



# How the REACH authorisation process affects and benefits companies

Atte Harrikari & Riku Montonen | Customized Student Business Project | 30 March 2017

## Disclaimer

The views expressed in this report are solely of the authors and of the interviewed companies, and do not necessarily represent the views or position of the European Chemicals Agency.

*During the report, you will find text in cursive and in boxes just like these sentences are. These are the comments by the authors and are based on the experiences from the interviews.*

## Preface

This project was a ‘customized student business project’ - a concept by Aalto University School of Business and was done by students **Riku Montonen** and **Atte Harrikari**. The client of the business project was the European Chemicals Agency (ECHA). The project was supervised by both Aalto University and the European Chemicals Agency. The supervisors were **Sami Tuomi** and **Tommi Vihervaara** from Aalto University and **Matti Vainio**, **Spyridon Merkourakis**, **Christoph Rheinberger**, and **Kalle Kivelä** from ECHA.

The authors would like to give many thanks to all the supervisors for their great guidance during the project and to all the company representatives who were interviewed for this project as well.

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Riku studies his fifth year at Aalto University. He is majoring in chemical engineering and has chosen elective courses handling environmental issues, economics, and legislation. During his career, he has participated in different application procedures, mainly for research funding. Through his studies, he has developed a keen understanding of the environmental impact assessment (the EIA) and the AfA procedure.

## Executive summary

This study was made in order to determine how the Application for Authorisation (the AfA) procedure impacts companies and their operating practices during and after the application process.

Changes in operating practices, which are initially made to use chemicals more safely, can, in turn, induce cost savings e.g. energy consumption, increased labor productivity, chemical portfolio reduction etc. One goal of this project was to gather evidence, if such economic benefits occur, and to quantify them. Impacts on human health and the environment and benefits to society from granting authorisation are already covered in the applications, which is why the main interest of this study was to find other types of benefits and co-benefits that may have arisen during or after the AfA. In addition, the project serves as a pilot and develops a methodology on how to conduct the investigations of regulatory impact assessment in the field.

Altogether 14 different Finnish companies and the Finnish Safety and Chemicals Agency (Tukes) were interviewed for this study. Based on the results, an analysis of the current situation of the AfA, its effects and benefits to the interviewed companies was compiled. A clear division of the companies was made to make handling of the results easier. The division was based on the sizes of the companies, the chemicals they use, and if they applied or not.

The goal of this study was to find co-benefits that may have arisen during the AfA. In the end, there was only one clear co-benefit, improved networking between the micro companies. This makes it easier for the companies to help their customers in finding a suitable partner if they themselves cannot respond to the needs of the client.

Another impact of the AfA was that for three large companies the AfA acted as a driving force that made them develop and change their processes to work with alternative chemicals. One large company also added the maintenance of personnel to the same health surveillance plan that the process workers had. Another large company mentioned that they had until now been looking for more economical alternatives, but in the future, their aim will be geared towards taking more measure to ensure the safety of their workers. Two micro companies improved their safety measures while using chemicals. These companies adopted the idea of using a foaming agent in their processes.

From the interviews, we were able to discover that a major challenge for the micro-enterprises was communication. Thus, the roles of the national authorities, consultants, chemical suppliers, and branch organizations are also discussed related to the information flow.

Most of the companies who applied acknowledge that they are now prepared to face challenges in the future and that they have gained valuable knowledge of the process. This will, in turn, help the companies to apply again if necessary in the future. All companies who applied were pleased about the lengths given for the review period

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## 1. INTRODUCTION

### 1.1. THE EUROPEAN CHEMICALS AGENCY

The European Chemicals Agency (ECHA), is an agency in the European Union. It was founded in 2007 and is located Helsinki, Finland. It manages the technical, scientific, and administrative aspects of the implementation of the REACH regulation. ECHA is the driving force among regulatory authorities in implementing the EU's chemicals legislation. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals, and addresses chemicals of concern.<sup>1</sup>

### 1.2. AALTO UNIVERSITY

Aalto University has nearly 20 000 students studying in a multidisciplinary community where science and art meet technology and business. It was founded in 2010 as Helsinki University of Technology, the Helsinki School of Economics, and the University of Art and Design Helsinki were merged. It has its main campus in Otaniemi in Espoo, Finland. The mission of Aalto University is to identify and solve grand challenges and build an innovative future.<sup>2</sup>

### 1.3. REACH

The REACH regulation (EC No 1907/2006) has been established in 1.6.2007 by the European parliament and council. REACH is an abbreviation for Registration, Evaluation, Authorisation and Restriction of Chemicals. The purpose of REACH is to secure the protection of health and environment, intensify competition in the chemical industry, and to guarantee an open mobility through the internal market area of the European Union.<sup>3</sup>

### 1.4. APPLICATION FOR AUTHORISATION

The authorisation procedure aims to assure that the risks from Substances of Very High Concern are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market.

Substances with the following hazard properties may be identified as Substances of Very High Concern (SVHCs)<sup>4</sup>:

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<sup>1</sup> <https://echa.europa.eu/about-us>

<sup>2</sup> <http://www.aalto.fi/en/about/>

<sup>3</sup> <http://www.Tukes.fi/en/Branches/Chemicals-biocides-plant-protection-products/Industrial-and-consumer-chemicals/The-REACH-Regulation/>

<sup>4</sup> <https://echa.europa.eu/regulations/reach/authorisation>

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances)
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII)
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances

After a two-step regulatory process, SVHCs may be included in the Authorisation List and become subject to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

Manufacturers, importers or downstream users of a substance on the Authorisation List can apply for authorisation.



