Strategies and Approaches of Companies in Portugal and Spain in Complying with the REACH Regulation

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Abstract

The implementation of the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation had been viewed to be the most ambitious chemicals legislation in the world and had placed a great challenge among the European Union (EU) member states. While government regulatory agencies were focused on how they can successfully implement and enforce the legislation, the industries' concern was to guarantee the compliance with the regulation. Despite the progress, implementation of the regulation still experienced significant problems in the quality of the information provided by companies in their registration dossiers. Given that the success of the REACH process depended primarily on the adequate and reliable information supplied by industries, there was a need to document and manage the knowledge gained and generated since its implementation. Data from survey questionnaires revealed that major issues and concerns identified by industries consisted of communication problems among participants in the implementation of the Substance Information Exchange Forum (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 safety data sheet. To address these issues and concerns, the European Chemicals Agency (ECHA) implemented the SIEF for EU-based chemical industries to form consortiums and jointly carry out registration and dossier submission. Participants identified SIEF as the best practice enabling companies to complete their registration and dossier submission, as well as the most efficient method in complying with REACH regulation.

Keywords*:* REACH regulation, European Union, ECHA, SIEF, industry

1. Introduction

The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), and the Classification, Labeling, and Packaging (CLP) regulations are chemicals legislation 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 was the first step of the EU's commitment to Agenda 21 on Sustainable Development. The European Commission's (EC) original legislative proposal on REACH COM(03) 644 (01) and COM(03) 644 (02) have undergone several reviews and reading procedures as well as debates on its adoption. The proposal on REACH amended the Directive 1999/45/EC, Directive 67/548/EEC, and regulation on Persistent Organic Pollutants (POPs). The REACH regulation (EC 1907/2006) was finally adopted on December 18, 2006 and enforced on June 1, 2007. It took seven years to finalize and enter into force the regulation but its implementation has different phases. The REACH regulation 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 of the environment, agriculture, food, customs, health, and safety services.

REACH regulation aims “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” (European Commission, 2006). REACH strictly implements the "no data, no market" policy. The industries in the EU region, manufacturing and importing chemical substances equal or more than 1 ton per year, are obliged to register the chemical substances that they put in the 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.

Supplementing the REACH Regulation is the Classification, Labeling 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 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 (European Commission, 2015) is the updated regulation on GHS-safety data sheet (SDS) and CLP of the EU, which is in accordance with the 5th edition of the United Nations (UN) GHS of CLP.

The REACH regulation is believed to be the most ambitious chemicals legislation in the world (ECHA, 2008). 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 their compliance with the REACH regulation.

While the response of the 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 in complying with the legislation. This study documented and analyzed 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. The study also identified the issues, concerns, and challenges encountered by chemical industries in complying with REACH regulations. It also documented appropriated mechanisms and best practices that chemical industries can use as decision support tool. Lastly, the study assessed methods and processes employed by industries in addressing and coping with the demanding requirement of REACH regulations; and recommended appropriate methods and strategies in dealing with the evolving chemical regulatory guidelines, maintaining industry standards and strengthening competitiveness in the global chemical industry market.

2. Methodology

2.1 Study Area

The study was conducted in two European countries, Portugal and Spain, taking into consideration the geographical constraint that the author spent in Spain (October 2016 to February 2017) and in Portugal (March 2017 to July 2017). The target populations were companies and industries located in Spain and Portugal that are registered in 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.

2.2 Study Design

The overall step in the conduct of the study is illustrated in Figure 1. Communication and meeting with the chemical industry organizations, FEIQUE in Spain and APEQ in Portugal, were one of the first and vital steps for proper channel and coordination with the industries.

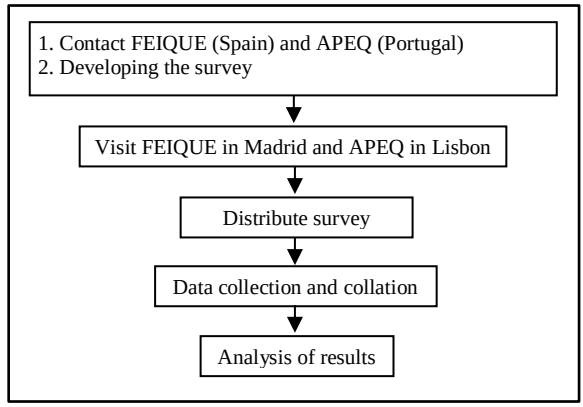


Figure 1. Overall step in the conduct of the study

The method of email/online survey was used in the study. This approach was chosen due to the efficiency in terms of communication and data collection considering the economic, time period and location of the industries.

The core of the study was the survey questionnaires sent to various chemical industries in Spain and Portugal. The link was prepared in the Google Chrome

Drive. The survey questionnaire incorporated both closed-ended and open-ended questions to produce quantitative and qualitative data results. The survey questionnaire was divided into three categories involving the companies in the implementation and complying with 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 the importance of the company's contribution to the study, as well its choice in terms of the appearance in the study 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. Type 1 was the type of company (business ownership, entity scale, industrial sector, operation level). Type 2 was company's role in the REACH regulation (the type of substances applied for registration, authorization, and restriction). Type 3 included the methods applied by companies in the registration of substances (preparation of dossier, complying with additional requirements and attendance to seminars). Lastly, type 4 was the challenges, issues, and problems encountered by companies in the registration process (strategies used to cope up and address the issues and problems).

The second category, "classification and labeling", inquired companies on their knowledge and responsibility on the 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 min to answer. Confidentiality regarding specific information provided by the participants was also assured.

