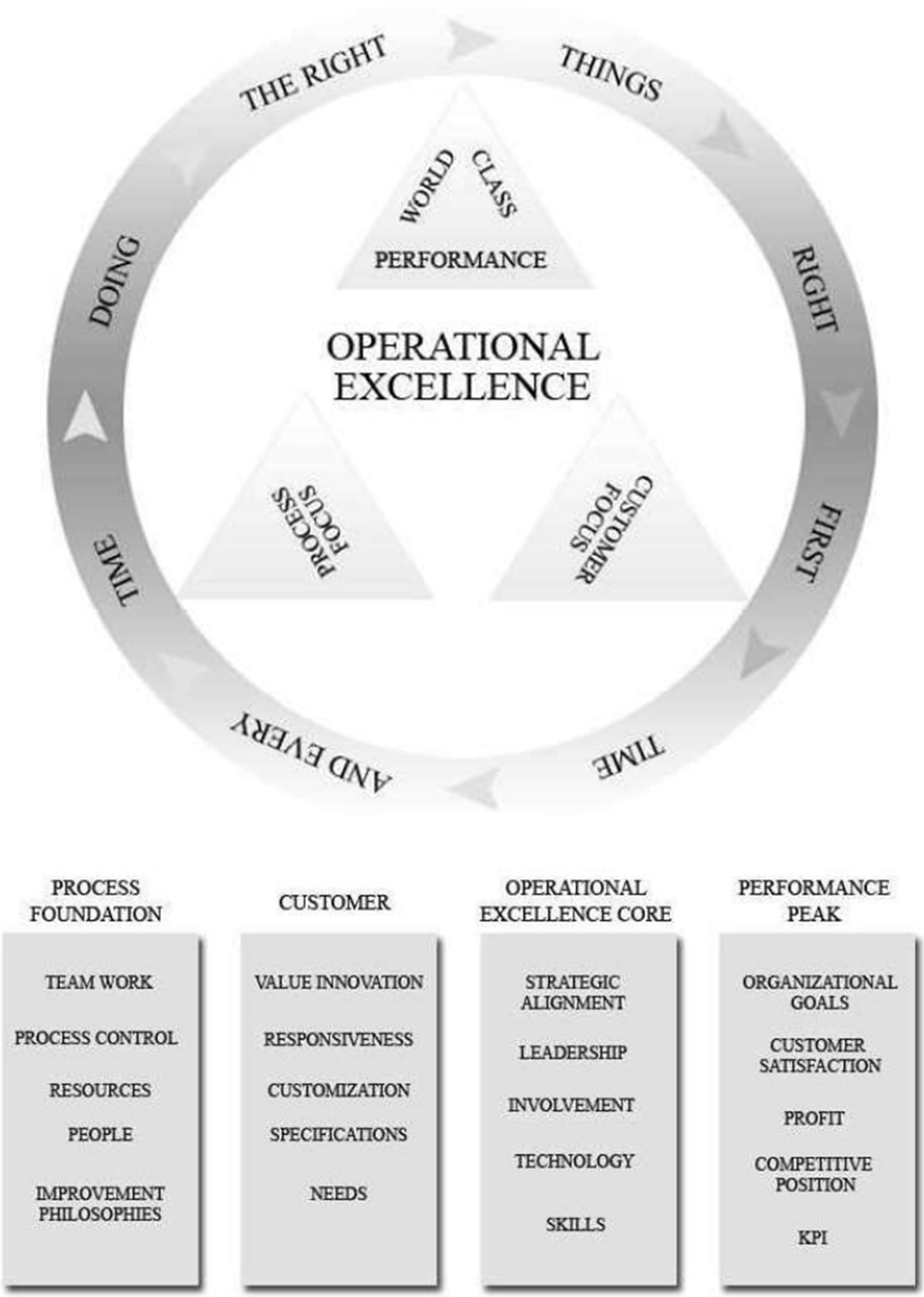


**FIGURE 4 MODEL OF OPERATIONAL EXCELLENCE (NAFTANAILA, RADU AND CIOANA, 2013)**

Operation Excellence is useful for food businesses as it helps a business to better understand its operations, and it helps to understand how the business is linked to its suppliers and customer in the value chain. In a world where food trends are moving very fast, and thus flexibility and agility is needed in food businesses, implementing the ongoing effort of Operations Excellence is a great method (Paquin & Prouty 2015).

The importance of operational excellence in food business has been shown in the "*Lessons learned from the 2014 Global Food Safety Training Survey"* by Campden BRI (2014). The conclusion of this report is that businesses will be most effective if they are proactive rather than reactive. This starts in the training of employees, if this training is done in line with figure 5 below, operational excellence will be created. This figure shows that the model for operational excellence is a continuous cycle. First standard operating procedures should be set, this should be incorporated in a knowledge system, this knowledge should then be transferred to the rest of the company, the results of this standard operating procedure need to be verified and validated, and based on these findings improvements should be made where necessary, from this improvement need the cycle starts over.

The "Model for Operational Excellence" below, and the "Operations Excellence Framework" on the previous page, both show a need for employee involvement. According to research by Phipps, Prieto and, Ndinguri (2013) employee involvement leads to organizational productivity.


FIGURE 5 MODEL FOR OPERATIONAL EXCELLENCE (CAMPDEN BRI, 2014).

How businesses structure their process water analysis plan can help a business improve its operations excellence, or their process water analysis plan can be a result of operations excellence. The process water analysis plan might affect different aspects of a company's Operation Excellence; generating more accurate information on the process water can increase the value stream, in the process water analysis plan formulation a lean production system could be implemented, and a better understanding of the process water could set a better standard operating procedure which then might be useful in increasing the employee involvement. How a process water analysis plan could affect operations excellence is to be researched in this thesis.

## 1.6 Processing water for dry bulk ingredients

The safety of the consumer is at the heart of European legislation on drinking water and food, the question which now needs to be answered is whether the legislation set for drinking water applies to the water quality used in the production of food, and more specifically dry foodstuffs. The legislation clearly describes two aspects in protecting consumer safety; water and the final food product, but it appears to not consider the effects of processing in the production. For example, in potato processing, at the same point where water is added to the process, so is a chemical which aids in the process. The water used was of drinking quality to the point where it was added to the process, but as soon as it is added to the process another ingredient makes it absolutely unfit to be consumed by humans at this point. Further processing steps will remove these parts to ensure safety for human consumption again. This raises the question if producers of dry food stuffs can divert from this legislation as long as food safety for humans can still be guaranteed.

The safety parameters for drinking water and food products have been set in such a way to ensure consumer safety now and in the long term. The quality for drinking water is set at a high level, as it considers that consumers will consume about 2 liters of the same source per day, and typically consumers do not have easy and convenient access to a different drinking water source. Safety parameters in food safety are set less strict as the exposure from food products is spread over multiple different products, the exposure from one product is less significant on a life than the exposure from drinking-water (WHO, 2017).

Based on this identified knowledge gap the following research question has been formulated:

How should European producers of dry bulk food ingredients approach their decisions on process water quality considering production efficiency and the food safety for the consumers of the final product?

To answer this main question the following sub questions will need to be answered:

- What are the ten most relevant chemical contaminants from the list of identified contaminants relevant for water quality, in relationship to the production of dry bulk ingredients?
- To what extent can chemical parameters divert from the directive 98/83 without compromising the food safety of the final product?
- To what extent can microbiological parameters divert from the directive 98/83 without compromising the food safety of the final product?
- What are the risks associated with different approaches to process water quality in relation to food safety?
- What are the Operation Excellence benefits for implementing a Process Water Quality Plan?

The objective of this research is to provide the industry with information on the legal requirements for the quality of process water, and to provide a clear overview on safety being influenced by the process water used. A company could use this research in its risk analysis for determining the water quality of the company's process water used in the production of dry bulk food ingredients.

Three hypotheses have been formulated as a basis for the risk analysis which will be conducted:

$H^1$: There is legal room to decide to divert from the drinking water quality standard for the quality of process water.
$H^2$ The microbiological parameters for the quality of process water can divert from the directive without compromising the food safety and suitability of the final product intended for human consumption.
$H^3$ The chemical parameters for the quality of process water can divert from the directive without compromising the food safety and suitability of the final product intended for human consumption.

Based on the found results dry bulk ingredients producing companies might be able to adapt their water processing activities and analysis frequency, as the risk analysis will identify what options are safe for the consumers, legally permitted in European law, and most cost efficient for the company.

Research on the possibility to lower the quality of water used in dry foodstuff production is relevant for dry foodstuff production companies, who want to lower their overall investment, and for end consumers of the produced food product, as it is their health which is concerned with this. This research will also be relevant for the European Governments as it is their task to ensure the safety of consumers, while also creating and maintaining an enabling business environment for production companies.

To elaborate on the production companies for whom this research is relevant; this research is applicable for producers of dry foodstuffs, who have their own water facility used in production, which will be able to meet the to be defined new parameters.

# 2 Materials and Methods

This research has descriptively identified the characteristics and patterns in safety parameters and analysis frequency on the identified contaminants in water used in the production of dry foodstuffs. This has been done because the processes where water is used in the production of dry foodstuffs has not been researched a lot in relation to the needed water quality. The water quality safe for human consumption has been described (De Jongh, et al., 2012), however, water used only as a processing agent which will only be consumed in very small quantities, as is the case for dry foodstuffs, has not yet been extensively researched.

The research has been a combination between a quantitative and qualitative research. The decision to conduct a quantitative research has been based on similar researches which have been conducted, for example the work by Pérez-Rodríguez, Skandamis and Valdramidis (2018) who evaluated food safety and quality in the vegetable industry. This research is relevant as it is concerned with food safety and it is about a similar industry; vegetable industry.

An alternative option for the research would have been a mixed research; qualitative and quantitative. As studies in health services have relevant similarities in how the research should be designed; both food and health cannot be seen as independent of the society or culture in which they are being researched, current policy and politics have a large influence on these subjects (McCusker and Gunaydin, 2014). The consideration to exclude a qualitative method is that this method type, although it raises more issues through a wider and more open inquiry, it has no objectively and verifiable result (Choy, 2014). As this research is concerning the safety and suitability of food products to be consumed by humans, a verifiable result is of high importance.

In order for this research to be relevant and of considerable quality, the research has been focused on literature research and interpretation of this literature. This research is relevant for production companies which produce dry food products with a low water activity. The data has been collected through desk research in online data banks and scientific publications using set search terms and key words. The structure, data banks used, search terms used, and the inclusion and exclusion criteria will be described next. As mentioned before the data for this study has been gathered through the following databases; google scholar, eur-lex, PubMed. These databases have been identified for their reliability. Google Scholar is used as a simple way to conduct a broad search for scientific publications. Eur-lex is the database for all European legislation. The third and final database which has been used is PubMed. This database has been identified as a reliable source for scholarly communications services (Williamson, & Minter, 2019).

