Exploring ISO 9001, REACH and regulations applicable to the plastic injection moulding industry in mainland China

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How can Monte Trading benefit from these regulations?

BACHELOR THESIS

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Management summary

All throughout the world businesses have to comply to different rules and regulations while they perform their economic activities. This research takes a closer look to the plastics industry as a whole, and then narrows the field of view down to a Monte Trading, a medium-sized exporter of plastic products from mainland China to the EU in an investigation to its specific situation.

The first part is done through a desk study into the applicable rules and regulations. Monte requests insights in ISO 9001 and REACH, so those are used as starting points. Further research reveals multiple comparable regulations, which contents are subsequently investigated.

Then, a closer look is taken to the specific situation of Monte itself. The current situation is examined, as well as the gaps why Monte currently does not comply to the aforementioned regulations. The prioritisation of compliance to the different regulations results in a framework for the implementation phase.

The changes required within (the supply chain of) Monte are listed and an implementation cycle is started. First the plan is drawn up, and then the actual implementation is executed. After that the results are examined and the implementation itself is adjusted in order to enhance the success of the implementation.

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1 Introduction

1.1 Background

Producers, products and clients are subjugated to rules and regulations, which aim to provide a smooth, fair and safe economic environment. These rules and regulations can be enforced by a number of organisations, ranging from local governmental agencies to industry organisations to worldwide legislation. It is not only required that companies prove to the enforcing bodies that they comply to these regulations, but it becomes increasingly important that companies can demonstrate to their customers that they do. Customers value the proof that companies handle their products in accordance with regulations concerning, for example, human safety, proper handling of hazardous materials and environmental friendly production processes.

The plastics industry handles quite a lot of such hazardous materials. The crude oil which lies at the basis of any plastic material can be toxic to the environment when not attended to carefully. But also the chemicals used to give the plastics the required colour, texture or whatever characteristic is required can be malicious if not handled with care. These potentially dangerous materials have regulations posed upon (the usage of) them.

The company at which this research is conducted is Monte Trading (Monte), a medium-sized exporter of plastic products from mainland China to the EU. It holds office in Shanghai and procures the majority of its products from a single plastic injection moulding factory. A company in Changzhou, Heng Chuang, was one of its first suppliers and is nowadays the largest. Monte buys around 60% of all its products from Heng Chuang, which makes up for around 70% of the factory's total production output. This relationship makes both companies dependent on each other; close cooperation and good communication are required.

1.2 Problem statement

In 2007 a new European regulation has been put into effect: REACH. This abbreviation stands for Registration, Evaluation, Authorisation and restriction of Chemicals and aims to provide detailed information about the chemicals used in products produced in or imported to the EU. Lately, Monte receives more and more questions from costumers about how it deals with REACH. However, at this moment Monte does not know precisely what REACH entails and what the consequences are for the company.

At the same time, Monte would like its main supplier, the factory in Changzhou, to get an ISO 9001 certification. The ISO 9001 is a standard that requires a decent quality management system to be put in place. Once the certificate has been issued, it will be easier for Monte to acquire new customers.

These developments have made the management of Monte curious about what other regulations, guidelines or certificates are relevant to their business. They would like to not only integrate REACH and ISO 9001 into their (and the factory's) business processes, but also to get an overview of the other regulations, guidelines and available certificates.

This leads to the following research question:

What regulations are relevant for plastic injection moulding companies and how can Monte Trading implement these in its upstream enterprise?[1]

This research question can be divided into the following sub questions:

- What regulations besides REACH and ISO are relevant for importers of plastic injection moulded products?
- How should the current situation at Monte or at its upstream partners be adapted in order to adhere to the desired regulations?

1.3 Goals

1.3.1 Company goal

The company goal is to comply with the REACH regulation and to get an ISO 9001 certification for the factory. Besides that, management would like to get an overview of the other regulations and guidelines relating to their business and how they might be able to benefit from them.

1.3.2 Research goal

The research goal is to contribute to the knowledge present on the different regulations, and to gain insight into the consequences and possibilities for Monte. Also, the steps to comply with REACH and to get an ISO 9001 certificate will be formulated and translated into concrete measures to be implemented by Monte. Finally, the implementation process is evaluated and adjusted if necessary. In doing so, the research goal is matched to the company goal.

1.4 Research structure and strategy

In order to find an answer to the research questions, the research is structured in the following way.

In order to establish a framework within which this research is carried out, a literature study is conducted. The subject of which will consist of Asian management, implementation and change management literature. After that, the research methodologies are discussed.

Then, a list of all the regulations applicable to the plastic injection moulding industry is created. The specifics are given for each one, and their relevance to Monte is investigated. The requirements, as well as the implications of the implementation, are stated. Based on the company characteristics and its specific demands, a prioritisation of the abovementioned regulations is made. This results in a list of regulations to be implemented by Monte. How these implementations should be conducted is investigated next. In order to properly ascertain the way forward, the current situation Monte finds itself in has to be evaluated. Information about the company draws an as-is picture. The prioritised list of regulations, combined with literature and the description of the current situation, will lead to the implementation phase and the to-be situation. First a plan is drawn up, and after the

[1] In the research question and throughout the rest of this report, the word “regulations” stands for the combination of regulations, guidelines and certificates.

actual implementation this process is evaluated and adjusted where necessary. In the end the research question can be answered. The research can be visualised as follows (figure 1):

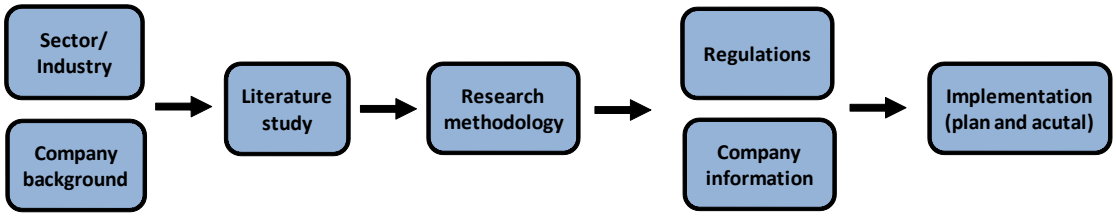

Figure 1 - research structure

This report is structured in such a way that the different stages as described in the research structure have their own chapter.

1. Introduction: background, problem statement, research strategy

   This chapter provides a general description of the problem owner, Monte, as well as the formulation of the problem statement itself. The research goals and strategy are established.

2. Literature study: clustered per topic

   A couple of fields of research are explored to provide a theoretical framework. The insights gained from these explorations provide relevant input for other stages of the research.

   The management style that predominates in mainland China has been the subject of many Western scholars in the last couple of decades. Pyke et al. (2000) describe the characteristics of the state owned enterprises which used to flourish and bring prosperity to their immediate environment. Other researchers like Lin and Germain (2003) come to the conclusion that this interdependence leads to an inefficient type of management which hinders growth of the company.

   The influence of culture on the way business is conducted is also taken into account. Hofstede's model of culture (1980) combined with specific measurable dimensions (2001) describes the essence of what sets one culture apart from the next. This viewpoint forms a starting point to which the background and implementation can be calibrated. A weak point of Hofstede however, as Fang (2009) points out, is that his model itself is constructed from his own Western viewpoint and may therefore be less suitable to describe other cultures.

   Furthermore, some observations of the concept of guanxi are made. This rather ambiguous mechanic of grounded kind turns is described by drawing on the studies of Alston (1989) and Ostland (1990), and was more recently investigated by Fan (2002) and Yueng (2006).

   In order to reach the goals changes will have to be made within Monte. In order to help put a handle on the change process, the value of the "hard" business change model of the DICE factors of Sirkin et al (2005) is explored.

3. Research methodologies: discussion of research approach

Two different methodologies are used, as this research covers two areas which have to be tackled differently. The exploration of the different regulations applicable to Monte is best done by a desk research. For the actual implementation of these regulations a case study is used.

4. Exploration of regulations: list of regulations and their relevance to the industry

   By carrying out a desk research the relevant regulations are identified. For each of these a short description of its intention and content is provided. Also, the obligatory requirements for compliance are explained.

5. Company information: description of injection moulding industry supply chain, current situation of the company, company characteristics

   In this chapter we take a closer look to Monte and its position within its supply chain. After the environment in which Monte operates is pictured, the internal processes and company information is examined. This current state where Monte finds itself in is then compared to the requirements of the, now prioritised, regulations. Gaps between the current state and desired situation are identified, and to be tackled in the implementation phase.

6. Implementation: implementation plan and actual implementation

   This chapter firstly describes the plan in which the previously identified gaps can be bridged. Then the process of actually implementing these changes is carried out and adjusted where necessary. This results in Monte to a large extent being compliant to the regulations. Loose ends are identified.

7. Conclusions and recommendations: including reflections

   Finally the result is evaluated. The research questions are answered and the limitations established. Of course, recommendation for further research is also provided.

The chapters follow each other in a natural order.

2 Literature study

2.1 Introduction

As this research is based upon companies in mainland China and certain changes within the processes of these companies, it is advisable to look into literature and establish what is already available on Asian management, Chinese culture characteristics in a business context, and business process change management. This chapter provides an exploration of the literature on these topics.

The end of this chapter gives a short summary of the identified literature and their models and presents some pointers for the implementation phase of this research.

2.2 Asian management

It is important to notice up front that there is no specific style of Asian management. The continent is so large, and consists of so many groups of people, that management approaches differ from country to country. For the larger countries differences may even be distinguished between regions (Leung and White, 2004). As Monte is located within mainland China, we will focus on that country.

China has a history of state owned enterprises (SEO's); large companies with a high focus on the region they operate in. Communities have a share in the enterprises in their locality, which creates a reciprocal dependence between the enterprise and the community. An SOE's primary goal is not necessarily to be highly profitable or to attain sustainable growth numbers. Rather it focuses its attention on being a valuable asset to the community and its employees, while bringing the economic policies and decisions adopted by the National People's Congress into effect (Starr, 2001). This mode of operation manifests itself in a lack of commercial prowess (according to our Western point of view). However, these SEO's continued to be successful, which led to the management styles and principles that are used within these enterprises to become more or less standard within the region. Private owned enterprises have moulded their own management to these examples.

Pyke et al. (2000) state that the communication of these enterprises is limited and largely focused to the downstream companies (customers). With regard to the internal management style, we can identify a less hierarchical structure than one would expect. The foremen are chosen amongst the workers themselves, reducing their willingness for formal control. However, Lin and Germain (2003) found that this formal control predicts growth in manufacturing enterprises.

2.3 Chinese culture in a business context

Hofstede (1980) was one of the first who backed his scientific research exploring cultural differences by a considerable amount of statistical data. His work is subsequently considered to be the most influential in the field of cross-cultural management (Fang, 2009). The past thirty years his view on cross-cultural management has become a paradigm to other scientists and practitioners of international management.

The Hofstede paradigm rests on the notion that across cultures the same managerial problems exist, but that they should be solved differently based on the culture in which they

are posed. To illustrate his idea of culture, he presents an onion model of culture. The values at the core are almost unchangeable, while the outer layers may come and go, and are affected by practises. The onion model of culture describes four types of manifestations of this culture:

- Core: values. Very slow to change, these values are heavily influenced by history.
- Layer 1: rituals. These encompass shared customs or habits. Traditions also range among this layer.
- Layer 2: heroes. These are either fictitious of real-life characters, both from the present and the past, to which people aspire; a role model which they hold in high regard.
- Layer 3: symbols. Brands or trademarks which people use to identify themselves with. These are often subject to trends and tend to change rapidly (in comparison to the other layers)

And then there are practices which link the layers with the each other and with the core values. These practices draw upon the contents on any combination of layers and/or the core. The picture in figure 2 below shows the onion model.

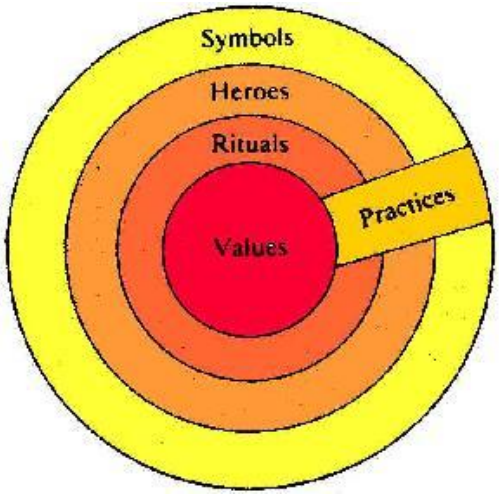

Figure 2 - Hofstede's onion model of culture
picture from: http://homepages.rtlnet.de/krkarwoth/priorities.html

This research does not explore in detail the culture characteristics of the outer layers, but rather focuses on the central, core values. However, in order to describe and compare one culture with another, a way to analyse these core values has to be used. To this end we can use different dimensions (or scales), to which we can appreciate certain aspects of core culture. Based on his research, Hofstede (1980) initially comes up with four dimensions. In a renewed version of his 1980's book he implements other research and extra data and adds a fifth dimension (Hofstede, 2001). These dimensions can be used to describe culture and give some concrete values to certain aspects of it. The dimensions are:

1. Power Distance: The extent to which the less powerful members within the culture accept that power is distributed unequally.
2. Individualism: The extent to which individuals are integrated into groups.
3. Masculinity: The extent to which roles are distributed between men and women.
4. Uncertainty Avoidance: The extent to which members are tolerant to uncertainty and ambiguity.
5. Long-Term Orientation: The extent to which members are valued for their ability to look to the long term

The scores of a country on these dimensions can be used to get an idea of the culture and to understand certain characteristics. When looking at the score of China on the different dimensions put forth by Hofstede, some points of attention have to be taken into account.

