SHELLA IRA TALAMPAS

STUDY ON THE DIFFERENT STRATEGIES AND APPROACHES FOLLOWED BY COMPANIES IN PORTUGAL AND SPAIN TO COMPLY WITH REACH REGULATIONS

UNIVERSIDADE DO ALGARVE
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Erasmus Mundus MSc in Chemical Innovation and Regulation
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Trabalho efetuado sob a orientação de:

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DECLARATION OF AUTHORSHIP

I declare that I am the author of this work, which is original. The work cites other authors and works, which are adequately referred in the text and are listed in the bibliography.

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Shella Ira Talampas

DEDICATION

This research project is dedicated to my DAD who taught me the value of integrity.

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ABSTRACT

The implementation of the REACH regulation still experiences significant difficulties in the quality of information provided by companies through their registration dossiers. Given that the success of the REACH process depends primarily on the adequate and reliable information supplied by industries, there is a need to document and manage the knowledge gained and generated since its implementation. This research study documents and examines the issues and concerns experienced as well as the best practices adapted by chemical industries in Spain and Portugal. To accomplish this, the study requested the assistance of chemical industry associations in Spain and Portugal during the period of 2016-2017, before the 2018 deadline for the REACH registration process. Discussion with the Federación Empresarial de la Industria Quimica Española (FEIQUE) in Spain and the Associação Portuguesa das Empresas Químicas (APEQ) in Portugal regarding the necessary data collection for the research study. Online survey questionnaires were then disseminated to member industries of the two associations. The survey questionnaire primarily involved the key processes of REACH – registration, evaluation, authorization and restriction. Out of the chemical industry members of APEQ and FEIQUE, 20 (56%) companies in Portugal participated while in Spain only 6 companies did. Result of the research study is largely based on these respondents. Data from survey questionnaires revealed that major issues and concerns identified by industries were primarily operational issues relating to the implementation of the Substance Information Exchange Forum (SIEF). Among these are communications problems among participants in the implementation of the SIEF, failure to reach an agreement on the sharing of existing data, testing cost and lack of response from suppliers in the use of substance and correction of errors in the SDS as well as difficulties in the use of REACH IT tools. The survey results also revealed that SIEF, where EU-based chemical industries form consortiums and jointly carry out registration and dossier submission, is among the best practices implemented by ECHA and identified by chemical industries. Industries also recognized ECHA's effort

in providing active and good support mechanism in complying with the REACH regulation.

Keywords: REACH regulation, European Union, regulatory, SIEF, industry

RESUMO

A implementação da Regulamentação REACH ainda apresenta dificuldades significativas na qualidade das informações fornecidas pelas empresas nos seus dossiers de registo. Dado que o sucesso do processo REACH depende principalmente de informação adequada e fiável fornecida pelas indústrias, é necessário documentar e interpretar a informação gerado desde a sua implementação. O presente estudo documenta e avalia as principais questões e preocupações sentidas pelas empresas da indústria química em Espanha e em Portugal, bem como as melhores práticas por elas adotadas na implementação do REACH. O estudo beneficiou da colaboração da Federação Empresarial da Indústria Química Española (FEIQUE) em Espanha, e da Associação Portuguesa das Empresas Químicas (APEQ) em Portugal. Prepararam-se inquéritos online que foram divulgados entre as indústrias membros das duas associações. O inquérito cobre os principais processos do REACH - registro, avaliação, autorização e restrição. De entre os associados da APEQ e da FEIQUE, 20 membros (56%) participaram em Portugal, e apenas 6 de empresas responderam em Espanha. O resultado do estudo de pesquisa baseia-se nos inquéritos e na informação disponibilizada on-line pela ECHA . Os dados dos inquéritos revelaram que as principais preocupações identificadas pelas indústrias focam questões operacionais relacionadas com a implementação dos "Substance Information Exchange Fora" (SIEF). Identificam-se dificuldades de comunicação entre os participantes, dificuldades em chegar a acordo sobre a partilha de dados existentes, o custo dos testes, a falta de resposta dos fornecedores sobre o uso de substância, a correção de erros nas folhas de segurança (SDS), bem como dificuldades no uso das ferramentas informáticas REACH. Os resultados da pesquisa também revelaram o SIEF, onde as indústrias químicas formam consórcios e realizam em conjunto a inscrição e a submissão de dossiers, é uma das melhores práticas identificadas pelas indústrias químicas e implementada pela ECHA. As indústrias também reconheceram o esforço da ECHA em fornecer um suporte ativo e bom para cumprimento do REACH.

Palavras-chave: Regulamento REACH, União Européia, regulamentar, SIEF, indústria

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LIST OF ABBREVIATIONS AND ACRONYMS

AFAQUIM	Asociación Española de Fabricantes de Productos de Química Fina or Manufacturers' Association of Pharmaceutical Chemistry
AIE	Agrupación de Interés Económico
AISE	International Association for Soaps, Detergents and Maintenance Products
ANFFECC	Asociación Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos
APA	Agência Portuguesa do Ambiente or Portuguese Environment Agency
APEQ	Associação Portuguesa das Empresas Químicas
APETRO	Associação Portuguesa de Empresas Petrolíferas
APIB	Associação Portuguesa dos Industriais de Borracha
APIP	Portuguese Plastic Industry Association
APT	Associação Portuguesa de Tintas
ASEFCA	Asociación Española de Fabricantes de colas y adhesivos
BRIICS	Brazil, Russia, India, China and South Africa
CAE	Classificação Portuguesa das Actividades Económicas
CAS	Chemical Abstracts Service
CEFIC	Conseil Européen des Fédérations de l'Industrie Chimique or European Chemical Industry Council
CELPA	Associação da Indústria Papeleira
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
CG/HCCS	Coordinating Group for the Harmonization of Chemical Classification Systems
CLP	Classification and Labelling of Chemicals
CMRs	Carcinogenic, Mutagenic or Toxic to Reproduction
CNAE	Clasificación Nacional de Actividades Económicas
COM	Commission
CSR	Chemical Safety Report

DGS	Direcção Geral de Segurança or Department of General Services
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EEC	European Economic Community
EFfCI	European Federation for Cosmetic Ingredients
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EMMC ChIR	Erasmus Mundus Master Course in Chemical Innovation and Regulation
EPDLA	European Polymer Dispersion and Latex Association
ESDS	Extended Safety Data Sheet
ETBE	Ethyl tert-butyl ether
EU	European Union
EU 28	European Union 28 Member States
F.O.B.	Free on Board
FEDEQUIM	Federación Empresarial Catalana del Sector Químico
FEIQUE	Federación Empresarial de la Industria Quimica Española
FIOVDE	Federação Das Indústrias De Óleos Vegetais Derivados E Equiparados
GDP	Gross Domestic Product
GHS	Globally Harmonized System
GROQUIFAR	Associação de Grossistas de Produtos Químicos e Farmacêuticos
H400/410	Hazard statements
IAPMEI	Instituto de Apoio Às Pequenas e Médias Empresas e ao Investimento
ICCM	International Conference on Chemicals Management
ILC 170	International Labor Organization Chemicals Convention No. 170
ILO	International Labor Organization
ILR 177	International Labor Organization Recommendation No. 177

IOMC	Interorganization Programme for the Sound Management of Chemicals
IP&P	Industry Programmes and Projects
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
MAPAMA	Ministerio Agricultura y Pesca, Alimentación y Medio Ambiente
MDI	Methylene diphenyl diisocyanate
MEP	Ministry of Environmental Protection
METI	Ministry of Economy, Trade and Industry
MHLW	Ministry of Health, Labour and Welfare
MMA	Ministry of the Environment
MSCA	Member States Competent Authorities
MSPS	Ministerio de Sanidad, Servicios Sociales e Igualdad
NLP	No-Longer Polymers
NONS	Notification of New Substances
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
OSOR	One Substance, One Registration
PIC	Prior Informed Consent
POPs	Persistent Organic Pollutants
PTA	Terephthalic acid
PVC	Polyvinyl chloride
R50/R53	Risk phrases
R&D	Research and Development
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RoW	Rest of the World
S.A.	Sociedad Anónima
S.L.	Sociedad de Responsabilidad Limitada

SAICM	Strategic Approach to International Chemicals Management
SCP	Sustainable Consumption and Production
SDS	Safety Data Sheets
SIEF	Substance Information Exchange Forum
SMEs	Small, Medium and Micro Enterprises
SVHC	Substances of Very High Concern
SRM	Solvent Resins
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
UNSCETDG	United Nations Sub-Committee of Experts on the Transport of Dangerous Goods
US$/ USD	United States Dollar
USA	United States of America
USEPA	United States Environmental Protection Agency
UTE	Uniones Temporales de Empresas
WSSD	World Summit on Sustainable Development

1. INTRODUCTION

1.1 Objectives

The REACH Regulation is believed to be the most ambitious chemicals legislation in the world [1]. The implementation of the regulation in the EU member states has been a great challenge for the sectors involved particularly the industries, member states' government agencies, ECHA and the European Commission. The government agencies are focused on how they can successfully implement and enforce the legislation while the industries concern is to ensure that they can comply with the REACH regulation.

While the response by companies to the REACH legislation can be considered impressive, the real challenge is collating lessons learned and using them in formulating strategies and mechanisms to address the difficulty of complying with the legislation. This study discusses the best practices of the companies in Spain and Portugal in complying with the REACH regulation involving the REACH four key processes namely registration, evaluation, authorization and restriction.

Therefore, the research project primarily aims to document and analyze the different strategies and approaches of chemical industries in Spain and Portugal to comply with REACH regulations. Specifically, the research study aims to:

a. Identify the issues, concerns and challenges encountered by chemical industries in complying with REACH regulations;

b. Document appropriated mechanisms and best practices that chemical industries can use as decision support tool;

c. Assess methods and processes employed by industries in addressing and coping with the demanding requirement of REACH regulations; and

d. Recommend appropriate methods and strategies in dealing with the evolving chemical regulatory guidelines, maintaining industry

standards and strengthening competitiveness in the global chemical industry market.

1.2 Importance of chemicals and chemical industry

Globally, chemicals are essential components in the advancement of technology and modern life. More than thousands of chemicals are found in the market and used to improve the quality of lives of people. People all over the world are living comfortably and are more productive because of the products resulting of these chemicals. The majority of developments in the world involve chemical reactions from the beginning of the production process of a product into another product up to disposal. The food, clothing, heat, power, telecommunication, furniture, fixtures, and vehicles that humans used involve chemicals. Chemicals are key to healthy living and modern convenience [2].

The skill of modern day manufacturing is in designing products that perform more effectively than their predecessors such as cleaning products, clothing, fragrances, insecticides, and paints [3]. These chemicals are known as consumer goods and generally applied in households for cleaning, pest control and hygiene purposes. Most of the chemicals in these products are among the toxic substances found in our homes. But with the recent innovations made by the manufacturers, the use of alternative chemicals and chemical processes in manufacturing these products contribute to the effectivity and efficiency of the lives of humans. Detergents, soaps, toothpaste, and shampoo are examples of cleaning products. Detergents, soaps and shampoo contain surfactants to remove dirt from the clothes, household articles, skin and hair. Most toothpaste contains the five ingredients namely fluoride, abrasives, flavors, humectants and detergents. The fluoride and abrasives help in the cleaning and protecting the teeth. These substances play an important role in the production of cleaning agents. Additionally, fragrances are added to some of the cleaning products. Fragrances are aromatic chemical compounds that make cleaning products and perfumes having a pleasant smell.

Another product used in households is the insecticide, which contains two types of pyrethroids namely permethrin and tetramethrin. These chemicals attack the nervous system of insects [4, 5] causing muscle spasms, paralysis and death [5]. Paints are also products applied in households that decorate, protect and lengthen the life of the materials. Paints contain pigments, binder or resin, extender, solvent and additives. Depending on the solvents used, paints are either oil-based or water-based. The solvents are used to reduce the viscosity of the paint for better application; pigments to impart color and opacity; binder or resin, a polymer forming a matrix to hold the pigment in place; extender strengthens the film and save the binder; and additives modifies the properties of the liquid paint or dry film [6].

Clothing is one of the most essential basic needs of people. Clothes undergo a range of chemical processes as well as treatments. Textiles and processes used in the manufacture of clothes have extensively improved such as permanent treatments based on nanoparticles and nanostructures to make textiles more resistant to water, stains, wrinkles, bacteria and mould [3]. Other products used in textiles are either highly specialized chemicals or simple chemicals or mixtures [3]. Biocides, flame retardants, water repellants and warp sizes are examples of highly specialized chemicals; while emulsified oils and greases, starch, sulfonated oils, waxes and other surfactants are simple chemicals or mixtures [3]. Chemicals bring about benefits upon which modern society is entirely dependent [3].

Generally, industries are using chemicals. Chemicals are critical in many industrial processes for developing products important to global standards of living [2]. There is hardly any industry where chemical substances are not used and there is no single economic sector where chemicals do not play an important role [7]. Chemicals are important in all aspects of medicine and agriculture to consumer goods, clean technologies and overcoming poverty. Thus, chemicals play an important role in the economy worldwide. As stated by the United Nations Development Programme (UNDP), chemicals are critical to the manufacture of many products and protection of human health, and an important contributor to the Gross Domestic Product (GDP) and employment. Most (69%) Europeans consider chemicals

unavoidable for their daily life and 75% relate them to industrial innovations [3]. Chemicals make a vital contribution both to the economic and social wellbeing of citizens in terms of trade and employment [3].

The chemical industry is one of the world's most vital and vibrant business sectors [8]. It has an estimated financial impact of over US$3.2 trillion, employs 7 million people, and supports 20 million additional jobs in related sectors [8]. Including indirect employment, there are more than 20 million people worldwide whose job depends on chemistry [9].

The European Union (EU) experienced the global crisis since 1999. The current level of employment is still far below the peak level before the crisis although the employment level stabilized since 2010 as illustrated in Figure 1.1 [10]. In 2015, chemical companies in the EU employed nearly around 1.2 million, wherein direct employment in the EU chemical industry decreased by an average annual rate of 1.7 percent from 1998 to 2015 [10]. But the sector generated a greater number of indirect jobs, which is three times higher compared through direct employment [10]. The Spanish and Portuguese chemical industries generated part of the 1.2 million employment of the EU. The Spanish chemical industry was also not exempted of the global crisis.

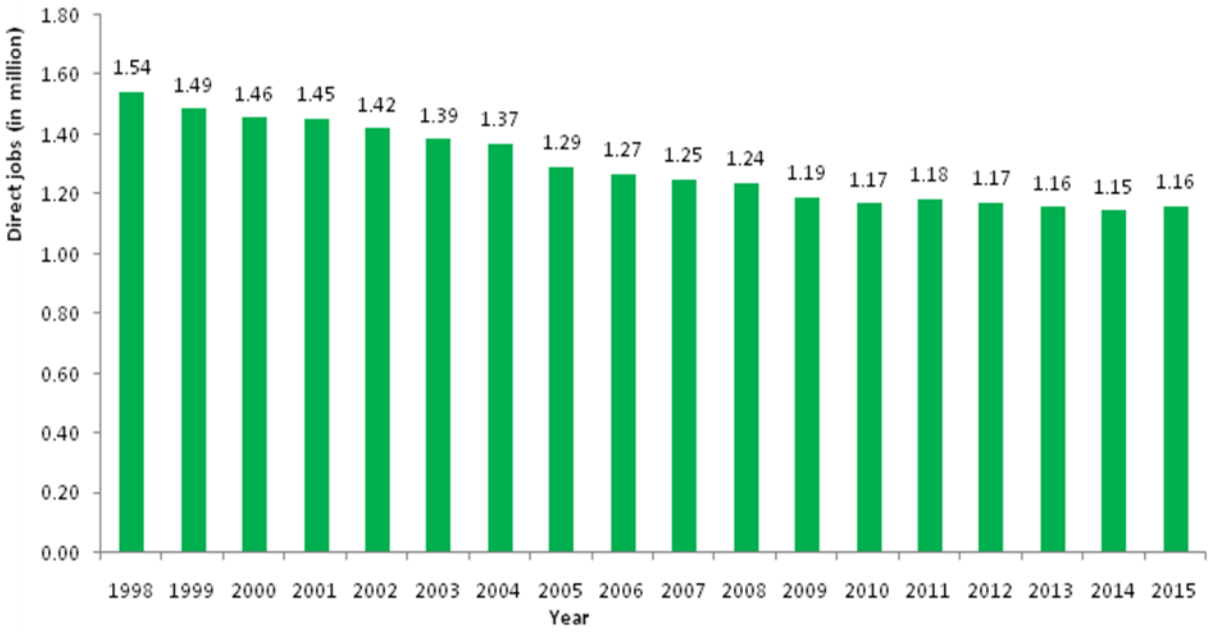


Figure 1.1 Employment in the EU Chemical Industry (Source: ref. 10)

Figure 1.2 demonstrates the accumulated growth of -1.7 percent of the direct employment in the chemical industry in Spain from 2007 to 2015 but it continuously increased from 2012 to 2015, wherein 9.6% increase is observed from 2014 to 2015 [11]. The number of employees working in the chemical industry grew by more than 6% in 2014 and currently creates 540,000 direct, indirect and induced jobs [12].

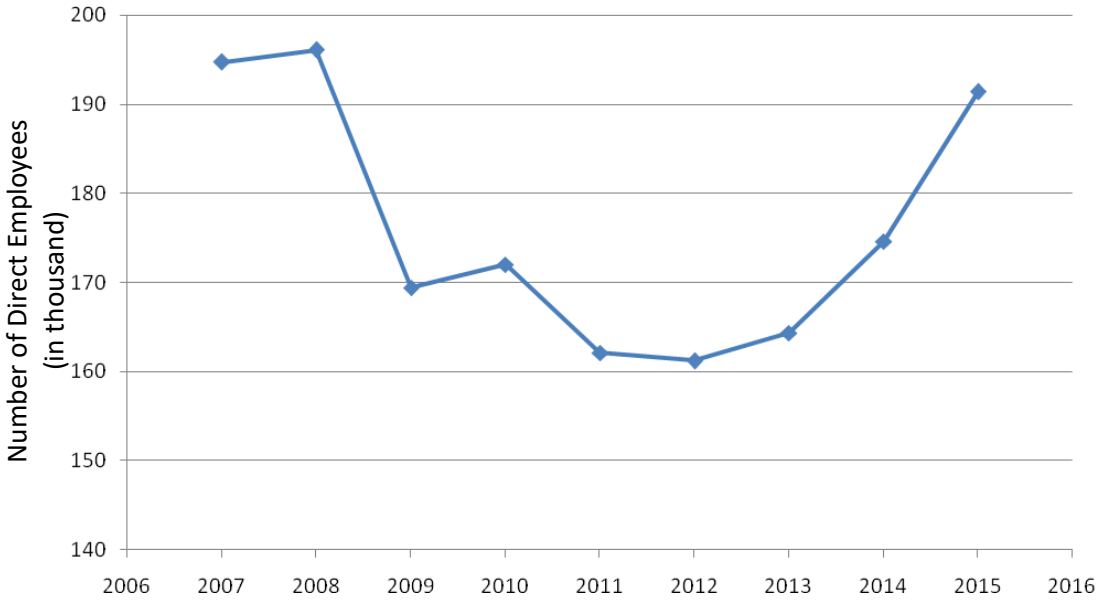


Figure 1.2 Direct employment in the chemical industry in Spain (Source: ref. 11)

However, the Portuguese petrochemical and chemical industry is small compared with other EU countries but it has a relevant impact and quite substantial in terms of employment with its recent new expansion projects and new factories [13]. The indirect and direct employment rate of the Portuguese chemical industry from 2004 to 2008 comprise the 0.5 percent of the total population of Portugal. As new production expands to meet growing global demand, employment in the business of chemistry will further accelerate [14].

1.3 Production and consumption of chemicals

The global chemicals industry has grown rapidly over the past several decades. The global chemical industry output climbed from US$ 171 billion in 1970 to over US$ 4.12 trillion in 2010 [7]. The increase in the production of chemicals will continue as the demand increases. It is projected that 31 percent of global chemical production and 33 percent of global consumption will be in developing countries by 2020 [15, 16]. Chemical sales worldwide has increased by 2.2 times from 1,622 billion Euro in 2005 to 3,534 billion Euro in 2015 [10]. Within the last decade in particular, this growth has been driven primarily by dramatic growth in developing countries and countries with economies in transition [7]. China, India, Russia and Brazil are some of the fastest growing sectors of the bulk and agricultural chemical industries, wherein their growth rates far exceed the growth rates for the chemical industries typically located in the United States, Japan and Europe [7]. Figure 1.3 and Figure 1.4 demonstrate China as the top region on the 2015 global chemical sales followed by the EU and United States. In 2015, the sales of chemicals globally is valued more than 3,500 billion Euro while the EU chemical products sales is worth more than 519 billion Euro encompassing majority of Europe's 615 billion Euro sales [10].

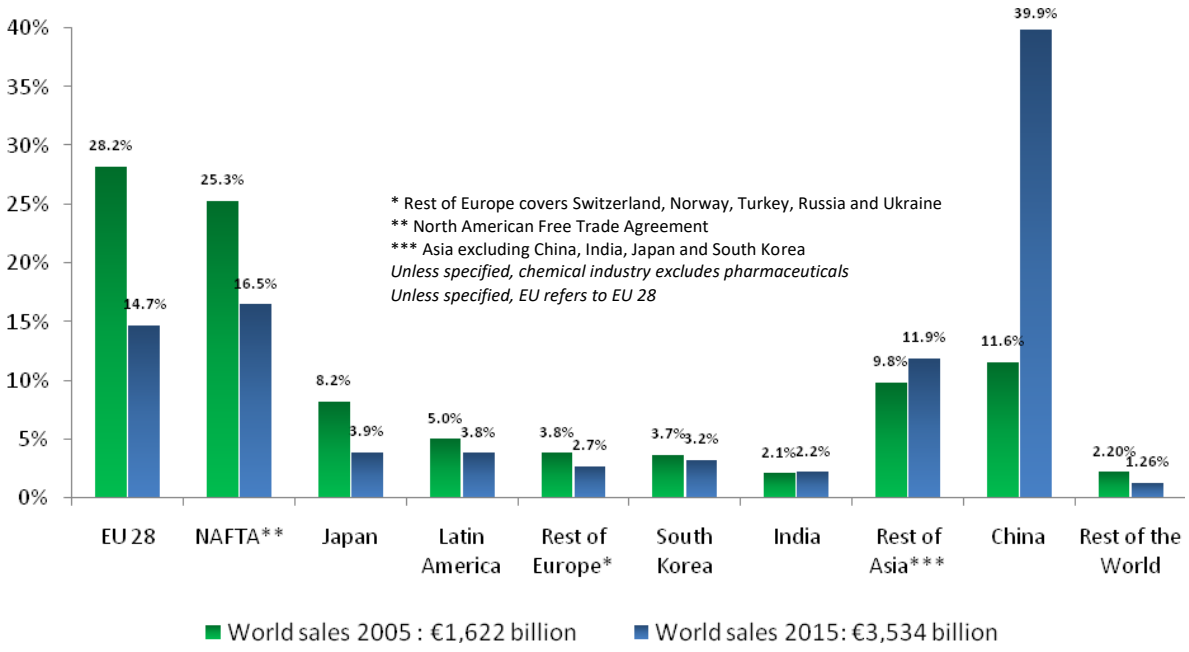


Figure 1.3 World Chemicals 2015 by Region [Source: ref.10].

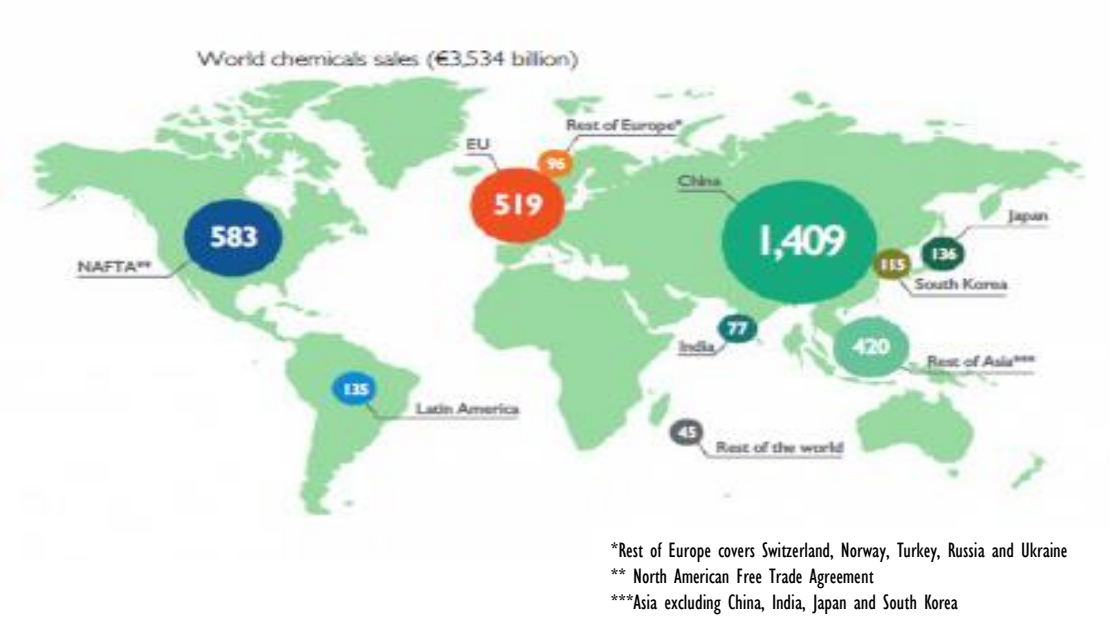


Figure 1.4 Geographic breakdown of world chemicals sales [10].

In the United Nations Industrial Development Organization (UNIDO) statistics report for the second quarter of 2016, the global manufacturing production maintained a positive growth in nearly all the industries in which high and medium high manufacturing industries held top positions [17]. The production of chemical products ranked third that rose by 3.9 percent, which is subsequent to the 4.3% production of pharmaceutical products and 4.2% manufacture of motor vehicles [17]. According to the Organisation for Economic Cooperation and Development (OECD) report, there is an expected increase in the production of chemicals globally from 2010 to 2050 as shown in Figure 1.5 [18].

The EU chemical industry production sale is categorized into 3 areas namely base chemicals, specialty chemicals, and consumer chemicals [10]. Base chemicals are grouped into petrochemicals, basic inorganics (industrial gases, fertilizers, other inorganics), and polymers (plastics, synthetic rubbers, manmade fibers) [10]. Base chemicals accounted majority of the total EU chemical sales since 2009 to 2015, in which they represented 59.5 percent of total EU chemicals sales in 2015 [10]. Specialty chemicals are classified into paints and inks, crop protection, dyes and pigments, and auxiliaries for industry [10]. Although the productions of specialty chemicals are in small volumes, they represented 28.0 percent of the EU sales on

chemicals [10]. Products traded directly to the populace such as soaps, detergents, toiletries, perfumes, fragrances and cosmetics are examples of consumer chemicals. These chemicals covered the 12.5 percent of the 2015 EU sales of chemicals [10]. The EU chemical industry sales in 2015 by the 3 sectors is illustrated in Figure 1.6.

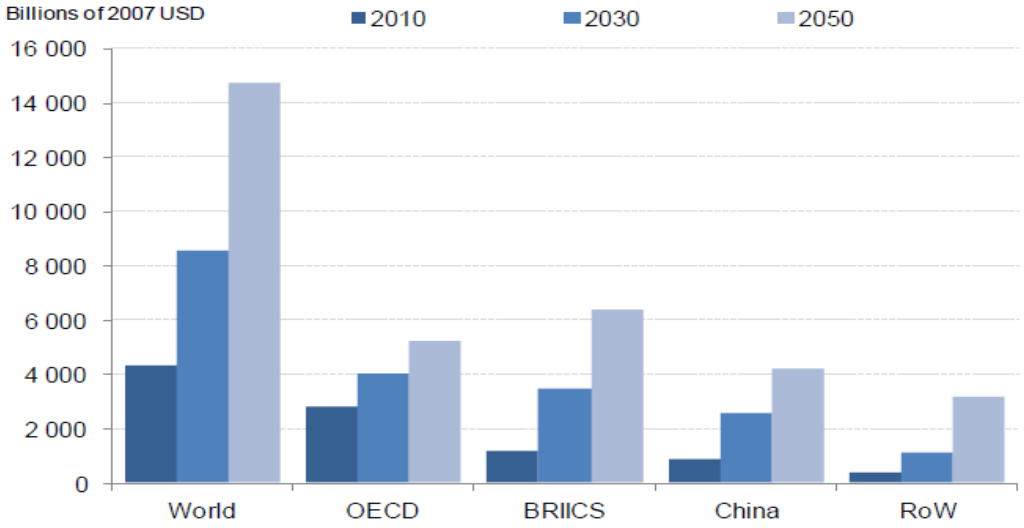


Figure 1.5 Projected chemicals production by region in sales: Baseline, 2010-2050 [18].

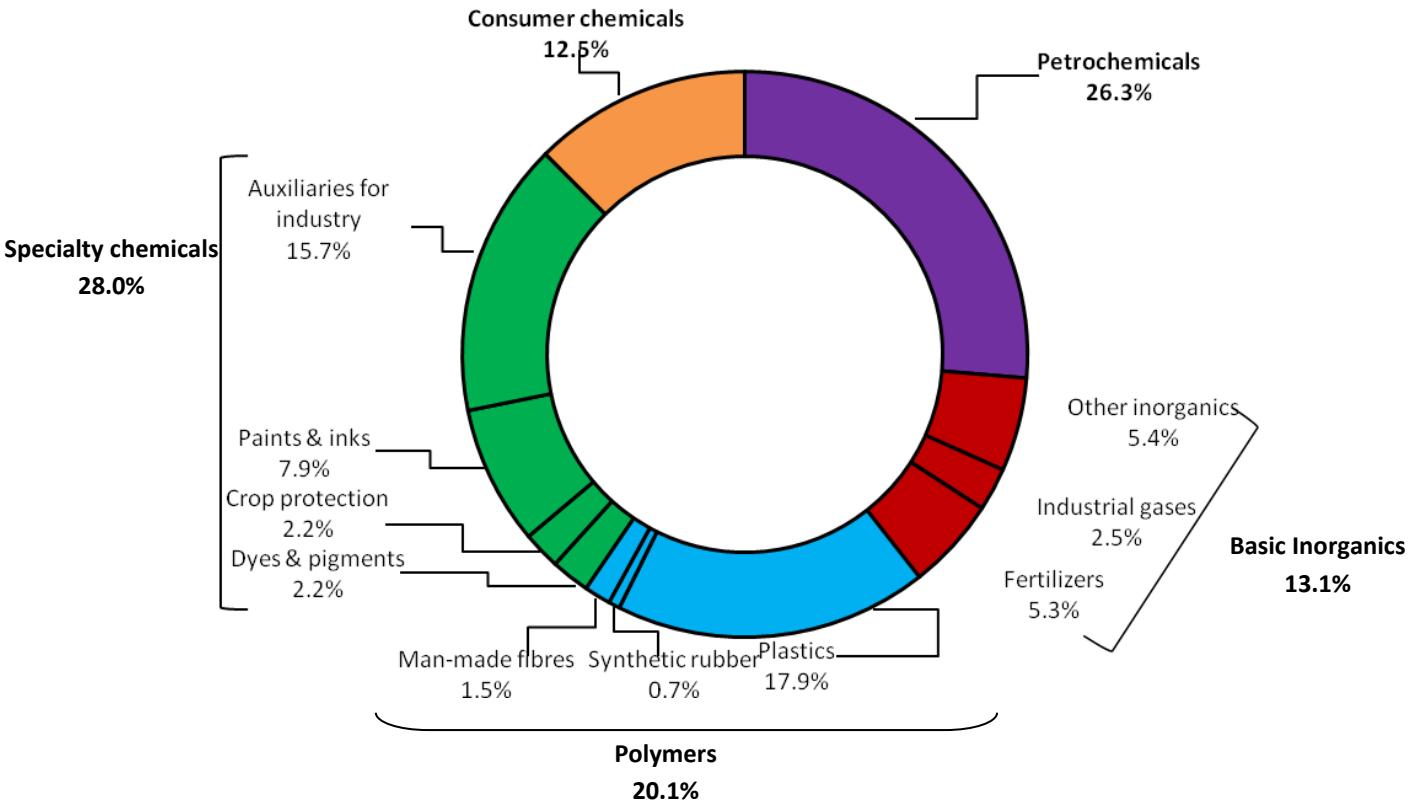


Figure 1.6 European Union 2015 chemical industry sales (Source: ref.10).

Eighty-five percent (85%) of the EU chemicals sales are from the 7 member states, wherein Germany is the largest chemicals producer followed by France, Netherlands, Italy, United Kingdom, Spain and Belgium [15]. While China is the leading region in global chemical sales in 2015, EU still dominates the world's share in the exportation and importation of chemicals. In 2015, the EU generated US$ 901 billion in exportation of chemicals while its importation of chemicals was worth US$ 761 billion [19]. Figure 1.7 and Figure 1.8 illustrate the top ten world exporters and importers of chemicals in 2015. The top ten exporters and importers accounted for 85.5% and 76.6% of the world chemicals in 2015 respectively [19].

The industrial sector has been the major consumer of chemicals in the European Union. This comprises 64.4% of the chemical consumption in EU [10]. The largest industrial users of chemicals are rubber and plastics (13.9%), construction (7.9%), pulp and paper (4.6%), basic metals (4.3%), and the automotive industry (4.3%) [10]. The remaining 35.6% comes from the other business sectors namely health and social work, agriculture, wholesale and retail trade, service, and other business activities [10]. Figure 1.9 illustrates the detail chemicals consumption of the different sectors in EU.

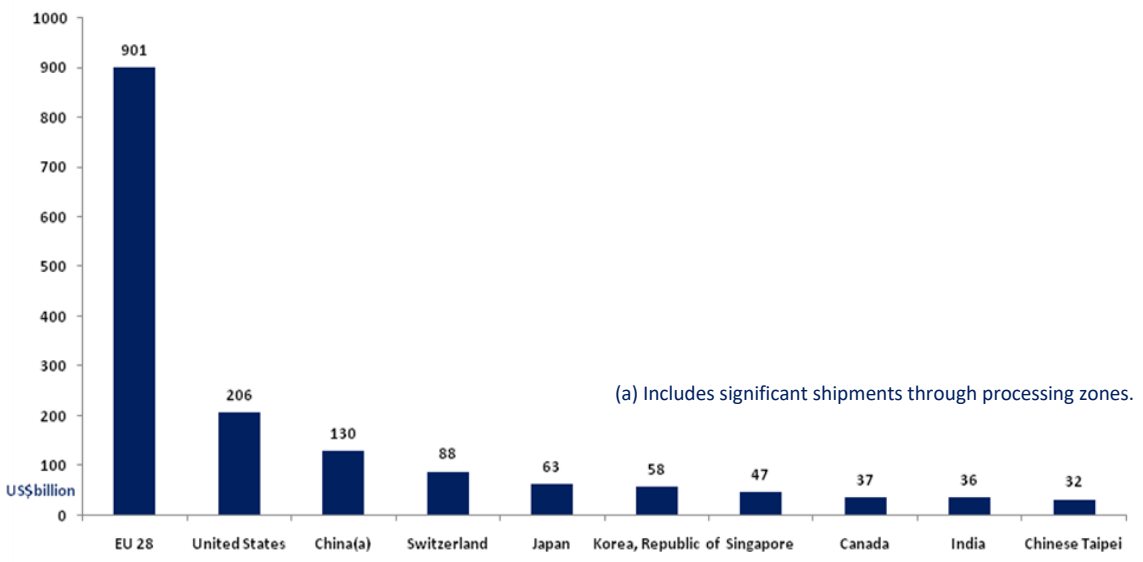


Figure 1.7 Global top ten chemical exporters (Source: ref. 19).