## 2. COMPANIES

Out of the 14 Finnish companies that were interviewed for the study, 13 use a chemical from the Candidate list. The chosen companies acted in various ways: some had applied alone, some as members of a consortium and some hadn't applied at all. There were companies of different sizes, ranging from local micro-sized to large global companies. 11 companies, including all the micro-enterprises, use Chromium Trioxide (Cr(VI)). The other three were using Sodium Dichromate, Diarsenic Trioxide or Hexabromocyclododecane (HBCDD). One company uses products that are coated with the Cr(VI) process and they are a customer for the majority of micro-companies.

The companies are presented in Table 1. The company size, the substances they use, and the decision they made about the AfA are presented in Figure 1. In addition, the Finnish Safety and Chemicals Agency (Tukes), which acts as the competent authority in Finland, was interviewed.

Table 1. Companies interviewed for this study

CrTe -Plating Oy Kova-Kromi Oy Kromatek Oy Pirkan Kovakromaus Oy Saizeri Oy Turun Kovakromi Oy Veljekset Wallenius Oy	Abloy Oy Bewi Styrochem Oy Boliden Kokkola Oy Hydroline Oy Kemira Chemicals Oy Oras Oy Wipro Infrastructure Engineering Oy
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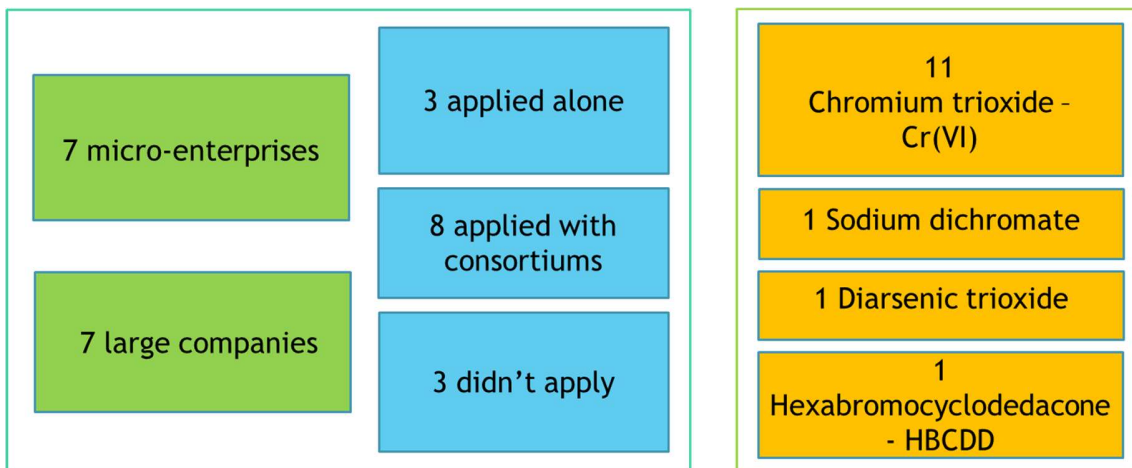


Figure 1. Company profiles and substances

## 3. METHODOLOGY

This chapter describes the methodology used so that it can be applied to similar future projects.

### 3.1. FINDING THE CO-BENEFITS

The changes in operating practices, which were made to use chemicals more safely, can, in turn, induce cost savings in e.g. energy consumption, increased labor productivity, and chemical portfolio reduction. These are defined as co-benefits. The main objective of the project was to find possible co-benefits, which could have occurred during the AfA. There were a couple of questions specifically tailored to inquire about the possible co-benefits of the AfA. In addition, we tried to gather information regarding the added benefits throughout the entirety of the interviews. For tailored questions see chapter 3.3.

### 3.2. INTERVIEWS

The aim was to conduct all the interviews at the company site, but eventually, due to time schedules and a limited budget, three interviews were done via Skype and one by phone. The interviews lasted from 30 minutes to about 1.5 hours. The notes with experiences and opinions of the representative(s) were written and saved for further review.

#### 3.2.1. Before interviews

ECHA had called most of the 14 companies informing that two students are coming to interview them in the coming months. ECHA also wrote a short introductory letter to be sent to the company representative(s) by the interviewers. In the e-mail, the background of the project, introduction of the interviewers, and suggestions for suitable time slots for the interview were provided.

#### 3.2.2. After interviews

After each interview, the minutes were sent to the company representative. This way the possible misunderstandings got corrected and the representative was given a chance to add or deepen their opinions/views that were not discussed during the interview. In addition to the minutes of the meeting, an additional questionnaire was also sent (see chapter 3.3.1).

### 3.3. QUESTIONNAIRE

The preliminary questionnaire was used as a basis for the interview. After the first interviews were conducted, the questionnaire got updated based on their results. The final form of the questionnaire can be found in **Appendix I**. The questions dealing with the co-benefits were the following.

- Has the AfA process impacted your company in a positive or negative way? Any impacts on the logistics, ventilation, energy consumption, use of chemicals, customer satisfaction, outsourcing, work efficiency, behavior in the workplace or amount of sick leaves?
- How could you use / how have you used the experience gained from the AfA?

#### 3.3.1. Additional questionnaire

To get a complete understanding of the impacts of the AfA, an indication of the devoted time and money used whilst completing the AfA requirements was needed. In order to answer this, we sent an additional short questionnaire to the company representatives. The additional questionnaire can be found as **Appendix II**.

## 4. RESULTS

In this chapter, we present the companies' experiences about the AfA. The opinions and views presented belong to the companies and are summarized from the minutes of meetings. We excluded the answers that were uncertain to prevent any misinformation based on guesses to end up with the results.

### 4.1. BEFORE APPLYING FOR AUTHORISATION

This section presents the initial views of the companies before engaging in the authorisation process. The companies were asked from what source they got their initial information about the need for authorisation.

#### 4.1.1. Source of information

Most of the micro-companies are somewhat active in their association, the Finnish Galvanotechnic Association (SGY). Moreover, through the association, the majority of the micro-companies heard about the authorisation first time. The news came from a consultant company, which provided chemical regulatory compliance services in one of the association's events. One of the micro-enterprises was already aware because they had discussed the topic with their customers and with their chemical supplier about the authorisation or had gotten some information from the Regional State Administrative Agency and environmental authority before a contact with a consultant.