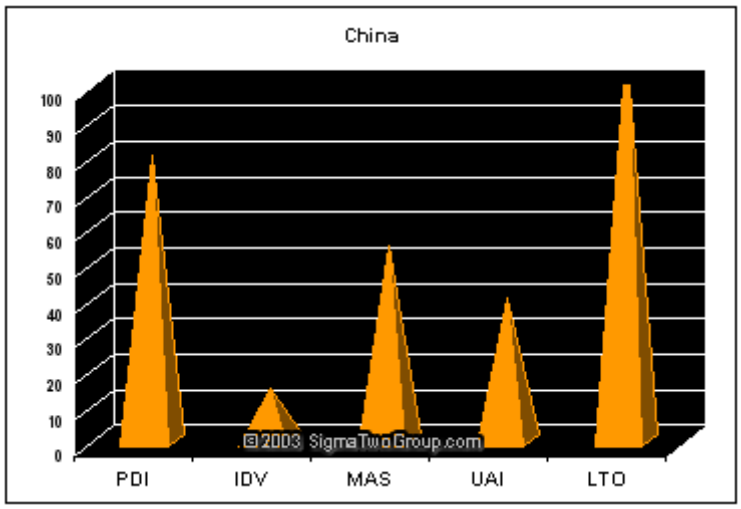

Figure 3 - China's score on Hofstede's dimensions
picture from: www.geert-hofstede.com

The high score on Power Distance indicates that power and position of employees have to be acknowledged. The low score on Individualism stresses the importance of loyalty, respect for experience and old age, and the significance of politeness. Declining an invitation or request is considered rude and could harm the relationship directly. While the low Uncertainty Avoidance manifests itself for example in the lack of decisiveness during meetings. Employees regard meetings merely as forums to exchange information and like time to think things over. The high score on Long-Term Orientation indicates perseverance, and not focussing on short term gains.

Hofstede's paradigm is also critised by Fang for being too *either-or*. Fang (2009. pp 159): "(this) may fit neatly with the Western nortions of clarity, consistency, and parsimony, it does not reflect the Asian approach to tolerance of ambiguity, inconsistency, and paradox". It is not by accident that the most well-known symbol of Eastern Asia is the yin yang. Both sides of the spectrum exist side by side and even within one another. Depending on the situation both the black and the white may come forth, manifesting the appropriate response or behaviour within individuals.

Another point of attention is the Chinese concept of guanxi. A concrete and widely accepted definition of this concept is not yet available, but certain elements appear in literature more

often than others. Guanxi is generally known as a special type of relationship between two persons (Alston, 1989), where favours are exchanged between these persons. Osland (1990) describes it as: "…a special relationship between a person who needs something and a person who has the ability to give something." In order for a relationship to form guanxi, there must be some sort of guanxi base. This guanxi base is classified by Fan (2002) into three categories: relationship by birth or blood, relationship by nature, relationship by acquired. Yueng (2006) identifies it as an integral part of what he calls the "Traditional Ethnic Chinese Capitalism".

Businesses should keep a couple of things in mind about guanxi in a business context. First of all, guanxi is a personal possession: people have it, not companies or institutions. So, when doing business, companies have to take this into account. An employee may use his guanxi to achieve company goals, but since it is his private property, it remains up to him whether or not he does so or not. An employee's guanxi will never become an organisational asset (Tsang, 1998).

Secondly, business guanxi is not the same as a business network. And business guanxi is also used in a B2G context; it is vital to retain good relationships with government officials, although guanxi should be used with care. Since most uses of this type of guanxi will result in bending or breaking the law, "There is no B2G guanxi network that is not tinted by corruption and no corruption without using guanxi" (Fan, 2002). And having guanxi with government officials being charged with or under investigation for corruption could be damaging for an organisation.

Thirdly, the role of business guanxi is likely to decrease in the future. Ongoing development of the market economy, the emergence of a democratic society and the growing information technology makes doing business in China increasingly transparent. This in turn will diminish the need for the use of business guanxi and makes its use more susceptible to charges.

2.4 Business process change models

Monte presses for an ISO 9001 certification, as the company believes that this will attract more customers, and reassure current ones. Robinson and Malhotra (2005) confirm this: "the mere fact that a supplier is registered resulted in a higher level of trust in suppliers' internal quality systems". However, the certification process will undoubtedly lead to required changes in business processes. This change project has to be managed.

There are infinitely different ways in which this change could be managed, and as much different models which describe the most ideal way to make the change happen. Many of those try to demarcate small, specific phases which the change project should address and flow through in order to reach the desired state. Among those are Kotter's eight step model (1996), Jick's ten step model (2001), Lewin's three step model (1946) or even a twelve step model from Mento et al (2002). However, these models are quite generic and can be used for all sorts of change project. As the subject of this research is rather small, it is more useful to use a model which provides concrete tools to support a change within business processes. Sirkin et al (2005) have studied change projects and identified four measurable factors that are critical for the success or failure of such a project. These are called the DICE factors:

1. Duration

Not the overall time of the project has an impact on whether or not a project will end in success, but rather the time between project reviews. The ideal time between reviews depends on the complexity of the project, but should be no longer than eight weeks. Highly complex projects should be reviewed fortnightly.

2. Integrity

   This is the ability of the team to finish the project on time. It depends on the skills of the individual members of the team, and the cooperation within the team.

3. Commitment

   Here a distinction is made between two groups of people which have to display commitment to the changes. First, there is the amount of commitment and visible backing of the project by influential executives. Second, it regards to what extent the people which are affected by the change, commit to the upcoming change.

4. Effort

   This is the amount of extra work required by the team members. The current workload should also be taken in to account.

In order to ascertain the probability that the project will end in success or failure, a score can be calculated for these five factors (two for the different types of commitment). When using a 1 to 4 scale with 1 being the best and 4 the worst score, a total score is calculated through a simple formula. This total score provides a good indication to the probability of success by plotting it in a graph as shown in figure 4 below.

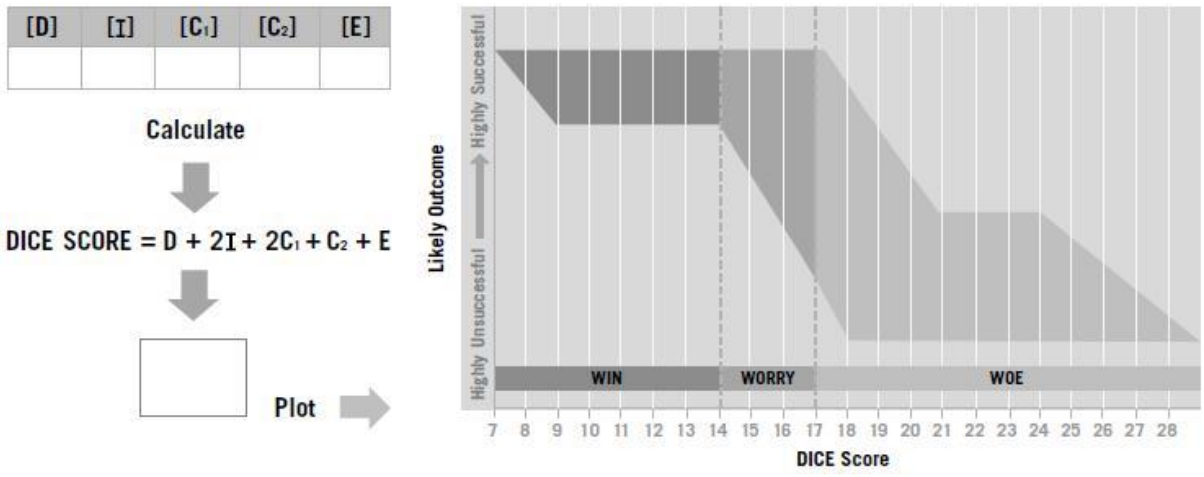

Figure 4 - Scoring the DICE factors (Sirkin et al, 2005)

When the final score is higher than desired, steps can be taken to improve the scores on the individual factors. This in turn will improve the chances for a successful outcome to the project.

Yueng and Mok (2005) point out a couple of pitfalls that should be considered during the implementation of an ISO in South East Asia. According to them, the biggest challenge lies in the institutional inertia of the company; reluctance to change undermines the

implementation process. Their second point deals with the mindset of Chinese workers, who tend to think (and work) from a quantity-oriented tradition. This clashes with the quality-based business processes from the ISO 9001 standard. Furthermore, Yueng and Mok indicate that there is a lack of qualified ISO auditors in China. This tends implementation processes to either be tailored to the external audit, or to try and 'fool' the auditors. Certifications acquired in this way do not fully embrace the ideas behind the ISO standard, and will lead to suboptimal solutions and practices.

If not only processes are required to change, but company culture as well, it is important to understand that a project's success may diminish in the future. Johnson (1992) comes up with a description of company culture and names his model the "cultural web" (see figure 5).

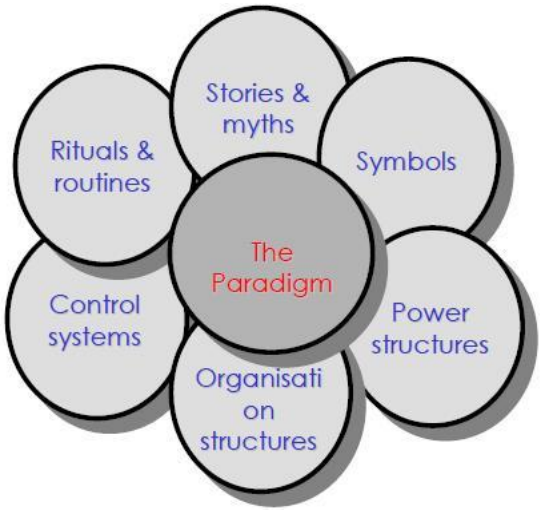

Figure 5 - Johnson's cultural web
Seel (2000)

His model implicates that the culture within a company is not easily changed, since the paradigm is often not the focus of the change. This paradigm entails the less-tangible aspects of the culture within an organisation. The outer layer consists of customisable facets, but these can only affect, or influence indirectly the overall cultural disposition. The influence the other way around, from the central paradigm towards the aspect of the outer layer, is stronger. So let's say a project succeeds in changing, for example, the power structures. In time, the central paradigm, which was not regarded during the change project, will shift the culture back into the old situation. The attained changes will disappear and if the central paradigm is not addressed during the change project at all, in time no lasting change will remain.

2.5 Summary

Hofstede's five dimensions of culture can be used to describe a culture by scoring certain aspects of it. The dimensions are Power distance, Individualism, Masculinity, Uncertainty avoidance and Long term orientation. The insights of Hofstede's view on culture will help during the implementation phase. It provides grip on how to approach Monte's employees and how to appeal to them to change.

As for how to deal with Monte's environment, the concept of guanxi can be of use. When doing business in China, it should not be underestimated. It is used to acquire information,

receive special treatment or to get things done in the first place. Business guanxi is a special type with its own dynamics, gains and pitfalls.

In order to make the implementation phase a long lasting success, one has to make sure that the change itself is achieved in a durable manner. Two pitfalls of change projects in South East Asia are the institutional inertia of the company, and the quantity-oriented mindset of its workers. The lack of qualified ISO auditors results in suboptimal business processes, through either tailoring to, or trying to 'fool' the external audit. As for change projects themselves, the DICE factors can be used to provide insight up front to the success probability of a project. However, the initial changes of such a project will diminish over time when the central paradigm is not addressed.

3 Research methodology

3.1 Introduction

As stated in Chapter 1, Monte is poorly informed on the subject of REACH. They do not exactly know what REACH entails and have problem identifying the consequences for the company. Secondly, they request that their main supplier gets ISO 9001 certified, for the purpose of upgrading their competitive advantage. Lastly, Monte would like to get more information about other regulations, guidelines or certificates that are relevant to their business. Furthermore, business processes have to be altered or adapted in order to attain an ISO 9001 certificate, and to comply with REACH. Any other regulations that might be relevant should be taken into account during the implementation process.

3.2 Research techniques

3.2.1 Desk research

Gaining insight into REACH, ISO 9001, and other related regulations requires an exploratory research technique. The use of the knowledge on these regulations is twofold. First, to map the specifics and to develop an understanding about the different regulations and their relation to one another. And secondly, to obtain instrumental tools which can be used during an implementation process.

In order to attain these goals, Verschuren & Doorewaard (1999) argue for a desk research approach. This type of research focuses on obtaining and analysing available information. The advantage of this approach is the high accessibility of information, the broad scope and a quick qualitative return. The disadvantage is that the information acquired is not specifically written for Monte's organisation, environment or situation. This could lead to the information not being applicable in this instance. However, structured filtering of all available information does lead to relevant documentation.

There might be thousands of regulations in effect nowadays, for all types of products, materials and processes. In order to establish what regulations are relevant for Monte it must not only be determined what regulations are applicable to the injection mould industry, but also where Monte can exert power in the supply chain.

To start with the latter, Monte cannot be placed directly into the typical supply chain for injection mould products. The company finds itself positioned between the injection mould factory and the retailer. However, since the major supplier is quite dependant on Monte, management has influence on how that supplier runs its business. Regulations applicable to injection mould factories will also be evaluated, since implementing them might result in a competitive advantage for Monte.

