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The impact of environmental regulations on competitiveness

Qualitative analysis of the REACH legislation applied to chemical companies in the province of Alessandria, Piedmont (IT)

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Introduction

The paper is intended to analyse the impact of the REACH regulation on the competitiveness of chemical companies in the province of Alessandria. In particular, it aims to verify the applicability of Porter's hypothesis (1995)[1] in the territorial context considered. This objective was achieved by conducting interviews involving professionals within the companies participating in the research.

The legislation subject of the thesis is Regulation (EC) No. 1907/2006, known as REACH, which seeks, through the registration, evaluation and authorisation of substances, to ensure a higher level of protection of human health and the environment, while aspiring to maintain and strengthen the innovative capabilities and competitive position of the European chemical industry.

The choice of this topic stemmed from an attachment to the subject of sustainability and the desire to apply the knowledge developed during my studies in a concrete context, thus delving into the dynamics of a territory (besides having great relevance to the subject of the research paper) to which I am very attached.

The structure of the thesis follows the process that led to the achievement of the stated objective. It started with an in-depth study of the regulation, focusing on the main processes and Articles. This investigation of the design of the directive made it possible to identify REACH as a case study of Porter's hypothesis (1995), according to which an environmental regulation may be able to trigger an innovation mechanism that offsets compliance costs, thereby increasing the competitiveness of the companies concerned. After clearly defining the objective of the research, the next step was to analyse the possible impacts, followed by the definition of the interview questions and the methodology of data collection to verify these. The interviews were then carried out, the transcripts of which can be found in the Appendix of the paper. After collecting the information, the participants' answers were analysed and compared.

[1]Porter M. E., and Claas van der Linde (1995) 'Green and Competitive: Ending the Stalemate', *Harvard Business Review*, 73(5).

The research allows conclusions to be drawn on the relationship between the regulation subject of the study and the competitiveness of the companies involved in the investigation. These conclusions, being the result of the contribution of the interviewees and the territorial context considered, are not generalisable, but provide interesting points for reflection and the possibility of building on the results obtained. This is because, in addition to offering a clear explanation and analysis of the regulation, this paper presents a list of questions that can be used by other researchers who share an interest in the same objective, evaluating the opportunity to expand the geographical area of relevance.

Chapter 1 The REACH regulation

In this Chapter we will analyse the functioning of the directive, which is aimed at achieving multiple objectives through provisions that apply to regulated substances. In addition, we will reveal which actors are involved.

After an initial presentation, we will focus on the main REACH processes which are registration, evaluation, authorisation, and restriction. Regarding registration and authorisation processes, we will cover the impact on companies, as the interview questions concentrate on these two procedures. On the one hand, the choice fell on the latter because of their revolutionary compared to regulations prior to REACH that already provided for the concept of restriction. The evaluation process, on the other hand, which is necessary for the authorisation to be activated, falls within the administrative sphere. A separate discussion will be made for two Articles that can have a major impact on companies, namely Article 14, which is still part of the registration requirements for some tonnage bands, and Article 31, which concerns the safety data sheet (SDS).

To conclude, we will report some Articles on mandatory communication requirements in the supply chain.

1.1 An overview of REACH

REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) is a European Union regulation covering the manufacture, use, and supply of substances, on their own or in mixtures/articles, within the European Economic Area (EEA). It entered into force on June 1, 2007, replacing several European directives and regulations with a single system.

What are the objectives?

The aim of the regulation is to ensure a high level of protection of human health and of the environment, to promote alternative methods for the hazard assessment of substances, to protect the free circulation of substances in the internal market, and to enhance competitiveness and innovation.

How are the objectives achieved?

These objectives are achieved through provisions dealing with substances, articles, and mixtures. First of all, it is important to understand what falls under the definition of substance, mixture, and article. According to Article 3 of the regulation, substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process. A mixture is defined as a mixture or solution composed of two or more substances, while an article is described as an object that during production is given a special shape, surface, or design determining its function to a greater extent than its chemical composition.

The provisions of REACH apply to the manufacture, use, and placing on the market, of substances on their own, in mixtures, or in articles within the European Economic Area. Therefore, the regulation directly affects all EEA companies operating in the chemical industry as manufacturers, importers, distributors, and downstream users. Likewise, the regulation indirectly affects all companies outside the EEA that want to market their chemicals in the European Union. The REACH regulation is based on the principle that it is the responsibility of manufacturers, importers, and downstream users to ensure the manufacture, placing on the market, or use of substances that do not have adverse effects on human health or the environment.

What are the actors involved?

Companies are classified for REACH purposes according to Article 3.

Under REACH, you are a manufacturer if as an individual or a company you are based in the EEA, and you produce or extract a chemical substance. Whereas you are not considered a manufacturer if you only blend substances into mixtures or use chemicals to produce articles, in this case, you are a downstream user.

Moreover, you are an importer if you buy a chemical product directly from a supplier based outside the EEA and bring it into the EEA territory, while you are not considered an importer if your non-EEA supplier has appointed an EEA-based only representative to register the substance, in this case again you are a downstream user.

An only representative assumes the duties and responsibilities of an importer of a substance under REACH for a company based outside the EEA. In general, this person has the same requirements for registering substances as manufacturers and importers.

Continuing, you are a distributor if you source a chemical substance or a mixture within the EEA, if you store it and then place it on the market for someone else (also under your own brand without changing its chemical composition in any way).

Finally, a definition of downstream user is proposed, i.e., 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 mixture, during his industrial or professional activities.

What are the applications?

One of the main policy drivers behind the regulation was the slow completion of risk assessments in the EU and the implementation of risk reduction strategies for existing chemicals (substances marketed in the EU before 1981). Of which only 20 % had publicly available data sets that allowed for minimal screening for risk assessment.

REACH addresses data gaps on the properties and uses of industrial chemicals to ensure proper management in the production and transport chain while protecting the environment and human health. In line with this policy driver, substances that are sufficiently covered by existing regulations are exempted wholly or partly from REACH, as they are not affected by data gaps and the risks are adequately managed.

Regarding exemptions to the regulation, which are listed in Article 2, they are not limited to substances sufficiently covered by existing regulation; some examples are given below.

Substances subject to full exemption include radioactive substances, substances in temporary storage under customs control (provided they are not processed or transformed in any way), and substances used in the interests of defence (when covered by specific national exemptions). And also, non-isolated intermediates, i.e., substances that appear between two successive chemical reactions and are not removed from the system except for sampling.

Waste, as defined in the EU's waste legislation, is exempt from REACH, but this does not apply to products recovered from waste.

REACH applies to any substance, mixture, or article you recover from waste that meets the end of waste criteria. However, it is sometimes possible to get an exemption for a recovered substance that has already been registered by someone else.

Regarding registration and authorisation requirements, these do not apply to substances used in scientific research and development, food and feedstuffs, and medicinal products.

In particular, registration is not required for substances that present a minimal risk due to their basic properties (e.g., water, nitrogen) and for naturally occurring substances for which registration is considered inappropriate or unnecessary. Furthermore, registration does not apply to substances that have already been registered, then exported and re-imported into the EEA by an actor in the supply chain, and to those that have already been registered and recovered through a waste recovery process.

Ultimately, it is important to remember that no company is exempt from chemical safety requirements.

1.2 In the REACH processes

The main processes of REACH are registration, evaluation, authorisation, and restriction. In the following analysis of the regulation, we will focus on these four processes. These latter will be explored in depth by referring to their ancillary processes and to the relevant Articles, which are contained in the directive, to provide a solid basis to study the impact they have on companies. Before proceeding with the analysis, it is important to understand the sequentiality that exists among the four processes and their consistency with the objectives of the regulation.

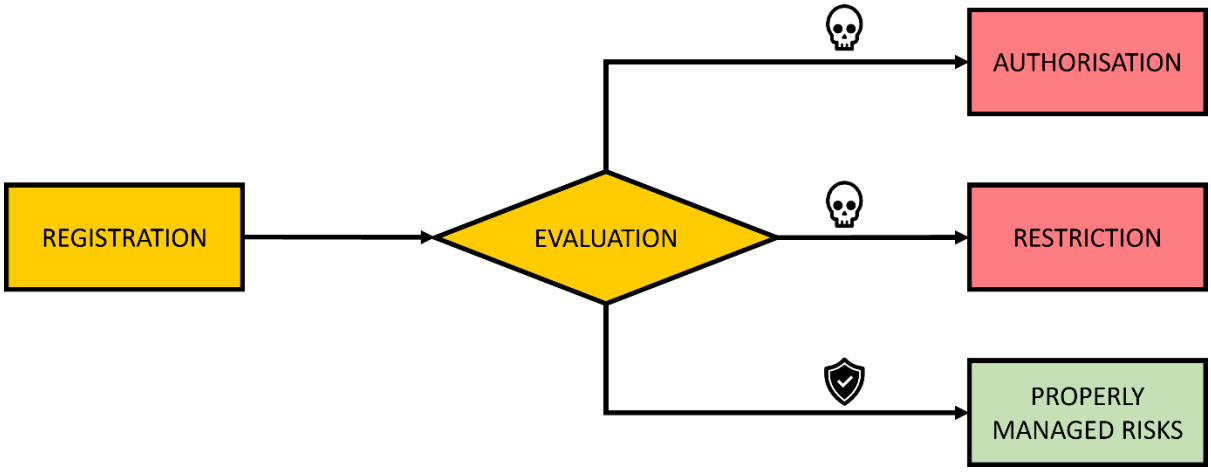

Figure 1:1 - The REACH flowchart

Figure 1:1 represents the flowchart of the regulation. The first process is registration, this one allows for the collection of information on the properties and hazards of a substance, which will be submitted to the European Chemicals Agency (ECHA). The second process is evaluation during which the Agency analyses the information received in order to ensure that the existing risks are under control. If the risks posed by the substance cannot be adequately managed, it may be subject to authorisation and restriction. On the one hand, if it is subject to an authorisation process, the substance can be manufactured, supplied, and used until the sunset date; thereafter, to continue manufacturing, supplying, and using the substance, authorisation must be applied for. On the other hand, if the substance is restricted, it can only be used under conditions set by ECHA.

It is now clear that the four processes are consistent with the goal of ensuring a high level of protection of human health and the environment. The objective is achieved through the collection of information on substances, the evaluation of the data by the appropriate body, and, if the risks associated with the substances cannot be adequately managed, the application of an authorisation or restriction. According to regulators, the processes of authorisation and restriction, through the imposition on the companies, encourage innovation, in terms of process and product with a view to increased competitiveness.

1.1.1 Registration

We are entering the first of the four main processes which is registration. This process addresses data gaps on the properties and hazards of substances in order to properly assess and manage the associated risks. Article 5, which is based on the principle "No data, no market", highlights the relevance of registration for EEA and non-EEA companies. According to it, substances, on their own, in mixtures or in articles, which are subject to registration, cannot be manufactured in the Community or placed on the market unless they have been registered. A company must register under several conditions. Firstly, if you are an EU manufacturer or importer of substances on their own or in a mixture. Secondly, if you are an EU manufacturer or importer of articles that meet the criteria outlined in the Guide to Requirements for Substances in Articles. Thirdly, if you are the only representative established in the EU and appointed by a manufacturer, formulator, or producer of articles based outside the EU to meet the importer registration requirements.

When is it necessary to register?

According to Article 6, save where the regulation provides otherwise, registration applies to substances manufactured and imported, on their own or in one or more mixtures, in quantities of one ton or more per year per enterprise. Regarding articles, with reference to Article 7, the regulation requires each manufacturer or importer to submit a registration to the Agency for each substance in such articles if both of the following conditions are met. The first one requires that the substance is present in such articles in quantities exceeding one ton per year per manufacturer or importer. The second one implies that the substance is intended to be released under normal or reasonably foreseeable conditions of use. Registration, for substances used in articles, is not required in the case of substances already registered for such use. According to Article 9, in order not to adversely affect innovation, registration does not apply for a period of five years to a substance manufactured in the Community or imported for process-oriented research and development purposes.

What information is needed?

The information required for registration is set out in Article 10 of the regulation. A registrant must submit the technical dossier and, where required consistent with Article 14, a chemical

safety report. The technical dossier includes a range of information. First of all, it should contain the identity of the manufacturers or importers, the identity of the substance, and the information on the manufacture and use of the substance. In addition, it involves the classification and labeling of the substance, the guidance on the safe use of the same, the study summaries, and the proposals for testing.

The scope and detail of information required for the registration, along with the fee, depend on the production or import volume and are higher for HPV substances (high production volume substances). There are four tonnage bands based on production or import volumes for standard registrations: 1-10 tons per year, 10-100 tons per year, 100-1 000 tons per year, and more than 1 000 tons per year.

Companies must ensure that the information contained in their registration dossiers is correct at the time of registration and that any changes are reported without delay.

According to article 13, information on intrinsic properties of substances can be generated by means other than tests. In particular, about toxicity to humans, the use of alternative methods is preferred over testing on vertebrate animals.

How does the process unfold?

According to Article 11, registration is based on the "One substance, one registration" principle. This means that producers and importers of the same substance must submit their registration jointly. For the purpose aforementioned, one registrant assumes the role of the lead registrant by submitting the information required by the technical dossier that is common to all registrants. Subsequently, each registrant submits the specific information of their company, assuming the role of following registrant.

According to Article 27, in the case of registration of a substance already registered, the potential registrant must request the sharing of information which are useful for the compilation of the technical dossier by the previous registrant(s). Previous and potential registrants should make every effort to agree on the sharing and the costs of accessing this information. The companies wishing to register a substance have to ask ECHA whether registration has already been submitted so that they are automatically put in touch with another potential, and previous registrants of the same substance.

Article 11 and Article 27 promote the sharing of data and therefore of costs, the reduction of duplication of effort, and animal testing. Moreover, they avoid the submission of conflicting information.

As mentioned above, all manufacturers or importers of chemicals in volumes greater than 1 ton/year/enterprise, if not exempt, must register such substances with the European Chemicals Agency in Helsinki. This obligation is extended to existing and newly developed substances manufactured and/or marketed in Europe. In particular, substances already manufactured prior to REACH (phase-in substances) had a transition period to meet the requirements. A deferred timetable for registration is applied to these phase-in substances if manufacturers had pre-registered the substances. Pre-registration had to be completed between June 1, 2008, and December 1, 2008. Only after preregistration was completed could phase-in substances be manufactured or imported until the end of the relevant registration window. The last deadline for REACH registration, which covers companies producing or importing chemicals in low volumes (between 1 and 100 tons per year), was May 31, 2018. Failure to pre-register resulted in the requirement to complete the registration process before resuming production or import.

What are the objectives of the process?

The registration process has been structured in such a way as to limit the economic impact on the companies involved. The registration fee, as well as the information requirements, increase together with production and sales volumes. Joint registration allows the sharing of data on substances limiting costs, duplication of efforts, and a number of tests performed. As part of testing, the regulation aims to promote alternative methods for hazard assessment, in line with one of its objectives. The impact on competitiveness is not only limited by acting on the costs incurred by companies for compliance, but also by exempting substances used in the development of products and processes.

It should be clear now that the regulation is designed to limit the impact on companies, since its objective is to gather information about the properties and hazards of substances. Unlike the authorisation process, which we will analyze later, the registration process is not intended to induce companies to stop producing the substances concerned.

The impact on companies?

Despite the design of the regulation, registration is a costly burden for manufacturers and importers, specifically, there are three types of costs. The first one is related to (shared) costs for data searches, test data, and chemical safety. The second one is linked to SIEF Consortium management costs, while the third one concerns ECHA fees (€64 to €33,201 depending on volume range and company size). The total cost for registration may be typically between €20,000 and €1,000,000, depending on the quantity of data required, the tonnage, and on other factors. Some potential registrants may not register at all if the market is not big enough.

What actions can companies take in response?

Except in specific circumstances (e.g., annual tonnage less than 1 tonne), if suppliers do not register the substances they supply to a downstream user, they will not comply with REACH, and consequently, they won't be able to legally supply those substances. The downstream user can protect his business from interrupted supply in a series of ways. Firstly, by identifying critical substances for his business. Secondly by checking the registration status of the substances and looking for alternative suppliers, if necessary. Thirdly, by checking that his uses are covered in the registration, particularly if he uses a substance in a novel way. This point will be better explained in the analysis of Articles 14 and 31. Finally, if no supplier has registered the substance the downstream user really needs, he should consider importing it directly.

1.1.2 Evaluation

After analyzing the registration process, we should focus on the evaluation process. ECHA and the Member States conduct two evaluations which are the Dossier evaluation and the Substance evaluation.

Dossier evaluation

The Dossier evaluation includes an examination of test proposals submitted by the companies and the verification of the compliance of the registration dossiers. ECHA checks that information outlined in the standard information requirements of REACH is available in the dossier or included in a testing proposal. This information is crucial for understanding

whether a chemical may pose a risk to human health and to the environment. ECHA automatically checks the completeness of each registration dossier and will then examine at least 5% of the registration per tonnage band in greater depth.

As said previously, Dossier evaluation covers two processes that are the compliance check and the examination of testing proposals.

Compliance Check

ECHA may examine according to Article 41 any registration dossier at any time to verify if the information submitted by registrants is compliant with the legal requirements, which are standard information requirements. In particular, they are cumulative, and they depend on the tonnage band.

Examination of Testing proposals

Registrants must submit a testing proposal if they intend to perform a new test listed in Annexes IX and X. According to Article 40, ECHA examines all testing proposals submitted by the registrants and makes sure that they address the actual information needed. It also avoids unnecessary testing, especially when testing involves the use of vertebrate animals.

Substance evaluation

The Substance evaluation process aims to clarify possible risks to human health or the environment deriving from the use of a substance. The first step of the Substance evaluation is the establishment by ECHA of a list of substances in the community rolling action plan (CoRAP) to be evaluated. These priority substances are chosen according to a risk-based approach. ECHA will present draft updates of the CoRAP annually to the Member States (on 28 February at the latest). Member States will carry out the evaluation, under the supervision of the ECHA responsible for its coordination then, from the publication of the CoRAP, the designated Member States have one year to evaluate the substance. The Substance evaluation process assesses all registration dossiers from all registrants specific to the same substance or group of substances, i.e., in order to take into account, the aggregated tonnages of production and combined exposure. Other available sources of information are also considered. In case the evaluation concludes that the risks are not sufficiently under control with the measures already in place, it may lead to the proposal of EU-wide risk management

measures. Which include restrictions, identification as an SVHC, harmonized classification, or other actions outside the scope of REACH.

1.1.3 Authorisation

Any Substance considered to be of Very High Concern (SVHC) might be introduced to the Candidate List. The inclusion in the Candidate List brings immediate obligations to the suppliers of the substance. From this list, substances with very high health and/or environmental concerns will be prioritised for inclusion in Annex XIV of REACH (authorisation list). Once the European Commission has included the substance in Annex XIV of REACH and from the moment the defined sunset date has passed, the substance cannot be placed on the market for use or used without the prior authorisation of the European Commission, unless that use is exempt from authorisation. REACH authorisation is a complex and expensive process, for this reason, the regulation encourages change and the development of safer alternatives.

How does the process unfold?

Applicants may apply for authorisation for their own use or uses for which they intend to place the substance on the market. In the authorisation process, it is not substances that need authorisation, but their use. If any of the substances are affected by authorisation, the next step is to develop a strategy on how to proceed in. This plan implies searching for safer alternatives and assessing the possibility to substitute them. In addition, it includes evaluating the importance of the substance to the business and supply chain. If the decision is to follow using the substance or placing it on the market after the sunset date, then the company should apply for authorisation, which is company-specific, supply chain-specific, and use-specific. Authorisation is granted after an economic assessment of the impact of removing the substance and an evaluation of the availability of safer alternatives.

What are the objectives of the process?

Authorisation aims to guarantee that the risks relative to substances of very high concern are properly controlled throughout their lifecycle. In addition, it promotes the progressive

replacement of these substances by other ones or by the implementation of new technologies, whether these are economically and technically available and feasible.

The impact on companies?

If the authorisation is granted by the European Commission, it is subject to the conditions described in the chemical safety report submitted in the application. The authorisation decision may stipulate additional conditions, namely the authorisation holder should continue his efforts to find safer alternatives after the decision. In addition, downstream users, who are covered by an authorisation granted to an actor up their supply chain, must comply with the conditions of the decision and notify ECHA within three months of the first supply of the substance. If the authorisation holder needs to continue using the SVHC after the review period, a review report must be submitted. The latter may also be initiated if the circumstances of the original authorisation have changed or new information on possible substitutes becomes available. Most Annex XIV substances are subject to authorisation at any quantity level/concentration (no threshold criteria).

The authorisation process is very complex and costly. In particular, it has an expiry date and must be reviewed every time the initial circumstances change or new information on safer alternatives becomes available. It should be clear that, unlike the registration process, it is very difficult to continue using the SVHC, consistent with the objective of the regulation.

In conclusion, it should be kept in mind that the objective of the regulation is not only to increase safety but also to stimulate innovation for increased competitiveness which doesn't occur if process/product innovation is introduced for mere compliance.

1.1.4 Restriction

Restrictions are an instrument to protect human health and the environment from unacceptable risks posed by chemicals. Specifically, they are normally used to restrict or prohibit the manufacture, placing on the market (including imports), or use of a substance, but may impose any relevant conditions, such as requiring technical measures or specific labeling.

A restriction can be applied to any substance on its own, in a mixture, or in an article, including those that do not require registration, for example, substances manufactured or imported below one tonne per year or certain polymers.

On-site isolated intermediates, substances used in scientific research and development, and substances that only pose a risk to human health due to their use in cosmetics are exempt from the restrictions of REACH.

1.3 Two very important Articles

We now turn to two articles that may be relevant for companies.

Article 14

According to Article 14, a chemical safety assessment and chemical safety report must be carried out for all substances subject to registration in quantities of 10 tonnes or more per year per registrant. If the registrant concludes that the substance meets the criteria for any of the hazard classes or categories in Annex I of Regulation (EC) No. 1272/2008 or is assessed as PBT or vPvB, the chemical safety assessment shall include the following additional steps. In order, it includes exposure assessment, including the generation of exposure scenarios (or the identification of relevant use and exposure categories, if appropriate), exposure estimation, and risk characterisation. These stages must cover all identified uses of the registrant. According to Article 3, identified use means a use of a substance on its own or in a mixture or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.

Article 31

The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled by Annex II:

(a) whether a substance or mixture meets the criteria for classification as hazardous by Regulation (EC) No 1272/2008; or

(b) whether a substance is persistent, bioaccumulative, toxic or very persistent by the criteria set out in Annex XIII; or

(c) whether a substance is included in the list established by Article 59(1) for reasons other than those referred to in points (a) and (b).

Any actor in the supply chain who is required, under Article 14, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment.

Any actor in the supply chain who is required to prepare a chemical safety report according to Article 14 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI. The SDS that has the exposure scenarios as an attachment is called an extended safety data sheet.

Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

The impact on companies?

When downstream users receive a safety data sheet, they need to identify and apply appropriate measures to adequately control the risks. When it is an extended SDS, they must additionally check whether the exposure scenario covers their own use of the substance and their conditions of use, otherwise, they should take alternative measures.

Uses not covered by the registrant may be acceptable if:

- The use and exposure are broadly inside the conditions, due to lower risk or similar use (such as “brushing” where “spraying” or “rollering” was registered).
- The user uses less than a tonne per year of the substance or mixture, and ECHA is notified within 6 months.
- The substance or mixture is being used for Process or Product Oriented Research and Development and ECHA is notified within 6 months of first use.

If Uses not covered do not fulfil one of these, the user will have to undertake one of the following:

- A Downstream User Chemical Safety Report within 12 months of receipt of the substance registration number through the safety data sheet and notify ECHA within 6 months (this may be the preferred solution for highly confidential process applications).
- Persuade the registrant to update the registration dossier to include the missing uses.
- Implement changes to use and risk management measures to align with those registered.
- Substitute the substance with a different substance for which an exposure scenario is not required or where exposure scenarios are available that cover their conditions of use.
- Substitute the process with a process not requiring the substance.
- Find another supplier who provides the substance or mixture with an exposure scenario that covers their use.

1.4 Communication requirements

Data sets resulting from the REACH should provide relevant information on the hazardous properties and environmental behaviour of substances. The most appropriate strategies for managing the associated risks should be evaluated concerning the intended use of the substances. Protection of the environment and consumers, one of the main objectives of the regulation, is achieved through the communication of critical information (such as properties, behaviour, and strategies) to all companies using REACH-regulated substances within their supply chain.