2.2.1 Spain

The chemical industry was the second-largest exporter of the Spanish economy (European Chemical Industry Council [CEFIC], 2014; 2017), which continuously contributed 43.3% exportation growth from 2007 to 2015 and 32.7 billion euro sales (exportation) in 2015 (FEIQUE, 2016). Spain had more than 3,000 companies in the chemical industry sector with major concentrations in Barcelona, Tarragona, and Huelva as shown in Figure 2 (FEIQUE, 2016). The companies were sent with the letter and directed to the

online link by FEIQUE, where the companies' representatives responded to the survey questionnaire. It was also the aim of the 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. Spain's main chemical production sites (FEIQUE, 2006)

2.2.2 Portugal

Although Portugal has fewer chemical companies compared to Spain, the online survey instrument was still used by the researcher due to its cost-effectiveness. Portugal had about 800 companies included in CAE13 20 in 2010 (CEFIC, 2014). Geographically, the chemical industry in Portugal was mostly located in two defined chemical industry hubs in Estarreja and Sines and in the industrialized areas of Lisbon and Oporto (CEFIC, 2014) as shown in Figure 2. The instructions for the companies in Portugal to access the survey questionnaire as indicated in the letter were identical to the ones in Spain.

Figure 3. Portugal's major chemical industry hubs (Agência para o Investimento e Comércio Externo de Portugal (AICEP, 2013)

2.2.3 European Chemicals Agency

As the regulatory authority of the REACH regulation, the ECHA's views, facts, and findings of the best practices of companies in the European Union (EU) in complying with the regulation were significantly important to the study. The information on the ECHA's website was used in the study to find relationships and links with the results of the survey questionnaire sent to the industries. ECHA had efficient updated data and reports concerning the four key essentials in the implementation of the REACH regulation, namely registration, evaluation, authorization and restriction.

2.3 Data Collection

The responses of the survey were gathered and recorded on 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 that 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 July 10 to 20, 2017. While for Spain was from July 20 to August 11, 2017. At the same time, the ECHA data and reports were obtained from the ECHA website.

2.4 Data Analysis

The study 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 that 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.

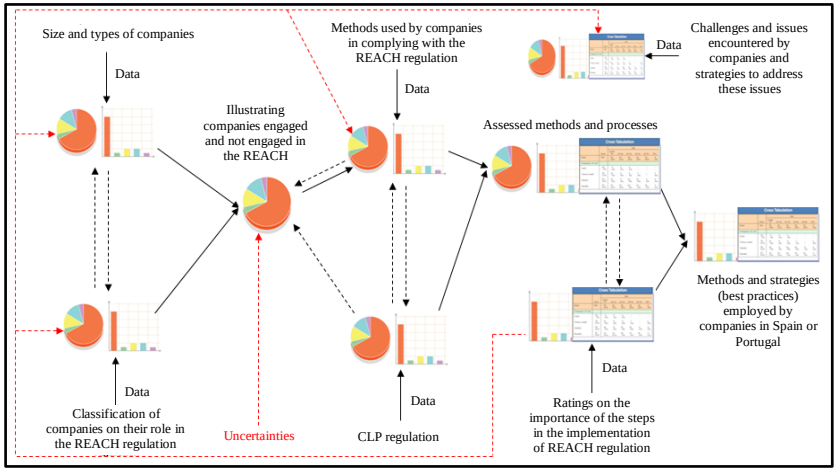
2.4.1 Spain and Portugal

The size and types of chemical companies in terms of business operation and organization were 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 with 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 for their choice of method, and how they were able to address the issues. The cost of the registration process was also integrated into the analysis. Another analysis was the response of the respondents on the CLP regulation, which was interrelated with the REACH regulation. Although the REACH defined the SDS rules while the CLP gave details on the labeling rules, the CLP labels were dependent on the SDS. If a company was a manufacturer or importer, the company was required under CLP regulation to classify substances that were subjected to registration, or to notification in line

with article 7 or 9 of REACH, even if the company did not place them on the market. The classification of a substance was mandatory for the REACH registration dossier.

Lastly, an analysis of 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 by connecting their 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 with the REACH regulation (Figure 4).



Note: 1) Spain and Portugal's 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 4. Flowchart for the data analysis of survey results from chemical companies

2.4.2 Data Analysis from ECHA

Tabulation and charts were provided to illustrate the comparison of Spain and Portugal in the entire EU members in relation to fulfilling the requirements of the REACH regulation in its four areas (Figure 5). 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.

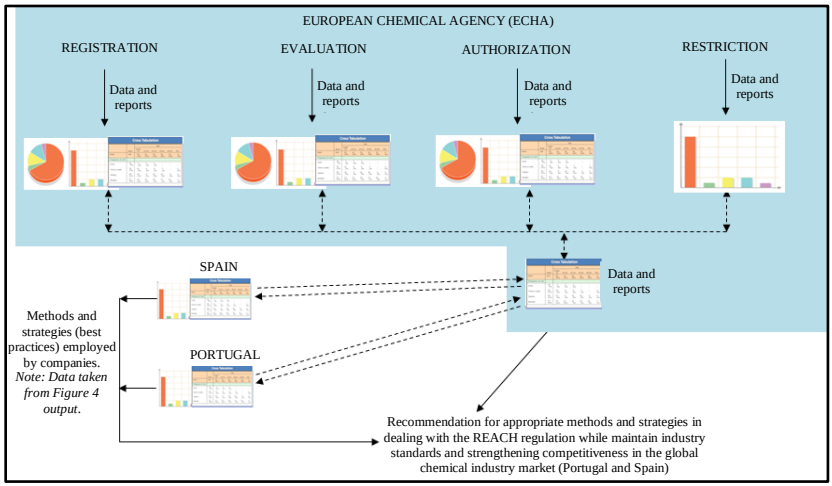


Figure 5. Flowchart for the data analysis of the survey results from ECHA and final output

3. Results and Discussion

3.1 Spain

Spain had six respondent companies. All the respondents were private entities and belonged to the Stock Corporation. Four of the six companies were large enterprises while the rest were small enterprises. Moreover, four of the respondents' market operation was worldwide, wherein three of these companies were large-scale entities and the other was a small-scale enterprise. The other two respondents' market operation was within the EU in which one company did not only operate in Europe but also in the Middle East and Africa. Out of the six respondents, two belonged in the specialty chemicals sector while the rest of the four companies were from petrochemicals, consumer chemicals, basic inorganics, and other chemicals.