As for the identification of the applicable regulations, a start is made by examining the cross referenced directives in the REACH regulation, and the directives referenced within those. In this case, information is filtered or included on the following characteristics: the plastic injection moulding industry, orientation on Europe and the timeline (whether or not up to date).

Then a turn is made to the practice and other regulations, which are apparently important to the industry, are identified. Compliance to regulations found in this way is obviously valued by other companies.

3.2.2 Case study

In order to accomplish the research goal it is necessary to specifically focus on Monte's situation. This narrows down the scope of research and requires a different research technique than the pre-used desk research. To build upon the results of the desk research, a case study is constructed around Monte. This enables a structured and concrete analysis of the specific situation in which Monte currently finds itself. Or as Cassell and Symon (2004, pp 325) put it: "The case study is particularly suited to research questions which require detailed understanding of social or organizational processes". The subsequent research results are directly applicable and less to none adaptations are required. A downside to this approach is the difficulty to generalise results. Especially since the object of this case study, Monte, is not specifically chosen to be studied. It was not predetermined to be a critical case, tailored to either confirm or falsify certain presuppositions. Of course, this research does aim to provide some grips for companies in a comparable situation. It has not however, a direct goal to be able to generalise the results originating from it, as the primary focus lies with Monte. So this lack of generalisability is acceptable.

In the case study information is collected in two separate manners. First, the documentation from within the company is collected and analysed. This information should be able to provide an unbiased view on processes and procedures. Key personnel within the organisation will be asked to either deliver this documentation or indicate where it might otherwise be obtained. In this stage no additional information, explanation or clarification pertaining any knowledge gaps is asked, in order to remain unbiased.

Second, in-depth interviews are conducted with key personnel. These interviews will focus on both generic and specific parts of business processes and are semi-structured in nature. The aim is known beforehand, as are the most important questions. However, the exact flow of the interview will be established during the conducting. The results of these interviews generate more practical information about the actual processes within Monte. This information is then used to complete the picture of the current situation at Monte, as well as to gain insight in and support for the change process.

3.3 Summary

In this research two different methodologies are applied. This is done in order to exploit the advantages of each individual method, while minimising the impact of their weaker aspects. The high accessibility of information, the broad scope and a quick qualitative return of the desk research during the exploratory phase is a perfect fit for the search of applicable regulations.

The actual implementation of business process changes does not fare well with this type of approach. Therefore a case study is picked to be the methodology of choice, as this enables an in-depth analysis of the actual situation at hand with a tailored approach. Combining the two methodologies in this way creates synergy in attaining the research goals.

4 Regulations and their relevance

4.1 Introduction

In this chapter some of the regulations applicable to the plastic injection moulding industry are identified. Besides that, for each of the regulations a short indication is provided as to what Monte should do in order to adhere to that specific regulation. For an actual prioritisation of the regulations we will first have to take a closer look to Monte. This is done in the next chapter.

In order to find the applicable regulations, the search strategy as discussed in chapter 3.2.1 is executed. After that, the resulting regulations are briefly described. In the conclusion of this chapter an overview of the regulations and their qualifications are summed up.

4.2 Regulations

4.2.1 REACH

In 2007 a new European regulation has been put into effect: REACH. REACH stands for Registration, Evaluation, Authorisation and restriction of Chemicals and aims to provide detailed information about the chemicals used in products produced in or imported to the European Union. This information not only increases the transparency of products but is also used to analyse the risk of products with (potentially) dangerous materials. Each company which imports or produces substances with certain (hazardous) characteristics are obligated to provide certain information to ECHA, the European Chemicals Agency. REACH distinguishes different actors and different forms in which substances can be present, each with their own set of obligations.

Monte does not have a direct role under REACH and the products it exports to the EU are articles, according to its definitions (see Appendix A). However, even though Monte does not have any obligations towards REACH, the regulation is still relevant. Since its customers will definitely have to deal with REACH it is advisable to investigate their obligations and to extract the consequences for Monte.

Appendix B states the applicable requisites. It can be concluded that the customers of Monte do not have to register any substances (no intended release), but may have to notify ECHA about some substances. An analysis of the raw materials going into the articles has to be made in order to ascertain whether these substances are subject to notification. This analysis can be conducted by comparing the respective materials' official ID-number to the lists available at ECHA. If these numbers are not readily available, the suppliers have to be contacted and the substances be identified in cooperation.

The official ID-number can be either an EC or CAS number. These numbers are up to ten digit codes assigned to substances. In the European Union the European Commission number (EC number) is commonly used, while the Chemical Abstracts Service (CAS) aims to make a complete database of all the substances described in literature. Although both numbers are built up in a similar way, with the last digit used as a check, a chemical substance often has different EC and CAS numbers.

Once it is clear whether or not the substances are subject to notification the following steps can be taken. Customers can be informed whether any action is required to comply with REACH, and Monte can reconsider using the substances it currently does.

4.2.2 ISO 9001

ISO (International Organisation for Standardization) has developed over 18,000 standards, covering all industries and processes. However, two of them have become the worldwide standard of choice in their field: the ISO standards 14001 and 9001. ISO 14001 focuses on environmental management systems, and ISO 9001 focuses on quality management and continual improvement.

ISO 9001 sets requisites on the quality management system of an organisation and the way in which it controls the quality of its processes. It is possible for organisations to have an external body perform an audit. If the organisation passes this audit, a certificate will be issued. This certificate shows that the organisation has adequately implemented all aspects of a quality management system. Even though there is no law or regulation requiring organisations to attain an ISO 9001 certification, customers value the confirmation that their suppliers are actively working with a decent quality management system. Some companies even demand such a certification from other companies before doing business with them.

As mentioned before, Monte does not want this certification for itself, but would like its main supplier to be certified. This makes sense since Monte does not produce any products; the products are manufactured at the factory in Changzhou and also shipped from there directly to Monte's customers.

In order to attain a certification, the current situation at the factory must be analysed and compared with the requirements as put forth by the standard. Any gaps found herein will have to be closed by adapting current business processes or implementing new ones.

Monte has indicated not to be interested in acquiring an ISO 14001 certification.

4.2.3 RoHS

The European Directive 2002/95/EC is better known as the RoHS directive. RoHS stands for Restriction of Hazardous Substances. This directive came into force in July 2006 and restricts the use of six hazardous substances in electrical and electronic equipment. These six substances are:

1. Lead (Pb)
2. Mercury (Hg)
3. Cadmium (Cd)
4. Hexavalent chromium (Cr6+)
5. Polybrominated biphenyls (PBB)
6. Polybrominated diphenyl ether (PBDE)

Two categories of products are exempt from this directive: medical devices and monitoring and control instruments. However, currently an amendment of the directive is being prepared to also include these products. When this amendment will come into effect is not known at this moment in time.

Monte has some customers whose final products fall under this directive, and have lately received some inquiries as to their compliance with RoHS. However, according to the

definitions of the directive (see Appendix C), Monte is also considered a producer. So, for the products that it exports to the EU and that are considered an EEE, Monte has to make sure that none of the six restricted substances are present.

4.2.4 EN 71

The European Directive 88/378/EC states that toys may not cause any harm to children. Following this directive, the European Committee for Standardisation (CEN) has formulated a standard for toys, the EN 71 standard. All toys sold in the EU have to comply with the directive, and the standard can be used to accomplish this. EN 71 sets requirements for the safety aspects of toys, and consists of eleven parts. Each part covers either a specific characteristic (such as physical properties, flammability, labelling) or a specific type of toy (such as chemical play sets, finger paint, swings and slides).

Since Monte only delivers products on their customers' orders, most of this standard should be implemented by their customers. However, the relevance of this standard for Monte lies within part 3: Specification for migration of certain elements. This specifically limits the amount of bioavailability of the following substances to the following levels per day:

- 0.2 µg for antimony,
- 0.1 µg for arsenic,
- 25.0 µg for barium,
- 0.6 µg for cadmium,
- 0.3 µg for chromium,
- 0.7 µg for lead,
- 0.5 µg for mercury,
- 5.0 µg for selenium,

In order to make sure that the products Monte supplies to their customers comply with this standard, the raw materials going into them have to be checked for these substances. Should one or more of these substances be used, their bioavailability will have to be established, and action undertaken accordingly.

This directive will be replaced by Directive 2009/48/EG by July 2013. This directive excludes certain allergenic fragrances to be used, and places migration limits on more substances (see Appendix D). A migration limit is based on the calculated maximum acceptable or tolerable daily intake (Piringer and Baner, 2008: 350).

4.2.5 2002/72/EC

Products that are intended to come into contact with foodstuffs are subject to specific regulation, and the substances allowed therein restricted. Directive 2002/72/EC lists the allowed substances for plastic materials and articles intended for this use. It also sets migration limits for the allowed plastic materials and articles to a maximum of 60 mg per kg of contained foodstuff, unless stated otherwise. The list of allowed substances and their restrictions or specifications can be found in Appendix E.

4.2.6 AP 89/1

The Council of Committee adopted this resolution, which focuses to restrict hazardous materials being used in the colourants of products that come into contact with foodstuffs. The directive distincts six groups of substances subject to restriction;

1. metals and metalloids
   The content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed:
   antimony: 0.05%, arsenic: 0.01%, barium: 0.01%, cadmium: 0.01%, chromium-VI: 0.01%, lead: 0.01%, mercury: 0.005%, selenium: 0.01%
2. aromatic amines
3. sulphonated aromatic amines
4. carbon black
5. polychlorinated biphenyls (PCB's)
6. inorganic cadmium pigments

Again, Monte should investigate the raw materials used in its products in order to ascertain whether they already comply with this resolution, or if further research is required.

4.2.7 ICTI Certificate

ICTI stands for the International Council of Toy Industries. It is an association, which consists itself of twenty toy trade associations from countries all over the world, including the Netherlands. It was established to ensure that toys are produced in safe and humane environments.

In order for a product to receive an ICTI certificate, the factory in which it is produced is required to meet specific operating conditions. This Code is divided into three areas:

1. Labour
   Covers issues like: "normal" working hours, rules for overtime, no child or forced labour, sickness and maternity benefits, right of employee representation.
2. Workplace
   Covers issues like: properly lighted and ventilated, clear emergency exits, safety equipment, adequate sanitary facilities, provisions for meals and other breaks.
3. Compliance
   Covers issues like: signing an annual statement of compliance, examining subcontractors, availability of the Code in the local language.

There are no laws forcing a company to comply with the ICTI Code, but the certificate indicates a proper way of operating in producing children's toys. Some companies do not want to do business with companies without this certificate and their numbers may be increasing in the future.

4.2.8 1005/2009/EC

The manufacture and use of substances that deplete the ozone layer is restricted under this directive. These are especially fluorides, chlorides, bromides. Appendix G contains the complete list of restricted substances.

4.3 Summary

An overview of the previously identified regulations, their main qualifications and their respective implementation priority is given below.

Regulation	Qualification
REACH	Restriction of substances
ISO 9001	Quality management certificate
RoHS	Restriction of substances
EN 71	Restriction of substances
2002/72/EC	Restriction of substances
AP 89/1	Restriction of substances
ICTI	Safe production of toys certificate
1005/2009/EC	Restriction of substances

Now that we have identified the list of regulations we are ready to take a closer look into Monte as a company. We will need to evaluate the current situation in order to pinpoint areas that need to be improved upon. These issues can later be addressed during the actual implementation.

5 Current situation

5.1 Introduction

This chapter describes the current situation Monte finds itself in. We start by taking a look to the supply chain of the plastic injection moulding industry, and elaborate on the position of Monte within that chain.

Then we bring in the regulations identified in the previous chapter and see what the current gaps are which have to be bridged before Monte can fully comply with them.

5.2 Generic Supply Chain

The process of producing a plastic injection moulding product starts with the processing of its raw material. In most cases, this starts with crude oil or natural gas being “cracked”. This cuts the molecules in the oil or gas, and smaller hydrocarbon monomers molecules are formed. Further processing results in a wide range of monomers. These monomers are then chemically bonded to each other to create long strings of polymers. Other additives, such as chlorine, nitrogen or oxygen, may be used during this process to alter the chemical composition of the resulting polymer. Each chemical composition translates into specific characteristics of the plastic.

The producer of plastic product chooses the plastic with the required characteristics. The polymers, which are still in granular form, are mixed with additives to alter some of the characteristics to meet customer demands. These can include: protection against degrading effects of light, bacteria or heat, flame retardancy or special surface requirements. The mixture is heated so it becomes fluid, and pressed into a closed die or mould. There, the plastic cools into a solid form and when the die is opened, the product is ejected. After some final actions, like cutting excess material from the injection point, the final product is finished.