Here are some articles on reporting obligations.

Article 32

The supplier of a substance on its own or in a mixture, which is not required to provide a safety data sheet in accordance with Article 31, shall provide the recipient with information on safe handling.

Article 33

Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) (in a concentration above 0,1 % weight by weight (w/w)) shall provide the recipient of the article with sufficient information (available to the supplier) to allow safe use of the article. In particular, at least the name of the substance should be communicated.

Article 34

Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain:

(a) new information on hazardous properties, regardless of the uses concerned.

(b) any other information that might call into question the appropriateness of the risk management measures (which are identified in a safety data sheet supplied to him), which shall only be disclosed for the identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

Article 37

Any downstream user has the right to make the use known in writing (at least the brief general description of the use on paper or electronically) to the manufacturer, importer, downstream user, or distributor who supplies him with a substance (either on its own or as a component of a mixture), to make an identified use of it. When disclosing a use, he shall provide sufficient information to allow the manufacturer, importer, or downstream user who has supplied the substance, to prepare an exposure scenario (or a use and exposure category, if necessary) to be used in the manufacturer, importer or downstream user's chemical safety assessment.

On the one hand, distributors shall pass on such information to the next actor or distributor up the supply chain. On the other hand, downstream users receiving such information may prepare an exposure scenario for the identified use(s) or pass the information to the next actor up the supply chain.

Chapter 2 PORTER'S HYPOTHESIS APPLIED TO REACH

This Chapter will introduce Porter's hypothesis (1995), of which REACH is intended to be a case study. To understand Porter's thinking (1995), one must start with the concept of product life cycle and design. The former highlights how the activities of companies, ranging from the production of the components of the final product to its disposal, can lead to a negative externality for society (Ashby, M. F. 2013)[2]. In the following, this externality, to be consistent with the terms used by Porter (1995), will be defined as pollution. The term pollution is limiting when applied to the scope of REACH, which focuses not only on the environment but also on human health. Consequently, when applying the hypothesis to REACH, reference will be made to a broader negative externality. The second concept highlights how the activities of companies that produce a negative externality are defined in the design phase of both process and product. Therefore, this negative output for society is a variable under the control of companies (Ashby, M. F. 2013).

After delving into how the design phase defines the life cycle of a product, we will enter the Porter hypothesis (1995) that starts from a fundamental principle, which defines pollution as an inefficiency for companies. According to this thinking, companies can benefit from environmental regulation that stimulates innovation, both process, and product, aimed at reducing inefficiencies. Porter (1995), contrasting a static view with a dynamic one, states that this change is only possible if companies consider processes and products as something non-fixed. The concept of design plays a key role in the dynamic view, as it allows companies to redefine the product life cycle by decreasing the negative externality for society. The change represents a cost for the company that brings a benefit in terms of efficiency. According to Porter (1995), the reduction of inefficiencies may not only decrease the cost of compliance but even offset it. If this happens, the competitiveness of companies increases as a result of environmental policy.

The final part of the Chapter focuses on the objective of the paper. REACH becomes a case study of Porter's hypothesis (1995), where negative externalities are defined as damage to the environment and human health caused by regulated substances. It is intended to

[2]Ashby, M. F. (2013) *Materials and the Environment: Eco-Informed Material Choice*. Second Edition. Oxford: Elsevier, pp. 49-68

investigate whether REACH, by acting on negative externalities, can trigger the innovation mechanism. Furthermore, it is intended to answer another important question, namely whether the innovation mechanism can more than compensate for compliance costs, as desired by regulators.

2.1 Companies control negative externalities

In this section, we will lay the foundation for understanding Porter's hypothesis (1995). First, the concept of the product life cycle will be introduced, and then we will move on to the concept of design. The focus will be on the relationship between the two, as it shows how the negative externality is under the control of companies (Ashby, M. F. 2013). This is the fundamental principle underpinning the dynamic view, which we will discuss later. This is the view in which environmental regulation becomes a stimulus for innovation and not a constraint for regulated firms.

2.1.1 The product life cycle

The product life cycle consists of several stages, each of which requires inputs and produces an output. Inputs are resources, such as raw materials and energy, which represent a cost for companies (Ashby, M. F. 2013). As the focus is on the negative externality, the output is pollution, which represents a cost to society and indirectly also to companies, as it demonstrates, according to Porter (1995), inefficient use of inputs.

Figure 2:1 shows one of the possible product life cycles (Ashby, M. F. 2013). The activities carried out by companies depend on the final product. Therefore, the below diagram is purely illustrative and not exhaustive of all possible value chains. However, there are similarities with the supply chain of the chemical industry to which REACH applies. Regulated substances can be considered as components of the final product. If one contextualises the diagram in the chemical industry, the production process is the mixing or manufacturing of articles. Substances may also be included as inputs in the process and not be part of the final product.

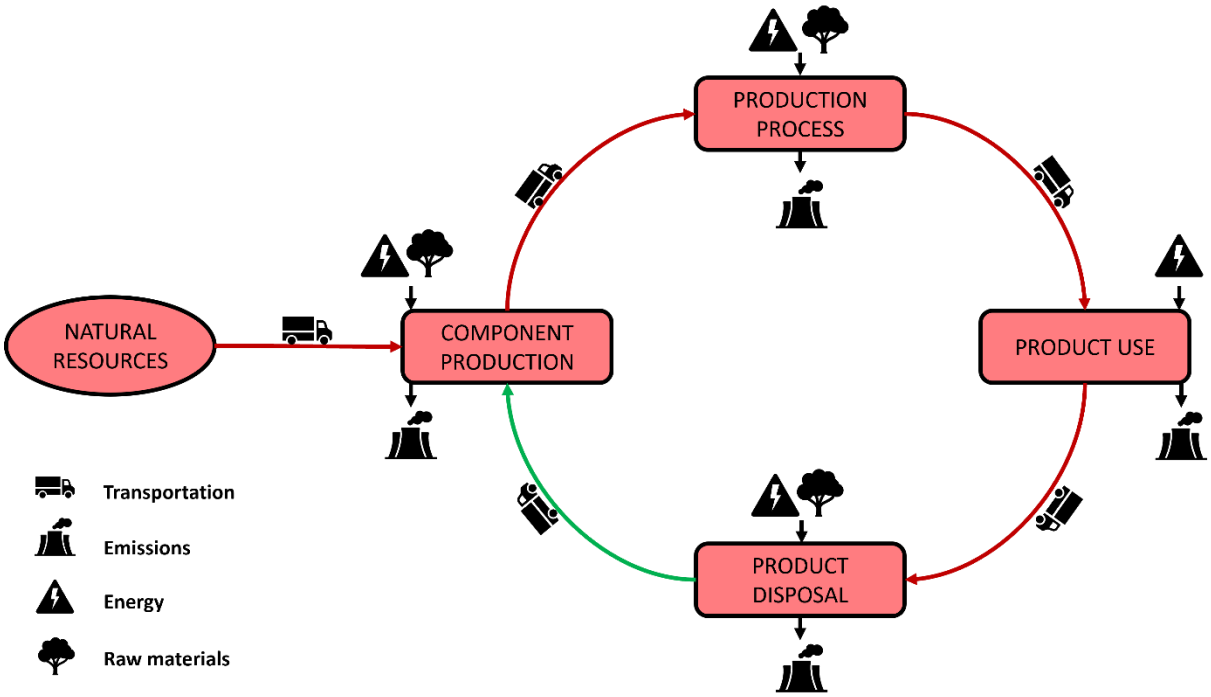

Figure 2:1 - The product life cycle

Referring to the example shown in the figure, the product life cycle begins with the extraction of natural resources, which are transported to the manufacturer. The manufacturer, using energy and raw materials, produces the components of what will be the final product. The components are sold to the downstream user, who, using energy and raw materials as input, makes the final product. Once the final product, which requires energy to operate, is manufactured, it is sold to customers. When the product reaches the end of its usefulness to the customer, it passes to the disposal phase. The disposal phase, using energy and raw materials, seeks to recover resources that can be used for the component manufacturing process. After the disposal phase, the life cycle of the product is completed (Ashby, M. F. 2013).

Using the definitions of the actors identified in Article 3 and applying the diagram to the chemical industry, the supplier of the components (substances) is the importer or manufacturer. There may be an intermediate step if the substance is sold to a distributor before reaching the downstream user. The downstream user introduces the resource into its production process to produce a mixture or article. The customer may be another downstream user, or the product might be destined directly for the consumer market.

The output, which in the diagram legend is defined as generic “emissions", in the case of REACH refers to damage to the environment and human health. In the production process of

substances, such damage may be caused by the release of harmful substances hazardous to the environment and humans, or by an accident occurring to a worker. The same applies to the production of the final product, but also all transport phases of substances, mixtures, and articles. Externalities can occur both during the use of the end product and afterward, for example, if a harmful substance is released into the environment.

2.1.2 The design phase

As already mentioned, the life cycle stages of a product require resources, such as energy and raw materials, and release pollution into the environment (producing a negative externality). Figure 2:2 represents how the life cycle stages are determined during product and process design (Ashby, M. F. 2013). On the one hand, product design defines the components used and the product architecture, i.e., how the components are assembled, influencing the process design. In addition, product design is functional to the use made by the end consumer, we speak of customer-centered design when product design begins with an understanding of customer requirements. The assembly of components, given by product architecture, determines the disposal phase. Process design, on the other hand, defines how the product is manufactured (Cantamessa, M., and Montagna, F. 2016)[3]. Therefore, the inputs and outputs of a product's life cycle are variables under the control of companies, which can intervene in the design phase (Ashby, M. F. 2013).

[3]Cantamessa, M., and Montagna, F. (2016) *Management of Innovation and Product Development: Integrating Business and Technological Perspectives*. London: Springer

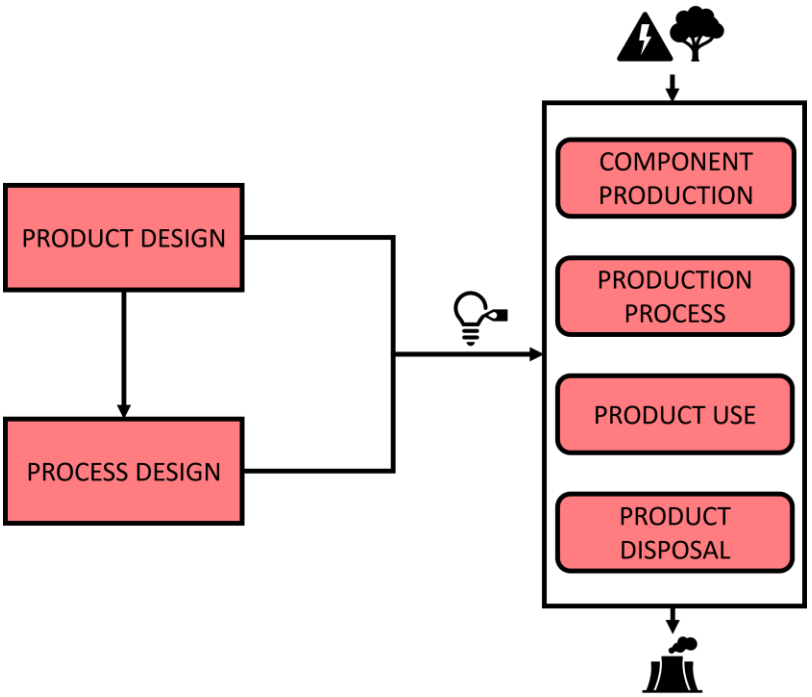

Figure 2:2 - Relationship between design and product life cycle

It is more difficult for a company to intervene in the product than in the process, precisely because of the relationship that exists between the product and process. Changing the product, if we are talking about complex products, most probably also requires intervention in the production process. Especially, if the innovation does not concern the simple replacement of a component, which might keep the assembly process unchanged, but the product architecture. As product architecture represents the relationship that exists between the components of the final product. Without considering that, in the case of a customer-centered approach, there should be a very complex market analysis work upstream (Cantamessa, M., and Montagna, F. 2016).

A different argument can be made for process innovation which, as mentioned above, is simpler, as it keeps the end product unchanged and intervenes in production. This is true when referring to a product industry, such as the chemical industry, and not a service industry. For the service industry, the process/service is the end product, so the roles are swapped (Cantamessa, M., and Montagna, F. 2016).

Product innovations in the chemical industry can affect a mixture, where a substance is replaced. This is a non-complex change, which does not trigger a process innovation. It is a different matter if we consider more complex chemistry, for example, the creation of an

active ingredient for use in pharmaceuticals. In this case, the design innovation certainly also activates a process innovation.

As far as process design is concerned, the change may affect a part of the handling process, or it may affect it in its entirety. In the first case, it is a marginal change that is easy to implement, which may concern, for example, the substitution of a substance for cleaning the machine between two processes. In the second case, it is a complex process innovation that can also have a major impact on the company in terms of adoption costs (Cantamessa, M., and Montagna, F. 2016).

REACH has the potential to trigger both process and product innovations, which may or may not be complex. The directive, through the authorisation and restriction process, can limit the use of certain substances. In addition, compliance costs, which include registration, may induce some companies to exit the market (Najjar, N., and Cherniwchan, J. 2018)[4]. If the discontinuity of supply or the limitations affects a substance used as a component in the production of the finished product, we have a product innovation. Consequently, if they affect a substance that is a resource in the production process, we have a process innovation.

2.2 Porter's hypothesis

According to Porter (1995), pollution often represents a form of economic waste for companies. When scrap, harmful substances, or forms of energy are discharged into the environment in the form of pollution, they are a sign that the resources have been used incompletely, inefficiently, or ineffectively. Moreover, companies must perform additional activities which add cost but do not create value for customers, for example, handling, storage, and disposal of discharges.

In the case of REACH, hazardous substances could involve costly safety measures, not to mention the economic and image impact in the event of damage to people or the environment. One of the companies interviewed, ICE S.p.A in Basaluzzo reported that it had carried out special drills with the fire brigade to manage the risk of an SVHC used in its processes. Within the supply chain, inefficiencies related to harmful substances could be

[4]Najjar, N., and Cherniwchan, J. (2018) 'Environmental Regulations and the Clean-Up of Manufacturing: Plant-Level Evidence from Canada', *University of Alberta School of Business Research Paper No. 2018-701*, pp. 7-20

linked to a mono-sourcing condition, where the substance becomes a constraint for the company's growth. This is because, if a hazardous substance is used, it means that there are not many alternatives available. Furthermore, the use of an SVHC could have a negative impact on brand image. The company Sutter, which participated in the interview, has a sustainable vision appreciated by its customers and replaces SVHCs even before the expiry date.

Environmental regulations address the negative externality to reduce it. The company's response to regulation determines the impact on its competitiveness. There are two possible opposing reactions to the directive. Porter (1995) contrasts a static view of a fixed trade-off between sustainability and competitiveness, in which the company passively undergoes environmental regulation, with a dynamic view, in which the company reacts to environmental legislation. From the latter perspective, the legislation becomes a stimulus for innovation to reduce the inefficiencies of which pollution is a manifestation. If the reduction more than offsets the compliance costs, the competitiveness of regulated companies increases. Conversely, if this is not the case, the companies concerned are at a competitive disadvantage.

In this paragraph, we will compare the two contrasting approaches in response to the introduction of an environmental policy. We will start with the static view and then move on to the dynamic view. In conclusion, the aim of the paper will be introduced, which is to use the REACH regulation as a case study of Porter's hypothesis.

2.2.1 Static view

The static view sees compliance with the regulation as an additional cost to companies. In the static view, the production process and the product are fixed and represent the boundary of the system in which the interaction between regulation and companies takes place. The regulation aims to limit the pollution of product life cycle stages by making companies that generate negative externalities on society as a result of their activities pay. Usually, polluting behaviours are reduced by imposing a tax on the polluter.

In the static view depicted in Figure 2:3, companies do not react to the cost imposed by the regulation, as the product and process are fixed. The inability of companies to react leads to

a fixed trade-off between sustainability and competitiveness. Regulation is seen as an additional constraint in a static system that leads to an increase in the costs incurred by companies. In this view, environmental regulations can only have a negative impact on companies, specifically, the regulations generate an additional cost that puts regulated companies at a disadvantage compared to competitors not subject to the same provisions.

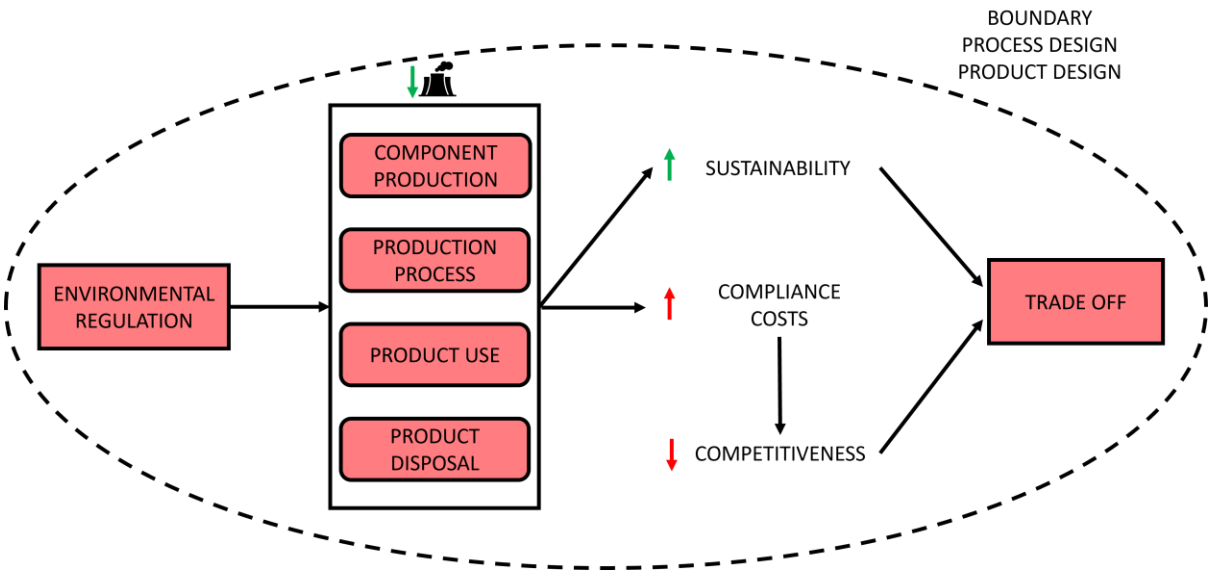

Figure 2:3 - Static view

Consider the REACH authorization process, which states that without authorization from ECHA a company cannot use or manufacture a substance of very high concern. A downstream user who sees his process and product as fixed can only apply for authorisation to continue using the substance. The application for authorization has a very high cost, which the downstream user is inevitably forced to bear. This cost places the company at a disadvantage compared to competitors outside the European Economic Area, which are not subject to the same constraints of the authorization process.

2.2.2 Dynamic view

According to Porter (1995), regulators and companies need to change their mindset about environmental sustainability. Pollution must not be considered something inevitable, or at least not always inevitable, and pollution must be framed in terms of inefficiency. Pollution is something inherent in a certain process and product, but that process and product can change. Environmental regulation is a constraint as long as the process and product are fixed, generating an additional cost for the company. If the design of the regulation is able to lead

to overcoming the inertia towards innovation, the constraint no longer exists, since the system in which the interaction between the company and regulation takes place has changed. For this reason, the boundary has been removed in the representation of the dynamic view in Figure 4.

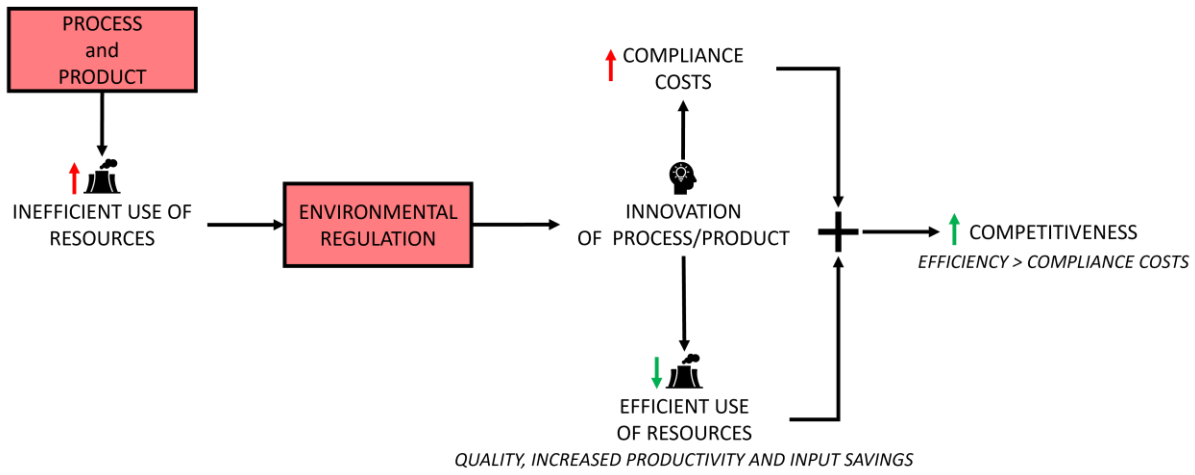

Figure 2:4 - Dynamic view

Following Porter's hypothesis (1995), pollution is the main manifestation of inefficiency in the design of the product or process. Therefore, if the regulation is realised in such a way as to stimulate innovation that eliminates or reduces this inefficiency, the regulation can increase the competitiveness of companies If we think in terms of productivity, a legislation that reduces the variable cost of production (by stimulating process innovation) leads to an increase in the company's competitiveness if the reduction is such that it offsets the cost of adoption.

If we consider the example above concerning the authorization process from the perspective of the dynamic view, the downstream user is no longer obliged to apply for authorization, as the product and the process are not to be considered fixed. If, on the one hand, the SVHC is a component of a final product, which could be a mixture or an article, the downstream user has the possibility to intervene in the product design in such a way as to replace the substance with a safer one. If, on the other hand, the SVHC is used in the production process, the company has the possibility to intervene with process innovation. By eliminating the dependence on the substance of very high concern, the constraint of regulation does not exist.

According to Porter's hypothesis (1995), innovation, whether of process or product, can increase the competitiveness of the company. Still referring to the SVHC example, the substitution of this substance could lead to the elimination of previously necessary safety procedures. In the event of a shortage in the supply of SVHC, which is a key resource in the production of the finished product, the use of an alternative substance could remove a limitation on company growth. In addition, if a process innovation for the elimination of SVHC is introduced, it could lead to higher productivity than the previous production process.

2.2.3 REACH as a case study

REACH is an environmental policy that addresses the negative externalities associated with substances marketed, used, and produced in the European Economic Area. The regulation intervenes through four main processes: registration, evaluation, authorisation and restriction. These can have a major impact on the companies concerned for several reasons. Firstly, it may lead to a chemical being restricted or requiring authorisation. Secondly, compliance costs may lead to a decision to no longer manufacture a substance (Najjar, N., and Cherniwchan, J. 2018). Thirdly, as a consequence of the first two points, it can lead to the interruption of the supply of substances, affecting production processes and finished products.

The regulation lends itself to being studied as a case study of Porter's hypothesis (1995), as it addresses externalities through provisions on substances. The extent of the impact on companies and, consequently, the outcome on competitiveness depends on the design of the regulation. Design is one of the main determinants of the two contrasting scenarios analysed previously (Dechezleprêtre, A., and Sato, M. 2017)[5].

For example, static view occurs if the costs associated with the registration and authorisation processes are so high that companies are better off reducing volumes or going out of business than being compliant. Or if ECHA restricts an SVHC of great economic importance without safer alternatives. In these cases, the impact of the regulation can only be negative on competitiveness. Conversely, the dynamic view occurs, for example, if the costs associated with the registration process are limited, as they grow with volumes, and the resulting

[5]Dechezleprêtre, A., and Sato, M. (2017) 'The Impacts of Environmental Regulations on Competitiveness', *Review of Environmental Economics and Policy*, 11(2), pp. 183-206

increase in communication flow allows inefficiencies to be identified and addressed through innovations. In the case of the dynamic view, the result on overall competitiveness needs to be further investigated, as the reduction of an inefficiency does not necessarily compensate for the costs of adoption and compliance.

The realisation of Porter's hypothesis (1995) is not only related to the ability of a regulation to trigger an innovation mechanism, as envisaged in the dynamic view. A key question is whether the increase in efficiency is able to cover the costs resulting from the directive. This is the only way to increase the competitiveness of the companies concerned. Otherwise, innovation becomes a way to limit impacts.