*We think that the companies who use Cr(VI) in their processes should have heard of the AfA for the first time from someone other than a consultant, for example, Tukes (Finnish Safety and Chemicals Agency) or the chemical supplier. It seems there has been a lack of communication between chemical suppliers and micro-enterprises. We observed that the more a company was active in their association events, the more of a chance there was for them to hear about the AfA because their supplier is active in the association. Moreover, micro companies often have fewer resources to search actively information about the subject, which makes the associations and authorities important sources.*

The trend for large companies was to gain knowledge from CEFIC branch organizations, which was the main source of information for three large companies. Others had heard about the AfA from a branch organization of Technology Industries of Finland or found out about the need of the AfA themselves. Nevertheless, one large company, which attended the same event with micro-sized companies, heard about the AfA first from the same consultant company. The results are presented more clearly in Table 2.

Table 2 How did the companies first hear about the need for AfA

Source of information	Micro enterprises	Large enterprises
Consultant	4	1
Supplier and/or customer	1	
Authorities	2	
Association		1
CEFIC branch organisations		3
Found out by themselves		1

*Clearly, the information flow has been greater with large companies thanks to their presence in different branch organizations. Additional human resources and a wide and active supply chain network have strongly influenced the information flow between different authorities, agencies, and companies.*

#### 4.1.2. First reactions

Some of the micro-companies had previously heard that the use of Cr(VI) will be subject to authorisation in the future and had taken the subject with caution. The companies were unaware which authority will be in charge of the authorisation process in the future. This was partly due to the fact that applying for authorisation via ECHA was a new legislative requirement for chromium coaters.

For all the companies, irrespective where they first heard about the AfA, the additional costs of the application were their first concern. Second, uncertainty about the scope of the process itself caused confusion for all enterprises. Third, the micro-companies felt that the authorities (especially ECHA) did not understand their industrial environment. For example, the majority of the micro companies said that the alternative solutions of today may work in laboratories, but there is no proof that it would work on the industrial level.

#### 4.1.3. Reactions from customers

The majority of the micro-companies mentioned that they had received worried inquiries from their customers regarding whether their product had toxic or dangerous chemicals in it and about the continuation of their business. Only two large companies discussed with their customers about products that contain a chemical in the Candidate list.

*Clearly, the clients have been worried about the continuation of their own businesses. They may have known that for example Cr(VI) is used in the manufacturing process, but they were not aware that it stays in the process and doesn't appear in the final product. This might be why many of the interviewed companies did not want to concern their customers about the AfA process.*

## 4.2. DURING THE APPLYING FOR AUTHORISATION

The companies were asked how they used the information about the AfA and what did they proceed to do. Reasons behind the decisions were asked as well and they will be dealt with in this chapter. Furthermore, we asked from the companies who decided to apply on their own or with a consortium, the time spent and work that was required for the application.

### 4.2.1. Companies related to the chromium scene

The micro-enterprises who were at the event in 2013 organized by SGY (the Finnish Galvanotechnic Association) agreed on building a consortium and hiring a consultant.

*Moreover, it seems that the chemical supplier has had a minor role in the discussions of joining the consortium. Few companies discussed with their suppliers, and a major part of micro-sized enterprises had not been informed of the possibility not to apply for authorisation themselves, but to be covered by an upstream application that was being prepared in parallel<sup>5</sup>. Furthermore, one company mentioned that they had discussed with the supplier the terms of orders to confirm after the date coating would have been restricted without authorisation, but there was no mention if the upstream application would get to the review period.*

Three companies were told by the supplier about the opportunity to use the upstream application and to continue their business without any further actions. The reasons why they still joined the consortium were the following:

- The companies thought their processes or operations did not fit under the scope of the supplier's application
- They did not want to be bound to the supplier

The micro-companies who joined the consortium had all the information needed to build the consortium and apply for authorisation. While the application was progressing, a few companies received information about the possible upstream application. However, the application at that point was so close to being finished that they decided to finish the application.

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<sup>5</sup> The application prepared by the CTAC consortium (<https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/10110/term>).

*In relation to the micro-sized companies who relied on the word of the consultant, the decision to join the consortium was too hasty. We think these companies who did not know about the upstream authorisation possibility, receiving an authorisation through building a consortium and hiring a consultant was their only option. Moreover, the micro companies who discussed with their suppliers thought it would be easy to join the consortium because many others had already joined. The consortium of the micro-companies gathered was one of the first ones to apply and there was not any previous experience in applications for authorisation that they could benefit from. Nevertheless, no micro-sized company said that they had actively searched for information about other submitted applications from different industry sectors. In the beginning of building a consortium, the lack of discussion and information caused uncertainty and this is what we think caused most of the confusion. Given the uncertainties, companies felt that it would be easier to prepare the application in collaboration with other companies from their sector.*

Three of the large enterprises used the same chemical as the micro-companies. One of the two companies which were present in the chromium consortium kick-off meeting decided to apply on their own. The reason was that the company thought they could get a longer review period when applying alone. They hired the same consultant as the consortium even though they interviewed other consultants as well. The company understood the importance of the AfA very quickly and got things running easier. The other one started the application process, but soon discussed with their supplier and contacted ECHA to ask about the uncertainties that the consultants could not elucidate for them. No permanent promises could be made on the length of the review period and they found out that the upstream application could be enough. They decided to withdraw from the application process and chose to be covered by their suppliers. The third one found no use for the consultant company nor the application because they had actively discussed with the chemical suppliers and decided that the supplier's application would be enough. Since then, they have actively been co-operating with the supplier and testing alternative chemicals for their production. They have also been present in a European (chromium) consortium and shared their views there.