The rest of the supply chain can be characterised as rather standard. The entire chain can be visualised as follows:

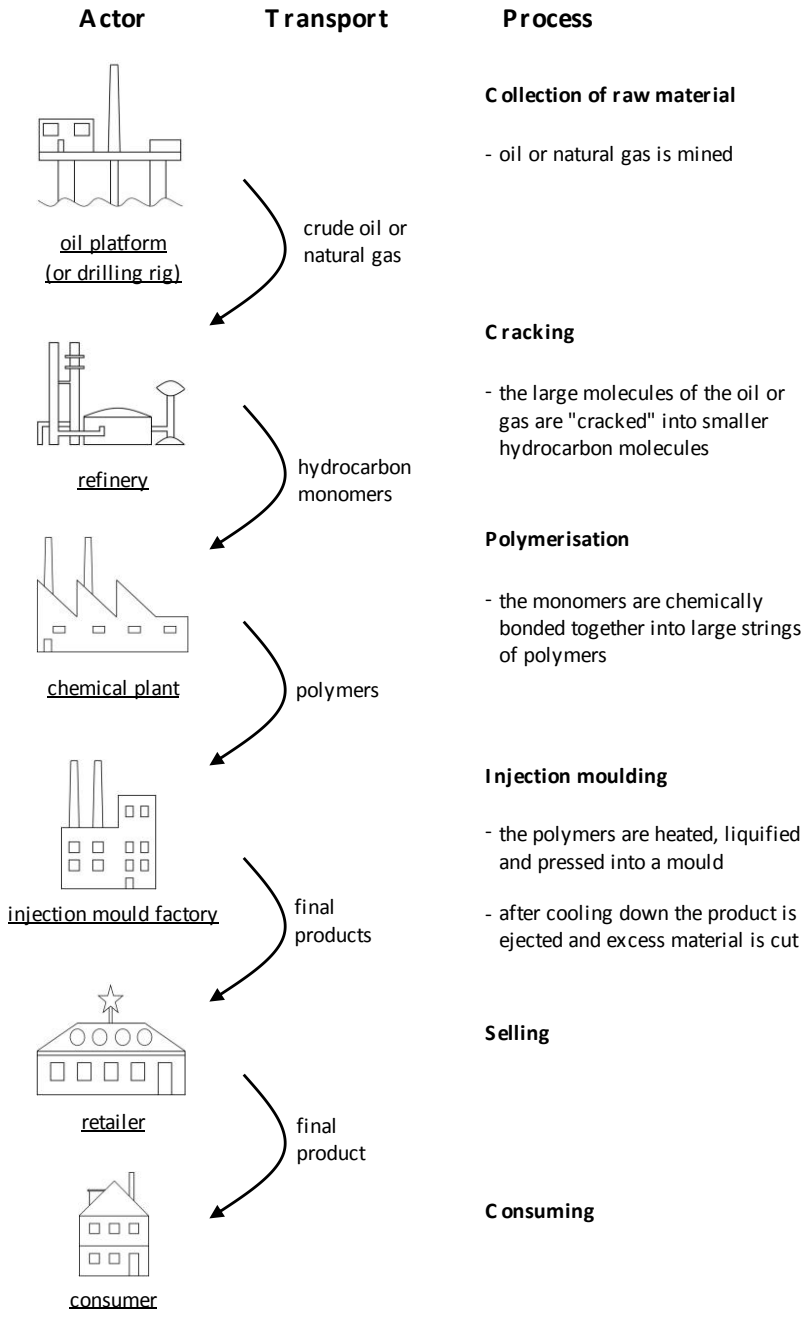

Figure 6 - visualisation of the generic supply chain of plastic injection moulding

5.3 Position within the Supply Chain

By interviewing the management of Monte and taking a first look on the business processes, the position of the company within this generic supply chain can be pinpointed. The interviews of the management in this stage are targeted towards identifying this position.

Positioning of Monte within its environment:

- What are the core activities of Monte?
- What are the characteristics of its suppliers and customers?
- Do you validate the described generic supply chain?

- If so, where do you think Monte fits within this generic supply chain?

It turns out that Monte does not fulfil one of the crucial roles within the supply chain of plastic injection moulding products, even though the described supply chain does indeed resemble the regular product flow. Monte positions itself between the injection mould factory and the retailer. Monte's customers are located in Europe, mainly in the Netherlands. The reason for the customers to do business with Monte is because of communication advantages, their insight in the plastic injection moulding industry and their network of secondary suppliers.

As for the communication advantages, customers deal directly with a Dutch (or at least English) speaking company. This makes it easy for them to make their wishes clear, comment on changes or discuss any problems. Monte maintains connections with the manufacturers and communicates the customers' orders to those.

The insight in the plastic injection moulding industry is also an asset that customers value. Monte can help develop product specifications. Part of the production process, for example, is the production of the mould. The form and material of the mould place restrictions on which plastics can be used and the dimensions of the end product. Monte can foresee mould problems during initial contact with its customer, point out mould possibilities and identify improvement opportunities.

Besides having connections with manufacturers and mould makers, Monte's business network also comprises other companies. These companies range from metal inserts providers, to painters, to printing offices. This network, combined with the fact that the manufacturers have (basic) assembly capabilities, lets Monte offer a complete package to its customer; from start to finish, from technical drawings to final assembly and individual packaging.

The quality specifications of the final product are agreed upon between Monte and its customers. And as Heng Chuang produces most of the products, it has to produce according to these quality standards. But these standards are generally higher than the factory is used to. In order to make sure that the final products adhere to the quality standards expected from the European customers, Monte has set up a quality control system at Heng Chuang. This system consists of multiple documents that have to be filled in, and multiple checks that have to be carried out during the production process. In order to make sure that this system is used and to streamline the communication, Monte has an employee located full time on the factory site. In practise, this employee does most of the quality monitoring. However, Heng Chuang remains ultimately responsible for the quality of the outgoing products.

5.4 Prioritisation of regulations

The regulations found in the previous chapter are ranked, based on their importance to Monte. Monte had a clear goal at the beginning of this research: its priority lies with the REACH regulation and the ISO certification for the factory. After that, there is no preference for one regulation or another. However, Monte requests that the implementation effort is minimised. The regulations that have similar consequences will therefore be implemented together. During the implementation phase, regulations other than REACH and ISO may be removed from implementation if the effort to comply turns out to be much greater than expected beforehand.

It makes sense to combine the implementation of the regulations that are about the restriction of substances, especially since some of them overlap. The implementation of these regulations could range from simple to complex, depending on the substances already used. ISO 9001 is specifically mentioned as one of the company's goals and is therefore prioritised over the remaining regulations.

So, the regulations are ranked as follows:

- REACH (priority of Monte)
- Regulations overlapping with REACH (restriction of substances)
- ISO 9001 (priority of Monte)
- Other regulations

This ranking leads to the following prioritisation of the regulations:

Regulation	Qualification	Priority
REACH	Restriction of substances	1
RoHS	Restriction of substances	2
EN 71	Restriction of substances	2
2002/72/EC	Restriction of substances	2
AP 89/1	Restriction of substances	2
1005/2009/EC	Restriction of substances	2
ISO 9001	Quality management certificate	3
ICTI	Safe production of toys certificate	4

5.5 Current situation regarding the regulations

Now that we have pictured the environment of Monte and the characteristics of the regulations to be complied with, we can take a closer look to the subject of the case study itself.

The first stage of this case study consists of mapping and analysing the available documentation about the company and its processes. All types of documentation are requested, ranging from organisation charts and process descriptions, to forecasts and inspection sheets. This information should be able to provide an unbiased view on processes and procedures. Key personnel within the organisation will be asked to either deliver this documentation or indicate where it might otherwise be obtained. In this stage no additional information, explanation or clarification pertaining any knowledge gaps is asked, in order to remain unbiased.

Surprisingly little information could be collected in this way. The small-scale of the enterprise enables a way of doing business where the manager can still control the entire operation. There never existed a need to formalise the procedures, a pressure to formulate methods, or a compulsion to nail procedures shut.

So in order to fully understand the dynamics of the processes within Monte the second stage of the information collecting phase of the case study is utilised. In-depth interviews with key personnel help to fill in the gaps that the analysis of just the documentation left. These interview will focus on specific parts of business processes and are semi-structured in nature. The aim is known beforehand, as are the most important questions. However, the exact flow of the interview will be established during the conducting. This resulted also in an unstructured result; no transcripts of the interviews are available. However, these interviews did bring to light the more practical information about the actual processes within Monte. This information is then used to complete the picture of the current situation at Monte, as well as to gain insight in and support for the change process.

For the regulations with the priority 1 and 2, an inventory of the products and substances currently used by the factory is created. This list is not so easy to make. The raw materials are not simply substances, but products consisting of multiple substances. In most cases these cannot be identified easily, since the specific documentation consisting this information is missing, or can simply not be provided by the supplier. This information can be found on a product's data sheet, MSDS or UL 94 file. Some of these files are already present in the company's archive, some could be attained from the supplier, but most could not be provided at all. An overview of the available files can be found in Appendix H.

Nothing in relation with the regulations with priority 3 and 4 is currently in place at Monte. Compliance with these regulations can only be attained by starting from scratch with their implementation.

5.6 Summary

Now that we have placed the regulations into a ranking, we can draw up an implementation plan of how to enable Monte to comply to them. In this plan we start by tackling the regulations about the restriction of substances (priority 1 & 2) together. The current use of these substances is unclear. The regulations with the lower priorities 3 and 4 are not addressed whatsoever at the moment.

6 Implementation

6.1 Introduction

This chapter describes the different steps taken in order to successfully implement business changes, with the goal of complying to REACH (and the other regulations with priority 2, concerning the restriction of substances), obtaining an ISO 9001 certificate (priority 3) and complying to ICTI (priority 4). The literature framework from chapter 2 is put into practice with its value weighed.

First, an implementation plan is drawn up. When the actual changes are carried through, the implementation process is evaluated.

6.2 Implementation plan

As the regulations of priority 1 and 2 are about the restriction of substances, a good starting point is to establish where these regulations overlap. An overview of which substances are mentioned in which regulations and what corresponding restrictions are placed upon them or their use, has to be made.

This overview of restricted substances can then be checked against the list of substances currently in use by Monte. For any substances that appear on both lists a decision must be made. The decision will be based on the imposed restriction, the level of current use of the substance and the requests of demands of the customer. Any of the following could be decided upon in such an instance:

- do not let the regulation be applied on the final product (if possible)
- substitute the substance with one that does not have a restriction placed upon it
- reduce the concentration of the substance within a product to make it fall within the boundary of the regulation (if applicable)

Individual substances and situations will be evaluated separately, in order to establish the best course of action.

For the implementation of the ISO 9001 norm and the acquisition of the certificate, the current business processes will be analysed and compared to the requisites put forth by the norm. As this part of the implementation will have the most impact on current ways of working and will probably provoke actual changes within the business processes, the DICE factors will be scored in order to identify any possible troublesome areas.

6.3 Implementation

6.3.1 Restricted substances

The regulations mentioned in Chapter 4 that pose restrictions on (the usage of) substances, do so on nearly 500 substances in total. All these are listed by their CAS-number with the respective restrictions noted. A sample of this list can be found in Appendix I. The available files of the substances currently in use by Monte (Appendix H) have now been filed in a central place where they are readily accessible.

None of the available files showed any (concentration of) substances which could violate the regulations, so it was agreed with Monte to round off this part of the implementation at this point. It is assumed that all raw materials fall within the boundaries of the regulations and when a customer specifically demands their product to be in accordance with any of the regulations, it is made sure that only products for which the right documentation is available, are used.

6.3.2 ISO 9001

As Monte wants its main supplier to be certified, their business processes will have to be analysed and checked against the requisites of the ISO 9001 norm. However, the certification process in China elapses somewhat differently. In order to apply for a certification, which can only be issued by a governmentally appointed organisation, it is best to use an intermediary consultant. These consultants prepare the application and necessary documents, and have long term contacts with the actual auditors. This is where guanxi comes in.

Monte has a strong relationship with the consultant they use for all their licensing since the start up of the company. This man previously worked for a large firm, but decided to start a company of his own. Most of the clients he had during his time at the large firm decided to house their business with his new company, and proved loyal (or committed) to persons rather than companies.

During the meetings with this consultant a lot of time and effort is put into maintaining a good relationship. They make inquiries not only about each other's businesses, but also are very particular in each other's personal affairs and families. When the subject of the conversation turns to the actual project at hand (ISO 9001 certification), the consultant ensures Monte that there is nothing to worry about. They will hand in all the necessary paperwork. When the auditor will visit the factory site the consultant will also be present. All that has to be done is for all parties involved to buy the auditor a nice dinner and make a couple of small or formal adjustments to the factory (-process) afterwards, as the auditor always has to have some remarks for their administration.

This dynamic of the ISO auditing process brings one of Yueng and Mok's pitfalls clearly to light. The focus does not lie on actually adhering to the standard, but on identifying the easiest way to pass the audit, and so the shortest route to certification. This does however, lead to an inferior business process. So, during the implementation phase, actors are stressed to keep in mind that the certification is not a goal in itself. Improved processes and better quality control is required for the certificate to bear any meaning.

6.3.3 Business process improvements

However, the management of Monte insists that actual changes take place in the business processes of their main supplier, and that the issued ISO 9001 certificate will not be just a superficial one. During the analysis, it becomes clear that some links in the process are non-existent or very poorly documented. There is no production planning drawn up, no documentation of purchased raw materials, and no training program for employees. Furthermore, there is no official agreement between Monte and the supplier as to how they communicate and which documents are to be used. The cooperation relies for the most part of verbal engagements between the two parties. This has to be resolved.

Without a written description of the business processes the expectations both parties have from each other differ and are subject to personal viewpoints. Therefore, a description is made and agreed upon by both parties. This description also contains the requirements placed upon the documents that are used in the processes (see Appendix J). In order to comply, some documents are adjusted and some have to made up entirely from scratch.