Figure 2:5 clearly represents the objective of the thesis paper, which, through interviews with companies, aims to answer the two "question marks" underlying Porter's hypothesis (1995). The first is whether the regulation led companies to innovate as expected in the dynamic view. The second is whether the innovations introduced more than offset the costs generated by the regulation by increasing the competitiveness of companies.

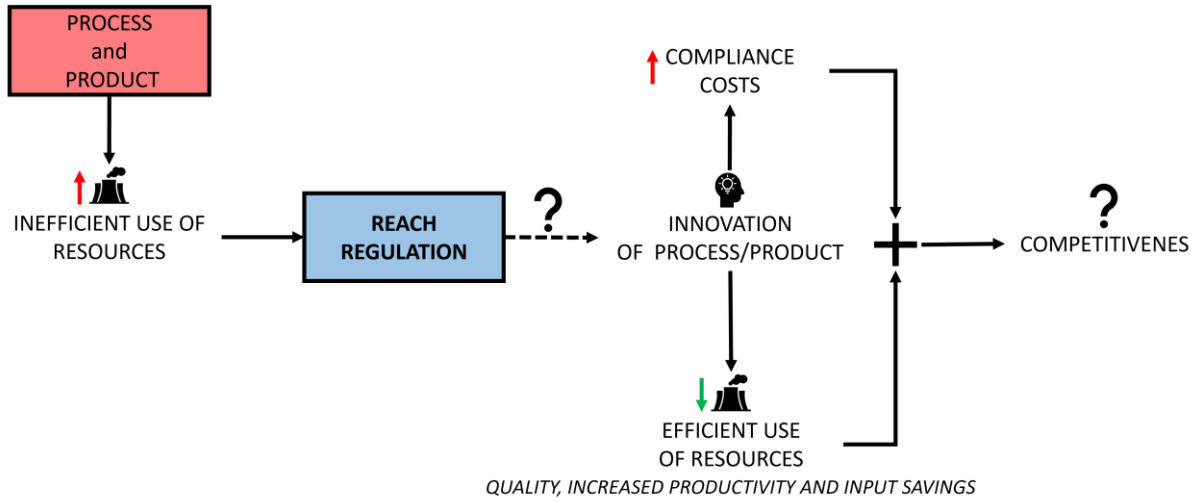

Figure 2:5 - The case study

Chapter 3 DEFINING INTERVIEW QUESTIONS

The following Chapter will introduce the analysis carried out on REACH for the identification of possible impacts on regulated businesses. This is an essential passage for conducting the interview, a logical step that follows the explanation of the regulation. Based on the identified impacts, questions will be asked to determine the extent of these and the effect on overall competitiveness. This is done in order to test the applicability of Porter's hypothesis (1995).

The interview questions and structure will be presented in the final part of the Chapter.

3.1 Analysis of REACH impacts

Before proceeding with the analysis, it is necessary to define what is meant by competitiveness. In the following, this concept will be divided into four dimensions, each corresponding to a subparagraph in the Chapter. The first concerns production costs, which are usually subject to environmental policies. The second covers innovation, a topic closely linked to Porter's dynamic view (1995), while the third examines the supply chain, on which, as we have already mentioned, REACH can have a strong impact. The last one analyses international relations, both in terms of imports and exports (Dechezleprêtre, A., and Sato, M. 2017).

For each of the dimensions listed above, the impacts of REACH were identified. For the identification, reference was made to the literature concerning the relationship between environmental policies and competitiveness. The general equilibrium models produced for other directives (in particular for air quality standards) and ECHA's periodic reports on the evaluation of the achievement of REACH objectives contributed to the investigation. The knowledge developed during the studies played a key role, as the analysis did not limit itself to reporting evidence from ECHA reports but attempted to infer impacts by exploiting the materials read (literature and similar projects on other regulations).

3.1.1 Production costs

Regulatory differences between companies, sectors, or jurisdictions can cause variations in relative production costs, distorting competition. A common thought among many is that

companies with stricter policies are at a disadvantage (Dechezleprêtre, A., and Sato, M. 2017). According to Porter (1995), however, there is no such cause-effect link between tight regulation and higher costs. In the following section, we will look in detail at REACH to see what the possible cost outcomes are.

The impacts were divided into two categories. The first relates to fixed costs associated with the registration and authorisation processes, whereas the second concerns variable costs. For both classifications, the possible effects of REACH are presented below.

3.1.1.1 Fixed costs

The costs associated with the registration and authorisation process have been defined as fixed costs. As explained in Chapter 1, the former involves a cost for registering a substance and the latter for applying for authorisation. Since registration is only carried out once by a company (not counting tonnage changes for which an update with missing information is required) and authorisation is valid until the next review, the costs associated with these processes do not vary with the quantities produced.

Registration

All manufacturers or importers of chemical substances in volumes exceeding 1 tonne/year/enterprise need to register them at the European Chemicals Agency (ECHA) in Helsinki. To register a substance, a company must pay a registration fee, the cost of searching for data, and the management costs of the SIEF Consortium. These fixed costs, by eroding profits, bring companies that are unable to sustain them to a crossroads (Najjar, N., and Cherniwchan, J. 2018). They can either decide to stop producing/importing, thus exiting the market, or they can reduce the volume to below 1 tonne per year (even by transferring part of the production to their subsidiaries outside the EU) (European Commission 2021)[6].

The impact of the registration process is not the same for all businesses. The companies most affected by the regulation are those with low productivity, since, given the high variable costs, registration can lead to a negative profit. The magnitude of the fixed costs associated with the regulation is key to understanding its impact. If these costs are relatively high, only highly productive firms comply by registering the substance. Instead, companies with low

[6]European Commission (2021) 'Study on the impacts of the 2018 REACH registration deadline'

productivity will adapt by reducing production to below 1 tonne per year or by exiting the market (Najjar, N., and Cherniwchan, J. 2018). The size of the market also plays a role in deciding whether to register a substance, as the cost of registration is spread over the units sold. This means that the greater the number, the lower the impact on the unit profit margin (Dechezleprêtre, A., and Sato, M. 2017).

Another discriminating factor between companies is size, as small and medium-sized enterprises (SMEs) find it more difficult to understand their obligations. Furthermore, they have limited resources to cope with the costs, administrative requirements, and adaptations requested by REACH. It should also be considered that the human capacity in terms of personnel and skills required to comply with REACH obligations is clearly limited in these companies. For this reason, they are likely to rely on external compliance consultants (Scruggs, C., Ortolano, L., Wilson, M., and Schwarzman, M. 2015)[7]. The last business differentiation element considered is the ability to absorb regulatory costs caused by market price sensitivity. In particular, if price sensitivity is high, the company cannot reflect the cost increase in the sales price and thus avoid reducing the unit profit margin (Dechezleprêtre, A., and Sato, M. 2017).

As already mentioned in Chapter 1, the registration process aims to expand the available data on the properties and hazards of substances. Therefore, the objective of REACH is not to induce companies to reduce production or exit the market in response to registration costs. In accordance with the goal, companies are encouraged to register jointly to reduce the cost impact. In addition, ECHA is increasing compliance support to ease the burden on companies, especially small and medium-sized ones (European Commission, 2021).

Based on the above, interviews with companies can be used to investigate the extent of the registration cost. It is the latter, together with differentiating factors (e.g., market size) that determine the effect of the process. This may concern the number of units produced, bringing them below one tonne per year, or continuity of supply. The mentioned impacts must be addressed by the questions alongside the decision driver on volumes and market exit.

[7]Scruggs, C., Ortolano, L., Wilson, M., and Schwarzman, M. (2015) 'Effect of company size on potential for REACH compliance and selection of safer chemicals', *Environmental Science & Policy*, 45, pp. 79-91

We can expect that the responses of companies will not be the same, as they differ in size, market, and productivity. Of great importance is the position in the supply chain since the registration requirements for a manufacturer are different from those for a downstream user. Most likely, the impact will be limited for medium-sized companies. This is what the ECHA reports have found and what we can deduct from the literature review. Overall, it can be said that the registration process, given its structure and purpose, is expected to have a limited impact on costs, except for SMEs.

Authorisation

Substances included in the authorisation list, after the defined expiry date, may not be placed on the market for a use or used without prior authorisation by the European Commission unless that use is exempt from authorisation.

The REACH authorisation process involves fixed costs that have a similar effect on companies as those analysed above for the registration of substances. Highly productive companies, large companies, companies in a large market, and companies in a market characterized by low price sensitivity are more likely to apply for authorisation, both in the case of applications for sale (producers and importers) and in that of applications for use (downstream users).

The authorisation process has a greater impact on companies than the registration process, as there are no threshold criteria. Most Annex XIV substances are subject to authorisation at any level of quantity/concentration, which is more costly and complex, plus the Commission can review an authorisation at any time. Therefore, it may be cost-effective to replace the SVHC by developing a safer substance or modifying the production process that requires it, instead of applying for authorisation.

The questions concerning the economic impact of authorisation, which must be submitted to companies, will be analogous to those for registration. This is because both processes entail fixed costs, the magnitude of which must be understood in order to have an insight into the possible effects. As fixed costs, they can determine entry or exit decisions (Najjar, N., and Cherniwchan, J. 2018). In particular, in the case of the authorisation process, volumes are not affected because there are no threshold criteria.

Accordingly, we expect a greater economic impact than the registration process. The resulting decisions will follow the discriminating factors already introduced for registration. Among

them, the position within the supply chain loses some relevance, as all actors can apply for authorisation and the obligation affects everyone independently. Nevertheless, manufacturers and importers are most likely to apply given the higher volumes.

We foresee a low number of applications, consistent with the objective of the regulation, compared to SVHC substitutions. This is because the process analysed is very complex and has an uncertain outcome. Moreover, many inefficiencies are usually associated with hazardous substances, so it would also be in the interest of companies to eliminate them. This is especially true for very plain production processes such as mixing, which is a simple substitution that does not affect the entire manipulation. In the case of complex chemicals, where process/product innovation is very elaborate, companies may opt to make an application of authorisation. It should also be considered that the economic analysis and the assessment of the availability of alternatives are carried out upstream of the granting of authorization. It is therefore possible that the conditions are not met, and that substitution is the only option.

3.1.1.2 Variable cost

Companies that comply with REACH face fixed costs and in some cases also an increase in variable costs. In this section, we will deal with the second type, which changes in proportion to the quantity produced or sold. In particular, the impact on productivity, on which REACH may have an indirect effect, and on raw materials used will be analysed. In conclusion, the possible reaction to this phenomenon in terms of pricing and portfolio decisions will be explored.

Let's start with productivity, where the increase in variable costs occurs, for instance, if a company is forced to implement a new production process or adopt a new substance that does not increase its efficiency (Najjar, N., and Cherniwchan, J. 2018). We contextualise the example to the REACH, considering a downstream user that produces articles and receives an extended SDS. According to the directive, it must check whether the exposure scenario covers its use of the substance and its conditions of use. This small case study provides an insight into the impact of a variable cost increase.

Suppose that the downstream user's use of the substance is not covered; to comply, the downstream user decides to replace the process that uses the substance with one that does not require it. This new process is less productive than the previous one and the downstream user now incurs higher variable costs. The increase in the marginal cost of production leads to an increase in the selling price of the item produced by the downstream user and, consequently, to a reduction in the volume sold (Najjar, N., and Cherniwchan, J. 2018).

According to the example, REACH may not only reduce the profitability of regulated companies through fixed costs but may also influence sales volume, prices, and revenues by changing variable costs (production costs) (Dechezleprêtre, A., and Sato, M. 2017). This is a very important point that relates to one of the questions the interview aims to answer. As mentioned in the previous Chapter, for Porter's hypothesis (1995) to occur, it is not enough for the innovation mechanism to be activated. What is crucial is the effect the change has on overall competitiveness. In this small case study, the efficiency of the initial state of the production process is worsened by directive-induced novelty.

Let us now turn to the impact on the cost of raw materials. Given the above, registration and authorisation processes can lead to increased production costs for manufacturers and importers. If this increase in expenditure occurs, it is logical to think that it is reflected, according to market sensitivity, on the downstream user since substances are inputs to produce articles/mixtures or used in production processes (Dechezleprêtre, A., and Sato, M. 2017). Downstream users are therefore subject to an increase in direct/indirect costs, the impact of which is comparable to that of a reduction in efficiency.

The type of response to rising production costs depends to a large extent on the structure of the market under consideration. Companies can increase prices to reflect costs without losing competitiveness in markets where demand is inelastic or higher than supply. Where profit margins are high, companies can absorb REACH costs in prices, but with limited impact on profitability. For companies operating with low-profit margins and in markets where they cannot increase prices without losing market share or profitability, REACH costs may lead to a decision to reduce or discontinue the supply of a specific substance/mixture/article (Dechezleprêtre, A., and Sato, M. 2017).

It is important to investigate the effect of REACH on variable production costs, both related to productivity and raw materials. Consequently, analyse the outcome on profits, sales volumes, prices, and revenues. A cost-related issue is that of the product portfolio, which has already been introduced earlier but takes a different perspective here. This aspect, in fact, also concerns companies that do not have to register or are not affected by the authorisation.

3.1.2 Innovation

As explained in the previous Chapter, for an increase in competitiveness to occur, environmental regulation must stimulate change. This section discusses the impact REACH had on innovation, namely the concept behind the dynamic view.

Let's start by analysing the objectives of the registration and authorisation process, to see if they are able to increase the entropy of companies. In the case of the authorisation process, this occurs. This is because the aim is to lead to the replacement of hazardous substances in the production process in which they are used through the development of processes that do not require such substances and the development of new safer substances that apply to the same use. This innovation drive is triggered by the fact that the cost of applying for authorisation is higher than the cost of replacing the hazardous substance. Instead, the registration process has the purpose of collecting information on properties and hazards in order to assess whether the risks associated with the substances can be adequately managed. However, the registration process, in turn, can lead to innovation (a downstream user receiving an extended SDS must check whether the exposure scenario covers its use of the substance and its conditions of use or take alternative action).

Based on the above, REACH may induce companies directly affected by the provisions to replace products and processes. In some cases, this substitution is almost compulsory. However, it is important to note that innovation can also be induced indirectly, as regulation changes the costs incurred by companies compared to the initial state before its adoption (Najjar, N., and Cherniwchan, J. 2018). As proof of this, reference can be made to the previous sections on fixed and variable costs. In response to that, companies are driven to overcome inertia toward change since they want to compensate/limit the increase in expenses with increased process efficiency.

To be introduced, innovation must lead to an increase in productivity, thereby reducing the variable cost to the point where the fixed cost of adoption is justified (Najjar, N., and Cherniwchan, J. 2018). When it comes to regulation-induced innovation, the increase in efficiency limits the negative impact of compliance costs. If these offset each other, Porter's hypothesis (1995) is fulfilled. Conversely, if this is not the case, the competitiveness of companies decreases. This is especially true if the novelty is introduced only for compliance, without the company leveraging the stimulus of the directive to improve the current state.

Not all companies have the same interest in intervening in the design phase. In particular, those that compete in a relatively large market and/or have a high level of productivity, thus selling the most units given the low marginal production cost, have a greater incentive to innovate by introducing new production processes and technologies in response to regulation. These companies are able to bear the fixed cost of adoption thanks to low variable costs and/or high volume (Najjar, N., and Cherniwchan, J. 2018).

According to the literature, the registration and authorisation processes can also have a negative impact on innovation. The former requires that new substances produced in volumes above one tonne per year must be registered in order to be marketed in the EEA. The resulting collection of data on the properties and hazards of substances can affect the time to market (European Commission 2021). These delays reduce the window of opportunity, the time available to exploit learning economies, and the accumulated advantage over competitors in the product development phase (Cantamessa, M., and Montagna, F. 2016). In addition to time, uncertainty about the return on investment also increases, as new substances may also be subject to authorisation in the future. If this happens, the chemical will most likely be removed from the market. Therefore, both processes may increase the risk of introducing innovations, which may lead companies not to undertake them (European Commission 2021).

We have seen how rising costs a driver for innovation can be, but the resources of companies, especially SMEs, are limited (Scruggs, C., Ortolano, L., Wilson, M., and Schwarzman, M. 2015). Expenses generated directly/indirectly by regulation, related to registration, authorisation, and pricing of raw materials, may hinder productive investments in innovation or efficiency improvements, slowing productivity growth. There is evidence in the literature that regulatory-induced environmental innovations tend to substitute other innovations, leaving

the overall level of innovation unchanged. Furthermore, R&D resources may be shifted to compliance activities to increase resources in that area (Dechezleprêtre, A., and Sato, M. 2017).

The interview with companies should touch on several points related to innovation. Firstly, it will analyse what changes have been introduced as a result of the registration and authorisation processes, focusing on the driver and the result in terms of efficiency. Secondly, it will consider which situations of inertia the legislation has led to overcoming. Third, it will examine what the overall outcome of competitiveness has been. Fourth, it will look at what was the effect of time to market and uncertainty in the development phase. Finally, the R&D budget and overall innovation rate will also be studied.

3.1.3 Supply Chain

In this section, we examine the impact of REACH on the supply chain. As a matter of fact, discontinuity in the availability of substances can have a strong impact on downstream users. We are talking about raw materials, the scarcity of which can lead to the interruption of production (European Commission 2021). This issue is closely related to what was said earlier about the product portfolio choices of manufacturers and importers. For this reason, the registration and authorisation processes become relevant again.

As stated in Chapter 1, except in specific circumstances (e.g., an annual quantity of less than 1 tonne), if vendors have not registered the substances they supply to a downstream user, they are not REACH-compliant and can no longer legally provide those substances. If suppliers do not apply for authorisation after the expiry date of a specific SVHC, they cannot legally deliver that chemical. Both processes have a cost and, consequently, can make the production/import of a substance unprofitable by discontinuing it or reducing its volumes (Najjar, N., and Cherniwchan, J. 2018). As a result, downstream users may suffer a disruption in supply.

There are several solutions that can be implemented by the downstream user to deal with this problem. If a substance he uses in his production process has not been registered, he may import the substance, replace it with a registered one or change the production process so that the substance is not needed. In the case of a substance subject to authorisation, the

downstream user may firstly apply for authorisation on behalf of the manufacturer/importer, secondly, replace the SVHC with a safer alternative for the same use, or even replace the production process requiring the SVHC. If these actions lead to unprofitable production, the downstream user might opt for rationalisation of its portfolio.

Another very relevant aspect of the supply chain concerns the reporting and information-sharing obligations under REACH. These can lead to greater investment in supply chains by EU/EEA companies, especially in countries outside the EU/EEA, in order to ensure REACH compliance. If this happens, it means that it is generally more difficult to switch to other suppliers in the short term. Indeed, if a company takes on the burden of supporting a non-EU supplier for the registration of a substance, it will do so in return for a contract of several years. Consequently, this reduces flexibility in supply chain choices and can decrease competitiveness (European Commission 2015)[8].

The impacts REACH may have on the supply chain are not only negative. ECHA's regular reports document that reporting requirements help uncover inefficiencies in processes and substances used which are addressed by rethinking the design phase (European Commission 2015).

On the one hand, interviews should deepen the supply chain topic by asking whether disruptions have occurred and what the impacts were. If, on the other hand, delivery interruptions did not occur, it is necessary to investigate what actions were taken to avoid them. With respect to communication requirements, benefits and investments are to be investigated. Concerning the latter, in particular, the effects on flexibility in the choice of the vendor must be analysed.

3.1.4 International Relations

One of the objectives of REACH is the protection of the internal market, so in this section, we will look at the impact on the import choices of EU companies. Another aspect that will be explored is that of exports to countries outside the European Economic Area. This part on

[8]European Commission (2015) 'Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs'

international relations has been saved for last since it is a direct consequence of what we have seen above.

Export

The insight behind environmental regulations is that they increase costs for domestic producers, which leads to a disadvantage in competing in foreign markets with companies that do not face similar policies (Dechezleprêtre, A., and Sato, M. 2017). There are two possible negative effects on exports which affect companies facing increased production costs. The first one is related to the reduction of export revenues (volumes) of continuing exporters, while the second one is linked to the exit of some companies from exports (Najjar, N., and Cherniwchan, J. 2022)[9].

The reduction in export volumes is the consequence of an increase in variable cost, whereas the exit from exports is due to the increase in (fixed and/or variable) production costs created by regulation (Najjar, N., and Cherniwchan, J. 2022). Following Melitz (2003)[10], if we assume that companies have to pay a fixed cost to enter the export market, the increase in costs leads some companies to no longer be able to pay for it. In relation to this, we must consider that the effect on exports is not the same for all companies, i.e., it is greater for the smaller exporters before regulation as they are the ones with the lowest level of productivity (Najjar, N., and Cherniwchan, J. 2022).

The REACH regulation can increase both fixed costs (registration and authorisation), by eroding profits, and variable production costs, affecting volumes, of companies that comply with the regulation, with consequent disadvantages in competing in foreign markets. Below we analyse the impacts of the registration and authorisation processes.

Since registration is required for substances manufactured in quantities of more than one tonne per year, the effect on export for European manufacturers is not so significant. A company that registers a substance and exports cannot be small and therefore have small sales volumes. As the cost of registration is spread over the units sold, the negative effect is

[9]Najjar, N., and Cherniwchan, J. (2022) 'Do Environmental Regulations Affect the Decision to Export?', *AMERICAN ECONOMIC JOURNAL: ECONOMIC POLICY*, 14(2), pp. 6-17

[10]Melitz, M. J. (2003) 'THE IMPACT OF TRADE ON INTRA-INDUSTRY REALLOCATIONS AND AGGREGATE INDUSTRY PRODUCTIVITY', *Econometrica*, 71(6), pp. 1695–1725

limited. For this reason, the impact of the registration process is greatest on the export of a downstream user subject to supply disruption.

The most significant impact on export is caused by the authorisation process, as there are no threshold criteria, it is very costly and complex, and it is intended to lead to the replacement of SVHCs. Let us consider a downstream user, located in the European Union, which produces articles. The article producer is currently using an SVHC included in the authorisation list in its production process. Once the expiry date has passed, the producer is faced with a choice between applying for authorisation or ceasing to use the SVHC. The downstream user decides not to register the SVHC, but to implement an alternative production process that does not require it. This process leads to an increase in variable production costs, thus to an increase in the marginal production cost. The downstream user is now at a disadvantage, compared to foreign companies not affected by REACH, when competing in the foreign market. For this reason, the producer is forced to increase the sales price, which leads to a reduction in export volumes. The increase in production costs could lead to the decision to exit the export market (Melitz, M. J. 2003).

In interviews, the effect of regulatory choices on export should be explored. Furthermore, it would be interesting to verify whether there is a difference in relevance between registration and authorisation, as identified in the analysis of impacts.

Import

As for exports, the analysis of imports will also assess and compare the impacts of the registration and authorisation processes.

As mentioned, several times, the REACH regulation requires the registration of imported substances in quantities exceeding one tonne per year. This process has a cost that the companies involved have to bear. It is therefore possible that a downstream user would prefer to buy from a manufacturer located in Europe, who has already registered the substance, rather than import it from abroad. Otherwise, it would be forced to assume the burden of compliance, unless an only representative has already done so. Importing would be preferable if no supplier has registered the substance that the downstream user needs. Therefore, the cost of registration is an expense for European producers, but it can give them

an advantage in internal competition against foreign competitors (Dechezleprêtre, A., and Sato, M. 2017).

Let us now turn to the second process considered. In the case of SVHCs, the downstream user would prefer a supplier, regardless of whether it is located in the EEA or not, that has applied for authorisation. An EEA supplier is more likely to bear the authorisation costs, as its main market is likely to be European and it is consequently able to amortise the costs over high sales volumes.

The negative effect of regulation, for companies that see their production costs increase, is certainly less on competition in the home market than in the foreign market. Since domestic companies are all subject to the same regulation, even if this does not have the same impact on all companies, and since substances supplied by foreign manufacturers are also liable to registration and authorisation (Dechezleprêtre, A., and Sato, M. 2017).

The interview should aim to find evidence that the REACH regulation has favoured imports from European Economic Area countries with a specific focus on the factors that led to this result.

3.2 Interview

After analysing the possible impacts of REACH on company competitiveness, we move on to the operational conduct of the interviews. This involves defining methodology and questions for the respondents.

3.2.1 Methodology

The methodology consists of profiling the companies of interest and the figures within them most appropriate to achieve the objectives set by the paper. Furthermore, the method and duration of the interviews were determined in order to extract as much value as possible from the participants' contributions.