All of the respondents classified their companies as manufacturers and downstream users (Figure 6). Five of these companies were also importers and/or only representatives of non-community manufactures (European

Economic Area (EEA)-based only representatives). These six companies handled mixtures and substances/intermediates. Figure 6 shows that the respondents filled more than one option on this question defining the company's role according to articles 3 and 8 of the REACH regulation.

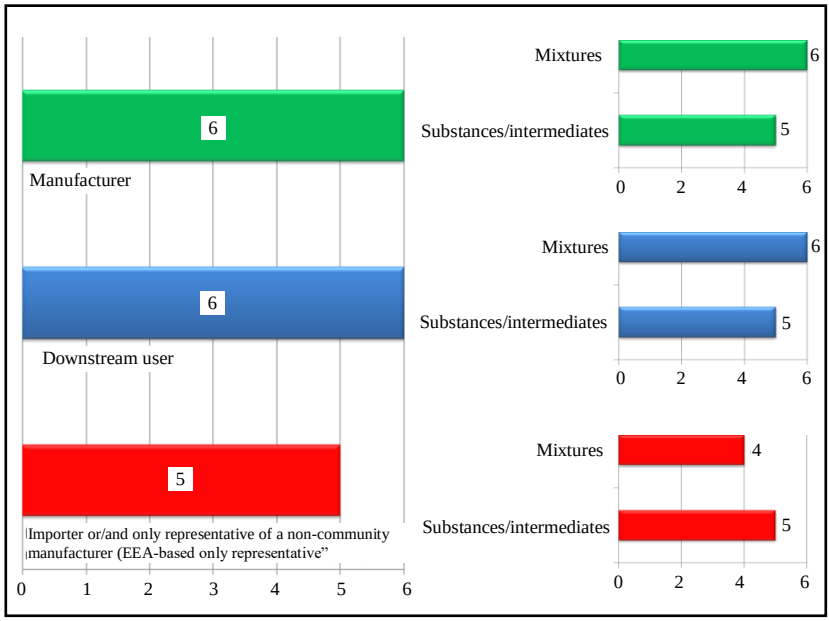


Figure 6. Spain: company's role in the REACH regulation (the type of substances applied for registration, authorization, and restriction)

Six of the respondents had registered their chemicals with ECHA although three of these companies still had some substances that need to be registered (Figure 7). Three of the companies also handled substances of very high concern (SVHC), wherein one company had applied for authorization and approved by ECHA while the other two have not applied yet for authorization, with one company indicated that they had an alternative substance replacing the SVHC. Furthermore, two of the companies had dangerous substances under the restriction and registered with ECHA. Most of the respondents had considered limiting or cancelling either manufacture, import and/or use of certain substances they handled under the REACH regulation due to the registration obligation and its related cost. Among the remaining, one company respondent did not consider limiting or cancelling the manufacture/import/use or reducing the volumes of substances under the REACH regulation while another respondent had not decided to cancel or limit or reduce for the moment.

Five of the respondents had carried out or will carry out the joint submission in the REACH registration of their substances. The joint submission method applied by these companies in the registration of substances can be considered as a best practice among industries in complying with REACH regulation. The respondents in Spain conformed to article 29 of the REACH regulation – the SIEF participation and one substance, one registration (OSOR) principle. Cost-benefit and efficiency, and data sharing obligation were the main reasons for the companies that jointly carried out the registration process. When it comes to sources of information on REACH regulation, all of the respondents in Spain found the ECHA information as most useful (Figure 8).

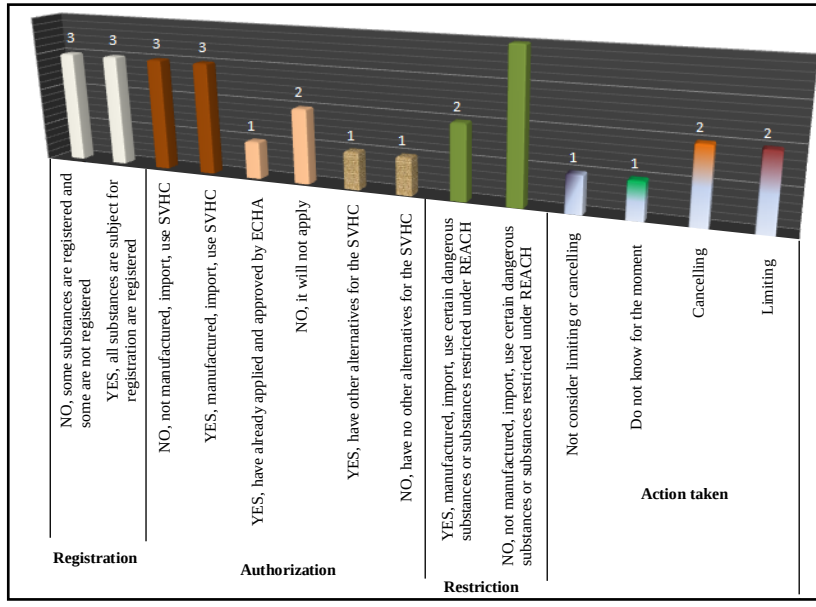


Figure 7. Spain: company's role in the REACH regulation (the type of substances applied for registration, authorization, and restriction)

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 was designating or appointing key personnel responsible for directly addressing the REACH regulation processes (Figure 8). All of the respondents in Spain had employees responsible for addressing REACH-related issues in their company.