Next, the missing links can be addressed. The absence of any planning tool at the factory whatsoever accounts for quite some communication problems and in order to smoothen the process, a tool has to be developed. It turns out that an Excel sheet will suffice. See Appendix K for an impression of the tool. Aimed at user friendliness rather than extensive possibilities, the tool enables the factory to quickly and simply update its planning, and each actor to check up on planning progress.

6.4 Adjusting the implementation

6.4.1 Hofstede's implications

The high score on Power Distance indicates that power and position of employees have to be acknowledged, or at least taken into account. Employees accept the hierarchy inside the company, and abide by the decisions lain upon them from upper management. However, this also hampers any attempt of trying to bond with them or truly winning them over to support the upcoming changes.

During the implementation the Chinese employees often agree and promise change, but regular supervision is required in order to make sure of these changes. Also, evasive answers like "we will come back to this" or "let me think about it" actually turn out to mean a hard "no". This is in line with Hofstede's low scores on Uncertainty Avoidance and Individualism, from which follows that declining an invitation or request is considered rude, but people are also uncomfortable in making hard commitments. The lack of Individualism also manifests itself in the unquestioned loyalty within groups. Groups will not turn on one of its members. Co-workers cover each other in case of mistakes or failures, and do not point to the guilty. This makes identifying exactly what went wrong where, in which way and by whom an almost impossible task.

The high score on Long-Term Orientation on the other hand, appears to be somewhat too high in this encountered instance; employees focus on the here and now. Few look past next week and even fewer have made concrete plans for the future.

6.4.2 Adjustments following the DICE factors and cultural web

As the alignment of the business processes between Monte and factory requires the largest changes in actual operations, the DICE factors are scored on this issue and troublesome area's identified.

In the table below (figure 7) each individual factor is evaluated and rated. The score is substantiated with an elaboration on the current situation regarding the specific factor. This elaboration and indeed the scoring itself is based on observations made by the author as no specific tools are described by Sirkin et al.

factor	score	elaboration
duration	1	review happens almost constantly, both parties are fully aware of the changes and consult each other on a daily basis
Integrity (x2)	2	the project is not overly complex, but most of the members have no experience with this kind of affairs
commitment 1 (x2)	2	Monte is fully committed as initiator, the factory executive is somewhat reluctant, not grasping the full benefits
commitment 2	3	employees do not see any benefits, only extra hustle
effort	1	extra effort required is low, and current workload is light
total	13	the total score still lies within the "win" sector, albeit by just 1 point.

Figure 7 - scored DICE factors

From the table above it is concluded that the commitment factors are scored the highest. In order to increase the probability of success for this project, commitment must be increased. To do so, it is stressed to the employees that by embracing the changes, work itself will be streamlined and less prone to hiccups. This in turn will lower the amount of rework that has to be done and increases the profitability of the enterprise. By appealing to the financial consequences the basis for change is enlarged and the score on the commitment factor lowered.

When we take another look at Johnson's cultural web, we can see that not all segments are addressed within this change project. The risk of relapsing into the old paradigm of working with a lack of interest in quality control is therefore substantial. The segments "organisation structures" and "control systems" are part of the project, the other four are not. However the segments "stories & myths" and "symbols" are considered less important, and in order to attain an actual shift of the central paradigm, extra attention is given to "rituals & routines" and "power structures". This distinction is made because of the fact that there simply are not much, if any, of the former matters present in the current situation. So the risk of these segments forcing the central paradigm back into its earlier position, is negligible.

To focus on the latter two segments, the followed procedures ("routines") are scrutinised on a weekly basis for the first couple of months, and any digression fed back to the responsible employee. This leads to a significant increase in procedure compliance. This also enhances the sense of involvement of all actors and changes the power structure to a more decentralised one, as employees feel more and more responsible for their own work.

6.5 Summary

During the implementation phase an elaborate list of all the restricted substances is created, and also an inventory is made of all the substances currently being used. The latter list is incomplete as it is sometimes impossible to acquire the proper information on raw materials

form the suppliers. Analysis of the lists shows that the raw materials, of which there is the right documentation available, do not contain any of the restricted substances.

The ISO 9001 certificate is applied for with the help of a consultant, who prepared the necessary paperwork. Using guanxi and some minor adjustments the certificate is issued. However, in order to ensure that some actual improvements in the business process are attained, these processes are formalised. The resulting actual changes are implemented while taking the implications of the Chinese (working) culture into account.

7 Conclusions and recommendations

7.1 Conclusions

The research question put forward in chapter 1 was:

What regulations are relevant for plastic injection moulding companies and how can Monte Trading implement these in its upstream enterprise?

The relevant regulations are identified and can be generally classified into a single type of regulation, namely the restriction (on the use of) certain substances. The lists of substances concerned by these regulations are combined and the nature of the restrictions summarised. Next, an inventory of the raw materials currently being used by Monte's main supplier is made and their substances checked against the list of restricted substances. This is not always possible as the required documentation is sometimes unavailable. However, when the documentation is available, the raw material and its content do not contain any restricted substances. It is decided that when a customer explicitly asks for compliance with certain regulation, only raw materials for which the documentation is available, are used.

Besides the research question answered, Monte would also like their main supplier to be ISO 9001 certified. It turns out that the actual certification is not hard to attain, as a befriended auditor will examine the site and business processes. Using guanxi ensures that he will request only minor changes before issuing the certificate. However, in order to realise actual improvements in the business processes, as Monte requested, an overview is made of the processes currently in place. These processes are formalised and agreed upon by both parties, and additional documentation or forms are created in order to smoothen communications and lower the possibility of errors.

During the implementation phase, insights from Hofstede's cultural dimensions are used to identify more successful implementation tactics, by drawing attention to the cultural implications to business life. This ensures a smoother implementation and enhances acceptability among actors.

In order to increase the probability of long lasting success of the implementation, the DICE factors are used. They lead to the conclusion that the commitment should be increased. Besides that, Johnson's cultural web provides an overview of aspects that need to be addressed in order to successfully change something within an organisation. Initially not all these aspects were taken into account and extra attention is given to "rituals & routines" and "power structures".

7.2 Reflections

The company goal was to comply with the REACH and to get an ISO 9001 certificate. Besides that, Monte would also like to get an overview of the other regulations and guidelines relating to their business and how they might be able to benefit from them.

During the implementation phase of this project it turned out that a lot of other regulations can be combined with the REACH regulation, as they pose restrictions on the substances being used. The restrictions in place are summed up, providing Monte with a full overview. The substances currently being used are checked against this list and no violation is found, at least not for the substances for which proper documentation is available.

The second company goal, ISO 9001 certification, is also attained. This is accomplished after careful evaluation of the business processes, comparison to the requirements and implementation of improvements

The process in which both company goals have been achieved was somewhat hampered due to the language barrier between the author and some of the actors involved. The employees of Monte (besides the Dutch manager) speak mediocre English, and the employees of Heng Chuang only speak Chinese. During the interviews and the implementation of business changes one of Monte's employees had to act as a two-way translator. This led to a couple of communication errors and misunderstandings. However, a secondary consultation and explanation sufficed in these cases.

The research goal was to contribute to the knowledge present on the different regulations, and to gain insight into the consequences and possibilities for any importer of plastic injection moulding products and for Monte in particular. The regulations are summarised and any overlaps identified. The resulting overview provides a solid database for all restricted substances.

The process changing and improving the business processes within Monte and its main supplier in order to acquire the ISO certification could have been structured as the actual certification process of the official auditors was somewhat taken over by the consultant. However, this did result in the certification and Monte is satisfied with the adaptations of the business processes, which have resulted in more efficient dealings and fewer errors.

7.3 Recommendations

In order to remain compliant with the regulations, Monte should regularly check the procured raw materials and keep the database of their documentation up to date. Furthermore it is recommended to find substitute suppliers for those raw materials for which currently no documentation is available. In that way Monte will always have an alternative in case a customer does demand such papers.

The changes realised in the business processes are not groundbreaking from an academical point of view, but did revolutionise the way of thinking within Monte and the factory. This change in perspective should be cherished. The benefits of a critical attitude to current workings and a structured approach to doing business are now clear to all the actors involved. Preserving this viewpoint will help future improvement projects to not only reach their full potential, but also to smoothen the implementation phases of them, as a lot of the resistance has now been taken away.

As this research did not reveal any restricted substances currently being used, the ways on how to deal with these substances are not investigated. Further attention can be given to this topic and could be the subject for future research.

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Appendix A – Definitions under REACH

REACH identifies five actors and three different types of products (article 3).

Actors:

1. *Manufacturer*
   means any natural or legal person established within the Community who manufactures a substance within the Community
2. *Importer*
   means any natural or legal person established within the Community who is responsible for import
3. *Downstream User*
   means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities
4. *Distributor*
   means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties
5. *Only representative*
   means any legal person inside the Community to fulfil, as an only representative of an non-Community manufacturer, the obligations on importers.

Products:

1. *Substance*
   means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
2. *Article*
   means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
3. *Preparation*
   means a mixture or solution composed of two or more substances.

Appendix B – Obligations under REACH

(Source – article 7 and 57)

The regulation states that the substances contained within articles should be registered if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Furthermore, ECHA should also be notified of substances within articles if they meet **any** of the following criteria (hazardous materials) of (a) to (f) **and both** (g) and (h) **and not** (i) or (j):

ANY

(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EC;
(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EC;
(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EC;
(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

BOTH

(g) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
(h) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).

NONE

(i) the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.
(j) the substance has already been registered for that use.

Appendix C – Definitions under RoHS

Electrical and electronic equipment or EEE:

means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields falling under the categories set out in Annex IA to Directive 2002/96/EC (WEEE) and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;

Producer:

means any person who, irrespective of the selling technique used, including by means of distance communication according to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts (3):

- manufactures and sells electrical and electronic equipment under his own brand;
- resells under his own brand equipment produced by other suppliers, a reseller not being regarded as the 'producer' if the brand of the producer appears on the equipment, as provided for in sub point (i); or
- imports or exports electrical and electronic equipment on a professional basis into a Member State.

Appendix D – Substance restrictions of Directive 2009/48/EG

ANNEX II

PARTICULAR SAFETY REQUIREMENTS

III. Chemical Properties

4. Toys shall not contain the following allergenic fragrances:

No	Name of the allergenic fragrance	CAS number
1	Alanroot oil (Inula helenium)	97676-35-2
2	Allylisothiocyanate	57-06-7
3	Benzyl cyanide	140-29-4
4	4 tert-Butylphenol	98-54-4
5	Chenopodium oil	8006-99-3
6	Cyclamen alcohol	4756-19-8
7	Diethyl maleate	141-05-9
8	Dihydrocoumarin	119-84-6
9	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
10	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
11	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
12	Dimethyl citraconate	617-54-9
13	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
14	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
15	Diphenylamine	122-39-4
16	Ethyl acrylate	140-88-5
17	Fig leaf, fresh and preparations	68916-52-9
18	trans-2-Heptenal	18829-55-5
19	trans-2-Hexenal diethyl acetal	67746-30-9
20	trans-2-Hexenal dimethyl acetal	18318-83-7
21	Hydroabietyl alcohol	13393-93-6
22	4-Ethoxy-phenol	622-62-8

23	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
24	7-Methoxycoumarin	531-59-9
25	4-Methoxyphenol	150-76-5
26	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
27	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
28	Methyl trans-2-butenoate	623-43-8
29	6-Methylcoumarin	92-48-8
30	7-Methylcoumarin	2445-83-2
31	5-Methyl-2,3-hexanedione	13706-86-0
32	Costus root oil (Saussurea lappa Clarke)	8023-88-9
33	7-Ethoxy-4-methylcoumarin	87-05-8
34	Hexahydrocoumarin	700-82-3
35	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
36	2-Pentylidene-cyclohexanone	25677-40-1
37	3.6,10-Trimethyl-3.5,9-undecatrien-2-one	1117-41-5
38	Verbena oil (Lippia citriodora Kunth)	8024-12-2
39	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
40	4-Phenyl-3-buten-2-one	122-57-6
41	Amyl cinnamal	122-40-7
42	Amylcinnamyl alcohol	101-85-9
43	Benzyl alcohol	100-51-6
44	Benzyl salicylate	118-58-1
45	Cinnamyl alcohol	104-54-1
46	Cinnamal	104-55-2
47	Citral	5392-40-5
48	Coumarin	91-64-5
49	Eugenol	97-53-0
50	Geraniol	106-24-1
51	Hydroxy-citronellal	107-75-5
52	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
53	Isoeugenol	97-54-1

54	Oakmoss extracts	90028-68-5
55	Treemoss extracts	90028-67-4

However, the presence of traces of these fragrances shall be allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof:

No	Name of the allergenic fragrance	CAS number
1	Anisyl alcohol	105-13-5
2	Benzyl benzoate	120-51-4
3	Benzyl cinnamate	103-41-3
4	Citronellol	106-22-9
5	Farnesol	4602-84-0
6	Hexyl cinnamaldehyde	101-86-0
7	Lilial	80-54-6
8	d-Limonene	5989-27-5
9	Linalool	78-70-6
10	Methyl heptine carbonate	111-12-6
11	3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

Element	mg/kg in dry, brittle, powder-like or liable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	4 500	1 125	56 000
Boron	1 200	300	15 000

Cadmium	1,9	0,5	23
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	13,5	3,4	160
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2).