3.2.1.1 Informants

It was decided to involve companies from the same geographical area. As we have seen from the previous analysis, the impact of REACH is closely related to the commercialized product (consequently to the market of interest and the position in the supply chain), the production process, and the size of the company. A variation in the spatial context would add complexity to the comparability of results and, consequently, to the assessment of the effects of the regulation on competitiveness

For the reason explained above, only companies with production facilities in the province of Alessandria were included. This is a hub of relevance at the Italian level, where the chemical industry has a widespread presence with an entrepreneurial network in which some giants stand out, whose turnover generates significant repercussions in the local area. There are also several production entities oriented to foreign markets and with product diversification covering a wide range of activities. The choice fell on the province of Alessandria also because of the weight of the ecological footprint left by this pole on the inhabitants of the area, which is linked to REACH's goal of increasing the level of protection of the environment and human health.

The identified professionals of interest must have a thorough knowledge of the regulation, occupy a job position that allows them to interface with REACH on a daily basis, and have been with the company for several years. These constraints were included because the questions, which will be presented later, are complex and articulate, as the result of an in-depth study of the directive and the literature on the impacts of environmental policies.

An attempt was made to involve as many companies as possible in the project, consistent with the geographic boundaries of the area of focus, the high standards required for participation, and the time frame necessary for conducting the interviews and subsequent analysis. In particular, ten enterprises were contacted, of which four agreed to be included in the thesis project.

3.2.1.2 Data collection

In order to collect the data necessary to answer the research question, it was decided to opt for a qualitative method, namely the semi-structured interview. This approach implies that

the interviewer provides guidance and direction, but does not preclude the possibility of interesting developments and deepening of certain topics by the participants.

The choice of such procedure was logical. As mentioned earlier, the impacts of REACH are determined by the factors, which we have called differentiators, that characterise companies, therefore the questions, although the result of an in-depth study, cannot capture this complexity. Moreover, no one knows the company better than one of its employees.

For data collection, a previously prepared structure was followed, containing a list of 17 macro-questions, which will be introduced later, discussed in detail with every respondent. Each interview, lasting approximately one hour, was recorded (transcripts can be found in the Appendix) and then analysed.

3.2.2 Questions and structure

Figure 3:1 represents the structure of the interview, which is divided into three groups of questions. It starts with the first-order effects, which concern the cost and supply chain impacts experienced by the company. This is followed by the second-order effect, which corresponds to the company's response to the stimuli (impacts) of REACH. The response was defined as product portfolio choices and process/product innovations. Furthermore, sales volumes and prices are variable under the company's control. Finally, third-order effects, resulting from the impacts of the regulation and company response, were explored from four perspectives of interest (Dechezleprêtre, A., and Sato, M. 2017).

The first of the third-order effects examines economic outcomes in terms of profits and market shares. The second concerns technological outcomes, defined as effects on productivity and the rate of innovation, while the third has to do with import and export outcomes. The last one, which focuses on social outcomes, aims to verify whether the objective of regulation on the protection of human health and the environment has been achieved.

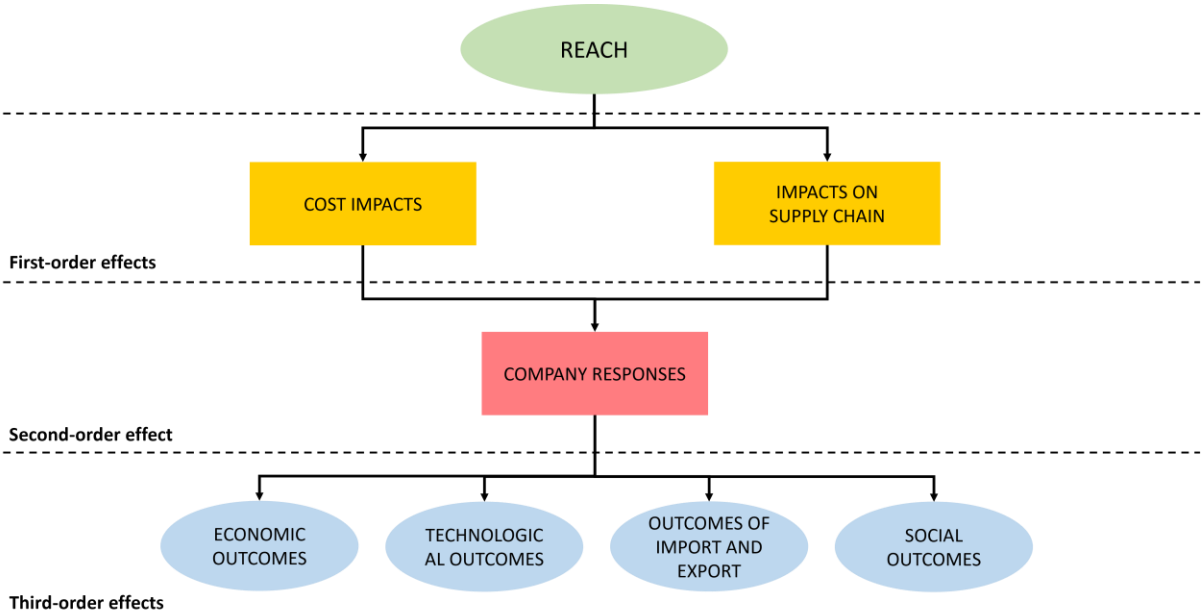

Figure 3:1 - Interview structure

Below are the interview questions, which contain all the insights gathered in the impact analysis. These have simply been grouped within the three macro categories explained above to follow a logical sequence in the treatment of topics.

Interview questions

Could you introduce me to the company you work for and the position you hold within the company?

What is the role, for the purposes of the regulation, of the company within the supply chain?

What are your main obligations for compliance with the regulation given your role in the supply chain?

First-order effects

COST IMPACTS

1. *What are the main costs incurred by the company for compliance with the regulation and how high are they?*
   - *Costs associated with substance registration*
   - *Costs associated with the application for authorization*
   - *Costs associated with the communication of information*

2. *What impact has the regulation had on production costs?*
   - *Direct costs*
   - *Indirect costs*

3. *What effect has the regulation had on the Research and Development (R&D) budget?*
   a. *Have R&D resources been shifted to compliance activities?*

4. *What effect has the regulation had on the time to market, hence on the cost of developing a new substance?*

IMPACTS ON THE SUPPLY CHAIN

1. *Has the company suffered any interruptions in supply as a result of the regulation? If yes, what impacts have they had?*
   Possible causes of interruption:
   - *uses not covered by the Extended Safety Data Sheet*
   - *reduction of product portfolio by suppliers:*
     - *cessation of supply of a substance included in the Substances of Very High Concern (SVHC)*
     - *non-registration of the substance by the supplier*

2. *Has the regulation strengthened the relationship between companies in the same supply chain?*
   a. *Has the company increased investments in the supply chain? If yes, what was the effect on flexibility in the choice of supplier?*
   b. *Have disclosure requirements increased transparency in the supply chain? If increased transparency has occurred, what effect has it had in identifying inefficiencies?*

Second-order effect

COMPANY RESPONSES

1. *What choices did the company make regarding the product portfolio?*

a. *Did the cost of registration lead to the decision to stop importing/producing a substance or to reduce its volume below 1 tonne per year?*
b. *Did the cost of applying for authorisation lead to the decision to stop importing/producing/using an SVHC?*

Determining factors:

- *Productivity of the company*
- *Company size*
- *Price sensitivity of the market*
- *Size of the market*

2. *Have process and/or product innovations been undertaken?*
   - *innovations introduced in response to the authorisation process*
   - *innovations introduced in response to supply interruptions*
   - *innovations introduced in response to inefficiencies*

3. *Has compliance with the regulation had any effect on sales prices?*
   a. *To cope with any increase in costs, was it decided to increase prices or reduce the profit margin?*

4. *Did compliance with the regulation influence production volumes?*

Third-order effects

ECONOMIC RESULTS

1 *What effects did the regulation have on the company's profits?*
   a. *Overall, has the innovation induced by the regulation offset the compliance costs or at least mitigated them?*

2 *What effect has the regulation had on market share?*

TECHNOLOGICAL RESULTS

1. *What effect has the regulation had on firm productivity?*

2. *Has the rate of innovation increased since the introduction of the regulation?*

   Relevance of factors such as:

   - *Transparency*
   - *Uncertainty*
   - *Time to market*
   - *R&D budget*
     a. *Did the cost of the regulation prevent productive investments otherwise undertaken?*
     b. *Have regulation-induced innovations replaced other innovations?*

IMPORT AND EXPORT RESULTS

1. *Has the regulation favoured imports from European Economic Area (EEA) countries?*
   a. *What was the impact of the registration process?*
   b. *What was the impact of the authorisation process?*

2. *What impact has the regulation had on exports to countries outside the EEA?*
   - *Exit from export*
   - *Volumes*
   - *Prices*
   - *Market shares*
     a. *What was the impact of the registration process?*
     b. *What was the impact of the authorisation process?*

SOCIAL RESULTS

1. *In your view, does the regulation serve the objective of ensuring a high level of protection of human health and the environment?*

Chapter 4 ANALYSIS OF INTERVIEWS

The paper has started by introducing REACH. Chapter 1 focused on regulatory processes and Articles relevant to companies in the European Economic Area. After delving into the directive, in Chapter 2 Porter's hypothesis (1995) is addressed. The latter states that environmental policy can lead to increased competitiveness by limiting negative externalities, in the form of pollution, generated by production activity. This phenomenon occurs because pollution represents a form of inefficiency that is reduced by regulation-induced innovations. Still within Chapter 2, REACH was introduced as a case study of Porter's hypothesis (1995). The applicability of the American academic's thinking had to be further investigated through interviews with companies.

In Chapter 3, an analysis of the possible impacts of REACH on the competitiveness of companies was carried out in order to define the interview questions aimed at verifying their occurrence. The interview was structured in three blocks as follow. The first concerns the consequences of the regulation on costs and the supply chain, while the second focuses on the company's reactions to them. The third investigated the outcome in terms of competitiveness (consequently, on the fulfilment of Porter's hypothesis), determined by the "stimuli" of the regulation and the companies' response.

In the following Chapter, the interviews conducted will be analysed. For each one, the company and the interviewee's role within it will be presented. This introduction is crucial in order to contextualise the answers, as REACH does not impact all regulated companies in the same way. Remember that provisions depend on the company's position within the supply chain, in particular, the obligations of a downstream user are not the same as those of a manufacturer or importer. The discriminating factors (e.g., market size) highlighted in the previous Chapter are also relevant.

The analysis, which will be repeated for all participating companies, will follow the interview structure. Thus, with one section for each of the three identified effects. Subsequently, the evidence obtained will be compared in the final part of the paper, where it will be noted how REACH had different impacts on different companies. However, it will be possible to make

some general observations on the relationship between regulation and competitiveness from the perspective of Porter's hypothesis (1995).

4.1 Sutter

The first interview concerned Sutter Industries S.p.A and took place on Monday, 12 September. The company was represented by Dr Fabrizio Lavezzato, who is responsible for the Research and Development Laboratory and Quality Control at the Borghetto Borbera headquarter. As part of his R&D work, he is also in charge of regulatory affairs. Therefore, he is accountable for everything related to the regulatory compliance of raw materials and finished products as the normal consumer knows them.

The legal form of the company is that of a joint stock corporation with a single shareholder, with a capital of EUR 3 million in 2022. The revenues were over EUR 39 million this year, with a profit of over EUR 3 million. Regarding employment, Sutter currently has 109 employees.

According to the Ateco code (an alphanumeric combination identifying an economic activity), the company is engaged in the production of soaps, detergents and organic surfactants. It is therefore identified as a downstream user for the purposes of REACH since it uses chemicals as part of its industrial business. Sutter purchases raw materials that it then uses in its formulations (mixtures), which are the finished product. Some raw materials, defined as such, are actually mixtures, such as perfumes and essences. The latter, in particular, are usually never a single substance.

The company's main obligation, given its position in the supply chain, is to verify the regulatory compliance of all raw materials used and all suppliers. Finished products, being mixtures, do not have to be registered.

Operationally, the company is structured into two business units. The first is the Consumer Business Unit, known for the Emulsio brand, which operates in the consumer market. Therefore, it targets consumers who regularly rely on large-scale distribution, specialised shops and retailers, providing quick and effective solutions to everyday household cleaning problems. The second is the Professional Business Unit, known for its Sutter Professional brand, which sells professional cleaning products through an extensive network of distributors. It operates in Spain, Portugal, France, Argentina, Chile and Brazil with its own

subsidiaries and in other countries through agreements with local distributors. It targets specialised users in hotels, restaurants, canteens, offices, schools, supermarkets, hospitals, laundries and cleaning industries.

After having presented the company and the role of the participant within it, we can proceed with the analysis of the interview. In the following, as anticipated, the question structure will be followed.

4.1.1 First-order effects

In this section, we will elaborate on Fabrizio Lavezzato's answers regarding the first-order effects of REACH on Sutter. Impacts that, as anticipated, focused on costs and the supply chain. We will first analyse the costs and then move on to the supply chain, following the order of the questions.

Cost Impacts

The company being a downstream user did not incur any registration costs, as it buys the substances it uses within its processes. This confirms that the role within the supply chain is a relevant discriminator in determining REACH impacts. Nevertheless, for non-compliant raw materials, Sutter had three possible ways forward. The first was to register as a company, while the second was to change the substance. The last possible route was to go to another supplier. Lavezzato confirmed to us that, due to the size of the company and the type of raw materials of which they did not receive sufficient information, it was not worth undertaking a registration process. The costs would have been too high and the resources to be deployed would have been too many. The company opted to turn to compliant suppliers.

The choice was justified by the fact that Sutter is not a multinational company with unlimited budgets for Research and Development. This confirms the evidence that the size of a company is a determining factor for the impact of a regulation (Scruggs, C., Ortolano, L., Wilson, M., and Schwarzman, M. 2015). We can imagine a large downstream user being able to register a substance, especially if it can provide a competitive advantage in terms of end-product differentiation. By assuming the cost of compliance for a multi-year contract, the advantage is made sustainable.

As far as the authorisation process is concerned, the company incurred no costs. Consistent with its sustainable vision, SVHCs were removed as soon as they were introduced in Annex XIV. Although it is possible to use them under certain conditions until the sunset date.

The only direct effects of REACH on costs noted are those related to regulatory compliance, linked to the verification of purchased substances. In order to be in compliance, the company must procure registered raw materials. In this regard, Lavezzato pointed out that, since before 2010, one R&D person (representing 20 per cent of total resources) has been dealing with regulatory affairs full-time. Compliance has become an R&D asset, because without it, the final product cannot be developed.

After analysing the direct cost impacts of regulation, which affected the R&D budget (one of the effects foreseen in Chapter 3), we turn to indirect ones. The latter were explored in terms of production costs and time to market. Talking about time to market, Lavezzato made an excursus on how the way of doing design has changed. This last point introduced the concept of uncertainty and is linked, together with the internal policy on SVHCs, to the consequence on the supply chain.

Let's start with production costs. Lavezzato confirmed that there was definitely an impact, as whoever registered in turn tried and tries to pass on the expenses incurred to their buyers. There may have been increases in raw materials, as is still the case today, to which Sutter tried to manage through careful formulation and choice of suppliers.

Now we will delve into how the way of approving a supplier has changed. This underlying aspect of product design bridges the boundary from cost impact, in terms of time to market, to supply chain impact. Lavezzato, who has been working in this field since 1999, revealed how before REACH came into force, it took a technical equivalence to approve a supplier. This term refers to two substances that have the same effect on the mixture (finished product). With the advent of REACH, this is no longer enough, as there is an upstream step that is regulatory compliance.

The supplier approval issue changes the way of designing and innovating. This because there are a number of requirements and restrictions to be taken into account in the early stages of development. Otherwise, there is a risk of producing a finished product with a raw material that cannot be used. This additional phase certainly lengthens the time to market.

The impossibility of using certain substances increases uncertainty in the development phase. This uncertainty, in the case of Sutter, has never prevented a product launch. It must be remembered that the company in question markets detergent products characterised by a fairly “easy” chemistry. The finished product is a mixture and, linking back to what was said in Chapter 2, this is not a complex product innovation. Since they are mixtures, it is possible to substitute raw materials while maintaining the usefulness of the finished product for the end customer. This increases uncertainty about the characteristics with which the formulations reach the market. These, being affected by additional constraints, may no longer have some excellent properties compared to before the adoption of REACH. For this reason and because of the availability of alternative chemicals, the Swiss company had the option of not registering non-compliant substances.

Impacts on the supply chain

As already mentioned, the aspect of a vendor's approval allows us to introduce the impact of REACH on the supply chain. Similar to the development of a new product, the regulation affects the day by day (i.e. existing products). Lavezzato gave us a snapshot of the current situation in the chemical industry, characterised by the scarcity of raw materials. In this already very complex framework, REACH adds constraints on the choice of raw materials. Since the substances that can be introduced into the production process must be REACH compliant. Sutter, by employing a full-time R&D resource on regulatory affairs, was able to limit both the impact on the time to market of new products and a disruption in the supply of raw materials.

The size of the company again becomes a relevant discriminating factor. This is because a smaller company might not be able to dedicate a resource to compliance or register non-compliant substances. Conversely, a large company, unlike Sutter, might consider registering a substance in order not to be forced to stop production. Not to mention that to replace a substance, a company must produce a product that allows it to do so (such as a mixture, in Sutter's case).

Sutter's sustainable vision of replacing all SVHCs can also cause a disruption in the supply of raw materials. This risk is being addressed in a similar way to that of REACH non-compliant substances. Therefore, thanks to intensive work at the R&D level.

The other aspect explored on the supply chain concerns the communication of information. According to Lavezzato's work experience, the information sharing required by REACH is not implemented as envisaged by the legislator. Sutter testifies to receiving safety data sheets that are not even up to date with CLP (Classification, Labelling and Packaging), despite the last deadline being 1 June 2015. This phenomenon affects both suppliers and the company itself, which experiences episodes of non-communication to large retailers rather than professional users. To maintain a fairly efficient communication flow, Sutter has implemented a number of tools, including questionnaires, e-mails and alerts sent constantly up and down the supply chain.

The flow of information, although ineffective, revealed regulatory inefficiencies. Therefore, these are not related to the production process, or the substances used (except in terms of REACH compliance). This aspect will be discussed in more detail in the section on third-order effects, where the outcome on innovation will be explored.

Observations

Fabrizio Lavezzato's answers show that some of the expected impacts have occurred. These concerned an increase in the company's costs in terms of R&D budget, raw materials and time to market (Dechezleprêtre, A., and Sato, M. 2017). There was also uncertainty in the development phase of a new product (European Commission 2021). This last aspect was explored in the third part of the interview to determine its effect on innovation.

As far as the supply chain is considered, the company has not experienced any procurement disruptions. This does not mean that REACH cannot cause such interruptions. Sutter was able to avoid the impact thanks to intensive R&D work and the availability of alternative raw materials. It must also be considered that the company has an advantage in this respect, as its finished products are mixtures characterised by “simple” chemistry.

In the case of Sutter, the communication of information did not highlight inefficiencies in the production process and the finished product, unlike what we had anticipated (European Commission 2015). If this had been the situation, these shortcomings could have been addressed at the design level (second-order effect).

In conclusion, company size, as has already been pointed out in the literature (Scruggs, C., Ortolano, L., Wilson, M., and Schwarzman, M. 2015), has proven to be a determining factor in the impact of an environmental regulation. In the specific context of REACH, a downstream user is in a privileged position compared to a manufacturer or importer.

4.1.2 Second-order effect

Let us now look at Sutter's response to the impacts identified in the previous section. Among the possible reactions to the REACH stimuli, the company's choices regarding product portfolio and design were explored. Then, the focus shifted to pricing and sales volumes decisions.

In Chapter 3, the cost of registration was identified as one of the possible causes for rationalising the product portfolio. It was assumed that the cost associated with this process could make the production of a given product unprofitable. Given Sutter's position in the supply chain, this phenomenon does not affect the company Lavezzato works for. A similar reasoning was made for the authorisation process, but here too Sutter was not concerned. This is because the company has never made any application for the use and marketing of SVHCs.

Although these REACH processes did not cause direct effects, indirect ones were also explored in the course of the interview. The latter refer to the issue of supply disruption. Raw material shortages can lead to the withdrawal of a product from the market, which can be addressed at the design level introducing the topic of innovation (European Commission 2021). If, on the one hand, the affected substances are used as components of the finished good, which may be a mixture or an article, action must be taken at the product design level. If, on the other hand, the involved chemicals are resources within production, the process must be re-engineered. As we saw in Chapter 2, such innovations can have a different level of complexity. This aspect is crucial because it determines the cost of adoption, both in terms of money and time, and may lead to the decision not to introduce changes, resulting in the elimination of the product (Najjar, N., and Cherniwchan, J. 2018).

Lavezzato explained that the company had experienced supply interruptions. These were due to the regulatory compliance obligation of suppliers and the internal policy of removing all

SVHCs. The problem was managed in the Research and Development phase by eliminating the affected substances. This was done through the introduction of very simple product innovations involving the substitution of chemicals within the mixtures (finished products). With regard to the production process, Sutter is in an advantageous situation. As there is no surplus of resources used at the process level that has led to substantial changes and innovations in that area. In any case, these are rather simple manufacturing procedures involving the mixing of liquids at reasonable temperatures.

After ascertaining that the product portfolio was not reduced, the impact on prices and volumes was analysed. Regarding the first aspect, Lavezzato was not able to quantify the effect. However, Sutter is trying to get more suppliers approved (i.e., REACH-compliant) to avoid cartel situations. Regarding the second aspect, again the R&D manager did not see any impact. This is because a lot of work has been done to avoid a drop in production due to raw materials no longer being approved following the adoption of REACH.

Observations

The second-order effect shows that REACH led to a reaction in terms of product innovation, without causing a reduction in the number of products marketed. Volumes were not affected, nor were sales prices. It therefore appears that the dynamic view predicted by Porter (1995) occurred, as Sutter removed the constraints introduced by REACH by intervening at the design level. In the continuation of the interview, we went on to analyse whether these changes increased competitiveness or not.

It is important to emphasise that the lack of impact on volumes, prices and product portfolio does not mean that REACH has no effect on these variables. This aspect was also emphasised by Lavezzato. It must be kept in mind that Sutter, although not a company with an unlimited budget, has the opportunity to deploy a compliance resource. Not to mention that the finished product itself, characterised by many alternative raw materials and a “simple” chemistry, puts the Swiss company in an advantageous situation.

4.1.3 Third-order effects

We conclude our analysis of the Lavezzato interview with third-order effects. These, resulting from the impacts and reactions of the company discussed above, determine the outcome of REACH on Sutter's competitiveness. Thus, the occurrence of Porter's hypothesis (1995) in the context of the Swiss group.

With regard to the economic aspect, it was not possible to quantify the effect on profits. There was no effect on market shares. As Sutter managed the impacts of REACH within the area of Research and Development.

Sutter introduced product innovations by replacing non-compliant substances. These changes did not lead to an increase in efficiency, except at the level of communication with the consumer and end user. It was possible to take a step forward in terms of sustainability, raw material management and policy on the use or non-use of certain substances, including SVHCs.

Since, as we saw in the previous section, there were no process innovations, the company's productivity stayed the same.

Although REACH affected the time to market and uncertainty in the development phase, the innovation rate remained more or less constant. No fewer products were made, but it is possible that some of them no longer had the outstanding properties that had characterised them before the regulation was adopted.

Lavezzato confirmed that REACH favoured sourcing from EEA suppliers, because in the absence of an only representative, Sutter (assuming the role of importer) would have to take over the registration. This has an impact not only on costs, but also on time.

With regard to exports, it does not appear that REACH is one of the drivers of competitiveness problems outside Europe.

From the respondent's point of view, REACH serves the objective of ensuring a high level of protection for human health and the environment. This is because it has provided a great clarity, through the registration process, on the hazardous characteristics of substances and

their handling. Moreover, the list of SVHCs allows dangerous chemicals to be removed well in advance of any restrictions may come into force.

Observations

Sutter saw an increase in its time to market and uncertainty in the development phase, but without a reduction in the number of products brought to market. REACH raised the costs incurred by the company, in terms of investment in regulatory compliance and raw materials, without affecting sales prices and volumes. Therefore, we can assume that the expenditure due to regulation has been limited. This is confirmed by the fact that exports to countries outside the EEA were not affected either. While, as far as competition in Europe is concerned, it appears that REACH benefits domestic companies. The regulation led to supply disruption, which Sutter addressed through product innovations. These have not resulted to efficiency gains except in terms of sustainability, consistent with the goal of the directive.

Based on this, we can say that in the case of Sutter, the dynamic view occurred, as the regulation acting on the negative externality pushed the company to innovate. The changes introduced did not lead to an increase in efficiency (although the issue of brand image and the value of sustainability for customers was not explored). If Porter's hypothesis (1995) is to be accepted, it occurs in the domestic market versus international competition for regulatory design and not so much for the company's response to impacts.

4.2 Ice

The second interview was conducted with ICE S.p.a. on Wednesday, September 14. The company was represented by Dr. Francesco Pilla, who is in charge of safety and REACH in particular. Pilla, as a REACH specialist, follows issues related to the import of raw materials. For the updating of the safety data sheets, ICE relies on an external consultant.

The legal nature of the company is that of a corporation. The group, based in Reggio Emilia, had revenues of more than EUR 187 million in 2021. The discrepancy in turnover highlights the difference in size compared to Sutter.

ICE is a niche manufacturer of active pharmaceutical ingredients (APIs) and specialty ingredients, focusing on the development and production of bile acid derivatives. It is the

world's leading producer of ursodeoxycholic acid (UDCA). ICE has an integrated global production network in Europe, Latin America, Asia and Oceania serving customers in more than 50 countries. Its four research and development centers have enabled it to develop a unique and comprehensive range of bile acid products, including generic APIs, excipients, and new chemical entities.

For the purposes of REACH, the company is a manufacturer. This entails the obligation to register all products placed on the market. Unlike Sutter, which, in its role as a downstream user, is not affected by this requirement. Again, the company is responsible to purchase only compliant raw materials and to use them according to the conditions specified in the safety data sheets received. ICE also has communication obligations, in particular it must provide the SDSs of its products to its customers and of the substances it uses to its employees. Customers, like ICE towards suppliers, must comply with what is specified in the SDSs.

As done in the previous analysis, the interview structure will be followed.

4.2.1 First-order effects

In this section, we will elaborate on Francesco Pilla's answers regarding the first-order effects of REACH on ICE.

Cost impacts

It was possible to discuss the impact of the registration cost in detail with ICE, as the company, being a manufacturer, is obliged to register the finished products it markets (including ursodeoxycholic acid and its derivatives). Pilla explained that they had engaged an external consultant, who did the required paperwork that was then sent to ECHA. Nevertheless, ICE bore the costs of the analysis, of the consultant and of the registration fee.

It has been emphasised that there are two types of registrations, which have already been discussed in detail in Chapter 1. These are the complete and the joint. The latter allows the cost of the analysis to be shared, which is the main component of the total expense of the process. In the specific company's situation, only full registrations were made. The exception concerned taurine, where the joint was done in the role of follow registrant.

Pilla has stressed repeatedly, that when he speaks of registrations made by the company, he is referring to the marketed products. For raw materials purchased, the supplier has always taken the obligation. This does not mean that ICE, as manufacturer, cannot bear the responsibility for the registration regarding the chemicals introduced into production (a similar argument was made for Sutter in its role of downstream user). As a matter of fact, in the case of the supply of a non-compliant substance, ICE has to assume the burden of registration. Pilla shared an anecdote on this subject, which concerned bromide. We will deal with this example later as it relates to the impact of the regulation on international relations. For the time being, we simply say that ICE has never registered materials because it has always purchased from conforming vendors.

An indication of the economic impact of registration was given. The order of magnitude for a complete one is EUR 20000. This is the expenditure that ICE and suppliers incurred for finished products and raw materials, respectively. The discussion on production costs impacts will be linked to this.

ICE, just like Sutter, has never applied for authorisation. This is because, although they have incoming SVHCs, these have not yet expired. Once this will happen, if they want to continue using such hazardous substances, they will have to apply for authorisation. Either ICE or the suppliers should take responsibility for this. The interviewee was confident that manufacturers (two/three globally), as they serve the whole world, will equip themselves for compliance. Behind this confidence is the number of applications of such substances, ranging from blue jeans to active ingredients for the pharmaceutical industry. Therefore, the sales volumes are high enough to justify the cost of authorisation. In addition, if alternatives were available, it would be in the company's interest to implement them, since it would increase safety in the plant and lead away from a situation of, almost, mono sourcing. This is crucial, as the availability, in terms of volume, of these SVHCs limits the company's growth. We concur with Pilla in stating that all these aspects, plus the criticality of the finished product marketed by ICE, will certainly push vendors to apply for authorisation and the competent authorities to issue it.

The last cost impact as a direct consequence of the provisions concerns the reporting of information. Which, in the case of ICE, regards the updating of safety data sheets. These must be revised when the regulations change (e.g., when the symbols or required contents are

modified). We were given an indicative expense figure of EUR 1000 per year, considering the updating of one/two sheets.

Let us now turn to the indirect effects of the regulation in terms of costs, starting with those on production. Consistent with Lavezzato's statement, Pilla confirms that the effort for registration is reflected in the raw material. In order to understand how the price of resources might fluctuate, let us consider the already mentioned figure of EUR 20000 associated with the REACH process. Since ICE receives 10000 to 20000 kg per supplier and a supplier does not provide one company, the impact REACH may have is negligible.

At the R&D level, the budget did not change. This is because the quantities of chemicals used are so minimal (below one tonne per year) that there is no need to incur expenses in this respect. Not to mention that the regulation, in order not to impact innovation, provides exemptions for substances employed in the development of processes and products. In addition, no R&D resources have been allocated to compliance. Pilla takes care of this as REACH specialist, representing a cost for the company, which is, however, amortised by the other functions he performs within the plant.

The regulation has had no impact on time to market at the moment. This is because ICE has the same products on the market from before REACH came into force.

Impacts on the supply chain

In terms of supply chain impacts, there were no disruptions. Risk of this happened in the case of bromide, mentioned above, due to a worldwide availability problem. The suppliers, being distributors, shouldered any rationalisation of the product portfolio by the manufacturers in place of ICE. It should be considered that for distributors, the supply channel is never single, so even if some player is non-compliant or exits the market, the substance remains available.

In Pilla's experience, REACH has undoubtedly strengthened supply channels. Indeed, it is preferable to buy from a compliant supplier in order not to have to bear the responsibility of registration. Therefore, REACH conformity is a requirement when choosing a supplier. The relationship between customer and vendor is consolidated if the former invests in the latter's compliance. The interview revealed that this has never happened in the case of ICE, but if

such an initiative had been taken, it would have been made against a multi-year contract. The multi-year contract allows a return on the investment.

ICE, as Sutter, pointed out shortcomings related to the communication requirement. In particular, concerning the updating of safety data sheets. No benefits were reported regarding transparency and identification of process or product inefficiencies.

Observations

The interview with Pilla indicates an increase in costs due to regulatory compliance. In particular, the registration process has both a direct effect, as ICE assumed the responsibility for the finished product conformity, and an indirect effect, as suppliers passed the compliance charge onto the price of raw materials. In addition to this, there is the use of a resource for compliance activities, even though this person performs other tasks within the plant, and the expense of updating safety data sheets. At the authorisation process level, no impact is reported as the SVHCs used have not yet expired.

Regarding the R&D area, REACH did not affect it. This is because belonging to the pharmaceutical industry, there can be very little variance on the finished product. Therefore, compliance, unlike with Sutter, cannot become an asset of R&D.

Similar to the R&D budget, another variable that has remained unchanged is time to market.

Among these cost factors, the main one is the registration process, which, according to Pilla, is around EUR 20000 per substance. This expense is borne by ICE for finished products and by suppliers for raw materials. The impact for ICE in terms of pricing and volume decisions will be discussed in more detail in the next section, but just considering the company's turnover it is clear that this figure is low. Regarding the effect on production costs, as mentioned above, on ICE's volumes the impact of REACH is negligible.

As far as supply chain impacts are concerned, the company has not experienced any disruptions due to REACH. We also have to consider that for ICE, in case of vendor non-compliance, it would not be a problem to bear the burden of registration, this limits the risk of interruptions in supply. There is a possibility of disruption at SVHC deadlines, but Pilla was confident that suppliers will apply for authorisation and it will be granted.

Like in the case of Sutter, ineffective communication was highlighted. Similar to what the Swiss company experienced, it did not reveal any product or process inefficiencies.

It can be concluded that the impact on costs and supply chain proved to be limited for ICE. The Basaluzzo company in contrast to Sutter, given its size, can consider taking over the registration. This process is unavoidable in case of no compliant producers, since, as we have seen, there is no possibility of product innovation.

4.2.2 Second-order effect

Let us now turn to ICE's responses to the impacts of REACH analysed in the previous section.

Pilla reported that the product portfolio has not been changed. This is because the company has been able to cope with all supply interruption risk situations, the driver of which is not REACH. In addition to the above, ICE was able to take charge of the registration of all its finished products. Regarding this last point, the company has two major advantages. The first is related to the finished products marketed, which, despite the small output volumes, have a high economic value, making it possible to absorb the expense on profit margins. The second is related to the size of the group, which has allowed the Basaluzzo plant to form a consortium with the Reggio Emilia plant, so many costs have been shared.

In terms of innovation, only the process was affected. Since products in pharmaceuticals, as mentioned earlier, are defined at ministerial level. One of the changes introduced by ICE concerned the intermediates transported. The modification had been made to avoid the release of dust, consistent with the use indicated in the extended safety data sheet.

The cost impact of REACH on ICE's suppliers and on the company itself was limited. Therefore, as far as pricing is concerned, the main driver on the increase of the company's price list is the scarcity of raw materials rather than the regulation. Although the effect on costs is limited, the interview revealed how REACH can put in a position to increase the selling price. The reason for this is that compliance is synonymous with quality, and quality is everything in the pharmaceutical industry.

Just like the price, there was an increase in volumes due to non-REACH-related phenomena. For example, worldwide use of the product, entry into new markets and expansion of existing ones.

Observations

Unlike Sutter, the Basaluzzo company introduced process innovations as a result of REACH. This confirms what was foreseen in the analysis of the regulation design. Therefore, the final part of the interview with ICE allowed us to take a closer look at the productivity result.

Because the impact of REACH has been limited, the company's responses could only be contained. Consequently, no changes attributable to REACH were identified in terms of product portfolio, volumes and sales price. With respect to the latter, a very interesting aspect was highlighted, linked to a possible competitive advantage provided by the differentiation of the finished product with quality certification.

The impacts of REACH, analysed in the previous section, and the resulting responses to these, need to be contextualised with respect to the size of the company. ICE is a multinational company, which has a very large revenue and budget. Moreover, it competes in a market with very high margins. Therefore, Pilla's evidence, as in the case of Sutter, does not exclude that the effects hypothesised in the analysis of the regulation may occur.

4.2.3 Third-order effects

The interview ended by discussing the effect of REACH on the company's competitiveness.

The economic result is almost inexistent. Market shares and profits increased as a result of the higher volumes mentioned above, but this growth can not be attributed to REACH-related causes.

In terms of innovation, only the processes were affected. These changes were originated from compliance with regulation, whose ultimate goal is to improve safety in the plant and environmental sustainability. To this objective, which brings a social benefit, ICE has tried to combine increased productivity wherever possible.

It has been pointed out that the obligation to comply has led to overcoming an inertia towards change, consequently the rate of innovation has risen.

Regarding international relations, similarly to what we have seen with Sutter, it appears that REACH has favoured imports from countries belonging to the European Economic Area. Proof of this is the Bromide episode mentioned above. Where ICE, due to the scarcity of raw materials, thought to make a non-EEA supplier compliant. In this specific scenario, when a quantity was released by an EEA supplier, the company was able to avoid going through the REACH process. This is because registering a substance entails a cost for the company in terms of money and time. It is a different matter if the non-EEA supplier uses an only representative, as in this case the company is not recognised as an importer. To conclude, we can say that regulatory compliance is a requirement when choosing a supplier and, consequently, European companies (which are "obliged" to be in conformity because their main market is domestic) have an advantage in internal competition.

The export outcome for ICE has not changed. It must be considered that their main finished product is ursodeoxycholic acid, which has four or five competitors worldwide. Hence, whatever effect REACH may have had, the impact is limited given the scarcity of alternatives. To this must be added that the Basaluzzo company, as a corporate group, is vertically integrated, therefore, they have their own suppliers of the raw material covering about 60% of their requirements. Since these vendors of the group also provide their competitors, any cost effects are also borne by them. Moreover, their customers are very large companies that market worldwide and, consequently, also in Europe. Therefore, as they should justify the supply chain to the reverse, they have an interest in compliance. It is necessary to underline that for these companies, for less complexity, it is convenient to conform to the most restrictive provider at the regulatory level, which allows them to produce a finished product that can be sold everywhere. In addition to ensuring compliance, REACH is synonymous with quality and safety, which are highly valued characteristics for ICE's clients.

In Pilla's experience, the regulation certainly has a positive impact on the environment, on safety in the workplace and, considering a product intended for the pharmaceutical industry, on security, in terms of control and quality, for the end consumer.

Observation

ICE saw an increase in costs caused by the registration of finished products and the price of raw materials. As mentioned above, this impact was limited, as was the company's

consequent reaction. This is confirmed at the level of profits and market shares, which show no change due to the regulation.

The company in Basaluzzo has introduced process innovations in response to REACH. In particular, for compliance with the uses indicated in the safety data sheet. This led to an higher innovation rate and the resulting realisation of the dynamic view. Where possible, this has been accompanied by an increase in productivity.

Similar to Sutter, an increase in internal competitiveness within the European Economic Area was noted. Also for ICE, it was not possible to quantify the changes in exports due to REACH. Nevertheless, with regard to international relations, another very interesting theme was introduced. Which sees the legislation as a quality certification that can differentiate the finished product introduced to the market.

We can conclude by saying that Porter's hypothesis (1995) occurred for ICE, since innovations were induced which increased the company's productivity. In addition to this, the company became more competitive in the domestic market and REACH products were also appreciated outside the EEA. The corporation, given its size, was able to absorb the cost increase with ease. It is important to emphasise that although an economic benefit occurred, REACH had above all a great social contribution.

4.3 Global Business Unit

The third interview, which took place on Friday 28 October, featured a large multinational company that has a reference plant of one of its Global Business Units (GBU) in the province of Alessandria. Specifically, our interlocutor was the person in charge of the regulatory affairs and stewardship function, which supports the product portfolio, of the GBU that has its headquarters in Italy. In his role, he deals with regulatory compliance, managing both European and non-European registrations required for exports, and provides business facilitation. Due to a very restrictive company policy, neither the name of the interviewee nor the name of the company can be revealed. Therefore, the attached interview transcript, as well as the following analysis, has been redacted in order not to allow the identity of the parties involved to be revealed. Nevertheless, all information relevant to the objective of the paper has been maintained.

In contrast to what was done previously for ICE and Sutter, it is not possible for us to frame the company in terms of marketed products and turnover. For the comparability of the evidence reported below with the analysis of the previous interviews, it is important to emphasise that the company in question is a very large multinational corporation (in particular, the largest chemical company that participated in the thesis project), which has offices all over the world and several GBUs that differ in terms of the product portfolio followed.

The Italian GBU is involved in the production, import and export of products. Therefore, for the purposes of the regulation, they are recognised as producers and importers, which entails the obligation to register the marketed and imported products. In addition, they are required to verify the compliance of their suppliers.

4.3.1 First-order effects

In this section, we will elaborate the first-order effects of REACH.

Cost impacts

The company, being both importer and manufacturer, was affected by REACH registration. Although one would tend to think that the cost of this process might be negligible for a very large company, a concern for costs was nevertheless evidenced. The components of the expenditure incurred are the same as those mentioned previously and relate, in particular, to the fee paid to ECHA, the analyses required and the employment of consultants. The first, which runs into thousands of euros, can be considered insignificant for this type of multinational. The second, regarding the experimental studies, requires a greater consumption of resources, which has always been justified by the turnover related to the product. Unlike other companies (such as ICE), they did not use consultants to prepare dossiers, thus avoiding the third cost component. This is because the multinational company has a corporate team to assess SVHC and one to monitor changes in legislation. In addition to this, there is a department of toxicologists, which deals horizontally with the various GBUs by defining study protocols.

In demonstration of the large size of the group, the interviewee confirmed that the company often played the role of lead registrant at the time of joint registration. Since it was the most

structured player with the largest volume and data ownership. The latter covered part of the required analysis.

Again, no proof of authorisation costs could be gathered, as the company was never involved in the process.

Let us now turn to the indirect effects caused by REACH, which did not affect production costs. Regarding the research and development budget, no impact occurred. The only evidence collected relates to the increase in time to market, consistent with the compliance obligations linked to the registration process. In particular, depending on tonnage, the preparation of the dossier can take between six months and two years.

Impacts on the supply chain

Impacts on the supply chain occurred as periodic disruptions of deliveries. In order to avoid this type of problem (similarly to what was experienced with Sutter), efforts were made to have more providers available. Therefore, if regulatory compliance was no longer guaranteed due to a change in legislation or if production was reduced/interrupted, there would always be a procurement channel.

With regard to the communication of information, the company has a system for monitoring and sharing SDSs, which ensures a high level of transparency and immediate updating of suppliers. In spite of this, the interviewee did not point out a strengthening in the relationships in the supply chain.

Observations

The company shows effects noted by Sutter, by ICE and common to both.

Similarly to Fabrizio Lavezzato, the respondent highlighted an increase in the time to market related to the registration process of new products introduced. In addition, just like to the Swiss multinational, interruptions in the supply chain were experienced.

Similarly to ICE, regulatory compliance is managed by a corporate function outside the research and development department. Therefore, the company is structured differently from Sutter.

Like the previous interviews, the impact on production and compliance costs was negligible. Regarding this last point, the difference in size of the company allowed it to play the role of lead registrant in multiple join registrations and not to make use of external consultants (unlike ICE). Therefore, the evidence that the size of a company is a discriminating factor of the impact of an environmental policy is confirmed (Scruggs, C., Ortolano, L., Wilson, M., and Schwarzman, M. 2015).

4.3.2 Second-order effect

Let us now look at the company's response to the above impacts.

In terms of product portfolio and volumes, there were no changes due to REACH. This is because the needs of the business are followed for compliance and production. Therefore, the business needs determine the output and the tonnage for which registration is applied regardless of the cost incurred.

Consistent with previous interviews, REACH was not identified as one of the drivers of price increases and it was confirmed that the regulation induces innovation. In relation to this last point, the innovations undertaken concerned both products and processes. Changes were introduced with a view to sustainability and, therefore, aimed at replacing SVHCs, the use of which is already evaluated during the development phase (similar to Sutter).

Observations

Unsurprisingly, given the size of the company, the following interview confirmed the evidence already found of a lack of effect on the product portfolio, volumes and sales price. In addition to this, similar to previous analyses, innovations were introduced in response to REACH.

The interview further reinforces the relevance of size as a discriminating factor (Scruggs, C., Ortolano, L., Wilson, M., and Schwarzman, M. 2015). This is because, the company involved is committed to compliance on business needs regardless of cost.

4.3.3 Third-order effects

The interview ended by discussing the effect of REACH on the company's competitiveness.

Consistent with a lack of impact on sales prices and volumes, the company's profits and market shares did not change as a result of REACH.

There was an increase in the rate of innovation (like for ICE and Sutter) aimed at achieving greater sustainability. Concerning improvements in processes, the interviewee emphasised that efforts were made to limit the negative impact on productivity.

The participant confirmed how the REACH regulation favoured imports from EEA countries especially in the years immediately following its introduction. Today, non-European suppliers, who are more price competitive, have also equipped themselves for compliance.

Regarding the export issue, it was pointed out that countries outside the EEA have taken inspiration to develop their own registration process, following REACH in almost all aspects. The European regulation, as highlighted several times, requires the registration of substances, thus demanding an assessment of environmental and human health impacts. For most countries, the analyses carried out for the European regulation are accepted. The respondent's task is to verify which experimental data ensure compliance with multiple directives, allowing studies not to be duplicated. Duplication of studies not only impacts costs but also generates sustainability issues. To conclude, despite the fact that the registration dossier must be supplemented with country-specific requirements, European companies have an advantage (with regard to REACH like regulations) as they possess, in addition to analyses, a structure for compliance.

As far as the social perspective is concerned, the respondent stated the usefulness of the regulation to the objective of ensuring a high level of protection of human health and the environment.

Observation

In terms of third-order effects, the interview confirmed the evidence already found. Thus, the lack of an effect on profits, market shares and an increase in innovation, whose benefits in terms of productivity were not found (or have yet to be proven). In addition, the company representative also stated that the regulation protected the internal market and achieved the desired social objective.

A very important finding concerning international relations was introduced, which places European companies at an advantage in facing REACH like regulations. Hence, the first mover advantage hypothesised by Porter (1995) emerged.

4.4 Italo Belge Colori S.r.l.

The three previous interviews involved multinational companies. Consistent with the literature, the effects experience by these companies and highlighted by the respondents were not only determined by their specific product and process, but also by their size and, consequently, by the resources available for compliance. Supporting the literature were the statements of Lavezzato, who testified that Sutter is not willing to bear the cost of registration unlike ICE and the Alessandria-based GBU (both larger). In addition to this, it emerged how the difference in size determines the choice of using a consultant (as in the case of ICE) or not (as in the case of GBU). Since the size of the companies was a discriminating factor in the impacts of REACH, it was necessary, for the sake of completeness, to make an effort to involve a small and medium-sized enterprise (SME) in the project. This effort led to the participation, on Wednesday 16 November, of Italo Belge Colori. The effects found by this SME give us a more complete view of the possible impacts of REACH.

Italo Belge Colori is a company based in Novi Ligure, which manufactures paints, varnishes and enamels, printing inks and synthetic adhesives (mastics). The turnover, which is approximately EUR 3 million, and the number of employees, which currently stands at 12, highlight the difference in size compared to the multinationals previously interviewed.

Italo Belge Colori was represented by Dr Edoardo Bisio. He holds the position of safety and quality control engineer within the plant. He is the resource that deals with the drafting of safety data sheets (with the support of an external consultant), safety in the working environment and quality control of the articles produced.

The company, as a downstream user, is not subject to the registration obligation. This is because it purchases substances and mixtures that are already registered. Mixtures are registered because they contain SVHCs, including formaldehyde, phenols and benzene, which were never purchased by Italo Belge Colori as substances but as components of formulations.

In the case of formaldehyde, if the substance exceeds a certain concentration in the mixture, the label of the final product may state carcinogenic agent.

Although Italo Belge Colori is not involved in registration, the company is not exempt from REACH obligations. Which require it to provide the safety data sheets of the paints it produces. This is because, as the articles marketed contain hazardous substances, sharing complete and comprehensive SDSs allows its customers to work safely.

As in previous interviews, Edoardo Bisio's answers will be analysed below following the structure of the interview and the clusters of questions. The discussion will be more streamlined than the previous ones given the size of the company. In particular, the company does not export outside Italy (except sporadically), has only Italian suppliers and has no research and development department.

4.4.1 First-order effects

First-order effects are reported in this section.

Cost impacts

The main cost incurred by Italo Belge Colori for compliance is associated with the communication of information. In order to meet this obligation, the company had to employ a resource and an external consultant to draw up the safety data sheets. To this must be added the expense (not only in terms of money, but also in terms of time) of requesting SDSs of the raw materials that make up the paints. These safety data sheets are used to create the SDS of the finished product. Therefore, it is necessary to contact suppliers in the event of an out-of-date or missing SDS.

Due to its position in the supply chain, the company is not affected by registration and authorisation. Consequently, it was not possible to investigate the impacts these processes may have on a small and medium-sized enterprise.

Let us now turn to the indirect effects REACH may have on expenses. Edoardo Bisio confirmed that REACH did not lead to an increase in production costs. Likewise, there was no impact on the R&D budget, as Italo Belge Colori S.r.l does not have an R&D department, and on the cost

of developing new substances (the product portfolio has not changed since REACH came into force).

Impacts on the supply chain

The supply chain impacts suffered by Italo Belge Colori were limited. The company did not experience any interruptions in deliveries even during the most critical period, when the registration deadlines for substances/mixtures came into force, because suppliers were equipped for compliance. What prevented disruptions in procurement during this transitional phase were stocks produced prior to the entry into force of the registration obligation, since these substances could be shipped under the old restrictions.

When analysing the possible impacts of REACH, it was hypothesised that mandatory reporting could strengthen relationships in the supply chain and lead to greater transparency that could uncover inefficiencies. The interview with Edoardo Bisio provided an insight into the dynamics of this process, which involves requesting SDSs from suppliers by email if these are missing or outdated. Therefore, this type of communication can hardly lead to an increase in transparency. Nevertheless, a form of loyalty towards suppliers who send complete and up-to-date sheets has been highlighted. Because these make it possible to create comprehensive SDSs for own products and, consequently, for own customers, creating added value for the company.

Observations

The interview with Edoardo Bisio, unlike the previous ones, saw the reporting obligation take on significance as a compliance cost. This is because the requirement led the company to hire a resource dealing with safety data sheets and to rely on an external consultant. This expense, which was also borne by the other companies participating in the project, was overlooked during the previous interviews as irrelevant, demonstrating once again how the size of a company is a discriminating factor in the impacts of an environmental regulation.

Similar to previous interviews, REACH was not recognised as a driver of increased production costs. This is an important evidence, as a small and medium-sized enterprise confirms the findings of multinationals. Therefore, company size was not found to be a discriminating

factor in the impact of REACH on production costs, which (for the pool of companies participating in the project) was irrelevant.

4.4.2 Second-order effects

After analysing the impacts the regulation has had on the company, we move on to the subsequent reactions.

Similar to previous interviews, REACH has had no effect on volumes, product portfolio or sales prices. Nevertheless, by introducing constraints that companies must undergo, REACH has pushed and, in some cases, obliged to innovate by introducing the use of materials and production processes that allow work to be done safely and efficiently.

On the subject of innovation, Edoardo Bisio told us that since the introduction of the legislation, their research has focused on products already on the market. They had to intervene on water-based paints because they contain formaldehyde (today impossible to eliminate completely). This is because REACH, when formaldehyde was confirmed as a carcinogen (it had previously been identified as a carcinogenic risk), led to a rethinking of the formulation of water-based paints. In particular, REACH has lowered the amount of formaldehyde that causes the risk phrase H341 to appear on the safety data sheet of the article, thus indicating it as carcinogenic and making the final consumer's choice to buy such product very unlikely. In order to cope with the new restrictions imposed by REACH on the concentration of formaldehyde, action had to be taken both upstream and downstream. Upstream, all mixtures that contained formaldehyde were revised to drastically reduce their content. Downstream, users such as Italo Belge Colori replaced old mixtures by switching to mixtures with "low" formaldehyde content, thus intervening in the formula.

Observations

The decision to introduce a small and medium-sized company into the thesis project stemmed from the desire to investigate those impacts for which no evidence had been found in the previous interviews and for which it was assumed that the lack of such evidence was due to the size of the participating companies (so far all multinationals). Despite the fact that Italo Belge has 12 employees and a turnover of "only" EUR 3 million, no effect was found on the product portfolio, sales prices and volumes. It should also be considered that the company,

as a downstream user, is in a privileged position since it is not affected by the registration and authorisation process. Therefore, the participation of Italo Belge Colori certainly reinforced the results of the study, but it cannot exclude such impacts as likely.

4.4.3 Third-order effects

The impact that the REACH regulation has had on Italo Belge Colori's competitiveness is negligible. This is because the company, having not suffered any changes in prices and sales volumes, did not see its profits and market share vary following the entry into force of the regulation. It was not possible to delve into the issue of international relations, as the company does not export (except rarely and with volumes well below one tonne) and has only Italian suppliers. The only evidence confirmed by Edoardo Bisio concerns an increase in the rate of innovation with a view to improving the initial state in terms of both safety and efficiency (without providing concrete examples on the effects on firm productivity).

According to the respondent, the legislation has achieved its objective of ensuring a high level of protection of human health and the environment.

Observations

Italo Belge Colori, similarly to multinationals, did not suffer any effect on profits and market share. Therefore, these impacts hypothesised in the analysis of the regulation were not reflected in our pool of companies, even though this also includes an SME.

Chapter 5 DISCUSSION OF RESULTS AND CONCLUSIONS

This Chapter of the paper will examine the evidence from the interviews conducted with companies and will include the contribution of a REACH expert. Together with the expert, it was possible to discuss in detail the impacts, hypothesised in the analysis phase of the regulation, which were not reflected in the participants' answers.

The insight from the companies and the specialist allows us to draw conclusions on the applicability of REACH as Porter's hypothesis (1995).

5.1 Companies evidence

This section summarises and explores the contents of Chapter 4, where the interviews conducted were analysed.

Figure 5:1 represents the companies participating in the project, indicating for each the turnover, the product marketed, the role within the supply chain and the obligations for compliance with the regulation. Therefore, all information differentiating the companies and, consequently, determining the impact of REACH is shown. This information is key to framing and understanding the effects experienced by the participants.

	Sutter	ICE	GBU	Italo Belge Colori
REVENUE	EUR 39 million	EUR 187 million	—	EUR 3 million
PRODUCT	Soaps Detergents Organic surfactants	Active pharmaceutical ingredients Specialty ingredients	—	Paints
ROLE	Downstream user	Manufacturer	Manufacturer Importer	Downstream User
OBLIGATION	Supplier Compliance	Registration Supplier Compliance Sharing SDSs	Registration Supplier Compliance Sharing SDSs	Supplier Compliance Sharing SDSs

Figure 5:1 - Companies' identikit

Consistent with the desire to gather as much evidence as possible and, consequently, to involve companies that are structurally different from each other, clear differences in turnover can be seen from the table. In particular, the pool includes only one small and medium-sized enterprise (Italo Belge Colori) and three multinationals. Of the latter, the company with the largest turnover is the GBU (although it was not possible to indicate the figure for privacy reasons), followed by ICE and Sutter.

Also with a view to enabling the achievement of the objective of the paper (the assessment of the impact of the regulation on competitiveness), the companies involved cover the main roles (in the supply chain) identified for the purposes of REACH. Since these, by defining the obligations for compliance, determine (together with size) the impacts of the environmental policy. Therefore, this thesis involved two downstream users (Italo Belge Colori and Sutter) and two manufacturers (ICE and the GBU). All companies are affected by the obligation to verify supplier compliance, while ICE and the GBU, as manufacturers, have to take over registration. Only Sutter is excluded from the SDS sharing obligation, as it is a downstream user that, unlike Italo Belge Colori, produces mixtures not containing SVHCs (removed by company policy).

Figure 5:2 schematises the first- and second-order effects experienced by companies. The diagram presents a tabular form, with the companies on the rows and the possible impacted “areas” on the columns. A traffic light symbol is present at the intersection of row and column to indicate the effect the regulation had on the business "area". In particular, the red colour indicates a negative impact, while the yellow colour a neutral impact, i.e., an impact that has no marked positive or negative meaning. Finally, the colour green indicates a positive impact. The absence of a traffic light symbol, replaced by a hatching, indicates that there was no impact detected by the participant or that the participant was unable to respond.

Figure 5:2 - First- and second-order effects

Analysing the figure above, it is possible to see that the impact of the regulation on fixed and production costs was considered negligible by almost all respondents. In particular, only Italo Belge Colori, being an SME, experienced a marked negative impact on fixed costs. With respect to the R&D budget and time to market, companies, which manage compliance through the R&D department and have introduced new products to the market, reported negative impacts. With respect to the supply chain, there were disruptions affecting Sutter and the GBU. Although a more or less efficient flow of information was evidenced, no markedly positive impacts (except from ICE) on supplier and customer relations were reported.

An overview of the representation in figure 5:2 shows that the predominant colour is yellow (neutral impact) followed by red (negative impact). There are many empty spaces on the right-hand side of the table corresponding to second-order effects, which concern product portfolios, volumes and prices. With the available evidence, it appears that the effect the regulation has had on costs and the supply chain is moreover negligible. This leads to the assumption that second-order impacts should also not be marked. The REACH consultant's contribution in the following section will help to clarify the remaining doubts.

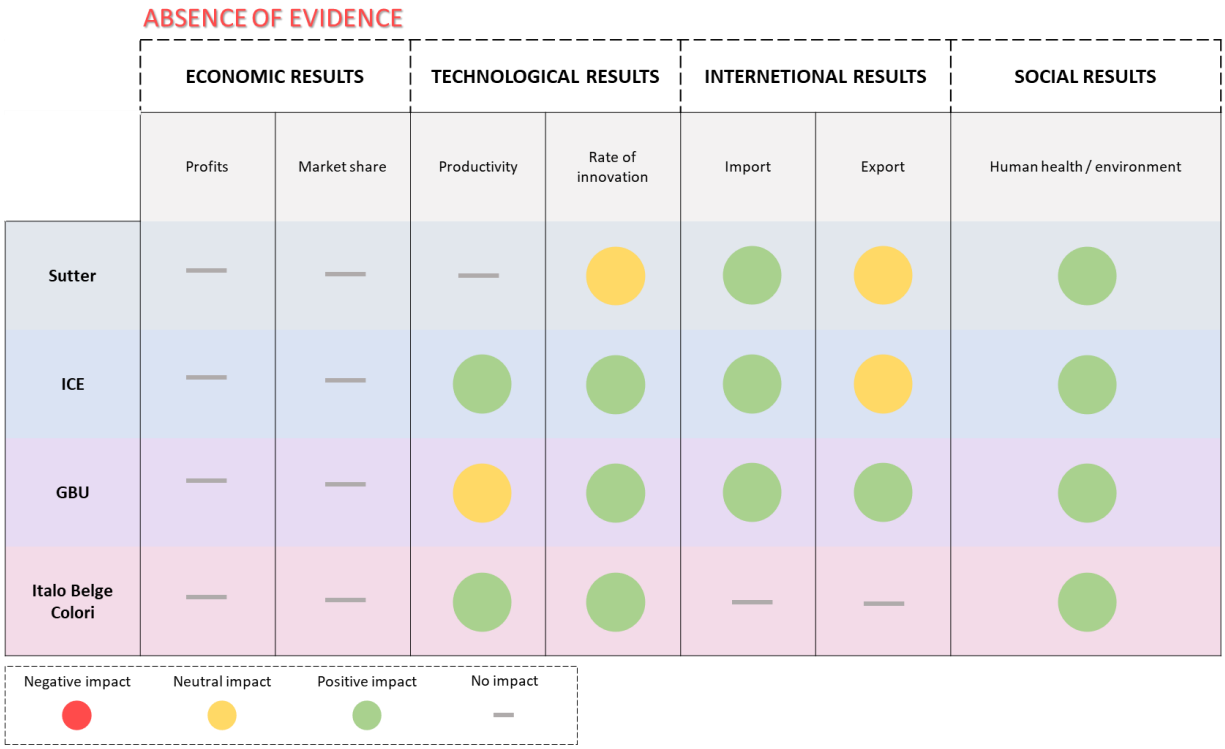

Figure 5:3 - Third-order effects

Figure 5:3 presents a similar tabular structure to that in figure 5:2, but applied to third-order effects in the 4 different perspectives. The predominant colour is green, followed by yellow, while there are no red dots. In particular, the respondents found benefits in terms of productivity, rate of innovation and imports. With respect to exports, the evidence is not so strong to show a positive impact of REACH. The only column with symbols of the same colour is the one relating to the social outcome, according to all respondents, REACH has achieved its goal of ensuring a higher level of safety of human health and the environment.

Similarly and consequently to the second-order effects, no impacts on the economic sphere were highlighted. Without these, it is difficult to give an assessment of the impact of the regulation on competitiveness. Based on the evidence from the interviews with companies, it can only be stated positively that the dynamic view of Porter's hypothesis (1995) has occurred, as almost all respondents report an increase in the rate of innovation. Innovation had a positive impact (not even that marked) on the productivity of companies. This impact, together with the increased protection of the internal market, leads one to think that the regulation has had a positive (though not so strong) impact on competitiveness. The consultant's contribution will allow us to verify with certainty whether this innovation

mechanism triggered by REACH has strengthened the competitive position of the European chemical industry.

5.2 An expert's opinion

After conducting the interviews with the four participating companies, Dr. Lara De Luca, REACH consultant at Capgemini, was involved in the thesis project. Thanks to her contribution, it was possible to investigate the impacts, hypothesised in the analysis phase of the regulation, that were not reflected in the answers of the interviewees.

Lara De Luca is an industrial chemist who has been involved in regulatory affairs in this field since 2008. Her career path led her to interface with chemical regulation already in 2004 in a paint company, as a formulator responsible for drafting SDSs and sharing them in the supply chain. After this experience, she entered the world of consultancy, working 12 years in a company that offered services aimed at preparing registration dossiers. Her current occupation sees her as a manager in Capgemini, an engineering consultancy company, where she still performs REACH advisory services for downstream users in the electronics, mechanical engineering and aerospace sectors.

The questions that were posed to the consultant focused on second-order effects (product portfolio, prices and volumes) and the economic result (profits and market share). There were many interesting insights from the discussion with the consultant on other aspects as well, which we will not mention in the following section in order not to make the discussion too burdensome. Therefore, I suggest to read the transcript of the interview in the appendix to the thesis.

Regarding the product portfolio and sales volumes, Lara De Luca, in her work experience, has often seen the registration or registration of a higher tonnage waived because the sharing costs (of the analysis for the preparation of the registration dossier) were too high. This phenomenon happened especially in the first period, particularly in the 2010 registration. It was a phenomenon that affected companies with a very large portfolio of very similar products in terms of specifications. These companies reduced their product portfolio and/or the volumes of certain products in order to incur less registration fees, concentrating production mainly on the flagship product (and paying high fees on it). Therefore, their

strategy was to reduce sales of certain products and try to push the higher tonnage product with very similar specifications. REACH therefore led to eliminating products or reducing their volumes to avoid registering too many substances that were all similar and added no value. This reasoning was done to avoid registrations with high costs, which for letters of access could be as high as EUR 100,000.

In conclusion on the second-order effects, according to the expert, REACH is not a major factor in the increase of production costs, as it has been amortised over the years. This is because ECHA has defined registration deadlines (2010, 2013 and 2019), the last of which concerned small quantities (under 10 tonnes). Moreover, this is a fixed cost (incurred only once), the impact of which could be limited by prioritising certain products for registration and through import choices. On this last point, at the beginning of 2010, some importers facing the registration obligation had decided to source from European producers who were already in compliance.

In spite of the above impacts, the REACH consultant shows no significant effect of the regulation on profits and market share.

5.3 Conclusions on the applicability of Porter's hypothesis

The REACH consultant's contribution made it possible to fill in the missing evidence concerning second-order effects and economic results. With respect to the former, we have a rationalisation of the product portfolio/reduction in volumes of low value-added substances; while REACH is not considered a driver of price increases (consistent with the companies' responses). With respect to the latter, no significant effects of REACH on both volumes and profits are reported. It must always be considered that the consultant presents evidence in aggregate and limited to her work experience.

Integrating the consultant's contribution to the evidence of the companies schematised previously, we can draw conclusions on the applicability of Porter's hypothesis (1995). These conclusions, being the result of the participation of a pool of four companies each with its own peculiar characteristics, cannot be generalised (the impact is specific to each company), however they offer interesting insights into the relationship between REACH and competitiveness. In addition, the evidence could be enriched/strengthened by other

researchers interested in expanding the number of companies participating in the project or focusing on other geographical contexts.

We can confidently say that the dynamic vision hypothesised by Porter has occurred. Thus, companies were induced to innovate in order to cope with regulatory constraints. The innovations introduced were aimed more at social than economic benefit. As a result, the competitiveness of European chemical companies has not been greatly enhanced so far. Probably the real benefits of REACH have yet to be realised. In fact, the European policy has paved the way for a series of similar regulations (REACH like), testifying of a world moving in the same direction of sustainability, both in the will of legislators and in the consumption choices of customers. In this trend, European companies may find themselves at an advantage as they have become more competitive in sustainability-oriented innovation.

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Appendix – Interview answers

1. Sutter – Fabrizio Lavezzato

Alberto Prato

Can you introduce me to the company you work for and the position you hold within it?

Fabrizio Lavezzato

My name is Fabrizio Lavezzato, I am responsible for the R&D laboratory and quality control of Sutter Industries S.p.A. Sutter is a company that develops and markets detergents, cosmetics and biocides for the consumer and professional markets. As part of my job, in the role of Research and Development, I am also responsible for regulatory affairs. I am therefore responsible for everything concerning the regulatory compliance of raw materials, i.e., the individual components we use in our products, and mixtures, i.e., the finished products as they are known to the normal consumer who goes to buy them in the supermarket.

Alberto Prato

What is the role, for the purposes of the regulation, of the company within the supply chain?

Fabrizio Lavezzato

For the purposes of the regulation, we are downstream users. We purchase raw materials that we then use in our formulations. Some raw materials, which we define as such, are actually formulations and mixtures themselves. First and foremost, perfumes and essences. Essences are usually never a single substance, but, as they are composed in turn of several substances, mixtures.

Alberto Prato

What are your main obligations for compliance with the regulation given your role in the supply chain?

Fabrizio Lavezzato

The main obligation is to verify the compliance of all raw materials we use and all suppliers.

One of the most important aspects, which is sometimes overlooked, is the fact that we have to try to be as little as possible in the situation of mono sourcing, i.e., in the situation of buying a raw material from a single supplier. For all or most of the raw materials, which we use, we have more than one approved supplier. Approving a supplier 20 years ago meant, almost exclusively, approving it from a technical point of view. Let me give you an example, consider that I use a raw material that I buy from supplier A, which has certain chemical and physical characteristics, and which behaves in a certain way within the formula. I want to buy the same raw material, or an equivalent raw material, from supplier B. Until twenty years ago, what was fundamental was technical equivalence. I can use supplier A or supplier B indiscriminately, because the effect of the raw material, which I buy from A or B, on the mixture is the same. With the advent of REACH, things have changed substantially. I have been working in this sector since 1999, before REACH came into force there was a certain amount of attention to regulatory issues, which then increased exponentially with the coming into force of the regulation. Since REACH, technical equivalence is no longer enough, but there is an upstream step that is regulatory compliance. Regulatory compliance has meant that the way products are designed has also changed. Many raw materials, which could have had established technical equivalence characteristics, we could not implement or alternative suppliers we could not implement. The reason was that they lacked those regulatory compliance requirements, first and foremost clarity on the REACH issue. The advent of REACH and then also the advent of CLP (an acronym for Classification, Labelling and Packaging), the related regulation that talks about classification and labelling, changed the way we do design and innovation. A series of requirements and restrictions have arisen that have to be taken into consideration at the beginning of the development of a new product (early stages), otherwise you risk developing a product with a raw material that you cannot use or finding yourself in a situation of mono sourcing.

Similarly, the regulation affects the day by day, i.e., the existing products. Imagine that approved supplier A does not supply you with the material, which is very common these days because everything is lacking. You could purchase this material from supplier B. Before proceeding, you have to check that supplier B has all regulatory guarantees, including REACH compliance.

Regulation, while it has changed the way we design, also has a strong influence on the way we handle everyday products that are already on the market.

Alberto Prato

What are the main costs incurred by the company for compliance with the regulation and how high are they?

Fabrizio Lavezzato

As a downstream user, we generally do not deal with raw material registration. If the head of the R&D lab at Roquette in Cassano Spinola or ICE in Basaluzzo were in my place, he would probably tell you that they have incurred raw material registration costs, because they are companies that produce raw materials. We, from a downstream user point of view, have not incurred any registration costs. This is because we purchase the substances we use within our production processes. For substances for which we did not have sufficient information at REACH level, we had three possible paths in front of us. We could register as a company, change substance or go to a supplier who had registered that substance. I am talking, of course, about things that happened from 2010 onwards, when there was the first registration deadline. For the size that we are as Sutter and for the type of substances that we did not find enough information about, it was not worthwhile to undertake a registration process. The costs of registration would have been too high and the resources we would have had to commit would have been too much. We chose to change substances or go to suppliers who would guarantee us compliance. We are a big company, but we are not a multinational with unlimited R&D budgets. We made the choice to go in the direction of looking for those who were compliant.

Our costs are related to managing regulatory compliance, checking that everything we were buying was compliant. Since before 2010, we have put one of the resources in R&D, which is five people, to deal full-time with regulatory affairs. It wasn't like that before, you did the safety data sheets by hand and adjusted a little bit as you could. REACH was one of the drivers that made it necessary to invest in resources for regulatory compliance management.

Alberto Prato

What impact has the regulation had on production costs?

Fabrizio Lavezzato

There may certainly have been impacts on production costs, as those who registered in turn tried and try to pass on to their buyers the costs they incurred in registration. There may have been increases in raw materials, as there still are, which we must try to manage through careful formulation and through a judicious choice of our suppliers.

Alberto Prato

He already answered my question on the impact of the regulation on the R&D budget, confirming that some resources were shifted to compliance activities.

Fabrizio Lavezzato

In fact, compliance became an axis of R&D. Maybe that wasn't even a bad thing, I have to say. Whereas before regulatory compliance was something diluted in the other activities, now it has become a pillar of R&D. Without regulatory compliance on REACH we cannot develop our recipes.

Alberto Prato

What effect has the regulation had on time to market?

Fabrizio Lavezzato

We made sure that there were none or that we minimised them, but it was not always easy. It wasn't easy because some substances we actually removed. In particular, some dyes we removed and some SVHC raw materials we removed. Although SVHCs could be used under certain conditions, we as a company policy decided to remove them. This meant that, in order to avoid delays and maintain time to market, we had to invest a lot of man days on this regulatory situation. REACH, I have to say, was one of the main points of work and still is one of the main points of work.

Alberto Prato

This point on time to market therefore relates to the discussion made on design, checking whether a substance will be available at the design stage of a product.

Fabrizio Lavezzato

Absolutely, it is crucial to check beforehand. When we did the conformity review of all the substances and realised that some had to be removed, we had to work quickly. Replacing a raw material is not so simple, especially in chemistry. If there is something that can go wrong, rest assured that it will go wrong. I'll give you an example, I replace a red with another red, even if it has the same colour Index not infrequently the new red is not stable, whereas the one from before, which on paper was absolutely the same raw material, was stable. There was a lot of work, which we had to do quickly, to avoid market discontinuity situations.

Alberto Prato

Does the impossibility of using certain substances, because they are non-compliant, increase the uncertainty of product development?

Fabrizio Lavezzato

It certainly increases the uncertainty of product development. It has never occurred to me that it would prevent the launch of a product. Since, we develop detergent chemicals, so a fairly “easy” chemistry, and we have a lot of raw materials available anyway. Consequently, rather than impacting the arrival of a product on the market, it increases uncertainty as to the characteristics with which that product arrives on the market. The fact of not being able to use certain fluorinated surfactants in waxes meant that the waxes introduced to the market did not have those excellent wetting characteristics that they could have had with those raw materials that we had to remove, without, however, preventing them from being launched. I always give the example of coke. Coke and zero coke are not really the same thing. Sometimes we are forced by circumstances to develop zero coke, which is certainly good but is not coke.

Alberto Prato

Has the company suffered an interruption in supply because of the regulation?

Fabrizio Lavezzato

Absolutely. Beyond the regulatory impacts of REACH, we have an internal policy of not using SVHC substances. The list of SVHC substances is not something crystallised, but something that is constantly evolving. The moment a substance becomes SVHC we remove it, because we have a corporate vision of sustainability and low impact on the user and the environment. This has certainly had an impact on the supply chain as well.

Alberto Prato

Has the regulation, through reporting obligations, strengthened the relationship between companies belonging to the same supply chain?

Fabrizio Lavezzato

One of the objectives of REACH is certainly to increase communication. In the real world, sometimes the objectives of regulations are not implemented as intended by the legislator. The obligation to communicate is there, but in telling you that it is regularly complied with, I would say something inaccurate. It is not regularly complied with by our suppliers to us and by us to our suppliers. This is because there are so many things to do and because regulations change all the time. Some companies communicate well, others do not. There are suppliers who, if you don't push, still send you or still have safety data sheets that are not even up-to-date with CLP, this is the real world. The transition period to the CLP regulation ended on 1 June 2015. Even today, there are still safety data sheets floating around that are not updated to CLP, but are updated to the DPD (Dangerous Preparations Directive). The real world sometimes does not go hand in hand with what the legislator envisages. We have always tried to be able, when an inspection is made, to show that we have done everything in our power to receive communication from the top of the supply chain and transfer it downwards. We are downstream users, but below us, in the supply chain, there are still the large retail chains rather than professional users. To avoid a lack of communication, we have put in place a whole series of tools, including questionnaires, emails and warnings that we regularly send both upwards and downwards, so that there is still a fairly efficient flow of information.

Alberto Prato

Has this exchange of information, although limited, brought inefficiencies to light?

Fabrizio Lavezzato

Certainly, this exchange of formations, more or less “forced”, brought inefficiencies to light. It brought to light inefficiencies of a regulatory nature, i.e., to verify that there were safety data sheets that were not up to date, to verify that there was information on biodegradability that was not available, and to verify that we ourselves, as a company, were not communicating the updates of our safety data sheets to our distributors in an efficient and

constant manner. The fact that we had to communicate led to discovering certain inefficiencies and resolving them or at least trying to resolve them. Communication in REACH, as in all other regulations, is not something so spontaneous. This is what happens in the working world and this is what I can see in my own small experience. As a company, we have made sure to push our suppliers and ourselves, towards our distributors and our customers, to provide as much information as possible.

Alberto Prato

So were regulatory inefficiencies solved rather than inefficiencies related to the raw materials used or the production process?

Fabrizio Lavezzato

From the point of view of inefficiencies in raw materials used, no. When the raw material was not REACH-compliant or the supplier of that raw material was not REACH-conformant, we looked for other ways. This is a resolution of an inefficiency, always related to compliance with the regulation.

Alberto Prato

What choices have been made regarding the product portfolio? Did you remove certain products from the market?

Fabrizio Lavezzato

We removed raw materials, of course, that were non-compliant and we constantly remove all SVHCs by internal choice. We have a standard questionnaire that each new or existing supplier for a new raw material has to fill in with all relevant regulatory information, including REACH compliance.

Alberto Prato

Has compliance with the regulation affected the sales prices of your products?

Fabrizio Lavezzato

It had no effect on sales prices, in the sense that it is not because of REACH that we changed our price policy.

Alberto Prato

Has compliance with the regulation had any effect on production volumes?

Fabrizio Lavezzato

Not even, because we did everything in such a way that there was no discontinuity in the market.

It is not that the answer to these two questions is “no” because the regulation has no effect on these two points. We had to work to avoid these effects. There were no effects because we worked to ensure that production did not drop, even though there were raw materials, as I told you before, that were no longer approved. Although these effects did not occur, the regulation is very heavy on this situation.

Alberto Prato

You told me earlier that raw material costs have increased. Has this had no effect on your sales prices?

Fabrizio Lavezzato

We do a list increase once a year, which takes into account formula costs, production costs and commercial costs. I am not able to quantify the effect of REACH on sales prices. Certainly we have made sure that we do not have discontinuity in the market and that we work to have more approved suppliers with the same raw material, therefore more REACH-compliant alternatives, so as to also calm any cartel situations on the raw material that would force us to spend more money to buy.

Alberto Prato

From what was said earlier, your company has undertaken product innovations to replace those raw materials that do not comply with the regulation.

REACH affects substances also used in production processes and can lead to innovation in that area as well. Does your company use substances in production processes?

Fabrizio Lavezzato

Very little. However, these are substances that we use, for example, to clean up lines rather than containers. They are substances that we then use in finished products. Let's say that there is not a surplus of substances used at process level that has led us to make substantial changes and innovations in that area. Also because, with very few exceptions, our production processes are fortunately quite simple. We always talk about mixing liquids at reasonable temperatures, and we also do not make powders or aerosols. Within our factory we are in a fairly favourable situation from this point of view.

Alberto Prato

What effect did the regulation have on the company's profits?

Fabrizio Lavezzato

On profits I would not be able to quantify.

Alberto Prato

What effect has the regulation had on market shares?

Fabrizio Lavezzato

I see no effect on market share. We managed everything quite well in the area of R&D and regulatory compliance.

Alberto Prato

The innovation induced by the regulation was product-related, leading to the replacement of non-compliant suppliers and raw materials. I guess there was no increase in efficiency caused by these REACH-induced changes.

Fabrizio Lavezzato

More than an increase in efficiency, there was an increase in entropy. We had to work hard to maintain the current situation.

Alberto Prato

Did you benefit from the substitution of suppliers and raw materials?

Fabrizio Lavezzato

The only benefit, which we had, was to be able to guarantee continuity of production.

If the question is: thanks to REACH, did you find suppliers who provided you with materials that you did not have before?

The answer is no.

Alberto Prato

So, the innovations you have undertaken have been instrumental to compliance with the regulation. Have you had any benefits, outside of compliance, from REACH-induced actions?

Fabrizio Lavezzato

At the process level, no. At the product level, we have had benefits on communication to the consumer and end user. Thanks to REACH, we have taken a step forward in terms of sustainability, raw material management and policy on the use or non-use of certain substances, including SVHCs.

Alberto Prato

Can we say that you have benefited more socially than economically?

Fabrizio Lavezzato

Absolutely. We have benefited socially and in terms of communication, not economically.

Alberto Prato

As you have not supported process innovations, the productivity of your company has not changed as a result of REACH.

Has the innovation rate increased since the introduction of the regulation? Among the possible factors, which may influence the rate of innovation, I have identified time to market and uncertainty as discussed above.

Fabrizio Lavezzato

The time to market can be affected by the regulation, as in the initial product development step we need to make a detailed analysis of all new substances and new suppliers that we are going to test.

We did not make fewer products, but we may have made products that, because of the regulation, did not have particular excellence. Since, some substances, which have very good properties, we could no longer use.

The rate of innovation has remained more or less constant.

Alberto Prato

Did the regulation favour imports from European Economic Area countries?

Fabrizio Lavezzato

We needed to make verifications for everything coming in from outside Europe. For everything coming from Europe, our standard supplier and raw material validation process is activated. Materials from outside Europe proved to be more difficult to evaluate. Where possible, we preferred European suppliers, as they gave us more information and demonstrated a deeper knowledge of the regulation.

Alberto Prato

Not to mention that if you buy outside the European Economic Area, you become an importer and have to register.

Fabrizio Lavezzato

Exactly. Unless they have an only representative.

Alberto Prato

By buying from a European supplier who has registered the substance, the company incurs a lower cost.

Fabrizio Lavezzato

Absolutely, both in terms of money and time.

Alberto Prato

Can we say, that wherever possible, REACH has led to favouring imports from companies in the EEA?

Fabrizio Lavezzato

Absolutely.

Alberto Prato

Was there a different impact between the registration and authorisation process in terms of imports?

Fabrizio

The only criterion, which we had, was to find substances and suppliers that had all the compliance requirements.

Alberto Prato

I imagine that a company located in the EEA, having its main market in Europe, is more likely to be compliant.

Fabrizio Lavezzato

Exactly. The bulk of our market is in Europe.

Alberto Prato

Were you at a disadvantage when exporting to countries outside the EEA?

Fabrizio Lavezzato

In general, no. It is very complex to export to the UK after brexit. We have a small business, should it grow there are a number of things we have to look out for in order to be able to export to the UK. The UK REACH is a regulation similar to the one that applies to the EEA. To sell in the UK I have to have an only representative or my distributor has to take care of all the regulatory compliance situations.

Alberto Prato

Have you experienced such an increase in costs, related to REACH compliance, that you have difficulties competing outside the EEA with other companies that are not affected by the regulation?

Fabrizio Lavezzato

REACH is not the driver of the competitiveness problem we have on costs outside Europe. It is indirectly, because we buy raw materials in Europe that cost more because of REACH. Another company outside the EEA buys cheaper raw materials because there is no REACH and no other requirements. This might be an indirect effect of the regulation, but even if it occurred, it is not such that it would lead to less competitiveness of companies located in the European Economic Area.

Alberto Prato

In your view, does the regulation serve the objective of ensuring a high level of protection of human health and the environment?

Fabrizio Lavezzato

Absolutely. It has provided a lot of clarity, through the registration process, on the hazardous characteristics of substances, on the handling of substances, and on which substances were of particular concern that were perhaps better not to be used. The fact that we have the SVHC list allows us to remove hazardous substances a little bit earlier than when any restrictions might come into effect.

2. ICE – Francesco Pilla

Alberto Prato

Could you introduce me to the company you work for and the position you hold within it?

Francesco Pilla

My name is Francesco Pilla, I deal with safety and, in particular, REACH, one of my definitions is REACH Specialist. Within the plant, I do not so much follow REACH updates, as we use an external consultant to update the safety data sheets. My job is to deal with issues that may arise on imports of raw materials. We are not the ones who register raw materials, because that is the responsibility of the suppliers. The main problems arise with raw materials arriving from non-EU countries, including China, if they are not registered.

The company I work for is ICE S.p.a of Basaluzzo, a multinational company whose main end product is ursodesoxycholic acid, which is used as an active ingredient in the pharmaceutical industry.

Alberto Prato

What is the role, for the purposes of the regulation, of the company within the supply chain?

Francesco Pilla

For the purposes of the regulation, we are manufacturers and as such are obliged to register the products we market. Our finished products, including ursodesoxycholic acid and its derivatives, have been registered for REACH compliance. We used an external consultant for the registration, who completed the required paperwork that was then sent to ECHA. We bore the costs of the consultant and the registration fee. To summarise, on the one hand we have the raw materials, whose registration is the responsibility of the supplier, and on the other hand we have the finished products, whose REACH registration is our responsibility.

REACH is a regulation that affects all movements of substances within Europe. For example, a product arriving from China to enter the European Economic Area must have a REACH registration. Each substance has its registration on the safety data sheet. The safety data sheets contain all the characteristics of the substances, in particular information on handling,

hazards, precautions to be taken and clothing to be used when handling. On the safety data sheet is the REACH registration number. We only handle those raw materials that have REACH registration, just as our products marketed in Europe have their own registration number. The use of the raw materials we purchase must comply with what is stated in the safety data sheet. The safety data sheet has an “exposure scenarios” section, in which the identified uses of the substance, the scope of use and the characteristics of the company using the substance are listed. Therefore, substances must be used according to the conditions specified by the supplier, this is a limit of applicability. The same applies to the products we market, which may only be used in a pharmaceutical context.

Alberto Prato

Have you ever applied for authorisation for any product you market or for any product you use in your processes?

Francesco Pilla

No, we have never applied for authorisation

Alberto Prato

I understand that your main obligation is to register the substances you market and to check the conformity of the raw materials you purchase.

Francesco Pilla

We demand, whenever a raw material arrives, that the safety data sheet shows the registration number to verify compliance with REACH. There are, then, characteristics and parameters of the substance that must correspond to those we require. Let me give you an example, if we buy a 99% acid, clearly, we are concerned about making the title of that substance to verify that it is indeed a 99% acid, this beyond REACH compliance. So, at the time of purchase, registration is important as is the specification of the substance. The same applies to the products we market, in addition to being registered, we have to make sure that the parameters, including impurity, are consistent with what the customer specifies.

In the case of raw materials and finished products, there are three types of registration, which are complete, partial and joint, i.e. shared with other companies. In the specific case of our

company, we had to make a joint registration for taurine, since we were not the first to register it. All other registrations we have done are complete.

If we, as a company, were to purchase, as a matter of necessity, a substance that has not yet been registered, the registration would be our responsibility. In such cases, we check whether there is a supplier who has already registered this raw material. If there is such a supplier, we contact him to find an agreement on sharing the registration. For many registrations, special analyses are required, which are very expensive. By finding a supplier who has already registered the substance, for a payment proportional to the expense incurred by him, it is possible to share the registration and avoid costly analyses, thus saving money and time. We had a similar case when importing bromide from China. We had to register the substance because the Chinese supplier did not have an only representative. In order to register the substance, we had checked if there was another supplier who had already registered it and we had enquired about the cost of sharing. Then, in this specific case of bromide, a quantity had been released from an EEA supplier. Therefore, we had been able to avoid the purchase from China and, consequently, the registration.

The cost of registration is determined by the analyses required. Registration, in itself, is a practice that will have its costs, but marginal compared to the analyses carried out to collect the data. A shared registration, as it allows you not to perform the analysis but to access the data collected by another registrant through cost sharing, is much cheaper and faster than a full registration.

Alberto Prato

What are the main costs incurred by the company for compliance with the regulation and how high are they?

Francesco Pilla

The costs of registering our finished products are the only costs, related to compliance with the regulation, that we incur. With regard to raw materials, as mentioned above, the responsibility lies with the supplier. In the case of the import of substances, which come from outside the European Economic Area, registration is our responsibility. We have never had to register following importation. We came close to doing the registration in the case of

bromide, which we mentioned earlier, but due to the costs and time involved in applying for registration, we preferred to proceed differently. It must also be remembered that a non-European supplier should rely on an only representative, who is in charge of fulfilling the registration obligation. If the supplier relies on an only representative, we, for the purposes of REACH, are not recognised as an importer, but as a downstream user. Therefore, it becomes easier to import. If this is not the case, there are two possible ways. The first one is to bear the registration costs, while, as in the case of bromide, the second one is not to approve the supplier.

Alberto Prato

What impact has the regulation had on production costs?

Francesco Pilla

Certainly, the cost of registration incurred by the supplier is reflected in the cost of the raw material. Indicatively, to give an order of magnitude, the cost for a complete registration is between €15,000 and €20,000. We receive quantities of raw materials ranging from 10,000 to 30,000 kg per supplier. Let us assume that the supplier incurred a registration cost of €20,000, if the supplier only sold to us the impact on the raw material cost would be about one euro per kilo. If we consider that they do not supply only us, the impact REACH may have on the raw material cost is a negligible amount.

Until recently, some raw materials cost up to three times as much. The increase in cost was due to transport and availability issues, but not to REACH compliance. The impact of REACH is very small on the quantities we use. Of some substances, we buy a million kilos per year and the supplier can spread the cost over the sales volumes.

Alberto Prato

I anticipate one of the last questions in the interview, and link to the case of the non-importation of bromide. Did the regulation favour imports from European Economic Area (EEA) countries?

Francesco Pilla

Surely the regulation leads to a preference for an EEA supplier, thus favouring a supplier with a registration. If we have to choose who to buy a raw material from among the various suppliers available, we will certainly not turn to the supplier who has not registered the substance. The registration process, besides being costly, is time-consuming. You may consider registering a substance if at a time of low availability of raw materials, as in the case of bromide, you cannot find a supplier who has already registered the substance. So, even if you found a way to buy directly from suppliers that cater to the Chinese market or the Indian market, through branches and subsidiaries that we have in China, it would not be convenient for you, as they, not having the regulation in REACH, will not be compliant and you, as the importer, have to take care of compliance.

Alberto Prato

Have you never applied for authorisation because you are not affected by extremely hazardous substances?

Francesco Pilla

We have hazardous substances, thus identified as SVHC, coming in, but not yet reaching the expiry date. Only after the expiry date must an application be made for authorisation. Since these are incoming substances, they are handled by suppliers. On the outgoing side, our finished products are non-hazardous and, therefore, not subject to authorisation.

Alberto Prato

Once you reach this deadline, could you have a problem with discontinuity of supply if you or your supplier does not apply for authorisation?

Francesco Pilla

There are two or three manufacturers of some SVHC substances that we use. These manufacturers serve the whole world, so they have to gear up to apply for authorisation. Considering the applications of these substances, from blue jeans to active ingredients for the pharmaceutical industry, the sales volumes are such that they justify the cost of authorisation. When an SVHC substance is used, alternatives are rarely already available. If alternatives were available, it would be in our company's interest to implement them, as it would increase safety in the plant and bring us out of a situation of, almost, mono sourcing. The availability,

in terms of volume, of these SVHCs limits the company's growth. To summarise, the sales volumes, the lack of alternatives, the economic impact, and the criticality of the finished product we produce will certainly push suppliers to apply for authorisation and the competent authorities to issue it.

Alberto Prato

What are the costs associated with communicating information in the supply chain?

Francesco Pilla

The cost that we have to bear, with regard to the communication of information in the supply chain, is the updating of safety data sheets. Safety data sheets have to be updated when the legislation changes, for example, when the symbols or the required content changes. To understand how much we are talking about, let's consider that in a year we will update one or two sheets, not even EUR 1,000 perhaps.

We have to provide safety data sheets of the finished products we sell to our customers and, of the raw materials we use to our employees. For finished products, it is we, as a company, who are in charge of producing the safety data sheet. For raw materials, the safety data sheet is sent by the supplier.

Although one of the objectives of the regulation is the communication of information, there are inefficiencies. The safety data sheets of raw materials, for example, we have them from 2015, 2018 and 2019 even though not all raw materials have the updated sheets. We keep asking for them to be updated, some suppliers respond to the request, others do not. Of the substances we use, which number about a hundred, four or five do not have updated safety data sheets.

Alberto Prato

What effect has the regulation had on the R&D budget?

Francesco Pilla

I spoke to Mr Bianchi, the R&D manager, who told me that they use such minimal quantities, i.e., below one tonne per year, that they do not have to incur expenses in this regard. Not to

mention that the regulation, in order not to impact innovation, provides exemptions for substances used in the development of processes and products.

Alberto Prato

Talking to Fabrizio Lavezzato, R&D manager at Sutter, it appeared that R&D resources were being shifted to compliance activities. Has this phenomenon also affected your company?

Francesco Pilla

The person in charge of the REACH regulation is me, as REACH Specialist. Dealing with REACH issues is only one of my tasks within the plant. If we want to give an indication of the cost to the company, we can consider the salary of a resource to be around €40,000 per year.

Alberto Prato

I imagine that at Sutter they have a full-time REACH person because, as a company, they have a vision of sustainability that leads them to replace SVHCs before they expire. Not to mention that by developing detergent chemicals through blending, they have more raw materials, even alternatives, to choose from, following a REACH-compliant principle.

Francesco Pilla

Belonging to the pharmaceutical industry supply chain, everything is established at ministerial level. Consequently, we can have minimal variance in what is the finished product, hence, in the raw materials we use.

Alberto Prato

What effect has the regulation had on time to market?

Francesco Pilla

At the moment, the regulation has had no effect. We have kept the same products from before REACH came into force.

Alberto Prato

Has the company suffered an interruption in supply because of the regulation?

Francesco Pilla

We did not suffer a disruption in supply because of the regulation. In the case of bromide, which we mentioned earlier, there was a risk of a disruption in supply, but this was due to a problem of worldwide availability of the substance and therefore not related to REACH. We had found a Chinese supplier, but it was non-compliant. In the meantime, another quantity was released and, for the reasons mentioned earlier, the non-EU supplier was not approved.

Faced with exorbitant increases in raw material prices, we go looking for a cheaper supplier outside the EEA. Non-compliance with REACH puts the non-EU supplier at a disadvantage, despite the lower selling price.

Alberto Prato

Have you seen your suppliers reduce their product portfolio? If yes, what impact has this had?

Francesco Pilla

Often, by the term 'supplier' we do not refer to the manufacturer, but to the distributor. Should a manufacturer reduce its product portfolio, the distributor takes over by replacing the manufacturer. Not to mention that the distributor relies on several manufacturers. Thus, even if one of these supply channels were to fail, the substance remains available.

Alberto Prato

Has the regulation, through reporting obligations, strengthened the relationship between companies belonging to the same supply chain?

Francesco Pilla

Undoubtedly, it has strengthened the supply channels. It is easier for me to buy from a compliant supplier than from a non-compliant one. Strengthening the internal market, I think, is one of the main objectives of REACH. Preventing EEA companies from sourcing outside Europe because it is cheaper. REACH compliance is a requirement when choosing a supplier.

Alberto Prato

Has the company increased investments in the supply chain? If yes, what was the effect on flexibility in the choice of supplier?

Francesco Pilla

We considered incurring part of the registration costs for a supplier that was not REACH-authorised. In the end, we decided to go a different route. We did not, therefore, invest in the REACH qualification of a supplier, but if we did, it would have been done against a supply contract for a certain substance over a certain number of years. Otherwise, you would not be able to return the investment.

The investment in the supplier is linked to the problem of availability, which reduces the choice of supply. If the raw material is only available from a non-compliant supplier, you, as a company, are obliged to invest in supplier compliance. The raw material, one way or another, must arrive.

Alberto Prato

What choices did the company make regarding the product portfolio?

Francesco Pilla

We did not change our product portfolio, because we were able to cope with all supply disruption risk situations by paying three times as much for raw materials. As mentioned before, the risk of supply disruption occurred due to issues not related to REACH.

Alberto Prato

You have, therefore, registered all the substances you were marketing before REACH came into force. From what I understand, the impact of the registration cost you incurred was minimal.

Francesco Pilla

The impact of the registration cost was minimal. You have to consider that although our products have a small quantity output in terms of weight, they have a high economic value. Therefore, the registration cost is not amortised so much on volume, but rather on profit margins.

We, as a company, had another advantage in terms of registration. At the time of registration, we made a consortium with the Reggio Emilia plant, which belonged to the same group, so many costs were shared.

Alberto Prato

Have process and/or product innovations been undertaken?

Francesco Pilla

We undertook process innovations, but not product innovations. One of these regulation-induced innovations concerned transported intermediates. The change had been made to avoid the release of dust, consistent with the use indicated in the extended safety data sheet. This is not really a process change, but an aspect of handling to comply with the regulation.

Alberto Prato

Has compliance with the regulation had any effect on sales prices?

Francesco Pilla

The main driver on the price increase was the increase in raw material costs due to scarcity, e.g., gas which increased tenfold, therefore, not specifically attributable to REACH. The regulation should put you in a position to increase your selling price, because compliance is synonymous with quality. Quality in the pharmaceutical industry is everything. However, it is important to aware of the very competitive prices of non-EU competitors.

Alberto Prato

What effect has the regulation had on market shares?

Francesco Pilla

Volumes increased due to non-REACH-related phenomena. For example, worldwide use of the product, entry into new markets and expansion of existing markets.

Alberto Prato

What effect did the regulation have on the company's profits?

Francesco Pilla

Profits have increased as a result of the increase in production volumes, hence sales, to which I referred earlier. Like the increase in volumes, the increase in profits is not related to REACH.

Alberto Prato

Overall, did the innovation induced by the regulation offset the compliance costs or at least mitigate them?

You mentioned earlier that you found yourself having to change a process so that the use of the substance was consistent with that identified in the safety data sheet. Was this change introduced for pure compliance with the regulation or did it bring benefits?

Francesco Pilla

The change comes about because of compliance with the regulation. The stimulus of the regulation is to increase safety in the plant and environmental sustainability. At the company level, you always try to combine what is safety with an increase in production. To recapitulate, the change is driven by regulation compliance. In some cases, it was possible to combine an increase in production volume.

Alberto Prato

Can we say, therefore, that there was more social benefit, which is also the ultimate purpose for which change is induced, than economic benefit?

Francesco Pilla

Certainly, more social.

Alberto Prato

In your experience, has REACH led to overcoming an inertia towards change?

Francesco Pilla

This phenomenon has occurred. REACH leads to innovating and resolving inefficiencies or otherwise improving the initial situation, in terms of safety and, where possible, productivity.

Alberto Prato

By overcoming inertia towards change, REACH has therefore increased the rate of innovation.

Francesco Pilla

It was one more reason to implement innovations. We can say that it increased the rate of innovation.

Alberto Prato

Did the regulation favour imports from European Economic Area (EEA) countries?

This is the question we anticipated in the first part of the interview.

Francesco Pilla

Certainly, with equal availability, European products were preferred because they were compliant.

Alberto Prato

Were you at a disadvantage when exporting to countries outside the EEA?

Francesco Pilla

Our main finished product is ursodeoxycholic acid. We have four or five competitors in the world. So, whatever effect REACH may have had, the impact is limited given the scarcity of alternatives. You also have to consider that we, as a corporate group, are vertically integrated, so we have our own raw material suppliers covering about 60 per cent of our needs. The suppliers of the group also supply our competitors, any effect on costs is reflected on us as well as our competitors. Therefore, competitiveness does not change. Furthermore, our customers are very large companies that market worldwide and, consequently, also in Europe, they would have to justify their supply chain in reverse. For these companies, for the sake of less complexity, it is better to align themselves with the most restrictive supplier at the regulatory level, which allows them to produce a finished product that can be sold anywhere. As mentioned earlier, even if we had a higher selling price due to regulations affecting European companies, including REACH, we would still be in an advantageous situation compared to non-EU competitors. We would be in an advantageous situation, because REACH, as well as other regulations and certifications, is synonymous with quality, safety and is a guarantee, beyond the mere conformity of the material with a view to future sale in the EEA.

Alberto Prato

In your view, does the regulation serve the objective of ensuring a high level of protection of human health and the environment?

Francesco Pilla

The regulation certainly has a positive impact on the environment, on safety in the workplace and, considering that we produce an active ingredient for the pharmaceutical industry, on safety, in terms of control and quality, for the end consumer.

3. GBU - Anonymous respondent

Alberto Prato

Could you kindly introduce me to the company you work for and the position you hold within the company?

Respondent

I am responsible for regulatory affairs and the product stewardship function, which supports the product portfolio, for one of the Global Business Units (GBU) of a multinational company. The GBU in question has a reference plant in the province of Alessandria. In my role as manager, I am in charge of product stewardship and support.

The company I work for is a very large multinational company, which has offices all over the world and several GBUs depending on the product portfolio being followed. In our GBU we deal with both production and import and export of products depending on the chemical we need. My function handles not only European registrations, but also registrations for exports to other countries around the world.

Alberto Prato

Can REACH compliance facilitate exports to countries that have implemented similar regulations?

Respondent

It depends on the countries, but generally yes. REACH was the forerunner of policies to regulate chemicals. The various countries have taken their cue to develop their own registration process, following REACH in almost all aspects. REACH requires the registration of substances, thus requiring an assessment of environmental and human health impacts. For most countries, the analyses carried out for European legislation are accepted. Our function is to check which experimental data ensure compliance with multiple directives, allowing studies not to be duplicated. Duplication of studies not only impacts costs but also generates sustainability issues. To conclude, we can say that what has been done for REACH is generally accepted or can be supplemented with specific information.

Alberto Prato

What is the role, for the purposes of the regulation, of the company within the supply chain?

Respondent

We are mainly producers and importers. We are not downstream users, except for specific cases.

Alberto Prato

What are your main obligations for compliance with the regulation given your role in the supply chain?

Respondent

Our obligations concern the registration of the products we market and import. In addition to that, we are required to check the compliance of our suppliers.

Alberto Prato

What are the main costs incurred by the company for compliance with the regulation and how high are they?

Respondent

The costs of REACH compliance may be considered insignificant for a company of our size, however, the focus on costs remains even for a multinational company.

The registration of a substance requires the payment of a fee to ECHA of a few thousand euros. This component of the cost can be considered negligible. Carrying out experimental studies requires the expenditure of more resources, but is supported by the turnover related to the product. Our company has never decided not to proceed with a project because the compliance costs were too high.

Alberto Prato

Given the size of your company, have you always played the role of lead registrant when registering your products?

Respondent

We have often played the role of lead, depending on the interest in the substance to be registered.

Alberto Prato

For some products did you already have proprietary data?

Respondent

Yes, something was already present. However, with REACH, precise indications were given as to how to carry out the studies and in what manner. Some tests, carried out before the regulation came into force, were used for compliance or sustainability-related assessments. In spite of this, registration required many tests to be carried out.

Alberto Prato

Have you ever applied for authorisation?

Respondent

No, in our GBU product portfolio we have never applied for authorisation.

Alberto Prato

What impact has the regulation had on production costs?

Respondent

I have no direct evidence that our company has increased costs in connection with REACH registration.

Alberto Prato

What impact has the regulation had on the Research and Development (R&D) budget?

Respondent

Our company ensures REACH compliance through the function for which I am responsible. A function that deals with the registration of substances and the approval of suppliers.

Alberto Prato

Did your company use consultants for registration?

Respondent

We have always taken over the preparation of the registration dossier. Our company includes a department of toxicologists, who deal horizontally with the various GBUs by defining the protocols of the studies. We are the entity that supports our GBU for compliance. There is also a corporate group for SVHC assessment and one for monitoring changes in legislation. Therefore, there are structures outside our GBU (but belonging to the company) on which we can rely.

Alberto Prato

What effect has the regulation had on the time to market, i.e. on the cost of developing a new substance?

Respondent

REACH has definitely increased the time to market. In particular, depending on the tonnage level, it is necessary to foresee a time to ensure compliance and, consequently, registration. The task of our function is to inform the business and foresee these times, which depending on the tonnage can range from six months to two years.

Alberto Prato

Has the company suffered any interruptions in supply due to the regulation? If yes, what impact have they had?

Respondent

This type of problem happens periodically. In order to avoid an interruption in supply, our goal is to have more suppliers available. This way, if regulatory compliance is no longer ensured due to a change in legislation/compliance or if there is a reduction/interruption in production, we have a second supplier available.

Alberto Prato

Has the regulation consolidated the relationship between companies belonging to the same supply chain?

Respondent

We have a system that allows us to monitor who we send the safety data sheets to, ensuring a high level of transparency and immediate updating of suppliers. It is an internal procedure that we follow and it works quite well. Nevertheless, I don't think it has been able to strengthen relationships in the supply chain.

Alberto Prato

What choices did the company make regarding the product portfolio?

Respondent

In the past, I cannot tell you what effect REACH may have had. Currently, we follow the needs of the business. If a certain product is required to be used at a certain tonnage, we apply the registration regardless of the cost incurred.

To ensure greater environmental sustainability, we carefully evaluate SVHCs. In particular, during the development phase of a product, we check for the presence of alternative substances.

Alberto Prato

I guess REACH did not affect production volumes.

Respondent

Production volumes have not changed as a result of REACH, but are in line with business needs.

Alberto Prato

Have process and/or product innovations been undertaken?

Respondent

Our R&D department continuously researches to innovate with a view to sustainability, improving our products in order not to use SVHCs. The innovations undertaken have involved products as well as processes.

Alberto Prato

Has compliance with the regulation had any effect on sales prices?

Respondent

REACH has not been a driver of price increases

Alberto Prato

Based on the above, I assume that your company has not seen any effect on profits and market share.

Respondent

There were no effects.

Alberto Prato

What effect did the regulation have on the company's productivity?

Respondent

It is difficult to give an answer. The goal is always that innovation does not impact productivity or that the impact is minimal.

Alberto Prato

Has the innovation rate increased since the introduction of the regulation?

Respondent

This has certainly occurred. REACH has stimulated innovation with a view to more sustainable products.

Alberto Prato

Has the regulation favoured imports from countries belonging to the European Economic Area (EEA)?

Respondent

The regulation has favoured imports from EEA countries. This phenomenon occurred especially in the years immediately following the introduction of REACH. Non-European suppliers, who are more competitive in terms of price, have also equipped themselves for compliance over time.

Alberto Prato

Countries have also equipped themselves for compliance by introducing REACH like regulations.

Respondent

Despite this, the REACH like regulation does not determine REACH compliance, as the European directive is more restrictive.

Alberto Prato

Can REACH help European companies to be REACH like compliant?

Respondent

Yes, even if you have to integrate the registration dossier with the specific analyses required by each country. Certainly, European companies have an advantage because they have a structure for compliance in addition to the analysis.

Alberto Prato

From your point of view, does the regulation serve the objective of guaranteeing a high level of protection for human health and the environment?

Respondent

Absolutely yes. It has stimulated greater attention to the issue of human health and the environment, not only in companies but also in external bodies (non-governmental associations).

4. Italo Belge Colori – Edoardo Bisio

Alberto Prato

Could you introduce me to the company you work for and the position you hold within the company?

Edoardo Bisio

My name is Edoardo Bisio and I work for Italo Belge colori S.r.l. A company with 12/13 employees that produces paints mainly in the industrial sector, so paints for drums (e.g. Eni drums), and then of course interior painting. In the company I perform the role of safety and quality control engineer; therefore, I deal with safety data sheets, safety in the workplace and quality in the production of paints (whenever a paint is made I carry out all the various checks so that it can then be placed on the market).

Alberto Prato

What is the role, for the purposes of the regulation, of the company within the supply chain?

Edoardo Bisio

We are downstream users of registered substances, as we do not produce raw materials subject to registration. As a downstream user, we buy already registered substances or mixtures from our suppliers. In particular, some mixtures introduced into our production process contain SVHCs (e.g. carcinogens and mutagens). Prominent among these SVHCs are formaldehyde, phenols and benzene; these are never purchased as substances but as components of formulations. Mixtures containing these types of substances are subject to registration. In the case of formaldehyde, if the substance exceeds a certain concentration in the mixture, the label may state carcinogenic agent.

Alberto Prato

What are your main obligations for compliance with the regulation given your role in the supply chain?

Edoardo Bisio

Being a downstream user, Italo Belge is not involved in registration. However, we are still obliged to provide the SDS of the paints we sell. This is because they contain certain substances that can cause problems. Providing a complete and comprehensive safety data sheet allows our customers to work safely.

Communication of the SDS is an obligation. Italo Belge relies on an external consultant for the final check. If the substance does not have any hazard statements (either on the person or the environment), then a pseudo-safety data sheet can be made, in which the substances/mixtures that make up the article are explained. Very often, when the material is shipped, the SDS is attached to the invoice.

Alberto Prato

What are the main costs incurred by the company for compliance with the regulation and how high are they?

Edoardo Bisio

We have never been affected by registration and authorisation costs. The main costs we incur are associated with the communication of information. In particular, related to the people working on the SDS (myself and the external consultant) and the request for the safety data sheets of all raw materials that make up the paint. These safety data sheets are used to create the SDS of the finished product. Therefore, it is necessary to contact suppliers in the event of an out-of-date or missing SDS.

Alberto Prato

What impact has the regulation had on production costs?

Edoardo Bisio

In general, raw materials did not increase due to REACH

Alberto Prato

What effect has the regulation had on the Research and Development (R&D) budget?

Edoardo Bisio

Being a small company, there is no R&D department. Innovation is done directly by the resources in paint production.

Alberto Prato

What effect has the regulation had on the time to market, hence on the cost of developing a new substance?

Edoardo Bisio

Since the introduction of REACH, we have not introduced any new articles. Our research has focused on products already on the market. In particular, we have had to intervene on water-based paints because they contain formaldehyde (which is impossible to remove completely today). REACH, when formaldehyde was confirmed as a carcinogen (it was previously identified as a carcinogenic risk), led to a rethinking of the formulation of water-based paints.

To cope with the new restrictions imposed by REACH on formaldehyde concentration, action had to be taken both upstream and downstream. Upstream, all mixtures that contained formaldehyde were revised to drastically lower the formaldehyde content. Downstream, we users replaced the old mixtures by switching to 'low' formaldehyde mixtures, thus intervening in the formula. REACH has put very specific constraints, regarding formaldehyde, on both quantity and safety in the workplace.

Alberto Prato

Has the company suffered any interruptions in supply as a result of the regulation? If yes, what impacts have they had?

Edoardo Bisio

Many suppliers have adapted, looking for a solution. Therefore, we did not suffer interruptions in supply or change a supplier due to compliance.

It happened when transitioning from unregistered to registered substance that there were problems with supplies. In spite of this, suppliers were able to adjust because previous stocks were sent under the old restrictions, giving them time to comply.

Alberto Prato

Has the regulation strengthened the relationship between companies in the same supply chain?

Edoardo Bisio

Receiving a well-done and up-to-date SDS is definitely an added value. Because the more comprehensive the Material Safety Data Sheets are, the easier it is to produce a complete SDS for our products and, thus, for our customers.

As far as the communication process is concerned, it consists of requesting an updated SDS by e-mail. Therefore, this type of communication can hardly strengthen relations in the supply chain.

Alberto Prato

What choices did the company make regarding the product portfolio?

Edoardo Bisio

Our product portfolio has not changed since REACH came into force.

Alberto Prato

Have process and/or product innovations been undertaken?

Edoardo Bisio

The greater the constraints, the greater the need to introduce innovations. REACH has pushed and, in some cases, obliged to innovate by introducing the use of materials and production processes that allow work to be done safely and efficiently.

This innovation mechanism affected water-based formaldehyde paints. When the amount of formaldehyde was lowered so that H341 did not appear on the safety data sheet, solutions had to be found. In particular, there was a switch to 'low' formaldehyde raw materials. This was an almost obligatory change, as it would be very difficult to try to sell a paint with a risk phrase indicating the presence of a carcinogenic substance.

Alberto Prato

Has compliance with the regulation had any effect on sales prices?

Edoardo Bisio

It had no effect.

Alberto Prato

Did compliance with the regulation influence production volumes?

Edoardo Bisio

It had no effect.

Alberto Prato

What effects did the regulation have on the company's profits?

Edoardo Bisio

It had no effect.

Alberto Prato

What effect has the regulation had on market share?

Edoardo Bisio

It had no effect.

Alberto Prato

What effect has the regulation had on firm productivity?

Edoardo Bisio

In general, you always try, when something causes you to make a change, to improve the initial state.

Alberto Prato

Has the rate of innovation increased since the introduction of the regulation?

Edoardo Bisio

The rate of innovation has increased since the introduction of REACH.

Alberto Prato

Has REACH influenced your import and export choices?

Edoardo Bisio

Since we are a small company, we only source from Italian suppliers and in a few cases we ship our products abroad (almost never outside Europe). For export, low quantities are involved (largely under one tonne).

Alberto Prato

In your view, does the regulation serve the objective of ensuring a high level of protection of human health and the environment?

Edoardo Bisio

No doubt. REACH is made to safeguard the health of workers, product users and the environment as much as possible.

5. REACH expert – Lara De Luca

Alberto Prato

I would kindly ask you to introduce yourself.

Lara De Luca

My name is Lara De Luca, I am an industrial chemist. I have been dealing with regulatory affairs in this field since 2008.

My career path led me to interface with chemical regulation since 2004, as a formulator in a paint company. I was in charge of creating the safety data sheets for the products we formulated and managing the information in the SDS throughout the supply chain.

I attended a master's course at the Turin Polytechnic, entitled 'safety engineer risk analysis'. It was a course of study with strong training on Decree 81 and industrial risk analysis. I graduated when the REACH regulation came into force, on which I did my thesis.

After completing my master's degree at the Turin athenaeum, I started working in a consulting company that was already active in the field of the pre-REACH directive. This company, when the current legislation came into force, needed a chemist for risk assessment (which would be my specialisation). I worked in this company for 12 years. I was in charge of preparing registration dossiers for chemical/pharmaceutical companies. For our clients, we followed the entire dossier and safety data sheet process, including experimental studies.

After this experience, I joined Capgemini; a company that does consulting mainly in the engineering field. I still deal with the regulation, but in different areas with respect to my previous job. I mainly work with downstream users (users of chemicals, articles and materials). Our clients are electronic, mechanical engineering and aeronautical companies. These are industries that have never handled these aspects as non-chemicals.

Alberto Prato

One of the questions, which I submitted to the companies participating in the project, was about compliance expenses. I did not receive clear answers regarding the amount of the registration cost.

Lara De Luca

The cost of registration has several components. Companies are required to pay a fee, which is published in the regulation. Fees vary both by company size (with reductions for small and medium-sized companies) and by the quantities registered. The highest fee for a large company that registers more than 1000 tonnes is EUR 30000. This figure represents the maximum cost, to have reductions (for the same tonnage) a company must prove to be medium/small. It has happened that micro-companies part of a large group have declared themselves micro in order to pay less tax. The regulation provides a criterion for determining whether a company falls under the definition of large, small and medium-sized. This criterion also takes into account the number of subsidiaries.

Another component of the registration cost is that of the consultant that companies had to use, as the preparation of the dossier requires very specific expertise. It is possible that some companies, which have internalised this expertise by hiring over the years, are able to handle the updating of dossiers in-house. Nevertheless, for ex novo registrations, the tendency is to rely on external consultants, whose cost in the case of a simple dossier is around EUR 3000/4000.

REACH has established a joint registration mechanism to reduce the cost impact. This mechanism involves the identification of a lead registrant, who has the greatest interest in being the lead registrant because it produces or imports the largest quantities, has its own experimental data and is the most structured. The lead registrant bears the main cost, to which the other registrants who join as members contribute. The member has to pay the cost of the letter of access to the data (which it does not own) for data sharing. The process that determines the cost of sharing, according to the regulation, must be transparent. The lead registrant allows other registrants to go ahead with the process against payment, the amount of which depends on the number of registrants (the greater their number, the more the cost is shared) and the tonnage (which requires more or less complex studies). Tonnage is relevant, as a member only bears the cost of sharing for analyses that are useful for compiling the dossier of the substance of his or her interest. This sharing cost can vary from EUR 2000 to EUR 80000. It depends on the type of studies to be shared. The more you go towards longer studies that also involve animals, the higher the cost. For old studies that are still allowed, the cost is not high. For new studies it can be as much as 300000 euro (cost to be shared among

registrants). If the registration process is conducted alone, the costs are entirely of the sole registrant who hopes that someone will join.

Another component of the registration cost is the chemical safety report. The CSR is required if you produce above 10 tonnes. This is taken care of by the consultant. Depending on the usage scenarios, the expense can vary from EUR 1000 to EUR 10000.

Medium-sized or small companies above one tonne are hardly lead registrants, as they tend to aggregate. I have often seen the registration of higher tonnage waived because the sharing costs were too high. When the cost is not amortised by earnings, companies decide to reduce production volumes. This happened especially in the first period, particularly in the 2010 registration. A common phenomenon of the first phase was that companies, which had a very large portfolio of very similar products in terms of specifications, reduced their product portfolio and/or the volumes of certain products. Therefore, these companies concentrated production mainly on the flagship product (paying high taxes on that). Their strategy was to reduce sales of certain products and try to push the highest tonnage product with very similar specifications. REACH therefore led to eliminating products or reducing their volumes to avoid registering too many substances that were all similar and did not add value. Such reasoning was done to avoid registrations with high costs, even for letters of access that could be as high as EUR 100000.

Alberto Prato

When you speak of a letter of access, are you referring to the sharing of analysis costs?

Lara De Luca

Not chemical analyses, which are to be done individually. This is because the chemical identity must characterise each substance. With regard to experimental studies (in general) on animals, the regulation stipulates, if data are already available, not to repeat these studies. Therefore, the company that has the data from these studies must make them available to other companies, which must not produce new data. The production of new data would entail the involvement of other animals, in order to reach experimental evidence that already exists. It is therefore compulsory, in the case of studies involving animals, to share data. Analytical-

physical studies can be carried out by each company, through data sharing, which is not mandatory in this case, something could have been saved.

Alberto Prato

Let us now turn to the authorisation mechanism, which did not affect the companies interviewed. Therefore, at the moment, I have no evidence of the cost of this process.

Lara De Luca

Authorisation costs are very high. Currently, I am supporting aviation companies that do not submit an individual authorisation, but are participating in developing one for their sector. Therefore, these companies will not bear any direct costs. The authorisation fee is very high. The main component of the total expenditure is related to the preparation of the dossier, which has a common part with the registration dossier (the identity of the substance and the data) that can be purchased by those who have already applied for registration. The preparation of the dossier requires a resource-intensive socio-economic assessment to support the lack of alternatives. In particular, it must be demonstrated that the alternatives are not capable of replacing the substance and the significance of the impact that the lack of authorisation would have on the supply chain.

The industry has a strong interest in the renewal, because of the impact it would have on jobs and certain areas. Authorisation can be pursued by a few companies, but it can be submitted at sector level. This is because the effect involves the whole sector, bringing a large number of companies to bear the expense. The preparation of the dossier has very high costs (over EUR 100000), as it involves economic and not only technical specialists.

Alberto Prato

What about the costs of information sharing not highlighted by the respondents?

Lara De Luca

The implementation of dedicated reporting tools has not been a widespread phenomenon. Formulators, who produce a large number of safety data sheets, have equipped themselves with software to process them. The tool has a cost related to the person in charge of it and to updating the application. For communication, some have equipped themselves (it is not an

obligation) with portals to which suppliers and customers can respectively upload and download certain information.

To conclude, the implementation of tools is a choice at the discretion of the company. IT helps, in particular, companies that handle a large number of SDSs.

Alberto Prato

From the interviews conducted, it appeared that the impact on the production costs of REACH was minimal.

Lara De Luca

It is not one of the main drivers of increased production costs, as it has been amortised over the years. ECHA defined registration deadlines (2010, 2013 and 2019), the last of which affected small tonnages (under 10 tonnes). Moreover, this is a fixed cost (incurred only once), the impact of which could be limited by prioritising certain products for registration and through import choices. On this last point, in early 2010, some importers faced with the registration obligation had decided to source from already compliant European producers.

Alberto Prato

I found no evidence of the product portfolio either.

Lara De Luca

As I told you before, the registration deadlines represented a moment of reflection on the products marketed, leading to the rationalisation and optimisation of the portfolio. REACH created a benefit, as it gave the input to address (through rationalisation or volume reduction) a situation that was known about.

SVHCs, until included in Annex 14, do not have a major impact on companies. These substances represent a cost as they have to be mapped. One must also consider that some substances, which have been on the candidate list for 10 years, will never enter Annex 14. The decision to reduce/remove SVHCs is very pre-emptive and linked to the fear that the substance will become subject to authorisation, which could put its availability at risk. Therefore, the removal of SVHCs is not related to management costs, but to the complexity

of submitting an application for authorisation against inclusion of the substance on the Authorisation List.

Producers of articles try to avoid SVHCs, as the management of such substances requires more resources and a database for communicating information to the final recipient.

The process of substitution of SVHCs is assessed at the recommendation stage for inclusion in Annex 14, thus before the deadlines are set.

Alberto Prato

Have you experienced any impact on sales prices in your professional activity?

Lara De Luca

To my knowledge, REACH has had little impact.

Alberto Prato

Can being REACH-compliant present an added value in international competition?

Lara De Luca

No, as it is a legal obligation. Following the "chemical strategy for sustainability" is an added value in terms of sustainability, leading to the development of eco-sustainable products and processes.

Over the years, many REACH-like regulations have come into being. REACH has served as a model for many non-European policies that did not exist before (e.g. China REACH and Turkey REACH). These regulations are based on the same principle, but are less restrictive in terms of regulation and framework. Therefore, being REACH compliant facilitates (does not guarantee) compliance with other REACH like regulations.

Chinese suppliers, prior to the implementation of China REACH, did not understand importers' requests for detailed analysis. As a result, Chinese manufacturers were sharing poor information. China then realised that in order to continue to have a market in Europe and be competitive, it would have to gear up for compliance. Therefore, China REACH (a REACH like regulation) came into force. The world is moving in the same direction.

Alberto Prato

Did you therefore find that REACH compliance can help a company comply with REACH like regulations?

Lara De Luca

Absolutely.

Alberto Prato

Is REACH a certification of quality that can be sold on the international market?

Lara De Luca

Having a registration is an advantage for manufacturers as it ensures business continuity for customers. In particular, users required their suppliers to belong to a supply chain whose companies subject to authorisation had sent the dossier to ECHA. This request arose from the need to maintain business continuity when deadlines arrived.

Unlike the registration process, authorisation creates quasi-monopoly situations. This is because it is only possible to buy from companies that hold the authorisation.

Alberto Prato

Do the volume choices relate to the evaluations made by the companies when the registration deadlines were reached?

Lara De Luca

Volume assessments were made to avoid a substance falling into the higher tonnage range and, consequently, requiring a more complex dossier. Even some companies decided not to register substances, keeping their volumes below one tonne.

Alberto Prato

How do you evaluate the impact of the regulation on the competitiveness of the European chemical industry?

Lara De Luca

REACH for pure chemical industries is an obligation. Therefore, it has prompted companies to broaden their decision-making parameters in the development phase to include health, safety and the environment.

REACH, by producing a lot of experimental data, has strengthened the knowledge of chemical groups. As a result, alert structures have been established that allow the continuation of development to be assessed already during the early design stages. Development is reconsidered if there is preliminary evidence (relating to safety, health and the environment) that the substance is problematic. Regulatory compliance becomes an asset for R&D, as it is pointless to design a new product if it has a functional/chemical group that could lead to the activation of future restrictions.

REACH has, therefore, increased competitiveness in innovation. This makes it possible to have a product that, in the long run, does not risk being banned in a few years. In addition to all the advantages for the environment and worker protection. Delving into the studies beforehand already gives a picture of the danger, which could lead to development being precluded. Despite this, industry perceives REACH as an upfront cost.

Alberto Prato

How strong is the end consumer's interest in environmental sustainability?

Lara De Luca

Consumers are becoming increasingly attentive and aware of environmental issues. REACH is the forerunner of the Eco-design regulation, which seeks to respond to this strong interest in sustainability. This directive envisages that in future every product will be accompanied by a digital passport. Evidence of this trend is also to be found in the current regulation, where it has happened that consumers request SDSs (the communication of which to end consumers is not compulsory for the purposes of REACH)

Alberto Prato

Given REACH like regulations, can companies in the European Economic Area have an advantage in international competition?

Lara De Luca

In exporting, visionary companies that have anticipated the regulations are certainly at an advantage. Moreover, the European safety data sheet is accepted by the non-European recipient who will convert it into its own format.

Alberto Prato

Can REACH trigger a process innovation mechanism and what can be the impact on productivity?

Lara De Luca

REACH mainly leads to product innovation. The application for authorisation can lead to rethinking the process, as not only an alternative substance is evaluated, but also an alternative technology. Usually, process changes have a possible negative impact.