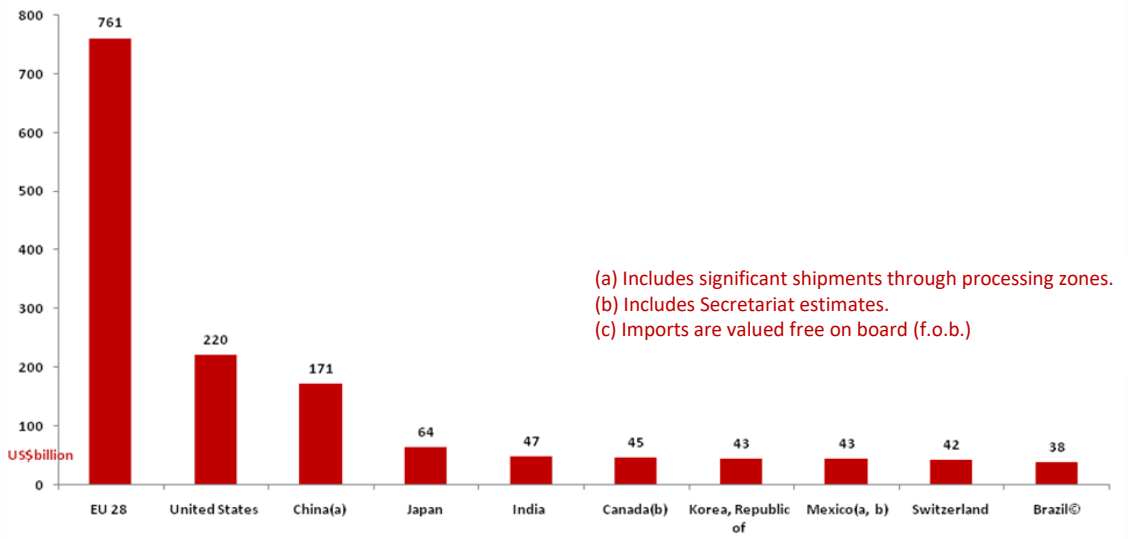


Figure 1.8 Global top ten chemical importers (Source: ref. 19).

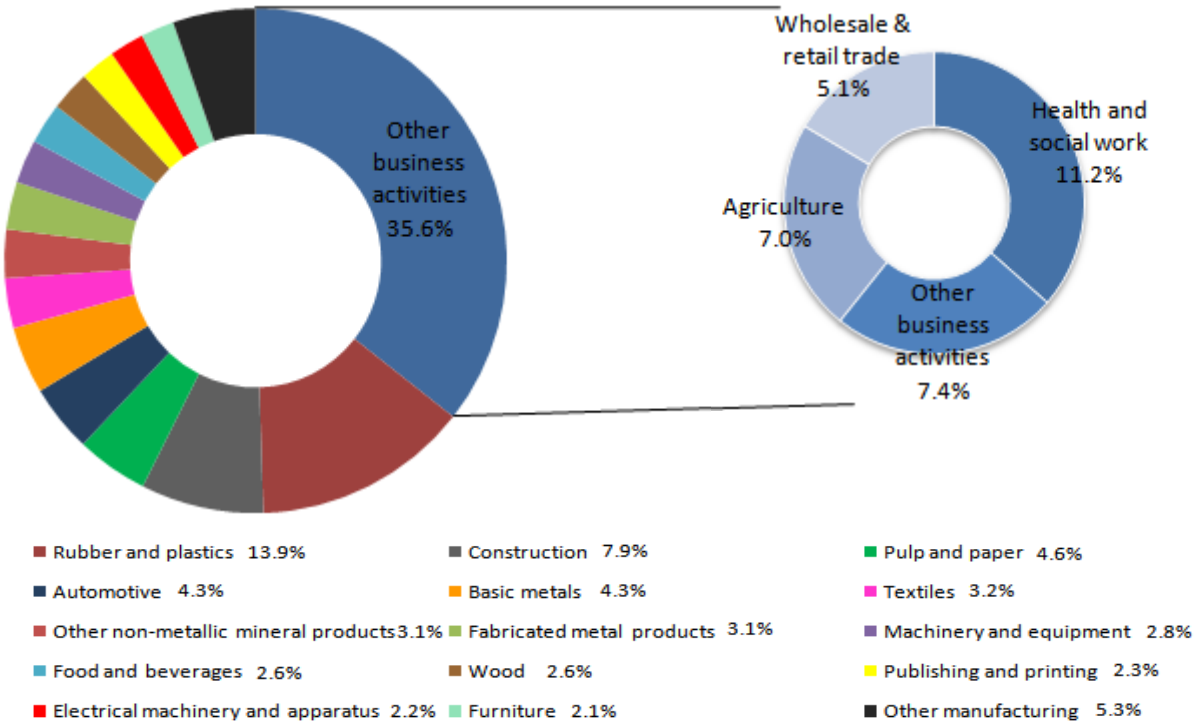


Figure 1.9 Customer sectors of the EU chemicals industry in 2015 (Source: ref.10)

In Spain, the pharmaceuticals is included in the chemical industry and the chemical industry was the second largest industrial sector of the Spanish economy in 2014 [20]; accounting 12.4 percent of manufacturing gross product as illustrated

in Table 1.1 [11]. It generated about 16 billion Euro of the gross value added from the chemical industry sales of 56 billion Euro in 2014 [11, 20]. The gross value added in the Spanish chemical industry rises to 14.7% from 2007 to 2014 [11]. Even though the Spanish industrial production overall dropped to 20 percent [20], the revenues of the chemical industry increased respectively at 3% from 2014 to 2015 [11] and about 17% from 2007 to 2015 generating 58 billion Euro sales in 2015 [11, 20]. Even the start of the crisis in 2007, the exportation of the chemical industry in Spain continued its growth at 43.3% (2007-2015) and 2.5% (2014-2015) with 32.7 billion Euro sales in 2015 [11]. Thus, the chemical industry is recorded as the second largest exporter of the Spanish economy and placing Spain among the seven biggest chemical countries in Europe [20, 21].

The production sale of the chemical industry in Spain is categorized into seven (7) groups namely basic chemicals; agrochemicals; paints, varnishes and inks; detergents, perfumes and cosmetics; other chemical products; man-made and synthetic products; and pharmaceuticals. The basic chemicals encompassed the largest portion of the sales of the chemical industry in 2015 followed by pharmaceuticals; and detergents, perfumes and cosmetics as demonstrated in Table 1.2.

Table 1.1 Spain's 2014 Distribution of Gross Industrial Product in million Euro (Source: ref. 11).

CNAE	Industrial Sector	2014	%2014	%2007	2014/2007
10, 11, 12	Food, Beverage & Tobacco	27.977	22.3	17.1	30.0 ↑
13, 14, 15	Textile, Clothing & Footwear	5.915	4.7	4.7	0.9 ↑
16, 17, 18	Paper, Publishing & Graphic Arts	8.044	6.4	7.9	-18.9
19	Coke & Refined Petroleum	1.345	1.1	1.8	-41.3
20, 21	Chemical & Pharmaceutical	15.533	12.4	10.8	14.7 ↑
22, 23	Non-metallic Minerals & Plastic Processing	10.597	8.4	10.8	-22.0
24, 25	Metallurgy & Metallic Products	15.616	12.4	15.1	-17.5
26, 27	Electrical, Electronic & Optical Equipment	7.383	5.9	6.7	-12.2
28	Machinery & Mechanical Equipment	7.547	6.0	5.8	3.9 ↑
29, 30	Transport	15.705	12.5	11.3	10.7 ↑
31, 32, 33	Various Manufacturing Industries	9.905	7.9	8.0	-1.7
TOTAL MANUFACTURING INDUSTRY		**125.567**	**100%**	**100%**	

Table 1.2 Spain's 2015 Distribution of Gross Sales of the Chemical Industry in billion Euro (Source: ref. 11).

Chemical Industry (CNAE 20+21)		(Billion Euro)	(%)
20	**Chemical Industry**	**42.190**	**72.7**
201	Basic Chemicals	24.125	41.6
2011	*Industrial Gases*	*1.367*	*2.4*
2012	*Dyes and Pigments*	*0.627*	*1.1*
2013	*Other Basic Inorganic Chemical Products*	*1.615*	*2.8*
2014	*Other Basic Organic Chemical Products*	*6.846*	*11.8*
2015	*Fertilizers and Nitrogen Products*	*1.993*	*3.4*
2016	*Plastics in Primary Forms*	*11.422*	*19.7*
2017	*Synthetic Rubber in Primary Forms*	*0.255*	*0.4*
202	Pesticides and Other Agro-chemical Products	0.898	1.5
203	Paints, Varnishes and Similar Coatings; Printing Inks and Mastics	4.053	7.0
204	Detergents, Perfumes and Cosmetics	7.935	13.7
2041	*Detergents*	*3.962*	*6.8*
2042	*Perfumes and Cosmetics*	*3.973*	*6.9*
205	Other Chemical Products	4.814	8.3
206	Man-made and Synthetic Rubbers	0.365	0.6
21	**Pharmaceuticals**	**15.866**	**27.3**
211	*Basic Pharmaceutical Products*	*3.885*	*6.7*
212	*Pharmaceutical Specialties*	*11.981*	*20.6*
TOTAL		**58.056**	**100.0**

The majority of the chemicals production in Spain is concentrated in four (4) regions Catalonia, Madrid, Andalusia, and Valencia as shown in Figure 1.10. The largest chemicals production in Spain is located in the region of Catalonia covering 43% of the chemicals production in Spain [21]. Also, one of the largest petrochemical industries in southern Europe is found in the province of Tarragona in the Catalonia region, comprising 23% of the chemicals production [21]. The chemicals production in this area is about 21 million metric tons per year [21]. Next to Catalonia is the Madrid region, comprising 13% of the country's chemicals production, which focus on pharmaceuticals and detergents [21]. The region of Andalusia is the third largest chemicals production, generating 12% of the production [21]. Moreover, the second largest chemical site is located in Andalusia in the Province of Huelva, in which inorganic and organic chemicals are the major products [20]. Lastly, the region of

Valencia comprises the 8% of the chemicals production in Spain [21]. The remaining 24% of the chemicals production is within the rest of the regions.

However, annual consumption of chemicals in Spain is not constantly increasing from 2007 to 2015. It varies every year, where the consumption of chemicals notably declined in 2009 but then gradually increased in 2015. Figure 1.11 shows the chemicals consumption of Spain from 2007 to 2015, with a growth of 8.3% to 63.157 million Euro in 2015. Moreover, the importation side of the Spanish chemical industry supplemented the economy totaling sales of 37,875 million Euro in 2015, demonstrating an increase of 20.4% from 2007 to 2015 and 7.9% from 2014 to 2015 [11].

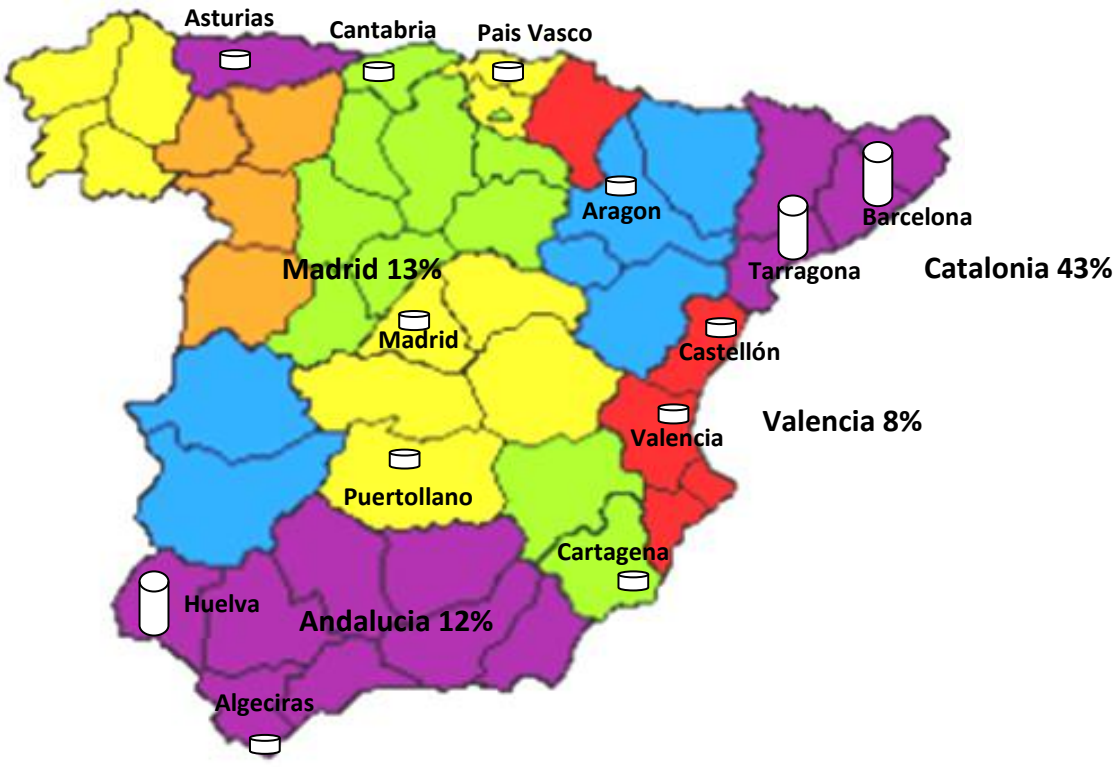


Figure 1.10 Geographic breakdown and main chemicals production locations in Spain (Source: ref. 11, 20).

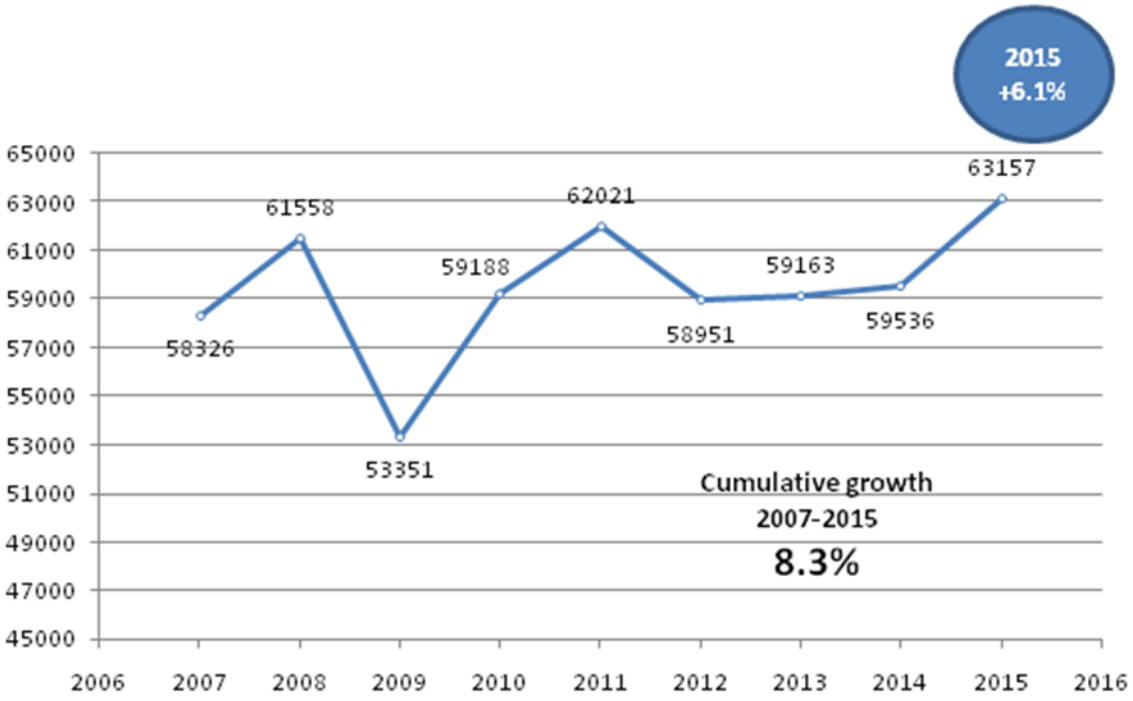


Figure 1.11 2007-2015 Spain's consumption of chemicals in million Euro (Source: ref. 11).

In the case of Portugal, the country's chemical industry is one of the technology-intensive industries that show significant growth potential [22], representing about 5.4% of the GDP of total Portuguese industry [20]. Although the Portuguese petrochemical and chemical industry is small compared to other EU countries, the annual turnover of chemicals and chemical products manufacturing has been continually steady. There are about 800 companies engaged in the chemical industry in Portugal and majority of these companies are small or micro entities [20]. However, the top 65 companies generate 66% out of the 4.4 billion Euro 2015 total sales of the country's chemical industry [20]. Further, the chemical industry has a significant impact in the national economy bringing about 5.4% of Portuguese industrial revenue [20]. In 2015, Portuguese exports on chemical products generated 5.2% of the total exports of goods by main groups of products while its importation was 10.7% of the total imports of goods by main partner countries [23]. Figure 1.12 and Figure 1.13 demonstrate the exportation and importation trends of chemical products in Portugal from 2011 to 2015 [23, 24, 25, 26, 27]. The chemical production in Portugal includes the basic chemicals; agro-

chemical products; paints, varnishes and inks; detergents, perfumes and toilet preparations; other chemical products; manmade fibers ; and pharmaceuticals. Table 1.3 illustrates Portugal's 2015 sales of products by the chemical industry by product type [28].

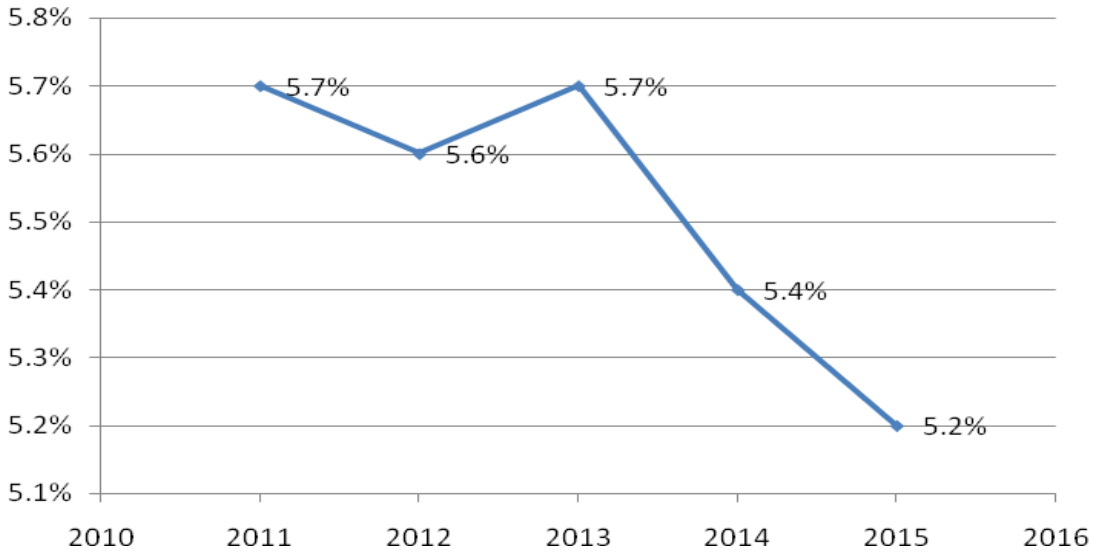


Figure 1.12 2010-2015 Portugal's percentage exportation of chemical products based on the total annual exports of goods (Source: ref. 24, 25, 26, 27, 27).

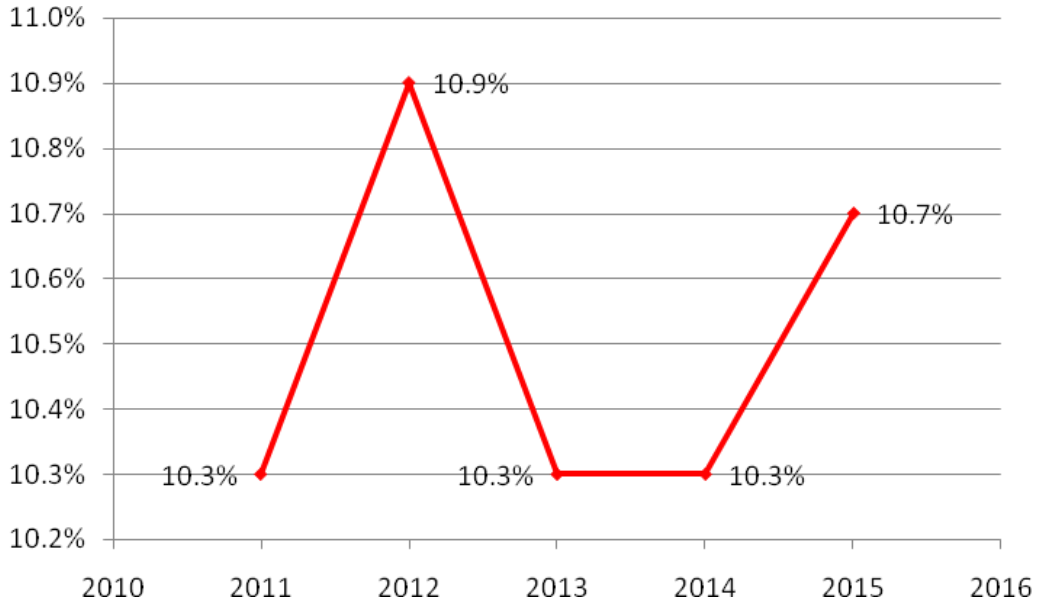


Figure 1.13 2010-2015 Portugal's percentage importation of chemical products based on the total annual imports of goods (Source: ref. 24, 25, 26, 27, 27).

Table 1.3 Portugal's 2015 Sales of Products by the Chemical Industry by product in billion Euro (Source: ref. 28).

Chemical Industry	(Billion Euro)	(%)
Chemical Industry	**3.807726726**	**85.95108**
Basic Chemicals	2.427346605	54.79203
Industrial Gases	*0.106040535*	*2.393633*
Dyes and Pigments	*0.020280511*	*0.457788*
Other Inorganic Basic Chemical Products	*0.112466905*	*2.538694*
Other Organic Basic Chemical Products n.e.c.	*0.863075259*	*19.48203*
Chemical or Mineral Fertilizers and Nitrogen Compounds	*0.208345498*	*4.702943*
Plastics in Primary Forms	*1.115785172*	*25.1864*
Synthetic Rubber in Primary Forms	*0.001352725*	*0.030535*
Pesticides and Other Agro-chemical Products	0.115414297	2.605225
Paints, Varnishes and Similar Coatings; Printing Inks and Mastics	0.37725030753	8.515599
Paints (except printing ink), Varnishes, Mastics and related products	*0.369607819*	*8.343086*
Printing Ink	*0.007642488*	*0.172512*
Detergents, Perfumes and Toilet Preparations	0.242319165	5.469824
Soap, Detergents and Glycerol	*0.112648676*	*2.542797*
Cleaning and Polishing Preparations	*0.042811313*	*0.966372*
Perfumes and Toilet Preparations	*0.086859176*	*1.960655*
Other Chemical Products	0.510008098	11.51231
Explosives	*0.023339188*	*0.526831*
Glues	*0.092501281*	*2.088014*
Essential Oils	*0.002363211*	*0.053344*
Other Chemical Products n.e.c.	*0.391804418*	*8.844126*
Man-made Fibers	0.135388254	3.056093
Pharmaceuticals	**0.622382344**	**14.04892**
Basic Pharmaceutical Products	*0.103274375*	*2.331193*
Medicaments	*0.519107969*	*11.71772*
TOTAL	**4.43010907**	**100.0**

The location of the chemicals industry in Portugal is not categorized by regions but on the two (2) defined hubs in Estarreja and Sines, and in the industrialized areas in Lisbon and Oporto [20, 21]. The hub of Estarreja/Aveiro embodies 11% in 2010 and 15% in 2015 of the total Portugal chemical industry, wherein Methylene diphenyl diisocyanate (MDI) is the major product for export [20, 21]. Chemicals used in the production process of MDI are also manufactured in the vicinity such as nitric acid, nitrobenzene, aniline, hydrogen, carbon monoxide and chlor-alkalis [20, 21]. Other chemical plants located in the area are PVC and urea-formaldehyde resins [21]. The Sines hub is a petrochemical complex and represents about 20% of the Portuguese chemical industry [20, 21]. Aside from the 10 million

tons refinery and ethylene plants; manufacturers of polyethylene, butadiene, ethyl tert-butyl ether (ETBE), carbon black, terephthalic acid (PTA), and urea formaldehyde resins are located in the zone [21]. Mostly in the Lisbon area are medium-scale plants of fertilizers, chlor-alkali products, fibers, specialties and pharmaceuticals; in which the chemicals sale in the area contributes 30% of the national output [20, 21]. The Oporto zone on the other hand has a refinery industry producing 400,000 tons/year aromatics namely benzene, toluene, and ortho xylene [20, 21]. There are also a number of small-scale companies in Oporto supplying chemicals for other industries [21].

1.4 International Initiatives on Chemical Safety

International initiatives on the safe use of chemicals are adopted to protect human health and the environment. The International Labor Organization (ILO) Chemicals Convention No. 170 (ILC 170) and Recommendation No. 177 (ILR 177) are the fundamental initiatives and principles in the safe use and management of chemicals. The ILC 170 and ILR 177 were adopted in 1990, wherein the ILC 170 took force in 1993 and the ILR 170 supplements the ILC 170. The vital application of the Convention and Recommendation 1990 is the protection of workers who are engaged in the use of chemicals in the workplace thus preventing and reducing the rate of incidents. Protection of the general public and the environment is also the endeavor of the convention. The harmonization of the classification, labelling and marking of chemicals was instituted in the ILC 170 and ILR 177, in which the classification of chemicals is based on the intrinsic health and physical hazards of a chemical.

Subsequently in 1992, the United Nations (UN) organized the Earth Summit known as the UN Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil. The UNCED established the Agenda 21, a comprehensive plan of action to be taken globally, nationally and locally by organizations of the United Nations System, Governments, and Major Groups in every area in which human

impacts on the environment [29]. Chapter 19 of Agenda 21 mandates the environmentally sound management of toxic chemicals, which includes assessment and reduction of chemical risks, harmonization of classification and labelling of chemicals, and prevention of illicit traffic of toxic and dangerous substances. The development of the globally harmonized system (GHS) for classification of chemicals and safety data sheets (SDS) is coordinated and managed by the Interorganization Programme for the Sound Management of Chemicals (IOMC) Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS) [30]. Three technical focal points are created to implement the mandate namely the International Labor Organization (ILO) for the hazard communication, the Organization for Economic Cooperation and Development (OECD) for the classification of human health and environmental hazards, and the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) and ILO for the physical hazards [30]. A newly created Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS Sub-Committee) is responsible for maintaining the GHS, promoting its implementation and providing additional guidance as needs arise, while maintaining stability in the system to encourage its adoption [30]. The GHS-SDS is based on the 4 existing programs specifically the EU directives for the classification and labelling of substances and preparations; US requirements for the workplace, consumers and pesticides; Canadian requirements for the workplace, consumers and pesticides; and UN recommendations on the transport of dangerous drugs.

Ten years after the first Earth Summit in 1992, the international plans and programs on environmentally sound chemical management and GHS for the classification and labelling of chemicals was reaffirmed at the World Summit on Sustainable Development (WSSD). The WSSD was held in Johannesburg, South Africa in 2002. The WSSD includes encouraging countries to implement the GHS as soon as possible with a view to having the system fully operational by 2008 [31]. Since the adoption of the first edition of the GHS in 2002, the GHS is updated and amended every 2 years. The revision is to reflect national, regional and international

experiences in implementing its requirements into national, regional and international laws, as well as the experiences of those doing the classification and labelling [30]. Now, the latest GHS is published in 2015 and on its sixth edition [30]. Many countries have already adopted and implemented the GHS. The system has been incorporated in each countries laws and regulations. The implementation of the GHS worldwide has been very cost-effective in terms of trade facilitation; regulatory promotion and execution; safe transport, handling and usage of chemicals; and reduction of animal testing. The GHS is beneficial to all sectors specifically the governments, industries, traders, workers, and consumers. Overall, the adoption of the GHS addresses both the protection of human health and the environment.

Follow up activities on the implementation of sound management of chemicals and wastes are continuously organized by the United Nations (UN). Another policy framework to foster the sound management of chemicals is the UN Strategic Approach to International Chemicals Management (SAICM), adopted at the International Conference on Chemicals Management (ICCM) in Dubai, United Emirates on 2006 [32]. SAICM was developed by a multi-stakeholder and multi-sectoral Preparatory Committee and supports the achievement of the 2020 goal agreed at the 2002 Johannesburg World Summit on Sustainable Development [32]. Other international initiatives are the Basel, Rotterdom and Stockholm Conventions. The work and actions of these three chemical and hazardous waste conventions, and the SAICM demonstrate the dramatic growth in the industry, which have seen global output climb from US$ 171 billion in 1970 to over US$ 4.1 trillion today [7]. The international conventions and treaties cited including the Montreal Protocol define framework to foster the sound worldwide management of chemicals.

1.5 Legislation and regulations

Globally, both existing and new chemicals are increasing rapidly in quantity specifically in developing countries. More than 248,000 chemical products are

commercially available (CAS 2011) and subject to regulatory and inventory systems [33]. Although industries producing and using these substances have a significant impact on employment, trade and economic growth worldwide; these substances can have adverse effects on human health and the environment [7]. In order for chemicals to be used properly, safely and in an environmentally-friendly and healthy manner, a regulatory framework must be put in place [34]. It is vital to have proper and correct management of these chemicals in order to avoid abusive usage and misuse, wherein these chemicals and their hazardous wastes can cause risks to human health and the environment. Therefore, chemicals must be effectively monitored and controlled.

The majority of countries worldwide have adopted the implementation of the UN level agreements and conventions in the regulation of chemicals such as the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals, Sustainable Consumption and Production (SCP) programme, and other environmentally sound chemical and hazardous waste management. Chemicals are regulated in countries under various laws by different government agencies. In the United States of America (USA), chemical laws and regulations are enforced by the United States Environmental Protection Agency (USEPA), and US Occupational Safety and Health Administration (OSHA). Federal chemicals initiatives in Canada are led jointly by Environment Canada and Health Canada. The Department of the Environment and Energy, and Office of the Chemical Safety - Department of Health of the Australian Government carry out a number of regulatory functions in relation to chemicals. Regulatory agencies on chemicals in other countries are the Ministry of the Environment (MMA) of Brazil; the Ministry of Economy, Trade and Industry (METI), Ministry of Health, Labour and Welfare (MHLW), and the Ministry of the Environment (MOE) of Japan; and the Ministry of Environmental Protection (MEP) of China.

The Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), and the Classification, Labelling and Packaging (CLP) regulations are chemicals legislations of the European Union (EU). The course of action for REACH in

the EU started in February 2001 with the proposal known as the White Paper. This is the first step of the EU's commitment to the Agenda 21 on Sustainable Development. The European Commission's (EC) original legislative proposal on REACH COM(03) 644 (01)[1] and COM(03) 644 (02)[2] have undergone several review and reading procedures as well as debates on its adoption. The proposal on REACH amended the Directive 1999/45/EC[3], Directive 67/548/EEC[4], and regulation on Persistent Organic Pollutants (POPs). The REACH regulation (EC 1907/2006) is finally adopted on 18 December 2006 and enforced on 01 June 2007. It took seven years to finalize and enter into force the regulation but its implementation have different phases. The EC 1907/2006 established the European Chemicals Agency (ECHA) as the regulatory authority; responsible in the administrative, technical and scientific functions of the REACH. The ECHA collaborates with the member state competent authorities in the implementation of the REACH regulation. Most of the member states competent authorities (MSCA) and designated national authorities are ministries or government agencies in charge in the environment, agriculture, food, customs, health, and safety services.

REACH regulations aim "to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances while enhancing the innovation and competitiveness of the EU chemicals industry; and to promote alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals" [35]. REACH strictly implements the "No Data, No Market" policy. The industries in the EU region who are manufacturing and importing chemical substances equal or more

[1] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}.

[2] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals.

[3] Concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

[4] COUNCIL DIRECTIVE of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

than 1 ton per year are obliged to register the chemical substances that they put in market in the countries within the EU member states. Non-EU companies exporting chemical substances within the EU territory are not required to register or pre-register their products. It is the obligation of the importers or a representative from a non-EU established in the EU to do the registration of a chemical substance marketed in the EU.

A pre-requisite of the registration process is the pre-registration of the chemicals manufactured and imported in the EU from June 2008 to December 2008. What is beneficial about the pre-registration is that companies with same substance can jointly submit a registration dossier to ECHA, which is reducing or eliminating animal testing for the toxicity of a substance and less regulatory costs. This process is known as substance information exchange forums (SIEF). More than 65,000 companies have signed up and submitted about 2.75 million pre-registrations of for about 150,000 substances in the pre-registration of the REACH-IT on the six months period [36]. As of 10 May 2016, ECHA has 145,299 unique substances in the pre-registration database of ECHA [37].

The registration requires the complete data and facts of the intrinsic properties of a substance namely physicochemical, toxicological and eco-toxicological information. These documents will be submitted to ECHA known as registration dossier, which is composed of a technical dossier and/or a chemical safety report. Companies manufacturing or importing a substance 10 tons and above annually are compelled to include the chemical safety report in the dossier aside from the technical dossier. There are 3 registration deadlines set by the ECHA depending on the quantity and type of chemicals produced and imported in the EU. The first two deadlines have been done in 2010 and 2013.

Phase-in chemical substances manufactured or imported equal or greater than 1000 tons as well as ≥ 1 ton CMRs[5] and ≥ 100 tons R50/R53[6] were set to

[5] Carcinogenic, mutagenic or toxic to reproduction.

[6] Risk phrases for substances that are very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment. R50/53 is H400/410 in the CLP regulation.

register on 30 November 2010. 14,783 out of the 20,723 dossiers accepted for processing for the 2010 registration deadline from the 27 EU member states and from the European Economic Area (EEA) countries (Norway, Iceland and Liechtenstein) successfully completed the process [38]. The majority of dossiers accepted for processing for the 2010 deadline were from the large-scale entities comprising 86% of all the companies of the EU and EEA region followed by 9% medium-scale, 4% small-scale and 1% micro enterprises [38]. A large number of the dossiers accepted for 2010 deadline are from Germany (23%). Spain and Portugal made up the 6% and 1% respectively of the EU countries whose dossiers accepted for processing for 2010. Table 1.4 shows the dossiers accepted by ECHA and completed the process for 2010. The 2010 registration showed the realization of the cost-effective SIEF, wherein 94% of the registrants jointly submitted the dossier as illustrated in Table 1.5.

Table 1.4 Number of dossiers accepted for processing and successfully completed for the 2010 deadline (Source: ref. 38).

Dossier Type	Accepted for Processing		Successfully Completed	
	Total*	For the 2010 deadline**	Total*	For the 2010 deadline**
Registration	19702	17174	14265	12312
Transported Isolated Intermediate	3544	2692	2699	1979
On-site Isolated Intermediate	1429	857	1037	492
Total	**24675**	**20723**	**18001**	**14783**

*Total includes dossier updates during the period.
**Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline.

Table 1.5 Breakdown of submissions of joint and individual registrants for the 2010 deadline (Source: ref. 38).

	% Accepted for Processing	Ratio Member/Lead**
Joint - Lead Registrant	12%	
Joint - Member Registrant	82%	6.7
Individual Registrant*	6%	

*Includes individual submissions for non-phase in substances.
**Number of Member Registrants for every Lead Registrant.

The deadline for 100 to 1000 tons per annum phase-in substances manufactured or imported in the EU was 31 May 2013. With the second deadline, 3,188 companies with 9,030 dossiers registered wherein 1,077 companies are coming from the small and medium enterprises (SMEs) [39]. Again, the fundamental principle of REACH "to reduce costs and avoid unnecessary testing on animals" is carried out on the second registration deadline. 8,317 dossiers are jointly registered covering 92% of the number of registrations. Table 1.6, Table 1.7 and Table 1.8 demonstrate the detailed 2013 statistics on number of registrations. Germany (31%) once more has the large number of registration dossiers received by ECHA followed by United Kingdom (11.9%), Italy (8.4%), the Netherlands (8.4%), France (8.3%), Belgium (7.2%) and Spain (7.2%). Portugal submitted 28 registration dossiers, which covers 0.31% of the registrations received by ECHA.

Table 1.6 Breakdown of submissions of joint and individual registrants for the 2013 deadline (Source: ref. 39).

	Number of Registrations
Registrations in Joint Submissions	8317
Lead	2156
Member	6161
Individual Registrations under REACH	713
Total	**9030**

Table 1.7 Breakdown by registrant company size for the 2013 deadline (Source: ref. 39).

	Number of Registrations
Registered by Large company	7299
Registered by SME	1731
Medium company	983
Small company	512
Micro company	236
Total	**9030**

Table 1.8 Breakdown by role in supply chain for the 2013 deadline (Source: ref. 39).

	Number of Registrations
Manufacturer	3611
Manufacturer and Importer	1083
Importer	2250
Only Representative of a non-EU manufacturer	2086
Total	**9030**

Continuous registration is ongoing for 1 to 100 tons phase-in[7] substances and non-phase-in[8] substances (substances not listed on the EINECS[9], ELINCS[10] and NLP[11] inventories) until 31 May 2018. The majority of companies for the last registration deadline will be coming from the small and medium enterprises (SMEs) although there are already SMEs that registered in the first and second deadline schedules. There are 106,213 unique substances in the European Commission (EC) inventory as of 07 November 2015, and 15,061 of these unique substances are in the ECHA official database containing information from 57,195 dossiers as of 19 December 2016 [3]. The inventory comprises of substances accounted as EINECS, ELINCS, and NLP. Substances under the previous European chemicals legislation (Directive 67/548/EEC) prior to the introduction of REACH are considered as registered [3]. These substances are called notified substances or NONS. Table 1.9 shows the number of NONS registered with ECHA [40]. Different types of registration are covered by REACH based on Articles 10, 17 and 18. Article 10 is the standard registration or full registration while Articles 17 and 18 are for substances with intermediate uses or a limited registration [3]. In the REACH regulation, a substance can be registered for up to three of these registration types with one dossier.

[7] Substances' listed on the European Inventory of Existing Commercial Chemical Substances (EINECS), or that have been manufactured in the EU or countries that have acceded to the EU before 2004 but not (yet) placed on the EU market, at least once after 1 June 1992, or are so-called 'no-longer polymers' and are commonly referred to as 'existing substances'.

[8] New substances not been manufactured, placed on the market or used in the EU before 01 June 2008. These include all substances that do not meet the definition of a phase-in substance.

[9] European Inventory of Existing Commercial Chemical Substances (inventory of substances that were deemed to be on the European Community market between 1 January 1971 and 18 September 1981).

[10] European List of Notified Chemical Substances (substances notified under Directive 67/548/EEC that became commercially available after 18 September 1981).

[11] No-Longer Polymers (substances commercially available between 18 September 1981 to 31 October 1993 and previously considered as polymers).

Registration dossiers by companies from the 1st of June 2008 to 15th May 2017 indicated that there are 46,191 registrations for 9,257 phase-in substances and 3,980 registrations for 1,574 non-phase-in substances excluding NONS [40]. The majority of these companies are large-scale entities comprising 85.90% of the group [40]. Updated data based on the classification by role in the supply chain composed of manufacturers (36.41%), manufacturers and importers (12.30%), importers (27.94%), and only representative of a non-EU manufacturer (23.35%) [40]. The vital target of REACH "Joint Submission" has definitely showed economical and environmental impacts to the companies in complying the REACH regulation. To add up from the first registration date to 16 May 2017, registration of companies by joint submission has been averagely consistent between 92% to 94%. Germany maintains on the top EU country which has the highest number of new registrations (25.63% of EEA).

Table 1.9 Notified substances (NONS, notified to Member State Competent Authorities under the previous European chemicals legislation - Directive 67/548/EEC) as of 15 May 2017 (Source: ref. 40).

	Number of Registrations	Number of Unique Substances
(a) Number of NONS Notifications	9963	5293
(b) of which have been claimed	5208	3796
(c) of which have been updated under REACH	1866	1589

Spain as well keeps the 7th place on the high ranking record of new registrations as of 14 May 2017 with a total of 3,420 (6.82% of EEA) registration numbers by companies granted by ECHA following submission of a registration dossier from 1st June 2008. These registration numbers consist of 1,751 unique substances excluding the NONS. Table 1.10 and Table 1.11 show the number of new registrations and NONS [41]. Large companies are the major contributor to the new registrations in Spain comprising 82.72% of 2,829 registration dossiers, followed by medium-scale (9.80%), small-scale (6.31%) and micro entities (1.17%). Once more the joint submission of REACH's cost-effective method established its value to the implementation of the regulation. Table 1.12, Table 1.13, Table 1.14 and Table 1.15 demonstrate the detailed REACH registration statistics of Spain.

Table 1.10 Spain's REACH dossier registrations by companies as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Total	**3420**	**6.82%**	**1751**	**16.17%**
Phase-in	2984	6.46%	1590	17.18%
Non Phase-in	436	10.95%	161	10.23%

Table 1.11 Spain's notified substances (NONS, notified to Member State Competent Authorities under the previous European chemicals legislation - Directive 67/548/EEC) as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
(a) Number of NONS Notifications	200	2.01%	194	3.67%
(b) of which have been claimed	200	3.84%	194	5.11%
(c) of which have been updated under REACH	73	3.92%	149	9.32%

Table 1.12 Spain's REACH registration types as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Registered as full registration	2576	6.43%	1151	17.38%
Registered as intermediate	879	8.08%	684	12.52%
Transported isolated intermediates	634	7.88%	508	12.78%
On-site isolated intermediates	293	8.05%	240	9.97%

Table 1.13 Spain's REACH registration by submission process as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Registrations in Joint Submissions	3128	6.71%	1537	18.29%
Lead	554	6.27%	N/A	N/A
Member	2574	6.81%	N/A	N/A
Individual Registrations under REACH	292	8.23%	236	8.50%
Total	**3420**	**6.82%**		

Table 1.14 Spain's REACH registration by company size as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Registered by Large company	2829	6.56%	1593	15.85%
Registered by SME	591	8.37%	345	14.30%
Medium company	335	8.72%	245	14.74%
Small company	216	9.45%	142	12.96%
Micro company	40	4.29%	26	7.49%
Total	**3420**	**6.82%**		

Table 1.15 Spain's REACH registration by role in supply chain as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Manufacturer	1621	8.88%	962	14.41%
Manufacturer and Importer	447	7.25%	370	12.55%
Importer	988	7.05%	598	14.60%
Only Representative of a non-EU manufacturer	361	3.08%	224	6.98%
Total	**3420**	**6.82%**		

Portugal on the other hand has less REACH dossier registrations ranking 21st of the 31 EU and EEA countries with 311 (0.62% of EEA) new registration numbers granted by ECHA and 211 (1.95% of EEA) unique substances as of 14 May 2017 (excluding the NONS). Table 1.16 and Table 1.17 show the overall summary of Portugal's REACH new dossier and NONS registrations. Large-scale companies are also the major contributor to the new registrations in Portugal comprising 74.27% of 311 registration dossiers. Portugal has around 800 enterprises involved in the manufacture of chemicals and chemical products industry in 2014 [20, 21].

Table 1.16 Portugal's REACH dossier registrations by companies as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Total	**311**	**0.62%**	**211**	**1.95%**
Phase-in	306	0.66%	205	2.21%
Non Phase-in	5	0.13%	6	0.38%

Table 1.17 Portugal's notified substances (NONS, notified to Member State Competent Authorities under the previous European chemicals legislation - Directive 67/548/EEC) as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
(a) Number of NONS Notifications	7	0.07%	6	0.11%
(b) of which have been claimed	7	0.13%	6	0.16%
(c) of which have been updated under REACH	5	0.27%	4	0.25%

There were only 65 chemical companies in Portugal considered as large and medium sized in 2010 although these companies represented 66% of the total sales of the sector [20, 21]. Therefore, it is expected that the majority of the registrations on 2018 will be coming from the small and micro companies. Table 1.18, Table 1.19, Table 1.20, and Table 1.21 illustrate the detailed REACH registration statistics of Portugal as of 14 May 2017.

Table 1.18 Portugal's REACH registration types as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Registered as full registration	248	0.62%	164	2.48%
Registered as intermediate	64	0.59%	49	0.90%
Transported isolated intermediates	23	0.29%	22	0.55%
On-site isolated intermediates	48	1.32%	36	1.50%

Table 1.19 Portugal's REACH registration by submission process as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Registrations in Joint Submissions	300	0.64%	202	2.40%
Lead	11	0.12%	N/A	N/A
Member	289	0.76%	N/A	N/A
Individual Registrations under REACH	11	0.31%	11	0.40%
Total	**311**	**0.62%**		

Table 1.20 Portugal's REACH registration by company size as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Registered by Large company	231	0.54%	173	1.72%
Registered by SME	80	1.13%	51	2.11%
Medium company	38	0.99%	37	2.23%
Small company	32	1.40%	21	1.92%
Micro company	10	1.07%	5	1.44%
Total	**311**	**0.62%**		

Table 1.21 Portugal's REACH registration by role in supply chain as of 14 May 2017 (Source: ref. 41).

	Number of Registrations	% of EEA	Number of Unique Substances	% of EEA
Manufacturer	218	1.19%	153	2.29%
Manufacturer and Importer	44	0.71%	37	1.25%
Importer	45	0.32%	42	1.03%
Only Representative of a non-EU manufacturer	4	0.03%	4	0.12%
Total	**311**	**0.62%**		

Supplementing the REACH Regulation is the Classification, Labelling and Packaging (CLP) of substances and mixtures regulation. The CLP regulation entered into force in January 2009 and aligns with the United Nations' Globally Harmonized System (GHS). With the CLP regulation, the hazards of chemicals are clearly defined, stated and communicated to the employees in the workplace and to the consumers in the market. The REACH and CLP regulations have been modified in conformity with the latest edition of the GHS. The Commission Regulation (EU) 2015/830 is the updated regulation on GHS-SDS and CLP of the EU, which is in accordance to the 5th edition of the UN Globally Harmonized System of Classification and Labelling of Chemicals.

2. METHODOLOGY

Four (4) aspects of the research methodology are enumerated in this chapter. First, the research design procedure defined the type of research design conducted, the population and sample, and measurement procedures. Second, the data collection procedure describing the type of instrument and methods used to acquire the data and the reason in choosing such methods. Third, the data analysis describing the specific instrument of analysis used to address the research objectives. Lastly, the limitations explaining any uncontrollable and unexpected conditions and situations which restricted the conduct of the research.

The research study is conducted in two European countries, Portugal and Spain, taking into consideration the geographical constraint that the researcher has spent in Spain (October 2016 to February 2017) and in Portugal (March 2017 to July 2017).

2.1 Research Design

The research study has employed a survey questionnaire that incorporates both closed-ended and open-ended questions aimed at producing quantitative and qualitative data results to identify the essential information needed for the research project. The research was designed to address the four key elements in the implementation of the REACH regulation specifically registration, evaluation, authorization and restriction. It was very important for the researcher to identify the issues, concerns, and challenges that the companies in Spain and Portugal encountered in processing their REACH registration. In this way, suitable and valued methods used by the industries were documented and assessed in order to come up with recommendations regarding appropriate techniques and strategies in coping up with the evolving chemical regulatory guidelines, maintaining industry standards and strengthening competitiveness in the global chemical industry market.

The target population of the research were companies and industries located in Spain and Portugal that have already undergone registration of the REACH regulation. Also included were companies that were on the process of registering their substances for the 2018 deadline. The chemical companies were members of the chemical industry organizations namely the Federación Empresarial de la Industria Quimica Española (FEIQUE) in Spain, and Associação Portuguesa das Empresas Químicas (APEQ) and other industry associations in Portugal. FEIQUE is the main body representing business interests of the chemical sector in Spain, with capacity to act face to the Administration, national and international professional organizations of employers and workers, social and economic entities, and all kinds of public or private agencies, Spanish or foreign, defense and representation of the interests of the chemical industry [42]. APEQ is an organization established in July 1994, which composed of businesses and employers of the chemical industry in Portugal involves in activities such as fiscal, social, economic, innovation, competitiveness, environmental and sustainability policies as well as labor policy [43].

The researcher outlined a diagram to summarize the processes in achieving the objectives of the research project for Spain and Portugal as shown in Figure 2.1. The purpose was to involve in the surveys three sectors the chemical industries and companies, ECHA and the MSCA. The current research project was involved only the first stage of the industry associations, FEIQUE and APEQ, and the industries (Figure 2.2).

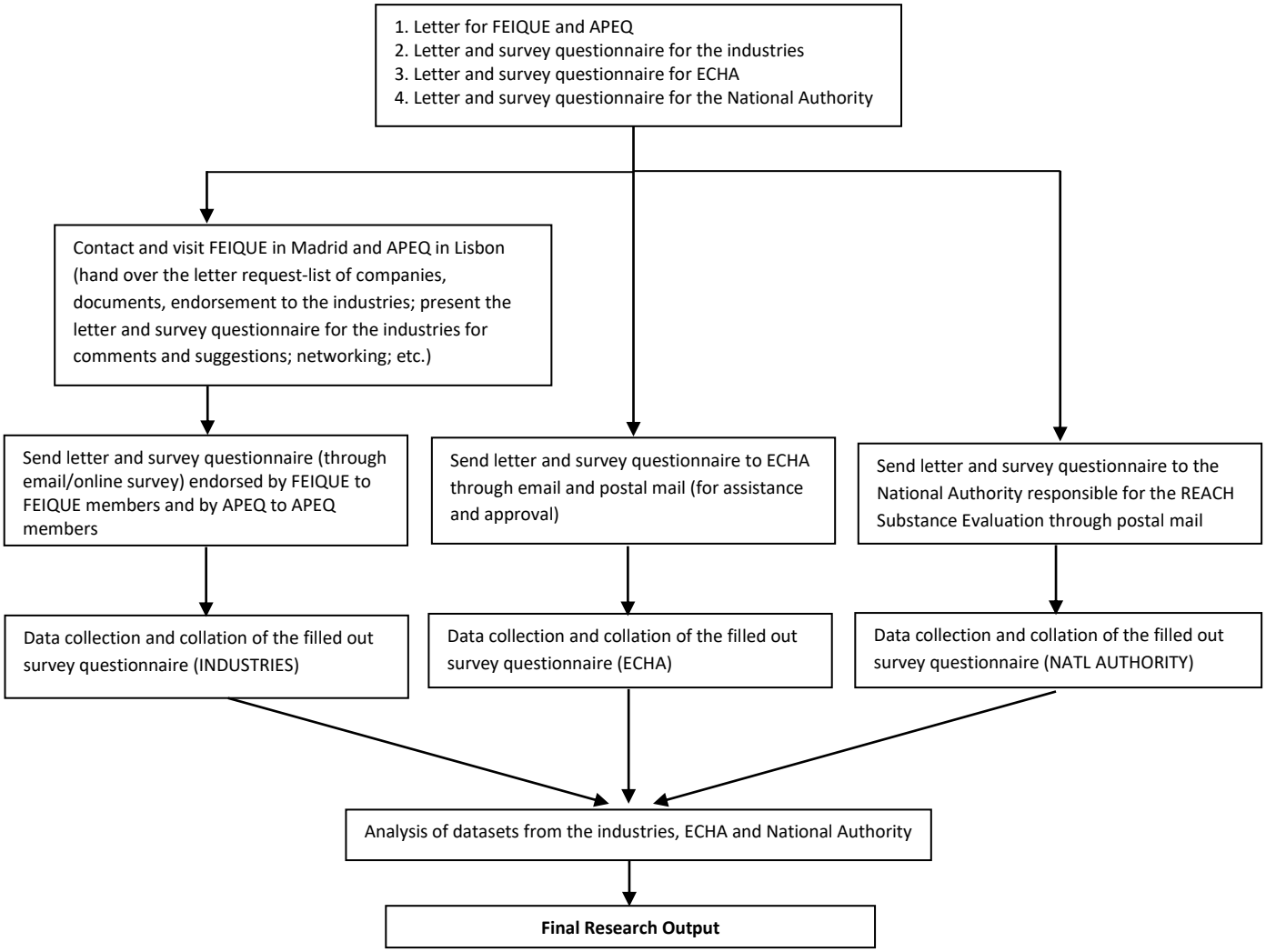


Figure 2.1 Initial method for the research project.

2.1.1 Spain

Prior to the dissemination of the survey questionnaire to the chemical companies in Spain, a meeting with FEIQUE was done on 23 February 2017 to discuss the request for an assistance and support from FEIQUE for the research project. The request was specifically on the endorsement to conduct survey to their member companies. Letter and survey questionnaire for the chemical industries (Annex 5.1 and Annex 5.2) were also formulated. It was the intention of the research project that these documents would be reviewed by FEIQUE prior to dissemination for proper channel and coordination with the industries. The method of email/online survey was used in the research project. This approach was chosen due to the

efficiency in terms of communication and data collection considering economic, time period and location of the industries. It was not practical and cost-effective for the researcher to visit and interview personally the chemical companies in Spain. Spain has more than 3,000 companies in the chemical industry sector, with major concentrations in Barcelona, Tarragona and Huelva as shown in Figure 2.3 [11]. The companies were sent with the letter and directed on the online link by FEIQUE, where the companies' representatives respond the survey questionnaire. It was also the aim of the research project to find and heed the involvement of the different company sizes, not only the large-scale but also the medium, small and micro levels industries.

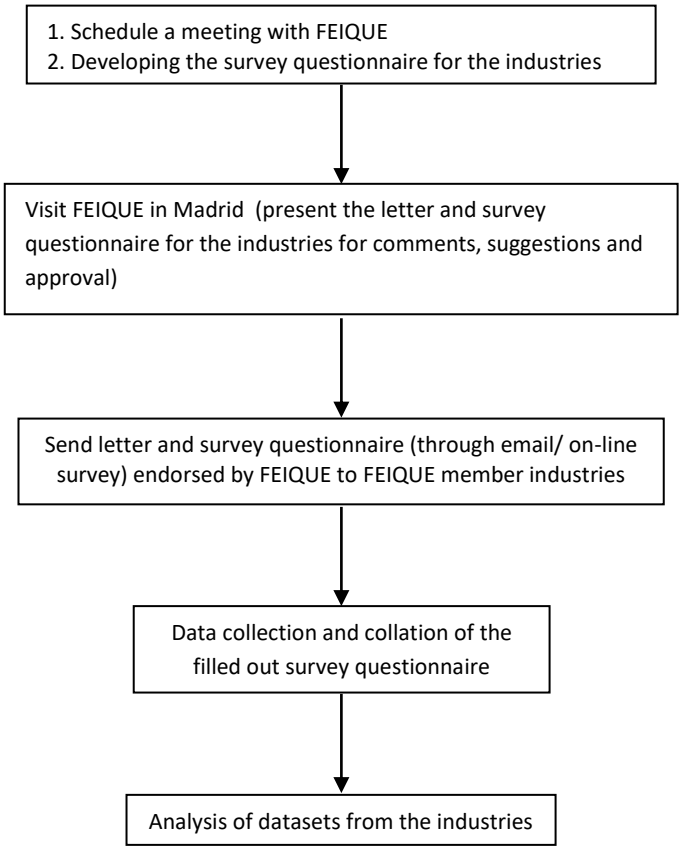


Figure 2.2 Final over-all method for the research project in Spain.

Figure 2.3 Spain's main chemical production sites (Source: ref. 11)

The letter for the industries gave details on the aims of the research study and the relevance of their participation. In the letter, the companies were instructed to proceed to an online link[12] in order to participate and respond the survey questionnaire. The survey questionnaire for the industries in Spain were divided into three categories involving the companies in the implementation and complying the REACH regulation namely the registration, classification and labeling, and over-all remark of the regulation process. The first part of the survey questionnaire explained again the importance of the company's contribution to the research project, as well its choice in terms of the appearance in the research project contribution, and basic information of the company such as name, address, telephone number, email address and contact/responsible for the REACH regulation. In the first category "Registration", four types of questions were asked from the companies as described below.

[12] https://docs.google.com/forms/d/e/1FAIpQLSe-DKQaJggtwATrffr-h4S6dwXwQ5tSsIpWjGT8R4Fw752J1g/viewform.

Type 1: The type of company (business ownership, entity scale, industrial sector, operation level).

Type 2: Company's role in the REACH regulation (type of substances applied for registration, authorization, and restriction).

Type 3: Methods applied by companies in the registration of substances (including preparation of dossier, complying with additional requirements, attendance to seminars).

Type 4: Challenges, issues and problems encountered by companies in the registration process (including strategies used in order to cope up and address the issues and problems).

The second category "Classification and Labeling" inquired companies on their knowledge and responsibility on the Safety Data Sheet (SDS) and Extended Safety Data Sheet (ESDS) in accordance with Commission Regulation (EU) No. 2015/830. The third category "Over-All" requested the companies to rate the importance of the different steps in the implementation of the REACH regulation. The survey questionnaire took no more than 15-20 minutes to answer. Confidentiality regarding specific information provided by the participants was also assured.

2.1.2 Portugal

The procedures used in Portugal were similar with Spain as illustrated in Figure 2.4. A meeting with the officers and representatives from APEQ last 12 April 2017 was carried out. The discussion in the meeting included the request for an endorsement to conduct survey to its members in the organization. The survey questionnaire was reviewed by APEQ prior to dissemination for proper channel and coordination with the industries. With the approval of APEQ, the letter and survey questionnaire link (Annex 5.3 and Annex 5.4) were sent through email to the chemical companies in Portugal by APEQ. Although Portugal has less chemical

companies compared to Spain, the online survey instrument was still used by the researcher due to its cost-effectiveness. Portugal has about 800 companies included in CAE[13] 20 in 2010 [21]. Geographically, the chemical industry in Portugal is mostly located in two defined chemical industry hubs in Estarreja and Sines and in the industrialized areas of Lisbon and Oporto [21] as shown in Figure 2.5.

The instructions for the companies in Portugal to access the survey questionnaire as indicated in the letter were identical the ones in Spain. The companies were instructed to proceed to the online link[14] in order to participate and respond the survey questionnaire. The survey questionnaire for Portugal was equivalent to the questionnaire provided to the chemical companies in Spain.

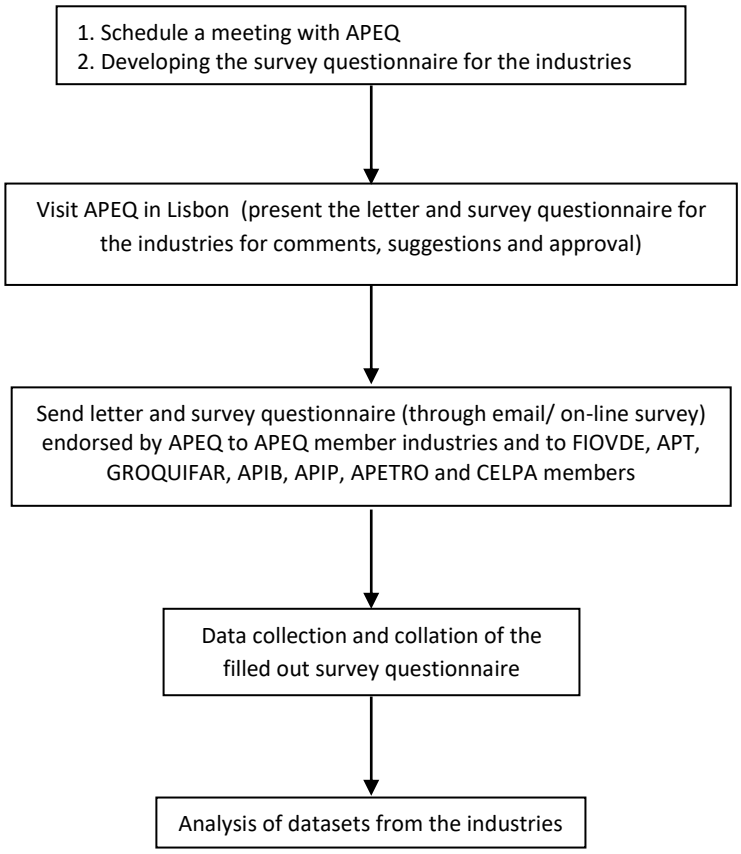


Figure 2.4 Final over-all method for the research project in Portugal.

[13] Classificação Portuguesa das Actividades Económicas (Portuguese Classification of Economic Activities).
[14] https://docs.google.com/forms/d/e/1FAIpQLSe-DKQaJggtwATrffr-h4S6dwXwQ5tSsIpWjGT8R4Fw752J1g/viewform

Figure 2.5 Portugal's major chemical industry hubs (Source: ref. 13)

2.1.3 ECHA

As the regulatory authority of the REACH regulation; the European Chemicals Agency (ECHA) views, facts and findings of the best practices of companies in the European Union (EU) in complying the regulation are significantly important to the research project. The information in the ECHA's website can be used by the research project to find relationships and links with the results of the survey questionnaire sent to the industries. ECHA has an efficient updated data and report concerning the four key essentials in the implementation of the REACH regulation namely registration, evaluation, authorization and restriction.

2.2 Data Collection

The responses of the survey were gathered and recorded in Google Drive. These answers and results were brought together and organized in a Microsoft Excel spreadsheet with separate columns and rows for the responses of each of the chemical companies who participated in the online survey. The responses from the member chemical companies of APEQ in Portugal and of FEIQUE in Spain were the primary data collected. The data collection for Portugal was from 10 July 2017 to 20 July 2017. While for Spain is from 20 July 2017 to 11 August 2017. At the same time also, the ECHA data and reports were obtained from the ECHA website.

2.3 Data Analysis

The research study had utilized both closed-ended (yes/no and multiple choice) and open-ended questions (allowing respondents to write and describe their answers) to capture quantitative and qualitative results. Analysis of the survey data involved qualitative and descriptive statistics. This analysis was processed using Microsoft Excel and converted into different types of graphs to clearly explain the data extracted from the online survey. The number of companies who participated in the online survey was the primary basis for the data analysis. The responses from the surveys collected from Spain and Portugal were independently analyzed.

2.3.1 Spain and Portugal

The size and types of chemical companies in terms of business operation and organization was categorized. The data were organized in graphs to describe the details of the composition of the chemical companies in the two countries involved in the research study. Subsequently, the companies were classified according to their role in the REACH regulation.

The outlined data extracted were then connected in the identification and recognition of the methods applied by these companies in Spain and Portugal in the REACH registration, authorization and restriction processes. These data were also linked to the issues, concerns and challenges that chemical companies encountered in complying the REACH regulation. Closed-ended questions were established to know the specific methods and issues encountered by the companies. These questions were followed by an open-ended query on the reason of their choice of method, and how they were able to address with the issues. The cost of the registration process was also integrated in the analysis. Another analysis was the replies of the respondents on the CLP regulation, which is interrelated with the REACH regulation. Although the REACH defines the Safety Data Sheets (SDS) rules while the CLP gives details on the labeling rules, the CLP labels are dependent with the SDS. If a company is a manufacturer or importer, the company is required under CLP regulation to classify substances that are subject to registration or to notification in line with Article 7 or 9 of REACH, even if the company does not place them on the market [44]. The classification of a substance is a mandatory of the REACH registration dossier.

Lastly, an analysis on the rating of the importance of the different steps in the implementation of the REACH regulation as declared by the chemical companies' respondents in Spain and Portugal. To exemplify the value of the means, graphs were drawn out individually for Spain and Portugal. These data were analyzed through connecting its relation with the preceding data analyses to obtain the appropriated mechanisms and best practices that chemical companies in the two countries have applied in complying the REACH regulation.

2.3.2 ECHA

Tabulation and charts were provided to illustrate comparison of Spain and Portugal to the entire EU members in relation to fulfilling the requirements of the REACH regulation in the 4 areas of the regulation. The final data collected from

ECHA were reports extracted from the agency's website on the significance of the various measures for companies to carry on in order to effectively comply with the REACH regulation. These reports were matched up to the answers of the respondents in Spain and Portugal. The tabulation was analyzed and evaluated by descriptive statistics to come up with a recommendation on the appropriate methods and strategies for the companies to employ in dealing with the REACH regulation while maintaining industry standards and strengthening competitiveness in the global chemical market.

2.3.3 Data Analysis Flowchart

The methods in the data analysis of the research project as described above is outlined in Figure 2.6 and Figure 2.7.

2.4 Limitations

While the research study is carefully prepared, there are still limitations and shortcomings. First, the study was conducted to only two European countries – Spain and Portugal each lasting for less than six (6) months each country, limiting the study's coverage and significance. While the study provides all FEIQUE-member companies in Spain and APEQ-member companies (and the member companies from the other 7 industry associations) in Portugal access to the online survey questionnaire, the second limitation will be on the number of respondents that responded to the online questionnaire. Given the limited timeframe given to both companies in Spain and Portugal to access and answer the online survey questionnaires, respondents that answered the online survey questionnaires within the allotted time period were the only ones included.

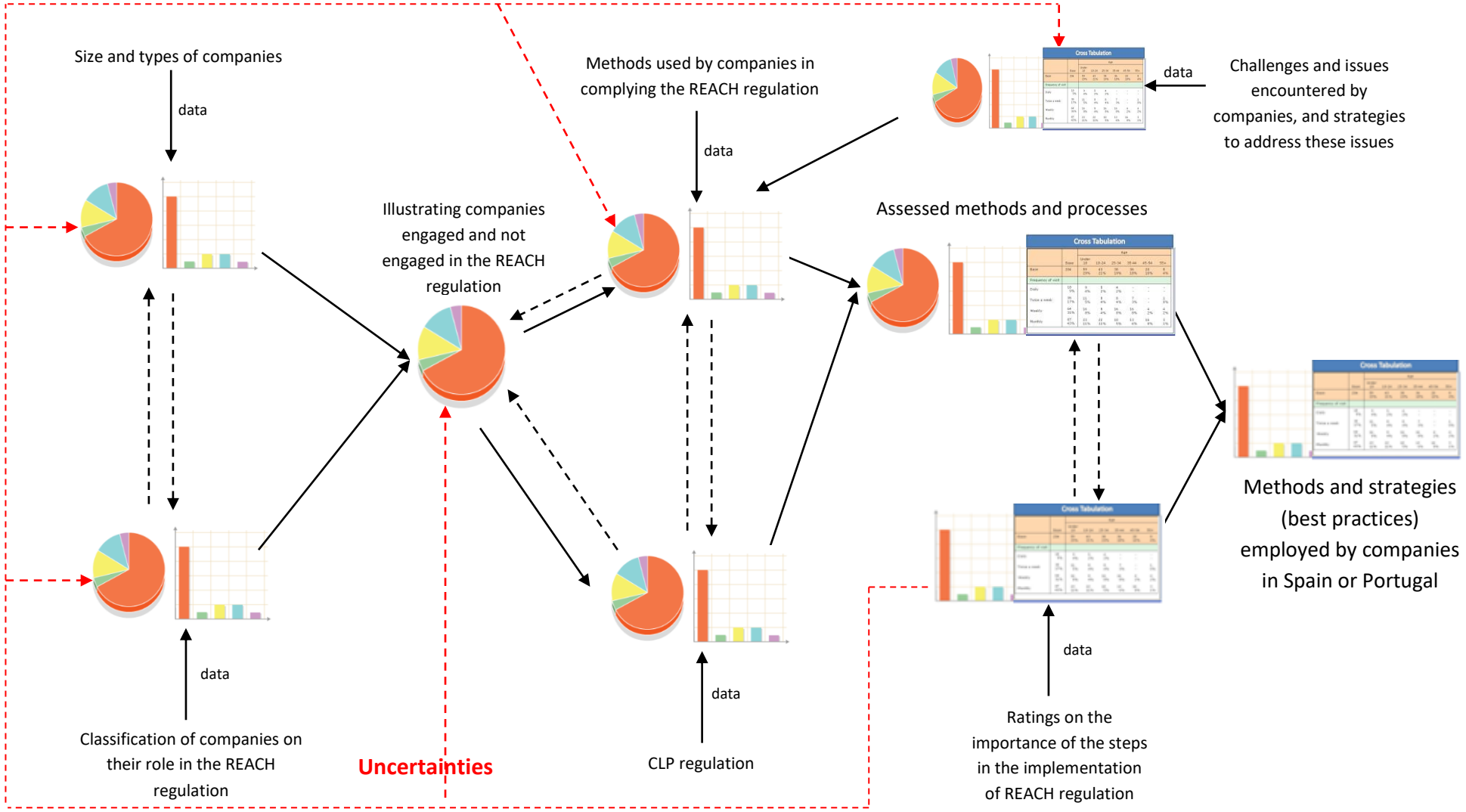


Figure 2.6 Flowchart for the data analysis of survey results from chemical companies. Note: 1) Spain and Portugal data were done individually. 2) Uncertainties represented responses that were not directly related or did not directly correspond to the question at hand or respondents that did not provide answers to any specific questions.

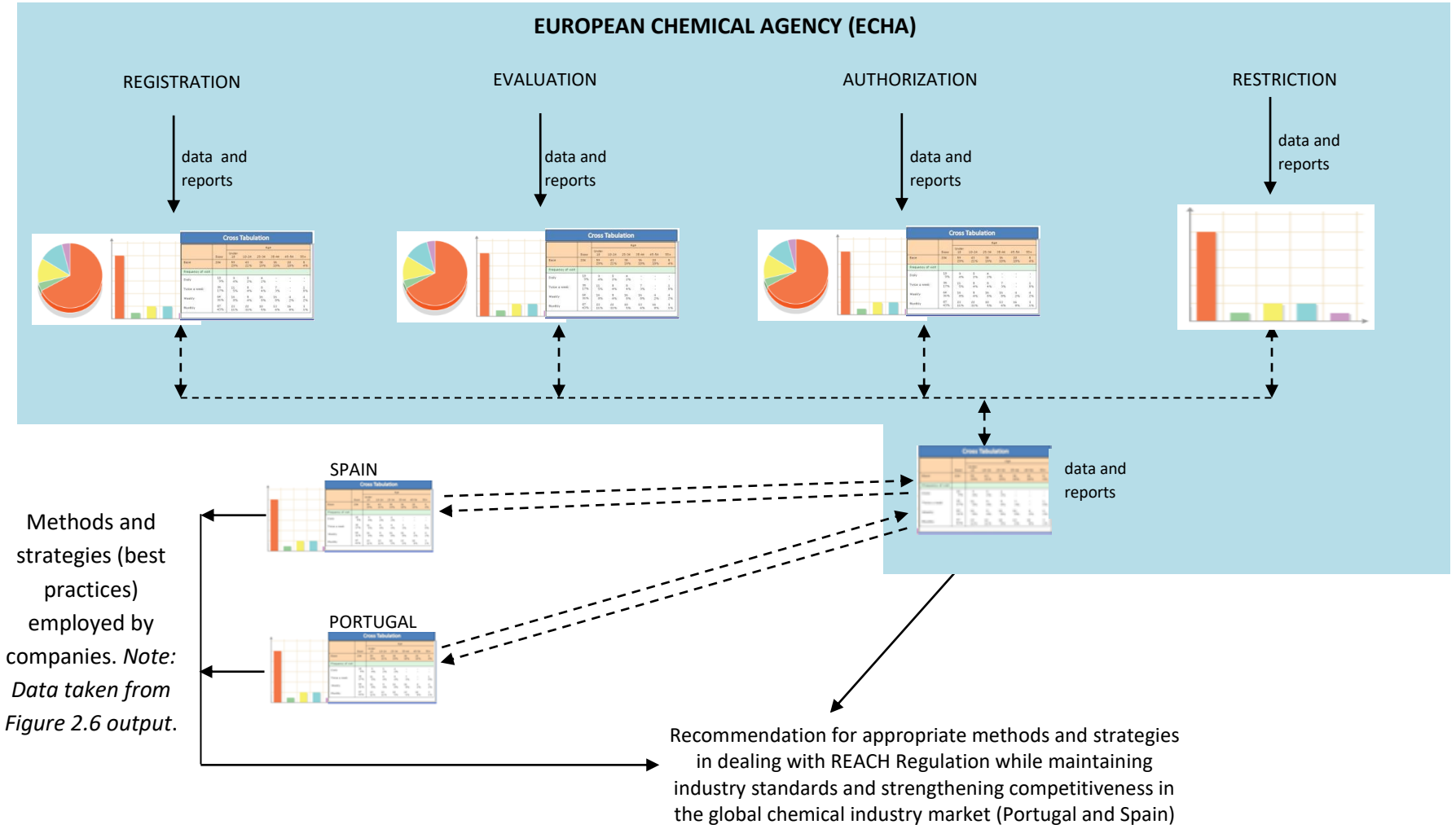


Figure 2.7 Flowchart for the data analysis of survey result from ECHA and final output.

3. RESULTS AND DISCUSSION

The results of the research study were obtained through the responses from the survey questionnaire provided to the chemical companies both in Portugal and Spain. Results of the survey from Portugal and Spain are shown in this chapter. The survey results were divided into three categories namely registration, classification and labeling, and over-all remark. Further, the registration category is sub-divided into four parts as described in the methodology chapter.

3.1 Spain

The survey questionnaire was disseminated to the chemical companies in Spain through the assistance of FEIQUE. There were six companies who submitted their responses on the survey.

3.1.1 Registration

Type 1: The type of company (business ownership, entity scale, industrial sector, operation level).

All the respondents of the survey in Spain are private entities and belong to the Stock Corporation (Sociedad Anónima–S.A.) business type of ownership. Four (4) of the six companies are large enterprise while the rest (2) are small enterprise as shown in Figure 3.1.

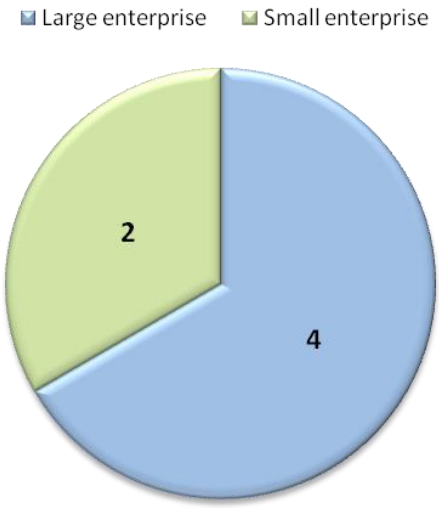


Figure 3.1 Spain: Classification of respondent companies based on scale.

Out of the six respondents, two belonged in the Specialty Chemicals sector while the rest of the four companies were from petrochemicals (1), consumer chemicals (1), basic inorganics (1, other inorganics), and other chemicals (1, basic chemicals). Figure 3.2 illustrates the classification of chemical industrial sectors of the respondents.

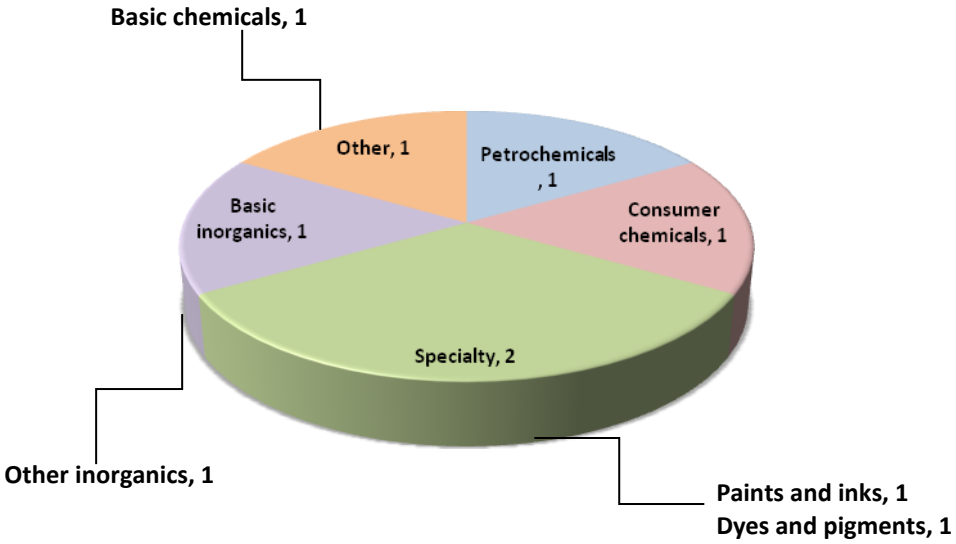


Figure 3.2 Spain: Classification of respondent companies according to sectors.

Four of the respondents' market operation is worldwide, wherein the three of these companies are large-scale entities and the other is a small-scale enterprise. The other two respondents' market operation is within Europe, in which one company does not operate only in Europe but also in the Middle East and Africa. Figure 3.3 shows the classification of marketing operation of the chemical industry respondents in Spain. The chemical industry is the second largest exporter of the Spanish economy [20, 21], which continuously contributed 43.3% exportation growth from 2007 to 2015 and 32.7 billion Euro sales in 2015 [11].

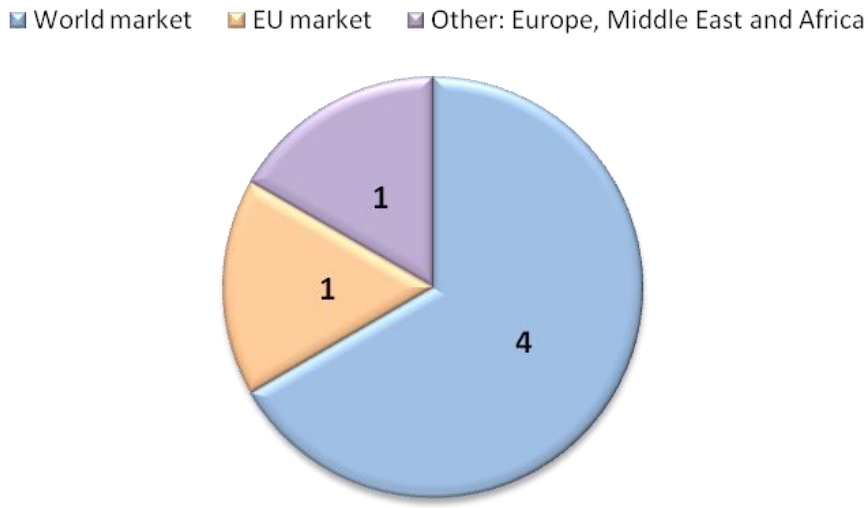


Figure 3.3 Spain: Marketing operation of respondents.

Type 2: Company's role in the REACH regulation (type and quantity of substances applied for registration, authorization, and restriction).

All of the respondents classified their companies as manufacturers and downstream users. Five of these companies are also importers and/ or only representatives of a non-community manufactures (EEA based "Only Representatives) as illustrated in Figure 3.4. Figure 3.4 shows that the respondents filled more than one option on this question defining the company role according to Articles 3 and 8 of Regulation (EC) no. 1907/2006. Further, the companies differ on the types of chemicals manufactured, used and imported. As shown in Figure 3.4, all of the manufacturer respondents (6) are producing mixtures, five of these companies are also producing substances/ intermediates. All respondents are both manufacturing and importing both substances/intermediates and mixtures.

Six of the respondents have registered their chemicals with ECHA although three of these companies still have some substances that need to be registered (Figure 3.5). The estimated average cost as declared by the respondents ranged from 35,000 € to 200,000 € while the substances to be registered is 50,000 €. The cost of registration depends on the number of substances.

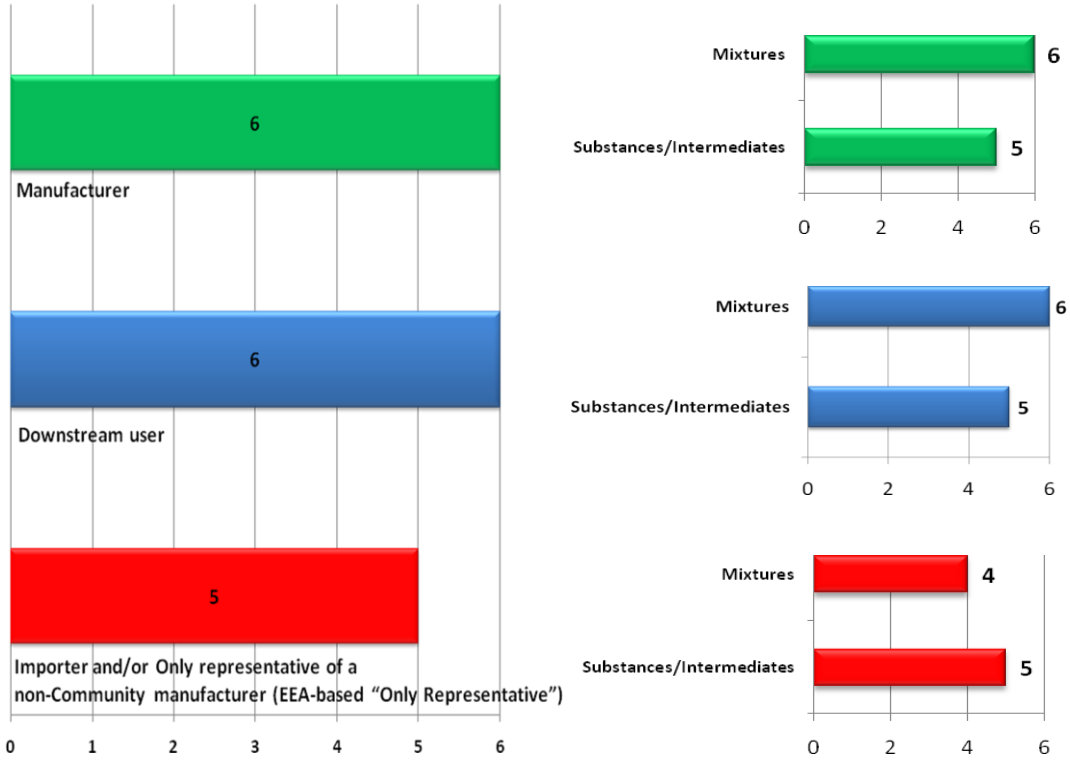


Figure 3.4 Spain: Respondent companies role under the REACH regulation.

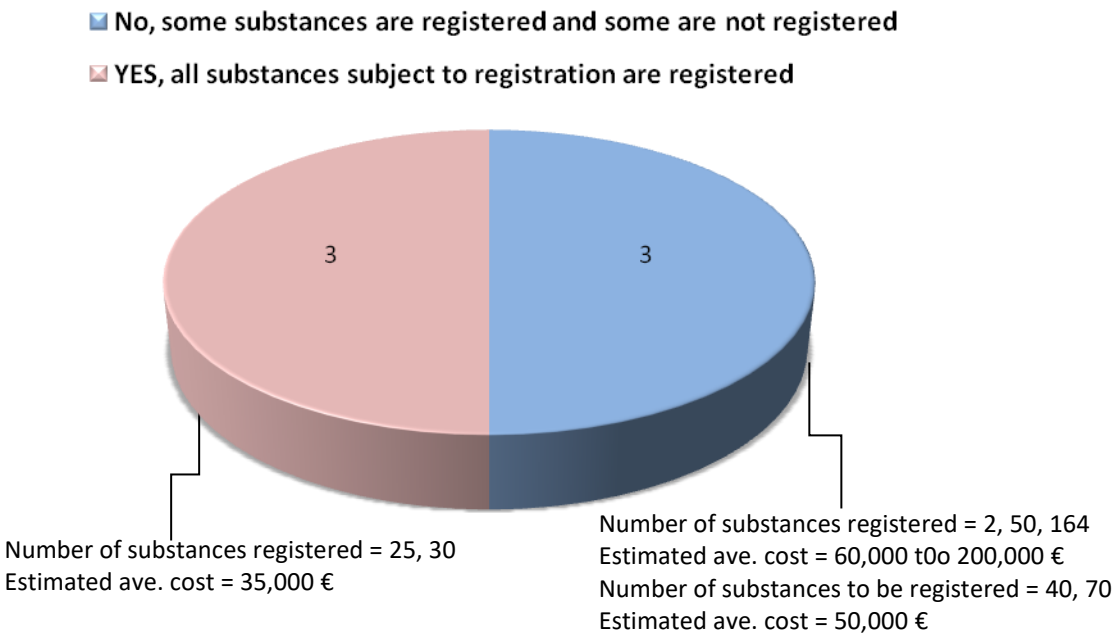


Figure 3.5 Spain: REACH registration of substances with corresponding number of substances registered and estimated average cost.

Three of the respondents are either engaged in the manufacture, import or use of substances of very high concern (SVHC) as shown in Figure 3.6. One of the three respondents handling SVHC has already applied for authorization and granted authorization by ECHA. However, the other two companies engaged in SVHC will not apply for authorization, with one company indicating that they have an alternative substance replacing the SVHC.

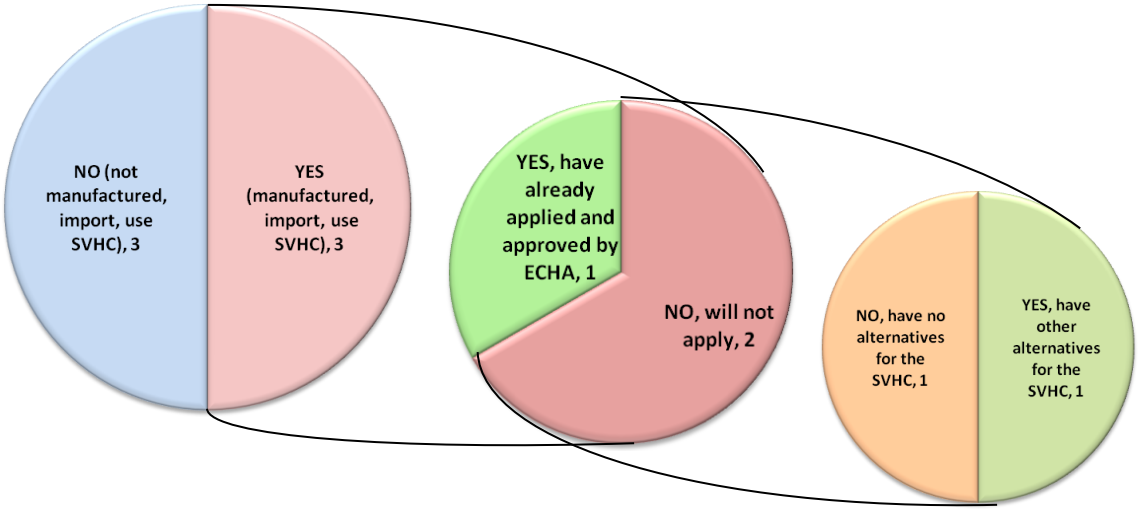


Figure 3.6 Spain: Respondents engaged in the manufacture, import and/or use of SVHC.

Out of the six respondents, two companies are handling substances under the REACH restriction category (Figure 3.7). Figure 3.7 also shows that the restricted substances used, manufactured and/or imported by these companies are registered with ECHA.

Most of the respondents in Spain have considered limiting (2) or cancelling (2) either manufacture, import and/or use of certain substances they handled under the REACH regulation (Figure 3.8) due to the registration obligation under REACH and its related cost. Among the remaining, one company respondent does not consider limiting or cancelling the manufacture/import/use or reducing the volumes of substances under the REACH regulation while another respondent has not decided to cancel or limit or reduce for the moment.

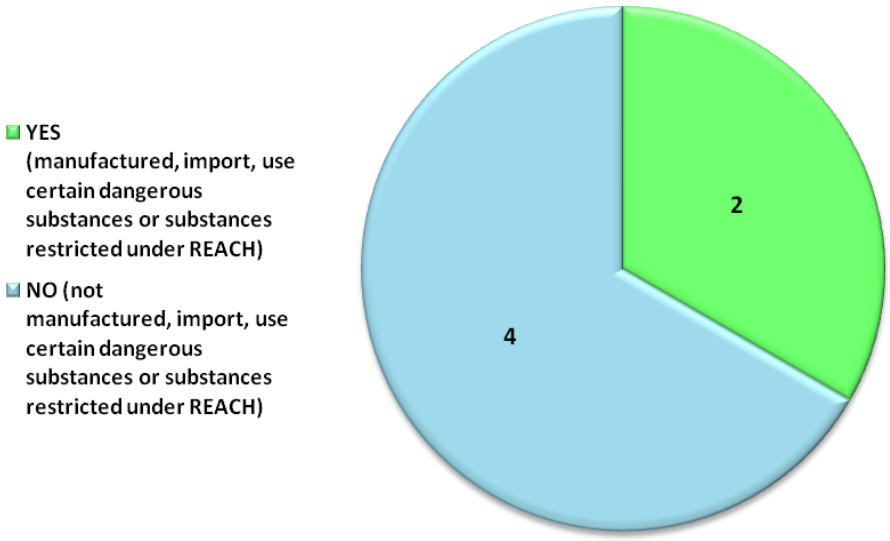


Figure 3.7 Spain: Respondents engaged in the manufacture, import and/or use of restricted substances under REACH.

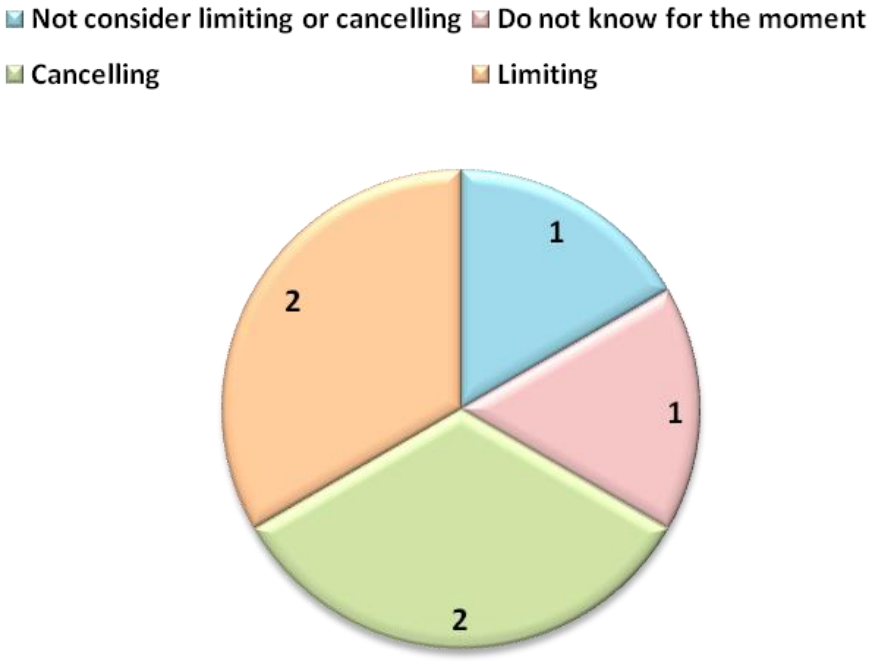


Figure 3.8 Spain: Respondents' course of action on certain substances due to registration obligation under REACH and its related course.

Type 3: Methods applied by companies in the registration of substances (including preparation of dossier, complying with additional requirements, attendance to seminars).

Five of the respondents have carried out or will carry out the joint submission in the REACH registration of their substances. One company did not respond to this question. The joint submission method applied by these companies in the registration of substances can be considered as best practice among industries in complying with REACH regulation. The respondents in Spain conform to Article 29 of Regulation (EC) 1907/2006 "SIEF participation" and OSOR principle. Cost benefit and efficiency, and data sharing obligation are the main reasons for the companies who jointly carried out the registration process.

When it comes to sources of information on REACH regulation, all of the respondents (6) in Spain have found the ECHA information to be most useful (Figure 3.9). Other sources of information received by the company respondents are from business associations such as FEIQUE, CEFIC, Eurocolor, ANFFECC, Frit Consortium, Inorganic Pigment Consortium, ASEFCA, FEDEQUIM, IP&P, Cosmetics Europe, and EFfCI (5); legislation (4); professional trainings, seminars and courses (3); and external company like consultants (3). The company respondents also find information useful from the internet (2); and their parent company or head office (2). The information from ECHA and business organizations indicated its usefulness in the effectiveness of complying with the REACH regulation.

One of the best practices for companies in complying with the REACH regulation is designating or appointing key personnel responsible in directly addressing the REACH regulation processes. All of the respondents in Spain have employees responsible for addressing REACH-related issues in their company. Three of the respondents have two employees in-charged while the other three companies have three, four and five employees as shown in Figure 3.10.

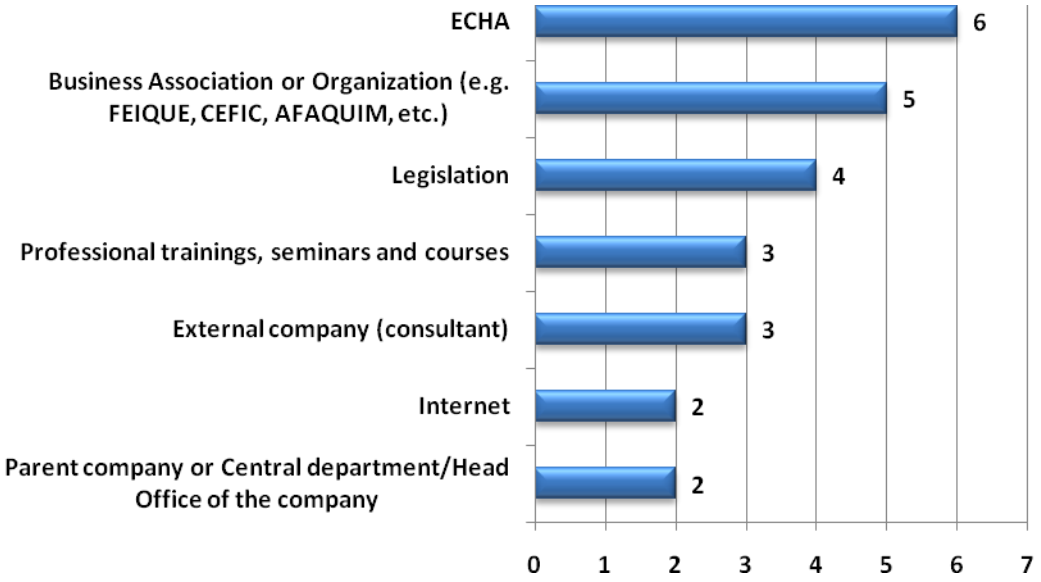


Figure 3.9 Spain: Respondents' sources of information on REACH regulation.

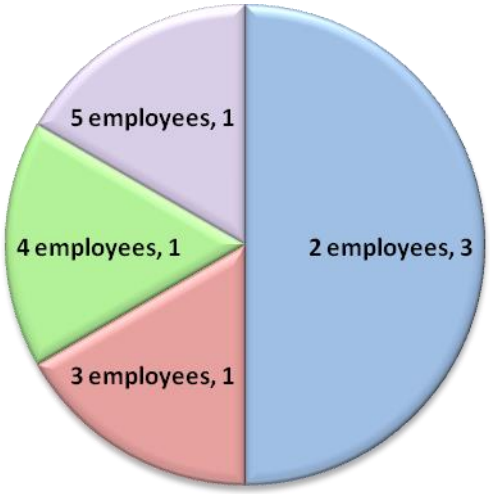


Figure 3.10 Spain: Number of employees in-charge in addressing REACH-related issues.

Type 4: Challenges, issues and problems encountered by companies in the registration process (including strategies used in order to cope up and address the issues and problems).

Five out of the six respondents report challenges, issues and problems encountered by their companies in the REACH registration process while one company did not answer on this query. As illustrated in Figure 3.11, four of the five

companies report issues on the cost for tests of the chemicals to be registered and communication with all potential registrants, downstream users and third parties who participated in the substance information exchange forum (SIEF)/ communication with previous registrant to reach an agreement on the sharing of existing data in the case of registered substances. Other issues brought up by the respondents are complexity of the IT tools in terms of installation and use by normal user (2), communication with ECHA (1), and not able to cope up the deadline set by ECHA on additional data or information (1). Joining the consortium in the registration process has once more proven a best practice in complying with the REACH regulation. According to the respondents, they were able to cope with the issue on communication with ECHA through the consortium that functions as the lead in the REACH registration. In terms of the issue on complexity of the IT tools, companies were able to address it through attendance to trainings of the personnel responsible in the REACH compliance. Companies have also support from their IT department in addressing REACH IT matters.

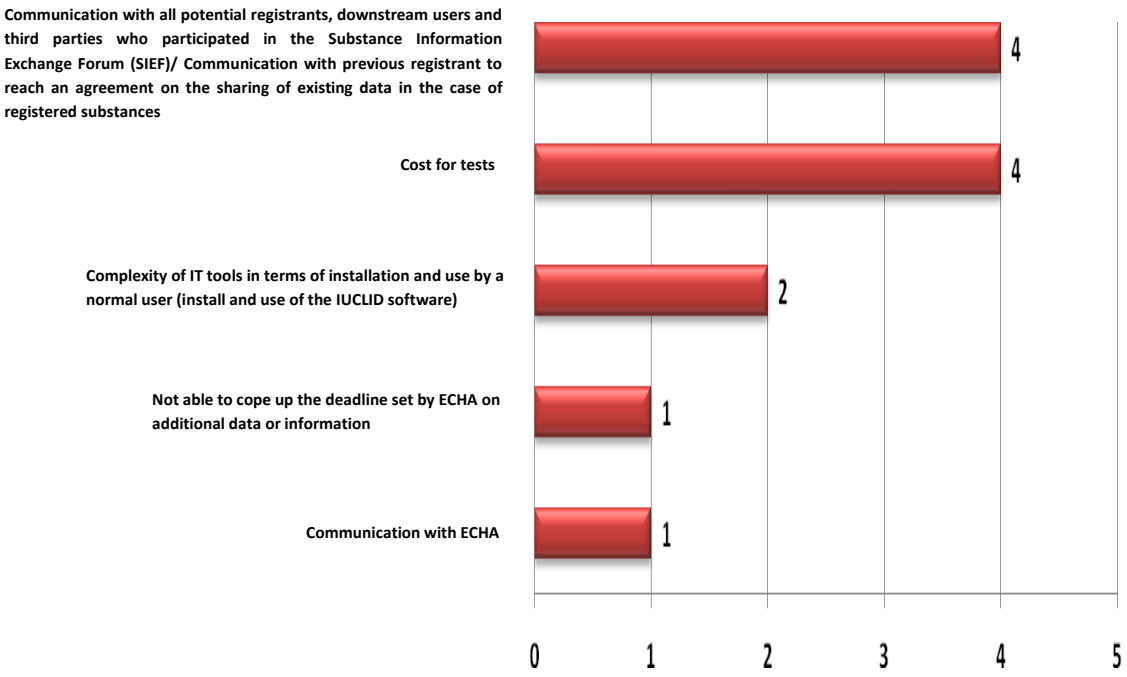


Figure 3.11 Spain: Challenges, issues and problems met by respondent companies during the REACH registration process.

Subsequently, three of the five companies who responded on the issues and concerns encountered during REACH registration have reported the same issues during the dossier and substance evaluations specifically on the cost for tests of the chemicals to be registered and communication with all potential registrants, downstream users and third parties who participated in the substance information exchange forum (SIEF)/communication with previous registrant to reach an agreement on the sharing of existing data in the case of registered substances (Figure 3.12). Other similar concerns are complexity of the IT tools in terms of installation and use by normal user (2), communication with ECHA (2), and not able to cope up the deadline set by ECHA on additional data or information (2). One respondent reports an issue on communication with the Member State Competent/National Authority. They were able to address the issues through the consortium and the personnel responsible on REACH compliance undergoing external training on the IT tools. Joining the consortium is another indication that SIEF and OSOR principle is an effective tool in complying with the REACH regulation.

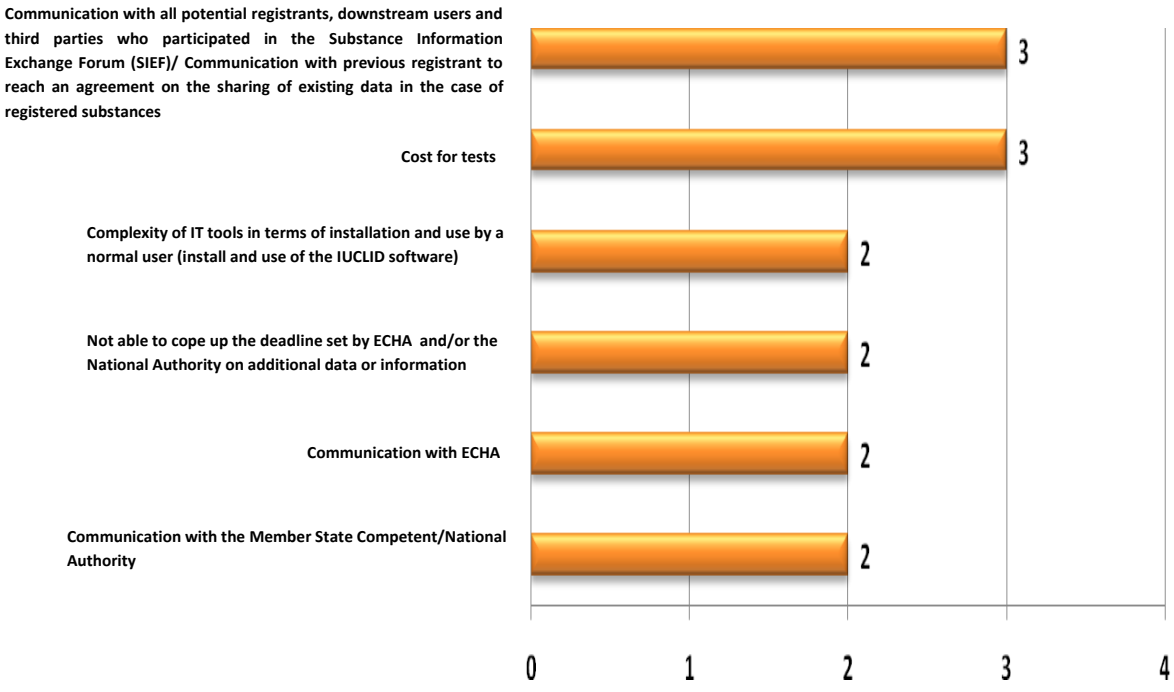


Figure 3.12 Spain: Challenges, issues and problems met by respondent companies during the Dossier and Substance Evaluations.

3.1.2 Classification and Labeling

Figure 3.13 and Figure 3.14 demonstrate the downstream user respondents' concerns on the availability and accessibility of the SDS by their suppliers as well as course of actions taken and involvement in the inclusion of their substance in the SDS. Three of the six respondents received SDS for all the substances from their suppliers while one company have either received or not for some substances and the remaining two companies have not received SDS for all substances (Figure 3.13). The best approach that the companies who did not receive SDS from their suppliers is by notifying their suppliers to provide the correct SDS version to avoid cancellation of orders on the next procurement. Another initiative done by one company is acquiring the information of the substances from other sources. For the companies who received SDS for all the substances procured have been provided with SDS in Spanish though one company confirmed that the supplier provides the SDS as per request. In accordance to Article 31 (5) of REACH regulation, "the safety data sheet shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise".

Inclusion of the substances handled by the downstream user respondents in the SDS provided by their suppliers is not an issue since they have discussed with the suppliers on the usage and inclusion of the substances in the SDS (Figure 3.14) but two of these companies have not received SDS for all the substances from their suppliers (Figure 3.13). Moreover, one downstream user did not discuss the inclusion of the substances with their suppliers since the usage of the substances has been included in the SDS and the suppliers provided the SDS of all substances used by the downstream user. Only two of the downstream users have fully understood the information of the safe use of chemicals in the SDS provided by the suppliers while the rest (4) understood a little (not mostly) of the information on the SDS provided by the suppliers. As stated in ECHA's REACH and CLP report, the role of downstream users of chemicals is important – by demanding better quality, user-friendly safety data from their suppliers, they can improve the safe use of chemicals [50].

Companies need to assemble the data needed for each substance, produce practical advice on how to use it safely and communicate it in their supply chain [50].

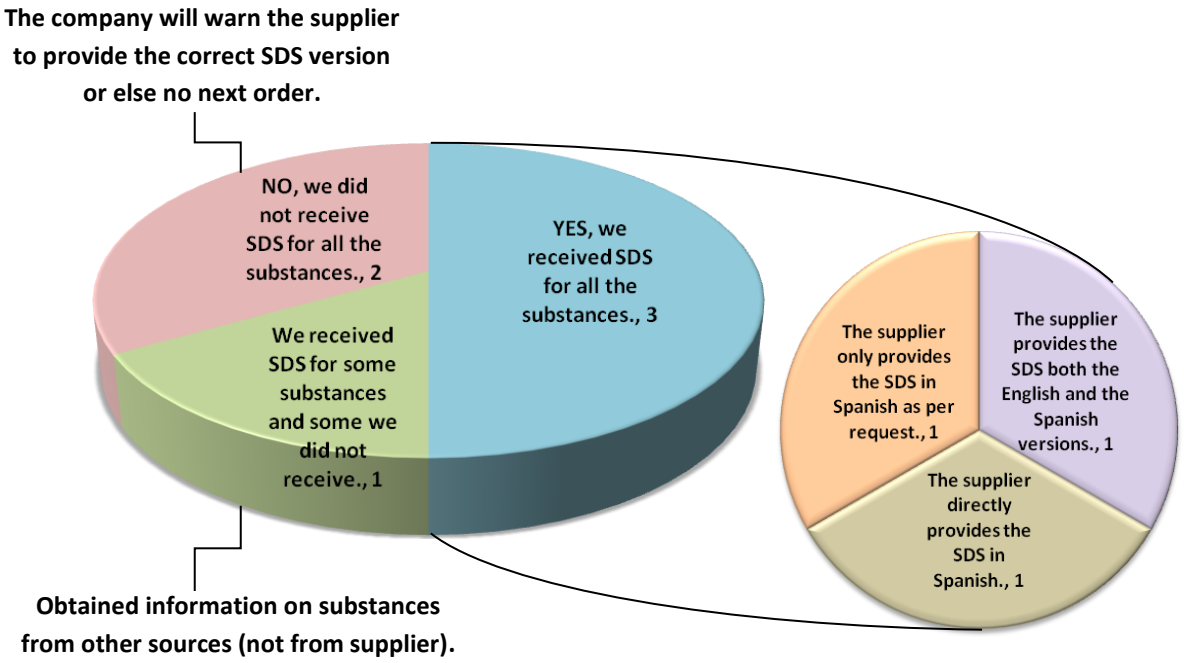


Figure 3.13 Spain: Downstream user respondents method of acquisition the SDS from their suppliers.

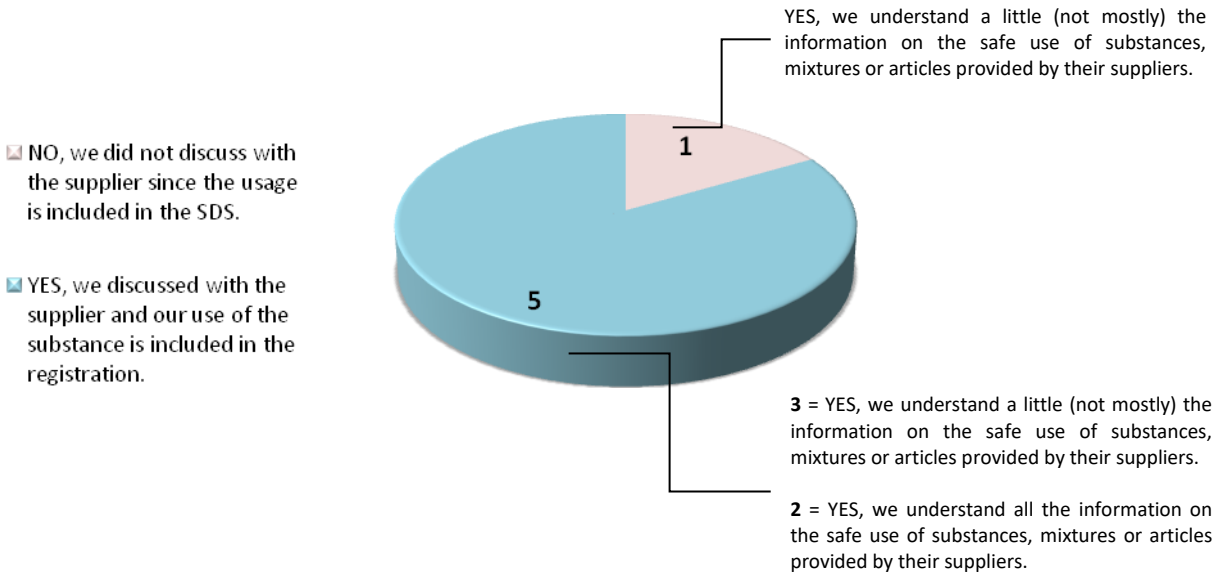


Figure 3.14 Spain: Downstream user respondents' involvement in the inclusion of their substances in the SDS.

Three of the five importer respondents prepared the SDS of the substances they purchased outside EU by themselves while the remaining two importers by their suppliers outside EU as shown in Figure 3.15.

Figure 3.15 Spain: Importer respondents' method of preparing the correct version of SDS.

Based on the survey result, all of the manufacturer respondents in Spain have provided the correct version of SDS to the downstream users as shown in Figure 3.16. Four of these manufacturers have discussed the use of the substances with the customers while the other two manufacturers have discussed the use of the substances in some cases only. Further, four of the manufacturer respondents also provided ESDS to their customers. One company provided ESDS on some substances only since they are still waiting for the final version of the exposure scenario of some substances. Another manufacturer company did not provide ESDS to customers since their suppliers did not provide them the ESDS as well.

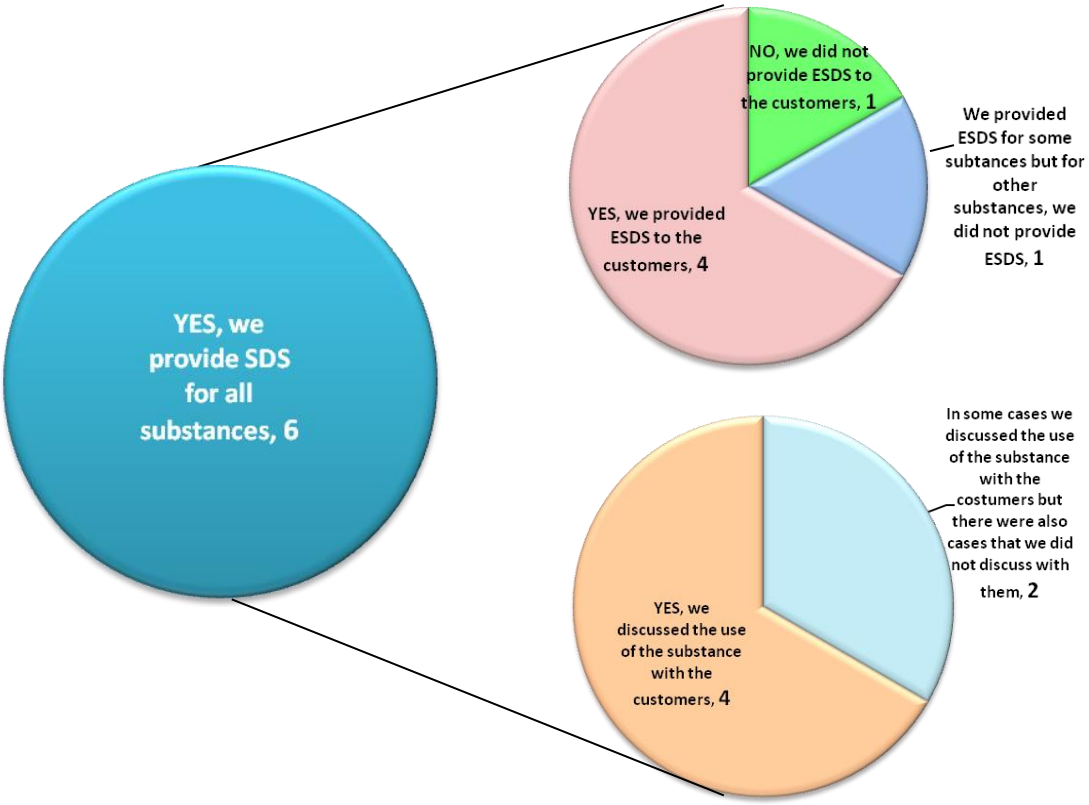


Figure 3.16 Spain: Manufacturer respondents' method of providing the correct version of SDS and ESDS to downstream users.

3.1.3 Overall Remarks

Information and Communication

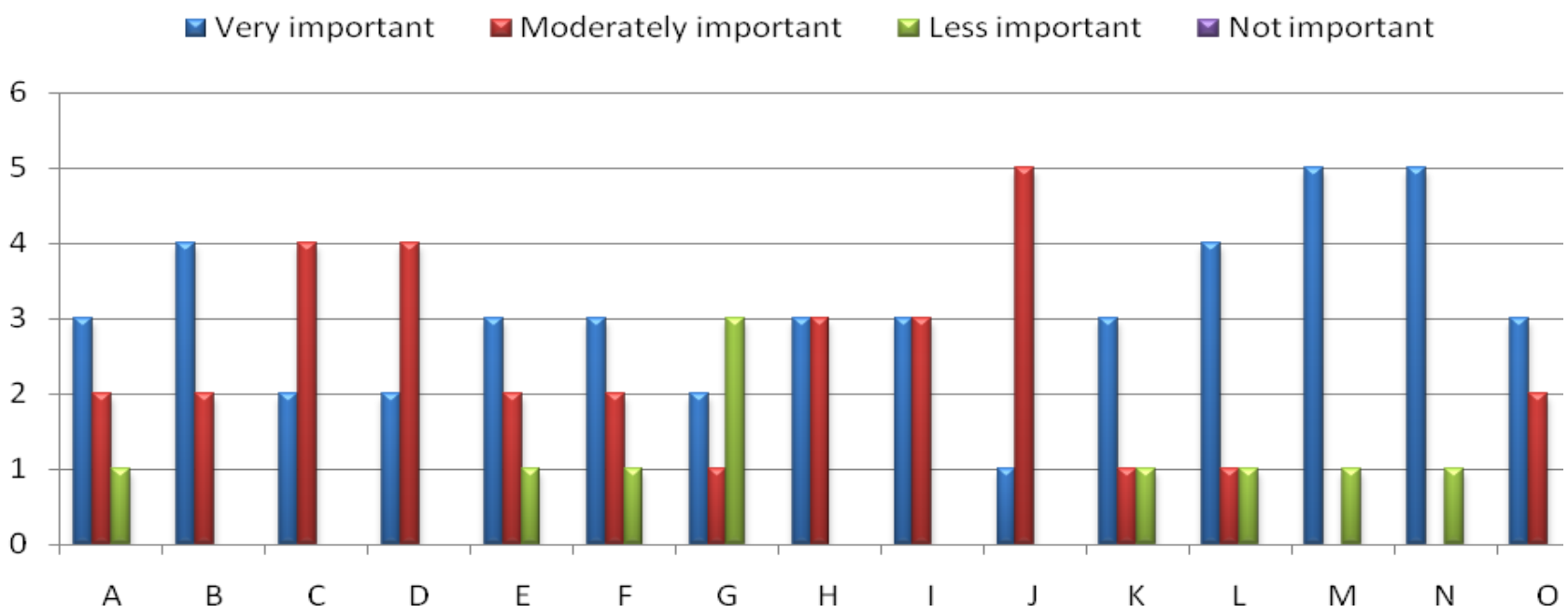
Five out of the total six respondents in Spain recognized that joint submission of data by multiple registrants and cost-sharing for tests are the most important aspects in terms of information and communication in complying with the REACH regulation (Figure 3.17). Other approaches confirmed by the respondents are as follows:

- agreement with other registrants and downstream users in carrying out or performing the tests (4);
- internet access and research on ECHA website (4);
- reading of materials on REACH regulations, methods, articles, etc. (3);

- creation of company's technical working group in the compliance and implementation of the REACH regulations and other chemical regulations (3);
- constant communication with ECHA from pre-registration to registration to evaluation to appeal to approval to updating (3);
- seek advice from consultants (3);
- consult with business associations/organizations, e.g. FEIQUE (3); and
- budget for the costs involved in the REACH process (3).

More than half of the respondents also acknowledged methods such as consultation or confer with other industries (4), constant attendance to seminars and training courses related with REACH regulations and other chemical legislation (3), and understanding the ECHA guidelines and constant inquiry on the guidelines updates (3) to be fairly important to the REACH regulation process.

In order to come up with the means of the answers provided by the respondents (Figure 3.17), the classification of importance of the different schemes in terms of information and communication aspect in complying with the REACH regulation are given values (4 = very important, 3 = moderately important, 2 = less important, 1 = not important). The top two results as shown in Figure 3.18 is consistent with the results in Figure 3.17, wherein the respondents in Spain give importance on cost sharing for tests and the joint submission of data by registrants in accordance with Article 11 of the REACH regulation. The joint submission of data conforms to the OSOR principle. The companies also give emphasis on networking and linkages, research and related literatures, constant attendance to seminars and trainings, and creation of a technical working group in fulfilling the REACH regulation. Generally, the respondents find all the schemes cited as significantly important in complying with the REACH regulation. Moreover, the information from ECHA's website has proven to be functional and useful to the companies.



A	**Reading of materials (REACH regulations, methods, articles, etc.**
B	**Internet access and research on ECHA website**
C	**Constant attendance to seminars and training courses related with REACH regulations and other chemical legislation**
D	**Understanding the ECHA guidelines and constant inquiry on the guidelines updates**
E	**Create a company's technical working group in the compliance and implementation of the REACH regulations and other chemical regulations**
F	**Constant communication with ECHA (from pre-registration to registration to evaluation to appeal to approval to updating)**
G	**Communication with the Member State Competent/National Authority**
H	**Seek advice from consultants**
I	**Consult with business associations/organizations (e.g. FEIQUE)**
J	**Consult or confer with other industries**
K	**Communication and participation in the Substance Information Exchange Forum (SIEF); sharing of data involving tests]**
L	**Agreement with other registrants and downstream users in carrying out or performing the tests]**
M	**Joint submission of data by multiple registrants**
N	**Cost sharing for tests**
O	**Budget for the costs involved in the REACH process**

Figure 3.17 Spain: Respondents perspective on the importance of the different information and communication schemes in complying with the REACH regulation.

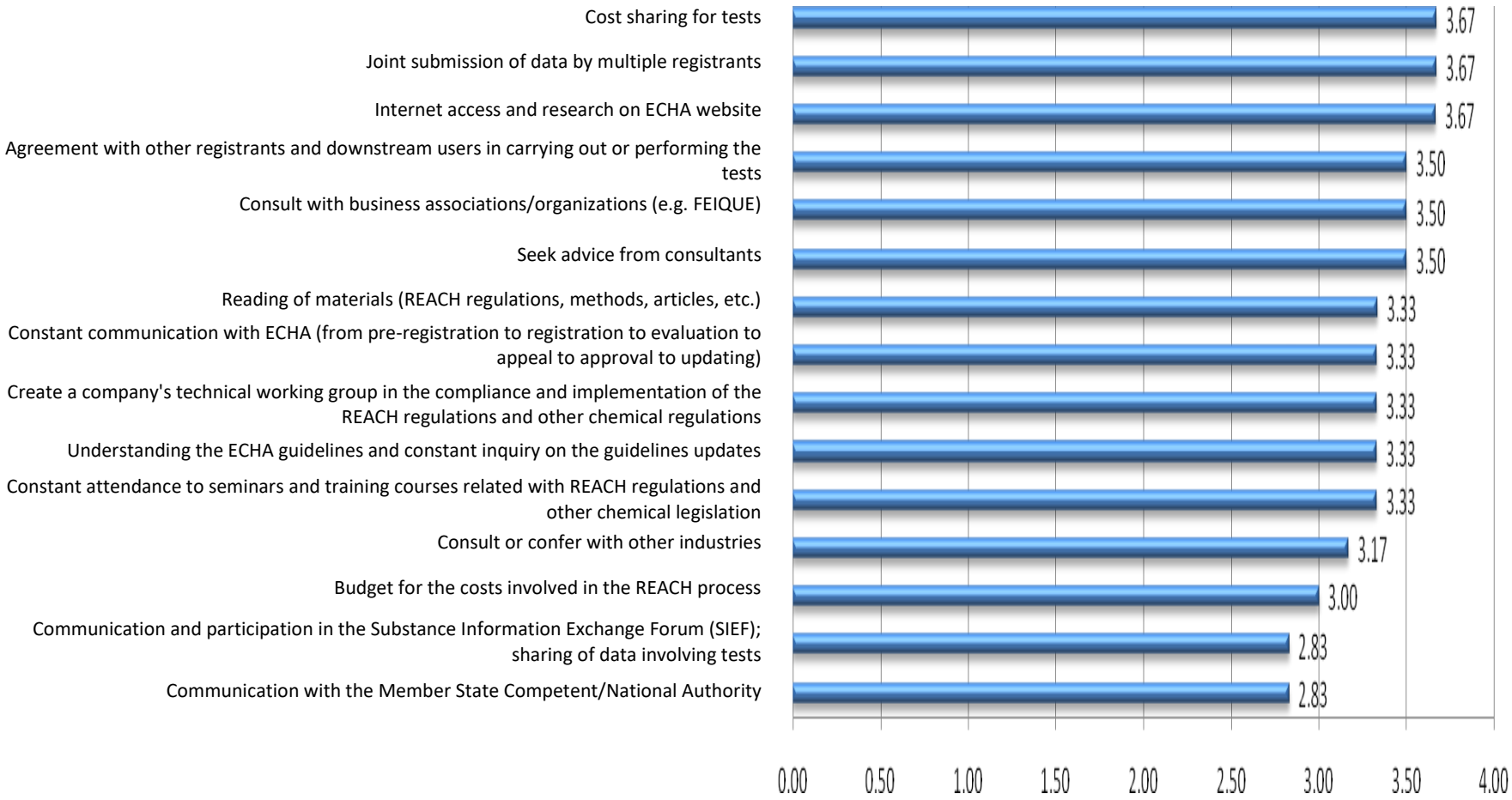


Figure 3.18 Spain: Means of the different information and communication schemes in complying with the REACH regulation.

Technical Aspects

In terms of technical aspects in complying with the REACH regulation, the majority of the respondents in Spain have identified that all of the choices in the survey questionnaire are significantly important (Figure 3.19). Five out of six respondents defined the following approaches as the most important in fulfilling the REACH regulation in the technical aspects in complying with the REACH regulation:

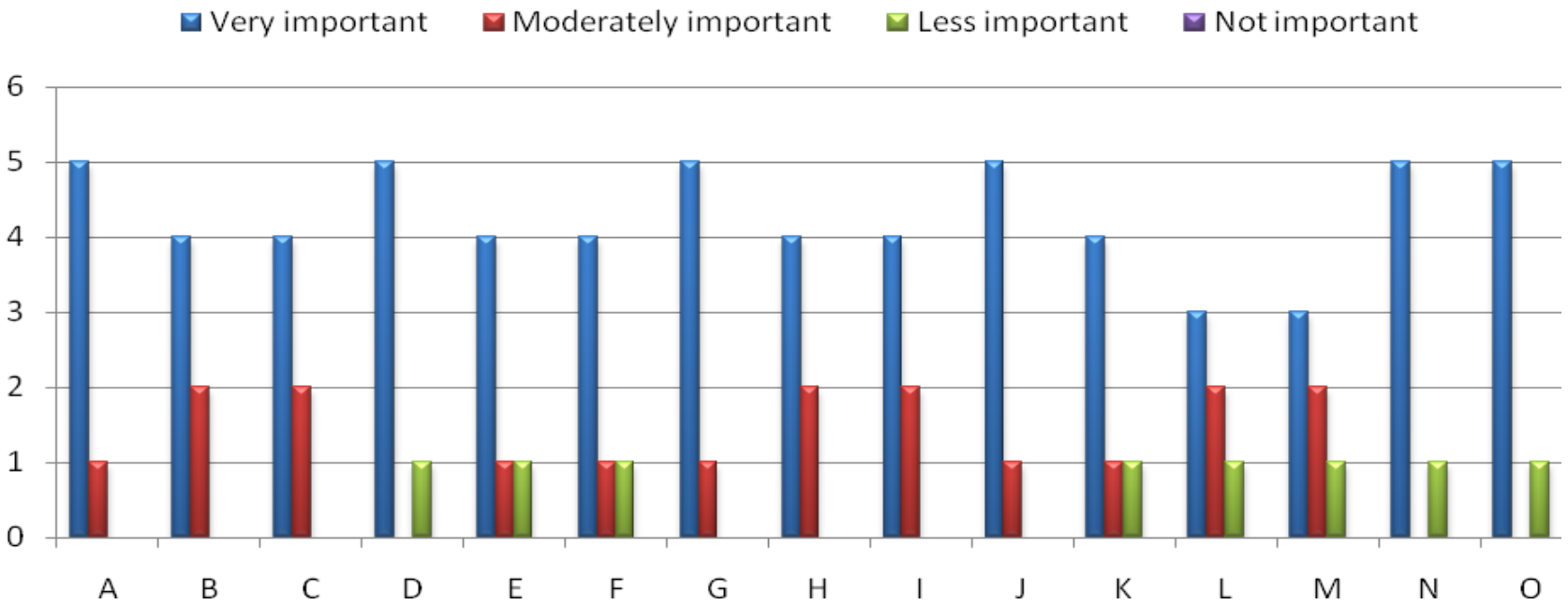
- preparation of checklist for the registration requirements, technical dossier, and updated Safety Data Sheet (SDS) in accordance with Commission Regulation (EU) No. 2015/830;
- access for workers to information of the chemicals that they use or may be exposed to in course of their work;
- proficiency in the installation and use of the IUCLID software; and
- updating of the registration dossier via REACH-IT or IUCLID.

Four out of six companies also recognized the methods to be highly important:

- identification of the classification of the chemical to be placed/registered; calculation of the quantity (tonnage) of a substance manufactured or imported or used per year;
- preparation and conduct of chemical safety report;
- quality of the SDS provided by manufacturers, importers and suppliers;
- duty to communicate information down and up the supply chain; and
- avoidance of unnecessary testing.

For the conduct of in-vivo and in-vitro tests however, three of the six company respondents agreed that these tests are very important while two companies considered as moderately important and one company as least important. Once more as defined in Article 25(1) of the REACH regulation, “In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.”

The means of the different technical schemes in complying with the REACH regulation is shown in Figure 3.20. Overall, the respondents consider all the technical methods as vital aspects in complying with the REACH regulation.



A	**Prepare checklist for the registration requirements**	**I**	**Duty to communicate information down and up the supply chain**
B	**Identification of the classification of the chemical to be placed/registered (article, mixture or substance/intermediate, phase-in or non-phase-in substances)**	**J**	**Access for workers to information of the chemicals that they use or may be exposed to in course of their work**
C	**Calculate the quantity (tonnage) of a substance manufactured or imported or used per year**	**K**	**Avoidance of unnecessary testing**
D	**Preparation of the technical dossier**	**L**	**Conduct of in-vivo tests**
E	**Preparation of the chemical safety report**	**M**	**Conduct of in-vitro tests**
F	**Conduct chemical safety assessment**	**N**	**Proficiency in the installation and use of the IUCLID software**
G	**Preparation of the updated Safety Data Sheet (SDS) in accordance with Commission Regulation (EU) No. 2015/830**	**O**	**Updating of the registration dossier via REACH-IT or IUCLID (either requested or spontaneous update)**
H	**Quality of the SDS provided by manufacturers, importers and suppliers**		

Figure 3.19 Spain: Respondents perspective on the importance of the different schemes in terms of technical aspect in complying with the REACH regulation.

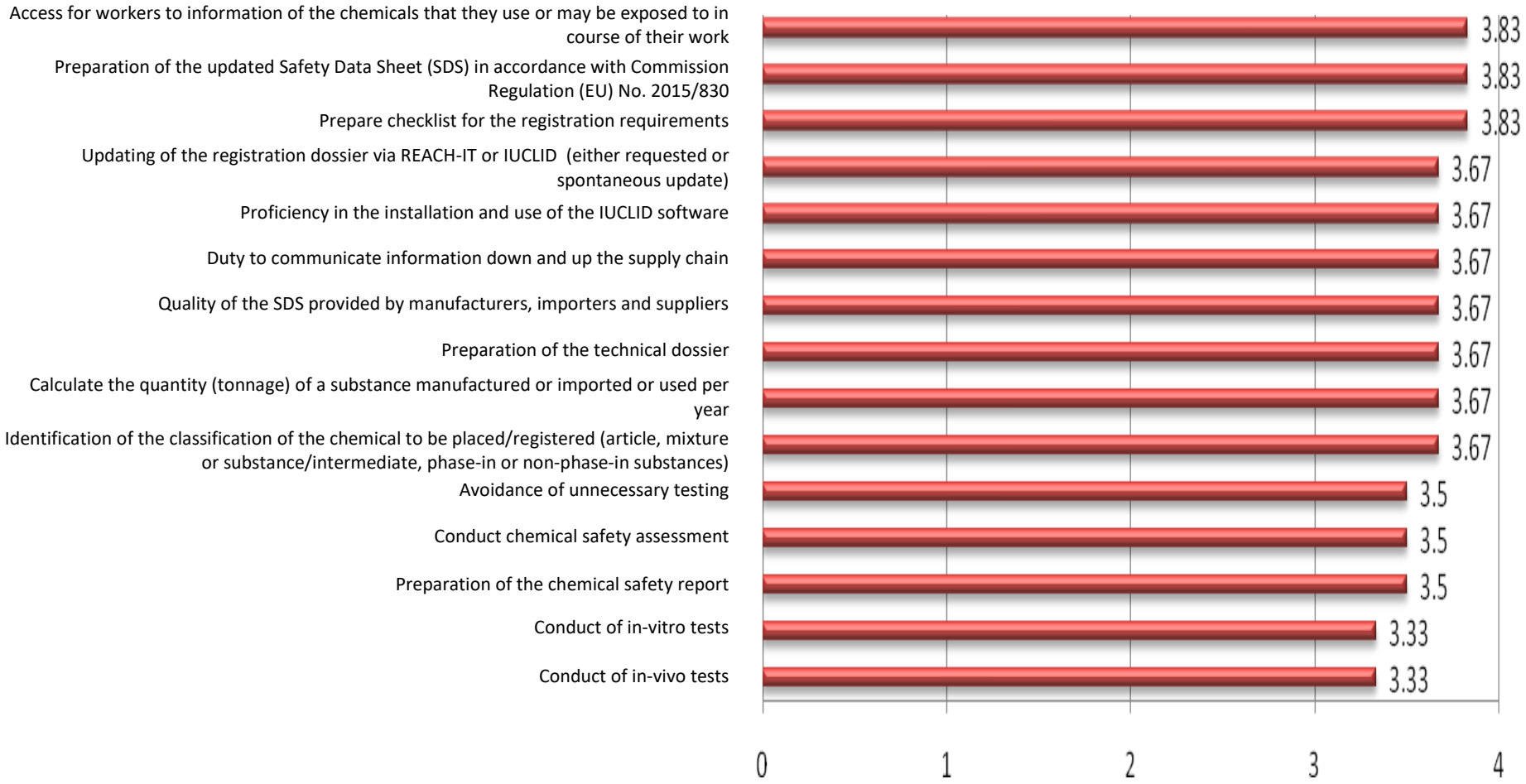


Figure 3.20 Spain: Means of the different technical schemes in complying with the REACH regulation.

3.2 Portugal

The survey questionnaire was disseminated to the chemical companies in Portugal through the assistance of APEQ. The association is composed of 36 chemical companies and were all provided with survey questionnaires. Fourteen percent of APEQ members are classified as large scale chemical industries while 86% are considered micro, small and medium enterprises (MSMEs). Further, the survey was sent to other 7 industry associations through APEQ as shown in Figure 2.4. Out of the total chemical companies, twenty submitted their survey results.

3.2.1 Registration

Type 1: The type of company (business ownership, entity scale, industrial sector, operation level).

Based on the submitted survey results, all the respondents of the survey were categorized as private entities, wherein majority or 14 companies belonged to the Public Limited Liability Company (Sociedade Anónima), followed by 4 Private Limited Liability Company (Sociedade por Quotas) and 1 Sole Shareholder Private Limited Liability Company (Sociedade Unipessoal por Quotas). Based on Annex I of Regulation (EU) No. 651/2014, companies whose categories are under the Public Limited Liability Company (Sociedade Anónima) are mostly medium scale and large scale enterprises as shown in Figure 3.21.

Of the total respondents, seven companies belonged in the Specialty Chemicals sector while four entities are from the polymers and basic inorganics sectors respectively (Figure 3.22). On the other hand, the consumer chemicals sector consists of 2 companies and the petrochemicals is only 1 among respondent companies. The remaining 5 companies are from the basic and other organics, peroxides and pharmaceuticals. Specialty chemicals are described as companies engaged in paints and rosin derivatives while the polymers companies are on plastics, and resins and dispersions. Basic inorganics companies are described as those coming from industrial gases, fertilizers and other inorganics. The pharmaceuticals industry is included in the chemical industry in Portugal.

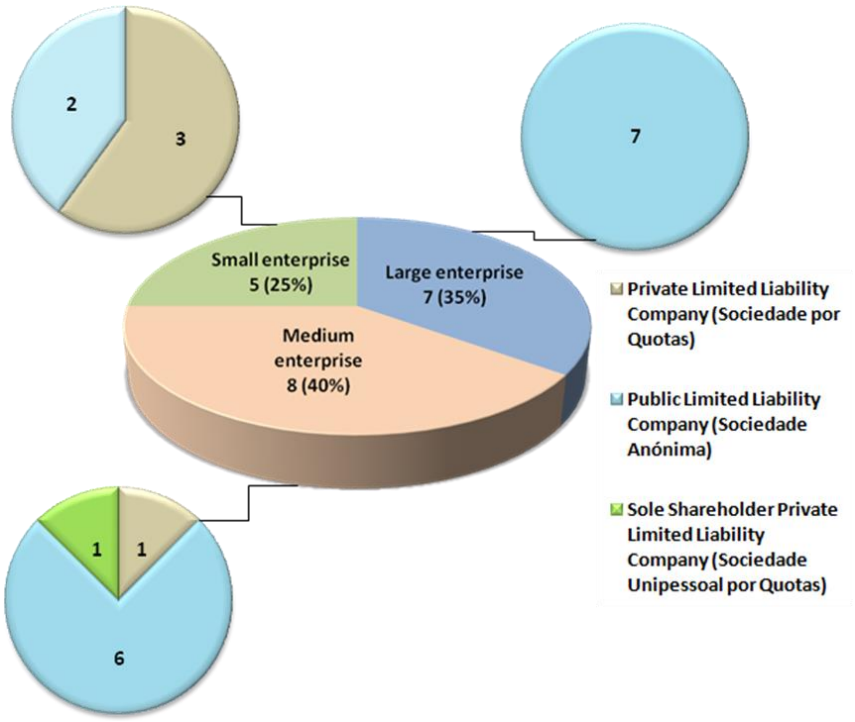


Figure 3.21 Portugal: Classification of respondent companies based on scale and ownership.

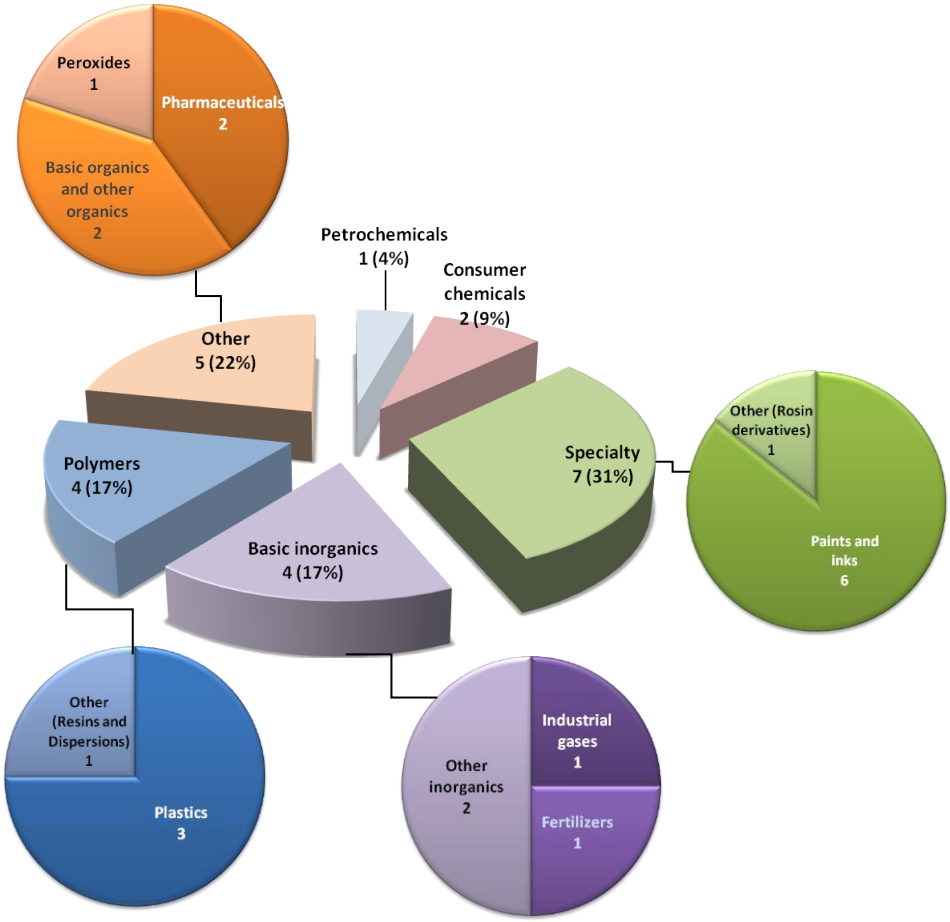


Figure 3.22 Portugal: Classification of respondent companies according to sectors.

From the respondents, 15 of the chemical companies are companies whose marketing operation is mainly worldwide, while companies whose market reach are only within the European Union and Portugal comprised 10% and 15% respectively as illustrated in Figure 3.23. This data agrees with the fact that the chemical industry in Portugal brings about 5.4 percent of industrial revenue [20], creating significant impact in the Portuguese economy and generating 5.2 percent of the total exports [23].

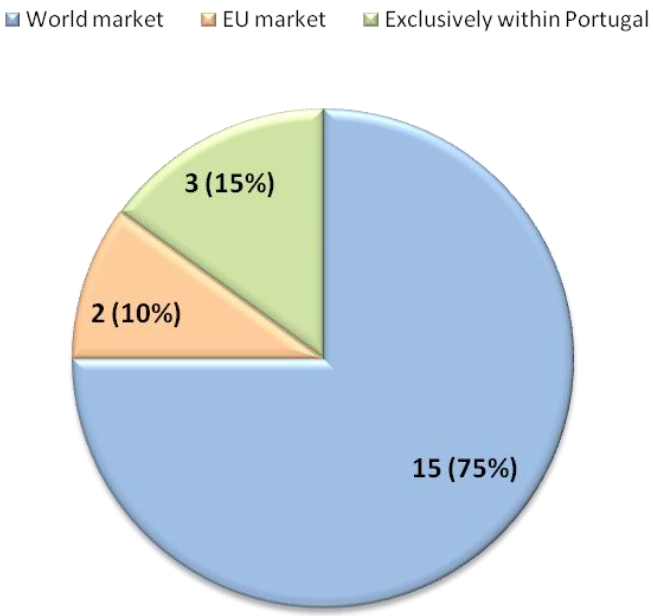


Figure 3.23 Portugal: Marketing operation of respondents.

Type 2: Company's role in the REACH regulation (type and quantity of substances applied for registration, authorization, and restriction).

The results revealed that most respondents classified their companies as downstream users comprising 17 companies of the total respondents. This is followed by 12 respondents classifying their companies as manufacturers and 10 of the respondents classified their companies as importers or/and only representatives of a non-community manufactures (EEA-based "Only Representatives) as illustrated in Figure 3.24. Further, the percentages shown in Figure 3.24 explained that some

respondents filled more than one option on this question in the survey. The company's role as stated is in accordance to the REACH regulation as defined in Articles 3 and 8 of Regulation (EC) no. 1907/2006. From the survey data, while the three company classifications have all differing quantities of chemical utilization as illustrated in Figure 3.24, it can be observed that substances/intermediates have the highest total usage, production and importation followed by mixtures and lastly articles. Survey data also reveals that utilization of the different chemicals imply that the company respondents are either using, manufacturing or importing substances/intermediates, mixtures and articles together.

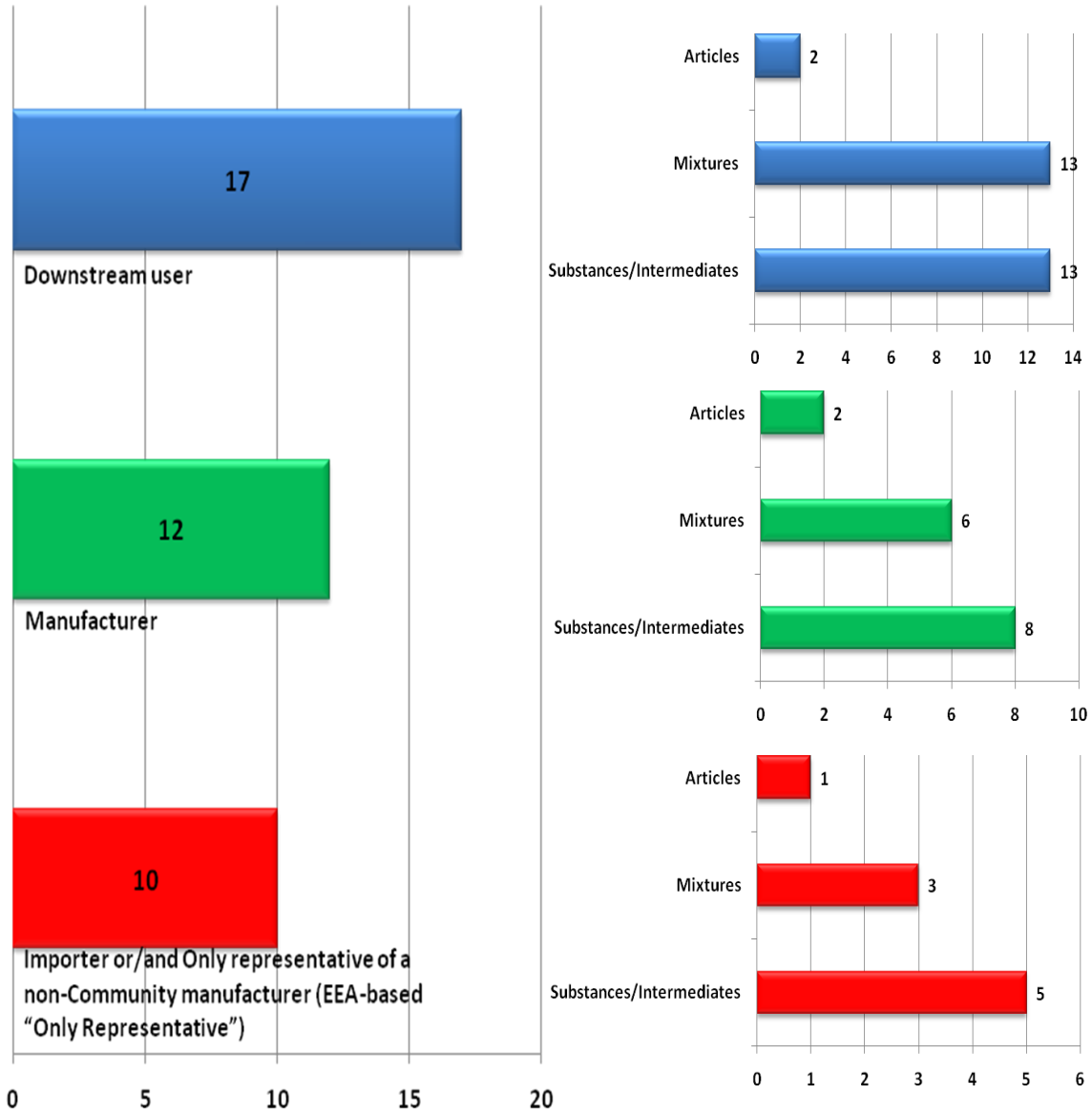


Figure 3.24 Portugal: Respondent companies role under the REACH regulation.

Most of the respondents have already registered their chemicals with ECHA as shown in Figure 3.25, wherein 13 have fulfilled the registration of all their substances with ECHA, and 5 responded as well that some of their substances are registered although they still have some substances that need to be registered. The estimated average cost of registration of the substances registered ranges from 60,000 € to more than 100,000 € and more than 250,000 € depending on the numbers of substances. The survey data also showed that only 1 of the company respondents still has substances that are yet to be registered. From Figure 3.25, companies have varying numbers of unregistered substances and have no knowledge on the estimated average cost of the substances to be registered. One (5%) of the respondents did not reply to this question.

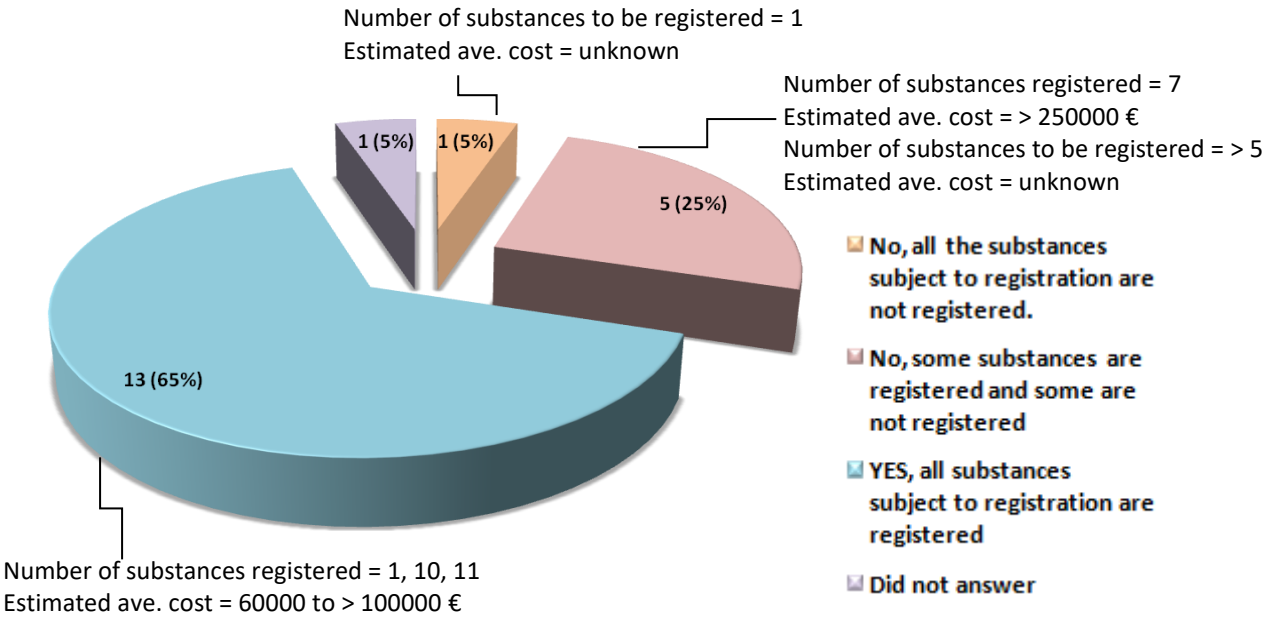


Figure 3.25 Portugal: REACH registration of substances with corresponding number of substances registered and estimated average cost.

Half of the respondents are either engaged in the manufacture, import or use of substances of very high concern (SVHC) as shown in Figure 3.26. Substances that may have serious and often irreversible effects on human health and the environment can be identified as SVHCs [45]. If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorisation List

[45]. This means that SVHC need an Authorization for specific uses, which is granted by ECHA. Three of the respondents engaged with SVHC have already applied and granted authorization by ECHA. Only one of the respondents still has not applied for authorization of their substance but is planning to apply. However, five of the companies handling SVHC will not apply for authorization, citing cost as the reason for the non-application. According to these companies, their best option in lieu of their application for authorization is to replace the SVHC as their Research and Development is working on finding an appropriate substitution. The aim of Authorization is to ensure that the risks from SVHC are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable [46].

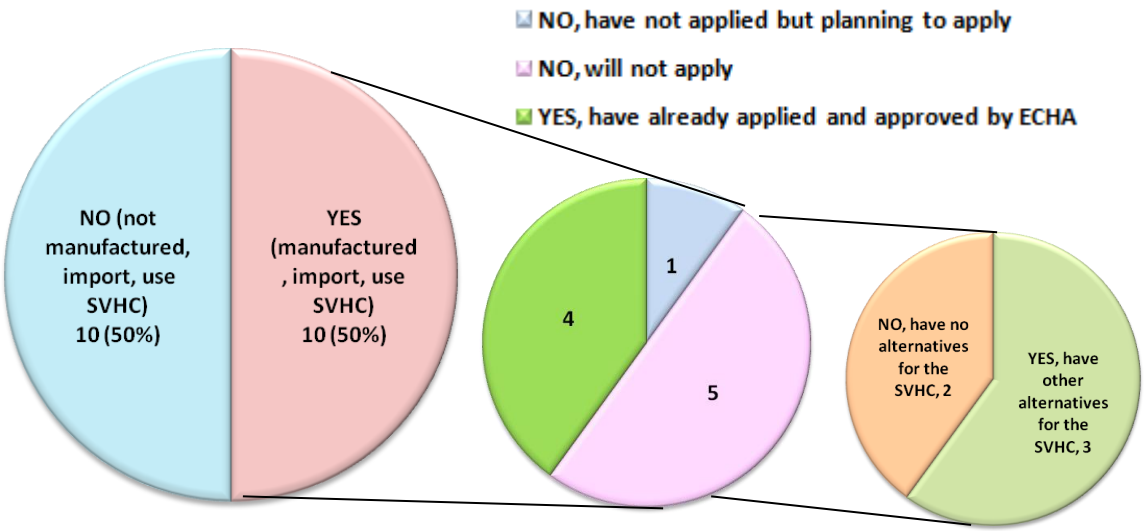


Figure 3.26 Portugal: Respondents engaged in the manufacture, import and/or use of SVHC.

Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals [47]. Restrictions may limit or ban the manufacture, placing on the market or use of a substance [47]. Based on the survey results nine of the respondents are either engaged in the manufacture, import or use of certain dangerous substances as listed in Annex XVII of Regulation (EC) no. 1907/20016 or substances restricted under REACH as illustrated in Figure 3.27. The best practice carried out by these companies is that their substances under

restrictions are registered with ECHA. One company did not respond to this question.

Due to the registration obligation under REACH and its related costs, two of the respondents have considered cancelling either the manufacture or import of certain substances (Figure 3.28). Seven of the respondents have not decided to cancel, limit or not to cancel. The remaining eight respondents have not considered limiting or cancelling the manufacture/import/use of certain substances or reducing the volumes of the substances.

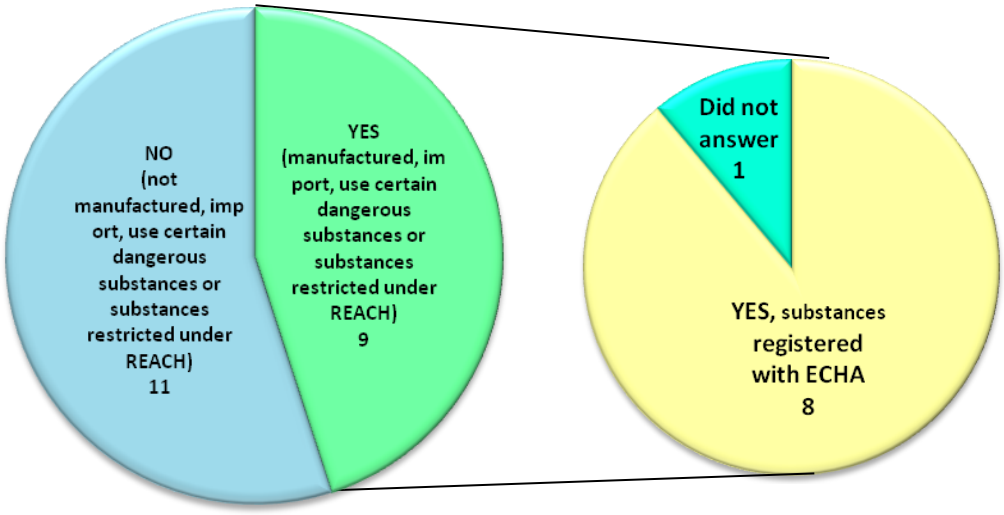


Figure 3.27 Portugal: Respondents engaged in the manufacture, import and/or use of restricted substances under REACH.

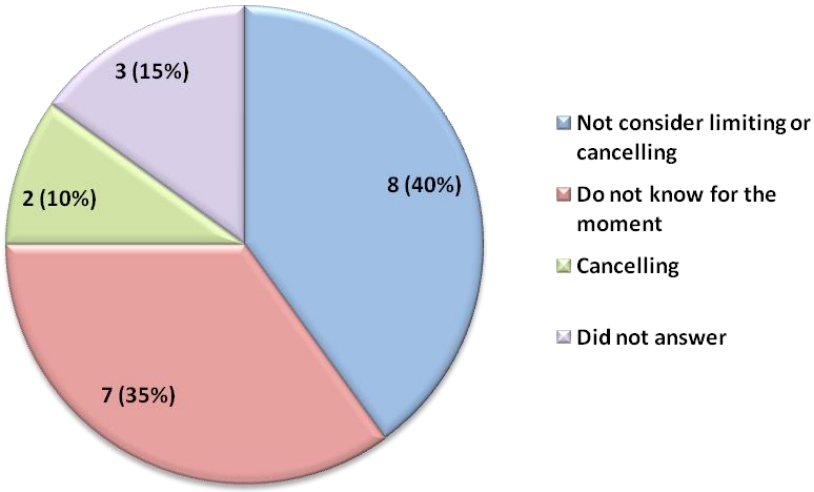


Figure 3.28 Portugal: Respondents' course of action on certain substances due to registration obligation under REACH and its related course.

Type 3: Methods applied by companies in the registration of substances (including preparation of dossier, complying with additional requirements, attendance to seminars).

In terms of methods applied in the registration of substances, almost two thirds (5 out of 8) respondents have carried out or will carry out the joint process in the REACH registration while the remaining three have individually registered their substances. Table 3.1 details the basis for the choice of method by the companies. Cost related and efficiency is the common reason for the companies who jointly carried out the registration process. For industry, duplication of work is minimized and unnecessary animal testing is avoided resulting in less regulatory costs [48]. A company respondent who previously applied individually for the registration has shifted to joint submission since the Substance Information Exchange Forum (SIEF) was established. According to Article 29 of Regulation (EC) 1907/2006 "All potential registrants, downstream users and third parties who have submitted information to the Agency in accordance with Article 28, or whose information is held by the Agency in accordance with Article 15, for the same phase-in substance, or registrants who have submitted a registration for that phase-in substance before the deadline set out in Article 23(3), shall be participants in a substance information exchange forum (SIEF)". Further, the Commission Implementing Regulation on joint submission of data and data-sharing entered into force last 26 January 2016 [49]. This regulation clarified that ECHA needs to ensure that the "one substance, one registration" (OSOR) principle is applied, whereby registrants of the same substance have to register the substance jointly [49]. To effectively implement the OSOR principle and better assist registrants to find the existing joint submission, lead registrant and co-registrants for their substances, ECHA updated the joint submission module in version 3 of REACH-IT [49]. With this system, it is no longer possible to submit an individual registration for a substance where a joint submission exists [49].

Table 3.1 Portugal: Reasons for the choice of method for the REACH registration process.

Jointly (with other companies) 63% respondents out of 8	***Individually (by your own company) 37% respondents out of 8***
It's mandatory to register in a joint submission since the publication of the EU regulation No. 2016/9 - Article 3: One Substance One Registration.	We don't choose the method for the registration process.
Process integration, costs, limited internal resources.	Both apply, jointly when there is already a SIEF.
Less costs.	Decision made by the company's headquarters
Cost, simplicity / ease.	-
Cost sharing	-

Sources of information on REACH regulation are essential factors for companies to have an effective compliance to the regulation. The company respondents (Figure 3.29) received most information from ECHA (18); business associations such as APEQ, APT, CEFIC, APQ, SRM, EPDLA, FIOVDE, AISE, CEPE and Fertilizers Europe (15); legislation (13); and from the internet (13). Also they obtained the REACH information from professional trainings, seminars and courses (12), national authority such as APA, IAPMEI, Helpdesk, and DGS (8), external company like consultants (7); parent company or head office (6); and media (1). As pointed out in the introduction and methodology chapters of this research project; ECHA is the regulatory authority responsible in the administrative, technical and scientific functions of the REACH regulation. Further, ECHA has an efficient updated information system in their website in the 4 key elements in the REACH regulation (registration, evaluation, authorization and restriction) including reports, advisories, guidelines, chemicals information and data, appeals, and others. Not only on REACH regulation but also other regulations managed by ECHA such as CLP, Biocidal and PIC as well as on nanomaterials. ECHA has also conducted free webinars and registering to the ECHA website, one can receive updates and news from ECHA. Aside from ECHA, the business organizations made an impact to the effectiveness of the REACH regulation implementation. Affiliation to different chemical industry organizations

has proven to be of great assistance to the companies in complying with the regulations.

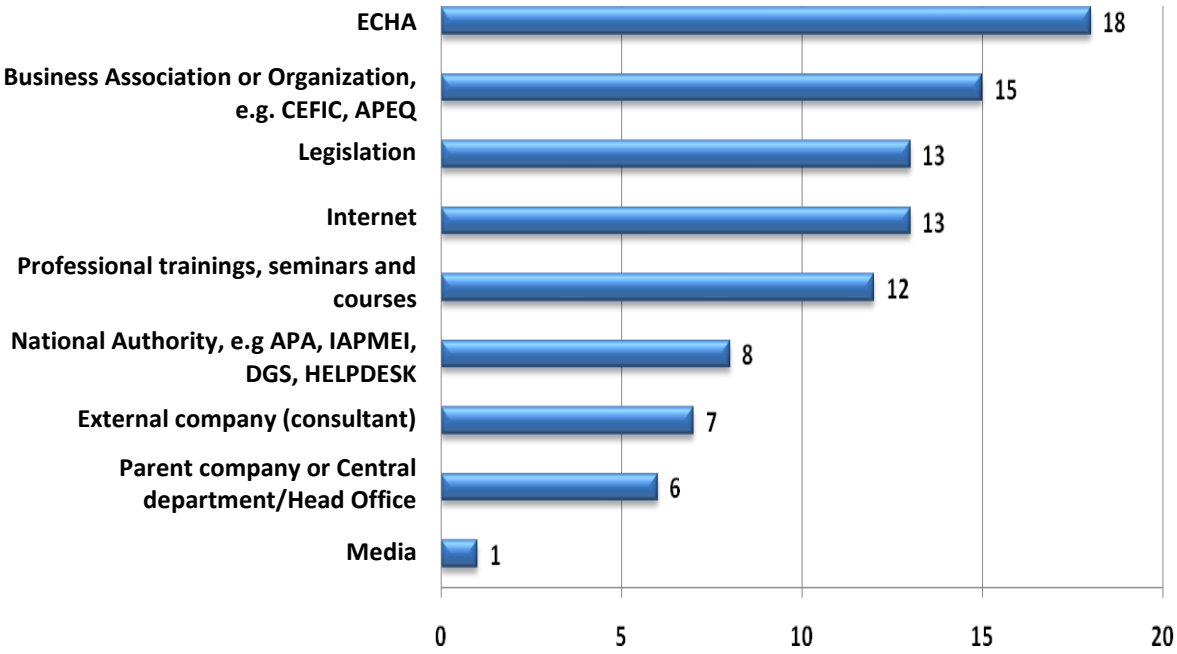


Figure 3.29 Portugal: Respondents' sources of information on REACH regulation.

Professional trainings, seminars and courses including meetings with chemical industry organizations facilitated in the effectiveness in complying the REACH regulation. In 2016, sixteen of the respondents have attended these professional sessions. Most of the companies in Figure 3.30, who attended 5 to more than 10 discussions in 2016, are medium-scale (1) and large-scale (3) entities. Four respondents who have not attended a single professional session on REACH related matters are two small-scale and two medium-scale companies. The main reasons cited by the respondents are the costs associated with attendance and lack of time as well as indicating that the responsibility is on the supplier and lack of information from the organizers. There are also small-scale company respondents who were able to participate in 2 to 4 meetings, seminars or trainings in 2016.

All of the respondents have employees responsible for addressing REACH-related issues in their company. This is one approach for effectively complying with the REACH regulation. The matters related to REACH regulation can be directly

addressed and responded by a designated employee. Eight of the company respondents have two employees in their respective company in-charged of REACH regulation (Figure 3.31), which comes from large-scale (3) and small-scale enterprises (3) respectively and medium-scale enterprise (2). For 4 to more than 5 employees in-charged in the each company's REACH-related matters are from the large-scale (3) and medium-scale entities (1).

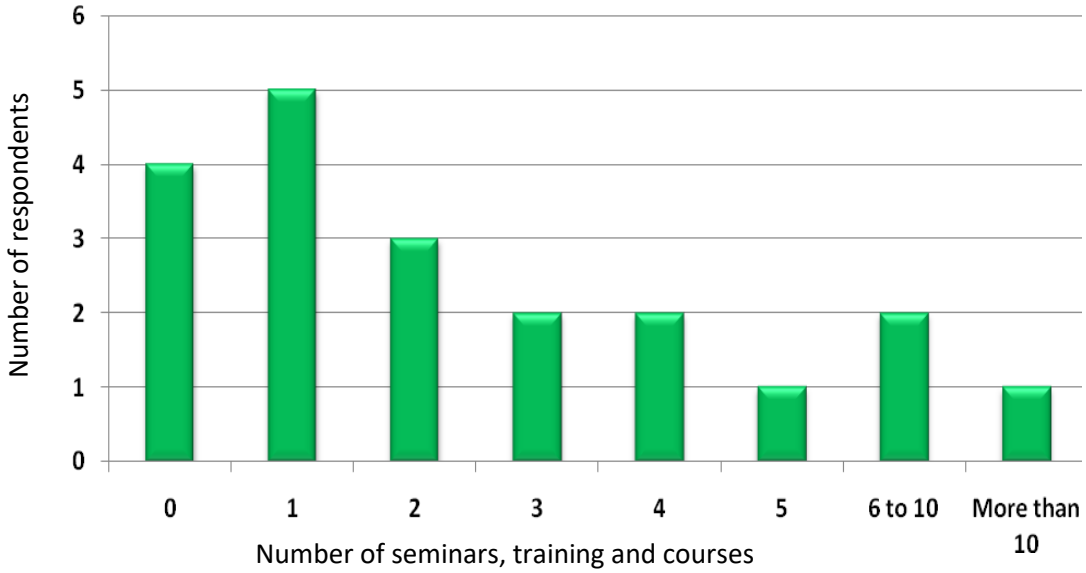


Figure 3.30 Portugal: Respondents approximate number of seminars, trainings and courses (including meetings with chemical industry organizations) attended in 2016 related to chemical legislations.

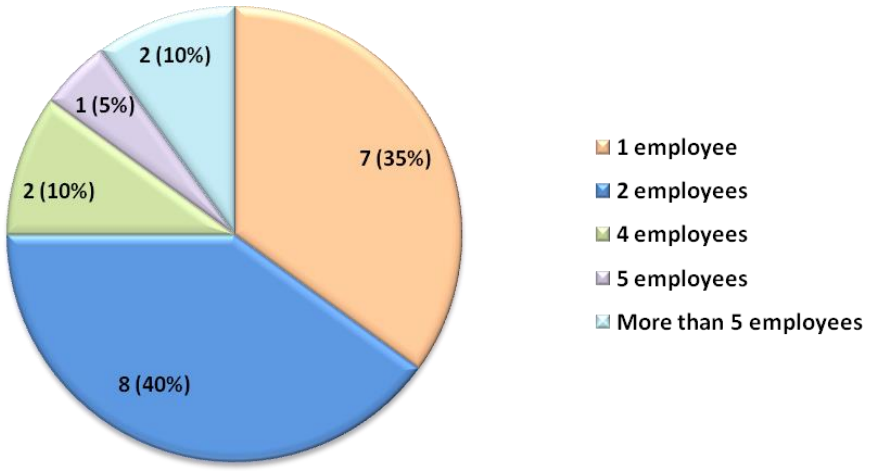


Figure 3.31 Portugal: Number of employees in-charge in addressing REACH-related issues.

Type 4: Challenges, issues and problems encountered by companies in the registration process (including strategies used in order to cope up and address the issues and problems).

Seven out of the 20 respondents report challenges, issues and problems encountered by their companies in the REACH registration process, 12 companies did not answer on this matter, and the remaining one responded that the issues are handled by the company's headquarters. Most of the companies (9) who did not reply on the issues and challenges query are companies who did not answer also the individual or joint submission query. The five of the seven respondents as illustrated in Figure 3.32 have issues on communication with all potential registrants, downstream users and third parties who participated in the substance information exchange forum (SIEF)/communication with previous registrant to reach an agreement on the sharing of existing data in the case of registered substances. The best approaches taken into action by the respondents are defining a company task force for the REACH-related matter and attending the consortium meetings. The formation of a task force supports the need for a company to have employees responsible for compliance with the REACH regulation, wherein issues and concerns can be directly and timely responded by assigned employees to avoid noncompliance and delays. Attendance to regulatory meetings such as the consortium meetings is significantly important strategy in the application of the OSOR principle, wherein companies are updated on the status of their joint submission of data and data-sharing to come up with an excellent and fair agreement between the companies involved. The second and fourth issues raised by the respondents are the complexity of the REACH IT tools (4) and communication with ECHA (1). They were able to address these issues with ECHA support. Free webinars, reports, guidelines, support tools and other information can be found in the ECHA website. The third issue is the cost for tests of the substances. Respondents (3) were able to address this concern by defining a budget for the process and joining consortia (another indication of joint submission efficiency and effectiveness). Other issue was from a downstream user wherein there was lack of

response from suppliers in terms of their uses of the substance and errors to be corrected on the SDS. This issue has led the company to change the criteria for choice suppliers to consider the quality of documentation over technical and price considerations.

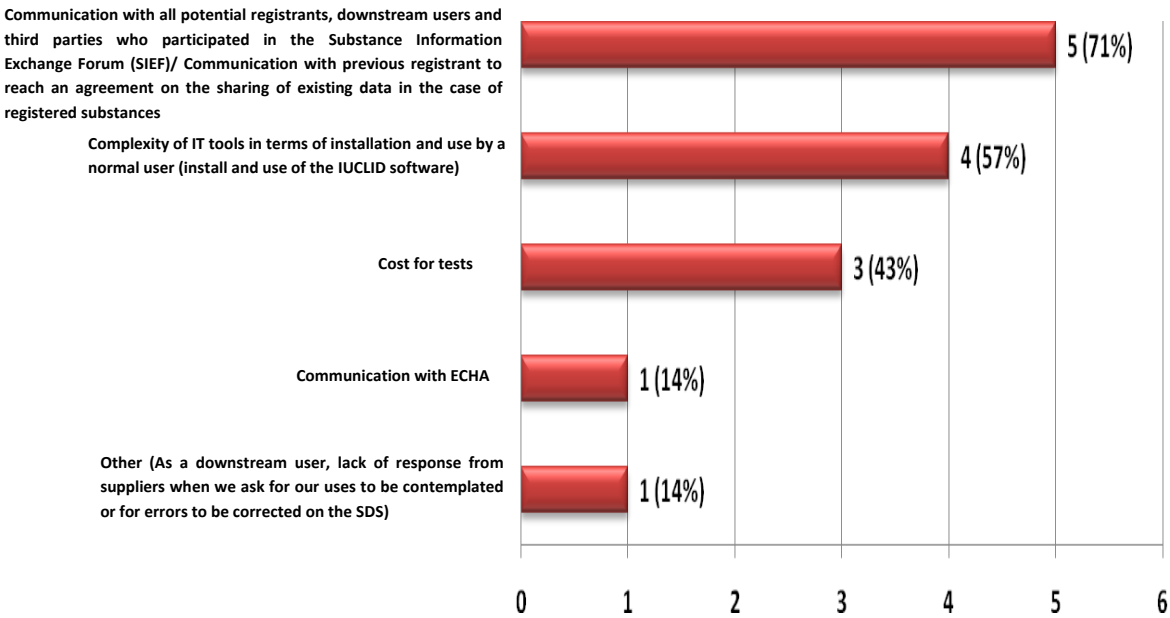


Figure 3.32 Portugal: Challenges, issues and problems met by respondent companies during the REACH registration process.

From the 20 companies, only five have reported issues and concerns during the dossier and substance evaluations while 14 entities did not answer on this part of the survey and one company responded that the issues are managed by the company's headquarter office. From those five companies (Figure 3.33), four have also reported issues in the registration process while one has not (Figure 3.32). The common problem encountered by all respondents during the dossier and substance evaluations is the updating of IT tools and errors, complexity of IT tools in terms of installation and use by a normal user (install and use of the IUCLID software). According to the companies, ECHA is providing a good support despite the complexity of REACH and IT tools. While discussing the type 5 issue, ECHA was shown to have an efficient data system. Other concerns such as the cost for tests of the substances (2), and communication with all potential registrants, downstream users and third parties who participated in the SIEF (2) have been appropriately

addressed by the companies through joining the consortium. This provides an additional indication that the SIEF and OSOR principle is working effectively. This also demonstrates that most companies are able to address the issues and concerns on REACH regulation efficiently.

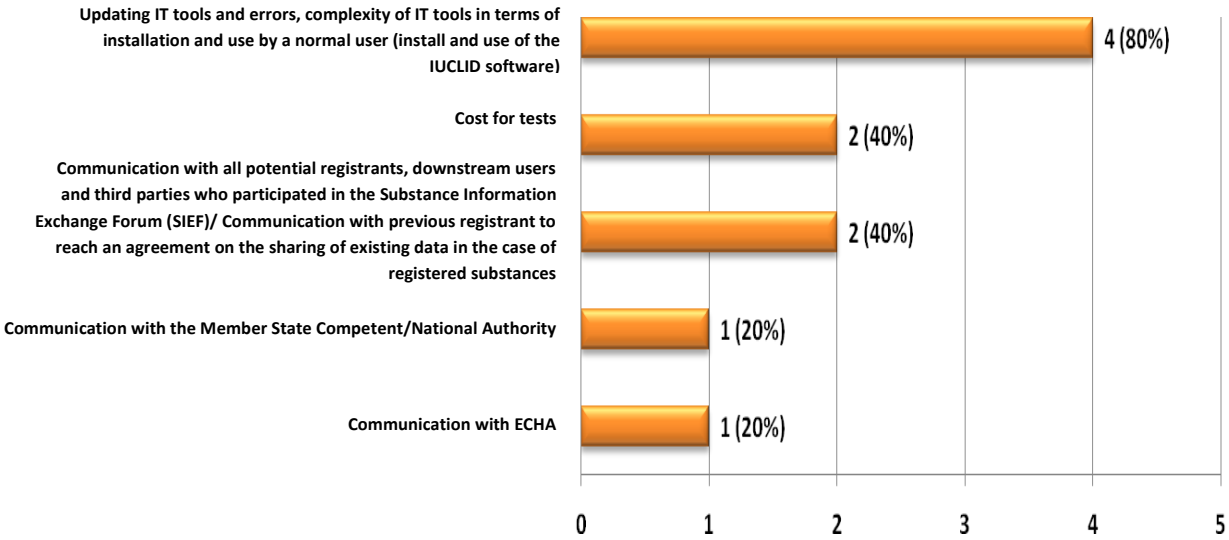


Figure 3.33 Portugal: Challenges, issues and problems met by respondent companies during the Dossier and Substance Evaluations.

3.2.2 Classification and Labeling

As mentioned in the introduction and methodology chapters, Classification, Labelling and Packaging (CLP) of substances and mixtures regulation supplements the REACH Regulation. Since 2009, CLP has been ensuring that the hazards presented by chemicals are clearly communicated to workers and consumers through the classification and labelling of chemicals [50]. Figure 3.34 exemplifies the downstream user respondents' concerns on the availability or accessibility of the safety data sheets (SDS) by their suppliers. Ten of the downstream user respondents have received SDS for all the substances from their suppliers while five respondents have either received or not for some substances. The remaining two downstream users have experienced not receiving SDS for all substances. The six out of the seven downstream users who did not receive SDS have warned their suppliers to provide the correct SDS version or else there will be no order on the next procurement. This

is one best approach by the companies as downstream users in order to comply with the REACH regulation.

The majority of the companies who received the SDS for all the substances have been directly provided with the SDS in Portuguese by their suppliers. According to the other downstream users, the supplier either only provides the SDS in Portuguese as per request or provides the SDS in a foreign language and they translate/create the Portuguese version or provides the SDS in English or Spanish - even if their company requested for the Portuguese version. Further, some downstream users have difficulty in acquiring all the SDS in Portuguese language. One respondent stated that they experienced all the options provided in the survey questionnaire. When downstream users receive a safety data sheet, they need to identify and apply appropriate measures to adequately control the risks [51]. It is significantly important that the downstream users understand the information in the SDS. The majority of the downstream users (14) have fully understood the information of the safe use of chemicals in the SDS provided by the suppliers while only one has understood mostly all the information in the SDS (Figure 3.35). It was admitted by two respondents that they understood a little (not mostly) of the information on the SDS provided by the suppliers. The downstream users must check that they cover their own use of the substance and their conditions of use or take alternative action when they receive exposure scenarios [51]. The role of downstream users of chemicals is important – by demanding better quality, user-friendly safety data from their suppliers, they can improve the safe use of chemicals [50]. In accordance to REACH Article 37 (2), any downstream user shall have the right to make known the use, at least the brief general description of use, in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own.

Another issue that needs to be addressed for the downstream user is the inclusion in the registration documentation of the substance used by them, which has been cited by a company respondent in Figure 3.32. Seven of the 17 downstream user respondents have discussed with the supplier on the usage and inclusion of the

substance in the registration while six respondents do not need to discuss with the suppliers since the usage of the substances are already included in the SDS. The remaining three companies have not discussed with their suppliers, no inclusion of their chemical usage in the SDS or CSR, and evaluating the SDS received by the company. One downstream user did not reply to the question. These numbers are illustrated in Figure 3.36.

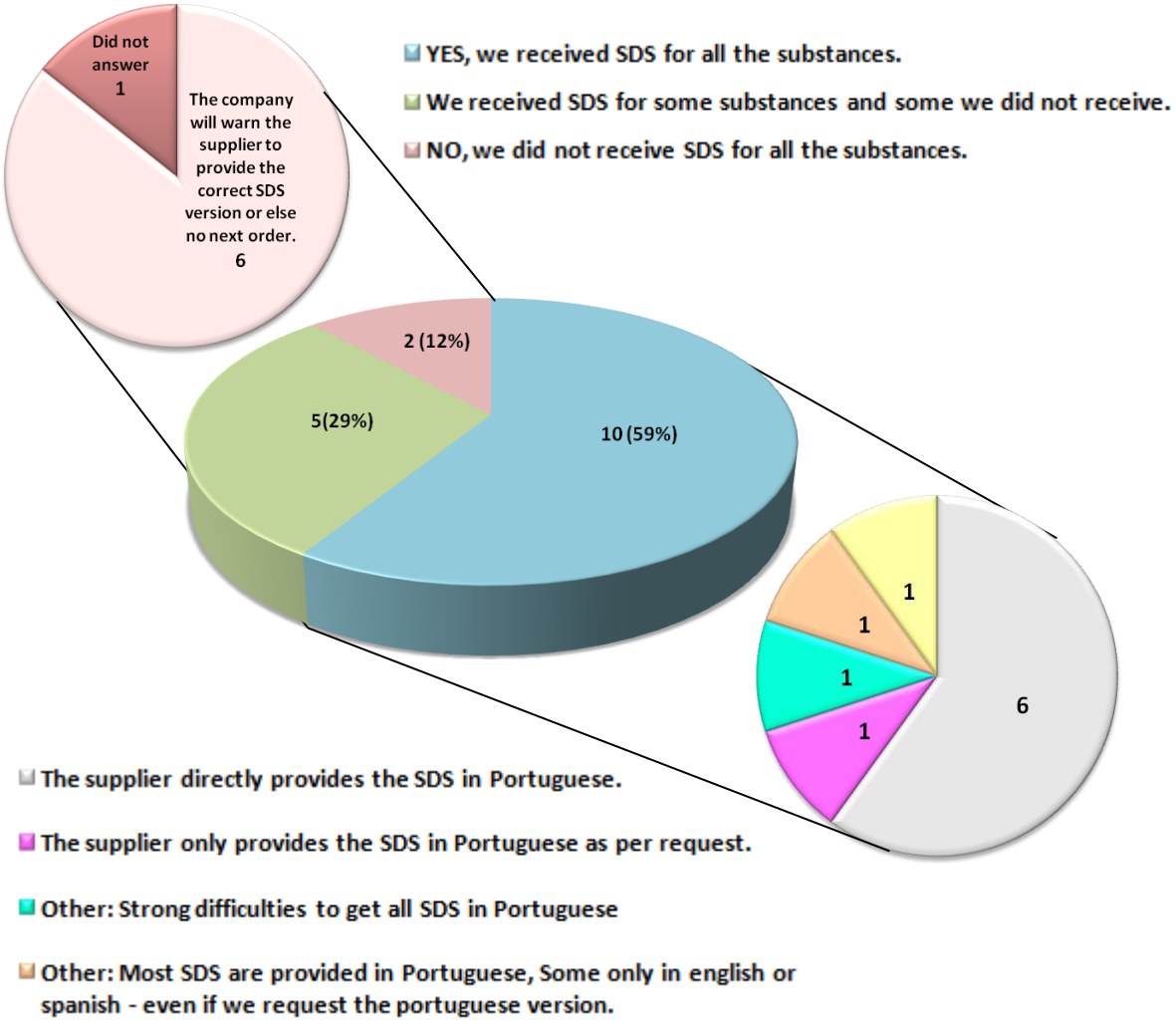


Figure 3.34 Portugal: Downstream user respondents method of acquisition the SDS from their suppliers.

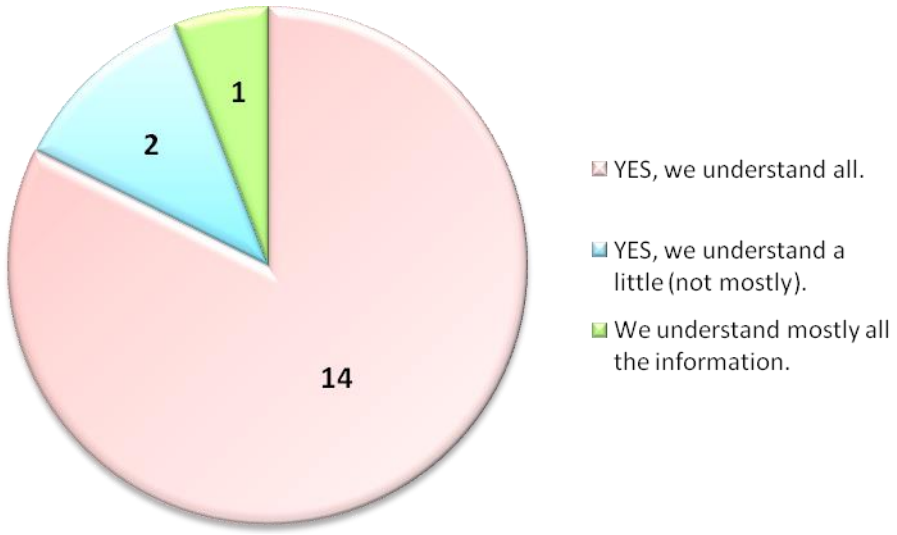


Figure 3.35 Portugal: Downstream user respondents' in understanding the SDS provided by their suppliers.

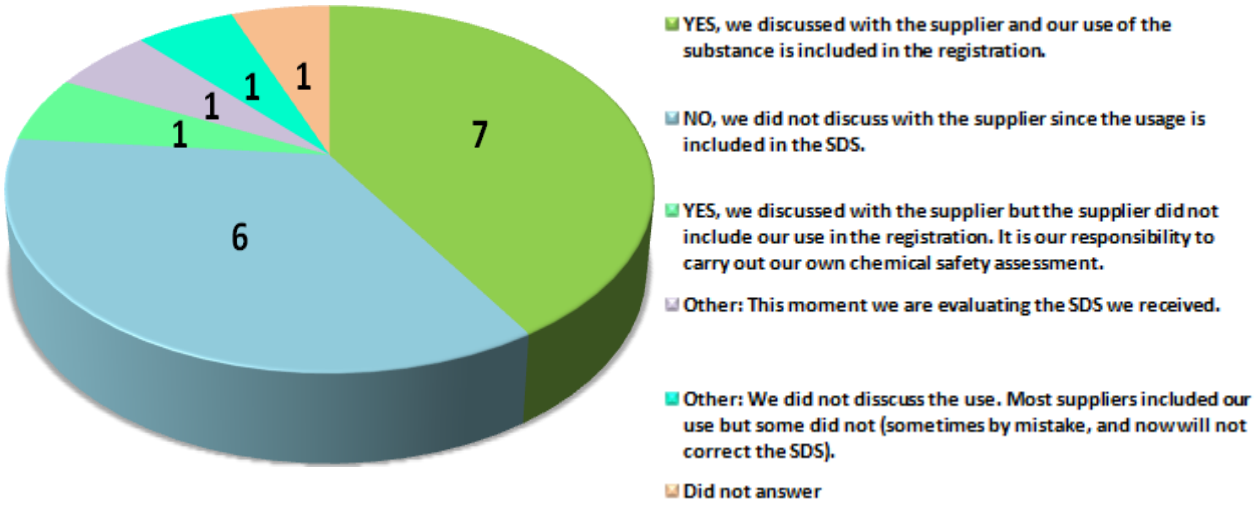


Figure 3.36 Portugal: Downstream user respondents' involvement in the inclusion of their substances in the SDS and Chemical Safety Report (CSR).

The correct version of the SDS of the substance handled by the importers is prepared either by the importers themselves or by the supplier outside EU. Six out of ten importer respondents replied that the SDS is being prepared by themselves and the other four respondents by their suppliers outside EU (Figure 3.37). Non-EU companies continue to have access to the EU market, either through their EU-based importers or by the only representatives that they have nominated [48]. By fulfilling

their registration obligations, companies demonstrate they are responsible and continue to have access to the market [48].

Figure 3.37 Portugal: Importer respondents' method of preparing the correct version of SDS.

Any manufacturer placing on the market a substance on its own or in a mixture or a mixture is a supplier as defined in Article 3 (32) of REACH. As supplier of a substance, it is the obligation of the manufacturers to provide a correct SDS to the downstream users. In the survey, 11 of the manufacturer respondents have provided SDS to the downstream users as shown in Figure 3.38. One of the manufacturers did not answer the question. Five have discussed the use of the substance with the customers, and five have discussed the use of the substance in some cases only. There is only one manufacturer who did not discuss the use of the substance with the customers since the company produces antibiotic which is not framed with the REACH regulation. Once more, one company did not respond to the query. Furthermore, six of the manufacturers have provided ESDS to the downstream users and only one provided ESDS for some substances they produced. The remaining four manufacturers do not provide ESDS to customers since they produced antibiotic, articles and intermediates. One manufacturer again did not reply to the question. The manufacturer respondents who did not respond to the questions come from different companies. An ESDS, with exposure scenarios attached, has to be supplied if a hazardous substance is registered in a quantity above 10 tonnes per year per

registrant [52]. Antibiotics are not framed by the REACH regulation. It is not generally desirable to compile SDSs for articles [53]. Overall the provisions concerning manufacturers, importers and only representatives registering on behalf of non-EU companies are functioning well, and companies are successfully submitting their registration dossiers in line with the anticipated schedule [48].

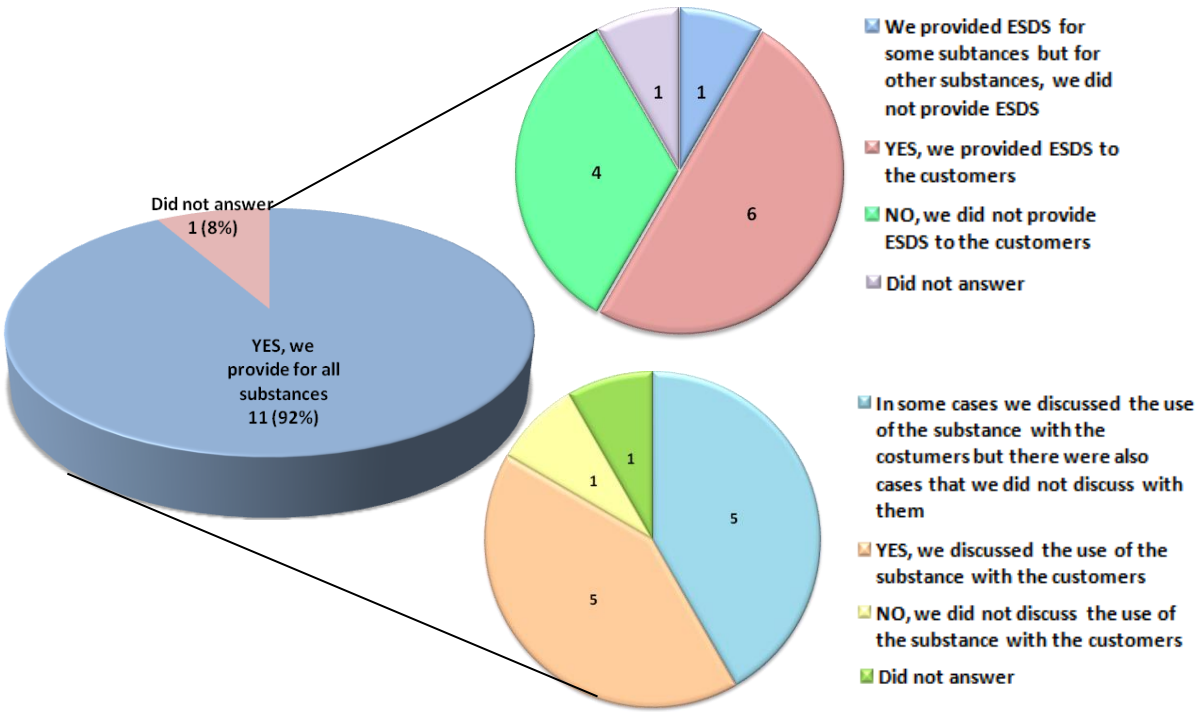


Figure 3.38 Portugal: Manufacturer respondents' method of providing the correct version of SDS and ESDS to downstream users.

3.2.3 Overall Remarks

Information and Communication

In terms of information and communication significance in complying the REACH regulation, eighteen of the 20 respondents have identified that internet access and research on ECHA website as the most important as illustrated in Figure 3.39. This is followed by:

- reading of materials such as REACH regulations, methods, articles, etc. (17); consultation with business associations/organizations (16);

- creation of a company's technical working group in the compliance and implementation of the REACH regulations and other chemical regulations (14);

- understanding the ECHA guidelines and constant inquiry on the guidelines updates (13);

- communication with the Member State Competent/National Authority (11); cost sharing for tests (11);

- budget for the costs involved in the REACH process (11); and

- communication and participation in the Substance Information Exchange Forum (SIEF)/sharing of data involving tests (10).

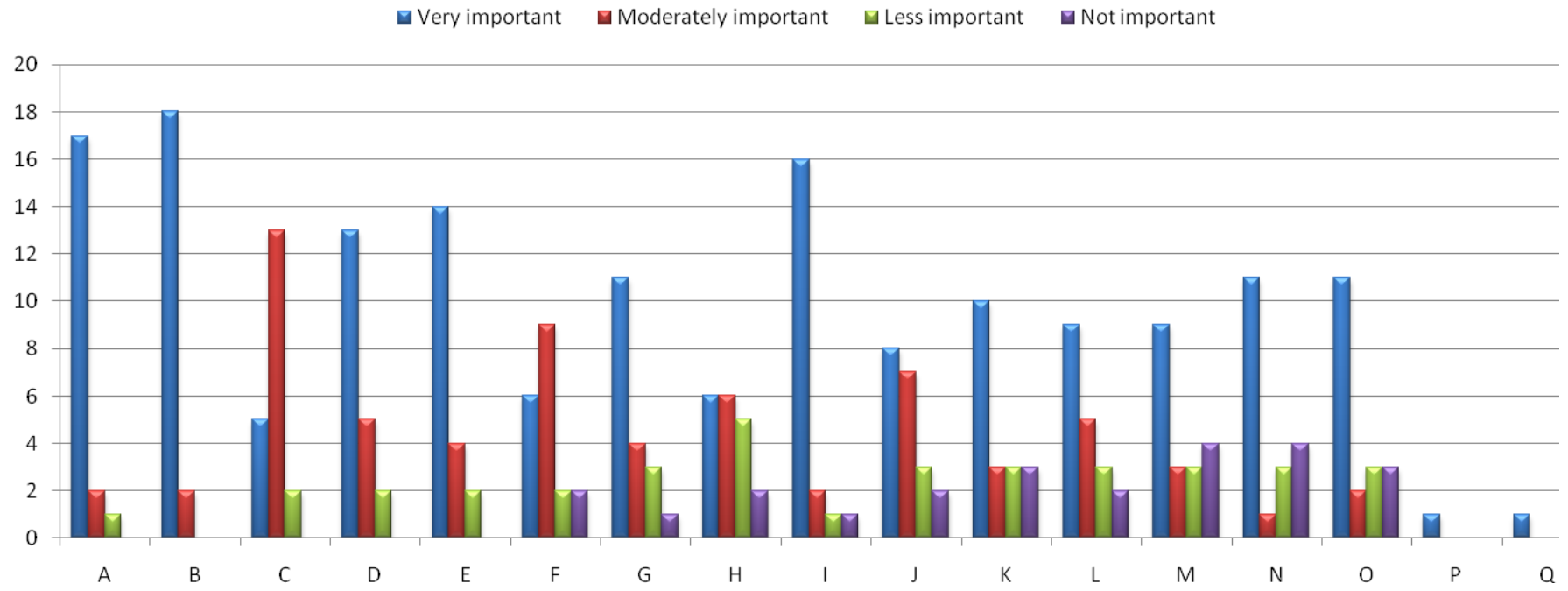
More than half of the respondents (13) implied that constant attendance to seminars and training courses related with REACH regulations and other chemical legislation is moderately important in the information and communication approach in complying the REACH regulation. The respondents also take into account as moderately important are constant communication with ECHA from pre-registration to registration to evaluation to appeal to approval to updating (9), consult or confer with other industries (7), and seek advice from consultants (6).

The means of the different information and communication approaches in complying with the REACH regulation is shown in Figure 3.40. The top six schemes as shown in Figure 3.39 is consistent with the results in Figure 3.40, wherein the respondents in Portugal see the key importance on research and related literatures, networking and linkages, constant attendance to seminars and trainings, and creation of a technical working group to comply with the REACH regulation. Overall,

the respondents consider all the information and communication schemes as essential elements in complying with the REACH regulation.

The survey result also revealed that respondents agree that ECHA has an efficient updating system. ECHA's website provides the necessary information on the REACH regulation. One of the best practices that can be cited was the case of one company in Portugal engaged in the production of cork granules, agglomerated cork composition and cork rubber products [54]. The company's main concern in complying with the REACH regulation was to verify that all the raw materials supplied to them did not contain SVHC [54]. The best tool that the cork company applied was using the information available at the ECHA website through searching the registration and available data of the raw materials [54]. Moreover, whenever there is a new raw material in the market that the company starts working with, they search for information on the substances at the ECHA website [54].

The Substance Information Exchange Forums (SIEF) help and facilitate REACH registrants in exchanging information on the substances that have been registered. According to ECHA's third report under Article 117(3) of REACH, most registrants share data wherein 98 % of the substances are registered jointly [55].



A	**Reading of materials (REACH regulations, methods, articles, etc.**	**J**	**Consult or confer with other industries**
B	**Internet access and research on ECHA website**	**K**	**Communication and participation in the Substance Information Exchange Forum (SIEF); sharing of data involving tests]**
C	**Constant attendance to seminars and training courses related with REACH regulations and other chemical legislation**	**L**	**Agreement with other registrants and downstream users in carrying out or performing the tests]**
D	**Understanding the ECHA guidelines and constant inquiry on the guidelines updates**	**M**	**Joint submission of data by multiple registrants**
E	**Create a company's technical working group in the compliance and implementation of the REACH regulations and other chemical regulations**	**N**	**Cost sharing for tests**
F	**Constant communication with ECHA (from pre-registration to registration to evaluation to appeal to approval to updating)**	**O**	**Budget for the costs involved in the REACH process**
G	**Communication with the Member State Competent/National Authority**	**P**	**Other (Consortiums)**
H	**Seek advice from consultants**	**Q**	**Others (The items of registration is not directly applicable but are important also)**
I	**Consult with business associations/organizations (e.g. APEQ)]**		

Figure 3.39 Portugal: Respondents perspective on the importance of the different information and communication schemes in complying with the REACH regulation.

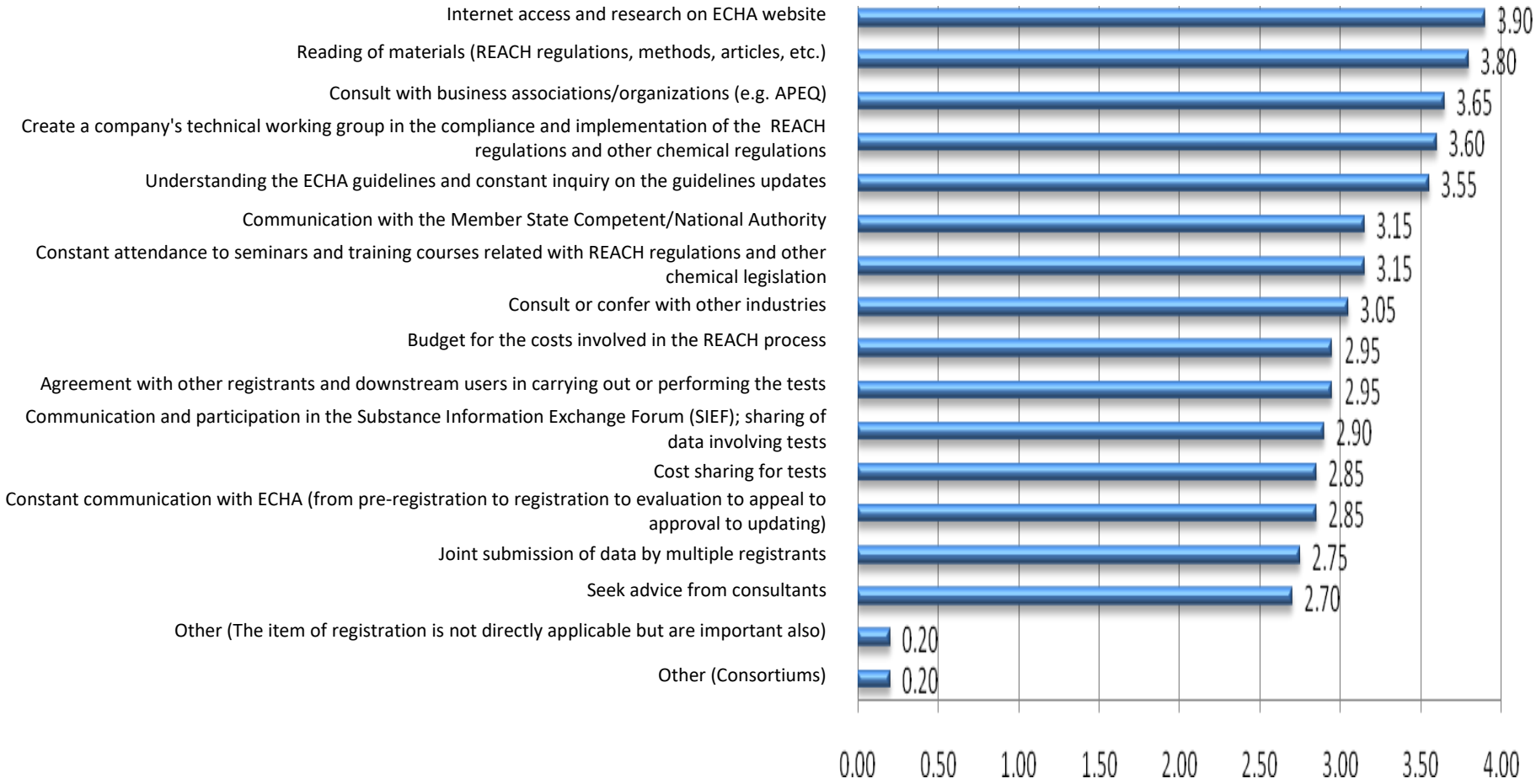


Figure 3.40 Portugal: Means of the different information and communication schemes in complying with the REACH regulation.

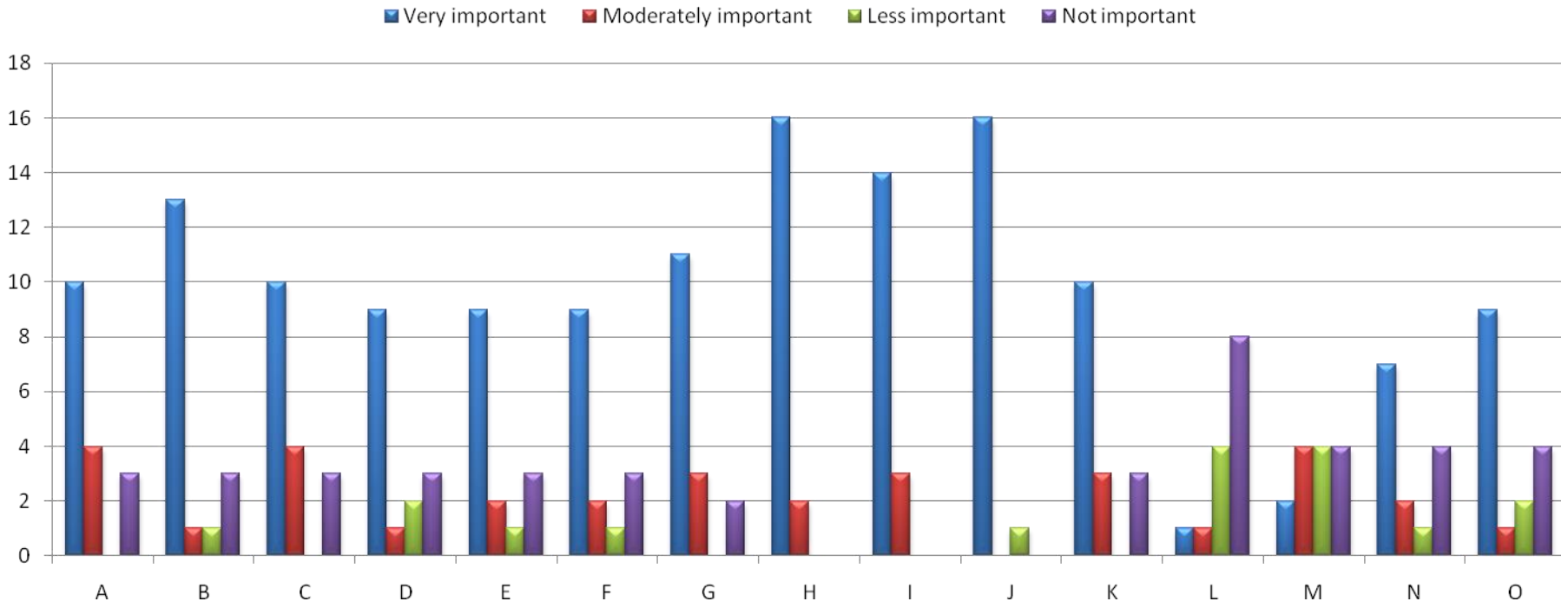
Technical Aspects

When it comes to the technical aspects in complying with the REACH regulation, the majority of the company respondents have recognized that all of the choices in the survey questionnaire are significantly important except for the conduct of in-vivo tests. Avoidance of animal testing or unnecessary testing is well defined in Article 25 of the REACH regulation, wherein testing of vertebrate animals shall be undertaken only as a last resort. ECHA has published in their website the version 2 “Practical guide on how to use alternatives to animal testing to fulfill your information requirements for REACH registration”. The manual is to advise company registrants on their obligations to avoid unnecessary testing on vertebrate animals and at the same time ensuring that the companies have sufficient information on the properties of the substances for classification and risk assessment [56]. Based on ECHA’s database of REACH registrations submitted by companies with over 6000 substances, the application of alternatives to animal testing has been widely used by the registrants [55].

The quality of the SDS provided by manufacturers, importers and suppliers (16), and access of workers to information of the chemicals that they use or may be exposed to in course of their work (16) are respectively the most important for the company respondents (Figure 3.41). Article 35 of the REACH regulation clearly stated the granting of access to information on the safety measures of chemicals for workers by their employers. Duty to communicate information down and up the supply chain (14), identification of the classification of the chemical to be placed/registered (13), and preparation of the updated Safety Data Sheet (SDS) in accordance with Commission Regulation (EU) No. 2015/830 (11) subsequently followed the most important in the technical sides in fulfilling the REACH regulation. The requirements for SDS and duty to communicate information down the supply chain for substances are well defined in Articles 31, 32, 33 and 34 of the REACH regulation.

Company respondents have also considered avoidance of unnecessary testing (10), preparation of checklist for the registration requirements (10), calculation of the quantity (tonnage) of a substance manufactured or imported or used per year (10). In addition, preparation of the technical dossier (9), preparation of the chemical safety report (9), conduct of chemical safety assessment (9), updating of the registration dossier via REACH-IT or IUCLID vital to the compliance of REACH regulation (9), and proficiency in the installation and use of the IUCLID software (7) are essentials in complying the regulation as affirmed by the respondents in the survey. Article 14 of the regulation defined the conduct of chemical safety assessment, preparation of chemical safety report and duty to apply and recommend risk reduction measures. It is also important that one must get familiar with how the registration information is structured and with the terminology used in the IUCLID application prior one start working with IUCLID [57]. The useful software documentation of IUCLID and REACH-IT are available on ECHA's website.

The means of the different technical strategies in complying with the REACH regulation is shown in Figure 3.42. The top five most important approaches and least important (conduct of in-vivo tests) for the respondents as shown in Figure 3.41 is in harmony with the results in Figure 3.42 Generally, the respondents consider the technical methods as necessary in complying with the REACH regulation.



A	**Prepare checklist for the registration requirements**
B	**Identification of the classification of the chemical to be placed/registered (article, mixture or substance/intermediate, phase-in or non-phase-in substances)**
C	**Calculate the quantity (tonnage) of a substance manufactured or imported or used per year**
D	**Preparation of the technical dossier**
E	**Preparation of the chemical safety report**
F	**Conduct chemical safety assessment**
G	**Preparation of the updated Safety Data Sheet (SDS) in accordance with Commission Regulation (EU) No. 2015/830**
H	**Quality of the SDS provided by manufacturers, importers and suppliers**
I	**Duty to communicate information down and up the supply chain**
J	**Access for workers to information of the chemicals that they use or may be exposed to in course of their work**
K	**Avoidance of unnecessary testing**
L	**Conduct of in-vivo tests**
M	**Conduct of in-vitro tests**
N	**Proficiency in the installation and use of the IUCLID software**
O	**Updating of the registration dossier via REACH-IT or IUCLID (either requested or spontaneous update)**

Figure 3.41 Portugal: Respondents perspective on the importance of the different schemes in terms of technical aspect in complying with the REACH regulation.

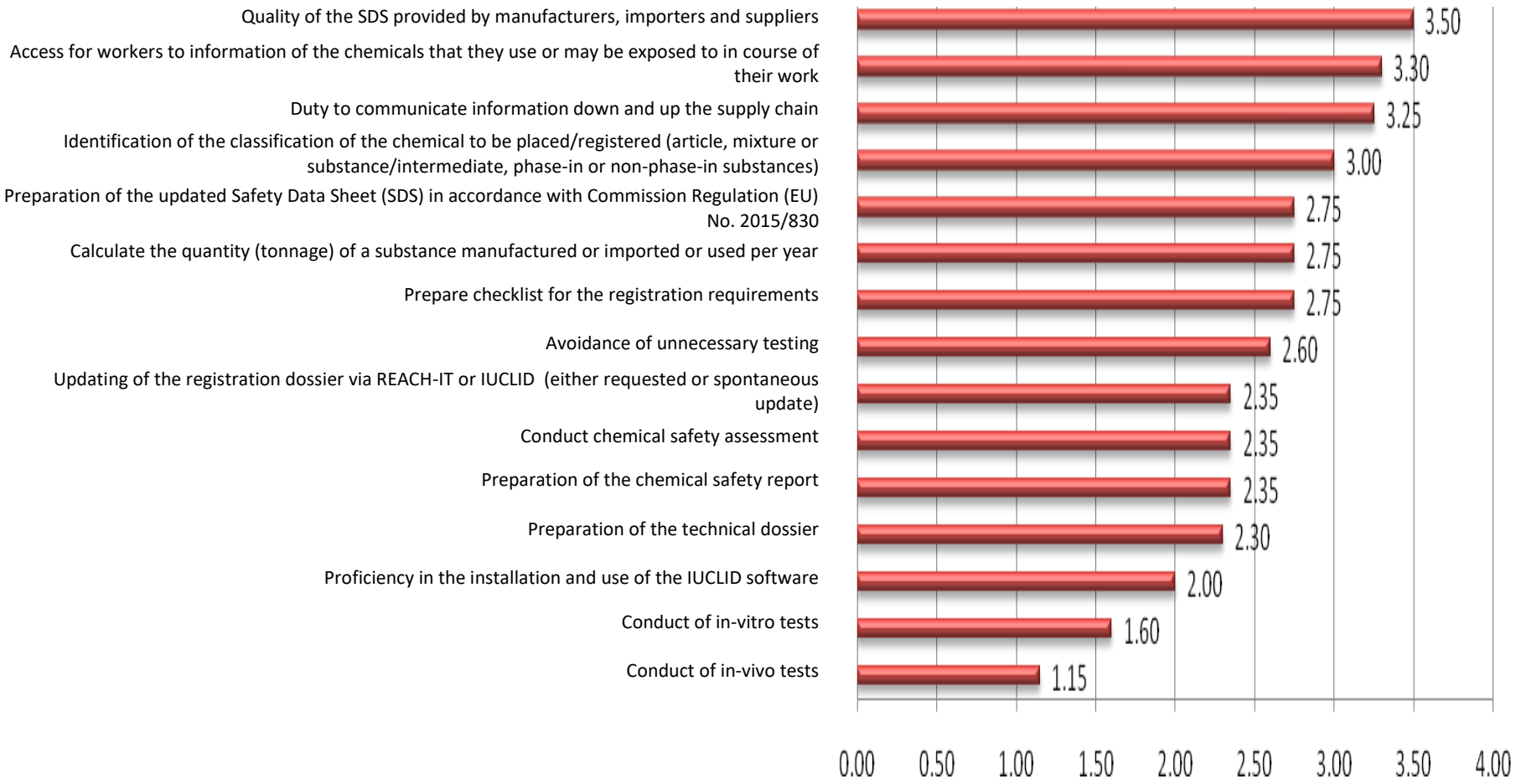


Figure 3.42 Portugal: Means of the different technical schemes in complying with the REACH regulation.

4. CONCLUSION AND RECOMMENDATIONS

This chapter presents the conclusions drawn from the study and the recommendation for the improvement of industry regulatory compliance practices. This study was intended to document the issues and concerns, mechanisms and best practices of the different chemical industries in Spain and Portugal in complying with the REACH Regulation.

CONCLUSION

Based on the survey results, respondents identified varying issues and concerns with regards to complying REACH regulations. Since the implementation of the Substance Information Exchange Forum (SIEF) requires EU-based companies from various countries to jointly carry the registration process, issues on communications with all potential registrants, downstream users and third parties participating in the substance information exchange forum can always occur. Another issue on communication is when previous registrants fail to reach an agreement on the sharing of existing data for registered substances. Another issue of importance is on the cost that will be incurred for testing of substances, especially when there is yet to be a defined budget for the test. Downstream users also find it a problem the lack of response from suppliers in the use of substances and the correction of errors in the SDS. Companies often find difficulties in dealing with the complexity of the REACH IT tools and communication with ECHA, particularly on the issue on the installation of IUCLID software, of updating IT tools and errors.

Dealing with the complexities of issues and concerns in complying with REACH regulation, companies found applicable strategies and mechanisms in order to comply with REACH regulations and requirements. Among the best practices by companies is to join in a consortium and the conduct of the joint registration and submission of dossiers. This practice not only enabled companies to complete their registration and dossier submission but was identified by them as the most efficient means of complying with REACH regulations.

The practice of a joint registration and submission has provided most companies in a consortium an efficient means of coping with the demands of the REACH regulations. It is also one way of managing the cost of registration in the most effective way through cost sharing. The joint mechanism of registration and submission also ensures the sharing of information among participating companies, providing vital information among the group. The ECHA, business associations, national authorities, consultants, parent companies and head offices as well as the media provide relevant sources of information that catalyze information gathering as well as other factors such as attendance to professional trainings, seminars and courses, legislations and the internet provide additional information materials essential for companies to effectively comply with the REACH regulation. Consequently, the process of joint undertakings by companies is a holistic approach, emphasizing unity of process and recognizing interactions between different chemical industries. The provision of an active and good support mechanism by the European Chemical Agency can also be considered as best practice as the compliance of chemical industries to the REACH regulation would definitely rely on the proactive support that ECHA is extending to the chemical industries.

In terms of supplying substantial information and provision of SDS from suppliers, to downstream users and clients, survey respondents from both Portugal and Spain were consensus in stating the importance of having a detailed and comprehensible SDS from the supplier. Respondents were also unanimous in indicating that provision of SDS should be mandatory as some suppliers only provide or feel the need to provide SDS on a per request basis, emphasizing that quality and user-friendly SDS from suppliers improved the safe use of chemicals in the supply chain.

Overall, the survey results from Spain and Portugal indicate that chemical industries from both countries experience the same issues and concerns although in varying degrees of difficulty. Results also revealed that industries from both countries applied similar strategies in dealing with the challenges as well as in

complying with REACH regulations. There are differing elements however: Spanish respondents view communication with member state competent/national authority as less important compared to industry respondents from Portugal. Portuguese industry respondent also viewed the conduct of in-vivo and in-vitro test as less to not important whereas their Spanish counterparts view the conduct of these tests as very important. Such differing views can be attributed to a range of factors that these chemical industries are involved with which are key to their operations.

However, given the few numbers of respondents compared to the actual number of chemical industries from both countries particularly from Spain, these results may not very well represent the majority of chemical industries. Such very small number of respondents may have limited the study result in terms comprehensiveness, the study nonetheless was able to provide functional information that can be use in knowledge building among different chemical industry players and regulatory bodies.

RECOMMENDATIONS

Based on the problem and after thorough analysis of data, the following recommendations are hereby made:

1. Among the best practices recognized by companies in complying with REACH regulations is joining a consortium and joint registration and submission of dossiers. This practice should be continued and further developed to strengthen existing systems. While the establishment of a formal cooperation such as a consortium is not compulsory, formation of product-specific consortia will enable various stakeholders to pool together different resources and effectively and efficiently comply with the regulations. Such joint efforts will enable members to build on the technical and scientific advantages of the consortia. The consortia can

also provide member companies with a stronger position when evaluating dossiers with the ECHA.

2. Among the issues raised by respondents is the communication problems experienced by potential registrants, downstream users and third parties participating in the substance information exchange fora (SIEF) as member companies are from various EU countries. As part of the SIEF, potential registrants and data holders should device an agreed system where registrants can effectively facilitate exchange of information and avoid duplication of study or vertebrate animal testing. Such system may include agreed method on the classification and labeling of materials, sharing of existing data for registered substances as well as agreed cost sharing as a means of reducing costs. Parties involved should agree in advance (prior to forming a consortium) on potential conflicting issues like information sharing, ownership and cost sharing, that might affect cooperation among registrants. Identifying who the lead registrant and co-registrant is also an important aspect to any planned SIEF or cooperation.

3. Cost sharing is a major issue among registrants particularly when they fail to reach an agreement. While forming a consortium is not mandatory, it is preferable that registrants will have already laid out rules or essential guidelines before any cooperation starts, particularly on cost elements, as participation to SIEF or a consortium can always change, especially when there are late pre-registrants, registrants and deactivation of potential registrants. Laying out particular guidelines, e.g. cost on substance testing, can eventually straighten potential gray area. Cooperating registrants should also be able determine mechanisms on cost distribution, notably on product or animal testing.

4. The lack of response from suppliers in the use of substances and error corrections in SDS should be given attention by any consortium. As a formally structured cooperation, consortia should establish mechanism to assist individual members to compel suppliers (as part of their responsibility to EU-based customers) to provide timely and accurate feedback to customer complaints and inquiries. The

establishment of helpdesks within a consortium can provide members the necessary assistance. In terms of individual customers, ECHA helpdesk can provide the needed influence to compel suppliers to provide needed information on their products, particularly SDS.

5. While the ECHA and the chemical companies have been providing the necessary capability building efforts in the form of trainings and seminars to comply with REACH regulations, IT-related trainings are important as well. Although companies rely much on their IT personnel to provide the necessary technical support, efforts should also be made to train company personnel involved or assigned to REACH regulation. There will always be difficulties in dealing with the complexity of IT tools, not only for REACH. As software often undergoes changes with newer and often unstable versions, installation and configuration as well as migrating from one version to another could lead to potential problems. Again IT people can only provide the needed assistance, thus, regulatory compliance personnel, who are the true users of these IT tools need the necessary training to be able to satisfy with REACH regulations.

6. Identifying and establishment of a company task force or a technical working group for the REACH-related matter as a best practice to properly address all aspects of the regulation. Such task force may be composed of legal, technical, administrative, financial and IT personnel to handle the range of issues and concerns in compliance process and offer a spectrum of best possible solutions in the orderly and timely submission and compliance of the REACH regulation.

7. The strict implementation in the provision of SDS from suppliers and to downstream users and clients should be put in place. Chemical industries should establish clear guidelines and policy to suppliers and to the industries themselves that inclusion and provision of SDS is mandatory. As a form of good practice, the mandatory provision of a quality and straight-forward SDS from suppliers and to downstream users and clients ensure safety of all persons along the supply chain involved in handling of chemicals.

5. ANNEXES

5.1 Spain: Letter for the chemical companies

Erasmus Mundus Master in
Chemical Innovation and Regulation

Erasmus Mundus

UAlg · Universitat de Barcelona · Alma Mater Studiorum Università di Bologna · Heriot Watt University

El Master Erasmus Mundus en Innovación y Regulación Química (EMMC ChIR) es un programa de máster desarrollado por el consorcio de universidades formado por la Universidad de Algarve (PT), la Universidad de Barcelona (ES), la Universidad de Bologna (IT) y la Universidad de Heriot Watt (UK) que FEIQUE apoya institucionalmente ante la Comisión Europea desde hace 5 años. El EMMC ChIR (http://emmcchir.org/) ofrece a sus estudiantes la formación adecuada desde el punto de vista científico, regulatorio y económico para gestionar los riesgos de los productos químicos de manera responsable y para cumplir con la legislación química en todo el mundo.

En el segundo año del programa EMMC ChIR, el estudiante debe llevar a cabo un proyecto de investigación/tesis de máster sobre su área de interés como requisito para la graduación.

La estudiante del Máster EMMC ChIR, Shella Talampas, está llevando a cabo el proyecto "Estudio sobre las diferentes estrategias y enfoques seguidos por las empresas en Portugal y España para cumplir con la regulación REACH", dirigido por el Profesor Daniel Sainz de la Universidad de Barcelona y la Profesora Isabel Cavaco de la Universidad del Algarve en Portugal.

Este proyecto de investigación tiene como objetivo identificar preocupaciones y problemas encontrados, así como documentar las mejores prácticas de las empresas en Portugal y España en relación al cumplimiento de la normativa REACH. El proyecto de investigación también tratará de evaluar de cómo las industrias son capaces de hacer frente a estos desafíos por medio de mecanismos eficaces y eficientes para cumplir con los exigentes requisitos de REACH y de cómo este estudio de investigación puede ser utilizado como herramienta de apoyo a las industrias estableciendo mecanismos apropiados para hacer frente a la evolución de las directrices de la reglamentación química.

Para poder seguir el estudio, sin embargo, existe la necesidad de recopilar los datos necesarios de las industrias químicas miembros de FEIQUE, utilizando para ello el método de encuesta.

En relación a esto, solicito tu amable colaboración, por medio de tus respuestas al cuestionario adjunto. La información proporcionada será un aspecto esencial para la finalización exitosa del trabajo planteado.
Toda la información proporcionada será tratada de forma confidencial y anónima y será utilizada única e exclusivamente para el proyecto de investigación. El EMMC ChIR proporcionará a su empresa una copia electrónica del informe final del proyecto de investigación.

Si desea comenzar con la encuesta, haga clic en el siguiente enlace:

https://docs.google.com/forms/d/e/1FAIpQLSe-DKQaJggtwATrffr-h4S6dwXwQ5tSsIpWjGT8R4Fw752J1g/viewform

(La encuesta puede resultar algo extensa y exhaustiva, no sería necesario completarla al 100% aunque sería importante centrarse a las preguntas vinculadas al objetivo del proyecto)

Les rogamos que responda el cuestionario antes del 11 de agosto de 2017. Si tiene preguntas o desea aclaraciones, no dude en ponerse en contacto por correo electrónico Shella Talampas shells.talampas@gmail.com o con el director del proyecto Prof. Daniel Sainz daniel.sainz@ub.edu.

Muchas gracias de antemano por vuestra posible colaboración, un abrazo

5.2 Spain: Survey questionnaire for the chemical companies

Erasmus Mundus Master in
Chemical Innovation and Regulation

Erasmus Mundus

UAlg UNIVERSIDADE DO ALGARVE · UNIVERSITAT DE BARCELONA · ALMA MATER STUDIORUM UNIVERSITÀ DI BOLOGNA · HERIOT WATT UNIVERSITY

Study on the different strategies and approaches followed by companies in SPAIN to comply with REACH regulations

The Research Project aims to identify the issues, concerns and problems encountered as well as document best practices of companies in SPAIN in complying with the REACH regulations. The research project will also attempt to assess how industries are able to address these challenges by means of effective and efficient mechanisms to cope with the demanding requirement of the REACH and how the research study can be used as decision support tool for industries in maintaining industry standards, establish appropriate mechanisms in dealing with the evolving chemical regulatory guidelines as well as strengthening competitiveness in the global chemical industry market.

Your feedback is essential for the success of this research. The following survey will take no more than 15-20 minutes of your time. We assure that all the information you provide through the survey will never be disclosed to third parties and will be used exclusively for the purposes of this research project. Thank you for your kind assistance and support to the research project.

If you are interested in the outcomes of this research project, we will be happy to send you a copy of the final report, by September 2017.

How would you like your company's contribution to appear?

☐ Name of company may appear in the publication.

☐ Name of company is confidential and will not appear in the publication.

Name of company	
Company Address	
Contact Person Responsible for the REACH	
Email Address	

REGISTRATION

Question no. 1 Please select the type of business ownership of your company.			
Private entity (entidad privada)		Public entity (entidad pública)	

If private ownership, please select the type.			
Sole trader or sole proprietor (empresario individual or autónomo)		Stock Corporation (Sociedad Anónima – S.A.)	
Limited Liability Company (Sociedad de Responsabilidad Limitada – S.L.)		Cooperative (Sociedad Cooperativa) or Labour Corporations (Sociedades Laborales)	
Temporary Business Associations (Uniones Temporales de Empresas – UTE) or Economic Interest		Groups (Agrupación de Interés Económico – AIE)	
Other: _____			

Question no. 2 Please select the size of your company based in Annex I of Regulation (EU) No.651/2014.			
Micro-enterprise (1-9 employees)		Medium enterprise (50-250 employees)	
Small enterprise (10-49 employees)		Large enterprise (above 250 employees)	

Question no. 3 Please select the industrial sector your company belongs.				
Petrochemicals		**Basic inorganics (please specify)**		
Consumer chemicals			Industrial gases	
Specialty (please specify)			Fertilizers	
	Auxiliaries for industry		Other inorganics	
	Paints and inks		**Polymers (please specify)**	
	Crop protection		Plastics	
	Dyes and pigments		Synthetic rubber	
	Other: _____		Man-made fibers	
Other (please specify) _____			Other: _____	

Question no. 4
Please select where your company operates.

Exclusively within Spain		World market	
EU market		US market	
Other_____			

Question no. 5
Please select your company's role under the REACH Regulation as defined in the Articles 3 and 8 Regulation (EC) No. 1907/2006.

Type	Substances/ Intermediates	Mixtures	Articles	Nanomaterials
Manufacturer				
Downstream user				
Importer or/and Only representative of a non-Community manufacturer (EEA-based "Only Representative")				

Question no. 6
Are all the substances manufactured, imported or/and used by your company subject to the REACH Regulation (EC No. 1907/2006) registered with the European Chemicals Agency (ECHA)?

YES, all substances subject to registration are registered.	
No, all the substances subject to registration are not registered.	
No, some substances are registered and some are not registered.	

Question no. 7
If your answer is YES all substances subject to registration are registered on Question no.6, please answer the following questions:

Please indicate below the number of substances that your company registered with ECHA.
_____

Please give the estimated average cost for the substances registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees).
_____

Question no. 8
If your answer is No, all the substances subject to registration are not registered on Question no.6, please answer the following questions:

Please indicate below the number of substances need to be registered with ECHA on May 2018. _____

Please give the estimated average cost of registration of the substances to be registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees). _____

Question no. 9 If your answer is No, some substances are registered and some are not registered on Question no.6, please answer the following questions:
Please indicate below the number of substances that your company registered with ECHA. _____
Please give the estimated average cost for the substances registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees). _____
Please indicate below the number of substances need to be registered with ECHA on May 2018. _____
Please give the estimated average cost of registration of the substances to be registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees). _____

Question no. 10 Please select the method that your company have carried out or will carry out for the registration process.	
Individually (by your own company).	
Jointly (with other companies)	
Please indicate reasons for the choice of method.	
_____	

Question no. 11 Please select whether your company considers reducing the manufacture/import volumes or cancelling the manufacture/import of certain substances or not because of the registration obligation under REACH and its related costs.				
Limiting			Not consider limiting or cancelling	
Cancelling			Do not know for the moment	

Question no. 12 Please select the source of information on REACH used by your company. Note*: You may select more than one option*.				
ECHA			Internet	
External company (consultant)			Media	
National Authority, e.g. MAPAMA, MSPS (please specify name of government agency) _____ _____			Business Association or Organization, e.g. FEIQUE, CEFIC, AFAQUIM, etc. (please specify name of business association or organization) _____	
Professional trainings, seminars and courses			Parent company or Central department/Head Office of the company	
Legislation			Other (please indicate) _____	

Question no. 13
Number of employees in-charged in addressing REACH-related issues in your company.

0		1		2	
3		4		5	
More than 5					

If your answer is zero (no employee in-charged of the REACH regulation), please state the reason.

_____

Question no. 14
Approximate number of seminars, trainings and courses (including meetings with chemical industries organizations) attended by your company in 2016 related in compliance with chemical legislations such as REACH, Classification, Labelling and Packaging (CLP), Prior Informed Consent (PIC), and other chemical regulations.

0		1		2	
3		4		5	
6 to 10		More than 10			

Question no. 15
If your answer to Question no. 14 is zero (do not attend seminars, etc.), please select reason for not attending. Note: You may select more than one option.

Lack of time	
Late information from the organizers	
Lack of information from the organizers	
Topic is too general	
Topic is too specific	
Costs associated with attendance	
Covered by external company (consultant) or upstream enterprise	
Responsibility of the supplier	
Other (please indicate) _____ _____	

Question no. 16 Please select the challenges, issues and problems met during the Registration process. Note: You may select more than one option.	
Communication with ECHA	
Communication with all potential registrants, downstream users and third parties who participated in the Substance Information Exchange Forum (SIEF)/ Communication with previous registrant to reach an agreement on the sharing of existing data in the case of registered substances	
Cost for tests	
Complexity of IT tools in terms of installation and use by a normal user (install and use of the IUCLID software)	
Not able to cope up the deadline set by ECHA on additional data or information	
Coping with the deadline set by ECHA	
Other (please indicate) _____	

Question no. 17 In reference to Question no. 16, please explain how your company was able to cope or address those issues and problems.
_____ _____ _____

Question no. 18 Please select the challenges, issues and problems met during the Dossier and Substance Evaluations. Note: You may select more than one option.	
Communication with the Member State Competent/National Authority	
Communication with ECHA	
Communication with all potential registrants, downstream users and third parties who participated in the Substance Information Exchange Forum (SIEF)/ Communication with previous registrant to reach an agreement on the sharing of existing data in the case of registered substances	
Cost for tests	
Updating IT tools and errors, complexity of IT tools in terms of installation and use by a normal user (install and use of the IUCLID software)	
Not able to cope up the deadline set by ECHA and/or the National Authority on additional data or information	
Other (please indicate) _____	

Question no. 19
In reference to Question no. 18, please explain how your company was able to cope or address those issues and problems.

_____

_____

_____

_____

_____

_____

Question no. 20
Does your company manufacture, import or use Substances of Very High Concern (SVHC)?

YES		NO	

If YES, has your company applied or will apply for authorization for the manufacture, import or use of Substances of Very High Concern (SVHC) or substances listed in Annex XIV of Regulation (EC) No. 1907/2006?

YES, have already applied and approved by ECHA	
YES, have already applied and waiting for the approval by ECHA	
YES, have already applied and disapproved by ECHA Please indicate reasons for the disapproval._____ _____	
NO, have not applied but planning to apply Please indicate reasons and does your company have other alternatives for these SVHC? _____ _____	
NO, will not apply Please indicate reasons and does your company have other alternatives for these SVHC? _____ _____	

Question no. 21
Does your company manufacture, import or use certain dangerous substances as listed in Annex XVII of Regulation (EC) No. 1907/2006 or substances restricted under REACH?

YES		NO	

If YES, is your substance registered with ECHA?

YES		NO	

If NO, does your company have plans to register the substance with ECHA?

YES		NO	

If NO, please state the reasons.
_____

CLASSIFICATION AND LABELLING

Please answer the questions wherein your company is involve as manufacturer, importer and/ or downstream user.

For DOWNSTREAM USERS (these includes industries wherein they purchased the imported substance from an EEA-based "Only Representative"), kindly answer Question Numbers 22, 23 and 24.

For IMPORTERS including Only representative of a non-Community manufacturer (EEA-based "Only Representative") "), kindly answer Question Number 25.

For MANUFACTURERS, kindly answer Question Numbers 26, 27 and 28.

Question no. 22 Is your company a downstream user?			
YES		NO	
If YES, does your company receive the Safety Data Sheet (SDS) from your supplier, wherein the SDS is in accordance with Commission Regulation (EU) No. 2015/830?			
YES, we received SDS for all the substances. How is the SDS provided to your company? Please select below option.			
	The supplier provides the SDS both the English and the Spanish versions.		
	The supplier provides the SDS in a foreign language and we translate/create the Spanish version.		
	The supplier only provides the SDS in Spanish as per request.		
	The supplier directly provides the SDS in Spanish.		
NO, we did not receive SDS for all the substances. How does your company handle this situation? Please select below option.			
	The company will warn the supplier to provide the correct SDS version or else no next order.		
	The company did not make any demands from the supplier.		
	Other (please specify) _____ _____		
We received SDS for some substances and some we did not receive. How does your company handle this situation? Please select below option.			
	The company will warn the supplier to provide the correct SDS version or else no next order.		
	The company did not make any demands from the supplier.		
	Other (please specify) _____ _____		

Question no. 23 Did your company discuss with your supplier the inclusion in the registration documentation for the use of the substance or inclusion of your uses in his Chemical Safety Report? Does the safety data sheet supplied include your use of the substance?	
YES, we discussed with the supplier and our use of the substance is included in the registration.	
YES, we discussed with the supplier but the supplier did not include our use in the registration. It is our responsibility to carry out our own chemical safety assessment.	
NO, we did not discuss with the supplier since the usage is included in the SDS.	
NO, we did not discuss with the supplier or make any demands from the supplier.	
Others (please indicate) _____ _____	

Question no. 24 Does your company understand the information on the safe use of substances, mixtures or articles provided by your suppliers?	
YES, we understand all.	
YES, we understand a little (not mostly).	
NO, we did not understand any.	
Other (please indicate) _____	

Question no. 25 Is your company an importer?				
YES			NO	
If YES, who prepared the correct version of the Safety Data Sheet (SDS) of the substance your company import?				
Your own company			Your supplier outside EU	

Question no. 26 Is your company a manufacturer?			
YES		NO	

If YES, does your company provide the correct version of the Safety Data Sheet (SDS) to your customers?	
YES, we provide for all substances.	
NO, we do not provide for all substances. Please state the reasons. _____ _____ _____	
We provide for some substances and for others not. Please state the reasons. _____ _____ _____	

Question no. 27 Does your company provide the Extended Safety Data Sheet (ESDS) to your customers in accordance with Commission Regulation (EU) No. 2015/830?	
YES, we provided ESDS to the customers	
NO, we did not provide ESDS to the customers Please state the reasons. _____ _____ _____	
We provided ESDS for some substances but for other substances, we did not provide ESDS Please state the reasons. _____ _____ _____	

Question no. 28 Have you discussed the use of the substance supplied with your customers in order to include their use in the registration documentation?	
YES, we discussed the use of the substance with the customers	
NO, we did not discuss the use of the substance with the customers Please state the reasons. _____ _____ _____	
In some cases we discussed the use of the substance with the costumers but there were also cases that we did not discuss with them Please state the reasons. _____ _____ _____	

OVER-ALL

Question no. 29
Please rate the following steps in the implementation of the REACH regulation in terms of importance.
Very Important; Moderately Important; Less Important; Not important.

INFORMATION & COMMUNICATION

Steps	**Very Important**	**Moderately Important**	**Less Important**	**Not Important**
Reading of materials (REACH regulations, methods, articles, etc.)				
Internet access and research on ECHA website				
Constant attendance to seminars and training courses related with REACH regulations and other chemical legislation				
Understanding the ECHA guidelines and constant inquiry on the guidelines updates				
Create a company's technical working group in the compliance and implementation of the REACH regulations and other chemical regulations				
Constant communication with ECHA (from pre-registration to registration to evaluation to appeal to approval to updating)				
Communication with the Member State Competent/National Authority				
Seek advice from consultants				
Consult with business associations/organizations (e.g. FEIQUE)				
Consult or confer with other industries				
Communication and participation in the Substance Information Exchange Forum (SIEF); sharing of data involving tests				
Agreement with other registrants and downstream users in carrying out or performing the tests				
Joint submission of data by multiple registrants				
Cost sharing for tests				
Budget for the costs involved in the REACH process				
Others (please specify) _____ _____				

TECHNICAL ASPECTS				
Steps	**Very Important**	**Moderately Important**	**Less Important**	**Not Important**
Prepare checklist for the registration requirements				
Identification of the classification of the chemical to be placed/registered (article, mixture or substance/intermediate, phase-in or non-phase-in substances)				
Calculate the quantity (tonnage) of a substance manufactured or imported or used per year				
Preparation of the technical dossier				
Preparation of the chemical safety report				
Conduct chemical safety assessment				
Preparation of the updated Safety Data Sheet (SDS) in accordance with Commission Regulation (EU) No. 2015/830				
Quality of the SDS provided by manufacturers, importers and suppliers				
Duty to communicate information down and up the supply chain				
Access for workers to information of the chemicals that they use or may be exposed to in course of their work				
Avoidance of unnecessary testing				
Conduct of in-vivo tests				
Conduct of in-vitro tests				
Proficiency in the installation and use of the IUCLID software				
Updating of the registration dossier via REACH-IT or IUCLID (either requested or spontaneous update)				
Others (please specify) _____ _____				

COPY OF THE FINAL REPORT			
Would you like to receive a copy of the final report for this research project?			
YES		NO	

5.3 Portugal: Letter for the chemical companies

Erasmus Mundus Master in
Chemical Innovation and Regulation

Erasmus Mundus

UAlg UNIVERSIDADE DO ALGARVE | UNIVERSITAT DE BARCELONA | ALMA MATER STUDIORUM UNIVERSITÀ DI BOLOGNA | HERIOT WATT UNIVERSITY

A implementação das normas europeias REACH tem trazido novos desafios à indústria portuguesa. É importante reunir de forma sistemática informação objetiva que traduza as reais dificuldades sentidas pela indústria e o nível de eficácia na implementação destas normas.

A APEQ foi contactada no sentido de contribuir para um projeto de investigação sobre as estratégias seguidas pelas empresas de indústria química em Portugal e Espanha para implementação das normas REACH. O projeto resulta de uma colaboração entre a Universidade do Algarve e a Universidade de Barcelona, e inclui o levantamento de informação através de um questionário online destinado às empresas portuguesas. Um questionário equivalente está a ser distribuído às empresas espanholas através da colaboração da FEIQUE.

Sugerimos assim a vossa contribuição para este estudo através do preenchimento do questionário online disponível em:

https://docs.google.com/forms/d/e/1FAIpQLSfnW0QIyBr8Jik_tOIG6sUv3MyWJ8KibF7YHjOMeY8peq6L3A/viewform

O preenchimento demora menos de 20 min, é estritamente confidencial e todas as perguntas são facultativas. O relatório final não identificará as empresas envolvidas, excepto quando explicitamente indicarem o contrário.

Pedimos por favor que complete o questionário até 20 de Julho de 2017.

Qualquer questão sobre este projeto pode ser dirigida à Prof. Isabel Cavaco, FCT-UAlg, icavaco@ualg.pt.

5.4 Portugal: Survey questionnaire for the chemical companies

Erasmus Mundus Master in
Chemical Innovation and Regulation

Erasmus Mundus

UAlg UNIVERSIDADE DO ALGARVE · UNIVERSITAT DE BARCELONA · ALMA MATER STUDIORUM UNIVERSITÀ DI BOLOGNA · HERIOT WATT UNIVERSITY

Study on the different strategies and approaches followed by companies in PORTUGAL to comply with REACH regulations

The Research Project aims to identify the issues, concerns and problems encountered as well as document best practices of companies in SPAIN in complying with the REACH regulations. The research project will also attempt to assess how industries are able to address these challenges by means of effective and efficient mechanisms to cope with the demanding requirement of the REACH and how the research study can be used as decision support tool for industries in maintaining industry standards, establish appropriate mechanisms in dealing with the evolving chemical regulatory guidelines as well as strengthening competitiveness in the global chemical industry market.

Your feedback is essential for the success of this research. The following survey will take no more than 15-20 minutes of your time. We assure that all the information you provide through the survey will never be disclosed to third parties and will be used exclusively for the purposes of this research project. Thank you for your kind assistance and support to the research project.

If you are interested in the outcomes of this research project, we will be happy to send you a copy of the final report, by September 2017.

How would you like your company's contribution to appear?

☐ Name of company may appear in the publication.

☐ Name of company is confidential and will not appear in the publication.

Name of company	
Company Address	
Contact Person Responsible for the REACH	
Email Address	

REGISTRATION

Question no. 1 Please select the type of business ownership of your company.			
Privately owned		Government-owned	
If private entity, please select the type.			
Private Limited Liability Company (Sociedade por Quotas)		Public Limited Liability Company (Sociedade Anónima)	
Sole Shareholder Private Limited Liability Company (Sociedade Unipessoal por Quotas)		Other: _____	

Question no. 2 Please select the size of your company based in Annex I of Regulation (EU) No.651/2014.			
Micro-enterprise (1-9 employees)		Medium enterprise (50-250 employees)	
Small enterprise (10-49 employees)		Large enterprise (above 250 employees)	

Question no. 3 Please select the industrial sector your company belongs.				
Petrochemicals		**Basic inorganics (please specify)**		
Consumer chemicals			Industrial gases	
Specialty (please specify)			Fertilizers	
Auxiliaries for industry			Other inorganics	
Paints and inks		**Polymers (please specify)**		
Crop protection			Plastics	
Dyes and pigments			Synthetic rubber	
Other: _____			Man-made fibers	
Other (please specify) _____			Other: _____	

Question no. 4 Please select where your company operates.			
Exclusively within Portugal		World market	
EU market		US market	
Other_____			

Question no. 5
Please select your company's role under the REACH Regulation as defined in the Articles 3 and 8 Regulation (EC) No. 1907/2006.

Type	Substances/ Intermediates	Mixtures	Articles	Nanomaterials
Manufacturer				
Downstream user				
Importer or/and Only representative of a non-Community manufacturer (EEA-based "Only Representative")				

Question no. 6
Are all the substances manufactured, imported or/and used by your company subject to the REACH Regulation (EC No. 1907/2006) registered with the European Chemicals Agency (ECHA)?

YES, all substances subject to registration are registered.	
No, all the substances subject to registration are not registered.	
No, some substances are registered and some are not registered.	

Question no. 7
If your answer is YES all substances subject to registration are registered on Question no.6, please answer the following questions:

Please indicate below the number of substances that your company registered with ECHA.
_____

Please give the estimated average cost for the substances registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees).
_____

Question no. 8
If your answer is No, all the substances subject to registration are not registered on Question no.6, please answer the following questions:

Please indicate below the number of substances need to be registered with ECHA on May 2018. _____

Please give the estimated average cost of registration of the substances to be registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees). _____

Question no. 9 If your answer is No, some substances are registered and some are not registered on Question no.6, please answer the following questions:
Please indicate below the number of substances that your company registered with ECHA. _____
Please give the estimated average cost for the substances registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees). _____
Please indicate below the number of substances need to be registered with ECHA on May 2018. _____
Please give the estimated average cost of registration of the substances to be registered in Euro (sum of all costs = ECHA fees + data fees-SIEF operating costs + tests + consultancy fees). _____

Question no. 10 Please select the method that your company have carried out or will carry out for the registration process.	
Individually (by your own company).	
Jointly (with other companies)	
Please indicate reasons for the choice of method.	
_____	

Question no. 11 Please select whether your company considers reducing the manufacture/import volumes or cancelling the manufacture/import of certain substances or not because of the registration obligation under REACH and its related costs.				
Limiting			Not consider limiting or cancelling	
Cancelling			Do not know for the moment	

Question no. 12 Please select the source of information on REACH used by your company. Note*: You may select more than one option*.				
ECHA			Internet	
External company (consultant)			Media	
National Authority, e.g APA, IAPMEI, DGS, HELPDESK (please specify name of government agency) _____ _____			Business Association or Organization, e.g. CEFIC, APEQ (please specify name of business association or organization) _____	
Professional trainings, seminars and courses			Parent company or Central department/Head Office of the company	
Legislation			Other (please indicate) _____	

Question no. 13
Number of employees in-charged in addressing REACH-related issues in your company.

0		1		2	
3		4		5	
More than 5					

If your answer is zero (no employee in-charged of the REACH regulation), please state the reason.

_____

Question no. 14
Approximate number of seminars, trainings and courses (including meetings with chemical industries organizations) attended by your company in 2016 related in compliance with chemical legislations such as REACH, Classification, Labelling and Packaging (CLP), Prior Informed Consent (PIC), and other chemical regulations.

0		1		2	
3		4		5	
6 to 10		More than 10			

Question no. 15
If your answer to Question no. 14 is zero (do not attend seminars, etc.), please select reason for not attending. Note: You may select more than one option.

Lack of time	
Late information from the organizers	
Lack of information from the organizers	
Topic is too general	
Topic is too specific	
Costs associated with attendance	
Covered by external company (consultant) or upstream enterprise	
Responsibility of the supplier	
Other (please indicate) _____ _____	

Question no. 16 Please select the challenges, issues and problems met during the Registration process. Note: You may select more than one option.	
Communication with ECHA	
Communication with all potential registrants, downstream users and third parties who participated in the Substance Information Exchange Forum (SIEF)/ Communication with previous registrant to reach an agreement on the sharing of existing data in the case of registered substances	
Cost for tests	
Complexity of IT tools in terms of installation and use by a normal user (install and use of the IUCLID software)	
Not able to cope up the deadline set by ECHA on additional data or information	
Coping with the deadline set by ECHA	
Other (please indicate) _____	

Question no. 17 In reference to Question no. 16, please explain how your company was able to cope or address those issues and problems.
_____ _____ _____

Question no. 18 Please select the challenges, issues and problems met during the Dossier and Substance Evaluations. Note: You may select more than one option.	
Communication with the Member State Competent/National Authority	
Communication with ECHA	
Communication with all potential registrants, downstream users and third parties who participated in the Substance Information Exchange Forum (SIEF)/ Communication with previous registrant to reach an agreement on the sharing of existing data in the case of registered substances	
Cost for tests	
Updating IT tools and errors, complexity of IT tools in terms of installation and use by a normal user (install and use of the IUCLID software)	
Not able to cope up the deadline set by ECHA and/or the National Authority on additional data or information	
Other (please indicate) _____	

Question no. 19
In reference to Question no. 18, please explain how your company was able to cope or address those issues and problems.

_____

_____

_____

_____

_____

_____

Question no. 20
Does your company manufacture, import or use Substances of Very High Concern (SVHC)?

YES		NO	

If YES, has your company applied or will apply for authorization for the manufacture, import or use of Substances of Very High Concern (SVHC) or substances listed in Annex XIV of Regulation (EC) No. 1907/2006?

YES, have already applied and approved by ECHA	
YES, have already applied and waiting for the approval by ECHA	
YES, have already applied and disapproved by ECHA Please indicate reasons for the disapproval._____ _____	
NO, have not applied but planning to apply Please indicate reasons and does your company have other alternatives for these SVHC? _____ _____	
NO, will not apply Please indicate reasons and does your company have other alternatives for these SVHC? _____ _____	

Question no. 21
Does your company manufacture, import or use certain dangerous substances as listed in Annex XVII of Regulation (EC) No. 1907/2006 or substances restricted under REACH?

YES		NO	

If YES, is your substance registered with ECHA?

YES		NO	

If NO, does your company have plans to register the substance with ECHA?

YES		NO	

If NO, please state the reasons.
_____

CLASSIFICATION AND LABELLING

Please answer the questions wherein your company is involve as manufacturer, importer and/ or downstream user.

For DOWNSTREAM USERS (these includes industries wherein they purchased the imported substance from an EEA-based "Only Representative"), kindly answer Question Numbers 22, 23 and 24.

For IMPORTERS including Only representative of a non-Community manufacturer (EEA-based "Only Representative") "), kindly answer Question Number 25.

For MANUFACTURERS, kindly answer Question Numbers 26, 27 and 28.

Question no. 22 Is your company a downstream user?			
YES		NO	
If YES, does your company receive the Safety Data Sheet (SDS) from your supplier, wherein the SDS is in accordance with Commission Regulation (EU) No. 2015/830?			
YES, we received SDS for all the substances. How is the SDS provided to your company? Please select below option.			
	The supplier provides the SDS both the English and the Portuguese versions.		
	The supplier provides the SDS in a foreign language and we translate/create the Portuguese version.		
	The supplier only provides the SDS in Portuguese as per request.		
	The supplier directly provides the SDS in Portuguese.		
NO, we did not receive SDS for all the substances. How does your company handle this situation? Please select below option.			
	The company will warn the supplier to provide the correct SDS version or else no next order.		
	The company did not make any demands from the supplier.		
	Other (please specify) _____ _____		
We received SDS for some substances and some we did not receive. How does your company handle this situation? Please select below option.			
	The company will warn the supplier to provide the correct SDS version or else no next order.		
	The company did not make any demands from the supplier.		
	Other (please specify) _____ _____		

Question no. 23 Did your company discuss with your supplier the inclusion in the registration documentation for the use of the substance or inclusion of your uses in his Chemical Safety Report? Does the safety data sheet supplied include your use of the substance?	
YES, we discussed with the supplier and our use of the substance is included in the registration.	
YES, we discussed with the supplier but the supplier did not include our use in the registration. It is our responsibility to carry out our own chemical safety assessment.	
NO, we did not discuss with the supplier since the usage is included in the SDS.	
NO, we did not discuss with the supplier or make any demands from the supplier.	
Others (please indicate) _____ _____	

Question no. 24 Does your company understand the information on the safe use of substances, mixtures or articles provided by your suppliers?	
YES, we understand all.	
YES, we understand a little (not mostly).	
NO, we did not understand any.	
Other (please indicate) _____	

Question no. 25 Is your company an importer?				
YES			NO	
If YES, who prepared the correct version of the Safety Data Sheet (SDS) of the substance your company import?				
Your own company			Your supplier outside EU	

Question no. 26 Is your company a manufacturer?			
YES		NO	
If YES, does your company provide the correct version of the Safety Data Sheet (SDS) to your customers?			
YES, we provide for all substances.			
NO, we do not provide for all substances. Please state the reasons. _____ _____ _____			
We provide for some substances and for others not. Please state the reasons. _____ _____ _____			

Question no. 27 Does your company provide the Extended Safety Data Sheet (ESDS) to your customers in accordance with Commission Regulation (EU) No. 2015/830?
YES, we provided ESDS to the customers
NO, we did not provide ESDS to the customers Please state the reasons. _____ _____ _____
We provided ESDS for some substances but for other substances, we did not provide ESDS Please state the reasons. _____ _____ _____

Question no. 28 Have you discussed the use of the substance supplied with your customers in order to include their use in the registration documentation?
YES, we discussed the use of the substance with the customers
NO, we did not discuss the use of the substance with the customers Please state the reasons. _____ _____ _____
In some cases we discussed the use of the substance with the costumers but there were also cases that we did not discuss with them Please state the reasons. _____ _____ _____

OVER-ALL

Question no. 29
Please rate the following steps in the implementation of the REACH regulation in terms of importance.
Very Important; Moderately Important; Less Important; Not important.

INFORMATION & COMMUNICATION

Steps	**Very Important**	**Moderately Important**	**Less Important**	**Not Important**
Reading of materials (REACH regulations, methods, articles, etc.)				
Internet access and research on ECHA website				
Constant attendance to seminars and training courses related with REACH regulations and other chemical legislation				
Understanding the ECHA guidelines and constant inquiry on the guidelines updates				
Create a company's technical working group in the compliance and implementation of the REACH regulations and other chemical regulations				
Constant communication with ECHA (from pre-registration to registration to evaluation to appeal to approval to updating)				
Communication with the Member State Competent/National Authority				
Seek advice from consultants				
Consult with business associations/organizations (e.g. APEQ)				
Consult or confer with other industries				
Communication and participation in the Substance Information Exchange Forum (SIEF); sharing of data involving tests				
Agreement with other registrants and downstream users in carrying out or performing the tests				
Joint submission of data by multiple registrants				
Cost sharing for tests				
Budget for the costs involved in the REACH process				
Others (please specify) _____ _____				

TECHNICAL ASPECTS				
Steps	**Very Important**	**Moderately Important**	**Less Important**	**Not Important**
Prepare checklist for the registration requirements				
Identification of the classification of the chemical to be placed/registered (article, mixture or substance/intermediate, phase-in or non-phase-in substances)				
Calculate the quantity (tonnage) of a substance manufactured or imported or used per year				
Preparation of the technical dossier				
Preparation of the chemical safety report				
Conduct chemical safety assessment				
Preparation of the updated Safety Data Sheet (SDS) in accordance with Commission Regulation (EU) No. 2015/830				
Quality of the SDS provided by manufacturers, importers and suppliers				
Duty to communicate information down and up the supply chain				
Access for workers to information of the chemicals that they use or may be exposed to in course of their work				
Avoidance of unnecessary testing				
Conduct of in-vivo tests				
Conduct of in-vitro tests				
Proficiency in the installation and use of the IUCLID software				
Updating of the registration dossier via REACH-IT or IUCLID (either requested or spontaneous update)				
Others (please specify) _____ _____				

COPY OF THE FINAL REPORT			
Would you like to receive a copy of the final report for this research project?			
YES		NO	

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