*The more resources the large companies had, the clearer evaluating the situation became. With fewer resources and the unexpected surprise of the requirements of the AfA, the micro-enterprises felt that they were generally forced to pay for the authorisation even if they knew that there is no economically feasible alternative compared to the current hard chrome coating. The micro-sized companies would have had other choices than applying, for example, to be covered by their supplier. Information on the different options should have primarily come from the supplier or the authorities. Consultants, on the other hand, have an interest in encouraging companies to apply for authorisation in order to expand their business.*

#### 4.2.2. Companies related to other substances

One of the large companies applied for authorisation even though there was an economical and technologically feasible alternative chemical entering the markets. It was not sure if the volume of the new chemical would serve all the companies in Europe who were thinking of changing their chemical to the new alternative. The suppliers did not apply for the old chemical, which was why in this case the company did not want to risk the continuation of their business. They applied for an old chemical in a consortium with a consultant which consisted of the members of a CEFIC branch organization. However, the company was able to change to the more environmental-friendly chemical during their review period and they were worried if the application would backfire and give “wrong” information to the customers that they would still be using the old chemical in their production process. Could it be possible to cancel the application if needed?

Another large company found also support from a CEFIC branch organization. Six companies from that organization created a consortium which hired a consultant for the authorisation process. The companies had made Best Available Techniques Reference Documents, (BREFs), together in the past and now they did the core of the work for the AfA together, but submitted their own applications, because everybody wanted to keep their business information confidential. At first, the consortium thought that they should buy access to the registration data from the chromium consortium with a big price tag on it. ECHA solved the situation by stating that it was not needed from the applicants and there should be enough public information online. The information was searched on ECHA’s website and it was easy to access. They had trouble understanding what was needed for the application even though they had participated in orientation events organized by ECHA. The process itself felt very confusing for the company in the beginning. The subject was not taken seriously; ambiguity arose among the workers and it was hard to sell the idea especially for the business people. After more details of the AfA, such as requirements for measurements, the requirements became clearer. The main reason for conducting the AfA was to secure their businesses. The company mentioned that the process they use serves the companies who make up most of the GDP of Finland, so stopping the process was not an option. Therefore, the company applied for authorisation.

*It seems that even if the instructions for conducting an AfA have been available, it has been confusing. We believe the main reason for this is language barriers or unclear websites. Due to confusion, a company mentioned they had worried for micro-sized companies and thought how the micro-sized enterprises with fewer resources could survive through the authorisation process.*

The last large company decided to apply on their own from the very beginning and also hired a consultant. They act as the importer of the chemical they use and wanted to apply for authorisation to maintain their status as an importer. On the other hand, they wanted



to secure their processes in the future. Since they have other chemicals on the candidate list, the company felt that it is a good experience to start doing the applications early on. They also had another decision pending on the chemical (intermediate status), which was the main reason for not starting the AfA immediately.

#### 4.2.3. Effects of consultant and consortium

All except one company was involved in consortia. The main reason for joining a consortium, for both large and micro companies, was the financial aspect. Applying alone would have increased the costs to an impossible level for micro companies based on the interviews. Even though the costs were quite high for the micro-sized ones, no company mentioned that as a negative effect on the company. The company with the smallest turnover mentioned the money wasn't used for anything unnecessary.

*We think the price of AfA was reasonable.*

The second main reason was that the majority of the companies did not have personnel who deal with this kind of tasks on a daily basis. The companies found that joining a consortium minimized the workload because it was coordinated by the largest companies and most of the work done by consultants.

The consultant companies did most of the work so the companies could focus on their own businesses. Reasons behind hiring the consultant were the following:

- Uncertainties and complexity regarding the application process. Especially the micro companies felt very unclear about the process.
- It would have been impossible to conduct the application on their own due to lack of resources and time, and language barriers.
- They needed expert skills in applying so that the application would be good enough to be evaluated by ECHA and others.

### 4.3. AFTER THE APPLICATION FOR AUTHORISATION

The time and money consumed for the AfA were collected and tabulated together by the authors. The interviewees were asked how they felt after the process and if they would apply again. Moreover, thoughts about what could be improved from their side or from the side of authorities are also discussed in this chapter.

#### 4.3.1. Micro companies in values

The micro companies had turnovers from 270 000 € to 1 700 000 € in the year 2015. After researching, we found out that the costs of AfA were between 36 000 - 45 000 € for each company of the consortium. Estimates exclude the working hours, which cost about 16 - 30 % in addition to the costs declared.

Figure 2 illustrates the costs of applying for authorisation as a percentage of the turnover. As mentioned above, the costs of the AfA were very close to each other. Comparing that to the outcome from Figure 2 it can be concluded that the costs of the AfA were very significant (>10 % of annual turnover) only for two of the companies.

Costs of AfA compared to micro companies' annual turnover

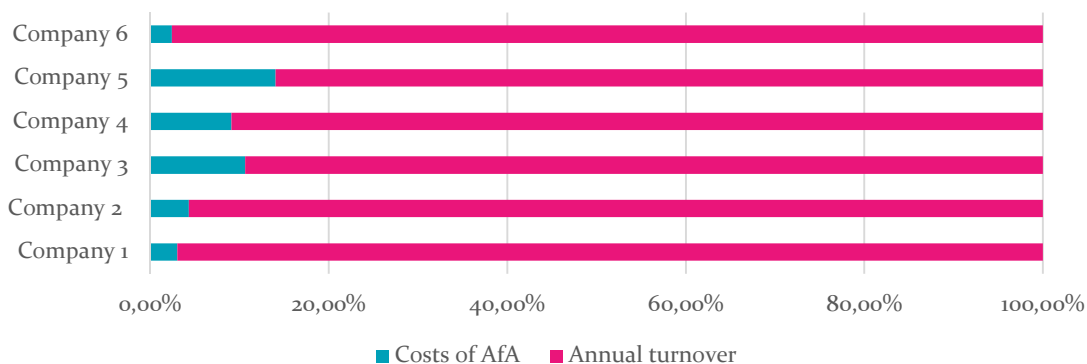
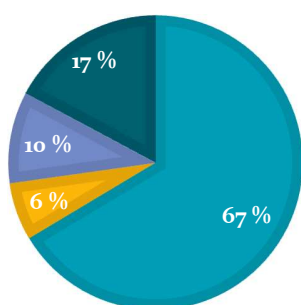