Appendix E – Substances and restrictions of 2002/72/EC

Nr	Cas nr	Name	Specs
10030	000514-10-3	Abietic acid	
10060	000075-07-0	Acetaldehyde	SML(T) = 6 mg/kg (2)
10090	000064-19-7	Acetic acid	
10120	000108-05-4	Acetic acid, vinylester	SML = 12 mg/kg
10150	000108-24-7	Acetic anhydride	
10210	000074-86-2	Acetylene	
10630	000079-06-1	Acrylamide	SML = ND (DL = 0,01 mg/kg)
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	SML = 0,05 mg/kg
10690	000079-10-7	Acrylic acid	
10750	002495-35-4	Acrylic acid, benzyl ester	
10780	000141-32-2	Acrylic acid n-butyl ester	
10810	002998-08-5	Acrylic acid, sec-butyl ester	
10840	001663-39-4	Acrylic acid tert-butyl ester	
11000	050976-02-8	Acrylic acid, dicyclopentadienylester	QMA = 0,05 mg/6 dm2
11245	002156-97-0	Acrylic acid, dodecyl ester	SML = 0,05 mg/kg (1)
11470	000140-88-5	Acrylic acid ethyl ester	
00000	000818-61-1	Acrylic acid hydroxyethyl ester	See 'Acrylic acid, monoester with ethyleneglycol'
11590	000106-63-8	Acrylic acid, isobutyl ester	
11680	000689-12-3	Acrylic acid, isopropyl ester	
11710	000096-33-3	Acrylic acid, methyl ester	
11830	000818-61-1	Acrylic acid, monoester with ethyleneglycol	
11890	002499-59-4	Acrylic acid, n-octyl ester	
11980	000925-60-0	Acrylic acid, propyl ester	
12100	000107-13-1	Acrylonitrile	SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
12130	000124-04-9	Adipic acid	
12265	004074-90-2	Adipic acid, divinylester	QM = 5 mg/kg in FP. For use only as comonomer
12280	002035-75-8	Adipic anhydride	
12310	000000-00-0	Albumin	
12340	000000-00-0	Albumin, coagulated by formaldehyde	
12375	000000-00-0	Alcohols aliphatic, monohydric,saturated, linear, primary (C4-C22)	
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	SML = 6 mg/kg
12761	000693-57-2	12-Aminododecanoic acid	SML = 0,05 mg/kg
12788	002432-99-7	11-Aminoundecanoic acid	SML = 5 mg/kg .
12789	007664-41-7	Ammonia	
12820	000123-99-9	Azelaic acid	
12970	004196-95-6	Azelaic anhydride	

13000	001477-55-0	1,3-Benzenedimethanamine	SML = 0,05 mg/kg
13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	QMA = 0,05 mg/6 dm2 (measured as 1,3,5-benzenetricarboxylic acid)
13090	000065-85-0	Benzoic acid	
13150	000100-51-6	Benzylal cohol	
00000	000111-46-6	Bis(2-hydroxyethyl) ether	See 'Diethyleneglycol'
00000	000077-99-6	2,2-Bis(hydroxymethyl)-1-butanol	See '1,1,1-Trimethylolpropane'
13180	000498-66-8	Bicyclo[2.2.1]hept-2-ene (= norbornene)	SML = 0,05 mg/kg
13210	001761-71-3	Bis(4-aminocyclohexyl)methane	SML = 0,05 mg/kg
13390	000105-08-8	1,4-Bis(hydroxymethyl)cyclohexane	
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML = 3 mg/kg
13510	001675-54-3	2,2 Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	SML(T) = 1 mg/kg (9) Authorised until1 January 2005
00000	000110-98-5	Bis(hydroxypropyl) ether	See 'Dipropyleneglycol'
00000	005124-30-1	Bis(4-isocyanatocyclohexyl)methane	See 'Dicyclohexylmethane-4,4`-diisocyanate'
13530	038103-06-9	2,2-Bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	SML = 0,05 mg/kg
13600	047465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)-2-indolinone	SML = 1,8 mg/kg
00000	000080-05-7	BisphenolA	See '2,2-Bis(4-hydroxyphenyl)propane'
00000	001675-54-3	BisphenolA bis(2,3-epoxypropyl)ether	See '2,2-Bis(4-hydroxyphenyl)propane-bis(2,3-epoxypropyl)ether'
13614	038103-06-9	BisphenolA bis(phthalic anhydride)	See 13530
13630	000106-99-0	Butadiene	QM = 1 mg/kg in FP or SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)
13690	000107-88-0	1,3-Butanediol	
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43)
13840	000071-36-3	1-Butanol	
13870	000106-98-9	1-Butene	
13900	000107-01-7	2-Butene	
14020	000098-54-4	4-tert-Butylphenol	SML = 0,05 mg/kg
14110	000123-72-8	Butyraldehyde	
14140	000107-92-6	Butyric acid	
14170	000106-31-0	Butyric anhydride	
14200	000105-60-2	Caprolactam .M5	SML(T) = 15 mg/kg (5)
14230	002123-24-2	Caprolactam, sodium salt .M5	SML(T) = 15 mg/kg (5) (expressed as caprolactam)
14320	000124-07-2	Caprylic acid	
14350	000630-08-0	Carbon monoxide	
14380	000075-44-5	Carbonylchl oride	QM = 1 mg/kg in FP
14411	008001-79-4	Castor oil	
14500	009004-34-6	Cellulose	
14530	007782-50-5	Chlorine	
00000	000106-89-8	1-Chloro-2,3-epoxypropane	See 'Epichlorhydrin'
14650	000079-38-9	Chlorotrifluoroethylene	QMA = 0,05 mg/6 dm2
14680	000077-92-9	Citric acid	

14710	000108-39-4	m-Cresol	
14740	000095-48-7	o-Cresol	
14770	000106-44-5	p-Cresol	
00000	000105-08-8	1,4-Cyclohexanedimethanol	See '1,4-Bis(hydroxymethyl)cyclohexane'
14841	000599-64-4	4-Cumylphenol	SML = 0,05 mg/kg
14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
15070	001647-16-1	1,9-Decadiene	SML = 0,05 mg/kg
15095	000334-48-5	Decanoic acid	
15100	000112-30-1	1-Decanol	
00000	000107-15-3	1,2-Diaminoethane	See 'Ethylenediamine'
00000	000124-09-4	1,6-Diaminohexane	See 'Hexamethylenediamine'
15130	000872-05-9	1-Decene	SML = 0,05 mg/kg
15250	000110-60-1	1,4-Diaminobutane	
15565	000106-46-7	1,4-Dichlorobenzene	SML = 12 mg/kg
15700	005124-30-1	Dicyclohexylmethane-4,4 -diisocyanat	QM(T) = 1 mg/kg in FP (expressed as NCO)
15760	000111-46-6	Diethyleneglycol .M5	SML(T) = 30 mg/kg (3)
15790	000111-40-0	Diethylenetriamine	SML = 5 mg/kg
15820	000345-92-6	4,4 -Difluorobenzophenon	SML = 0,05 mg/kg
15880	000120-80-9	1,2-Dihydroxybenzene	SML = 6 mg/kg
15910	000108-46-3	1,3-Dihydroxybenzene	SML = 2,4 mg/kg
15940	000123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
15970	000611-99-4	4,4 -Dihydroxybenzophenone	SML = 6 mg/kg
16000	000092-88-6	4,4 -Dihydroxydipheny	SML = 6 mg/kg
16150	000108-01-0	Dimethylaminoethanol	SML = 18 mg/kg
16240	000091-97-4	3,3 -Dimethyl-4,4 -diisocyanatobiphen	QM(T) = 1 mg/kg in F(expressed as NCO)
16360	000576-26-1	2,6-Dimethylphenol	SML = 0,05 mg/kg
16450	000646-06-0	1,3-Dioxolane	SML = 0,05 mg/kg
16480	000126-58-9	Dipentaerythritol	
16570	004128-73-8	Diphenylether 4,4 -diisocyanate	QM(T) = 1 mg/kg in FP(expressed as NCO)
16600	005873-54-1	Diphenylmethane 2,4 -diisocyanat	QM(T) = 1 mg/kg in FP (expressed as NCO)
16630	000101-68-8	Diphenylmethane 4,4 -diisocyanat	QM(T) = 1 mg/kg in FP (expressed as NCO)
16660	000110-98-5	Dipropyleneglycol	
16694	013811-50-2	N,N -Divinyl-2-imidazolidinone	QM = 5 mg/kg in FP
16704	000112-41-4	1-Dodecene	SML = 0,05 mg/kg
16750	000106-89-8	Epichlorohydrin	QM = 1 mg/kg in FP
16780	000064-17-5	Ethanol	
16950	000074-85-1	Ethylene	
16960	000107-15-3	Ethylenediamine	SML = 12 mg/kg
16990	000107-21-1	Ethyleneglycol .M5	SML(T) = 30 mg/kg
17005	000151-56-4	Ethyleneimine .M1	SML = ND (DL = 0,01 mg/kg)
17020	000075-21-8	Ethylene oxide	QM = 1 mg/kg in FP
17050	000104-76-7	2-Ethyl-1-hexanol	SML = 30 mg/kg
17160	000097-53-0	Eugenol .M5	SML = ND (DL = 0,02 mg/kg,

			analytical tolerance included)
17170	061788-47-4	Fatty acids, coco	
17200	068308-53-2	Fatty acids, soya	
17230	061790-12-3	Fatty acids, tall oil	
17260	000050-00-0	Formaldehyde	SML = 15 mg/kg
17290	000110-17-8	Fumaric acid	
17530	000050-99-7	Glucose	
18010	000110-94-1	Glutaric acid	
18070	000108-55-4	Glutaric anhydride	
18100	000056-81-5	Glycerol	
18220	068564-88-5	N-Heptylaminoundecanoic acid	SML = 0,05 mg/kg (1)
18250	000115-28-6	Hexachloroendomethylenetetrahydrophthalic acid	SML = ND (DL = 0,01 mg/kg)
18280	000115-27-5	Hexachloroendomethylenetetrahydrophthalic anhydride	SML = ND (DL = 0,01 mg/kg)
18310	036653-82-4	1-Hexadecanol	
18430	000116-15-4	Hexafluoropropylene	SML = ND (LD = 0,01 mg/kg)
18460	000124-09-4	Hexamethylenediamine	SML = 2,4 mg/kg
18640	000822-06-0	Hexamethylene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
18670	000100-97-0	Hexamethylenetetramine .M1	SML (T) = 15 mg/kg (expressed as formaldehyde)
00000	000123-31-9	Hydroquinone	See '1,4-Dihydroxybenzene'
18820	000592-41-6	1-Hexene	SML = 3 mg/kg
18880	000099-96-7	P-Hydroxybenzoic acid	
19000	000115-11-7	Isobutene	
19060	000109-53-5	Isobutylvinylether	QM = 5 mg/kg in FP
19150	000121-91-5	Isophthalic acid	SML = 5 mg/kg
19210	001459-93-4	Isophthalic acid, dimethyl ester	SML = 0,05 mg/kg
19270	000097-65-4	Itaconic acid	
19460	000050-21-5	Lactic acid	
19470	000143-07-7	Lauric acid	
19480	002146-71-6	Lauric acid, vinylester	
19510	011132-73-3	Lignocellulose	
19540	000110-16-7	Maleic acid .M5	SML(T) = 30 mg/kg (4)
19960	000108-31-6	Maleic anhydride .M5	SML(T) = 30 mg/kg (4) (expressed as maleic acid)
00000	000108-78-1	Melamine	See '2,4,6-Triamino-1,3,5-triazine'
19990	000079-39-0	Methacrylamide	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
20020	000079-41-4	Methacrylic acid	
20050	000096-05-9	Methacrylic acid, allyl ester	SML = 0,05 mg/kg
20080	002495-37-6	Methacrylic acid, benzyl ester	
20110	000097-88-1	Methacrylic acid, butyl ester	
20140	002998-18-7	Methacrylic acid, sec-butyl ester	
20170	000585-07-9	Methacrylic acid, tert-butyl ester	
20530	002867-47-2	Methacrylic acid, 2-(dimethylamino) ethylester	SML = ND (DL = 0,02 mg/kg, analytical tolerance included)
20890	000097-63-2	Methacrylic acid, ethyl ester	
21010	000097-86-9	Methacrylic acid, isobutyl ester	

21100	004655-34-9	Methacrylic acid, isopropyl ester	
21130	000080-62-6	Methacrylic acid, methyl ester	
21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	
21280	002177-70-0	Methacrylic acid, phenyl ester	
21340	002210-28-8	Methacrylic acid, propyl ester	
21460	000760-93-0	Methacrylic anhydride	
21490	000126-98-7	Methacrylonitrile	SML = non detectable (DL = 0,020 mg/kg, analytical tolerance included)
21550	000067-56-1	Methanol	
21730	000563-45-1	3-Methyl-1-butene	QMA = 0,006 mg/6 dm2. For use only in polypropylene.
21940	000924-42-5	N-Methylolacrylamide	SML = ND (DL = 0,01 mg/kg)
22150	000691-37-2	4-Methyl-1-pentene .M1	SML = 0,02 mg/kg .
22331	025513-64-8	Mixture of (40 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (60 % w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm2
22350	000544-63-8	Myristic acid	
22390	000840-65-3	2,6-Naphthalenedicarboxylic acid, dimethylester	SML = 0,05 mg/kg
22420	003173-72-6	1,5-Napthalene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
22450	009004-70-0	Nitrocellulose	
22480	000143-08-8	1-Nonanol	
22550	000498-66-8	Norbornene	See 'Bicyclo[2.2.1]hept-2-ene'
22570	000112-96-9	Octadecylisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
22600	000111-87-5	1-Octanol	
22660	000111-66-0	1-Octene	SML = 15 mg/kg
22763	000112-80-1	Oleic acid	
22780	000057-10-3	Palmitic acid	
22840	000115-77-5	Pentaerythritol	
22870	000071-41-0	1-Pentanol	
22937	001623-05-8	Perfluoropropyl perfluorovinyl ether	SML = 0,05 mg/kg
22960	000108-95-2	Phenol	
23050	000108-45-2	1,3-Phenylenediamine	QM = 1 mg/kg in FP
00000	000075-44-5	Phosgene	See 'Carbonylchl oride'
23170	007664-38-2	Phosphoric acid	
00000	000000-00-0	Phthalic acid	See 'Terephthalic acid'
23175	000122-52-1	Phosphorous acid, triethylester	QM = ND (DL = 1 mg/kg in FP)
23200	000088-99-3	o-Phthalic acid	
23230	000131-17-9	Phthalic acid, diallyl ester	SML = ND (DL = 0,01 mg/kg)
23380	000085-44-9	Phthalic anhydride	
23470	000080-56-8	alpha-Pinene	
23500	000127-91-3	beta-Pinene	
23547	009016-00-6	Polydimethylsiloxane (MW >6800)	In compliance with the specifications laid down in Annex V
23590	025322-68-3	Polyethyleneglycol	
23650	025322-69-4	Polypropyleneglycol (Molecular weight greater than 400)	
23651	025322-69-4	Polypropyleneglycol	

23740	000057-55-6	1,2-Propanediol	
23770	000504-63-2	1,3-Propanedio	SML = 0,05 mg/kg
23800	000071-23-8	1-Propanol	
23830	000067-63-0	2-Propanol	
23860	000123-38-6	Propionaldehyde	
23890	000079-09-4	Propionic acid	
23920	000105-38-4	Propionic acid, vinylester	SML(T) = 6 mg/kg (2) (expressed as acetaldehyde)
23950	000123-62-6	Propionic anhydride	
23980	000115-07-1	Propylene	
24010	000075-56-9	Propylene oxide	QM = 1 mg/kg in FP
00000	000120-80-9	Pyrocatecho	See '1,2-Dihydroxybenzene'
24057	000089-32-7	Pyromellitic anhydride	SML = 0,05 mg/kg (expressed as pyromellitic acid)
24070	073138-82-6	Resin acids and rosin acids	
00000	000108-46-3	Resorcino	See '1,3-Dihydroxybenzene'
24100	008050-09-7	Rosin	
24130	008050-09-7	Rosin gum	See 'Rosin' .
24160	008052-10-6	Rosin tall oil	
24190	009014-63-5	Rosin wood	
24250	009006-04-6	Rubber, natural	
24270	000069-72-7	Salicylic acid	
24280	000111-20-6	Sebacic acid	
24430	002561-88-8	Sebacic anhydride	
24475	001313-82-2	Sodium sulphide	
24490	000050-70-4	Sorbitol	
24520	008001-22-7	Soybean oil	
24540	009005-25-8	Starch, edible	
24550	000057-11-4	Stearic acid	
24610	000100-42-5	Styrene	
24760	026914-43-2	Styrenesulphonic acid	SML = 0,05 mg/kg
24820	000110-15-6	Succinic acid	
24850	000108-30-5	Succinic anhydride	
24880	000057-50-1	Sucrose	
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	SML = 5 mg/kg
24888	003965-55-7	5-Sulphoisophthalic acid, monosodium salt, dimethyl ester	SML = 0,05 mg/kg
24910	000100-21-0	Terephthalic acid	SML = 7,5 mg/kg
24940	000100-20-9	Terephtalic acid dichloride	SML(T) = 7,5 mg/kg (expressed as terephtalic acid)
24970	000120-61-6	Terephthalic acid, dimethyl ester	
25080	001120-36-1	1-Tetradecene	SML = 0,05 mg/kg
25090	000112-60-7	Tetraethyleneglycol	
25120	000116-14-3	Tetrafluoroethylene	SML = 0,05 mg/kg
25150	000109-99-9	Tetrahydrofuran	SML = 0,6 mg/kg
25180	000102-60-3	N,N,N ,N -Tetraki(2-hydroxypropyl) ethylenediamine	
25210	000584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)

25240	000091-08-7	2,6-Toluene diisocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO)
25270	026747-90-0	2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg in FP (expressed as NCO)
25360	000000-00-0	Trialkyl(C5-C15)acetic acid, 2,3-epoxypropylester	QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43)
25385	000102-70-5	Triallylamine	In compliance with the specifications laid down in Annex V
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
25510	000112-27-6	Triethyleneglycol	
25600	000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg
25910	024800-44-0	Tripropyleneglycol	
25927	027955-94-8	1,1,1-Tris(4-hydroxyphenyl)ethane	QM = 0,5 mg/kg in FP. For use only in polycarbonates
25960	000057-13-6	Urea	
26050	000075-01-4	Vinylchl oride	See Council Directive 78/142/EC
26110	000075-35-4	Vinylidene chloride	QM = 5 mg/kg in FP or SML = not detectable (DL = 0,05 mg/kg)
26140	000075-38-7	Vinylidene fluoride	SML = 5 mg/kg
26155	001072-63-5	1-Vinylimidazole	QM = 5 mg/kg in FP
26320	002768-02-7	Vinyltrimethoxysilane	QM = 5 mg/kg in FP
26360	007732-18-5	Water	In compliance with Directive 98/83/EC
26170	003195-78-6	N-Vinyl-N-methylacetamide	QM = 2 mg/kg in FP

Appendix G – Restricted substances under 1005/2009/EEC

According to Annex I of Directive 1005/2009/EEC

Group	Substance			Ozone-depleting potential (1)
Group I	CFCl3	CFC-11	Trichlorofluoromethane	1.0
	CF2Cl2	CFC-12	Dichlorodifluoromethane	1.0
	C2F3Cl3	CFC-113	Trichlorotrifluoroethane	0.8
	C2F4Cl2	CFC-114	Dichlorotetrafluoroethane	1.0
	C2F5Cl	CFC-115	Chloropentafluoroethane	0.6
Group II	CF3Cl	CFC-13	Chlorotrifluoromethane	1.0
	C2FCl5	CFC-111	Pentachlorofluoroethane	1.0
	C2F2Cl4	CFC-112	Tetrachlorodifluoroethane	1.0
	C3FCl7	CFC-211	Heptachlorofluoropropane	1.0
	C3F2Cl6	CFC-212	Hexachlorodifluoropropane	1.0
	C3F3Cl5	CFC-213	Pentachlorotrifluoropropane	1.0
	C3F4Cl4	CFC-214	Tetrachlorotetrafluoropropane	1.0
	C3F5Cl3	CFC-215	Trichloropentafluoropropane	1.0
	C3F6Cl2	CFC-216	Dichlorohexafluoropropane	1.0
	C3F7Cl	CFC-217	Chloroheptafluoropropane	1.0
Group III	CF2BrCl	halon-1211	Bromochlorodifluoromethane	3.0
	CF3Br	halon-1301	Bromotrifluoromethane	10.0
	C2F4Br2	halon-2402	Dibromotetrafluoroethane	6.0
Group IV	CCl4	CTC	Tetrachloromethane (carbon tetrachloride)	1.1
Group V	C2H3Cl3 (2)	1,1,1-TCA	1,1,1-Trichloroethane (methylchloroform)	0.1
Group VI	CH3Br	methyl bromide	Bromomethane	0.6
Group VII	CHFBr2	HBFC-21 B2	Dibromofluoromethane	1.0
	CHF2Br	HBFC-22 B1	Bromodifluoromethane	0.7
	CH2FBr	HBFC-31 B1	Bromofluoromethane	0.7

	C2HFBr4	HBFC-121 B4	Tetrabromofluoroethane	0.8
	C2HF2Br3	HBFC-122 B3	Tribromodifluoroethane	1.8
	C2HF3Br2	HBFC-123 B2	Dibromotrifluoroethane	1.6
	C2HF4Br	HBFC-124 B1	Bromotetrafluoroethane	1.2
	C2H2FBr3	HBFC-131 B3	Tribromofluoroethane	1.1
	C2H2F2Br2	HBFC-132 B2	Dibromodifluoroethane	1.5
	C2H2F3Br	HBFC-133 B1	Bromotrifluoroethane	1.6
	C2H3FBr2	HBFC-141 B2	Dibromofluoroethane	1.7
	C2H3F2Br	HBFC-142 B1	Bromodifluoroethane	1.1
	C2H4FBr	HBFC-151 B1	Bromofluoroethane	0.1
	C3HFBr6	HBFC-221 B6	Hexabromofluoropropane	1.5
	C3HF2Br5	HBFC-222 B5	Pentabromodifluoropropane	1.9
	C3HF3Br4	HBFC-223 B4	Tetrabromotrifluoropropane	1.8
	C3HF4Br3	HBFC-224 B3	Tribromotetrafluoropropane	2.2
	C3HF5Br2	HBFC-225 B2	Dibromopentafluoropropane	2.0
	C3HF6Br	HBFC-226 B1	Bromohexafluoropropane	3.3
	C3H2FBr5	HBFC-231 B5	Pentabromofluoropropane	1.9
	C3H2F2Br4	HBFC-232 B4	Tetrabromodifluoropropane	2.1
	C3H2F3Br3	HBFC-233 B3	Tribromotrifluoropropane	5.6
	C3H2F4Br2	HBFC-234 B2	Dibromotetrafluoropropane	7.5
	C3H2F5Br	HBFC-235 B1	Bromopentafluoropropane	1.4
	C3H3FBr4	HBFC-241 B4	Tetrabromofluoropropane	1.9
	C3H3F2Br3	HBFC-242 B3	Tribromodifluoropropane	3.1
	C3H3F3Br2	HBFC-243 B2	Dibromotrifluoropropane	2.5
	C3H3F4Br	HBFC-244 B1	Bromotetrafluoropropane	4.4
	C3H4FBr3	HBFC-251 B1	Tribromofluoropropane	0.3
	C3H4F2Br2	HBFC-252 B2	Dibromodifluoropropane	1.0
	C3H4F3Br	HBFC-253 B1	Bromotrifluoropropane	0.8
	C3H5FBr2	HBFC-261 B2	Dibromofluoropropane	0.4
	C3H5F2Br	HBFC-262 B1	Bromodifluoropropane	0.8
	C3H6FBr	HBFC-271 B1	Bromofluoropropane	0.7
Group VIII	CHFCl2	HCFC-21 (3)	Dichlorofluoromethane	0.0

CHF2Cl	HCFC-22 (3)	Chlorodifluoromethane	0.1
CH2FCl	HCFC-31	Chlorofluoromethane	0.0
C2HFCl4	HCFC-121	Tetrachlorofluoroethane	0.0
C2HF2Cl3	HCFC-122	Trichlorodifluoroethane	0.1
C2HF3Cl2	HCFC-123 (3)	Dichlorotrifluoroethane	0.0
C2HF4Cl	HCFC-124 (3)	Chlorotetrafluoroethane	0.0
C2H2FCl3	HCFC-131	Trichlorofluoroethane	0.1
C2H2F2Cl2	HCFC-132	Dichlorodifluoroethane	0.1
C2H2F3Cl	HCFC-133	Chlorotrifluoroethane	0.1
C2H3FCl2	HCFC-141	Dichlorofluoroethane	0.1
CH3CFCl2	HCFC-141b (3)	1,1-Dichloro-1-fluoroethane	0.1
C2H3F2Cl	HCFC-142	Chlorodifluoroethane	0.1
CH3CF2Cl	HCFC-142b (3)	1-Chloro-1,1-difluoroethane	0.1
C2H4FCl	HCFC-151	Chlorofluoroethane	0.0
C3HFCl6	HCFC-221	Hexachlorofluoropropane	0.1
C3HF2Cl5	HCFC-222	Pentachlorodifluoropropane	0.1
C3HF3Cl4	HCFC-223	Tetrachlorotrifluoropropane	0.1
C3HF4Cl3	HCFC-224	Trichlorotetrafluoropropane	0.1
C3HF5Cl2	HCFC-225	Dichloropentafluoropropane	0.1
CF3CF2CHCl2	HCFC-225ca (3)	3,3-Dichloro-1,1,1,2,2-pentafluoropropane	0.0
CF2ClCF2CHClF	HCFC-225cb (3)	1,3-Dichloro-1,1,2,2,3-pentafluoropropane	0.0
C3HF6Cl	HCFC-226	Chlorohexafluoropropane	0.1
C3H2FCl5	HCFC-231	Pentachlorofluoropropane	0.1
C3H2F2Cl4	HCFC-232	Tetrachlorodifluoropropane	0.1
C3H2F3Cl3	HCFC-233	Trichlorotrifluoropropane	0.2
C3H2F4Cl2	HCFC-234	Dichlorotetrafluoropropane	0.3
C3H2F5Cl	HCFC-235	Chloropentafluoropropane	0.5
C3H3FCl4	HCFC-241	Tetrachlorofluoropropane	0.1
C3H3F2Cl3	HCFC-242	Trichlorodifluoropropane	0.1
C3H3F3Cl2	HCFC-243	Dichlorotrifluoropropane	0.1
C3H3F4Cl	HCFC-244	Chlorotetrafluoropropane	0.1

	C3H4FCl3	HCFC-251	Trichlorofluoropropane	0.0
	C3H4F2Cl2	HCFC-252	Dichlorodifluoropropane	0.0
	C3H4F3Cl	HCFC-253	Chlorotrifluoropropane	0.0
	C3H5FCl2	HCFC-261	Dichlorofluoropropane	0.0
	C3H5F2Cl	HCFC-262	Chlorodifluoropropane	0.0
	C3H6FCl	HCFC-271	Chlorofluoropropane	0.0
Group IX	CH2BrCl	BCM	Bromochloromethane	0.1

Appendix H – Overview of available material sheets

material	type	Data sheet	MSDS	UL 94 Vo
ABS	h701			yes
	qimei765	yes	yes	no
	qimei757	yes	yes	no
	daqing750	yes	no	no
	jihua0215A	no	no	
	PA-707	no	yes	no
	PA-709	no	yes	no
	PA-717C	no	yes	no
	PA-727	no	yes	no
	PA-747	no	yes	yes
	PA-747R	yes	yes	no
	PA-747F	no	yes	no
	PA-747S	no	yes	no
	PA-757	yes	yes	yes
	PA-757N	no	yes	no
	PA-758	no	yes	yes
	PA-765	no	yes	no
	PA-765A	yes	yes	yes
	PA-765B	no	yes	no
	PA-1013B	yes	no	no
PA	101L	yes	yes	no
	Zytel 70G35HSLX BK357 (35% GF)	yes	no	no
	Delrin 100 NC010	yes	no	no
	Delrin 570 NC000 (20% GF)	yes	no	no
	IXEF 1032/0008	yes	no	no
	K223-D2TP3	yes	no	no
	LNP Staramide B40	yes	no	no
	RTP 205 Z	yes	no	no
	2851-30 (30% GF)	no	no	yes
	A 30 S FN30	no	no	yes
PA66 15%GF	Lanxess AKU15%	yes	yes	no
PBT	553M	yes	no	yes
	1300 FNC1	yes	no	no
	1300T	yes	no	yes
	2100	yes	no	no
	4115	yes	no	no
PBT-ABS	AB9515	yes	no	no
	AB9530	yes	no	no
PC	GE 141R	yes	yes	no
	4704	yes	no	no
PC-ABS	GE C2800	yes	yes	yes
	S451	yes	no	no
PBT-PC	507	yes	no	no
	1212	yes	no	no
	3706	yes	no	yes
PCT	CG033 BK010T (30% GF)	yes	no	no
	CG033 NC010 (30% GF)	yes	no	no
	CG923 NC010 (20% GF)	yes	no	no
	CG933 NC010 (30% GF)	yes	no	no
	CG933 BK010 (30% GF)	yes	no	no
PE	HD5502AA	yes	no	no
PMMA	F850	yes	no	no
POM	C4520	yes	no	no
	C9021	yes	yes	yes
PP	yangzi J340	yes	no	no
	SK energy R370Y	no	no	no
	800E	no	no	no
	7031L1	yes	no	no
	7032E3	yes	no	no
	7032KN	yes	no	no
	7033N	yes	no	no
	9799	yes	no	no
	M1600	yes	no	no
	P9335 MG	yes	no	no
	EP300H	no	yes	no
	lambent 119	no	yes	no

		Restrictions (on the usage) of the substance								
								2009/48/EC		
								mg/kg	mg/kg	mg/kg
Cas number	Substance	REACH	2002/72/EC	AP 89/1	EN 71	RoHS	1005/2009/EC	in dry, brittle, powder-like or liable toy material	in liquid or sticky toy material	in scraped-off toy material
002499-59-4	Acrylic acid, n-octyl ester		60 mg per kg foodstuff							
000925-60-0	Acrylic acid, propyl ester		60 mg per kg foodstuff							
002998-08-5	Acrylic acid, sec-butyl ester		60 mg per kg foodstuff							
000107-13-1	Acrylonitrile		SML = not detectable (DL = 0,020 mg/kg, analytical tolerance included)							
000124-04-9	Adipic acid		60 mg per kg foodstuff							
004074-90-2	Adipic acid, divinylester		QM = 5 mg/kg in FP. For use only as comonomer							
002035-75-8	Adipic anhydride		60 mg per kg foodstuff							
097676-35-2	Alanroot oil (Inula helenium)							100		
000000-00-0	Albumin		60 mg per kg foodstuff							
000000-00-0	Albumin, coagulated by formaldehyde		60 mg per kg foodstuff							
085535-84-8	Alkanes, C10-13, chloro (Short Chain	restricted								
000057-06-7	Allylisothiocyanate							100		
000080-56-8	alpha-Pinene		60 mg per kg foodstuff							
091728-14-2	Aluminium							5625	1406	70000
007664-41-7	Ammonia		60 mg per kg foodstuff							
007789-09-5	Ammonium dichromate	candidate list								
000120-12-7	Anthracene	candidate list								
090640-80-5	Anthracene oil	candidate list								
090640-81-6	Anthracene oil, anthracene paste	candidate list								
091995-15-2	Anthracene oil, anthracene paste, ant	candidate list								
007440-36-0	Antimony		60 mg per kg f	0,0005	bioav. pd: 0.2 µg			45	11,3	560
007784-42-1	Arsenic		60 mg per kg f	0,0001	bioav. pd: 0.1 µg			3,8	0,9	47
000056-35-9	Bis(tributyltin)oxide (TBTO)	candidate list								
000080-05-7	BisphenolA		See '2,2-Bis(4-hydroxyphenyl)propane'							
001675-54-3	BisphenolA bis(2,3-epoxypropyl)ether		See '2,2-Bis(4-hydroxyphenyl)propane-bis(2,3-epoxypropyl)ether'							
038103-06-9	BisphenolA bis(phthalic anhydride)		See 13530							
010043-35-3	Boric acid	candidate list								
007440-42-8	Boron							1200	300	15000
000353-59-3	Bromochlorodifluoromethane						prohibited			
000074-97-5	Bromochloromethane						prohibited			
000420-47-3	Bromodifluoroethane						prohibited			

Appendix J - Business Processes

N.B. All documents written in bold are further explained below. In this Appendix the required information for each of these documents is stated.

Receive order

Upon receipt the order is inspected to ensure that:

a. it holds at least the following necessary information:
   - details of customer
   - product identification
   - materials used
   - quantity
   - date of delivery
   - method of packaging & shipping
   - price

b. the company possesses the corresponding (where applicable):
   - **Inspection Sheet (IS)**
   - **Machine settings**
   - **Incoming Goods Sheet (IGS)**
   - **Assembly Instructions (AI)**

If the order lacks any of the above mentioned, the customer is contacted and required to provide the missing information.

If the order holds the abovementioned, it is given a unique order identification number. Then it is evaluated to check whether its production fits the planning; the order specifications, such as product type, quantity and delivery date, are taken into consideration.

Finalise order

If the order can be accepted, the customer is informed of acceptance and a signed confirmation is sent. If the schedule does not allow the order to be produced according to the specifications, the customer is contacted. If possible, the order is revised so that it can fit the schedule. The customer is informed of acceptance and a signed confirmation of this revised order is sent.

A copy of the confirmation is stored, and a **Production Order Tracking Sheet (POTS**) is created.

Planning

The schedule is updated with the new order. In the schedule at least the following dates are set:

date of delivery

date of starting production

date of ordering materials

A new version of the schedule is stored.

Purchase materials

The order is consulted to ensure that all and correct materials are purchased. The suppliers are contacted and a signed **purchase order** is sent after an agreement has been reached.

A copy of the purchase order is stored.

Receive materials

Upon arrival, the goods are checked with the purchase order and/or the IGS. If the goods satisfy the specifications, the purchase order and/or IGS is signed and stored. The POTS is updated.

If any non-conformance is detected, the supplier is contacted and a new purchase order is created. If this would cause the delivery date of the end product to become unattainable, the customer is contacted immediately.

Production

Before the start of any production cycle, the machine settings and used materials are checked and the POTS is updated. Only employees who have received the appropriate training will be producing the products. To this end, the **Training Sheet (TS)** is filled in, listing all employees who will produce the products and what training they have received for this product. Also, employees have taken notice of the applicable IS and the specific production order.

At regular intervals the Quality Manager will take a sample test and update the POTS accordingly.

Assembly (when applicable)

Assembly can only start when the POTS indicates that all components are either produced correctly or do not have any defects according to the IGS.

Only employees who have received the appropriate training will be assembling the products. To this end, the Training Sheet (TS) is filled in, listing all employees who will assemble the products and what training they have received for this product. Also, employees have taken notice of the applicable AI and the specific production order.

At regular intervals the Quality Manager will take a sample test and update the POTS accordingly.

Packaging

The products are packaged according to the order specifications or AI. Boxes are provided with **box stickers**. At least 1 item of every batch is provided with a **batch sample identification** and stored at the factory. The POTS is updated accordingly.

Shipping

After an agreement has been reached with the shipping company, a signed **shipping order** is sent for confirmation and the POTS is updated accordingly.

Loading

The **shippings item list** is consulted before the actual loading takes place. The “planned” part of this document is filled in by the customer. If the actual loading deviates from this document, a verbal confirmation from the customer is required.

When the actual shipping has taken place, the POTS is updated accordingly.

Explanation of documents

This lists the information that is minimally required for each document.

- Assembly Instructions (AI)
- Batch sample identification
- Box stickers
- Incoming Goods Sheet (IGS)
- Inspection Sheet (IS)
- Machine settings
- Production Order Tracking Sheet (POTS)
- Purchase order
- Shipping order

Assembly Instructions (AI)

- Cover page:
  - project name
  - products
  - version number
  - date of last change
  - photo of end product
- Bill of materials (per product):
  - part number
  - quantity
  - part name
  - material/specifications
- Actual assembly instructions, for each step:
  - instructions written out in text
  - photo(s)/schematic(s) displaying the step
  - text and photo(s)/schematic(s) highlighting points of extra attention
- Packaging instructions (if applicable)
  - instructions written out in text
  - photo(s)/schematic(s) displaying the process and/or end result
- Known problems:
  - version number
  - date of last change
  - description of the problem
  - photo(s)/schematic(s) of the problem (if available)

Batch sample identification

- Product name
- Order number
- Production date
- Manufacturer name

Box stickers

- Order number
- Product name
- Quantity
- Net weight
- Gross weight
- Box number
- Delivery address

Incoming Goods Sheet (IGS)

- General information:
  - project name
  - part name
  - part number
  - delivery time
  - date of last change to sheet
  - person making the change
  - version number
- Batch information:
  - name manufacturer
  - order number
  - date received
  - total quantity ordered
  - quantity checked
- Product specifications:
  - weight
  - material
  - measurements
- Picture of the product
- Extra points of attention
- Accepted/Rejected?
- Explanation if rejected

Inspection Sheet (IS)

- General information:
  - project name
  - part name
  - part number
  - material
  - colour
  - weight
  - date of last change to sheet
  - person making the change
  - version number
- Description of product:
  - photos from different angles

    - highlighted area's to be inspected
    - written instructions on how to inspect
    - clear criteria for accepting/rejecting
- Known problems:
    - version number
    - date of last change
    - description of the problem
    - photo(s)/schematic(s) of the problem (if available)

Machine settings

- machine type
- pressure
- temperature

Production Order Tracking Sheet (POTS)

- General information:
    - order number
    - project name
    - order date
- Plastic parts – materials:
    - part name
    - IS number + version
    - material type used
    - quality check
    - date
    - remarks on the materials
- Non plastic parts:
    - part name
    - IGS number + version
    - supplier
    - delivery date
    - quality check
    - remarks on the non plastic parts
- Plastic parts – production:
    - part name
    - production start
    - production finish
    - date
    - quality check
    - remarks on the production
- Assembly:
    - AI number
    - assembly start
    - assembly finish
    - quality check
    - remarks on assembly
- Packaging:

    - date
    - quality check
    - sample of batch
    - remarks on packaging
- Shipping:
    - number of boxes
    - number of products
    - date
    - box stickers

Purchase order

- contact details of factory
- contact details of supplier
- date
- type of materials
- amount
- delivery date

Shipping items list

- shipping date
- loading date
- planned per product:
    - product name
    - amount per box
    - number of boxes
    - total quantity
    - volume
- actual per product:
    - amount per box
    - number of boxes
    - total quantity
- remarks on loading
- date

Shipping order

- contact details of factory
- contact details of shipping agent
- contact details of addressee
- date
- type of goods sent
- amount
- weight
- delivery date

Training Sheet (TS)

- order number
- product name/number

- IS number
- AI number
- per employee:
  - name
  - received training of IS
  - received training of AI
  - date of training

Appendix K - Planning Sheet

Input part

Sheet start date : 18-7-2011

Change start date

Order ID MT10001

Hide

Show

Update schedule

order ID	project name	quantity	processes	what?	start date	days
MT10001	example project	400	incoming goods	good 1	2011-07-19	0
			incoming goods	good 2	2011-07-19	0
			incoming goods	good 3	2011-07-20	0
			production	part 1	2011-07-21	5
			production	part 2	2011-07-23	2
			assembly	component 1	2011-07-23	4
			assembly	component 2	2011-07-27	2
			packing	entire product	2011-07-30	3
			shipping to Shanghai	entire order	2011-08-03	0

Output part