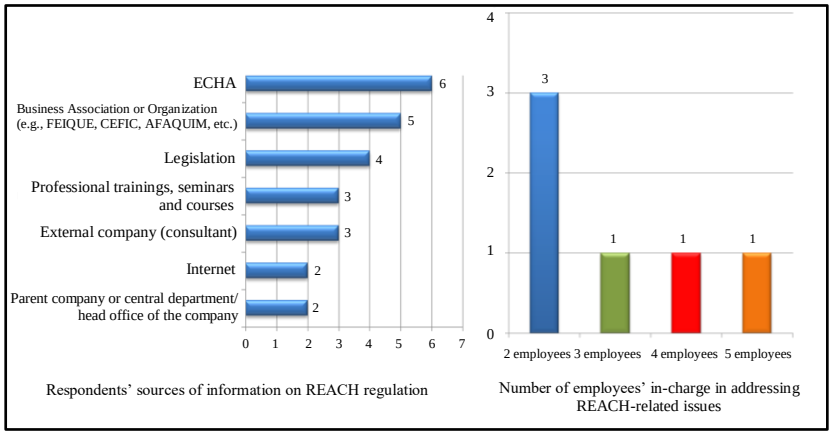


Figure 8. Spain: methods applied by companies in the registration of substances (including preparation of dossier, complying with additional requirements, attendance to seminars)

During the registration process and dossier and substance evaluations, most of the respondents in Spain reported issues on communication with all potential registrants, downstream users and third parties who participated in the SIEF)/communication with the previous registrant to reach an agreement on the sharing of existing data in the case of registered substances, and cost for tests of the chemicals to be registered. 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 the complexity of the information technology (IT) tools, companies were able to address it through attendance to training of the personnel-responsible in the REACH compliance. Companies had also support from their IT department in addressing REACH-IT matters.

In accordance with article 31 (5) of the 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." 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. According to ECHA, 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. One company

provided ESDS on some substances only since they were still waiting for the final version of the exposure scenario (Figure 9). Another manufacturer company did not provide ESDS to customers since their suppliers did not provide them with the ESDS as well.

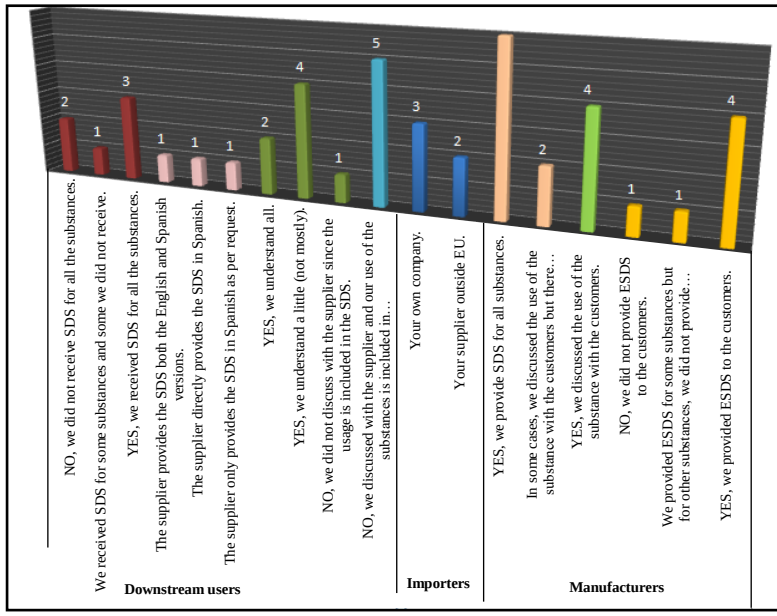
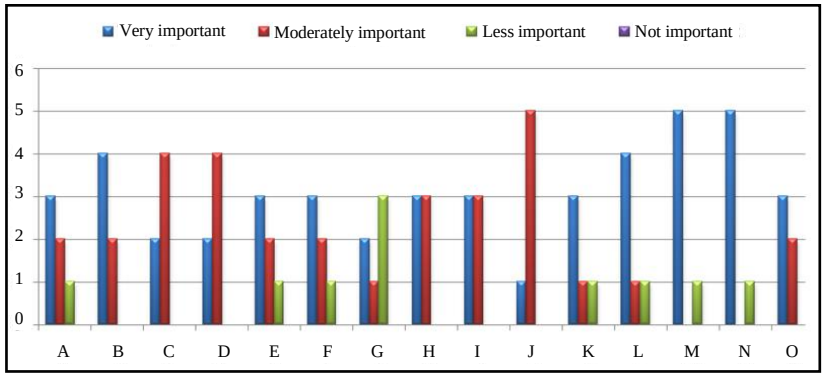


Figure 9. Spain: CLP issues and concerns of respondents in Spain

Five out of the total six respondents in Spain recognized that joint submission of data by multiple registrants and cost-sharing for tests were the most important aspects in terms of information and communication in complying with the REACH regulation (Figure 10). The joint submission of data conforms to the OSOR principle.

To come up with the means of the answers provided by the respondents (Figure 11), the classification of importance of the different schemes in terms of information and communication aspect in complying with the REACH regulation was given values (4 = very important, 3 = moderately important, 2 = less important, 1 = not important).



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

The top two results as shown in Figure 10 is consistent with the results in Figure 11, wherein the respondents in Spain gave importance on cost-sharing for tests and the joint submission of data by registrants in accordance with article 11 of the regulation. Generally, the respondents found all the schemes cited in Figure 11 as significantly important in complying with the REACH regulation. Moreover, the information from ECHA's website had proven to be functional and useful to the companies.

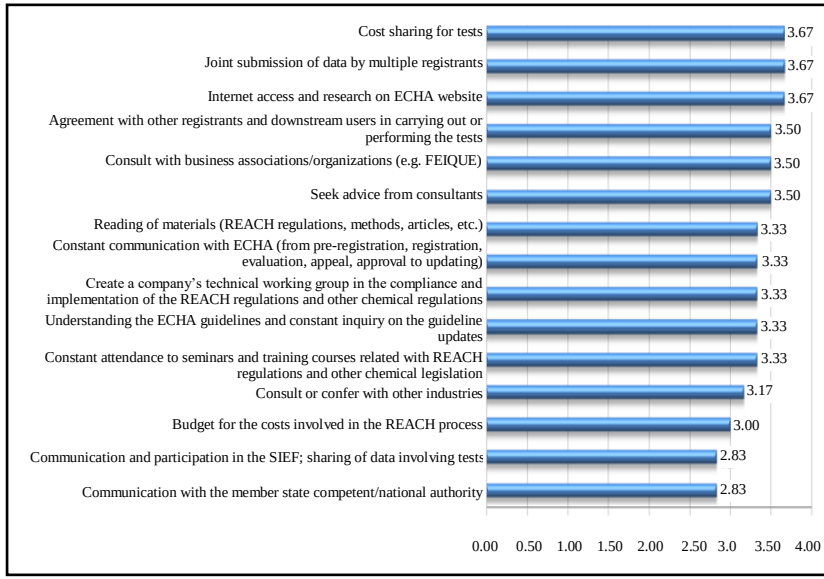


Figure 11. Spain: information and communication schemes in complying with the REACH regulation

In terms of technical aspects in complying with the REACH regulation, the respondents considered all the technical methods as vital aspects in complying with the regulation (Figure 12), wherein the following approaches were defined as the most important in fulfilling the REACH regulation: (a) access for workers to information of the chemicals that they use or may be exposed to in course of their work; (b) preparation of checklist for the registration requirements, technical dossier, and updated SDS in accordance with Commission Regulation (EU) No. 2015/830; and (c) prepare checklist for the registration requirements.