Figure 3 represents the distribution of time consumed for applying for authorisation. The companies consumed most of their time gathering information from their databases and setting it to the correct format. Attending meetings took the second biggest share. Additional measurements and changes in practices were made as well which will be discussed in chapter 4.3.3.. Figure 4 represents the overview of the distribution of costs of applying for authorisation. As can be observed, the consulting fees took nearly half of the costs of the process. The working hours as a percentage of the real costs were 23 % on average and there were variations in terms of the measurement fees and the work interruption costs. Interruptions were due to attending the meetings and being away from the operations and processes of the factory sites.

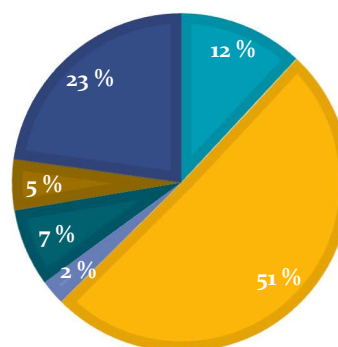
## WORKING HOURS

- Gathering information and setting the correct format
- Additional measurements
- Changes in practises
- Meetings



## DISTRIBUTION OF COSTS

- Regulatory charges
- Consulting charges
- Travelling costs
- Measurement costs
- Work interruptions
- Working hours



### 4.3.2. Large companies in values

For those large companies who applied by themselves, the costs as a percentage of a turnover were almost lower than for the companies who applied in consortia (< 0.2 %). The distribution of costs consumed for applying for authorisation was nearly identical to that of the micro companies but on a different scale. Large companies had no additional measurements included or changes in practises. The portion of time consumed to the meetings was approximately 30 %. The rest of the time was used to gather information from their databases and to set the documents into the correct format.

Both the micro and large companies were happy for the length of the review period given. The customers who had been worried about the continuation were pleased in knowing that the companies got an adequate the review period. If the companies would apply again in the future, the majority will make the same decisions in terms of joining a consortium and hiring a consultant. A minority of micro-companies announced that they would have deeper discussions with their suppliers.

*It should be noted that the majority of the companies would apply again with the same main decisions, even though they had confusion and uncertainties during the process. Now, the companies are aware of what AfA is like.*

Almost all micro-companies were happy about all the work that the consultant companies did. The large companies felt that the consultants were very effective and even if they had had personnel managing these kinds of applications, it would have taken them at least twice the time that it took the consultant company.

*As it has been mentioned previously, a company preparing the application on its own would be much less effective compared to a consultant company.*

The large companies, who applied alone, felt that the process was very expensive, even though the authorisation process costs were negligible compared to their turnover. These companies provided mostly negative feedback. The majority of the small companies and the minority of the large companies thought that the application process was complex and bureaucratic. Most of the micro-companies felt that the discussions in the context of their application for authorisation focused too much on alternatives rather than the use applied for. Alternatively, few enterprises noted that there was a reason for everything that contributed to the application, even though they also admit that there was a lot of bureaucracy.

Another example is a trialogue conversation on which the chromium consortium made a complaint to ECHA according to one micro-company. The companies present at that meeting felt that they couldn't get their voices heard and felt that the other participants did not have a clear view of the process. Moreover, the micro-companies felt some specialists in the trialogue conversation were unaware of the operating environment of chromium coating. During the authorisation process, a minority of the micro-sized companies said ECHA was not always reachable during the authorization process.

#### 4.4. EFFECTS

The main goal of this project was to search for co-benefits of the AfA process. Co-benefits are defined as changes in operating practices, initially made to use a chemical more safely, but which can, in turn, induce cost savings in e.g. energy consumption, increased labor productivity and chemical portfolio reduction. Moreover, this chapter also describes other outcomes and benefits of how the AfA has affected the companies.

##### 4.4.1. Co-benefits

Eventually, there was only one item that qualified for co-benefit - improved networking. The micro companies gained a better knowledge of their consortium member's businesses, which in turn raises the customer satisfaction. This was the case for the majority of the companies in the chromium consortium even though some reported that the communication activity remained the same. Due to the AfA, they recognize each other's capabilities better and can help customers to find a perfect match more efficiently.

Moreover, a majority of chromium consortium companies have been more in contact with each other thanks to improved networking. Discussion with other companies has been open and free during the authorisation process. They have had conversations about the market conditions as well as the environmental protection of the company. Furthermore, two enterprises mentioned they have become more active in the association due to the AfA.

##### 4.4.2. Benefits

The largest impacts that the AfA had were the following: one company changed entirely to an alternative chemical in their process and two large companies using Cr(VI) switched some of their production lines to run with Cr(III) instead. The companies mentioned these changes were going to happen anyway, but the AfA made them find time for these changes to be implemented earlier.

Few companies gained new data during the process thanks to the measurements. A majority of the companies had already a sufficient amount of data for the AfA, thus they did not get any new information. Thanks to the AfA, one company adopted the idea of using a foaming agent in their process baths from better-performing companies and can improve their process safety. On the other side, the company with one of the best health and safety performance felt that the consortium application did not do them much favor since others did not perform as well. The large companies did not adopt new ideas from other companies.

Due to the AfA, a minority of micro-sized companies and the majority of large companies informed that they have had more serious thinking of alternative solutions. Few companies said that their process workers have been notified more about the hazardous nature of the substances of concern.