## 2.1 Identifying top 10 relevant contaminants

The key search terms which have been used are; analysis, chemical, directive 98/83, food, food safety, microbiological, process water, processing, regulation 178/2004, water quality, all contaminants as listed in table 1. The inclusion criteria were; the source must have been written in either English or Dutch, not dated before the year 2000, preferably dated after 2010. In order for this research to be relevant only data which are not older than 20 years will be used, where data not older than 10 years are preferred. However, where legislation is dated from before the year 2000 it was still considered if no updated versions have been published, as this legislation continues to be relevant until updated. The source must have been written in either English or Dutch to ensure that the researcher was able to interpret the source without a need to translate, which would potentially have led to misinterpretation of the source.

A list of the top 10 relevant contaminants for food products from the list as described in table 1 in the introduction has been based on data from the Rapid Alert System for Food and Feed (RASFF). Through an analysis of the notifications on 'dietic foods, food supplements, fortified foods' over the years 2017 to 2019, the most occurring correlational contaminants have formed the top 10 contaminants for this research. The following search terms were entered into the portal; notified from: 01/01/2017, notified till: 31/12/2019, product type: food, product category: dietic foods, food supplements, fortified foods.

## 2.2 Research on possibility to deviate parameters

The second and third sub questions were concerned with researching the top 10 relevant contaminants for dry food products. A minimum of three sources has been collected for the top 10 relevant chemical contaminants in both water and dry foodstuffs and the microbiological contaminants as described in table 2. For each contaminant the following parameter values were needed; maximum tolerable value of the contaminant in water, maximum tolerable value of the contaminant in food products. The parameters were calculated as a tolerable daily intake for an adult of 60 kg. The assumption of 60 kg for an adult was taken from the scientific opinion report of the EFSA CONTAM Panel (2012). An average parameter value was calculated based on the three identified parameters, this average value has been reduced to show no decimals. The value was reduced and not rounded in order to provide a safety measure. The same calculation decision was taken in the calculation of the standard deviation for the three identified parameters.

After the data had been collected, the data was organized to create a clear overview so that an analysis could be performed. The data was analyzed through a descriptive statistical analysis. The average value and standard deviation for each contaminant were evaluated and presented in bar charts for each contaminant, showing the values for food besides the values for water. Based on the found reasoning between the legislation type, higher precautionary in water due to larger exposure, it was expected to find a multiplication factor between the food levels and the water levels for contaminants.

## 2.3 Formulating process water management strategies

Four different strategies for process water management have been described. The first strategy is to follow the current parameters and to follow the current analysis frequency. The second strategy follows the current parameters set, but has a different analysis frequency. The third strategy had different parameters, but followed the current analysis frequency. And the fourth strategy had different parameters and different analysis frequencies.

The value for the current parameter (same parameter), is based on the parameter as set for water. As the parameters for food were defined as a total per day, the parameter for water was multiplied by 2, as the water parameter set as amount per litre, and the average consumption of water is two litres per day (EFSA NDA Panel, 2010).

The analysis frequency have been adjusted following conditions about the factor found from the lowest parameter identified for food to the water parameter. If the factor was lower than 2; the analysis frequency was kept at 3 times per year. If the factor was between 2 and 25; the analysis frequency was reduced to 2 times per year. If the factor was higher than 25; the analysis frequency was reduced to the minimum of 1 time per year.

## 2.4 Risk Analysis

For the diversions which were identified as safe, a risk analysis has been conducted following the risk analysis matrix as used for the British Retail Consortium Certification (BRC) body, as this certification is a GFSI level certification (British Retail Consortium, 2005). This high-level method has been used to ensure validity of the results for the companies which will use the results.

The risk analysis matrix evaluated risks on two values; severity, and likelihood of occurrence. The risk scores were calculated by multiplication of the score on likelihood of occurrence and the scores for severity.

Severity was defined by the safety concern for consumption. Each variable has been scored on a scale from 1 to 5, at which 1 is very low and 5 is very high. The lowest score of 1 for severity indicated that no medical attention was required, the medium score of 3 indicated that medical attention would be required but a full recovery would be expected, and the high score of 5 indicated that medical attention would be required and a full recovery would be unlikely. This scale of severity is based on the Establishment-based Risk Assessment (ERA) model for food establishments as set by the Canadian Food Inspection Agency (2019).

For likelihood of occurrence a score of 1 indicated that no reported cases in Europe were found, a score of 2 indicated less than 1 case since the implementation of the RASFF portal, a score of 3 indicated 1 reported case since the implementation of the RASFF portal, a score of 4 indicated 2-50 reported cases since the implementation of the RASFF portal, the high score of 5 indicated that at least one case was reported in the RASFF portal over the past year. This scale has been adapted from the Hazard Analysis of Critical Control Points (HACCP) as described in the BRC Global Standard for food safety 8 (2005). The search terms put in the RASFF portal were; subject: "*Contaminant"* Notified from: 01/01/2001, Notified till: 31/05/2020, Product type: food, product category: 'dietic foods, food supplements, fortified foods', Risk Decision: serious.

After the calculation was made each risk had a score, scores were evaluated as followed; 1-4 safe, 5-9 potentially unsafe and will require more research, 10-25 unsafe.

As the severity scores were based on high values of the contaminants; the risk score is higher than would be reasonably expected with the parameter set. An adjusted risk analysis has been done based on a lower likelihood of occurrence, this adjustment was based on guidelines for risk management as provided by NASA (2017). For the contaminants where the parameter set was at least a factor 10 compared to the NOEL the likelihood of occurrence score was reduced to 1, where the factor was between 3 and 10; a reduction of one point was made to the likelihood of occurrence score , and where the factor was less than 3; no reduction was made.

An adjustment to the proposed new analysis frequencies, needed to be made based on the risk score found. The frequency analysis of the contaminants were based on the risk score found, the high risks should be analyzed 3 times, the medium scores 2 times, and the low scores 1 time.

The data which has been used as input for this risk analysis was internal data from AVEBE, a potato processing company, and public data available, for instance food safety reports and data available from the RASFF portal.

The data collected to this point will be used by a business to formulate a Process Water Analysis Plan, this plan states which analyses need to be conducted, and this research is used to endorse why these analysis should be done.

## 2.5 Identifying Operation Excellence benefits

In order to find how implementing a Process Water Analysis Plan would benefit the Operation Excellence, a semi- structured interview with 4 expert interviewees was held. Sample sizes are difficult to determine for qualitative research. Baker and Edwards (2012) have gathered opinions from 14 experts in an effort to answer the question "*How many qualitative interviews is enough?"* the conclusion of this discussion paper was that '*it depends'.* All of the experts indicated that the number of interviews which is enough depends on a lot of different aspects; what is the nature and purpose of the research, but also it is important to consider the level of degree, and the time which is available to conduct the research. According to Smith, Flowers and Larkin (2009) the sample size for qualitative research should be in the range of 3 to 16. Where the lower end would be suitable for undergraduate research, and as the level of the degree increases, so should the sample size. Based on the two sources given above, it was decided that this research at undergraduate level would work with a sample size of 4 respondents.

The interviewees were selected as followed; two interviewees work at the sponsor company Avebe, this ensured vertical depth. The two other interviewees work at two different companies; the Dutch department of Defense, and PizzaSi. This brings the interview sample size to four.

The interview questions were designed to answer the sub question; *What are the Operation Excellence benefits for the best approach as found in the risk analysis?* The interview consisted of 8 questions, each question aimed to find how the implementation of a process water analysis plan could affect different aspects of Operation Excellence. The aspects of Operation Excellence which were researched were; strategy, value stream, lean production systems, employee involvement and standard operating procedures.

The 8 interview questions were:

- How would you describe/define Operation Excellence?
- How can a Process Water Quality Plan affect a product's value stream?
- How can a Process Water Quality Plan affect a company's strategy? Or is the decision to write this plan a result of a strategy?
- How does a Process Water Quality Plan fit in a lean production system?
- What are important aspects in the development of Standard Operating Procedures?
    - How could a Process Water Quality Plan be used in this development?
- Where can employee involvement be found? When is 'Why' explained to employees?
- What are Operation Excellence benefits of the implementation of a Process Water Quality Plan?

The results of the interviews have been written in an interview report format. The results have been written based on the form by Meulenberg (1990). The section start with an introduction where the subject is given, the name of the interviewer, the name of the interviewees, the data of the interviews, the duration time of the interviews, and the place the interview were conducted. The core of the report describes the interview in the third person, and where relevant citations from the interviews were given. The section was concluded with a characterisation of the interviews and remarks on the reliability of the information obtained. The interview transcripts on which the results were based can be found in Annex II.

# 3 Results

This chapter will show the results which have been found, and shortly discuss these findings. The ten identified relevant contaminants were researched to find their parameters in food. The difference in the parameters for food and water was analyzed. Based on these findings four different strategies were formulated, and analyzed through a risk matrix to determine the optimal strategy for a food business. Through interviews with four experts from the business environment, the Operation Excellence benefits of implementing a process water quality plan were identified.

## 3.1 Contaminants

First the relevant contaminants for this research needed to be identified. Table 2 below gives the top 10 relevant contaminants as found by analyzing the data from RASFF (Rapid Alert System for Food and Feed), the notifications which have been used can be found in Annex 1. From the RASFF portal the most occurring contaminant was Benzo(a)pyrene with 15 occurrences, followed by Polycyclic aromatic hydrocarbons with 10 occurrences. The contaminants of Aluminium, Arsenic, Cadmium, Nickel and manganese had only occurred once in the time frame of 2017-2019. These contaminants were included as they did occur in both the RASFF portal and in the list of contaminants which should be monitored in water as shown in table 1 in the introduction. The contaminants in the table are shown in order of their frequency of occurrence.

TABLE 2 RELEVANT CONTAMINANTS IN WATER AND FOOD (RASFF NOTIFICATIONS COMPARED TO CONTAMINANTS MONITORED IN WATER BASED ON EU LEGISLATION)

| Contaminant | Count of occurrences |
|---|---|
| Benzo(a)pyrene | 15 |
| Polycyclic aromatic hydrocarbons (PAH) | 10 |
| Lead | 9 |
| Mercury | 3 |
| Cyanide | 2 |
| Aluminium | 1 |
| Arsenic | 1 |
| Cadmium | 1 |
| Nickel | 1 |
| Manganese | 1 |

Concerning microbiological contaminants there was only one occurrence of a problem concerned with E. coli in the products. Taking the contaminants from table 1 as a guideline, the microbiological contaminants of E. coli and *Clostridium Perfringens* were further researched. The zoonoses report of 2018 by EFSA and the European centre for disease prevention and control has found E. coli to be the third most commonly reported zoonoses (EFSA and ECDC, 2019). Research by Grass, Gould and Mahon (2012) has identified *Clostridium Perfringens* as the second most common cause for bacterial foodborne disease out brakes in the United States over the period 1998 to 2010.

For the microbiological contaminants it has been researched if they are relevant in raw materials, if these materials will undergo processing under high temperatures. As for the contaminant of E. coli the European Council has set a parameter as an indication value (European Council, 1998). This use of E. coli as indicator of bacteriological quality of water has been supported by research from Odonkor and Ampofo (2013). *Clostridium Perfringens* also is used as an indicator parameter, according to Stelma jr. (2018) this contaminant is a useful indicator of sewage contamination in water.

Although these microbiological contaminants are relevant for both water, and water used in production of food, and in food, these parameters are mainly used as indicators of contamination with water. As these contaminants are not set at a stringent level to ensure food safety, but more so set to warn producers and processors that their raw material is contaminated, these contaminants will not be researched for new parameters nor new analysis frequencies.

Table 3 on the next page shows the results from the data search for tolerable daily intake for an adult of the identified contaminants in food. For each found parameter the source is given in the column to the right. An average parameter value was calculated based on the three identified parameters, this value has been reduced to show no decimals. The value was reduced and not rounded in order to provide a safety measure. The same calculation decision was taken in the calculation of the standard deviation, as can be found in the last column of table 3.

**TABLE 3 PARAMETERS FROM RESEARCH**

| Contaminant | TDI per day | Source | TDI per day | Source | TDI per day | Source | Average (rounded) | Standard deviation (rounded) |
|---|---|---|---|---|---|---|---|---|
| Benzo(a)pyrene | 60 µg | The Commission of the European Communities (2006). | 3000 µg | Tongo, Ogbeide & Ezemonye (2016). | 30 µg | Iniaghe, Ossai, et.al. (2014). | 1030 | 1706 |
| PAH | 60 µg | The Commission of the European Communities (2006). | 3000 µg | Tongo, Ogbeide & Ezemonye (2016). | 30 µg | Iniaghe, Ossai, et.al. (2014). | 1030 | 1706 |
| Lead | 30 µg | EFSA (2012). | 72 µg | Joint FAO/WHO Expert committee on Food Additives (2011). | 37 µg | EFSA CONTAM Panel (2010). | 46 | 22 |
| Manganese | 3 mg | EFSA NDA Panel (2013). | 9 mg | Health Canada (2007). | 8 mg | US EPA (2007). | 7 | 3 |
| Mercury | 34 µg | Joint FAO/WHO Expert committee on Food Additives (2011). | 72 µg | EFSA CONTAM Panel (2012). | 600 µg | ATSDR (1999). | 235 | 316 |
| Cyanide | 120 µg | EFSA CONTAM Panel (2019). | 3000 µg | ATSDR (2020). | 2000 µg | Feeley, Agudo, et. al. (2012). | 1707 | 1462 |
| Aluminum | 10000 µg | Stahl, Tashan & Brunn (2011). | 8571 µg | EFSA AFC Panel (2008). Supported by EFSA (2011). | 20000 µg | Joint FAO/WHO Expert committee on Food Additives (2012). | 12857 | 6227 |
| Arsenic | 18 µg | EFSA Panel on Contaminants in the Food Chain (2009). | 18 µg | ATSDR (2020). | 20 µg | Benford, Alexander, et. al. (2011). | 19 | 1 |
| Cadmium | 21 µg | EFSA CONTAM Panel (2009). | 48 µg | Joint FAO/WHO Expert committee on Food Additives (2011). | 60 µg | ATSDR (2012). | 43 | 20 |
| Nickel | 168 µg | EFSA CONTAM Panel (2015). | 660 µg | Tietz, Zelmer, et. Al. (2018). | 1100 µg | Haber, Bates, et. al. (2017). | 643 | 466 |

The data from table 3 have been summarized in figures 6 - 10 below and on the next page..

In the figures the average parameter value from table 3 is compared to the parameter value as set for water, as can be found in table 1. The average value is represented by the left green bar, the value for water is represented by the right bar. The error bars in the figures show the standard deviation for each parameter value from table 3. For some of the contaminants the value for water is not visible because this value was too low. The purpose of these figures is to visualize how the values for water and food are significantly different. The parameter for Arsenic are very close and do not significantly differ from the values found to the value set for water. These graphs visualize the difference between the parameter set for water and how the data shows parameters could be set for food. The parameters for Aluminium, Manganese, Nickel and Cadmium show a significant difference from the values found, including the standard deviation, and the value as set for water. For the other contaminants the average parameter is much higher compared to the parameter as set for water, but the standard deviation comes close to the parameter value for water.

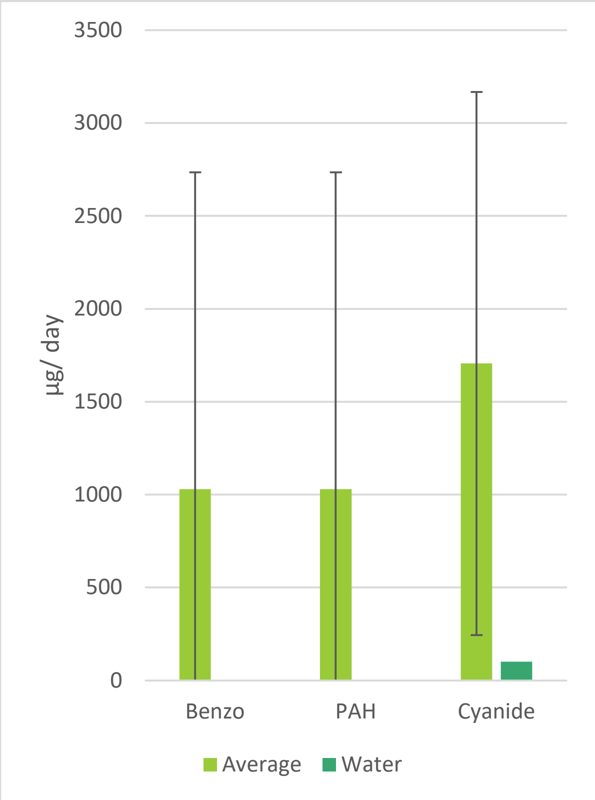


FIGURE 6 PARAMETER COMPARISON (PART 1)

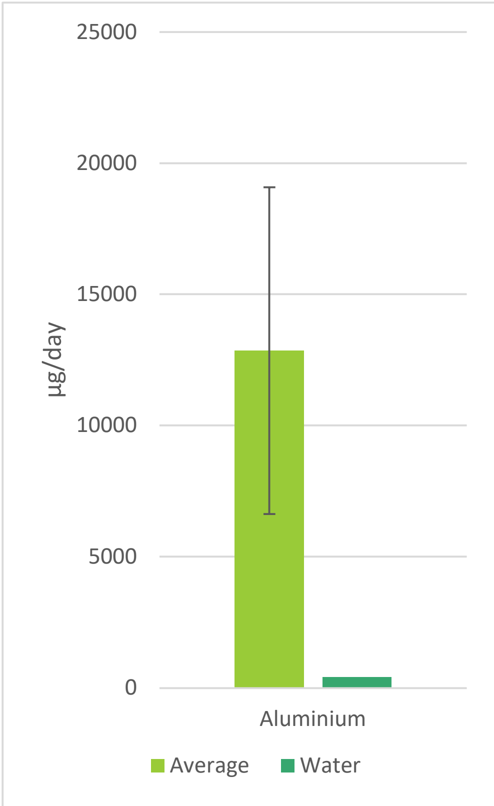


FIGURE 7 PARAMETER COMPARISON (PART 2)

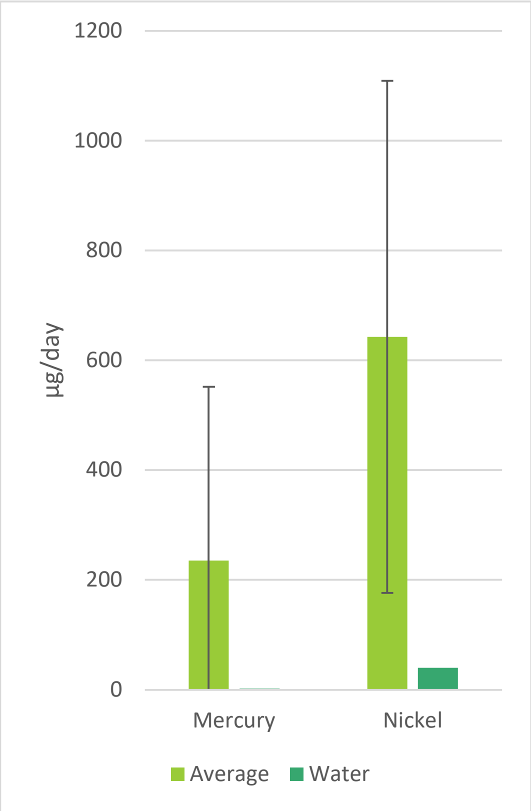


**FIGURE 8 PARAMETER COMPARISON (PART 3)**

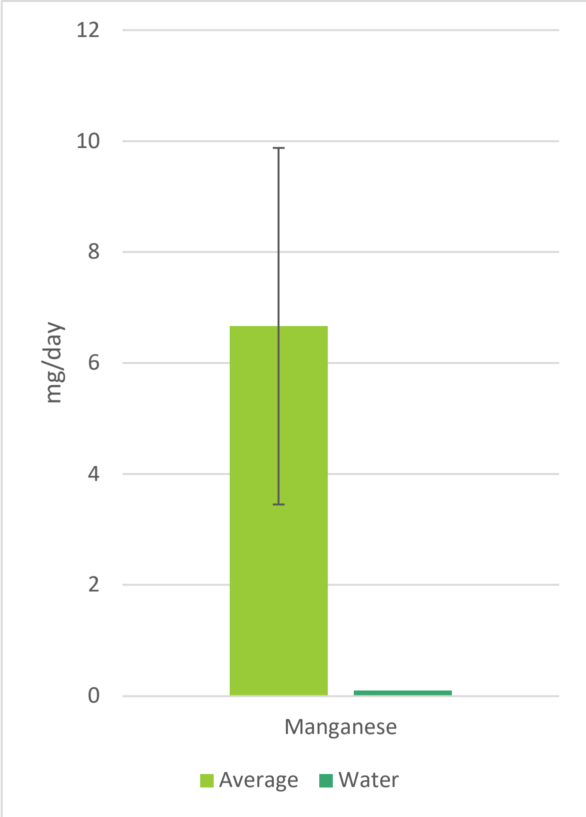


**FIGURE 9 PARAMETER COMPARISON (PART 4)**

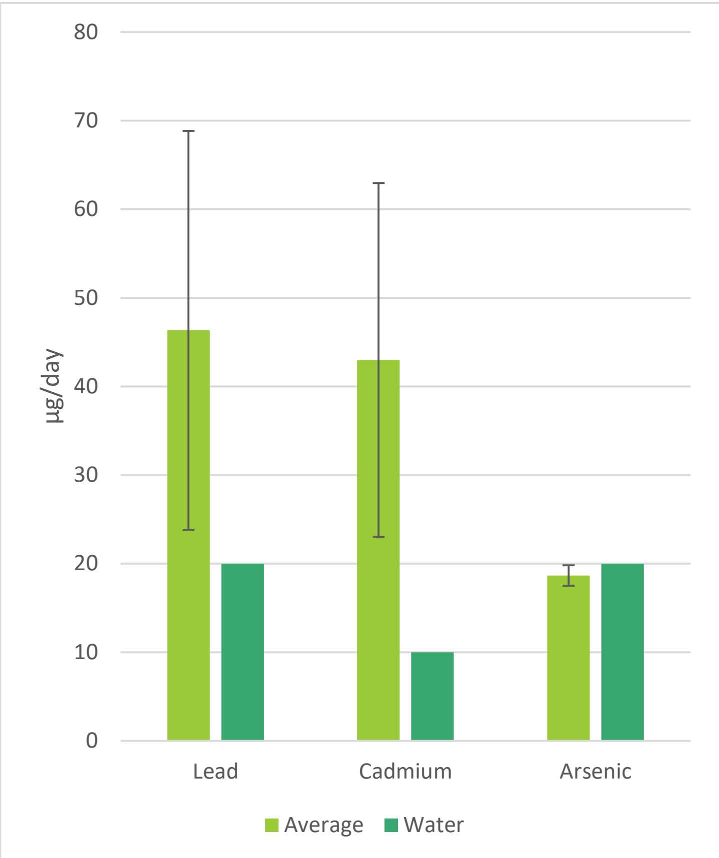


**FIGURE 10 PARAMETER COMPARISON (PART 5)**

## 3.2 Strategies for water quality

As the significance in the parameter difference had been identified, new strategies for water quality on the researched contaminants were defined. As stated, before the four strategies are defined as; Same quality and same analysis frequency, same quality and different analysis frequency, different quality and same analysis frequency, and different quality and different analysis frequency. Table 4 below states these four strategies. The analysis frequency has been based on a company which has an annual water use of 9000 $m^3$.

The reduction in analysis frequencies in table 4 below would be a reduction of 1.9% from the total analysis to be performed, based on the analysis frequencies as given in table 1 in the introduction.

TABLE 4 WATER QUALITY STRATEGIES

| **Strategy** | Same, Same | | Same, Different | | Different, Same | | Different, Different | |
|---|---|---|---|---|---|---|---|---|
| **Chemical Contaminant** | P | A | P | A | P | A | P | A |
| Arsenic | 20 µg/day | 3 | 20 µg/day | 3 | 18 µg/day | 3 | 18 µg/day | 3 |
| Benzo(a)pyrene | 0,01 µg/kg | 3 | 0,01 µg/kg | 1 | 0,5 µg/kg | 3 | 0,5 µg/kg | 1 |
| Cadmium | 10 µg/day | 3 | 10 µg/day | 2 | 48 µg/day | 3 | 48 µg/day | 2 |
| Cyanide | 100 µg/day | 3 | 100 µg/day | 3 | 120 µg/day | 3 | 120 µg/day | 3 |
| Lead | 20 µg/day | 3 | 20 µg/day | 3 | 37,5 µg/day | 3 | 37,5 µg/day | 3 |
| Manganese | 0.1 mg/day | 3 | 0.1 mg/day | 1 | 3 mg/day | 3 | 3 mg/day | 1 |
| Mercury | 1 µg/kg | 3 | 1 µg/kg | 2 | 100 µg/kg | 3 | 100 µg/kg | 2 |
| Nickel | 40 µg/day | 3 | 40 µg/day | 2 | 168 µg/day | 3 | 168 µg/day | 2 |
| PAH | 0,1 µg/kg | 3 | 0,1 µg/kg | 2 | 0,5 µg/kg | 3 | 0,5 µg/kg | 2 |
| Aluminium | 400 µg/day | 3 | 400 µg/day | 2 | 8571 µg/day | 3 | 8571 µg/day | 2 |

In the table "P" stands for the parameter and "A" stands for the analysis frequency per year.

## 3.3 Risk Analysis

As the different strategies have been defined, the risk analysis per contaminant will follow in table 5 on the next page. In the first column containing the risk scores, based on parameters close to the NOEL, there are 6 out of 10 contaminants with a high-risk score, and only manganese had a low risk score as result.

TABLE 5 RISK ANALYSIS ON RELEVANT CONTAMINANTS

| | Data from RASFF | | Likelihood of Occurrence | NOEL | Sources | Severity | Risk Score | Parameter | Likelihood of Occurrence (adjusted) | Risk Score |
|---|---|---|---|---|---|---|---|---|---|---|
| **Contaminant** | 2000-2019 | 2019 | | | | | | | | |
| Arsenic | 13 | 1 | 5 | 48 µg/day[24] | EFSA CONTAM Panel (2009). | 4 | 20 | 20 µg/day | 4 | 16 |
| Benzo(a)pyrene | 21 | 1 | 5 | 3mg/kg b.w.[25] | EFSA Panel (2008). | 3 | 15 | 0.01 µg/kg b.w. | 1 | 3 |
| Cadmium | 0 | 0 | 1 | 3 mg/day[26] | EFSA Panel (2009). | 5 | 5 | 10 µg/day | 1 | 5 |
| Cyanide | 2 | 0 | 4 | 21.6 mg/day[27] | EFSA CONTAM Panel (2019). | 2 | 8 | 100 µg/day | 1 | 2 |
| Lead | 40 | 3 | 5 | 37.8 µg/day[28] | [1] EFSA CONTAM Panel (2010). | 4 | 20 | 20 µg/day | 5 | 20 |
| Manganese | 0 | 0 | 1 | 11 mg/day[29] | EFSA NDA Panel (2019). | 1 | 1 | 0.1 mg/day | 1 | 1 |
| Mercury | 26 | 1 | 5 | 0.6 µg/kg b.w.[30] | EFSA CONTAM Panel (2012). | 3 | 15 | 0.1 µg/kg b.w. | 4 | 12 |
| Nickel | 1 | 0 | 3 | 168 µg/day[31] | EFSA CONTAM Panel (2015). | 4 | 12 | 40 µg/day | 2 | 8 |
| PAH | 21 | 4 | 5 | Benzo(a)pyrene 3 mg/kg b.w.[25] | EFSA Panel (2008). | 3 | 15 | 0.1 µg/kg b.w. | 1 | 3 |
| Aluminium | 3 | 0 | 3 | 600 mg/day[32] | EFSA AFC Panel (2008). | 3 | 9 | 400 µg/day | 1 | 3 |

As described in the methodology the likelihood of occurrence risk score was adjusted based on the difference between the parameter set and the NOEL which was found in literature. After these adjustments were made only 3 out of 10 contaminants were found to have a high risk score. 5 out of 10 contaminants were found to have a low risk score based on this calculation, and 2 out of 10 contaminant were found to have a medium risk score.

Taking the risk scores found, the analysis frequencies proposed for the new strategies needed to be adjusted. Based on the adjustment requirements given in the methodology the new analysis frequencies were calculated. The adjusted analysis frequencies can be found in table 6 below.

TABLE 6 OVERVIEW OF ADJUSTED STRATEGY

| **Contaminant** | **Analysis frequency (per year)** | **Contaminant** | **Analysis frequency (per year)** |
|---|---|---|---|
| Arsenic | 3 | Manganese | 1 |
| Benzo(a)pyrene | 1 | Mercury | 3 |
| Cadmium | 2 | Nickel | 2 |
| Cyanide | 1 | PAH | 1 |
| Lead | 3 | Aluminium | 1 |

## 3.4 Operation Excellence Interviews

In order to find the Operation Excellence benefits four in depth interviews were held. The following people have been interviewed:

- Mandy Michauk, Avebe; QA Manager, interviewed on July 14, 2020
- Peter van der Meulen, Avebe; QESH Manager, interviewed on July 15, 2020
- Marina Bouman, Dutch Ministry of Defence; employee food hygiene and safety, interviewed on July 21, 2020
- Stefano Laudadio, PizzaSi; Chief Pizza Officer, interviewed on July 23, 2020

The results from the interviews are given below. Based on the method described in the methodology the results are given per interview question. The transcripts of the interviews can be found in Annex II of this document.

### 3.4.1 How would you describe/define Operation Excellence?

When the interviewees were asked to define the term Operation Excellence the main term mentioned was ‘efficiency’. Mr. van der Meulen and Mr. Laudadio both noted that Operation Excellence is about striving to be excellent in every part of business. “ *The goal is to create an excellent product, an excellent customer experience, and also an excellent working environment”* – Stefano Laudadio

### 3.4.2 How can a Process Water Quality Plan affect a product’s value stream?

One of the interviewees found themselves to not be sufficiently knowledgeable to answer this question.

According to Ms. Bouman having a process water quality plan ensures a company to have strong control over the vulnerable resource which water is. Water as seen in the process stream, is vulnerable as there are many possible contamination points.

Ms. Michauk described how a business has an environmental context, which influences how water is important, and how different sourcing strategies might be needed based on the business' environmental context. How a business handles its process water, which would be determined through a process water quality plan, can affect the value of the water after it has left the business. It was also indicated that water as a resource has a strong connection to sustainability; considering the climate change which is happening and will probably continue, it is probable that water might become a very scarce and very expensive resource.

Mr. van der Meulen described how a process water quality plan can affect the value stream of a product as costs are reduced. It was argued that the formulation of a process water quality plan would most probably result in less analyses performed than in a situation without such a plan, and that less analyses performed would reduce the costs, and reduced costs would increase the profit margin of a product.

Striving to be of World Class was indicated as being a part of Operation Excellence. "… *If this is the goal, you need to be able to explain everything you do and why you do it"* – Peter van der Meulen

### 3.4.3 How can a Process Water Quality Plan affect a company's strategy? Or is the decision to write a Process Water Quality Plan a result of a strategy?

All interviewees argued that a process water quality plan is a result of a company's strategy. First a strategy is set by a company, if it fits in the specific strategy the decision will be made to formulate a Process Water Quality Plan.

Ms. Bouman noted that the ideal situation would be to start with a Process Water Quality Plan and use this in formulating a strategy. The reason given as to why this is not usually the case in the food industry was; *"What tends to happen at new businesses is that the growth of the business goes at a much faster rate than the development of a good quality plan."* – Marina Bouman

### 3.4.4 How does a Process Water Quality Plan fit in a lean production system?

The core answer which was given was that a Process Water Quality Plan fits in a lean production system as it contributes to efficiency. Efficiency is about doing the right things, doing the tests and analyses which are suited to ensure safety, and as Mr. van der Meulen noted: *" it is important to link everything you do to your strategy and to set Key Performance Indicators (KPI)".* An interesting note from Mr. van der Meulen was that in their opinion the program; *World Class Operation Management (WCOM)* is in its core very similar to lean production system.

### 3.4.5 What are important aspects in the development of Standard Operation Procedures?

Three of the interviewees found the readability and understandability of the Standard Operation Procedure the most important thing to keep in mind during the writing process. It was also noted several times that legislation should be the foundation to the procedures, and that it is very important to include this in such a manner that the procedure is still easy to understand.

Ms. Bouman noted the importance of including the right people in the writing process, if this is done incorrectly problems can occur: "*If it is done the typical way* [only the quality department writing the SOP, rather than including the person involved in the actual process described] *, it is not uncommon to see that the SOP is not received well, because the employees find that the instructions simply cannot be followed in their situation. This is a typical example of having the responsibility in the wrong place."*

Mr. Laudadio had more focus on the product aspect of the standard operation procedure: *"When we write standard operation procedures our main goal is to work on consistency and again ensuring a lean process."*

### 3.4.6 How could a Process Water Quality Plan be used in this development?

A Process Water Quality Plan could be used as background information in writing a Standard Operation Procedure according to Ms. Bouman and Mr. Laudadio. An important note on this is that one should be careful to only use the information to understand what needs to be in the procedure, and to not include too much information, in order to ensure readability. This was also the main concern of Ms. Michauk; in using a plan like the Process Water Quality Plan there is a high risk of including too many technical terms.

### 3.4.7 Where can employee involvement be found? When is 'why' explained?

Ms. Michauk and Mr. van der Meulen both stated that it is very important to explain 'why' when introducing new employees. A good introduction program should be in place, and in this introduction some time should be taken to explain the quality system at the company and this should be done by someone from the quality department, as this person is best able to explain the 'why' parts of the quality system.

Three of the interviewees pointed out the importance of 'key people' throughout the organization, who are able to explain 'why'. Examples of key people are; team leaders and HACCP team members.

The importance to explain 'why' was formulated as followed by one of the interviewees: *"If you do not properly explain why something is done, it is very difficult to convince someone to do something."* – Mandy Michauk

### 3.4.8 What are Operation Excellence benefits of the implementation of a Process Water Quality Plan?

The number one Operation Excellence benefit of implementing a Process Water Quality Plan which was noted was the increased efficiency. *"More control leads to more efficiency."* Another benefit which was mentioned was that better control on quality would result in less deviations in the final products, which would in turn benefit the company's image towards customers.

Mr. van der Meulen and Ms. Bouman expressed that the implementation of a Process Water Quality Plan would result in a company understanding what needs to be done concerning the management of water and the analyses on water, why this needs to be done, and how it needs to be done. All of this information can be very useful in explaining procedures to employees.

# 4. Discussion

In the previous chapter the results have been described. In this chapter the results found will be discussed, and compared to the literature review. A reflection on the methods used will also be given for each sub-question. The objective of this research was to answer the following question: *How should European producers of dry bulk food ingredients approach their decisions on process water quality considering production efficiency and the food safety for the consumers of the final product?*

## 4.1 What are the ten most relevant chemical contaminants from the list of identified contaminants relevant for water quality, in relationship to the production of dry bulk ingredients?

The ten chemical contaminants found to be most relevant are; arsenic, benzo(a)pyrene, cadmium, cyanide, lead, manganese, mercury, nickel, PAH, and aluminium. These results are deemed reliable as they were found through a correlation between the occurrence of notifications in the RASFF portal and being set as important in literature; Directive on the quality of water intended for human consumption, European Council (1998). Research conducted by Thompson and Darwish also has shown that the contaminants Arsenic, Benzo(a)pyrene, Cadmium, Lead, Mercury, Nickel and PAH are relevant for both food and water (2019).

Identifying the ten most relevant chemical contaminants makes this research more relevant to the food industry, as the contaminants and parameters which have been researched are most likely to be an issue in the food industry.

The research has gone according to plan. The use of the RASFF portal was found to be the best reliable available source for this bachelor research. The method was suitable for this research, however, larger research on food safety issues related to water quality would have been interesting to this research too. The relatively narrow time inclusion criteria have helped in providing more comparability between the contaminants, as some of the contaminants considered had only been notified to the RASFF portal since 2017.

## 4.2 To what extent can chemical parameters divert from the directive 98/83 without compromising the food safety of the final product?

The extent to which chemical parameters can divert from the directive 98/83 without compromising the food safety of the final product was influenced by two factors; legislation and data on safe limits for contaminants. As found in the literature research the legislation for parameters of contaminants in drinking water has been set strict, as the assumed daily consumption is high, while the assumed consumption for foods is lower and thus the legislation for parameters of contaminants in food is often less strict (WHO, 2017). However, the literature research also found that the European Council has implemented the ALARA principle for food production (European Council, 1993). Based on this legislation there is no legal room to divert from the parameters set in the directive. The data research on safe limits for contaminants in foods found that 9 out of the 10 contaminants have a higher parameter to ensure safety than the parameter set for water. Only for the contaminant of Arsenic, the parameters showed no significant difference.

This research was based on three sources per contaminant, as was proposed in the research proposal. The data search to find three sources for each contaminant was found more difficult than expected. Data availability which was still relevant was limited. Many sources found did not comply with the inclusion criteria of being dated after the year 2010. Also, the different values which were found were very different, because of this the reliability of the data is limited. This research gives a reasonable indication that the parameters set for contaminants in water are much stricter than the parameters set for contaminants in food. As the values found were so vastly different, new research methods could result in interesting new values. For companies it would be important to stay up-to-date on these type of new found safe values for contaminants.

## 4.3 To what extent can microbiological parameters divert from the directive 98/83 without compromising the food safety of the final product?

The extent to which the microbiological parameters can divert from the directive 98/83 is very limited. As the microbiological parameters set in the directive have been set as indicators for contamination of the water (European Council, 1998). Researching the extent to which it is possible to divert was relevant as this would either support why companies should follow these parameters, or it could indicate that a company can safely reduce the analysis conducted and therefore safe on analysis costs.

## 4.4 What are the risks associated with different approaches to process water quality in relation to food safety?

Researching the risks associated with different approaches has been relevant as this shows which approach could actually be implemented by a company. If an approach would have been to conduct very few analysis, the overall production costs would significantly decrease, however the risk analysis shows that the risks for food safety are too high. Management decisions which could be based on this research needed to have a broader overview of this decision. The risk analysis was conducted using the method described in the BRC Global Food Standard (2005), this method bases risk on two variables; likelihood of occurrence, and severity. This method was chosen as the source for this method was found most reliable. However, a risk analysis that would have been based on three variables; likelihood of occurrence, severity, and likelihood of detection, would have been a better method on evaluating the risk for this research. As setting parameter and analysis frequencies change the likelihood of detection, these changes would have made a more distinct difference in this type of risk analysis.

## 4.5 What are the Operation Excellence benefits for the best approach as found in the risk analysis?

Identifying the Operation Excellence benefits is relevant as this indicates what implementation will actually improve for a business.

The main association with Operation Excellence was also perceived to be the main benefit of implementing a Process Water Analysis Plan. Throughout the interviews, there have been several notions of the importance of efficiency, and the importance of cost reduction as a contributor to efficiency. This result found corresponds with the literature (Gleich & Sautter, 2008; Campden BRI, 2014; Jaeger et al., 2014), all three of these sources have indicated efficiency as an important part of Operation Excellence.

Another interesting result is the importance of control. Several interviewees have pointed out how control over materials and processes is important in the food business, this aids the efficiency but it is also important in ensuring that the business is well perceived by customers and consumers. The importance of this control had also been found in the literature study; in figure 3 Operations Excellence Framework (Jaeger et al. 2014), on page 9 in the introduction, this aspect is noted as an important aspect of resources flowing into the process.

An interesting result was the link made between Lean Production Systems and WCOM by one of the interviewees. In their opinion these two systems have the same core; always linking one's actions to one's strategy and KPI's. In the opinion of the interviewee, a Process Water Quality Plan is a great example of a project in both of these systems. Jaeger et al. (2014) descries an indicator of Operation Excellence in strategy is the future plan toward world-class and lean production systems. Again, the result of the interviews and literature are corresponding.

The importance of employee involvement as it is described by Jaeger et al. (2014), was endorsed by the interviewees. The result of the interviews is that one of the most important moments of employee involvement is found in training. The importance of training is also described by Campden BRI (2014). There was a small notion that a Process Water Quality Plan might be used to support the training program by providing information and background knowledge, enabling the trainer to better explain the reasoning behind methods. The correlation between the literature on employee involvement and the possibility that a Process Water Quality Plan might be useful in this process is remarkable The reliability based on this research is not strong as there has been only one notion of this possible benefit, it is likely that this is due to the small sample size in this interview.

The sample size taken for this research is in line with the available literature on interview sample sizes (Sarah Baker and Rosalind Edwards, 2012; Smith, Flowers and Larkin,2009). The reliability of the results would increase with a larger interview sample size.

Technology has proven itself very useful in this part of the research, as the pandemic obscured the option on face-to-face interviews. Through the video conference platforms of Microsoft Teams and Zoom, it has been possible to safely interview the four interviewees.

The interview answers have limited depth, this could have been increased had more follow-up questions been asked.

# 5. Conclusion and Recommendations

Water is one of the most common ingredients in food production. Legislation on water quality is mainly focussed on water intended for direct human consumption, drinking water. The question has arisen how the water quality and monitoring should be arranged in the production of dry food ingredients, and whether over-analyzing took place in the current situation. This research sought to answer the question: *How should European producers of dry bulk food ingredients approach their decisions on process water quality considering production efficiency and the food safety for the consumers of the final product?*

In this chapter, the conclusions are made based on the findings from the literature review combined with the results found. The conclusions are given per sub-question. After the conclusions are given, the short- and long-term recommendations will be explained.

## 5.1 Conclusions

The extent to which chemical parameter can safely divert from the directive 98/83 without compromising the food safety of the final product is found to be significant for several contaminants. However, the European Council has implemented the As Low As Reasonably Attainable principle, which states that contaminants should always be reduced to the lowest level which is reasonably attainable. The analysis frequency can safely divert for the contaminants Benzo(a)pyrene, Cadmium, Cyanide, Manganese, Nickel, PAH, and Aluminium. These frequency analyses per year can safely be reduced to; 1, 2, 1, 1, 2, 1, and 1. Based on the findings in the interview conducted this reduction of analyses is a cost reduction and also a reduction in the company's environmental footprint.

The microbiological parameters of *E.Coli* and *Clostridium Perfringens* can not divert from the directive as the purpose of the parameter is to indicate contamination of the water. The parameters set for these contaminants can not be diverted from while ensuring the overall food safety of the final product.

All contaminants should meet the parameters as set in directive 98/83, the analysis frequency can safely be adapted. If a contaminant is found to be of high risk, the analysis frequency shall be three times per year; if a contaminant is found to be of medium risk, the analysis frequency shall be two times per year; if a contaminant is found to be of low risk, the analysis frequency shall be once per year.

The Operation Excellence benefits for implementing a Process Water Quality Plan are increased efficiency, as a waste of resources is reduced and only value-adding analyses will be performed. Implementation of the analyses frequencies as mentioned above will reduce the overall number of analyses performed by 2.12%, which will increase the businesses' efficiency. As efficiency is about doing the right things, a Process Water Quality Plan helps to ensure that the right things are done in relation to process water management. Another benefit of implementing a Process Water Quality Plan is the increased control of the raw material of water. Implementing a Process Water Quality Plan can benefit a business' Operation Excellence as it is a good example of implementing a lean production system, and it indicates the future plan towards world-class.

European producers of dry bulk ingredients should approach their decision on process water quality by setting their analysis frequency of contaminants based on a risk analysis calculated based on two variables; likelihood of occurrence, and severity. Based on this risk analysis the frequency of analysis can be reduced according to the risk score found; high-risk contaminants should be analyzed according to the directive 98/83, medium risk contaminants should be analyzed on a reduced frequency of -33% compared to the frequency set in directive 98/83, and the low-risk analysis should be analyzed on a frequency of -66% compared to the frequency set in directive 98/83. Considering the ALARA principle, a company shall not reduce its parameters for contaminants.

The data collected to this point should be summarized in a plan; a Process Water Quality Plan, which can be implemented by a company. The implementation of this plan has been found to have the following Operation Excellence benefits; the company can grow in Operation Excellence as the company is creating more value for the value chain through providing more information and thus certainty along the chain. Also, this approach is a signal that the company has a plan to world-class as a company has shown to consider all aspects of sustainability.

## 5.2 Recommendations

Implement the analysis frequencies found in this research

On the short term a company should implement the analysis frequencies this research has identified for the top 10 relevant contaminants. The analysis frequencies which have been proposed are repeated in table 7 below. The implementation of these frequencies will reduce a company's total number of analyses by 2.12%, the cost reduction which results from this reduction are highly variable per company therefore the cost reduction cannot be given in this recommendation.

TABLE 7 ANALYSIS FREQUENCIES PROPOSED

| Contaminant | Analysis frequency (per year) | Contaminant | Analysis frequency (per year) |
|---|---|---|---|
| Arsenic | 3 | Manganese | 1 |
| Benzo(a)pyrene | 1 | Mercury | 3 |
| Cadmium | 2 | Nickel | 2 |
| Cyanide | 1 | PAH | 1 |
| Lead | 3 | Aluminium | 1 |

Determine analysis frequencies for contaminants

On the short term a company should use the method described in this research to conduct a risk analysis for other contaminants, which have not been researched in this thesis, in order to formulate a better-founded process water quality monitoring program. Through researching this a company can increase its Operation Excellence as efficiency and control will increase as a result.

Determine use of Process Water Quality Plan in Employee Involvement

As both literature and the results form the interview indicate the importance of employee involvement, and how employee involvement can improve a company's productivity, a company should on consider how a process water quality plan can be used to educate and involve employees in this important aspect of a food business. In the interview conducted there was one interviewee who indicated that this plan can be used in employee involvement, therefor it would be interesting for a company to use this plan, as it is implemented in the processes, to involve their employees in these specific processes.

Periodic re-evaluation of process water quality monitoring.

As continuous development happens everywhere the likelihood of occurrence of contaminants in water might change. Therefore, a periodic re-evaluation shall be held on the set process water quality monitoring system. This re-evaluation would also be in line with the literature on Operation Excellence, continuous improvement is crucial in ensuring Operation Excellence.

Monitoring of implemented changes

As a company decides to implement changes on its process water quality monitoring program, it is important to monitor the effects of these implemented changes. It should be closely monitored if and how these changes affect product quality, but also how these changes affect the overall costs of production. It is expected that these changes will negatively affect the costs of production, and thus resulting in a lower overall cost of production, but this should be monitored in order to confirm this expectation.

This research has formulated an approach for European producers of dry bulk food ingredients, and has researched the analysis frequency for ten contaminants. Further research should be performed to determine the analysis frequencies for the parameters from the directive 98/83. A laboratory research should be conducted to determine how different contaminant parameters in water used in production affect the contaminants found in the final dry food ingredients.

Performing analyses is a complicated activity, finding what the optimal time use for different analyses steps is in relation to cost is equally complicated. The costs for analyses vary per company, as the synergy between different analyses vary for each company. As this research has found that it the analysis frequency can safely divert from the directive 98/83, there also is the option to research the optimal combination of analyses to be performed where food safety is ensured, and optimal use of time and equipment is set. Finding this synergistic point in analysis would be a company specific research. This process of finding the synergistic point would also have to be repeated when new insights are found in relation to analyses to be performed, and in relation to developments in analyses techniques.

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# Annex 1:

## RASFF Notifications on ‘dietic foods, food supplements, fortified foods’ from 01/01/2017 to 31/12/2019 (Identified as relevant)

| Classification | Date of case | Notifying country | Subject | Risk decision |
|---|---|---|---|---|
| Alert | 16-3-2017 | Germany | shigatoxin-producing Escherichia coli (stx1+ /25g) and Bacillus cereus (62000 CFU/g) in barley grass powder from Germany | Serious |
| alert | 13-4-2017 | Czech Republic | high content of aluminium (15760 mg/kg - ppm) in food supplement from Austria | Serious |
| alert | 23-5-2017 | Netherlands | benzo(a)pyrene (17.2 µg/kg - ppb) and polycyclic aromatic hydrocarbons (PAH4 196 µg/kg - ppb) in food supplement from China, via Hong Kong | Serious |
| information for attention | 19-6-2017 | Hungary | mercury (1.379 mg/kg - ppm) in food supplement from New Zealand | Serious |
| alert | 7-7-2017 | Netherlands | benzo(a)pyrene (113.2 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum of PAH4: 359.9 µg/kg - ppb) in food supplement from Hungary | Serious |
| alert | 10-7-2017 | Netherlands | lead (9.6 mg/kg - ppm) in zeolite from Germany | Serious |
| alert | 27-7-2017 | Netherlands | benzo(a)pyrene (13.2 µg/kg - ppb), dioxins (1.78 pg WHO TEQ/g), polycyclic aromatic hydrocarbons (sum of PAH4: 171.3 µg/kg - ppb) and chlorpropham (0.095 mg/kg - ppm) and unauthorised substance anthraquinone (0.377 mg/kg - ppm) in hemp oil from the Netherlands | Serious |
| information for follow-up | 1-8-2017 | Netherlands | mercury in creatine food supplement from Germany | not serious |
| alert | 18-8-2017 | Finland | benzo(a)pyrene (4.9 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum PAH4: 38.6 µg/kg - ppb) in omega-3 capsules from China | Serious |
| alert | 22-8-2017 | Czech Republic | lead (12 mg/kg - ppm) in green clay from the Czech Republic | Serious |
| alert | 28-8-2017 | Poland | lead (426.6 mg/kg - ppm) and mercury (0.26 mg/kg - ppm) in food supplement from China, via the United Kingdom | Serious |
| alert | 13-9-2017 | Germany | lead (12.8; 11.8; 9.7; 19.4; 24.4 mg/kg - ppm) and high content of aluminium (46300; 39250; 28750; 39250; 71750 mg/kg - ppm) in zeolite and bentonite powder from Germany, with raw material from Poland | Serious |
| alert | 14-9-2017 | Germany | high content of cyanide (6083 mg/kg - ppm) in apricot kernels extract capsules from Germany | Serious |
| alert | 26-9-2017 | Poland | lead (3.7 mg/kg - ppm) in food supplement from China, via the United Kingdom | Serious |
| alert | 16-10-2017 | United Kingdom | too high content of cyanide (1996; 31 mg/kg - ppm) in organic apricot kernels from the United Kingdom | Serious |
| alert | 11-12-2017 | Poland | polycyclic aromatic hydrocarbons (sum of PAH4: 99.7 µg/kg - ppb) in powdered chlorella from China | Serious |
| alert | 1-2-2018 | Netherlands | benzo(a)pyrene (9.5 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum of PAH4: 121.5 µg/kg - ppb) in food supplement from the Netherlands | Serious |
| alert | 23-2-2018 | Slovakia | benzo(a)pyrene (248; 27.7 µg/kg - ppb) and polycyclic aromatic hydrocarbons (990; 117 µg/kg - ppb) in spirulina plus chlorella food supplement from the Czech Republic, with raw material from China | Serious |
| alert | 7-3-2018 | Germany | benzo(a)pyrene (120.4 µg/kg - ppb) and polycyclic aromatic hydrocarbons (PAH4: 1103 µg/kg - ppb) in food supplement from Germany, with raw material from China | Serious |
| alert | 6-4-2018 | Germany | benzo(a)pyrene (6.7 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum of PAH4: 30 µg/kg - ppb) in black cumin seed oil capsules from Germany | Serious |
| alert | 16-5-2018 | Germany | lead (8.56; 32.6 mg/kg - ppm) and mercury (0.188 mg/kg - ppm) and high content of aluminium (41877; 73851 mg/kg - ppm) in zeolite and bentonite powder from the Netherlands | Serious |
| alert | 13-6-2018 | Netherlands | benzo(a)pyrene (11.7 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum PAH4: 83.7 µg/kg - ppb) in chasteberry powder from Spain, via Belgium | Serious |
| information for attention | 21-9-2018 | Poland | benzo(a)pyrene (46.7 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum PAH4: 229 µg/kg - ppb) in chlorella powder from Poland, with raw material from China | Serious |

| | | | | |
|---|---|---|---|---|
| alert | 9-10-2018 | Netherlands | benzo(a)pyrene (15.8 µg/kg - ppb) and polycyclic aromatic hydrocarbons (548 µg/kg - ppb) in ginseng, guarana and ginkgo biloba capsules from Hungary | Serious |
| alert | 9-10-2018 | Netherlands | benzo(a)pyrene (20.4 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum of PAH4: 739 µg/kg - ppb) in ginkgo biloba capsules from Hungary | Serious |
| alert | 31-10-2018 | Belgium | polycyclic aromatic hydrocarbons (221.6 µg/kg - ppb) in green coffee food supplement from Belgium, with raw material from the United Kingdom | Serious |
| alert | 2-11-2018 | Slovenia | nickel (89 mg/kg - ppm) in food supplement from India, via the United Kingdom, packaged in Slovenia | Serious |
| alert | 5-11-2018 | Netherlands | lead (10.2 mg/kg - ppm) in zinc citrate used as an ingredient in food supplements from the United Kingdom and the Netherlands | Serious |
| alert | 7-11-2018 | France | benzo(a)pyrene (45.8 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum of PAH4: 195 µg/kg - ppb) in purified micronized propolis capsules packaged in France with raw material from China via Spain and via Belgium | Serious |
| alert | 4-12-2018 | Hungary | polycyclic aromatic hydrocarbons (284.62 µg/kg - ppb) in dried gingko biloba leafs processed in Hungary, with raw material from China, via Germany | undecided |
| alert | 17-12-2018 | Poland | benzo(a)pyrene (328.7 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum of PAH4:1593.3 µg/kg - ppb) in chlorella from China | Serious |
| information for attention | 2-1-2019 | Lithuania | unauthorised substances manganese glycinate chelate and iron glycinate chelate in food supplement from Poland | not serious |
| alert | 18-1-2019 | Hungary | polycyclic aromatic hydrocarbons (71.62 µg/kg - ppb) in ginkgo biloba leaf powder from China, via Germany | Serious |
| alert | 5-2-2019 | Ireland | unauthorised substance magnesium orotate (high intake: 500 mg/day) in food supplement from the United Kingdom | Serious |
| information for attention | 5-2-2019 | Czech Republic | unauthorised substance magnesium in metal form (particles) in food supplement from Serbia | undecided |
| alert | 27-3-2019 | Belgium | polycyclic aromatic hydrocarbons (sum of 4PAH = 80.4 µg/kg - ppb) in propolis powder from China, via Germany | Serious |
| information for attention | 5-6-2019 | Czech Republic | unauthorised substance magnesium in metal form (particles) in food supplement from the United States | Serious |
| alert | 6-6-2019 | Estonia | benzo(a)pyrene (44.1 µg/kg - ppb) and polycyclic aromatic hydrocarbons (sum of PAH4: 220.4 µg/kg - ppb) in spirulina from Finland, with raw material from France | Serious |
| information for attention | 30-8-2019 | Czech Republic | mercury (164000 mg/kg - ppm) in food supplements from India | Serious |
| alert | 11-9-2019 | Belgium | arsenic (30.7 mg/kg - ppm) in food supplement from the Netherlands traded online | Serious |
| alert | 12-9-2019 | Netherlands | polycyclic aromatic hydrocarbons (1110 µg/kg - ppb) in chlorella powder from China, via France | Serious |
| alert | 4-10-2019 | Portugal | lead (12 mg/kg - ppm) in food supplement from Spain | Serious |
| information for follow-up | 10-10-2019 | Estonia | cadmium (1.5; 1.9; 2.4 mg/kg - ppm) in food supplement from unknown origin, packaged in Lithuania, via Latvia | undecided |
| alert | 25-11-2019 | Estonia | polycyclic aromatic hydrocarbons (sum of 4 PAH's= 62.9 µg/kg - ppb) in spirulina tablets from Finland | Serious |
| information for follow-up | 4-12-2019 | Poland | polycyclic aromatic hydrocarbons (sum of PAH4= 62.9 µg/kg - ppb) in spirulina tablets from China | not serious |
| alert | 19-12-2019 | Estonia | polycyclic aromatic hydrocarbons (sum of PAH4: 152.4 µg/kg - ppb) in resveratrol supplement from the United States, via the United Kingdom | Serious |
| alert | 19-12-2019 | France | lead (23 mg/kg - ppm) in green clay from France | Serious |
| information for attention | 24-12-2019 | Poland | polycyclic aromatic hydrocarbons (84.4 µg/kg - ppb) in spirulina powder from China | not serious |

# Annex 2

## Interview Transcripts

Interviewer: Esmee van der Woude

Interviewee: Mandy Michauk, QA Manager, Avebe Ter Apelkanaal

Date: July, 14, 2020

Location: Online through Microsoft Teams

Duration: 38 minutes

How would you describe/define Operation Excellence?

Operation Excellence means that you focus on two important parameters; one being productivity, being your nominal output, and the second is the quality of that output. These two parameters do not come first or second priority, they are both a top priority. The main point is; if you only focus on nominal output, your business numbers might be very good, but on the other side you might have a lot of waste and customer complaints, which would weaken your position in the market. Having a good nominal output, processes which work highly efficient, and you might also be very cost efficient, could put you in a good market position on the pricing aspect, but if your image suffers due to a lack of quality, as you have no control over your quality, your business is still very vulnerable.

How can a Process Water Quality Plan affect a product's value stream?

Looking at the raw material of water, you can put this in relation to your value stream through the sustainability of your product. It is a fact that if you control your water efficiently and effectively, i.e. less analyses, this will have a positive effect on the environment as less chemicals are used. Another factor is that improved water management will not only affect how you manage water within your company, it will also affect your waste water, this improved water management will result in less pressure on the environment.

In a value stream it is also important to consider what source is used for the water. The consideration if drinking water can be used is based on how much water the company will be using, and where the company is located. For example, you build a large production facility near a very small town, and you find that your water usage would be equal to half of the drinking water capacity of the town. If that is the case you need to think about alternatives. But it could also be that the location you have chosen for your company is a very dry area, where a lot of damage to the environment will be done if your company uses that much ground water.

How can a Process Water Quality Plan affect a company's strategy? Or is the decision to write this plan a result of a strategy?

I would have to say the latter. Where you will source your process water is a strategic decision, based on that decision you would move on to create a Process Water Quality Plan. The first decision is to choose whether the company should use the water from the drinking water net, which would require very little analyzing as this will be ensured by the drinking water company, or you could choose to use surface water which you process yourself, which would require a lot of resources. The sourcing of water is a strategic decision, and your process water quality plan is a result of that decision. At Avebe it is visible how the company strategy affects water control. In the early days Avebe was highly contaminating the water in the area, the waste water from the factory was pumped into the canals. Nowadays, due to the strategy change towards sustainability, the water management is Avebe's pride; the water which leaves the factory is cleaner than the water which enters the factory. For a company like Avebe it is not possible to source its water from the drinking water net, this would result in low water pressure for the surrounding households whenever the factory is running full capacity.

How does a Process Water Quality Plan fit in a lean production system?

Looking at the future, it is very much possible that water will become a scarce product. If the climate change continues, surface water might become a very costly raw material. In that case it will be necessary to be as efficient and effective as possible in water management. Reducing water usage where possible, and company's should also think about how the water usage is organized throughout their entire facility. For example, using drinking water for cleaning and showering would be something to reconsider. This might result in having to define a new strategy, improving process water control and also analyzing and testing of water. It could be considered to start using process water, as opposed to drinking water, in cleaning and showering, and to use drinking water only for the purpose of actual consumption.

Also in a water analysing laboratory Lean could be implemented. Less testing and analysing would require less labour. As labour costs are among the main costs of a company, this reduction would be a large reduction in overall costs.

What are important aspects in the development of Standard Operating Procedures?

This really depends on your type of business; are you a single location company, in which case all of the procedures only need to be applicable to your location, or are you a company with several locations maybe even in different countries. In the latter case you need to split your SOP's, you will have SOP's which can be used for all locations, and you will have SOP's which have the same core but are altered for each specific location. In writing an SOP it is very important that it adds value to the company. An SOP should be written with a goal, and should be able to meet that goal.

If you were to write an SOP for water control, your input would include the local legislation, and you would write out every process step and who is responsible in each step. When this SOP is written for each location, these SOP's will be discussed among the locations in an effort to make them as uniform as possible. If you improve transparency and uniformity in quality management, you will be able to work more efficiently.

How could a Process Water Quality Plan be used in this development?

This is an interesting question. You need to consider in what aspect this really is of added value to your SOP. I don't think there is a lot of added value. The goal of an SOP is to create uniformity in how things are done. When an SOP contains too much information, it is less likely to be used. An abundancy of information will not be memorized nor used by employees. In that case an SOP does not meet its purpose. Your goal is to ensure that employees perform different tasks in the same way, with that your goal in writing is that the document is clear and understandable. A pitfall in writing SOP's is using a lot of technical terms. Background information on processes is interesting and useful to management, but for an employee the instructions need to be clear and applicable. Personally, I like to write my SOP's in two parts; one introducing part where I explain more about what and why, and in the second part I really give instructions which explain what exactly needs to be done.

Where can employee involvement be found? When is 'Why' explained to employees?

This can be done at several points. First of all it is important to have a good introduction program for new employees. In this introduction program the quality system should be well explained. It is important to have someone from the quality department explain this quality system, and this person can definitely explain why things need to be done a certain way.

Another method how 'why' can be communicated is through Key persons throughout the organization, such as team leaders, HACCP team members, and product managers. Good training of these key persons by the quality department will enable them to explain 'why' to their co-workers.

If you do not properly explain why something is done, it is very difficult to convince someone to do something.

What are Operation Excellence benefits of the implementation of a Process Water Quality Plan?

I think this is very much depending on the product. For a company like Avebe, the added value is not specifically found in the quality of the water, but rather in the efficiency and effectiveness of water control. Better water control lead to higher efficiency. Less samples, less analyses, less chemicals, less labour costs.

And of course, when there is high control on water quality, the risk on deviations in the final product is reduced. Less deviations in turn will ensure a better image for the company to the outside world.

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Interviewer: Esmee van der Woude

Interviewee: Peter van der Meulen, QESH Manager, Avebe Ter Apelkanaal

Date: July, 15, 2020

Location: Online through Microsoft Teams

Duration: 20 minutes

How would you describe/define Operation Excellence?

I think this is a very broad concept. I am a QESH manager, meaning that I am responsible for food safety, sustainability, and quality in general. Operation Excellence sounds like it is really aimed at operation and production, but it is a lot broader if you ask me. QESH definitely is included. I think that the goal of Operational Excellence is to continuously improve. Looking at where you can improve, and this is done throughout the entire company. This can be within QESH looking how to do quality assurance, increasing automation and process guidance, rather than doing a lot of things at the end of the process like in Quality Control. That is a good example of Operation Excellence to me. Operational Excellence is also looking how production can be optimized, how can you use resources to get the most results, and how do you reduce your overall labour while ensuring safety. But to me the main point in Operational Excellence is found in continuous improvement.

How can a Process Water Quality Plan affect a product's value stream?

If you were to express value stream in money, it could be a positive effect as your plan indicates that you need to test less, less tests will reduce the costs of production, which will increase the margin of profit on the product. On the other hand, having more controlling at the beginning of the process, and having more data which can be used to indicate and analyze trends can also be your cost reduction. Working more efficiently and thereby reducing costs.

Operation Excellence is also about the desire to be a world class company, if this is the goal you need to be able to explain everything you do and why you do it. A plan like this would perfectly fit in there. This is also my personal opinion, if you are unable to explain why something needs to be done, you should really reconsider doing it at all.

How can a Process Water Quality Plan affect a company's strategy? Or is the decision to write this plan a result of a strategy?

In the case of Avebe it was definitely the result of a strategy. The decision to move from Quality Control to Quality Assurance. The formulation of a plan like this is a logic result of this decision. First strategy, then follows a Process Water Quality Plan.

How does a Process Water Quality Plan fit in a lean production system?

If I remember correctly Lean is a system which can be used to reach Operation Excellence. At Avebe we work with WCOM, world class operational management. I think this is a different name while the core is the same. It is important to link everything you do to your strategy and set Key Performance Indicators. I believe a Process Water Quality Plan fits in really well here. The development of such a plan is a great example of a Lean project.

What are important aspects in the development of Standard Operating Procedures?

I do not really write many SOP's. But when I do I find the challenge in ensuring that the reader understands the SOP. The SOP should not become too much of a politically correct document, although there sometimes are legislative requirements as to what has to be included. The challenge is to include what the legislation requires, and to still write it down in a practical and applicable way.

Where can employee involvement be found? When is 'Why' explained to employees?

This is an important point in settling in of new employees. But it is also important to explain 'why' at each department, the department work meetings would be  good moment to do so. And sometimes there is not that much to explain, legislation might simply require you to do certain things.

Explaining 'why' is really an important task of managers. Explaining 'why' may sometimes be useful in the SOP document, but this is more often not the case.

What are Operation Excellence benefits of the implementation of a Process Water Quality Plan?

In this plan one will have considered legislation and customer demands. This plan ensures that it is known what needs to be done, why this needs to be done, and you will also have a document explaining how this can best be done. Having a plan like this ensures that you can explain all these aspects. When actually working on the things from the plan it is clear why things need to be done, and what this is all based on, is easier to explain.

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Interviewer: Esmee van der Woude

Interviewee: Marina Bouman, Dutch Ministry of Defence employee food hygiene and safety

Date: July, 21, 2020

Location: Online through Microsoft Teams

Duration: 25 minutes

How would you describe/define Operation Excellence?

I think it is mainly about efficiency. How efficiently are you handling your resources, and how efficient is your control?

I think Operation Excellence, when you want all parts of your company to be excellent, is very important in the food business. In my experience quality is something which tends to suffer under efficiency in this sector. Production needs to be as efficient as possible and everything needs to be as cost efficient as possible, and only after that is ensured there might be some consideration on how to safeguard the quality. In these cases it is very important to have your control at such a level, that you are always able to make well educated decisions. Based on good control, and a good overview of your control, you can make valid predictions towards the future.

How can a Process Water Quality Plan affect a product's value stream?

Good controlling of process water is very important. Even if you have great control over the quality, there still are many factors which could affect this downstream in the process. This is de difficulty of water, downstream things can go wrong and this go really bad really fast. And if things do go wrong a recall will need to take place. A lot of food companies tend to be afraid of having to perform a recall procedure. I do not think having an recall is really a bad thing, performing a recall is also a way to show your customers that you pay close attention to your product quality, and that you know exactly what to do when the quality standard is not being met. Where people are involved in a process mistakes will surely happen, being able to admit this as a company is showing how strong you truly are. If you are not able to recognize and fix your own problems, you risk that things might get out of hand to the point that the national food safety authority needs to step in. I think that this latter situation is far more damaging to your business than initiating a recall because you noticed a deviation early.

How can a Process Water Quality Plan affect a company's strategy? Or is the decision to write this plan a result of a strategy?

In the ideal situation the plan would result in a strategy. However, it is usually the other way around; businesses choose their strategy, and only afterwards a quality system will be discussed.

The basis taken for a quality system is typically legislation for food businesses. A good quality system would start with a company looking at what legislation is relevant, and giving this information to the quality department who can use this to write a good quality plan.

What tends to happen at new businesses is that the growth of the business goes at a much faster rate than the development of a good quality plan. Especially for businesses starting very small; starting with making some nice treats at a birthday party to being a supplier for a large food event. That transmission can go really fast, so fast that there is barely time to realize that a lot of legislation is applicable. A lack of knowledge is found here; someone who is a great chef will not take his time to consider writing a process water quality plan. Those type of plans are written by quality departments, which are absent in small businesses.

How does a Process Water Quality Plan fit in a lean production system?

This really is about efficiency. When a plan like that is ready, it is known what sample needs to be taken at what time and what needs to happen with the information gathered. This is a great fit in a lean production system. It is better to perform checks and prevent, than having to correct mistakes afterwards. Although it does cost extra time to take samples and perform analyses, it costs more time and money to correct mistakes afterwards.

What are important aspects in the development of Standard Operating Procedures?

To me it is really important that the people working with the document are able to actually understand what it says, and that they can actually work with it. SOP's are based on legislation, which sometimes leads to unreadable documents. Besides the fact that they are very difficult to read, it is typically not true that certain procedures can only be done one specific way. Input from the actual work floor is really important because they truly understand how a process works most efficiently. Finding synergy between what legislation states and what works best in real life is really important in writing good SOP's. Determining who is responsible and involving the right people in writing the SOP's is also really important. Typically an SOP is written by someone in the quality department, I prefer to have someone from the work floor writing out the process and explaining what needs to be done at each step and having that document checked by the quality department. If it is done the typical way, it is not uncommon to see that the SOP is not received well, because the employees find that the instructions simply cannot be followed in their situation. This is a typical example of having the responsibility in the wrong place.

It is also important to constantly remember who your reader will be. Are you writing an SOP for the person cleaning the dishes, or his manager who needs to supervise the entire kitchen, or is it for the food safety controller? These factors always need to be considered.

How could a Process Water Quality Plan be used in this development?

I think it should be the basis of your SOP. That document states what the actual demands are for your water. The document should be used as reference material for the quality department. In the actual process of taking the sample it wont really be relevant, at that point it is only interesting what, where, and when samples need to be taken.

Where can employee involvement be found? When is 'Why' explained to employees?

First of all you have your HACCP team, with team members from all 'layers' of the organization. In this team a lot is explained about why certain thing need to be done. The hope is that these team members feel that much involved with the company what they will be proud to share this information. Involving employees in the process of writing instructions enlarges the feeling of responsibility. During the writing process it happens that there is some dialogue about 'why' in processes, and you hope that this is shared with other co-workers.

By not just writing SOP's and implementing them from the quality department, but instead involving employees you enlarge your support base. Through dialogue a work floor employee can indicate how things work best in real life, and the quality employee can adjust where needed in order to comply with legislation.

What are Operation Excellence benefits of the implementation of a Process Water Quality Plan?

If the plan is well written, it is clear what analysis needs to be done, how this needs to be done, and it is clear to employees why these analyses need to be done. When employees understand 'why' they are less likely to forget to do a certain task. Through this plan it is also clear what needs to be done with the information data gathered, which will hopefully lead to a better understanding of the data collected. If the full plan is implemented it is possible to react fast if problems would occur.

Having a plan like this also helps in awareness about this really common and 'simple' raw material. Water is usually of good quality, especially in the Dutch working environment. But it is so important to realize that even this 'simple' raw material will be in contact with your products, and thus is a very important raw material.

And overall, more control leads to more efficiency.

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Interviewer: Esmee van der Woude

Interviewee: Stefano Laudadio, Chief Pizza Officer

Date: July, 23, 2020

Location: Online through Microsoft Teams

Duration: 17 minutes

How would you describe/define Operation Excellence?

For our company it means using lean processes to achieve excellent results. It is about the efficiency of the use of resources throughout the operation. The goal is to create an excellent product, an excellent customer experience, and also an excellent working environment. The business is about more than just creating a final good product, the entire work flow and experience surrounding it is very important.

How can a Process Water Quality Plan affect a product's value stream?

That's a question I am not able to answer, because in this subject I am not knowledgeable enough.

How can a Process Water Quality Plan affect a company's strategy? Or is the decision to write this plan a result of a strategy?

Probably the second. It would be the result of an overall strategy where things like this are implemented.

How does a Process Water Quality Plan fit in a lean production system?

This is a question which could do with more brainstorming, but I reckon the straightforward answer is that a lower number of tests, means that there is less to think about, its less work, and then this time and effort saved can be used to work on different tasks.

What are important aspects in the development of Standard Operating Procedures?

When we write SOP's our main goal is to work on consistency and again ensuring a lean process. We want that the SOP will ensure that every production cycle, every pizza prepared, is absolutely the same every single time. We also want it to be a Lean process, so the waste should be managed, the time spend on preparing should be as low as possible, and the efficiency of the costs form the main focus.

How could a Process Water Quality Plan be used in this development?

At a manufacturing level it could be useful as to ensure Lean processes.

Where can employee involvement be found? When is 'Why' explained to employees?

We tend to have a very flat organization, so our organization is typically very open. We usually run conversations with the team, where we update them on what is going on in the company.

What are Operation Excellence benefits of the implementation of a Process Water Quality Plan?

I reckon that the main benefit would be that you use your resources more efficient, because you know what you have to do, you do not spend time or energy on non-value adding analysis. You can use that time and resources saved to spend in different parts of your process.

For our company, water really is a key ingredient, so it is very important to keep a close eye on this ingredient. Having such a plan could help in ensuring the quality too.