For the conduct of in vivo and in vitro tests however, three of the six company respondents agreed that these tests were 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."

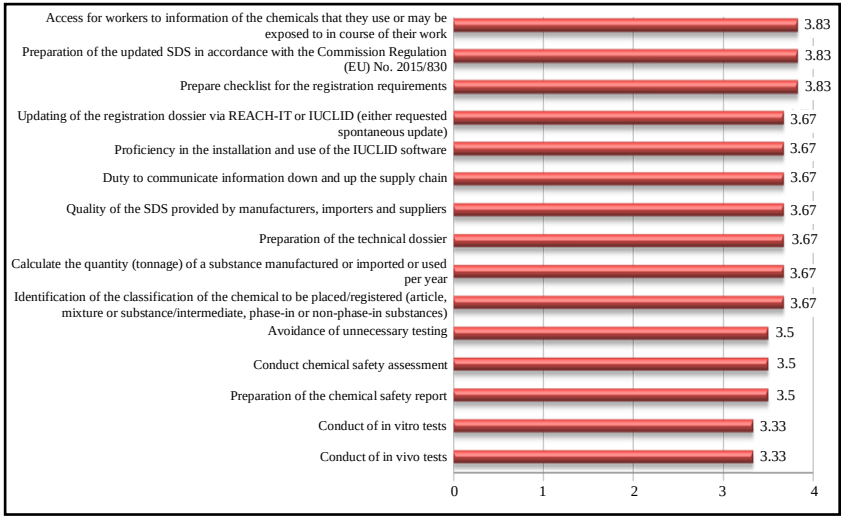


Figure 12. Spain: technical schemes in complying with the REACH regulation

3.2 Portugal

Portugal had 20 respondent companies and all were private entities, wherein seven were large-scale, eight medium-scale and five small-scale. From the respondents, 15 of the chemical companies whose marketing operation was mainly worldwide, while companies whose market reach were only within the EU and Portugal comprised 10 and 15%, respectively. This data agreed with the fact that the chemical industry in Portugal brings about 5.4% of industrial revenue (CEFIC, 2017) creating a significant impact in the Portuguese economy and generating 5.2% of the total exports (Instituto Nacional de Estatística, 2015). Seven companies belonged in the specialty chemicals sector while four entities were from the polymers and basic inorganics sectors. The consumer chemicals sector consisted of two companies and the petrochemicals were only one among respondent companies. The remaining five companies were from the basic and other organics, peroxides and pharmaceuticals.

The results revealed that most respondents classified their companies as downstream users comprising 17 companies of the total respondents. This was followed by 12 respondents classifying their companies as manufacturers. Ten of the respondents classified their companies as importers or/and only representatives of non-community manufactures (EEA-based only representatives). It was observed that substances/intermediates had the highest total usage, production, and importation followed by mixtures and lastly articles.

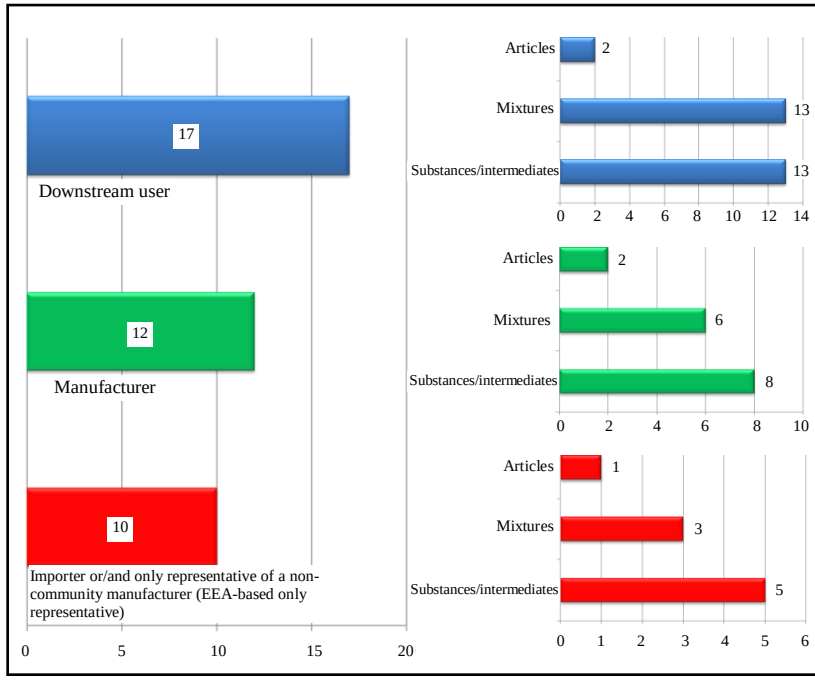


Figure 13. Portugal: company's role in the REACH regulation (type and quantity of substances applied for registration, authorization, and restriction)

Most of the respondents had already registered their chemicals with ECHA, wherein 13 fulfilled the registration of all their substances, and five responded that some of their substances were registered although they still had some substances that need to be registered (Figure 14). Only one of the company respondents still had substances that were yet to be registered. Half of the respondents were either engaged in the manufacture, import or use of substances of very high concern. Three of the respondents engaged with SVHC had already applied and granted authorization by ECHA. Only one of the respondents still have not applied for authorization of their substance but was planning to apply. However, five of the companies handling SVHC would 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 was to replace the SVHC as their research and development were working on finding an appropriate substitution.

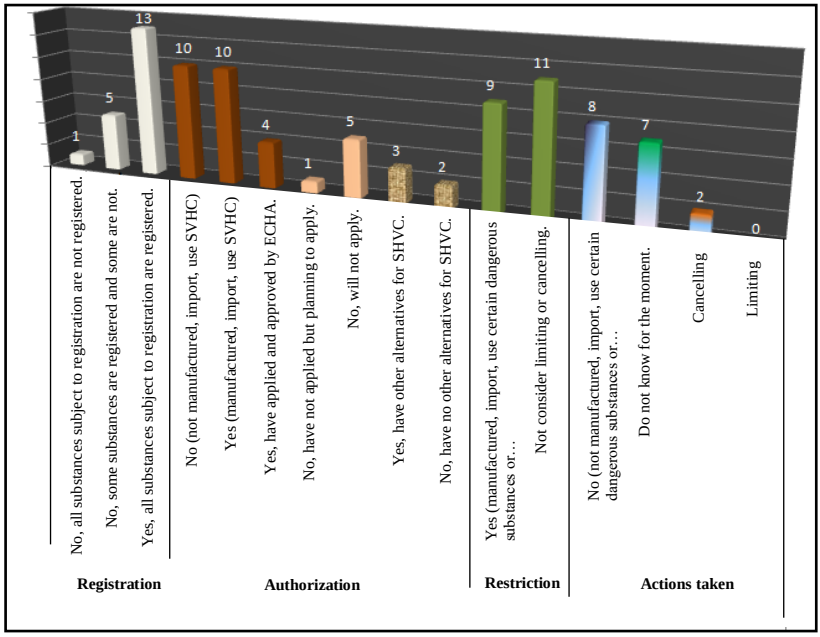


Figure 14. Portugal: company's role in the REACH regulation (type and quantity of substances applied for registration, authorization, and restriction)

Nine of the respondents were either engaged in the manufacture or importing and using of certain dangerous substances as listed in annex XVII of Regulation (EC) No. 1907/20016 or substances restricted under REACH. The best practice carried out by these companies was that their substances under restrictions were registered with ECHA. Due to the registration obligation under REACH and its related costs, two of the respondents had considered canceling either the manufacture or import of certain substances. Seven of the respondents had not decided to cancel, limit or not to cancel. The remaining eight respondents had not considered limiting or cancelling the manufacture/import/use of certain substances or reducing the volumes of the substances.

In terms of methods applied in the registration of substances, almost two thirds (five out of eight) respondents had carried out or will carry out the joint process in the REACH registration while the remaining three had individually registered their substances. Table 1 detailed the basis for the choice of method by the companies. Cost-related efficiency was the common reason for the companies that jointly carried out the registration process. For industry, duplication of work was minimized and unnecessary animal testing was

avoided resulting in less regulatory costs (ECHA, 2016a). A company respondent who previously applied individually for the registration had shifted to joint submission since the SIEF was established. According to article 29 of the REACH regulation "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 SIEF".

Table 1. Portugal: Methods applied by companies in the registration of substances (preparation of dossier, complying with additional requirements, attendance to seminars)

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: OSOR.	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	-

Further, the Commission Implementing Regulation on joint submission of data and data-sharing entered into force last 26 January 2016 (ECHA, 2016b). This regulation clarified that ECHA ensured that the OSOR principle was applied, whereby registrants of the same substance have to register the substance jointly (ECHA, 2016b). 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 (ECHA, 2016b). With this system, it was no longer possible to submit an individual registration for a substance where a joint submission exists (ECHA, 2016b).

All of the respondents had employees responsible for addressing REACH-related issues in their company. In 2016, sixteen of the respondents had attended these professional sessions. Four respondents had not attended a

single professional session on REACH-related matters. The main reasons cited by the respondents were the costs associated with attendance and lack of time indicating that the responsibility was on the supplier and lack of information from the organizers.

Sources of information on REACH regulation were essential factors for companies to have effective compliance with the regulation. The company respondents received most information from ECHA, business associations, legislation, and the internet as shown in Figure 15. The result also revealed that respondents agreed that ECHA had an efficient updating system (Figure 16).

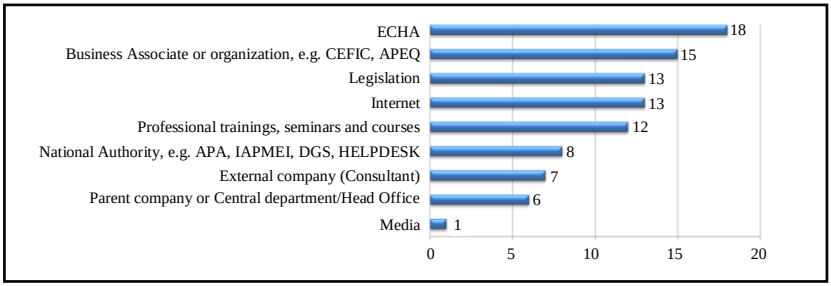


Figure 15. Portugal: respondents' sources of information on REACH regulation

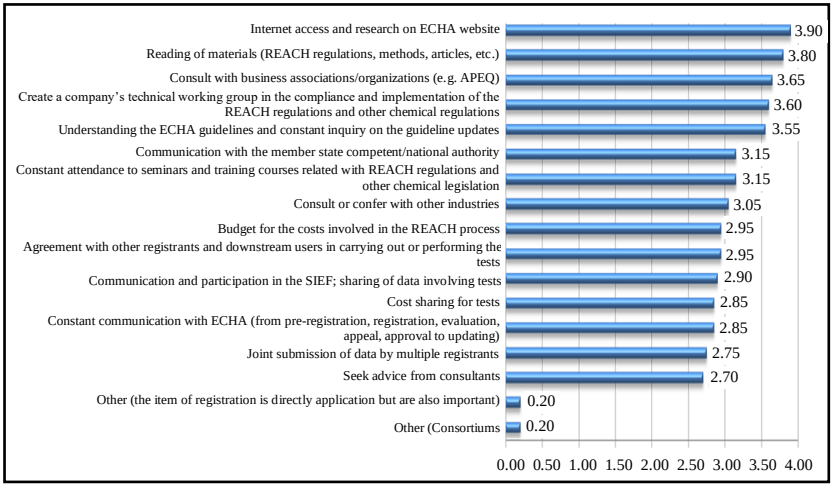


Figure 16. Portugal: information and communication schemes in complying with the REACH regulation

ECHA's website provided 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 (Proplast, 2011). The company's main concern in complying with the regulation was to verify that all the raw materials supplied to them did not contain SVHC (Proplast, 2011). 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 (Proplast, 2011). 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 (Proplast, 2011). The SIEF helped and facilitated 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 shared data wherein 98% of the substances were registered jointly (ECHA, 2017).

Seven out of the 20 respondents reported 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 were handled by the company's headquarters. Only five had 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 were managed by the company's headquarter office. The formation of a task force supported 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. They were able to address these issues with ECHA support. According to the companies, ECHA provided good support despite the complexity of REACH and IT tools. Respondents were able to address the concern on costs for tests by defining a budget for the process and joining consortia – another indication of joint submission efficiency and effectiveness. This provided an additional indication that the SIEF and OSOR principle was working effectively.

Based on ECHA's report, CLP had been ensuring that the hazards presented by chemicals were clearly communicated to workers and consumers through the classification and labeling of chemicals since 2009. As illustrated in Figure 18, 10 of the downstream user respondents received SDS for all the substances from their suppliers while five respondents either received or not for some substances. The remaining two downstream users experienced not receiving SDS for all substances. Six out of the seven downstream users who did not receive SDS warned their suppliers to provide the correct SDS version or else

there would be no order on the next procurement. Most of the companies that received the SDS for all the substances had been directly provided with the SDS in Portuguese by their suppliers. Further, the majority of the downstream users fully understood the information of the safe use of chemicals in the SDS provided by the suppliers while only one understood mostly all the information.

Figure 17 also showed that six out of the 10 importer respondents replied that the SDS was being prepared by themselves and the other four respondents by their suppliers outside the EU. Eleven of the manufacturer respondents provided SDS to the downstream users.

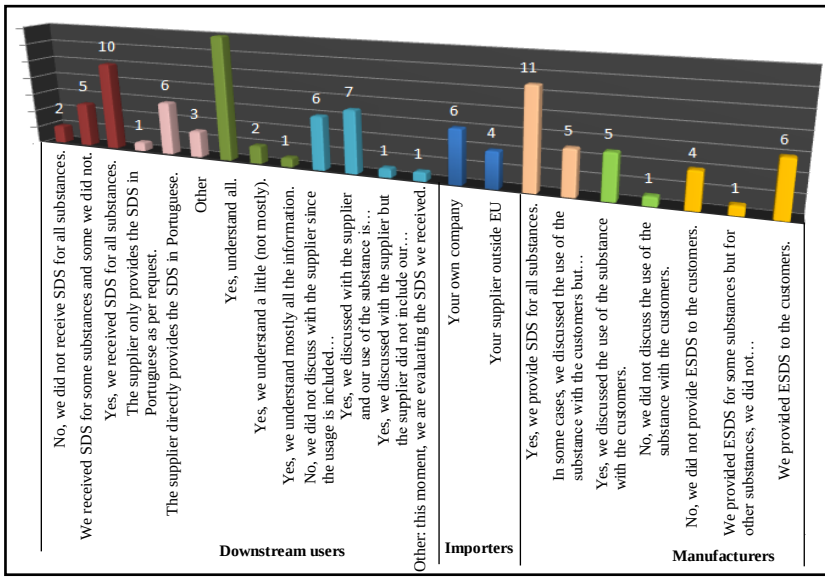


Figure 17. Portugal: CLP issues and concerns of respondents

Five discussed the use of the substance with the customers, and five expounded the use of the substance in some cases only. There was only one manufacturer who did not elaborate the use of the substance with the customers since the company produced antibiotic which is not framed with the regulation. The remaining four manufacturers did not provide ESDS to customers since they produced antibiotics, articles, and intermediates. 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 (ECHA, 2016c). Antibiotics are not framed by the REACH regulation. It is

not generally desirable to compile SDSs for articles (ECHA, 2015). 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 (ECHA, 2016a).

When it comes to the technical aspects in complying with the regulation, the majority of the company respondents recognized that all the technical methods were significantly important except for the conduct of in-vivo tests (Figure 18). Avoidance of animal testing or unnecessary testing was well defined in article 25 of the REACH regulation, wherein testing of vertebrate animals shall be undertaken only as a last resort.

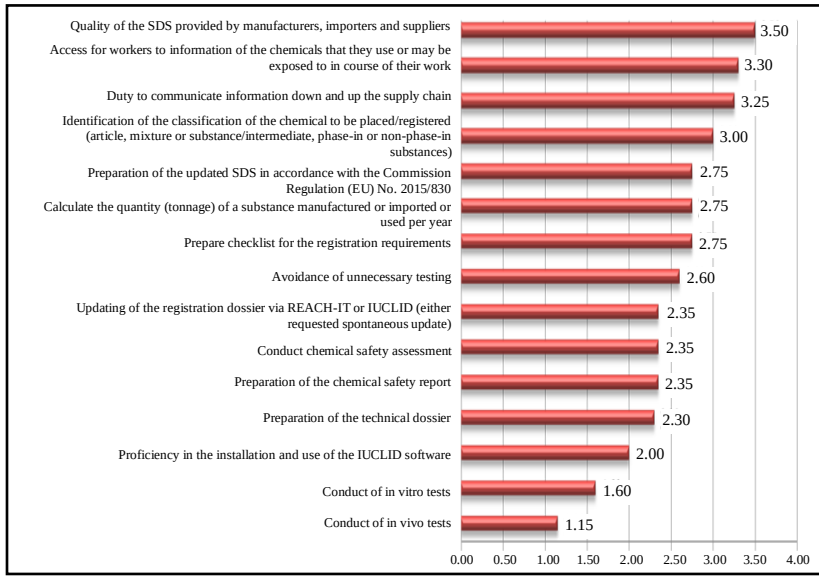


Figure 18. Portugal: technical schemes in complying with the regulation

ECHA published on 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 advised 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 (ECHA, 2016). Based on ECHA's database of REACH registrations submitted by companies with

over 6000 substances, the application of alternatives to animal testing had been widely used by the registrants (ECHA, 2107).

4. Conclusion and Recommendation

Communication issues impact the compliance process with REACH regulation. The study revealed that communication issues occur among potential registrants, downstream users and third parties participating in the SIEF. Such issues emanate from various factors such as failing to reach an agreement data sharing for registered substances, cost-sharing to be incurred for substance testing especially in the absence of a defined budget for such testing. Downstream users were also concern about the lack of response from suppliers in the provision SDS for substance as well as the correction of errors in the SDS. Companies also had issues in communicating with ECHA with regards to the use, updating and rectifying REACH-IT tools.

The provision of SDS to downstream users and other clients should be mandatory. Among the issues and concerns being brought out in the study was the provision of SDS from suppliers. Survey respondents recognized the importance of having a quality and user-friendly SDS as a mandatory requirement for suppliers to improve the safe handling and use of chemicals in the supply chain.

Affiliation in a consortium is considered a best practice. Among the best practices recognized by respondents to comply with REACH regulation was affiliation or joining in a consortium and participate in the joint registration and submission of dossiers. Respondents identified such practices as the most efficient means of complying with REACH regulations. They described the practice of joint registration and submission provides an efficient means of coping with the demands of the regulations and one way of managing cost through cost-sharing. Respondents also recognized the practice as a means of ensuring information sharing among participating companies.

Massive information source gathering is key to REACH compliance. Respondents recognized the importance of having a massive information source gathering in the REACH regulation compliance process. They identified these sources coming from the ECHA, business associations, national authorities, consultants, parent companies, head offices, and the media to catalyze information gatherings. Respondents also identified

attendance to seminars, professional training, short courses, legislation as well as the internet as potential material sources essential for effectively complying with REACH regulations.

ECHA's proactive support is regarded as essential to REACH compliance. Another key factor that survey respondents recognized effective in the REACH regulation compliance was ECHA's active and valuable support mechanism as the compliance of chemical industries to the REACH regulation particularly rely on the proactive support of the agency extended to chemical industries.

Chemical industries in Portugal and Spain both experience the same issues and concerns but with varying difficulty levels. This was shown in how respondents differed in some elements. In responding to individual questions, respondents from Spain viewed that communication with member state competent/national authority less important as to that of respondents from Portugal. Portuguese respondents viewed the conduct of in-vivo and in-vitro tests as less or not as important as to their Spanish counterparts that viewed the conduct of these tests as very important. While it was not stated in the results, these differing views can be attributed to a range of factors that these chemical industries were involved with, which was a key to their operations.

Results showed that respondents from Portugal and Spain applied similar strategies to comply with REACH regulation. While there were different circumstances involved as stated in the results and discussions, respondents practiced identical methods and processes to comply with REACH regulation.

After a thorough analysis of data, the following recommendations are hereby made:

4.1 Continuation and Strengthening of Existing Systems

Among the best practices recognized by respondent companies in complying with REACH regulation was affiliation in a consortium including participating in joint registration and submission of dossiers. Hence, it is recommended to continue the best practice and strengthen the existing systems among chemical industries. This includes the formation of product-specific consortia to enable various stakeholders to pool together different resources to effectively and efficiently comply with the regulations and will eventually build technical and scientific advantages of the consortia.

4.2 Development of an Agreed System to Facilitate Information Exchange

As part of SIEF, potential registrants and data holders should devise an agreed system where stakeholders can effectively facilitate the exchange of information and avoid duplication of study or vertebrate animal testing. Such a system may include the agreed method on the classification and labeling of materials, sharing of existing data and agreed cost. There should also be an agreement in advance (prior to forming a consortium) on the potential conflicting issues that could affect cooperation among registrants. Identifying who the lead and co-registrant is also an important aspect of any planned SIEF or consortium.

4.3 Laying out of Essential Guidelines on Cost-Sharing

It is recommended 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. Such practice can eventually straighten potential gray areas. Cooperating registrants should also be able to determine mechanisms on cost distribution, notably on the product or animal testing.

4.4 Establishment of Effective Mechanisms to Address Customer Complaints and Inquiries to Suppliers

It is recommended that consortium should establish a mechanism to assist individual members to compel suppliers to provide timely and accurate feedback to customer complaints and inquiries. The establishment of helpdesks within a consortium can provide members the needed assistance as well as the establishment of ECHA helpdesk to compel suppliers to provide essential information on the safe handling and usage of their products.

4.5 Provision of Periodic Capacity Building for Regulatory Compliance Personnel on REACH-Related IT Tools

There is a need to provide periodic training and seminars to regulatory compliance personnel on REACH IT-related tools to equip them with the needed skills for them to satisfy the REACH-IT tools requirement and the REACH regulation as a whole.

4.6 Identification and Establishment of a Task Force or Technical Working Group for REACH-Related Matters

It is recommended that the identification and establishment of a company task force or technical working group for REACH-related matters to address all aspects of the regulations. Such task force may be composed of legal, technical, administrative, financial and IT personnel to handle the range of issues and concerns in the compliance process and offer a spectrum of best possible solutions in the orderly and timely submission and compliance of the REACH regulation.

4.7 Establishment of Clear Guidelines and Strict Implementation in the Provision of SDS from Suppliers

Chemical industries should establish clear guidelines and policies to suppliers and the industries themselves that inclusion and provision of SDS are mandatory. As a form of good practice, the mandatory provision of quality and straight-forward SDS from suppliers and to downstream users and clients ensures the safety of all persons along the supply chain involved in the handling of chemicals.

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