Only one company, out of all interviewed ones, said that they have increased the supervision of their chemicals and they updated their risk assessments and the guidance of their personal protective equipment on the global company level. One company added the maintenance personnel to the same health surveillance program the process workers have.

Besides the examples above, applying for authorisation did not bring any improvements to the processes or operations for the companies. However, the companies who applied for authorisation now know how to apply for new authorisations in the future. One large company mentioned they would have gotten more out of the AfA meetings if they had personnel who understand these processes better.

*For two micro companies, improvements in process safety were achieved. Even though there were lots of companies who did not report any improvements to the operations or processes due to AfA, all the companies who applied got experience about the process. This knowledge might result in lower consumption of time and money in the possible future applications. The companies would have probably gotten even more out of the process if they have understood the aim of the AfA process. We think this is critical for micro-sized companies: they may not have enough resources to hire someone to operate full time with the environmental legislation and can't get all the benefits AfA can offer especially if applying alone.*

*Nevertheless, it seems that AfA has worked as an eye-opener for about half of the companies, who reported that they now have a more open attitude towards alternative solutions. Maybe this round of applications can affect the companies' views of their processes in the long term.*

#### 4.4.3 Other outcome

Only one micro-sized company mentioned that they have included some of the costs of the AfA to their prices. The six other micro companies could not do the same because the competition in the industry is high and raising the prices would drive the customers away to a different country. Also, most of the companies have only one main/big customer and raising the prices could lead to discussions with customers about possible renegotiations of the terms of the contract. A minority of the micro-sized companies are afraid that the chemical suppliers/importers might raise their prices in the future even if the price of the raw material is quite stable. One company pointed out that this way they would have to pay for the costs of the AfA in two different ways.

One micro-sized company mentioned that if a new technology is implemented, the costs from the change of process has to be included in the prices. However, money is not the only problem. One of the large-sized companies pointed out that if they were to change the process, a great many other issues should be discussed with the customers as well. The micro-companies said this could scare the customers away and make them import the product from outside of the EU. Yet, one important customer for many chromium coaters has used a significant amount of financial resources to find alternatives for Cr(VI) coating.

For one large company, the rise of the price of their product became necessary when they changed to an alternative chemical that was more expensive than the one previously used. They said it was relatively easy to do because all their competitors in Europe seemed to include the costs as well. The company did not feel that its customers would start importing the product from other jurisdictions such as Asia.

*Since the costs resulting from the AfA were small, no increase in product prices should be needed. On the other hand, if the companies are to change the process at some point, the cost of that could be passed on to the product prices. This happened in the last example where the chemical was changed. In the very same example, it was mentioned that when the processes are changed at the EU level, it might have a global effect as well. This, in turn, can improve the competitiveness of the chemical industry of the EU, which is one of the goals of REACH.*

#### 4.5. AUTHORITIES INVOLVED IN THE AUTHORISATION PROCESS

In this chapter, we discuss the role of the authorities (Tukes (Finnish Safety and Chemicals Agency) and ECHA) and also present information on how other EU companies from the same sector have responded to the authorisation requirement.

##### 4.5.1. Information from other EU companies

A majority of the micro-sized companies were in contact with their partner companies in Sweden, the Great Britain, and Germany during the AfA process. The experience from partnering micro- and small-sized companies was interesting to the micro companies in Finland. All the companies in other countries had chosen to follow the upstream application. That could have been an option also for most micro companies, which is why they noted that the information about the application procedure should be more uniform throughout Europe.

*In all the countries mentioned, it seems that the flow of information has been better (or the companies have been more active in researching information). In Finland, the companies were not receiving enough information about the available options and were forced to apply for the application themselves. One company had expected that information would be better in Finland, since ECHA is located there. We think that the companies might benefit more from the information flow in countries where activity in associations has been greater.*

The questions about EU that came up in many interviews among the chromium coaters were the following:

- Are the companies treated equally all over Europe?
- Is market surveillance similar in every country and is enforcement of the regulations the same in every EU member state? The customer of the chromium coaters had

experiences that the enforcement concerning the chemical legislation is different around Europe.

A couple of large companies mentioned that human health and environmental issues are considered as a high priority in the EU. For example, all the companies using substances from the Candidate list, within the EU, have to apply for authorization. However, this impedes their competitiveness relative to other companies outside of the EU and requires the deployment of budgetary and human resources.

*Since the companies located outside the EU do not have to apply for authorisation, some companies within the EU felt that the AfA lowers their competitiveness. The micro-companies mentioned that the hazardous substances handled by the chromium coaters are generally used safely and the performance characteristics of the products cannot be achieved with the available current alternatives. That is why these companies expressed the view that the expenses incurred due to the AfA (paid to consultants and authorities) did not bring added value to the operations of the companies. This might be true from the perspective of the companies. However, from the EU perspective, we think that the AfA allows the companies to continue their processes by acting at the same time as an incentive for creating future innovation. Therefore, the AfA can also raise the competitiveness of EU relative to the other continents, which was discussed earlier in chapter 4.4.3. Regarding enforcement it has to be noted that coordinated and harmonised enforcement is a key factor in the success of the REACH regulation and this is one of the main goals of the Forum for enforcement established by REACH. Given that it is a new process, there is not so much information available on the enforcement of authorisation.*

#### 4.5.2. Tukes

A minority of the micro companies and two large were hoping that Tukes (Safety and Chemical Agency) would take a bigger role in communicating to companies. The majority of all the companies mentioned that they would like Tukes to inform them about the legislation and safety changes considering every operation of the companies, because Tukes informs in Finnish and for that reason is easier to approach, and the companies want to keep themselves up to date with the current legislative requirements. Unfortunately, it is not easy for Tukes to get information about and to come into contact with the smallest companies. One solution to this problem could be informing the local Centres for Economic Development, Transport and the Environment (ELY-centers) about the AfA so that they could together with Tukes try to find and contact the smaller companies

During this study it was noted that if the AfA was a new subject for ECHA it certainly was new for Tukes too. Surprisingly, Tukes has not received a lot of questions considering the AfA from companies. Due to a lack of support and information from the authorities, some micro-sized companies thought that the authorities would not want to support small-sized



production in Finland and that it would be easier to move to only certain territories in the EU to make the surveillance easier.

*Communication from the authorities is important for the understanding of the AfA process. If the material considering the AfA, that is available on ECHA's website in English, would have reached the micro-companies in Finnish, the confusion in the beginning (and during) the application process could have been partially avoided and trust in the authorities would be enhanced.*

*It seems there is a gap in the flow of information from both parties, i.e. the companies and Tukes. Tukes mentioned that it has been hard to find all the contact information of the micro-companies in Finland. They said it would be easier if the companies would contact Tukes and then together they could find out the best way to provide the information in the future, e.g. by subscribing to the e-mail newsletter, KEMInfo, that is published a couple of times a year.*

*On the other hand, and as mentioned earlier, especially micro-sized companies hardly search information about the changes in legislation and they could be more active in that regard. Co-operation with the authorities could first, give the authorities a chance to perform better in terms of informing the companies about the changes and second, reduce the micro-companies' need to search for changes when they could be informed of the changes effectively.*

#### 4.5.3. ECHA

ECHA's role in the authorisation process was a question that many companies had. The majority of micro-sized companies mentioned that it was hard to reach ECHA during the process, the information received was not beneficial to them, and they had the feeling that ECHA did not comprehend the true environment of the industry. For one large company, ECHA turned out as a faceless organization, which had no direct contact persons. The company felt that they couldn't get any response to their questions from ECHA. They suggested that each applicant/consortium should have a contact person. However, ECHA clarified that this was actually the case.

*We think that most of the companies misunderstood the position of ECHA in the process. Some of the companies realized the fact that ECHA is not directly involved in the preparation of the application, but many had hoped that ECHA could have more been involved in this part of the authorisation process. It seems that there has been a lack of flow of information between ECHA and companies or the companies haven't actively tried to search for information about the process. Even if they had, the information was hard to find.*

ECHA visited some of the chromium coaters during the authorisation process and the companies felt this probably helped ECHA to understand the process and the industry better.

*Even though ECHA has visited the companies and there were pre-submission information session well before the application for authorization was submitted, we think these could have been done before the companies had started conducting the AfA. We think this kind of visit is useful. Then a company can explain the situation of their process and if they even see any alternatives for it to ECHA. After the visit, it could be considered if the downstream AfA is necessary for their situation after all<sup>6</sup>.*

There were also two big companies who did not have much contact with ECHA because they weren't the leaders of the consortium which were said to have been more in contact with ECHA. Two other large companies said that they first met with ECHA in the dialogue conversations, but the consultants handled all the other form of communication. The customers of the chromium consortium members also mentioned that they haven't discussed with ECHA enough about the alternative solutions and the role of the consultant.

*It seems the companies who put more effort into the project got more out of it and were left with more positive feelings. We think that ECHA might have become faceless for some companies because these companies did not put that much effort into the application. Therefore, when they eventually had to discuss with ECHA they had problems contacting the right people. A timelier interaction with ECHA could have made it easier for the companies to contact them also later on in the process.*

A minority of the companies said that the instructions on how to prepare the authorisation application seemed to be unclear. One of them proposed that if the contents were presented more clearly, the application procedure would become easier to understand and to compile and the total costs could be lower.

*We think this is true. The clarity of the information can be improved. In addition, it seems that the more experience ECHA gains on the authorisation process from all actors the lower the costs of the AfA will become.*

The public consultation on alternatives was also unclear for one micro-sized company. They wondered how different authorities or companies find themselves to comment on the applications. The customer of the majority of the micro companies had thought about commenting on the consortium's application during its public consultation phase because they think that it might have positive effects on process development. However, the micro companies did not seem to have encouraged the commenting of the applications and no comment by the customer was submitted.

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<sup>6</sup> In addition, ECHA organises applicant-specific pre-submission information sessions where potential applicants can be informed about the authorisation and how to apply (<https://echa.europa.eu/applying-for-authorisation/pre-submission-information-sessions>).

## 5. CONCLUSION

This study was made to find out how the AfA procedure impacts companies and their operating practices during and after the applying process. In this report, we presented the methodology on how we conducted the investigations and presented the questions that were asked from the companies.

For this report, 14 Finnish companies of different sizes, and The Finnish Safety and Chemicals Agency (Tukes), were interviewed. The results were mostly divided into two groups: micro-enterprises and large enterprises. This was because the backgrounds and answers from micro companies and large companies were very similar to each other.

A majority of the micro-companies were informed about the AfA by the consultant companies. We think that there has been a lack in information flow between the suppliers and the companies because a major part of the micro-sized companies did not know about the upstream application possibility. However, the large companies are informed from CEFIC branch organizations and the information flow was better due to more resources available compared to the micro-sized companies. Few micro-sized companies discussed with their suppliers about the authorisation, but they decided to join the consortium anyway. All the large companies that dealt with Cr(VI) withdrew from the consortium because they could assess the situation more clearly on their own.

Based on the opinions of the companies, finding and understanding the instruction to conduct the AfA was difficult, and the process was complex and bureaucratic. However, some companies found all the efforts required in the authorisation process were justified. As the projects progressed, irrespective of the company size, the role of consortiums and consultants became very clear. The main reason for joining a consortium was the financial aspect and lack of the personnel specifically working with the environmental/human health issues. The main reasons for hiring a consultant were the following: the complexity of the application process, resources and time needed to prepare the application, language barriers, and expert skills in applying. Those companies which hired a consultant mentioned that they would hire the consultant again, even if the company had a person working with environmental/human health legislation.

There was only one clear co-benefit. It was the improved networking amongst the micro-companies. They now know each other better, which makes it easier for the companies to help their customers in finding a suitable partner if they themselves can't respond to the needs of the client. Other results worth noting were the following: for three large companies, the AfA requirement acted as an incentive and made them change and develop their production ahead of schedule. One of them also added the maintenance personnel to the same health surveillance plan that the process workers had. One large company mentioned that, until now, they had been looking for more economical alternatives, but in

the future, the scope will change towards the safety aspects as well. Amongst the micro companies, one managed to adopt the idea of using a foaming agent in the coating process, which can improve the process safety.

Eventually, all the companies who had applied were happy about the length of the review period given. Most of the companies who applied feel that they are now more prepared to face the future challenges and have gained valuable knowledge of the process, though some felt that they are still a little confused. The knowledge will help the companies to apply again if it will become necessary in the future. Most of them said that they would do everything the same way in terms of hiring a consultant, building a consortium or applying.

The price of the AfA was reasonable. The costs of the AfA were significant for only two companies. On average, two-thirds of the time, the companies were gathering information from their databases and setting the information in the correct format. Nevertheless, half of the costs came from consultant fees. For micro-sized companies, it is hard to pass on the costs of the AfA to the prices of their products, but in the future, if Cr(VI) will be substituted, the new process costs could be included, and this is what the companies would try to do based on the opinions of the interviews.

We also found out that communication has been a major challenge, especially in the cases of the micro-enterprises. According to the interviews, the flow of information has been better in other EU countries, but especially micro-sized companies ponder how the circumstances vary outside the EU and in different parts of the EU. A common source of information for the micro companies in Sweden, Germany, and Great Britain seems to have been the associations and chemical suppliers. Another study could be made to compare the differences and get a better view on how the AfA process could be improved. Tukes had received few questions considering the AfA from companies. Nevertheless, most of the companies wanted Tukes to inform them about the legislation and changes in safety requirements in general, because Tukes provides the information in Finnish. However, there is a big information gap between Tukes and the small companies in Finland, because Tukes has difficulties in reaching the small companies in Finland effectively. On the other hand, the companies feel that the authorities strive to inform them in a more efficient manner. Ways to enhance the information flow should be investigated. For example, ECHA has been an unknown authority in the authorisation process for most of the companies and the commenting system for applications has been unclear for a few companies as well.

Because small players will probably face difficulties when upgrading to alternative solutions, a minority companies believe that additional funding for research for new alternatives is needed. Three companies mentioned that in the future, the role of the sector associations, the consortiums, and ECHA will be even more important and that they can promote the discussion about problems and solutions. Some were wondering how strict the legislation will become in the coming years when they may have to apply again. During the review

period the companies are asked to for example do specific measurements with a certain frequency to stay active during the review period as well. The companies said to put effort to them which makes the chemical use safer.

*The problem that needs to be addressed is that many micro companies do not tend to be too active in looking for information related to new legislation. Being proactive in finding the relevant information could help with the concerns that some of the companies have about the future.*

*We think that in the future, information about the AfA should be easier to find and available in every applicant's native language, e.g in the local authority's information channel.*

# APPENDIX I –QUESTIONNAIRE

## Questionnaire

- What is the role of the interviewee in the company?
  - What is the mission/vision of the company?
  - How did the company hear about AfA?
  - Has the information flow been good? With ECHA, personal association, Tukes, consultant?
  - How did you react to the news?
- 
- Why have you or have not applied for authorisation?
  - How fast had you to start the applying process?
  - When did you hear about it first and when did you start doing the application?
  - What did you feel about the AfA? Personal experiences, working community experience, working hours put into AfA. Was there any bias to AfA?
  - What has changed when you have gotten the permit? What changed during the application process?
  - Did any customer ask you about the permit? Or did they not have an impact?
  - Has AfA process impacted your company in a positive or negative way?
  - Any impacts on the work safety or environment?
  - **Any impacts on the logistics, ventilation, energy consumption, use of chemicals, customer satisfaction, outsourcing, work efficiency, behavior in the workplace or amount of sick leaves? (Co-benefits!)**
  - How could identical companies, different representatives, and partners help you if you are going to apply again?
- 
- **How could you use / how have you used the experience gained from the AfA? (Could also be a co-benefit!)**
  - If you were to apply again what would you do differently?  
Was there anything that you felt was unnecessary in AfA?
  - Any comments or feedback to us or ECHA?

## APPENDIX II – ADDITIONAL QUESTIONNAIRE

### Additional questionnaire

1. Was it difficult to reach ECHA during the AfA process? If yes, please explain why. Did you try to contact any other authorities?
2. Was the consultant the first information source for you? If not, please write from whom did you hear about AfA.
3. According to previous interviews, the time consumed to AfA has been something from 1 to 3 man-months. Please write down to which activities the time was spent on and how much per activity. The activities are, for example, collecting data from your databases, additional measurements and attending meetings.
4. If you applied, what was your reason for applying? Why did you think that you should apply?
5. What were the difficulties in applying? (e.g. building a consortium, deciding about common things, making the opinions uniform, finding information about the process)
6. Did your customers ask you to apply or would the upstream application be enough?
7. Some companies have mentioned that the process took more than they thought. If you agree, please explain what part of the process took the most effort. You can also mention if the process wasn't as big as you thought. (Different parts are, for example, making the application and discussing with other members of the consortium.)
8. How big part of your annual turnover the AfA costs were? How much do you use the chemical in question?
9. From whom would you have waited to hear from the application need? (ECHA, SYKE, Tukes, association, chemical supplier?)
10. Divide the costs of AfA in the following categories:
  - Fees
  - Consulting
  - Additional measurements
  - Working hours
  - Other

Feedback and comments: