

# **Segmentation of potential SME Market for ECHA Cloud Services for REACH Registration**

**Final Segmentation Report**

prepared for

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# Segmentation of potential SME Market for ECHA Cloud Services for REACH Registration

August 2017

## Final Segmentation Report

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## **Disclaimer**

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## List of Abbreviations

|                |  |
|----------------|--|
| <b>CSM</b>     | Critical Success Factor  |
| <b>EBIT</b>    | Earnings Before Interest and Taxes   |
| <b>ECHA</b>    | European Chemicals Agency  |
| <b>EEA</b>     | European Economic Area   |
| <b>EU</b>      | European Union   |
| <b>H&amp;S</b> | Health and Safety  |
| <b>HSE</b>     | Health and Safety Executive  |
| <b>IPR</b>     | Intellectual Property Rights   |
| <b>IUCLID</b>  | International Uniform Chemical Information Database  |
| <b>KCF</b>     | Key Component Manufacturer   |
| <b>LoA</b>     | Letter of Access   |
| <b>PR</b>      | Public Relations   |
| <b>REACH</b>   | Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals |
| <b>SIEF</b>    | Substance Information Exchange Forum   |
| <b>SKU</b>     | Stock Keeping Unit   |
| <b>SME</b>     | Small and Medium-sized Enterprise  |
| <b>UEAPME</b>  | European Association of Craft, Small and Medium-sized Enterprises  |
| <b>UK</b>      | United Kingdom   |

## Executive Summary

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All existing chemical substances manufactured in, or imported into, the European Economic Area (EEA) in quantities of between one and 100 tonnes per year need to be registered by 31 May 2018. Many registrants are expected to be inexperienced with regulatory work; some of them may be located outside the chemicals sector, and there will be more micro, small and medium-sized enterprises (SMEs) than for the previous registration deadlines. In order to alleviate the technical demand on SMEs and further support them in fulfilling their obligations under REACH, ECHA intends to offer SMEs the functionalities of IUCLID, the mandatory tool for preparing the registration dossiers, from an ECHA hosted and managed infrastructure (a product called "ECHA Cloud Services"). To ensure that a sufficiently large community of SMEs decide to adopt the ECHA Cloud Services as soon as it is released to the public, ECHA commissioned the present market segmentation study.

At first, the project team analysed data from the Eurostat Structural Business Statistics and from the REACH-IT pre-registration database provided by ECHA, in order to develop a hypothesis on the market structure and the SME target population. The hypothesis has been refined through semi-structured interviews with industry experts, in order to define potential market segments, establish the decision drivers and identify the owners of the decision of using, or not, the ECHA Cloud Services. The market segments have been validated through interviews with SMEs and populated through an EU-wide survey (to which a total of 732 individual, and mostly complete, responses have been received).

During the stakeholder consultation, it became apparent that the preparation of the registration dossier via IUCLID is only a component of the registration process and cannot be seen in isolation. Many SMEs will never use the software directly, instead outsourcing part or the whole registration process to specialist contractors. Therefore, the project team looked into the benefits sought by the actors in terms of the registration process as a whole, as well as those sought on the use of the IUCLID software.

For the purposes of this project, we distinguished between three types of segments:

- **Product builder and supplier segments**, which manufacture and import chemical substances (products) and which therefore own registration duties. These have been further defined by their attitudes towards registration:
  - **Planners.** The Planners are companies that set apart resources for the registration of their substance portfolio and will phase the registration to smooth cash-flow and EBIT impact. Typically, they have in-house regulation expertise and understand the registration process, either because they already registered substances for the previous deadline or because they attended training organised by industry associations and public authorities. They may carry out the registration process in-house, but many will outsource parts of it, either to access specialist expertise or due to limited in-house resources. Planners tend to be medium-sized chemical manufacturers and distributors, with previous experience of registration of substances. Only around 36% of small enterprises declared that they already have a financial budget in place for the registration. The percentage goes further down (23%) when considering micro-enterprises with a financial plan ready. The project team estimates Planners constitute 35-40% of the market.
  - **High Stock Keeping Units (SKUs).** The High SKUs have their competitive advantage on being able to supply a large range of products, at very short notice, to their customers. They tend to be small and medium-sized manufacturers and distributors of chemical products. The segment captures enterprises with a deep understanding of their customer

and product applications (typically, formulators such as dye importers) and companies that operate as chemical distributors in localised chemical clusters, which may or may not have the same deep knowledge of customers' applications. The project team's best estimate is that they represent between 15-25% of the SME target population, overlapping with the Strugglers segment.

- **Key Component Manufacturers (KCFs).** The KCFs tend to be innovative companies supplying specialty chemicals with a high added value that are not easily sourced. Their clients are dependent on guaranteed supply and will therefore subsidise or pay for registration. Most of the KCFs do not have previous experience with the registration process, mainly supplying substances in low tonnages. Typically, they are medium-sized chemical manufacturers found in sophisticated and complex supply chains (e.g. aerospace, automotive).
  - **Strugglers.** The Strugglers are all those companies that are still verifying whether they have to register their substances and did not set apart resources for registration purposes. Typically, they are microenterprises and small companies which, historically, have not had any substantial budget for regulatory compliance and these costs have never figured in their business model. Over 50% of Strugglers operate in industries that are not classified as chemical activities. The project team's best estimate is that Strugglers represent between 25-30% of the SME target population, overlapping with the No-Hoppers segment.
  - **No-Hoppers.** These are companies which have gone (or will go) out of business once they have verified and understood the cost of registration of their substances. These tend to be microenterprises and small companies, evenly distributed amongst the industrial sectors and across the EEA. No-Hoppers were often prudently run family businesses and they blame the European Union for hitting them with, what they perceive to be, a burdensome Regulation designed for large organisations. The project team's best estimate is that, at the moment, they constitute around 15% of what was the SME target population. The final size of this segment, at June 2018, will be determined by the effectiveness of the actions taken by, not only ECHA, but also the European Commission and the national and regional authorities.
  - **Ignorers.** These companies either believe they do not have registration duties or have decided to take the risk because of lax enforcement.
- **Advice givers**, which assist and guide the above especially on whether there is a requirement to register. Further distinguished between:
    - **Trainers**
    - **Advice givers**
  - **Experts**, further divided into:
    - **Service providers**, which can act as contractors for components of the registration process (QSAR modelling, toxicology testing, IT services) or act as a "one stop shop" and undertake the whole process on behalf of the client (consultants and sourcing and registration service providers).
    - **In-house experts**, mainly amongst the Planners segment.

The key issue for many SMEs is the cost of registration and, in particular, the cost of the Letters of Access and of participating in the Substance Information Exchange Forums (SIEFs). ECHA has limited powers on this matter, but should raise awareness amongst the European Commission and the Member States Competent Authorities on the struggles that SMEs are facing for this registration

*deadline and on the potential impacts on competitiveness and employment. Nevertheless, various possibilities within ECHA's remit are suggested:*

- *Encourage the European Commission and the Member States to mobilise resources to support the registration of substances by SMEs for the 2018 deadline;*
- *Provide information on available funding for compliance on the ECHA website, along with examples of completed successful applications;*
- *Require the notification of the SIEF costs and publish the information;*
- *Provide best practice examples of SIEF pricing;*
- *Provide successful stories of SMEs that challenged SIEF pricing;*
- *Provide examples of well-justified opt out cases;*
- *Improve communication on the ease of challenging SIEF pricing and on the possibility to opt out on the basis of the failure to adhere to the principles of fairness, transparency and non-discrimination defined in the Implementing Regulation on joint submission and data-sharing;*
- *Allow the use of data obtained from in vitro and in silico studies when these are not of an inferior quality to data obtained from in vivo studies;*
- *Provide best practice examples of consultancies pricing for registration services.*

*With regard to the ECHA Cloud Services, the Agency will have to carefully consider how to improve the perception of privacy and security of the database by the stakeholders. A confidentiality agreement may be signed between ECHA and the registrants, granting (or not) permission to the Agency to access pre-submission data. ECHA could also communicate the key security features of its IT system (disaster recovering tests, reports of independent auditors and of internal audits on security features).*



# 1 Introduction

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## 1.1 Overview

The objective of the study was to obtain detailed market segmentation information on Small and Medium-sized Enterprises (SMEs) potentially interested in using the cloud services that are being developed<sup>1</sup> by the European Chemicals Agency (ECHA), in particular, the functionalities of the IUCLID software, the mandatory tool for preparing registration dossiers. This, in order to support the Agency in its planning of the promotional activities of the cloud services and, more generally, provide ECHA with a better understanding of the chemical industry and the related market.

This project follows on from needs identified in the 2013 REACH review. The last registration deadline (31 May 2018) concerns companies that manufacture or import substances in quantities between 1-100 tonnes a year and it is expected to be quite different from the 2010 and 2013 deadlines: ECHA is expecting to receive around 60,000 registration dossiers for up to 25,000 unique substances, three times as many registration dossiers and substances with many more SMEs and importers likely to be involved.

One of the key challenges identified with the 2018 registration is the need to inform new registrants of their duties and how to better comply with them, including providing information on the already existing support and the development of further support where gaps are identified.

This report provides information on the market segments identified, their specific needs and their gaps in knowledge and understanding of the REACH registration requirements. It also provides recommendations on how to fill the gaps and on how to best reach each target.

## 1.2 Approach

The study had to meet three specific objectives:

- Work Package 1: provide detailed information of the potential SME target population;
- Work Package 2: develop understanding on motivation, means and key messages for reaching out to identified segments;
- Work Package 3: validate and present the results.

The project team followed a four-stage approach:

**Stage 1: Review of available data.** Building on the findings of CSES et al (2015), the project team consulted the Eurostat Structural Business Statistics database and analysed an extract of the REACH-IT pre-registration database provided by ECHA.

**Stage 2: Discussion with industry experts.** The project team carried out semi-structured interviews with industry experts in order to develop a hypothesis in terms of the market map and market segments, identify the decision makers and establish the factors which might affect their decision on whether or not to adopt the cloud service.

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<sup>1</sup> As of June 2017.

**Stage 3: Validation of the market map and market segments.** The project team carried out interviews of actors within each segment in order to verify the market hypothesis and understand the attitudes (behavioural factors) of the companies within each segment towards the registration process and IUCLID.

**Stage 4: EU-wide survey of potential registrants.** In the final stage of the project, an EU-wide survey was launched to populate the segments and link behavioural factors to demographics information.

A final validation workshop was held in Helsinki on 16 June 2017 to present and discuss the results with the Registration Unit experts at ECHA.

This report is structured as follows:

- Section 2 presents the methodology followed to gain a detailed understanding of the potential SME target population (Stage 1). The analysis of Eurostat data is presented in Section 2.1 and the analysis of the REACH IT pre-registration database is provided in Section 2.2. Stages 2 and 3 (expert and SME interviews) are described in Section 2.3 and 2.4, while Section 2.5 details the results of the survey;
- Section 3 presents the market segments and the segment audits;
- Section 4 provides hints for the communication strategy and some recommendations.

In addition, Annex 1 provides the guide followed for interviewing SMEs, Annex 2 the survey questionnaire and Annex 3 the comments received through the survey and via phone/email.

## 2 Potential SME Target Population

### 2.1 Analysis of Eurostat Data

The first objective was to develop an understanding of the population of existing SMEs in the European Union and the European Economic Area affected by REACH. CSES et al (2015) identified some key issues for SMEs in terms of their ability to comply with registration requirements and their needs in terms of tools and support. One of the important findings of this study was that 27% of all firms that responded to the telephone interviews and 22% that responded to the online survey said that they considered withdrawal or non-registration. Fourteen percent of the companies that responded to the telephone interviews and 15% of those that replied to the online survey said that their products were no longer profitable.

More than 90% of respondents to the surveys launched in the context of CSES et al (2015) had used ECHA supporting instruments, with around 39% responding that they found these instruments to be extremely or very useful. Some of the key issues identified with these instruments were the need for supporting structure in national languages, and the need to ensure that the instruments are suited to SMEs.

EC (2015)<sup>2</sup> provides statistics for SMEs and large enterprises in the EU28 in 2014 (Table 2-1). Table 2-2 presents the number and percentage of SMEs<sup>3</sup> in industrial sectors where companies are likely to have REACH registration obligations (manufacturers or importers of chemicals on the EU market).

| Factor                    | Micros                | Small                 | Medium                | SMEs                  | Large                 | Total       |
|---------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-------------|
| Number of enterprises     | 20,710,324<br>(92.7%) | 1,373,365<br>(6.1%)   | 224,811<br>(1.0%)     | 22,308,500<br>(99.8%) | 43,766<br>(0.2%)      | 22,352,260  |
| Number of people employed | 39,274,088<br>(29.2%) | 27,452,716<br>(20.4%) | 23,452,412<br>(17.3%) | 89,894,216<br>(66.9%) | 44,438,724<br>(33.1%) | 134,422,944 |
| Value added in €billion   | €1,358<br>(21.1%)     | €1,169<br>(18.2%)     | €1,188<br>(18.5%)     | €3,715<br>(57.8%)     | €2,710<br>(42.2%)     | €6,425      |

| Sector  | Data      | EU28  | Norway | Switzerland |
|---|-----------|-------|--------|-------------|
| C19.2 Manufacture of refined petroleum products | Total     | 1,038 | 9      | 9           |
|   | Micro     | 588   | 9      | 2           |
|   | Small     | 247   | 0      | 4           |
|   | Medium    | 110   | 0      | 1           |
|   | Large     | 92    | 0      | 3           |
|   | % of SMEs | 91.0% | 100.0% | 77.8%       |

<sup>2</sup> EC (2015): Annual Report on European SMEs 2014/2015, available at: <http://ec.europa.eu/DocsRoom/documents/16341/attachments/2/translations/en/renditions/native> on 15 November 2016.

<sup>3</sup> Where SME is defined by number of employees, following the EU definition, available here: [http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition\\_en](http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en)

**Table 2-2: Numbers and percentages of SMEs in REACH registrants industrial sectors in the EU28, Norway and Switzerland in 2013-2014\***

| Sector   | Data      | EU28                | Norway           | Switzerland |
|--|-----------|---------------------|------------------|-------------|
| C20 Manufacture of chemicals and chemical products                               | Total     | 28,329              | 202              | 446         |
|  | Micro     | 18,000              | 141              | 169         |
|  | Small     | 6,080               | 24               | 160         |
|  | Medium    | 2,870               | 30               | 94          |
|  | Large     | 800 <sup>+</sup>    | 7                | 23          |
|  | % of SMEs | 95.1%               | 96.5%            | 94.8%       |
| C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations | Total     | 4,200               | 32               | 181         |
|  | Micro     | 2,024               | 17               | 57          |
|  | Small     | 960                 | 6                | 47          |
|  | Medium    | 770                 | 6                | 51          |
|  | Large     | 460                 | 3                | 26          |
|  | % of SMEs | 89.4%               | 90.6%            | 85.6%       |
| C24.1 Manufacture of basic iron and steel and of ferro-alloys                    | Total     | 2,548               | 15               | 15          |
|  | Micro     | 1,685               | 6                | 4           |
|  | Small     | 498                 | 3                | 6           |
|  | Medium    | 178                 | 4                | 3           |
|  | Large     | 189                 | 2                | 2           |
|  | % of SMEs | 92.7%               | 86.7%            | 86.7%       |
| C24.4 Manufacture of basic precious and other non-ferrous metals                 | Total     | 3,500               | 22               | 49          |
|  | Micro     | 2,370 <sup>+</sup>  | 6                | 19          |
|  | Small     | 583                 | 2                | 18          |
|  | Medium    | 394                 | 7                | 7           |
|  | Large     | 174 <sup>+</sup>    | 7                | 5           |
|  | % of SMEs | 95.6%               | 68.2%            | 89.8%       |
| G46.75 Wholesale of chemical products <sup>4</sup>                               | Total     | 27,590 <sup>^</sup> | 271 <sup>^</sup> | :           |
|  | Micro     | 23,614 <sup>E</sup> | 231 <sup>E</sup> | :           |
|  | Small     | 3,412 <sup>E</sup>  | 33 <sup>E</sup>  | :           |
|  | Medium    | 498 <sup>E</sup>    | 5 <sup>E</sup>   | :           |
|  | Large     | 67 <sup>E</sup>     | 1 <sup>E</sup>   | :           |
|  | % of SMEs | 99.8%               | 99.6%            | :           |

*Notes: \*All data for the EU28 refer to 2013, unless otherwise specified. All data for Norway and Switzerland to 2014, unless otherwise specified. <sup>+</sup>2012 data. <sup>^</sup>2014 data. <sup>E</sup>Estimated*

Table 2-2 suggests that there may be around 35,000 SMEs with REACH registration duties. Not all the companies classified with those six NACE codes presented in the table will have to register for the 2018 deadline. However, many companies classified with different NACE codes may act as importers of small tonnages of chemicals and will therefore have to register by 2018. Table 2-3 presents the list of these NACE codes<sup>5</sup>. It is not possible to estimate the actual percentages of companies that would have to register by 2018 within each industrial sector (by NACE code).

<sup>4</sup> The number of enterprises in G46.75 by chemical size has been estimated by applying the percentages available for the 3-digits NACE code G46.7 “Other specialised wholesale” to the total number of enterprises in G46.75.

<sup>5</sup> An initial list has been provided by ECHA experts. This has been complemented by industry experts that have been interviewed for the purpose of the market segmentation. A1 “Crop and animal production, hunting and related service activities” has been added by the project team, as analysing the French nanomaterials notification system, one of the finding has been that many dyes, some of which may be in the nano-form, are used in this sector.



| Table 2-3: NACE Codes of companies with REACH Registration duties |   |
|---|---|
| NACE Code   | Description   |
| A1  | Crop and animal production, hunting and related service activities  |
| B5  | Mining of coal and lignite  |
| B6  | Extraction of crude petroleum and natural gas   |
| B7  | Mining of metal ores  |
| B8  | Other mining and quarrying  |
| B9  | Mining support service activities   |
| C10.4   | Manufacture of vegetable and animal oils and fats   |
| C11   | Manufacture of beverages  |
| C12   | Manufacture of tobacco products   |
| C13   | Manufacture of textiles   |
| C14   | Manufacture of wearing apparel  |
| C15   | Manufacture of leather and related products   |
| C16   | Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials |
| C17   | Manufacture of paper and paper products   |
| C18   | Printing and reproduction of recorded media   |
| C19   | Manufacture of coke and refined petroleum products  |
| C20   | Manufacture of chemicals and chemical products  |
| C21   | Manufacture of basic pharmaceutical products and pharmaceutical preparations  |
| C22   | Manufacture of rubber and plastic products  |
| C23   | Manufacture of other non-metallic mineral products  |
| C24   | Manufacture of basic metals   |
| C25   | Manufacture of fabricated metal products, except machinery and equipment  |
| C26   | Manufacture of computer, electronic and optical products  |
| C27   | Manufacture of electrical equipment   |
| C28   | Manufacture of machinery and equipment n.e.c.   |
| C29   | Manufacture of motor vehicles, trailers and semi-trailers   |
| C30   | Manufacture of other transport equipment  |
| C31   | Manufacture of furniture  |
| C32   | Other manufacturing   |
| C33   | Repair and installation of machinery and equipment  |
| D35.2   | Manufacture of gas; distribution of gaseous fuels through mains   |
| E36   | Water collection, treatment and supply  |
| E38.2   | Waste treatment and disposal  |
| F41   | Construction of buildings   |
| F42   | Civil engineering   |
| F43   | Building completion and finishing   |
| G46   | Wholesale trade, except of motor vehicles and motorcycles   |
| G46.1.2   | Agents involved in the sale of fuels, ores, metals and industrial chemicals   |
| G46.4   | Wholesale of household goods  |
| M72   | Scientific research and development   |
| M75   | Veterinary activities   |
| Q86   | Human health activities   |

Since 1 June 2008, 6,766 registration dossiers have been submitted to ECHA for 3,510 unique substances manufactured or imported in quantities between 1 to 100 tonnes per year, of which around 15% (1,035 registration dossiers for 804 unique substances) have been submitted by SMEs<sup>6</sup>. Figure 2-1 and Figure 2-2 present the breakdown by role in the supply chain and by country.

<sup>6</sup> NONS excluded. Last update: 23 September 2016. Statistics available at: [https://echa.europa.eu/documents/10162/13629/reach\\_2018\\_result\\_stats\\_en.pdf/7b6e9643-7649-4df8-9e02-46c7481a85aa](https://echa.europa.eu/documents/10162/13629/reach_2018_result_stats_en.pdf/7b6e9643-7649-4df8-9e02-46c7481a85aa)

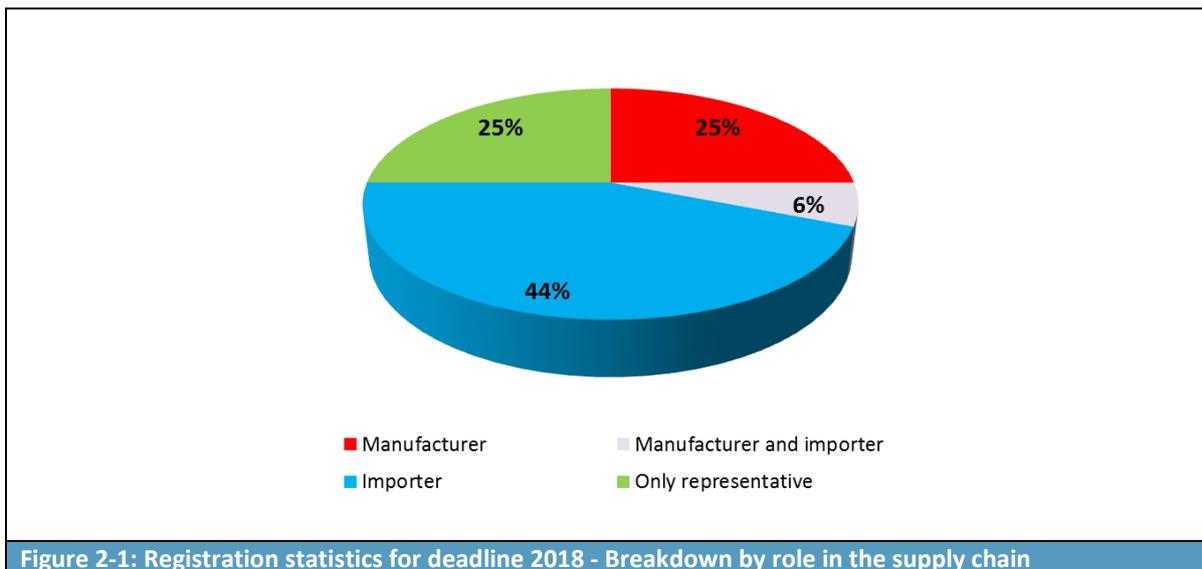


Figure 2-1: Registration statistics for deadline 2018 - Breakdown by role in the supply chain

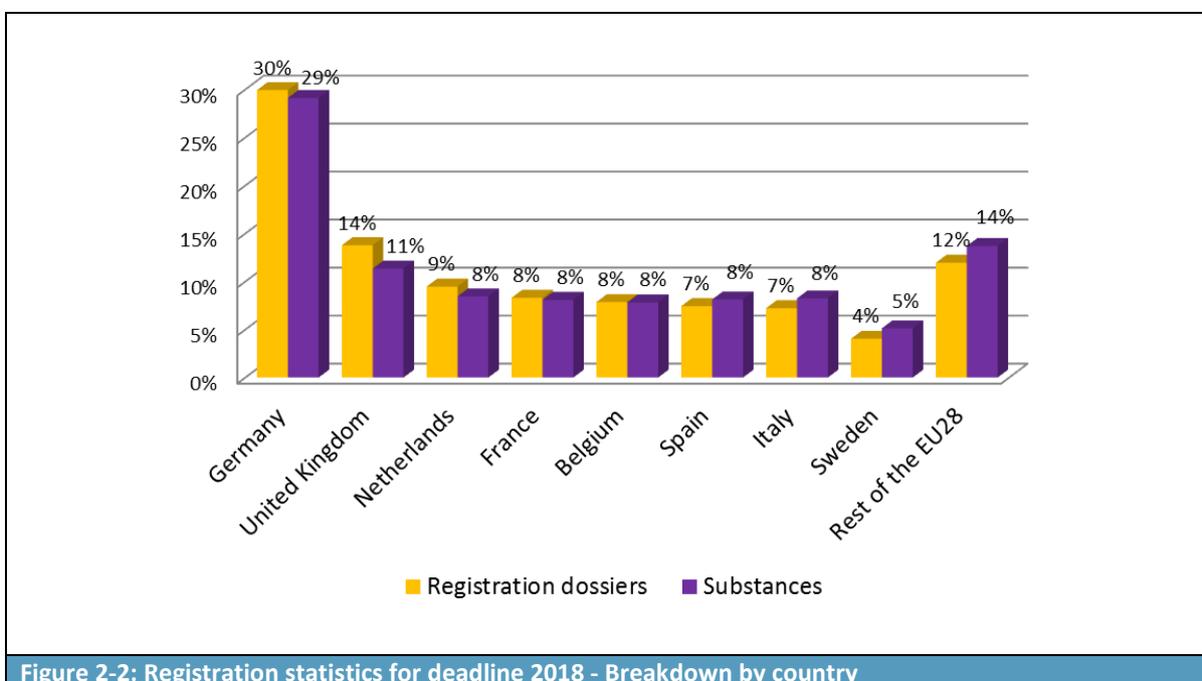


Figure 2-2: Registration statistics for deadline 2018 - Breakdown by country

## 2.2 Analysis of the REACH-IT Database

### 2.2.1 Overview of Raw Data

The data available on REACH-IT has been used to develop an initial hypothesis on how the market of SMEs registrants is structured and to develop potential segments for the final segmentation process via consultation.

The login database provided to the project team by ECHA gives 69,321 entries, with information organised in a number of database fields including:

- Name and contact details
- Role (manufacturer, importer, downstream user, only representative)

- Size of company (micro, small, medium and large)
- Numbers of pre-registrations and/or registrations by REACH deadline year; and
- Country.

Each of the entries is also accompanied by information concerning:

- The Universally Unique Identity (UUIDs) - effectively logging the identity of the computer terminal accessing the database; and
- Most recent login date.

Table 2-4 and Table 2-5 provide headline statistics on the 69,321 database entries.

| Table 2-4: Headline statistics on the 69,321 database entries (by declared role and size) |             |            |  |             |            |
|---|-------------|------------|--|-------------|------------|
| Entries by declared role  |             |            | Entries by declared size of enterprise |             |            |
| Role  | No. entries | Percentage | Size of enterprise                     | No. entries | Percentage |
| Manufacturer, Importer  | 345         | 0.5%       | Micro                                  | 23,451      | 33.8%      |
| Downstream user   | 7           | 0.0%       | Small                                  | 17,785      | 25.7%      |
| Manufacturer  | 3,022       | 4.4%       | Medium                                 | 11,862      | 17.1%      |
| Importer  | 2,865       | 4.1%       | Large                                  | 16,221      | 23.4%      |
| Only Representative   | 3,139       | 4.5%       |  |             |            |
| Left blank (could be multiple role)   | 59,943      | 86.5%      |  |             |            |

| Table 2-5: Headline statistics on the 69,321 database entries (by declared country) |             |            |               |             |            |
|---|-------------|------------|---------------|-------------|------------|
| Country   | No. entries | Percentage | Country       | No. entries | Percentage |
| AUSTRIA   | 785         | 1.1%       | LATVIA        | 207         | 0.3%       |
| BELGIUM   | 1,814       | 2.6%       | LIECHTENSTEIN | 39          | 0.1%       |
| BULGARIA  | 881         | 1.3%       | LITHUANIA     | 222         | 0.3%       |
| CROATIA   | 31          | 0.0%       | LUXEMBOURG    | 223         | 0.3%       |
| CYPRUS  | 311         | 0.4%       | MALTA         | 45          | 0.1%       |
| CZECH REPUBLIC  | 1,096       | 1.6%       | NETHERLANDS   | 5,707       | 8.2%       |
| DENMARK   | 450         | 0.6%       | NORWAY        | 357         | 0.5%       |
| ESTONIA   | 156         | 0.2%       | POLAND        | 2,578       | 3.7%       |
| FINLAND   | 1,355       | 2.0%       | PORTUGAL      | 391         | 0.6%       |
| FRANCE  | 4,183       | 6.0%       | ROMANIA       | 557         | 0.8%       |
| GERMANY   | 8,781       | 12.7%      | SLOVAKIA      | 488         | 0.7%       |
| GREECE  | 898         | 1.3%       | SLOVENIA      | 231         | 0.3%       |
| HUNGARY   | 658         | 0.9%       | SPAIN         | 2,616       | 3.8%       |
| ICELAND   | 29          | 0.0%       | SWEDEN        | 1,380       | 2.0%       |
| IRELAND   | 6,129       | 8.8%       | UK            | 22,079      | 31.9%      |
| ITALY   | 4,644       | 6.7%       |               |             |            |

## 2.2.2 Treatment of Raw Data

When undertaking the first analysis of these headline statistics, it became obvious that the extract from the database also contained multiple entries. The UUID only provides unique identity of a computer system and not an individual and it was clear that a number of entries came from the declared email address and/or company and/or the same email address was used to (pre) register information for a number of legal entities sharing the same general name but with slight variations, such as country. It was also observed that, at the extreme end of the spectrum, one individual email

address (from a company appearing to be based in China) was responsible for 14,246 of the 69,321 entries (i.e. 20%). There were also two examples of other significant multiple entries (but of a lower order - around 3,000+ entries).

It was clear from this duplication that the database export in its raw state was unlikely to provide reliable information on the structure and attributes of the companies/individuals and some cleaning would be required to remove the duplication while still retaining information within the duplicated entries. It was also clear from some of the contact details given that the database contained spoof/dubious email addresses and contact details.

Having considered several options (for example, ISP address, first few characters from company names, declared telephone numbers, etc.) entries on the raw database export were grouped by declared email address (with all text strings converted to lowercase) and information from multiple entries were collated to give:

- Total numbers of pre-registrations/registrations;
- Countries identified (with more than one being possible for entries grouped/collated from multiple entries);
- Declared size of company (where again, more than one size was possible for entries grouped/collated from multiple entries);
- Most recent login year for the declared email address; and
- Contact information (email address, telephone number and name of the last company in the list in the case of multiple entries).

This collation process suggests that there are at most<sup>7</sup> 29,924 entries from unique declared email addresses. 26,980 of these were single entries on the database and the remainder - 2,944 - were collated from multiple entries. In other words, 2,944 individuals (judged by declared email address) are responsible for 42,341<sup>8</sup> of the entries on the starting raw database of 69,321.

The collated data has been used to provide two different types of datasets for further analysis and refinement for the purposes of the study. One dataset provides presence/absence information for each of the fields (for example, whether the collated entry includes a full registration or pre-registration only) and also the totals for each grouped field (for example, total number of substances registered across collated entries). These datasets can be used in a number of ways but the key purpose here is to extract potentially reliable information pertaining to real individuals at real SME companies. The data and statistics prepared for this update are intended to provide overview statistics to inform the methodology rather than a full analysis of trends within different compartments of data that might be considered once a final focussed dataset is extracted from the larger collated dataset. Regarding that focus, using pivot tables and filters we have collated information on a gradual focussing of data based on various filters of consistency and relevance. This provides the number of entries on the collated dataset that meet the conditions including the following:

- No conditions (i.e. the full collated dataset)
- Has any registration
- Non-phase-in only
- Entries covering several different countries

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<sup>7</sup> At most because the data are grouped by email address, but there are examples where two or more individuals from the same company have entered information on the database and this has not been accounted for but may be considered as a second phase of data cleaning.

<sup>8</sup> 69,321 minus 26,980

- Entries covering only one country
- Has entries covering several different sizes of enterprise
- Entries of consistent company size
- Entries for SMEs

Table 2-6 provides an overview of the numbers of entries meeting these conditions on the collated database. Data for each company size relates only to entries where the company size is consistent (i.e. any multiple entries consistently give the same company size) and so the total across the company sizes will not add up to the unfiltered (All) category because inconsistent entries have been filtered out. As can be seen from this, entries for SMEs are fairly consistent regarding country but, although together entries for SMEs outnumber those for large companies, the number with an actual registration is relatively low.

| Table 2-6: Overview of numbers of entries meeting different conditions |        |            |            |             |            |
|--|--------|------------|------------|-------------|------------|
|  | All    | Micro only | Small only | Medium only | Large only |
| Total number of entries  | 29,923 | 5,853      | 9,657      | 6,318       | 6,945      |
| Has any registration   | 5,656  | 423        | 746        | 916         | 3,125      |
| Non-phase-in only  | 201    | 15         | 48         | 36          | 91         |
| Entries covering several different countries                           | 806    | 10         | 30         | 43          | 409        |
| Entries covering only one country                                      | 29,117 | 5,843      | 9,627      | 6,275       | 6,536      |
| Has entries covering several different sizes of enterprise             | 1,150  | n/a        |            |             |            |
| Entries of consistent company size                                     | 28,773 | n/a        |            |             |            |

### 2.2.3 Refining Data Using Grouped Conditions

The tables below provide information on the number of entries conforming to a grouped set of criteria that may help to focus on the most relevant set of individuals present on the database. These grouped criteria are as follows, with the last two groups present to differentiate between those with a full registration versus those with pre-registration only:

- Only entries for consistent companies and only SMEs;
- Only entries for consistent companies, consistent countries and only SMEs;
- Only entries for consistent companies, consistent countries and only SMEs and with a full registration (there are none in this list with non-phase-in only); and
- Only entries for consistent companies, consistent countries and only SMEs and with a pre-registration but no registration.

Information on the following three variables has been explored:

- Table 2-7: Number of entries on the database from single email identity - where this is an indicator of the reliability of the dataset (where it is assumed that the larger number and size of multiple entries in the dataset the less reliable the data);
- Table 2-8: Last login year - which would seem to indicate the likely current integrity of the email address/contact details (i.e. whether the individual email address, if real, still works); and
- Table 2-9: Country - where, if the refined data is to be used as part of a representative sampling there is a need to ensure that all countries are represented.

In Table 2-7, data in the left columns denote the number of entries made by individuals on the original raw dataset as a range. The numbers under the remaining columns describe the number of entries on the collated database that contains multiple entries of that magnitude. So, for example, under the 'all entry' column, 26,980 of the entries are composed of single entries on the original raw dataset, 826 are from the collation of 2-10 entries on the raw dataset, two entries are the collation of 3,001-4,000 entries on the raw dataset. As can be seen from Table 2-7, removing the entries for large companies/entries where more than one size of company is entered reduces the frequency of multiple entries and the number of entries making up the refined dataset.

| <b>Table 2-7: Number of entries on the database from single email identity</b> |       |  |  |  |  |  |
|--|-------|--|--|--|--|--|
| <b>Number of entries on the database from single email identity (from-to)</b>  |       | <b>ALL entries (including large companies)</b> | <b>Only entries for consistent companies and only SMEs</b> | <b>Only entries for consistent companies, consistent countries and only SMEs</b> | <b>Only entries for consistent companies, consistent countries and only SMEs and with a full registration (there are none in this list with non-phase-in only)</b> | <b>Only entries for consistent companies, consistent countries and only SMEs and with a PRE registration but NO registration</b> |
| 1  |       | 26,980   | 20,979   | 20,979   | 1,979  | 18,999   |
| 2  | 10    | 2,701  | 826  | 746  | 96   | 650  |
| 11   | 20    | 128  | 15   | 13   | 1  | 12   |
| 21   | 50    | 77   | 3  | 2  | 0  | 2  |
| 51   | 100   | 20   | 2  | 2  | 0  | 2  |
| 101  | 200   | 15   | 1  | 1  | 0  | 1  |
| 201  | 300   | 2  | 2  | 2  | 0  | 0  |
| 301  | 400   | 3  | 0  | 0  | 0  | 2  |
| 401  | 500   | 1  | 0  | 0  | 0  | 0  |
| 501  | 750   | 3  | 0  | 0  | 0  | 0  |
| 751  | 1000  | 0  | 0  | 0  | 0  | 0  |
| 1001   | 2000  | 0  | 0  | 0  | 0  | 0  |
| 2001   | 3000  | 0  | 0  | 0  | 0  | 0  |
| 3001   | 4000  | 2  | 0  | 0  | 0  | 0  |
| 4001   | 10000 | 0  | 0  | 0  | 0  | 0  |
| 14,126   |       | 1  | 0  | 0  | 0  | 0  |

From Table 2-8 on most recent login year, for those consistent SME entries with a registration, it is clear that the vast majority logged in within the last year whilst the vast majority of those with a pre-registration only have not logged in for several years.

| Table 2-8: Last login year |   |   |   |   |   |
|----------------------------|---|---|---|---|---|
| Last login year            | ALL entries (including large companies) | Only entries for consistent companies and only SMEs | Only entries for consistent companies, consistent countries and only SMEs | Only entries for consistent companies, consistent countries and only SMEs and with a full registration (there are none in this list with non-phase-in only) | Only entries for consistent companies, consistent countries and only SMEs and with a PRE registration but NO registration |
| 2008                       | 8,224                                   | 7,354   | 7,344   | 0   | 7,344   |
| 2009                       | 3,516                                   | 2,858   | 2,846   | 0   | 2,846   |
| 2010                       | 2,400                                   | 1,912   | 1,898   | 26  | 1,872   |
| 2011                       | 1,698                                   | 1,340   | 1,332   | 47  | 1,285   |
| 2012                       | 1,313                                   | 1,003   | 999   | 42  | 957   |
| 2013                       | 1,602                                   | 1,236   | 1,230   | 199   | 1,030   |
| 2014                       | 1,206                                   | 868   | 866   | 128   | 738   |
| 2015                       | 1,213                                   | 834   | 827   | 126   | 701   |
| 2016                       | 8,751                                   | 4,423   | 4,403   | 1,508   | 2,895   |

Regarding countries, all countries are represented, as shown in Table 2-9. However, for those SME entries with a registration there is a slightly curious distribution (for example there are more entries in Greece than the Netherlands).

Overall it seems sensible to suggest that the data is more useful as a means to focus further consultation and research efforts than to provide any representative information on the location and nature of 2018 SME registrants. As a result, for the purpose of this study, the database has been reduced to provide a manageable list of email addresses to which a short questionnaire could be sent or, at least, an email sent in order to check the validity of the identity.

An initial cut to the 4,403 email identity entries that meet the following conditions appears a sensible starting point:

- Only entries for consistent companies, consistent countries and only SMEs and with a full registration and logged in in 2016; and
- Only entries for consistent companies, consistent countries and only SMEs and with a PRE registration but NO registration and logged in in 2016.

Table 2-10 provides a profile of these entries.

| Table 2-9: Entries by declared country |   |  |  |  |   |
|--|---|--|--|--|---|
| Country                                | ALL entries<br>(including large<br>companies) | Only entries for<br>consistent<br>companies and<br>only SMEs | Only entries for<br>consistent<br>companies,<br>consistent<br>countries and<br>only SMEs | Only entries for<br>consistent<br>companies,<br>consistent<br>countries and<br>only SMEs and<br>with a full<br>registration<br>(there are none<br>in this list with<br>non-phase-in<br>only) | Only entries for<br>consistent<br>companies,<br>consistent<br>countries and<br>only SMEs and<br>with a PRE<br>registration but<br>NO registration |
| AUSTRIA                                | 678   | 396  | 390  | 40   | 350   |
| BELGIUM                                | 1,236   | 665  | 653  | 83   | 570   |
| BULGARIA                               | 804   | 675  | 674  | 36   | 638   |
| CROATIA                                | 31  | 12   | 12   | 5  | 7   |
| CYPRUS                                 | 220   | 179  | 179  | 16   | 163   |
| CZECH<br>REPUBLIC                      | 742   | 479  | 470  | 58   | 412   |
| DENMARK                                | 372   | 239  | 235  | 26   | 209   |
| ESTONIA                                | 147   | 116  | 114  | 9  | 105   |
| FINLAND                                | 489   | 291  | 288  | 17   | 271   |
| FRANCE                                 | 2,743   | 1,867  | 1,848  | 136  | 1,712   |
| GERMANY                                | 5,903   | 3,940  | 3,911  | 332  | 3,579   |
| GREECE                                 | 764   | 632  | 631  | 147  | 484   |
| HUNGARY                                | 613   | 470  | 464  | 36   | 428   |
| ICELAND                                | 26  | 20   | 19   | 3  | 16  |
| IRELAND                                | 358   | 204  | 195  | 17   | 178   |
| ITALY                                  | 4,135   | 3,305  | 3,295  | 285  | 3,010   |
| LATVIA                                 | 180   | 139  | 138  | 13   | 125   |
| LIECHTENSTEIN                          | 29  | 21   | 20   | 2  | 18  |
| LITHUANIA                              | 188   | 144  | 142  | 7  | 135   |
| LUXEMBOURG                             | 84  | 34   | 32   | 4  | 28  |
| MALTA                                  | 44  | 33   | 32   | 1  | 31  |
| NETHERLANDS                            | 1,501   | 848  | 830  | 86   | 744   |
| NORWAY                                 | 294   | 164  | 160  | 13   | 147   |
| POLAND                                 | 2,385   | 1,805  | 1,798  | 212  | 1,586   |
| PORTUGAL                               | 352   | 231  | 229  | 29   | 200   |
| ROMANIA                                | 502   | 345  | 342  | 19   | 323   |
| SLOVAKIA                               | 346   | 233  | 229  | 12   | 217   |
| SLOVENIA                               | 205   | 130  | 130  | 17   | 113   |
| SPAIN                                  | 2,062   | 1,404  | 1,390  | 205  | 1,185   |
| SWEDEN                                 | 589   | 343  | 334  | 29   | 305   |
| UNITED<br>KINGDOM                      | 3,875   | 2,584  | 2,561  | 181  | 2,379   |
| <b>TOTAL</b>                           | <b>29,923</b>                                 | <b>21,828</b>  | <b>21,745</b>  | <b>2,076</b>   | <b>19,668</b>   |

| <b>Table 2-10: First cut to a consistent potentially reliable list of entries for consultation</b> |                             |  |  |              |
|--|-----------------------------|--|--|--------------|
|  |                             | <b>Only entries for consistent companies, consistent countries and only SMEs logged in in 2016</b> |  |              |
|  |                             | <b>With a full registration</b>  | <b>With a pre-registration but no registration</b> | <b>Total</b> |
| Total number of entries  |                             | 1,508  | 2,895  | 4,403        |
| Pre-registrations  | Pre-regs 2010               | 909  | 602  | 1,511        |
|  | Pre-regs 2013               | 883  | 815  | 1,698        |
|  | Pre-regs 2018               | 933  | 2,673  | 3,606        |
| Registrations  | Registrations 2010          | 930  | 0  | 930          |
|  | Registrations 2013          | 684  | 0  | 684          |
|  | Registrations 2018          | 187  | 0  | 187          |
|  | Non phase ins               | 97   | 80   | 177          |
| Role   | Manufacturer, Importer      | 74   | 1  | 75           |
|  | Downstream user             | 2  | 0  | 2            |
|  | Manufacturer                | 746  | 31   | 777          |
|  | Importer                    | 586  | 44   | 630          |
|  | Only Representative         | 110  | 6  | 116          |
|  | Blank (poss. multiple role) | 55   | 2,816  | 2,871        |
| Size   | Micro                       | 285  | 832  | 1,117        |
|  | Small                       | 512  | 1,152  | 1,664        |
|  | Medium                      | 711  | 911  | 1,622        |
|  | Large                       | 0  | 0  | 0            |
| Country  | AUSTRIA                     | 28   | 30   | 58           |
|  | BELGIUM                     | 72   | 86   | 158          |
|  | BULGARIA                    | 26   | 95   | 121          |
|  | CROATIA                     | 5  | 3  | 8            |
|  | CYPRUS                      | 10   | 15   | 25           |
|  | CZECH REPUBLIC              | 45   | 74   | 119          |
|  | DENMARK                     | 14   | 27   | 41           |
|  | ESTONIA                     | 7  | 5  | 12           |
|  | FINLAND                     | 12   | 28   | 40           |
|  | FRANCE                      | 101  | 307  | 408          |
|  | GERMANY                     | 262  | 619  | 881          |
|  | GREECE                      | 114  | 96   | 210          |
|  | HUNGARY                     | 28   | 45   | 73           |
|  | ICELAND                     | 2  | 0  | 2            |
|  | IRELAND                     | 13   | 48   | 61           |
|  | ITALY                       | 215  | 430  | 645          |
|  | LATVIA                      | 11   | 13   | 24           |
|  | LIECHTENSTEIN               | 1  | 3  | 4            |
|  | LITHUANIA                   | 6  | 21   | 27           |
|  | LUXEMBOURG                  | 3  | 8  | 11           |
|  | MALTA                       | 1  | 4  | 5            |
|  | NETHERLANDS                 | 69   | 114  | 183          |
|  | NORWAY                      | 10   | 12   | 22           |
|  | POLAND                      | 111  | 151  | 262          |
|  | PORTUGAL                    | 23   | 28   | 51           |
|  | ROMANIA                     | 11   | 21   | 32           |
|  | SLOVAKIA                    | 5  | 19   | 24           |
|  | SLOVENIA                    | 9  | 12   | 21           |
| SPAIN  | 145                         | 175  | 320  |              |
| SWEDEN   | 21                          | 52   | 73   |              |
| UNITED KINGDOM   | 128                         | 354  | 482  |              |

## 2.2.4 Potential for Refinements Based on Number of Logged Pre-registrations

The numbers of substances pre-registered can also be a means to screen out potentially unreliable entries to the database. Here, other users of these data have assumed that any entry for an SME with >1,000 substances pre-registered is unlikely to be a real entity and that any below 20 substances pre-registered are almost certainly serious entries and in other ECHA work this 20 pre-registrations cut-off is being used to identify consultees.

The validity and implications of this logic has been explored using the subset of 4,403 entries on the database representing entries for consistent companies, consistent countries and only SMEs logged in in 2016 (as provided in Table 2-10).

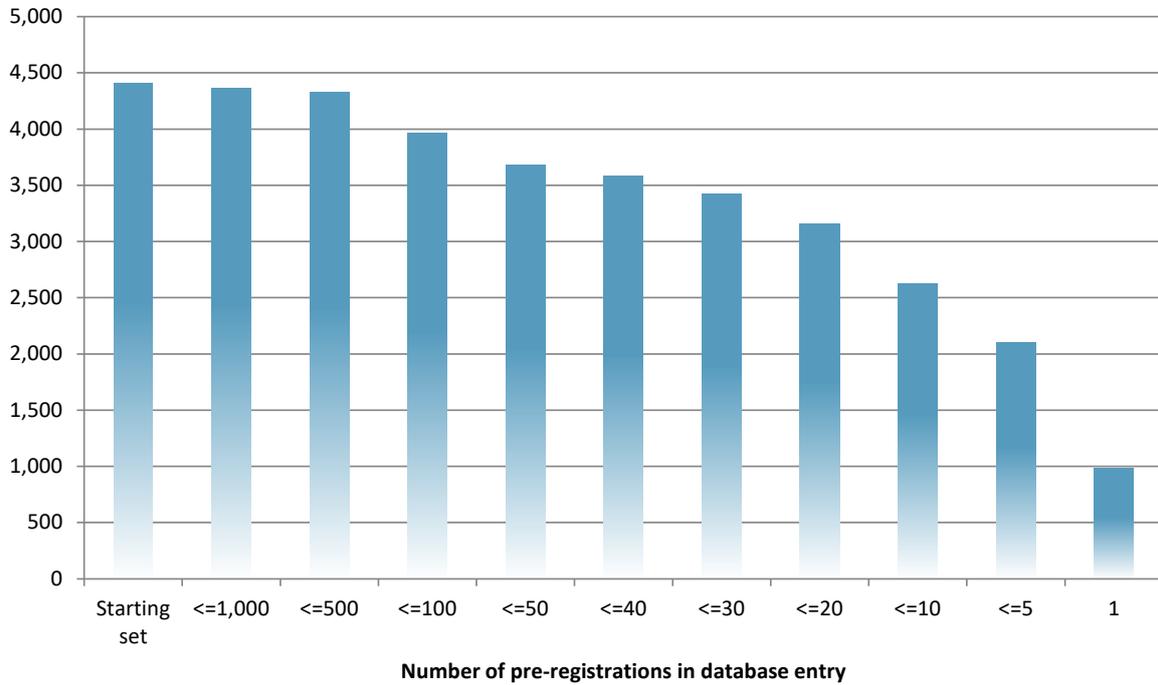
Figure 2-3 below provides two graphs, one showing the size of the pool of 4,403 entries in Table 2-10 (only) and the numbers that remain in the pool at different cut off points for numbers of pre-registered substances. The other graph shows a breakdown of the 4,403 entries in terms of the numbers of substances pre-registered.

As can be seen from the figure, with a total of 3,156 entries, SMEs logging 20 or fewer pre-registrations make up the bulk of the pool of 4,403. Entries of above 1,000 pre-registrations make up a small number of the total (39) and entries of 501-1,000 make up a similarly small number (36).

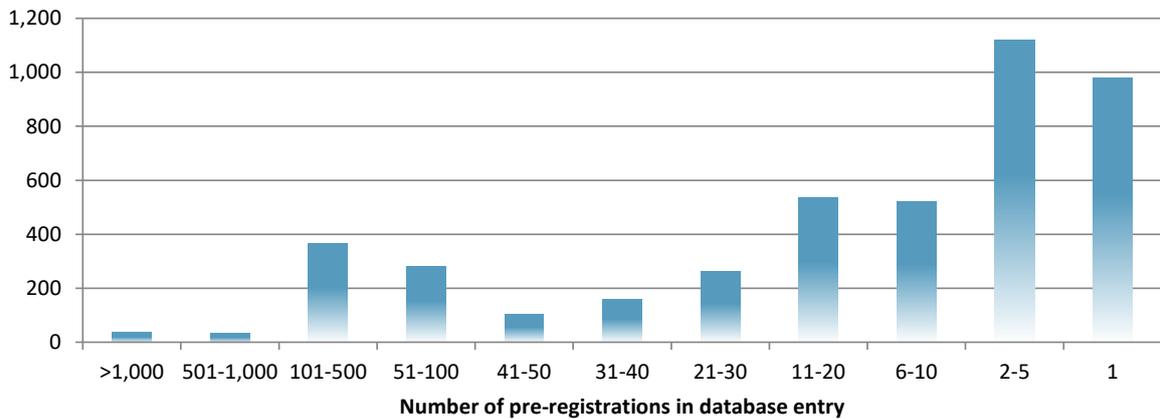
Applying the logic of selecting only entries logging 20 or fewer pre-registered substances (as being used in other ECHA studies using these data) results in a reduced list for potential consultation with the profile set out in Table 2-11. As can be seen from this table, this reduced sample set still provides a fairly good coverage of all of the field descriptors. However, as we identified in the Skype conference, it is possible that the use of this 20 pre-registrations criterion may actually be excluding certain industries/industry groups that have, rightly or wrongly, pre-registered more than 20 substances.

Figure 2-3: Breakdown of the pool of 4,403 entries by numbers of pre-registrations

### Size of 'pool' at different cut-off points for numbers of substances pre-registered



### Breakdown of the 4,403 'pool' by numbers of substances pre-registered



**Table 2-11: Potentially reliable list of entries\* for consultation based on a cut-off of 20 pre-registered substances**

|                                |                             | With a full registration | With a pre-registration but no registration | Total        |
|--------------------------------|-----------------------------|--------------------------|---|--------------|
| <b>Total number of entries</b> |                             | <b>1,069</b>             | <b>2,087</b>                                | <b>3,156</b> |
| Pre-registrations              | Pre-regs 2010               | 622                      | 302   | 924          |
|                                | Pre-regs 2013               | 518                      | 390   | 908          |
|                                | Pre-regs 2018               | 528                      | 1,880                                       | 2,408        |
| Registrations                  | Registrations 2010          | 677                      | 0   | 677          |
|                                | Registrations 2013          | 415                      | 0   | 415          |
|                                | Registrations 2018          | 89                       | 0   | 89           |
|                                | Non phase ins               | 23                       | 38  | 61           |
| Role                           | Manufacturer, Importer      | 62                       | 0   | 62           |
|                                | Downstream user             | 2                        | 0   | 2            |
|                                | Manufacturer                | 597                      | 17  | 614          |
|                                | Importer                    | 329                      | 18  | 347          |
|                                | Only Representative         | 83                       | 5   | 88           |
|                                | Blank (poss. multiple role) | 26                       | 2,047                                       | 2,073        |
| Size                           | Micro                       | 365                      | 792   | 1,157        |
|                                | Small                       | 255                      | 676   | 931          |
|                                | Medium                      | 449                      | 619   | 1,068        |
|                                | Large                       | 0                        | 0   | 0            |
| Country                        | AUSTRIA                     | 20                       | 22  | 42           |
|                                | BELGIUM                     | 50                       | 67  | 117          |
|                                | BULGARIA                    | 20                       | 79  | 99           |
|                                | CROATIA                     | 5                        | 2   | 7            |
|                                | CYPRUS                      | 9                        | 14  | 23           |
|                                | CZECH REPUBLIC              | 37                       | 58  | 95           |
|                                | DENMARK                     | 13                       | 20  | 33           |
|                                | ESTONIA                     | 6                        | 4   | 10           |
|                                | FINLAND                     | 9                        | 27  | 36           |
|                                | FRANCE                      | 72                       | 228   | 300          |
|                                | GERMANY                     | 161                      | 411   | 572          |
|                                | GREECE                      | 109                      | 88  | 197          |
|                                | HUNGARY                     | 23                       | 36  | 59           |
|                                | ICELAND                     | 2                        | 0   | 2            |
|                                | IRELAND                     | 7                        | 43  | 50           |
|                                | ITALY                       | 132                      | 284   | 416          |
|                                | LATVIA                      | 10                       | 12  | 22           |
|                                | LIECHTENSTEIN               | 1                        | 2   | 3            |
|                                | LITHUANIA                   | 5                        | 16  | 21           |
|                                | LUXEMBOURG                  | 1                        | 5   | 6            |
|                                | MALTA                       | 1                        | 3   | 4            |
|                                | NETHERLANDS                 | 45                       | 68  | 113          |
|                                | NORWAY                      | 9                        | 12  | 21           |
|                                | POLAND                      | 98                       | 114   | 212          |
|                                | PORTUGAL                    | 18                       | 22  | 40           |
|                                | ROMANIA                     | 9                        | 18  | 27           |
|                                | SLOVAKIA                    | 4                        | 16  | 20           |
|                                | SLOVENIA                    | 6                        | 10  | 16           |
| SPAIN                          | 98                          | 118                      | 216   |              |
| SWEDEN                         | 16                          | 43                       | 59  |              |
| UNITED KINGDOM                 | 73                          | 245                      | 318   |              |

**\* NOTE: Table only includes entries for consistent companies, consistent countries and only SMEs which logged in in 2016 with <=20 pre-registrations**

To explore possible reasons for differences in the number of entries with high/low number of pre-registrations we undertook a quick analysis of the 4,403 entries, dividing them up into six categories based on numbers of pre-registrations so that comparisons could be made and any patterns, identified. Table 2-12 provides the number of entries in each of the six categories for number of pre-registrations and the percentage of these entries conforming to each of the fields/descriptors in the database.

As can be seen by comparing the percentages for different pre-registration categories, for the majority of fields/descriptors there is only small variation between the categories and no clustering is evident towards the higher or lower ends of the spectrum. For a few fields/descriptors there are some values that appear to be slightly inconsistent with those for other pre-registration categories (highlighted in blue in the table). None of these, however, appear to be very significant and the variation could easily be explained by the smaller number of entries in the higher size category and the fact that small changes in numbers in the fields/descriptors will create a larger increase/decrease in percentage. It is concluded that there is no pattern in the data itself that can provide an explanation for the observed differences between entries in terms of numbers of pre-registered substances.

| Table 2-12: Profile of entries by number or pre-registrations |        |           |         |        |       |       |
|---|--------|-----------|---------|--------|-------|-------|
| Number of pre-registrations                                   | >1,000 | 501-1,000 | 101-500 | 51-100 | 21-50 | 1-20  |
| Number of entries   | 39     | 36        | 367     | 280    | 525   | 3,156 |
| Pre-regs 2010   | 49%    | 61%       | 54%     | 43%    | 43%   | 29%   |
| Pre-regs 2013   | 64%    | 81%       | 69%     | 61%    | 60%   | 29%   |
| Pre-regs 2018   | 100%   | 100%      | 97%     | 98%    | 94%   | 76%   |
| Registrations 2010  | 5%     | 22%       | 20%     | 20%    | 22%   | 21%   |
| Registrations 2013  | 13%    | 25%       | 23%     | 22%    | 21%   | 13%   |
| Registrations 2018  | 3%     | 11%       | 11%     | 8%     | 6%    | 3%    |
| non phase ins   | 3%     | 17%       | 13%     | 13%    | 5%    | 2%    |
| Manufacturer, Importer  | 3%     | 0%        | 1%      | 0%     | 2%    | 2%    |
| Downstream user   | 0%     | 0%        | 0%      | 0%     | 0%    | 0%    |
| Manufacturer  | 0%     | 6%        | 14%     | 14%    | 14%   | 19%   |
| Importer  | 15%    | 33%       | 24%     | 22%    | 22%   | 11%   |
| Only Representative   | 0%     | 3%        | 2%      | 2%     | 3%    | 3%    |
| Left blank (could be multiple role)                           | 85%    | 72%       | 64%     | 63%    | 63%   | 66%   |
| Small   | 41%    | 28%       | 41%     | 42%    | 40%   | 37%   |
| Micro   | 18%    | 25%       | 14%     | 15%    | 14%   | 29%   |
| Medium  | 41%    | 47%       | 44%     | 43%    | 46%   | 34%   |
| Large   | 0%     | 0%        | 0%      | 0%     | 0%    | 0%    |
| AUSTRIA   | 3%     | 0%        | 2%      | 0%     | 1%    | 1%    |
| BELGIUM   | 0%     | 3%        | 2%      | 4%     | 4%    | 4%    |
| BULGARIA  | 0%     | 0%        | 1%      | 3%     | 2%    | 3%    |
| CROATIA   | 0%     | 0%        | 0%      | 0%     | 0%    | 0%    |
| CYPRUS  | 0%     | 0%        | 0%      | 0%     | 0%    | 1%    |
| CZECH REPUBLIC  | 0%     | 3%        | 2%      | 3%     | 2%    | 3%    |
| DENMARK   | 0%     | 0%        | 1%      | 0%     | 1%    | 1%    |
| ESTONIA   | 0%     | 0%        | 0%      | 0%     | 0%    | 0%    |
| FINLAND   | 0%     | 0%        | 1%      | 0%     | 0%    | 1%    |
| FRANCE  | 8%     | 8%        | 11%     | 8%     | 8%    | 10%   |
| GERMANY   | 26%    | 47%       | 22%     | 28%    | 23%   | 18%   |
| GREECE  | 0%     | 0%        | 1%      | 1%     | 1%    | 6%    |
| HUNGARY   | 0%     | 0%        | 2%      | 1%     | 1%    | 2%    |
| ICELAND   | 0%     | 0%        | 0%      | 0%     | 0%    | 0%    |
| IRELAND   | 3%     | 0%        | 1%      | 0%     | 1%    | 2%    |
| ITALY   | 13%    | 22%       | 17%     | 18%    | 20%   | 13%   |

| Table 2-12: Profile of entries by number or pre-registrations |        |           |         |        |       |      |
|---|--------|-----------|---------|--------|-------|------|
| Number of pre-registrations                                   | >1,000 | 501-1,000 | 101-500 | 51-100 | 21-50 | 1-20 |
| LATVIA  | 0%     | 3%        | 0%      | 0%     | 0%    | 1%   |
| LIECHTENSTEIN   | 3%     | 0%        | 0%      | 0%     | 0%    | 0%   |
| LITHUANIA   | 0%     | 0%        | 1%      | 0%     | 1%    | 1%   |
| LUXEMBOURG  | 0%     | 0%        | 0%      | 0%     | 1%    | 0%   |
| MALTA   | 0%     | 0%        | 0%      | 0%     | 0%    | 0%   |
| NETHERLANDS   | 13%    | 3%        | 5%      | 8%     | 4%    | 4%   |
| NORWAY  | 0%     | 0%        | 0%      | 0%     | 0%    | 1%   |
| POLAND  | 0%     | 6%        | 5%      | 1%     | 5%    | 7%   |
| PORTUGAL  | 3%     | 0%        | 1%      | 1%     | 1%    | 1%   |
| ROMANIA   | 0%     | 0%        | 1%      | 0%     | 0%    | 1%   |
| SLOVAKIA  | 0%     | 0%        | 0%      | 0%     | 0%    | 1%   |
| SLOVENIA  | 0%     | 0%        | 0%      | 0%     | 1%    | 1%   |
| SPAIN   | 5%     | 3%        | 9%      | 8%     | 9%    | 7%   |
| SWEDEN  | 0%     | 0%        | 1%      | 1%     | 2%    | 2%   |
| UNITED KINGDOM  | 26%    | 3%        | 15%     | 14%    | 11%   | 10%  |

Using criteria based on numbers of pre-registrations criterion may be excluding certain industries/industry groups that have, rightly or not, pre-registered more substances than seems sensible. In particular we identified that 20 pre-registrations may be too small as a cut-off point because some industries (such as dyes/pigments) may have more than that and such industries might inadvertently be excluded.

To explore whether this could be the case we have examined entries logging more than 500 substances (of which there are 75 in the pool of 4,403) in more detail. We extracted the domain names from email addresses given for these entries and turned them into html links. We then visited all 75 of the resulting websites to identify: whether they existed and, if so, for what type of company/sector and likely size. We then compiled the list into categories of companies/sectors. Table 2-13 provides the findings in terms of numbers of entries/sectors.

As can be seen from Table 2-13, 33 of the 75 entries logging >500 pre-registrations (44%) relate to dyes/pigments and food/flavours/fragrances and these sectors make up a similar proportion of entries of >1,000 pre-registrations. Distributors and/or importers also make up a substantial number of entries. It should be added that none of the entries appeared to be from companies that were obviously large (i.e. it looked feasible that the companies/entities could be the SMEs claimed). Two important observations seem to come from this list:

1. That it may not be safe to assume that all entries with more than 1,000 pre-registrations are bogus – only around 5% of the entries with >1,000 pre-registrations appeared dubious. That said, only 113 of the 29,923 entries from single email address entities on the whole database log more than 1,000 pre-registrations; and
2. Perhaps more importantly, that the absence of other sectors would imply that sectors such as dyes/pigments, food/flavours/fragrances and distributors and/or importers may be more clustered towards the higher end of the range because these companies are involved with greater numbers of different substances. Thus, using the low level of below 20 pre-registrations to focus consultation may potentially miss out on some sectors and/or result in them being under represented in a sampling process.

Whilst the above cannot be proved with certainty without also examining the other entries with fewer pre-registrations, the analysis does suggest that numbers of pre-registrations should not be used as a

means to focus consultation for this study. Doing so does not reduce the number of entries significantly but, in the process, may exclude/under represent certain sectors and distort the sample significantly.

| Table 2-13: Sectors logging more than 500 or 1,000 pre-registrations |  |          |  |          |
|--|--|----------|--|----------|
|  | All entries with over 500 pre-registrations logged |          | All entries with over 1,000 pre-registrations logged |          |
|  | Number   | Percent  | Number   | Percent  |
| Coatings   | 4  | 5%       | 2  | 5%       |
| Custom chemistry   | 5  | 7%       | 3  | 8%       |
| Dyes/pigments  | 15   | 20%      | 7  | 18%      |
| Food/flavours/fragrances   | 18   | 24%      | 9  | 23%      |
| Distributor or Importer/distributor                                  | 12   | 16%      | 8  | 21%      |
| REACH Services   | 6  | 8%       | 5  | 13%      |
| Other categories (of which 'questionable')                           | 15 (6)   | 20% (8%) | 5 (2)  | 13% (5%) |
| <b>Total number</b>  | <b>75</b>  | <b>-</b> | <b>39</b>  | <b>-</b> |

## 2.3 Expert and SME Interviews

An internal meeting was held at the beginning of the project, in order to define the market hypothesis and some potential segments to be tested. A first step was the identification of the possible needs of the companies with registration duties. Initially, we defined two separate markets:

**Market 1** - the need (which defines the market) is to be compliant with EU regulation and therefore achieve:

1. Regulatory compliance
2. Insurance compliance
3. Access to market/avoid having to withdraw substance from market
4. Satisfaction of key client requirement.

Proposed drivers behind segment behaviour in this market include:

- Some segments may regard registration as a grudge purchase and choose to minimise cost and/or time by providing minimal information to be registered;
- Some segments may perceive they are not competent and/or confident enough to follow the registration process and may employ consultants;
- Some segments may be time and/or resource-constrained and outsource registration.

**Market 2** - this market perceives that green, safety and environmental credentials are a necessity or a benefit their clients and customers seek in doing business with them. The companies within this market:

1. Seek to protect human health and the environment
2. Are ethical and green as a brand
3. Want to enhance communication with downstream users
4. Want to use information availability as a competitive advantage
5. Want to demonstrate safety.

Therefore, the need is to demonstrate environmental and Health and Safety (H&S) responsibility in their processes and promote those values to develop brand. Segments in this market are likely to be active as ‘Experts’ and advisors in EU and Trade Environmental and H&S policy groups and pro-active in their public relations (PR).

At the same time, the project team started compiling a list of influencers who can determine the behaviour of some of the segments:

- Insurance companies
- Key Clients
- Trade associations
- Green/environmental pressure groups
- Consultants (REACH registration full service providers, ICT services providers, toxicologists, test labs)
- National Competent Authorities
- Green investors
- Banks/loans providers.

In order to verify this initial hypothesis, we carried out semi-structured interviews with chemical industry experts (Table 2-14).

| Table 2-14: Organisations interviewed to validate the market hypothesis      |
|--|
| Risk & Policy Analysts Ltd – Consultancy – United Kingdom                    |
| Oeko Institut - Consultancy - Germany  |
| FoBiG – Toxicological Consultancy - Germany                                  |
| Health and Safety Executive (HSE), REACH Competent Authority – UK            |
| UEAPME   |
| Federchimica – Italy   |
| Centro REACH – Consultancy – Italy   |
| Health and Safety Authority - Ireland  |
| ECHA – Finland   |
| Global Chemical Management at the International Fragrance Association (IFRA) |
| REACH Haldesk – France   |
| Ministry of the Environment – France   |
| European Association of Chemical Distributors (Fecc)                         |

During the interviews, we sought to validate the hypothesised segments and key influencers and to define additional ones, if necessary. We asked interviewees to select the most important segments in terms of number of companies and to indicate the people who hold the ultimate decision on registering substances within each “segment typical company” (that could be the owner, the product manager, the key account manager, the H&S practitioner, the IT expert, the key clients, etc.). In addition, we asked interviewees to describe two SMEs that sit at the extremes in terms of behavioural factors but also of products and sectors served. The ultimate goal was to have a broad description of one or more SMEs that could represent each segment.

The experts were also confronted with the potential factors influencing the decision to register or not to register a substance:

- a) There is a regulatory obligation to register the substances if the companies want to continue to place them on the market.

- b) What will determine whether they place them on the market? Possible factors working in tandem include:
- a. Profitability of individual substances
    - i. Low versus high margin substances?
    - ii. Low margin substance but produced as a by-product so would otherwise require disposal?
  - b. Guarantee of ongoing demand from customers
    - i. Is the substance critical to customers?
    - ii. Will they help fund the costs of registration?
    - iii. What is the likely future trend in demand – is it likely to remain constant, increase or decrease?
  - c. The tonnage that will be registered and hence the costs of registration
    - i. Level of data on chemical properties that are already held
    - ii. The likely hazard profile of the product portfolio – are most toxic or non-toxic?
    - iii. Are there other manufacturers to share part of the costs?
- c) Other influencing factors may include:
- a. Level of support from trade association
  - b. Helpdesks
  - c. Financing.

The reiteration of this exercise with different experts and the subsequent validation of the resulting market structure with representatives from the segments defined ensures that the final hypothesis does not differ too much from reality.

Once we felt we were not gaining additional insight through expert consultation, we started interviewing SMEs to check whether they fitted into one (or more) of the segments defined. The interviews evolved around their attitudes towards the obligation to register substances and tried to link the companies' characteristics (size, sector of activity, number of substances to be registered, etc.) with their behavioural patterns. The interview guide, with the list of questions asked during the interviews, is provided in Annex I.

Face-to-face interviews, telephone interviews and consultation via email were carried out with a range of companies, including:

- Two small enterprises located in Italy, importing dyes for the textile, leather and paper manufacturing sectors;
- One medium distributor of chemical products located in the Netherlands, importing a wide range of substances;
- Two essential oil manufacturers, one in France and one in the UK;
- One charcoal importer in Poland;
- One small distributor of chemical products for the metal industry in the UK;
- One micro-enterprise manufacturing activated carbon in the UK.

Additional validation of the market structure and of the segments defined came once the EU-wide survey was launched: many companies, in addition or instead of replying to the survey, contacted us via email and telephone to tell us about their problems and experience with the registration process.

The EU-wide survey was carried out to populate the segments, linking behavioural factors to demographics information. The results are presented in the following sub-Section.

## 2.4 The Survey

The survey was open between 8 May and 2 June 2017.

In total, 39,896 invitations were sent by email to SMEs: 21,810 email addresses came from the REACH-IT database<sup>9</sup>; 18,086 contact details were bought from the KOMPASS Business Inventory (KBI).

In order to select the contact details to buy from the KBI, the following filters were used:

- Country: All EU Member States + Norway and Liechtenstein (no contact details are present for Iceland);
- Turnover: < €50 M
- Number of employees: < 250
- NACE code (around 9,000 contact details for the following codes):
  - C19.2: Manufacture of coke and petroleum products
  - C20: Manufacture of chemicals and chemical products
  - C21: Manufacture of basic pharmaceutical products and pharmaceutical preparations
  - C24.1.2: Manufacture of basic metals
  - G46.1.2: Agents involved in the sale of fuels, ores, metals and industrial chemicals
  - G46.75: Wholesale of chemical products
- The remaining 9,000 contact details are of companies active in the following NACE codes:
  - C10.4 Manufacture of vegetable and animal oils and fats
  - C13 Manufacture of textiles
  - C14 Manufacture of wearing apparel
  - C15 Manufacture of leather and related products
  - C16 Manufacture of wood and of products of wood and cork
  - C17 Manufacture of paper and paper products
  - C18 Printing and reproduction of recorded media
  - C26 Manufacture of computer, electronic and optical products
  - C27 Manufacture of electric equipment
  - E36 Water collection, treatment and supply
  - E38 Waste treatment and disposal
  - M72 Scientific research and development
  - M75 Veterinary activities
  - Q86 Human health activities.

Around 6,677 emails have bounced back, of which 5,142 from the REACH-IT database and 1,535 from the KBI. Cefic and FECC helped in fostering participation by circulating the invitation to their members

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<sup>9</sup> Excluded all entries that selected “L – Large” for size of the company.

and ECHA publicised the survey through its newsletter. In addition, the link to the survey was made available on Risk & Policy Analysts' website to offer others with an interest the opportunity to provide a response.

A total of 819 responses have been received. The responses were reviewed and analysed for empty, duplicate or meaningless responses, leaving 732 individual and mostly complete responses. Any responses that provided some information on the company (name, country, activity), as well as answers to Q5 (Are you aware of the EU REACH Regulation?) and at least one other question, have been retained.

In addition, 109 companies replied that they were not going to participate in the survey because they do not have registration duties:

- 6 companies because they are manufacturing/importing substances in quantities below the one tonne per year threshold;
- 64 companies because they are not manufacturers or importers of substances;
- 4 companies because they are importing substances from outside the EU;
- 14 companies because they have registered substances for the other deadlines and do not have substances to register by 2018;
- 19 companies because they went out of business due to the costs and complexity of the registration process;
- 2 companies because they were not sure yet about their registration duties.

## 2.4.1 Analysis of Information about the Company

This sub-section provides the analysis of responses to questions 2, 3 and 4. These all provide background information on the companies responding to the survey.

### **Question 2: Country in which the Business is Located**

Question 2 asks respondents to indicate the country in which they are located. There were 732 responses to this question. Figure 2-4 below shows the breakdown by country with Table 2-15 presenting the number and percentage of responses received from each country. Respondents were able to tick all countries that apply so the total number of responses exceeds the number of individual survey responses.

| Country        | No. of invitations sent | No. of responses | % of all responses | Participation rate by invitations sent |
|----------------|-------------------------|------------------|--------------------|--|
| Austria        | 398                     | 10               | 1%                 | 2.5%                                   |
| Belgium        | 2,497                   | 34               | 5%                 | 1.4%                                   |
| Bulgaria       | 690                     | 16               | 2%                 | 2.3%                                   |
| Croatia        | 12                      | 1                | 0%                 | 8.3%                                   |
| Cyprus         | 184                     | 3                | 0%                 | 1.6%                                   |
| Czech Republic | 475                     | 16               | 2%                 | 3.4%                                   |
| Denmark        | 239                     | 20               | 3%                 | 8.4%                                   |
| Estonia        | 366                     | 8                | 1%                 | 2.2%                                   |
| Finland        | 292                     | 17               | 2%                 | 5.8%                                   |
| France         | 9,096                   | 165              | 23%                | 1.8%                                   |
| Germany        | 6,762                   | 107              | 15%                | 1.6%                                   |
| Greece         | 643                     | 8                | 1%                 | 1.2%                                   |

Table 2-15: Number and percentage of responses by country (in alphabetical order) (n=732)

| Country        | No. of invitations sent | No. of responses | % of all responses | Participation rate by invitations sent |
|----------------|-------------------------|------------------|--------------------|--|
| Hungary        | 470                     | 18               | 2%                 | 3.8%                                   |
| Iceland        | 19                      | 0                | 0%                 | 0.0%                                   |
| Ireland        | 202                     | 5                | 1%                 | 2.5%                                   |
| Italy          | 4,934                   | 69               | 9%                 | 1.4%                                   |
| Latvia         | 142                     | 6                | 1%                 | 4.2%                                   |
| Liechtenstein  | 21                      | 0                | 0%                 | 0.0%                                   |
| Lithuania      | 515                     | 8                | 1%                 | 1.6%                                   |
| Luxembourg     | 58                      | 2                | 0%                 | 3.4%                                   |
| Malta          | 32                      | 3                | 0%                 | 9.4%                                   |
| Netherlands    | 996                     | 45               | 6%                 | 4.5%                                   |
| Norway         | 168                     | 6                | 1%                 | 3.6%                                   |
| Poland         | 1,827                   | 35               | 5%                 | 1.9%                                   |
| Portugal       | 854                     | 32               | 4%                 | 3.7%                                   |
| Romania        | 350                     | 12               | 2%                 | 3.4%                                   |
| Slovakia       | 233                     | 7                | 1%                 | 3.0%                                   |
| Slovenia       | 130                     | 11               | 2%                 | 8.5%                                   |
| Spain          | 4,152                   | 88               | 12%                | 2.1%                                   |
| Sweden         | 337                     | 22               | 3%                 | 6.5%                                   |
| United Kingdom | 2,617                   | 63               | 9%                 | 2.4%                                   |
| Other          | 398                     | 17               | 2%                 | 4.3%                                   |

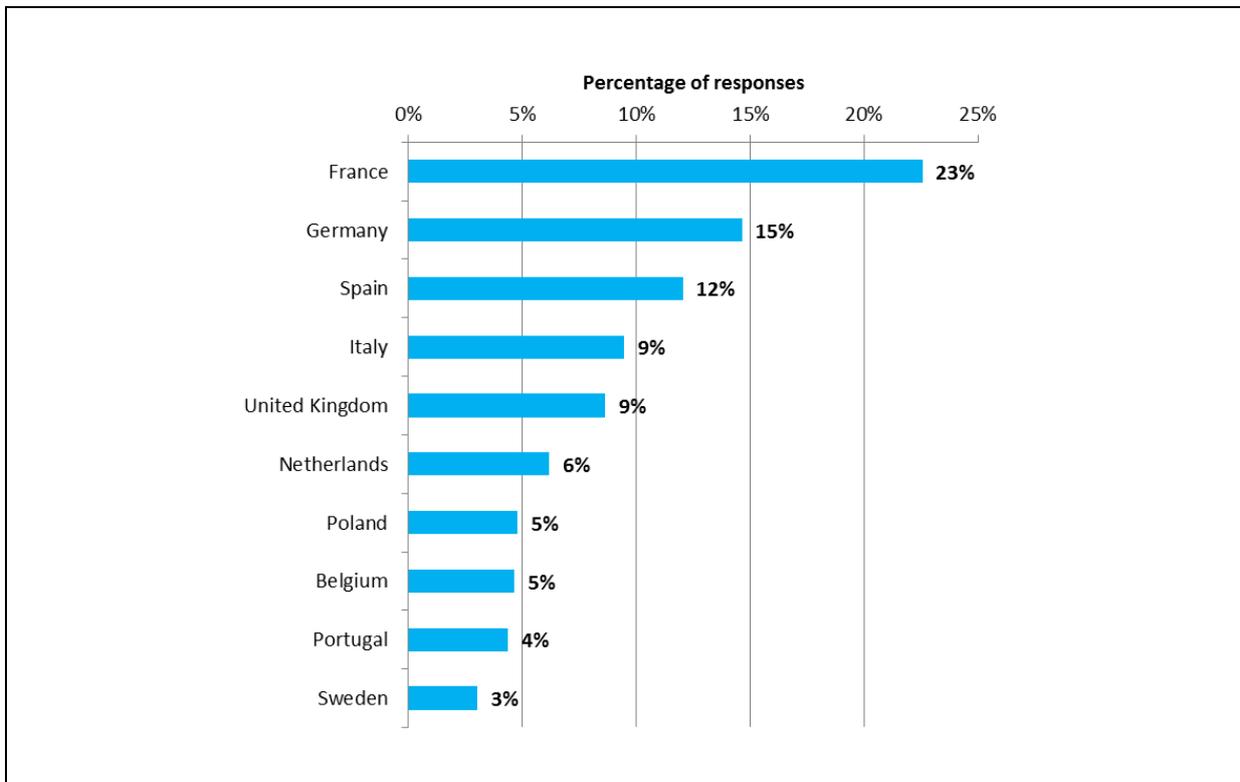
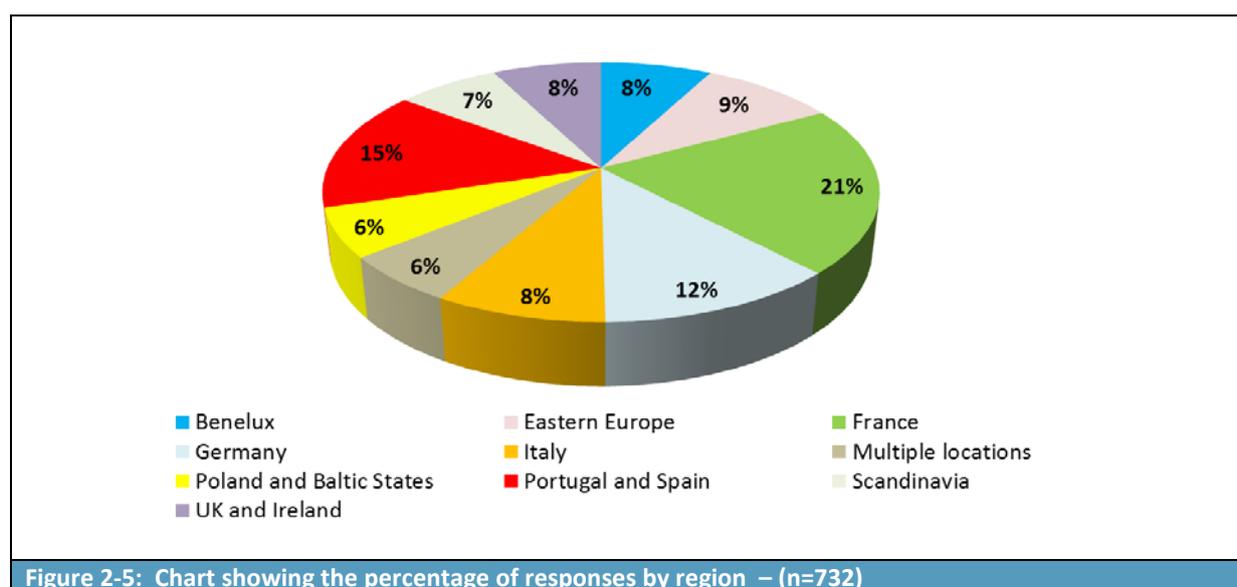


Figure 2-4: Chart showing the percentage of responses by country – TOP TEN (ordered from highest to lowest) (n=730)

In order to provide another level of analysis, responses have been aggregated by geographical regions. Companies that indicated being active in different countries have been aggregated in the entry “Multiple locations”.

| Company size   | Number of responses | % of all responses |
|--|---------------------|--------------------|
| Benelux (Belgium, Luxembourg, the Netherlands)   | 56                  | 8%                 |
| Eastern Europe (Bulgaria, Croatia, Cyprus, Czech Republic, Greece, Hungary, Romania, Slovakia, Slovenia) | 68                  | 9%                 |
| France   | 152                 | 21%                |
| Germany  | 86                  | 12%                |
| Italy  | 61                  | 8%                 |
| Japan  | 1                   | 0%                 |
| Malta  | 2                   | 0%                 |
| Multiple locations   | 43                  | 6%                 |
| Poland and Baltic States (Estonia, Latvia, Lithuania)  | 44                  | 6%                 |
| Portugal and Spain   | 110                 | 15%                |
| Scandinavia (Denmark, Finland, Norway, Sweden)   | 52                  | 7%                 |
| Switzerland  | 2                   | 0%                 |
| UK and Ireland   | 55                  | 8%                 |



### Question 3: Size of the Company

Question 3 asks respondents to indicate whether their company is a micro, small, medium or large enterprise. Only Representatives were asked to refer to the size of the non-EU entities that they represent. Figure 2-6 shows the breakdown of responses by size. Table 2-17 provides the percentage of responses from each company size. In total there were 718 responses to this question. Notably, 60 large enterprises participated in the survey. Although their responses have not been considered

<sup>10</sup> Numbers presented in Tables 2-15 and 2-16 do not coincide because companies indicating different countries (e.g. the Netherlands and Austria) have been aggregated in Table 2-16 in “multiple locations”.

for populating the SME segments, they served as a means of comparison for validating the segments defined.

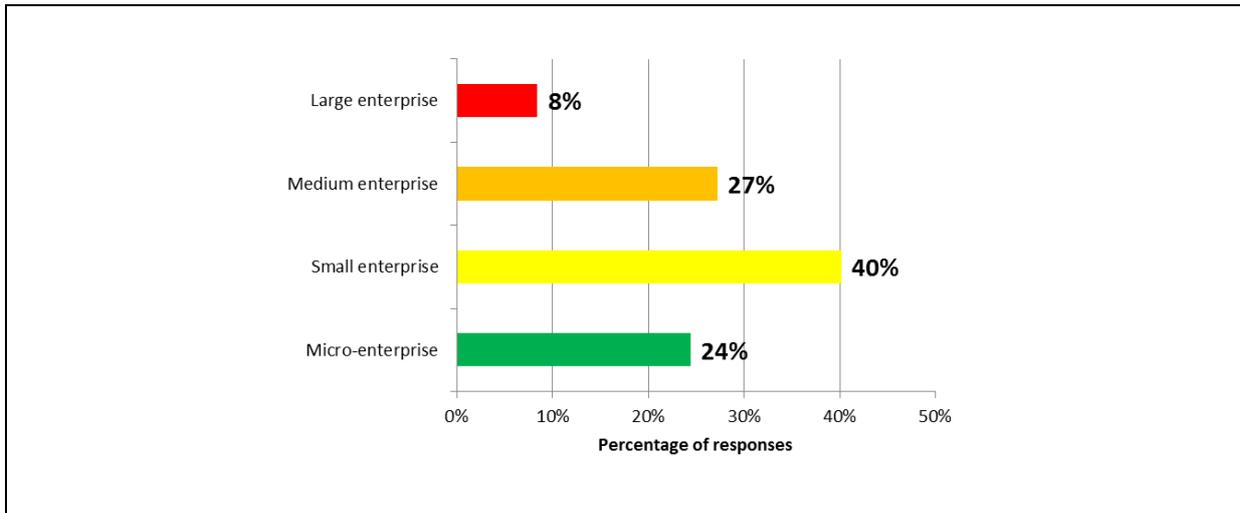


Figure 2-6: Chart showing the percentage of responses by size (n=718)

| Company size      | Number of responses | % of all responses |
|-------------------|---------------------|--------------------|
| Micro-enterprise  | 175                 | 24%                |
| Small enterprise  | 288                 | 40%                |
| Medium enterprise | 195                 | 27%                |
| Large enterprise  | 60                  | 8%                 |

#### Question 4: NACE Codes Reflecting Primary Activities

Respondents were asked to tick all the NACE codes that apply in terms of their primary activities. There were 723 individual responses to this question but these cover 966 NACE codes due to many of the respondents identifying more than one NACE code that was relevant to their company. Figure 2-7 shows the top 10 NACE codes that were most commonly identified. Table 2-18 provides the number and percentage of responses received across all of the NACE codes.

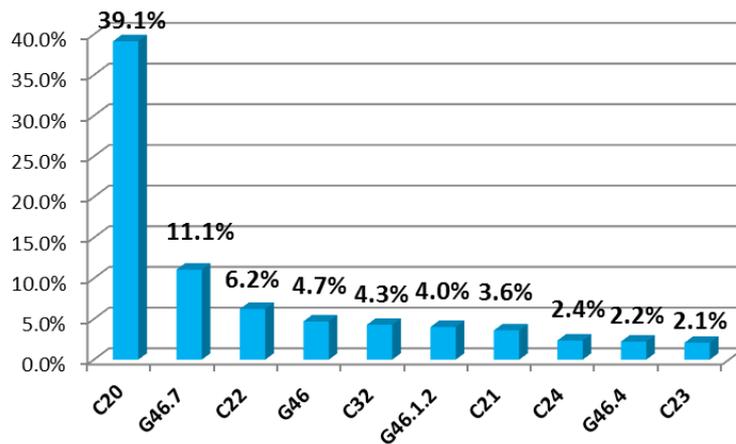


Figure 2-7: Chart showing the percentage of responses by NACE code, top 10 only from highest to lowest (n=723)

Table 2-18: Number and percentage of responses by NACE code (n=723)

| Description   | Number of responses | % of all responses |
|---|---------------------|--------------------|
| A1 Crop and animal production, hunting and related service activities   | 6                   | 0.8%               |
| A2 Forestry and logging   | 1                   | 0.1%               |
| B5 Mining of coal and lignite   | 0                   | 0.0%               |
| B6 Extraction of crude petroleum and natural gas  | 0                   | 0.0%               |
| B7 Mining of metal ores   | 0                   | 0.0%               |
| B8 Other mining and quarrying   | 7                   | 1.0%               |
| B9 Mining support service activities  | 0                   | 0.0%               |
| C10 Manufacture of food products  | 9                   | 1.2%               |
| C11 Manufacture of beverages  | 5                   | 0.7%               |
| C12 Manufacture of tobacco products   | 2                   | 0.3%               |
| C13 Manufacture of textiles   | 6                   | 0.8%               |
| C14 Manufacture of wearing apparel  | 2                   | 0.3%               |
| C15 Manufacture of leather and related products   | 2                   | 0.3%               |
| C16 Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials | 4                   | 0.6%               |
| C17 Manufacture of paper and paper products   | 6                   | 0.8%               |
| C18 Printing and reproduction of recorded media   | 8                   | 1.1%               |
| C19 Manufacture of coke and refined petroleum products  | 7                   | 1.0%               |
| C20 Manufacture of chemicals and chemical products  | 283                 | 39.1%              |
| C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations  | 26                  | 3.6%               |
| C22 Manufacture of rubber and plastic products  | 45                  | 6.2%               |
| C23 Manufacture of other non-metallic mineral products  | 15                  | 2.1%               |
| C24 Manufacture of basic metals   | 17                  | 2.4%               |
| C25 Manufacture of fabricated metal products, except machinery and equipment  | 11                  | 1.5%               |
| C26 Manufacture of computer, electronic and optical products  | 9                   | 1.2%               |
| C27 Manufacture of electrical equipment   | 5                   | 0.7%               |
| C28 Manufacture of machinery and equipment n.e.c.   | 6                   | 0.8%               |
| C29 Manufacture of motor vehicles, trailers and semi-trailers   | 2                   | 0.3%               |
| C30 Manufacture of other transport equipment  | 0                   | 0.0%               |

**Table 2-18: Number and percentage of responses by NACE code (n=723)**

| Description   | Number of responses | % of all responses |
|---|---------------------|--------------------|
| C31 Manufacture of furniture  | 1                   | 0.1%               |
| C32 Other manufacturing   | 31                  | 4.3%               |
| C33 Repair and installation of machinery and equipment                              | 3                   | 0.4%               |
| D35 Electricity, gas, steam and air conditioning supply                             | 2                   | 0.3%               |
| E36 Water collection, treatment and supply  | 5                   | 0.7%               |
| E38.2 Waste treatment and disposal  | 11                  | 1.5%               |
| F41 Construction of buildings   | 0                   | 0.0%               |
| F42 Civil engineering   | 2                   | 0.3%               |
| F43 Building completion and finishing   | 0                   | 0.0%               |
| G45 Wholesale and retail trade and repair of motor vehicles and motorcycles         | 1                   | 0.1%               |
| G46 Wholesale trade, except of motor vehicles and motorcycles                       | 34                  | 4.7%               |
| G46.1.2 Agents involved in the sale of fuels, ores, metals and industrial chemicals | 29                  | 4.0%               |
| G46.3 Wholesale of food, beverages and tobacco                                      | 2                   | 0.3%               |
| G46.4 Wholesale of household goods  | 16                  | 2.2%               |
| G46.45 Wholesale of perfume and cosmetics   | 4                   | 0.6%               |
| G46.46 Wholesale of pharmaceutical goods  | 5                   | 0.7%               |
| G46.6 Wholesale of other machinery, equipment and supplies                          | 2                   | 0.3%               |
| G46.7 Other specialised wholesale   | 80                  | 11.1%              |
| K64 Financial service activities, except insurance and pension funding              | 1                   | 0.1%               |
| M70.2 Management consultancy activities   | 4                   | 0.6%               |
| M72 Scientific research and development   | 3                   | 0.4%               |
| M74.9 Other professional, scientific and technical activities n.e.c.                | 1                   | 0.1%               |
| M75 Veterinary activities   | 1                   | 0.1%               |
| Q86 Human health activities   | 1                   | 0.1%               |
| Not disclosed   | 9                   |                    |

In order to provide a more aggregated level of analysis of the companies' activity, one single NACE code has been assigned per company. Those companies indicating to be both manufacturers and distributors have been considered primarily manufacturers. Subsequently, we aggregated the NACE codes in groups of activities, as detailed in Table 2-19 and Figure 2-8.

**Table 2-19: Number and percentage of responses by group of activities (n=723)**

| Description                                     | Number of responses | % of all responses |
|---|---------------------|--------------------|
| Chemical manufacturers (C20)                    | 283                 | 39%                |
| Other manufacturing sectors (all other C codes) | 222                 | 30%                |
| Chemical distributors (G46.75 and G46.12)       | 98                  | 13%                |
| Other distributors (all other G codes)          | 75                  | 10%                |
| Other sectors (all other codes)                 | 45                  | 6%                 |
| Not disclosed                                   | 9                   |                    |

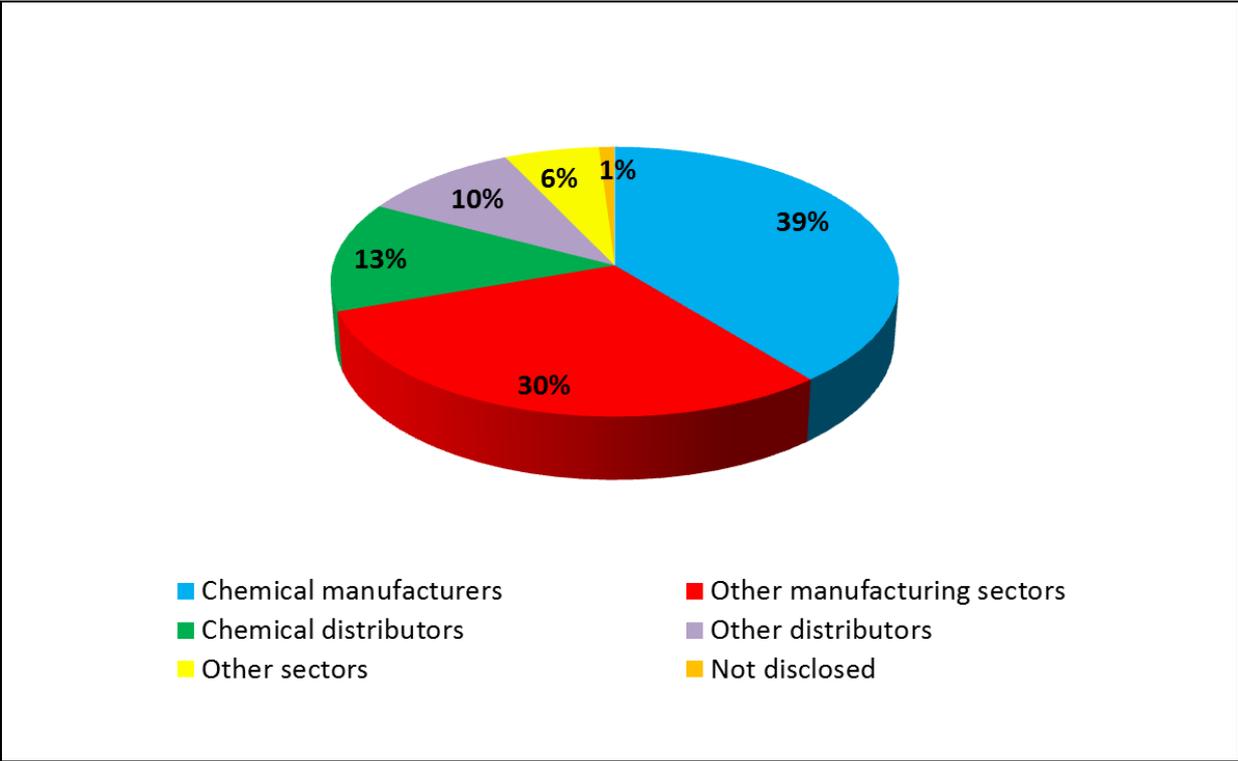


Figure 2-8: Percentage of responses by group of activity (n=723)

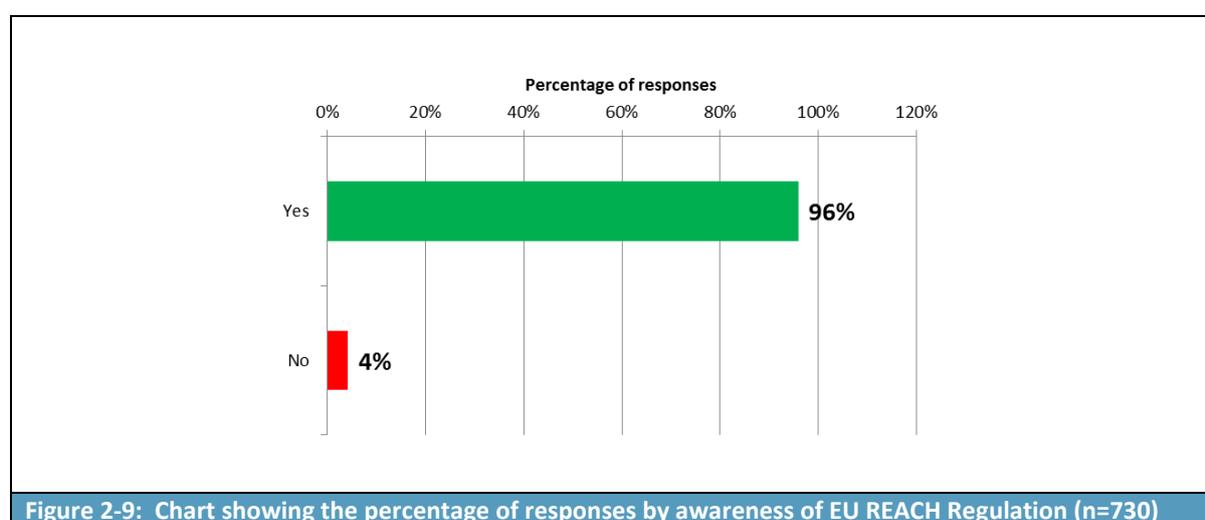
## 2.4.2 Understanding and Awareness of the REACH Regulation

This sub-section provides the analysis of responses to questions 5, 6, 7, 8, 9, 10 and 11.

### Question 5: Awareness of the EU REACH Regulation

This question required a 'yes' or 'no' response. In total, 730 responses were received to this question. Figure 2-9 provides a chart showing the breakdown of responses while Table 2-20 provides a summary of the number and percentage that answered 'yes' or 'no'.

| Table 2-20: Number and percentage of responses by awareness of EU REACH Regulation (n=730) |                     |                    |
|--|---------------------|--------------------|
| Aware of EU REACH Regulation   | Number of responses | % of all responses |
| Yes  | 700                 | 96%                |
| No   | 30                  | 4%                 |



### Question 6: How They Became Aware of EU REACH Regulation

There were seven possible answers available for respondents to select from. Again they could select more than one answer where appropriate. Space was also provided for respondents to add an 'other' response. In total, 697 individual responses were received, with some selecting more than one option (for a total of 732). Figure 2-10 provides a chart showing the most common reasons while Table 2-21 presents the number and percentage of responses against the seven possible answers and those who selected an 'other' reason.

| Table 2-21: Number and percentage of responses by reasons they became aware of EU REACH Regulation (n=732) |                     |                    |
|--|---------------------|--------------------|
| Reason became aware of EU REACH Regulation   | Number of responses | % of all responses |
| European Chemicals Agency (ECHA)   | 226                 | 31%                |
| National or regional authorities/inspectors  | 101                 | 14%                |
| European trade association   | 33                  | 5%                 |
| National trade association   | 138                 | 19%                |
| Suppliers  | 63                  | 9%                 |
| Peers  | 54                  | 7%                 |
| Customers  | 47                  | 6%                 |
| Other  | 70                  | 10%                |

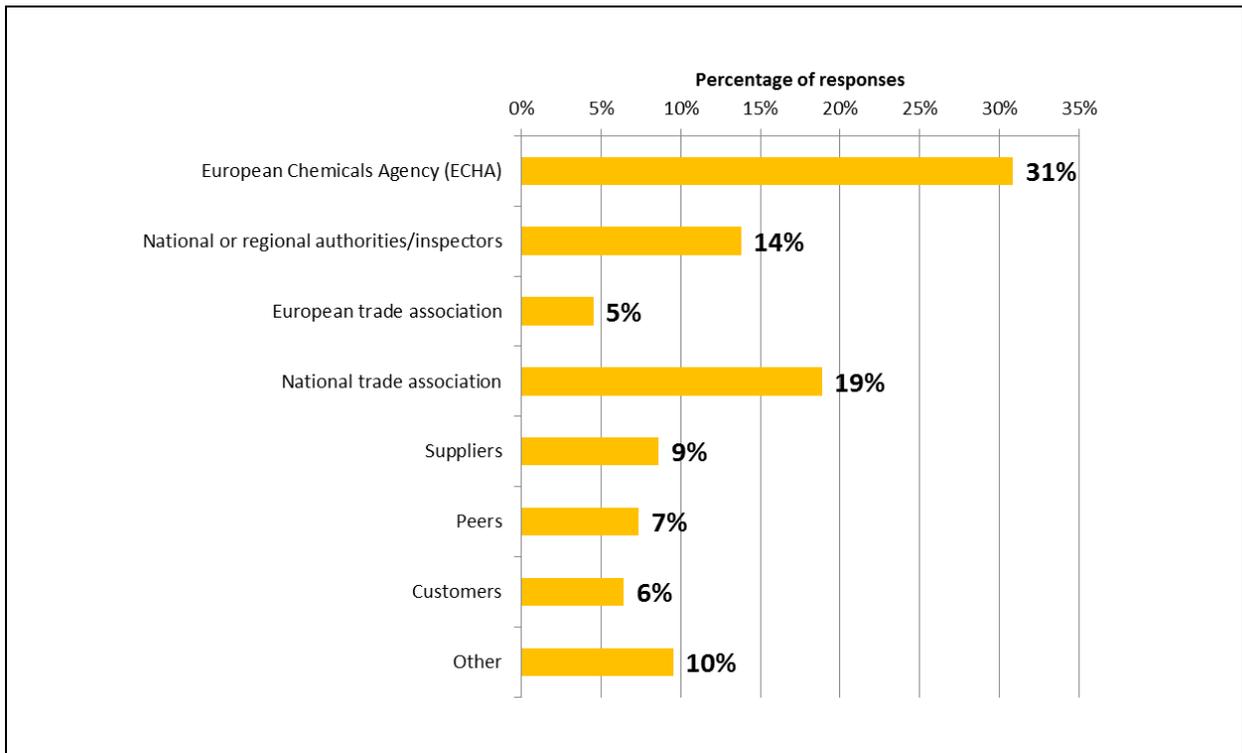


Figure 2-10: Chart showing the percentage of responses by reasons they became aware of EU REACH Regulation (from highest to lowest) (n=732)

**Question 7: Awareness that Chemical Substances Manufactured or Imported into EEA Between 1 and 1 000 Tonnes Need to be Registered by 31 May 2018**

Question 7 asked respondents to indicate whether they were aware of the requirement for registration of all chemical substances manufactured or imported into EEA between 1 and 1,000 tonnes need to be registered by 31 May 2018. In total, 730 responses were received to this question. Figure 2-11 presents a chart showing the proportion of ‘yes’ and ‘no’ responses to this question. Table 2-22 presents the number and percentage of respondents that replied ‘yes’ or ‘no’.

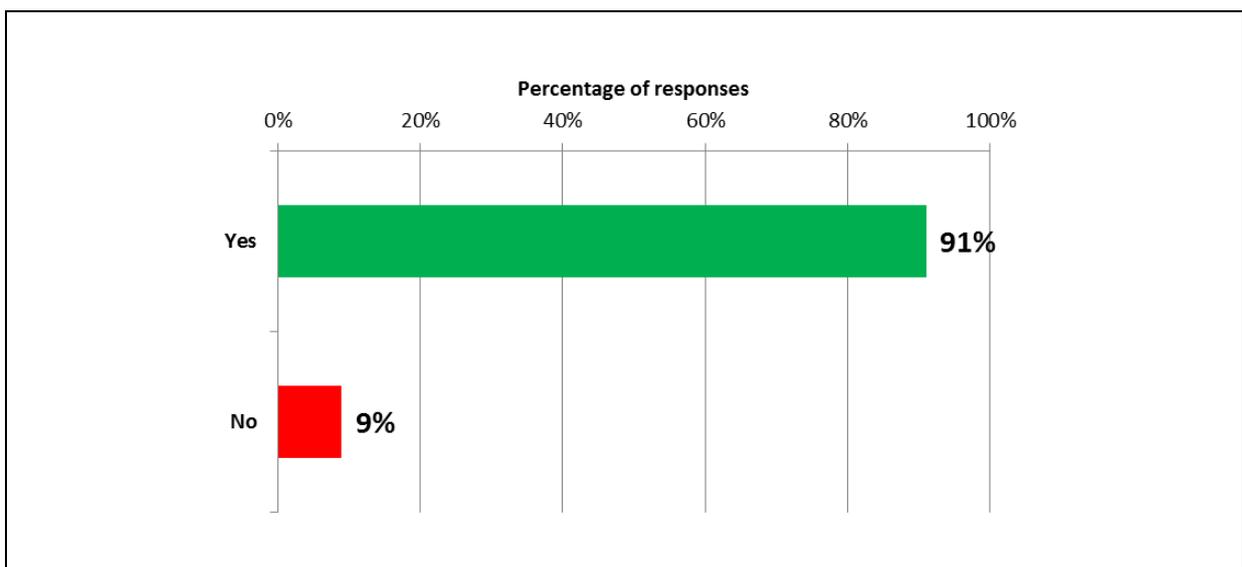


Figure 2-11: Chart showing the percentage of responses by awareness of need for registration (n=730)

| Table 2-22: Number and percentage of responses by awareness of need for registration (n=730) |                     |                    |
|--|---------------------|--------------------|
| Aware of need for registration   | Number of responses | % of all responses |
| Yes  | 665                 | 91%                |
| No   | 65                  | 9%                 |

**Question 8: Advice Sought to Comply with Registration Duties**

Respondents were asked to answer ‘yes’ or ‘no’ when asked if they sought advice on what they had to do to comply with registration duties. In total, there were 726 responses to this question. Figure 2-12 presents a chart showing the proportion of respondents that did and did not seek advice. Table 2-23 provides a breakdown on the numbers and percentage answering ‘yes’ or ‘no’.

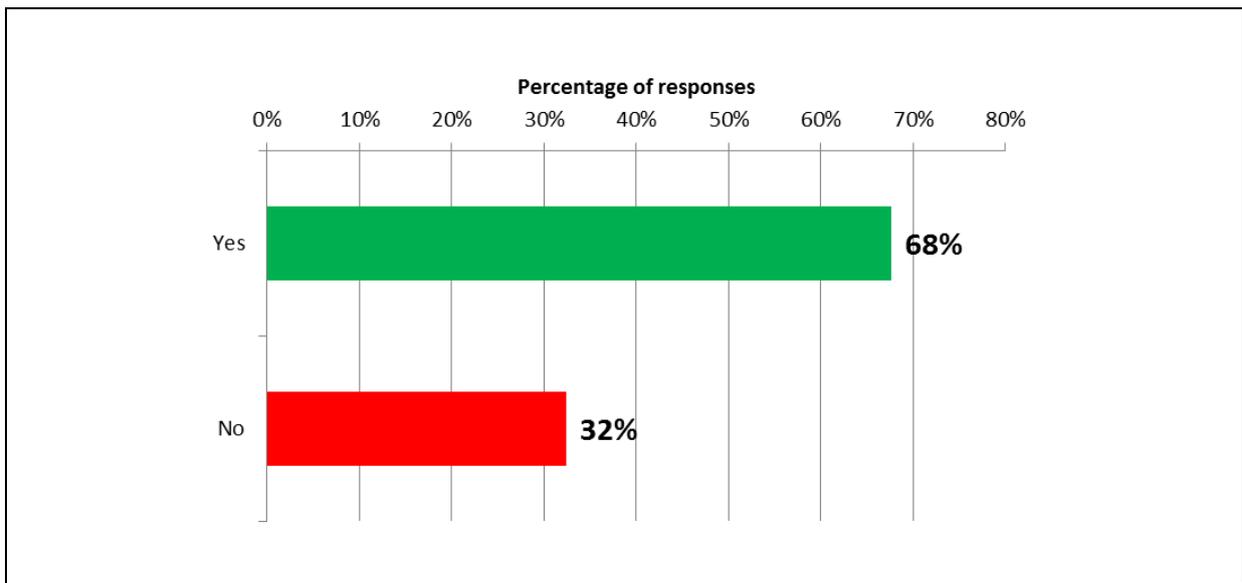


Figure 2-12: Chart showing the percentage of respondents that sought advice (n=726)

| Table 2-23: Number and percentage of respondents that sought advice (n=726) |                     |                    |
|---|---------------------|--------------------|
| Sought advice on what to do to comply with registration duties              | Number of responses | % of all responses |
| Yes   | 491                 | 68%                |
| No  | 235                 | 32%                |

**Question 9: Who Was Contacted for Advice**

Question 9 asked respondents to indicate who they contacted for advice on their registration duties. Nine possible answers were provided with space for respondents to indicate ‘other’ where they contacted another organisation or individual for advice. In total, 506 individual responses were received to this question, with some indicating to have contacted two or more different stakeholders for advice. Figure 2-13 presents a chart showing the most common sources of advice. Table 2-24 provides a full breakdown of the number and percentages contacting each of the nine possible answers as well as those who approached an ‘other’ source. Again, respondents could tick all the answers that apply so the number of responses (1,038) is greater than the number of individual respondents.

| Table 2-24: Number and percentage of respondents by who was approached for advice (n=506) |                     |                    |
|---|---------------------|--------------------|
| Who was contacted for advice  | Number of responses | % of all responses |
| ECHA help-desk  | 170                 | 34%                |
| National help-desk  | 141                 | 28%                |
| National or regional authorities  | 90                  | 18%                |
| European trade association  | 44                  | 9%                 |
| National trade association  | 132                 | 26%                |
| Suppliers   | 98                  | 19%                |
| Peers   | 76                  | 15%                |
| Customers   | 28                  | 6%                 |
| Consultancy   | 223                 | 44%                |
| Other   | 36                  | 7%                 |

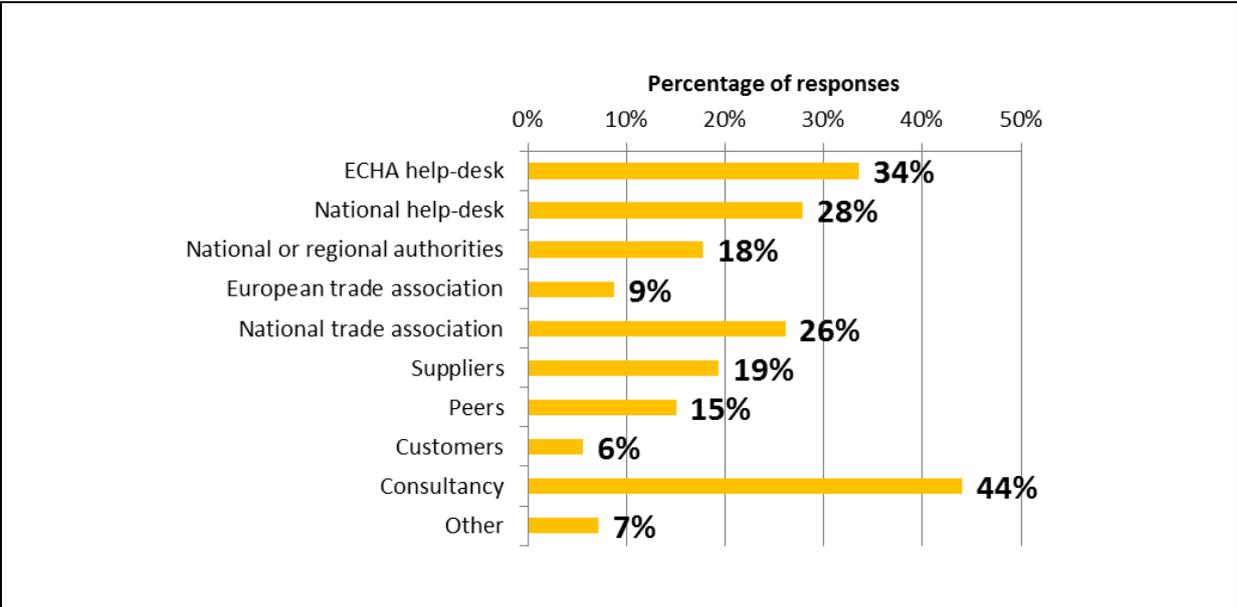


Figure 2-13: Chart showing who was contacted for advice (highest to lowest) (n=506)

**Question 10: Extent of REACH Registration Duties**

Respondents were asked whether they believe that they have REACH Registration duties. Four possible answers were available to this question and in total, 718 responses were received. Figure 2-14 presents a chart showing the proportion of responses to each of the four answers. Table 2-25 presents the full breakdown of responses giving the number and percentage agreeing with each answer.

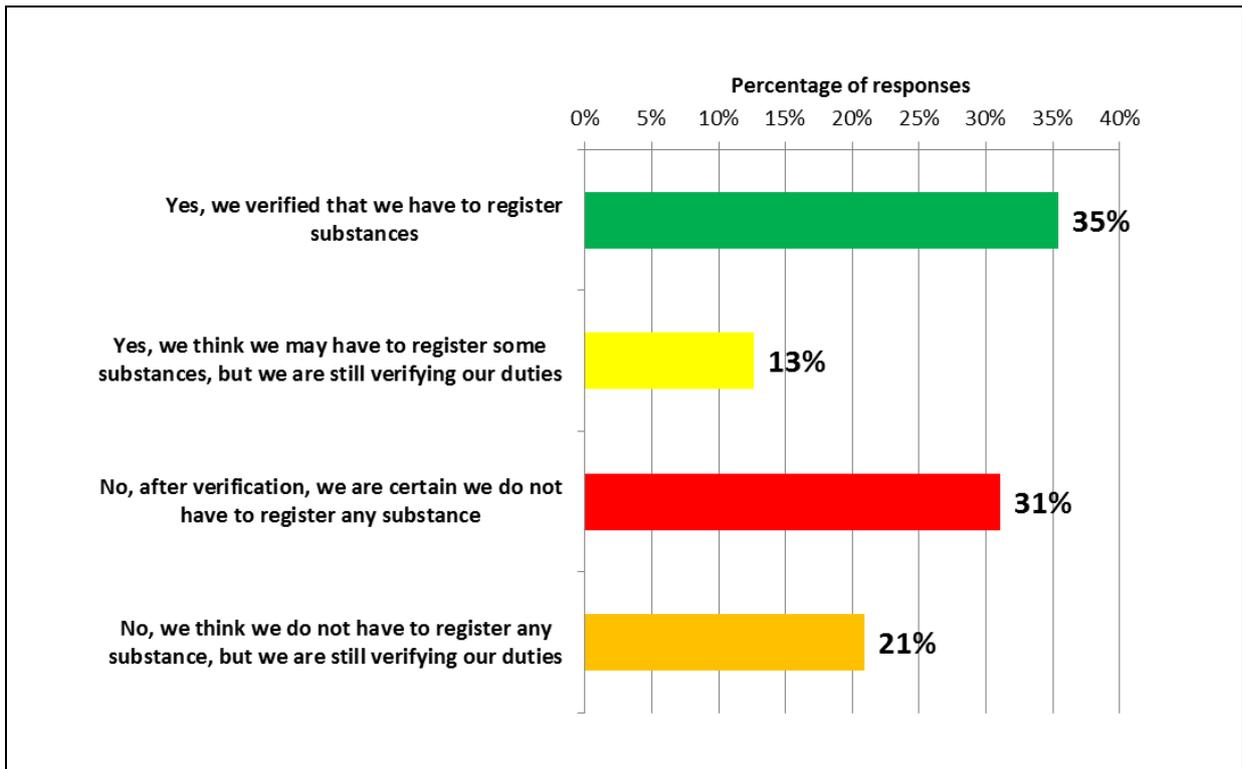


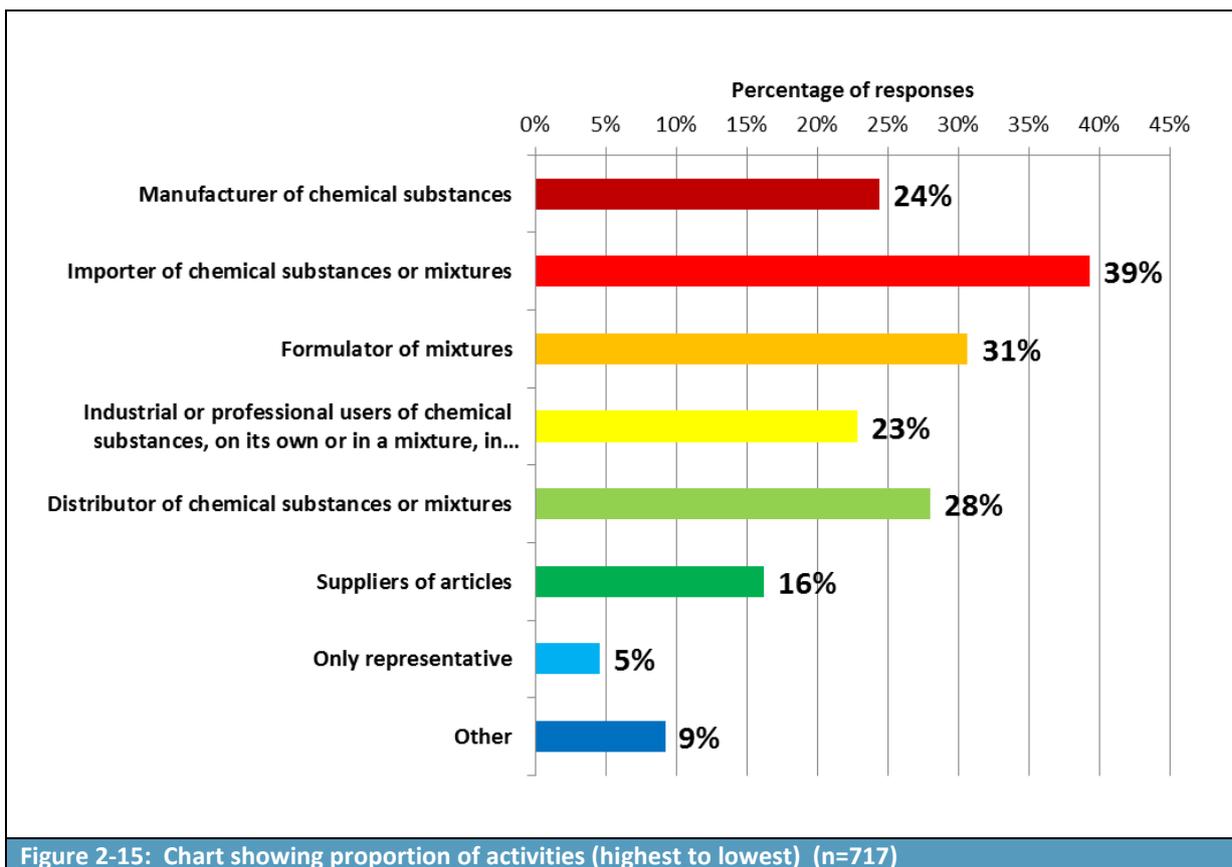
Figure 2-14: Chart showing whether respondents believe they have REACH Registration duties (n=718)

Table 2-25: Number and percentage of respondents according to their belief that they have REACH Registration duties (n=718)

| Extent of REACH Registration duties   | Number of responses | % of all responses |
|---|---------------------|--------------------|
| Yes, we verified that we have to register substances  | 254                 | 35%                |
| Yes, we think we may have to register some substances, but we are still verifying our duties (e.g. checking the quantities, consulting the national helpdesk) | 91                  | 13%                |
| No, after verification, we are certain we do not have to register any substance   | 223                 | 31%                |
| No, we think we do not have to register any substance, but we are still verifying our duties (e.g. checking the quantities, consulting the national helpdesk) | 150                 | 21%                |

**Question 11: Description of Activities in EEA Regarding Chemical Substances**

This question asked respondents about their activities in the EEA regarding chemical substances. Seven answers were provided plus space for ‘other’. 717 respondents answered this question but each respondent could tick more than one answer so the total number of responses is greater (1,257). Figure 2-15 presents a chart showing the proportion of responses, from highest to lowest. Table 2-26 provides the full breakdown of responses, number and percentage by type of activity.



**Table 2-26: Number and percentage of respondents according to their activities in the EEA regarding chemical substances (n=717)**

| Activities  | Number of responses | % of all responses |
|---|---------------------|--------------------|
| Manufacturer of chemical substances   | 175                 | 24%                |
| Importer of chemical substances or mixtures   | 282                 | 39%                |
| Formulator of mixtures  | 220                 | 31%                |
| Industrial or professional users of chemical substances, on its own or in a mixture, in professional or industrial activities (end users) | 164                 | 23%                |
| Distributor of chemical substances or mixtures  | 201                 | 28%                |
| Suppliers (manufacturers/importers/wholesalers/retailers) of articles   | 116                 | 16%                |
| Only representative   | 33                  | 5%                 |
| Other   | 66                  | 9%                 |

Those answering ‘No after verification, we are certain we do not have to register any substance’ to Question 10 were not required to answer any further questions.

### 2.4.3 Planning for Registration

This sub-section provides the analysis of responses to questions 12, 13, 14 and 15.

**Question 12: Number of Chemical Substances to Register for the 2018 Deadline**

Question 12 asked respondents how many chemical substances they are going to register for the 2018 deadline. Eight possible answers were provided plus 'don't know'. There were 438 responses to this question for '1-10 tonnes per annum' and 421 responses for '10-100 tonnes per annum'. Figure 2-16 presents a chart showing the variation in responses and the most common responses. Table 2-27 provides the full breakdown of responses giving the number selecting each answer and the percentage.

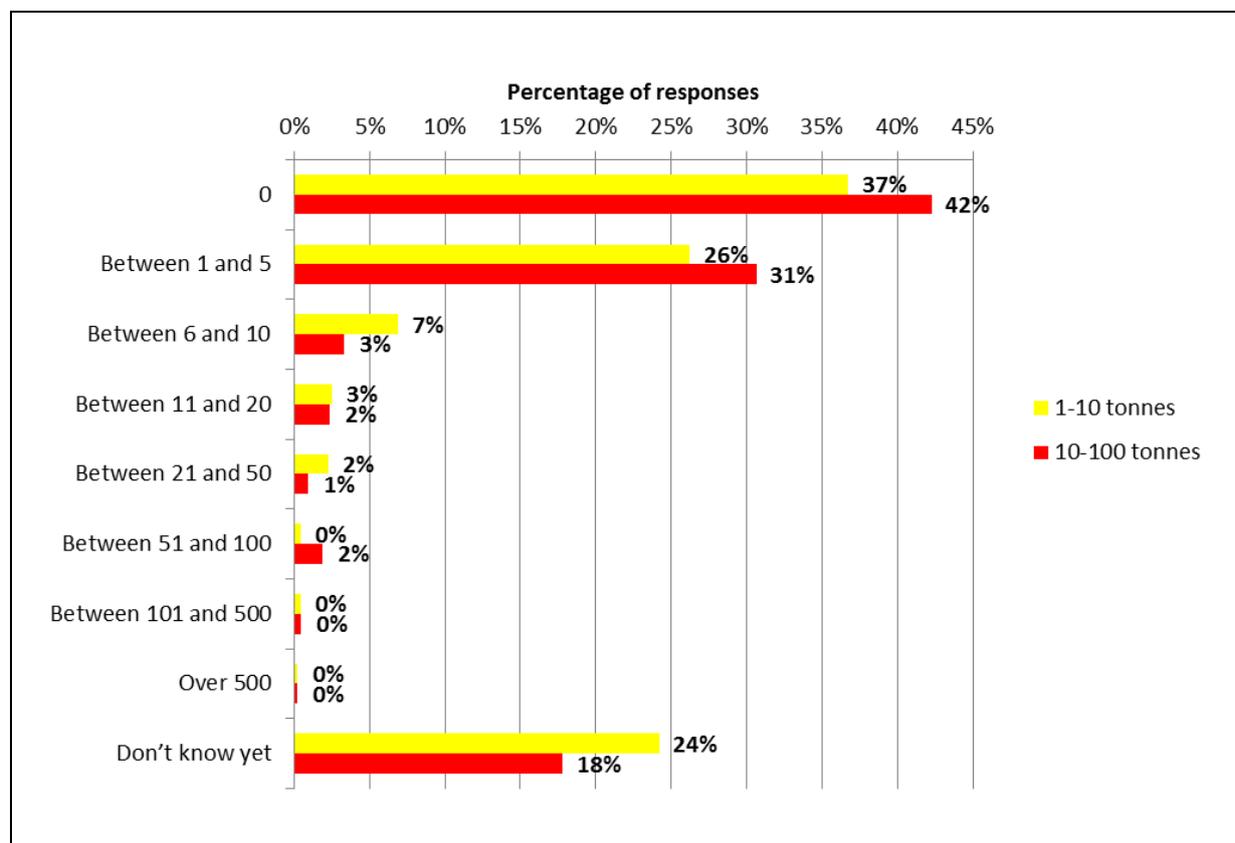


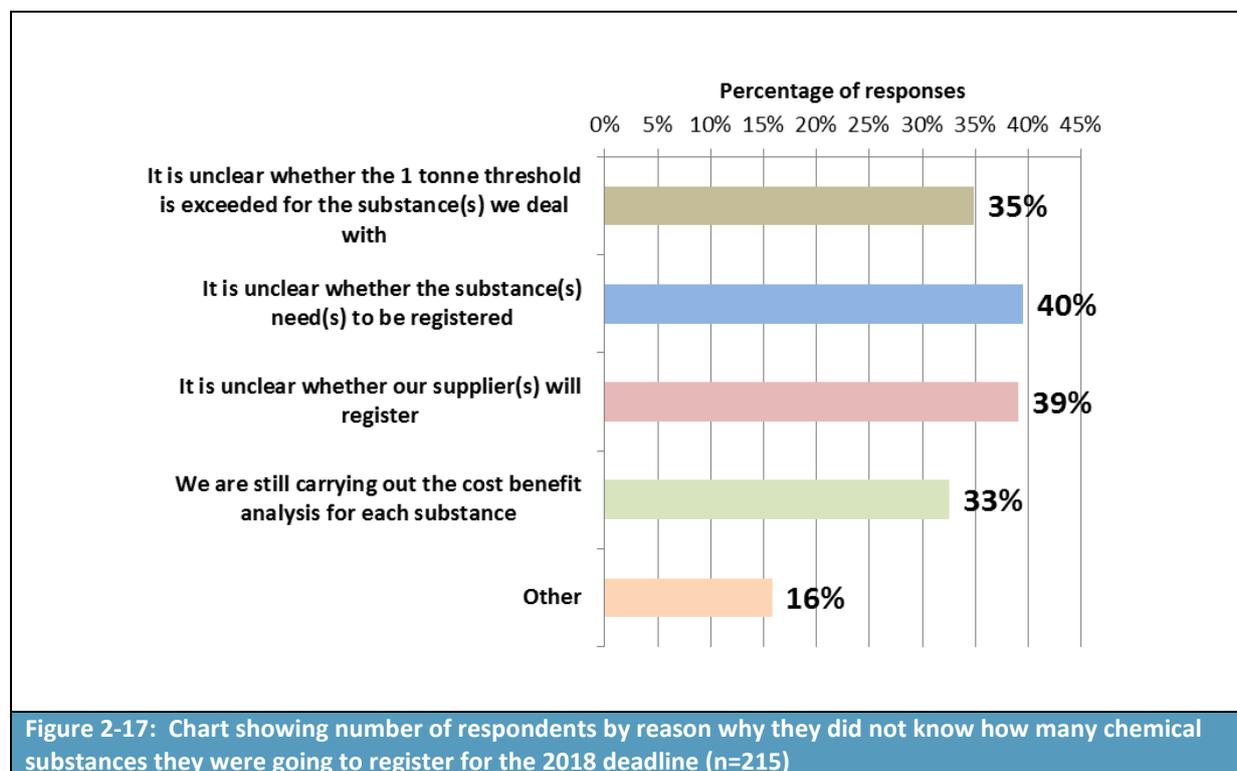
Figure 2-16: Chart showing number of chemical substances that respondents expected to register by 1-10 tonnes (n=438) and 10-100 tonnes (n=421)

Table 2-27: Number and percentage of respondents according to the number of chemical substances they are going to register by 1-10 tonnes (n=438) and 10-100 tonnes (n=421)

| Number of chemical substances to be registered | 1-10 tonnes         |                    | 10-100 tonnes       |                    |
|--|---------------------|--------------------|---------------------|--------------------|
|  | Number of responses | % of all responses | Number of responses | % of all responses |
| 0  | 161                 | 37%                | 178                 | 42%                |
| Between 1 and 5                                | 115                 | 26%                | 129                 | 31%                |
| Between 6 and 10                               | 30                  | 7%                 | 14                  | 3%                 |
| Between 11 and 20                              | 11                  | 3%                 | 10                  | 2%                 |
| Between 21 and 50                              | 10                  | 2%                 | 4                   | 1%                 |
| Between 51 and 100                             | 2                   | 0%                 | 8                   | 2%                 |
| Between 101 and 500                            | 2                   | 0%                 | 2                   | 0%                 |
| Over 500                                       | 1                   | 0%                 | 1                   | 0%                 |
| Don't know yet                                 | 106                 | 24%                | 75                  | 18%                |

**Question 13: Clarification from Those Answering “Don’t Know” to Question 12**

Question 13 was only asked to those who responded ‘don’t know’ to Question 12 with the aim being to identify reasons why the respondents were not sure how many chemical substances they were going to register. Four possible reasons were suggested with space for the respondents to record an ‘other’ response if necessary. There were 215 responses to this question. This compares to 106 ‘don’t know’ responses to Question 12. We assume the difference is due to some of the respondents not selecting “Don’t know yet” in Q12 but answering Q13.



**Table 2-28: Number and percentage of respondents by reason why they did not know how many chemical substances they were going to register for the 2018 deadline (n=208)**

| Reason  | Number of responses | % of all responses |
|---|---------------------|--------------------|
| It is unclear whether the 1 tonne threshold is exceeded for the substance(s) we deal with | 75                  | 35%                |
| It is unclear whether the substance(s) need(s) to be registered                           | 85                  | 40%                |
| It is unclear whether our supplier(s) will register                                       | 84                  | 39%                |
| We are still carrying out the cost benefit analysis for each substance                    | 70                  | 33%                |
| Other   | 34                  | 16%                |

**Question 14: Registration of Substances Used as Intermediates**

Respondents were asked to indicate which substances would be registered in full and which as intermediates only. Six possible answers were available. The pattern of responses is shown in Figure 2-18 with the full breakdown of results given in Table 2-29. Respondents were asked to differentiate between 1-10 tonnes, with 315 responses, and 10-100 tonnes per annum, with 283 responses.

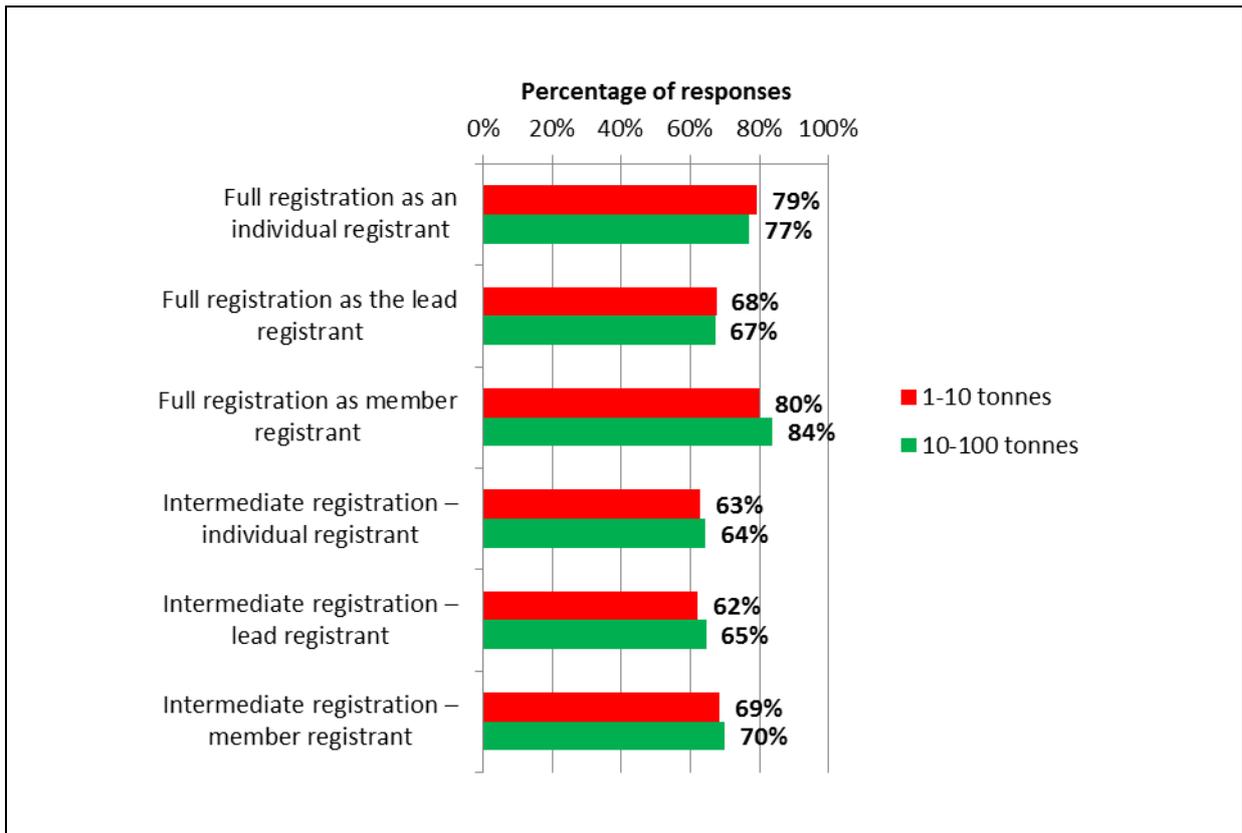


Figure 2-18: Chart showing number of intermediates that respondents expected to register by 1-10 tonnes (n=315) and 10-100 tonnes (n=283)

Table 2-29: Number and percentage of respondents according to the number of intermediates they are going to register by 1-10 tonnes (n=315) and 10-100 tonnes (n=283)

| Number of chemical substances to be registered    | 1-10 tonnes         |                    | 10-100 tonnes       |                    |
|---|---------------------|--------------------|---------------------|--------------------|
|   | Number of responses | % of all responses | Number of responses | % of all responses |
| Full registration as an individual registrant     | 250                 | 79%                | 218                 | 77%                |
| Full registration as the lead registrant          | 213                 | 68%                | 190                 | 67%                |
| Full registration as member registrant            | 252                 | 80%                | 237                 | 84%                |
| Intermediate registration – individual registrant | 198                 | 63%                | 182                 | 64%                |
| Intermediate registration – lead registrant       | 196                 | 62%                | 183                 | 65%                |
| Intermediate registration – member registrant     | 216                 | 69%                | 198                 | 70%                |

**Question 15: Timing of Submission of Registration Dossiers**

Question 15 asked respondents to identify when (month and year) they expected to submit their registration dossiers and the indicative number that would be submitted per month. There were thirteen possible answers plus ‘don’t know yet’. In total, there were 140 respondents indicating the period of submission for a total of 1,064 dossiers. In addition, 150 respondents do not know yet when (or if) they will be submitting the dossiers. Figure 2-19 provides a chart showing the expected pattern of submission. Table 2-30 gives the full breakdown of results including number of responses per month, total number of submissions per month, and percentage identifying each month and year.

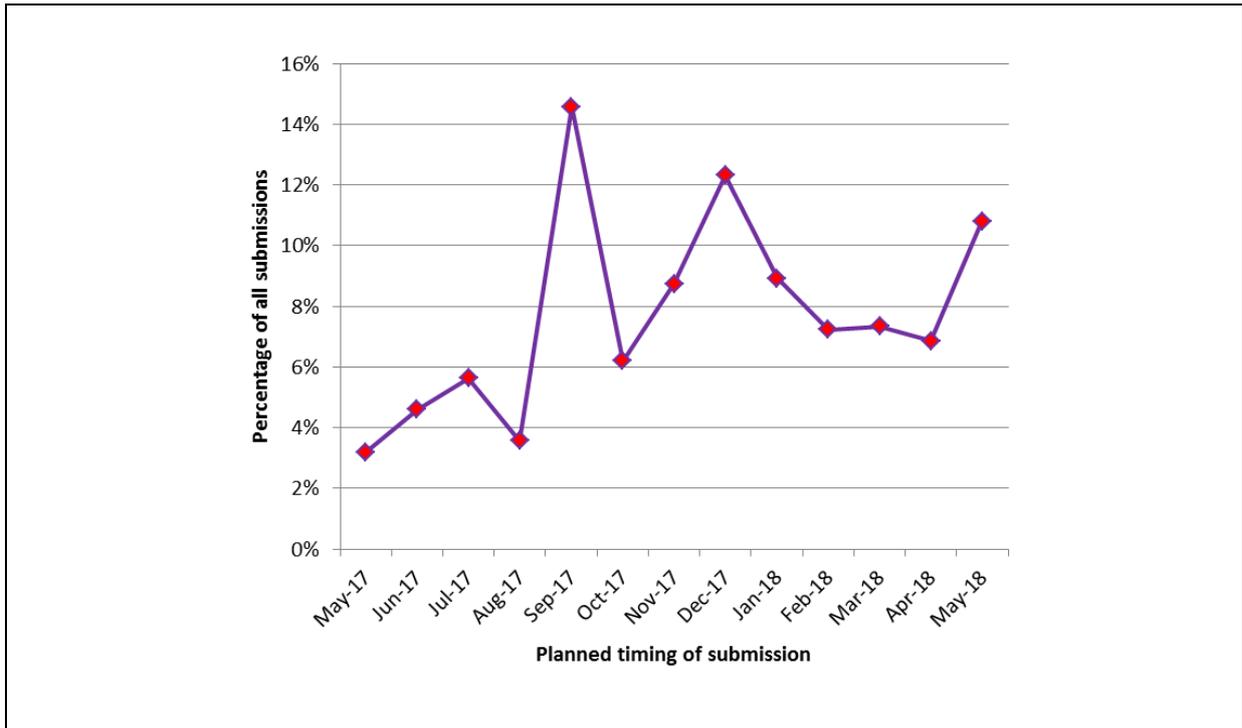


Figure 2-19: Chart showing planned timing of submission of registration documents (n=140)

Table 2-30: Number and percentage of respondents by planned timing of submission of registration documents (n=140)

| Month and year | Number of responses | Count of submissions | % of all submissions |
|----------------|---------------------|----------------------|----------------------|
| May 2017       | 46                  | 34                   | 3%                   |
| June 2017      | 48                  | 49                   | 5%                   |
| July 2017      | 46                  | 60                   | 6%                   |
| August 2017    | 37                  | 38                   | 4%                   |
| September 2017 | 43                  | 155                  | 15%                  |
| October 2017   | 44                  | 66                   | 6%                   |
| November 2017  | 44                  | 93                   | 9%                   |
| December 2017  | 55                  | 131                  | 12%                  |
| January 2018   | 47                  | 95                   | 9%                   |
| February 2018  | 39                  | 77                   | 7%                   |
| March 2018     | 41                  | 78                   | 7%                   |
| April 2018     | 46                  | 73                   | 7%                   |
| May 2018       | 46                  | 115                  | 11%                  |
| Don't know yet | 150                 |                      |                      |

#### 2.4.4 Experience with the Registration Process

This sub-section covers Questions 16 to 33, i.e. to the end of the survey.

##### **Question 16: Trade Association Membership**

Question 16 asked respondents to indicate if they are members of a trade association. Respondents were asked to reply 'yes' or 'no'. There were 514 responses to this question. Figure 2-20 shows the proportion of 'yes' and 'no' answers. Table 2-31 provides the numbers and proportion of respondents.

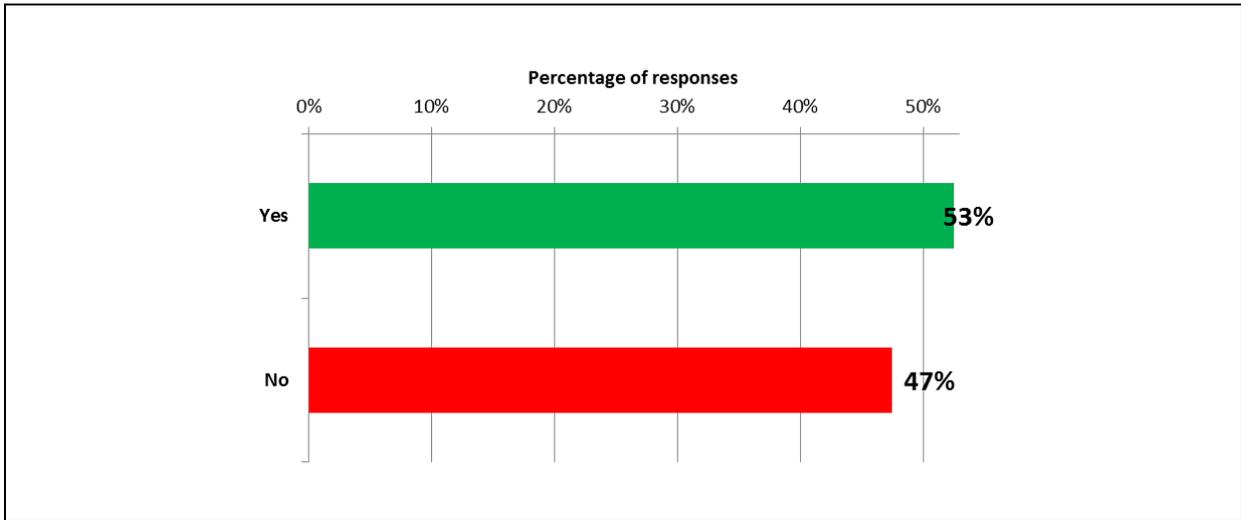


Figure 2-20: Chart showing proportion of trade association membership (n=514)

Table 2-31: Number and percentage of respondents by trade association membership (n=514)

| Month and year | Number of responses | % of all responses |
|----------------|---------------------|--------------------|
| Yes            | 270                 | 53%                |
| No             | 244                 | 47%                |

**Question 17: Perception of Extent to Which Trade Associations Reflect the Interests of their Company**

Respondents were asked to indicate how well trade associations represent the interests of their company. A scale of 0 to 10 was used, where 0 is 'not at all' and 10 is 'very well'. There were 435 responses to this question. Figure 2-21 presents a chart showing the variation in results. Table 2-32 provides the full breakdown showing the number and proportion of respondents assigning each score.

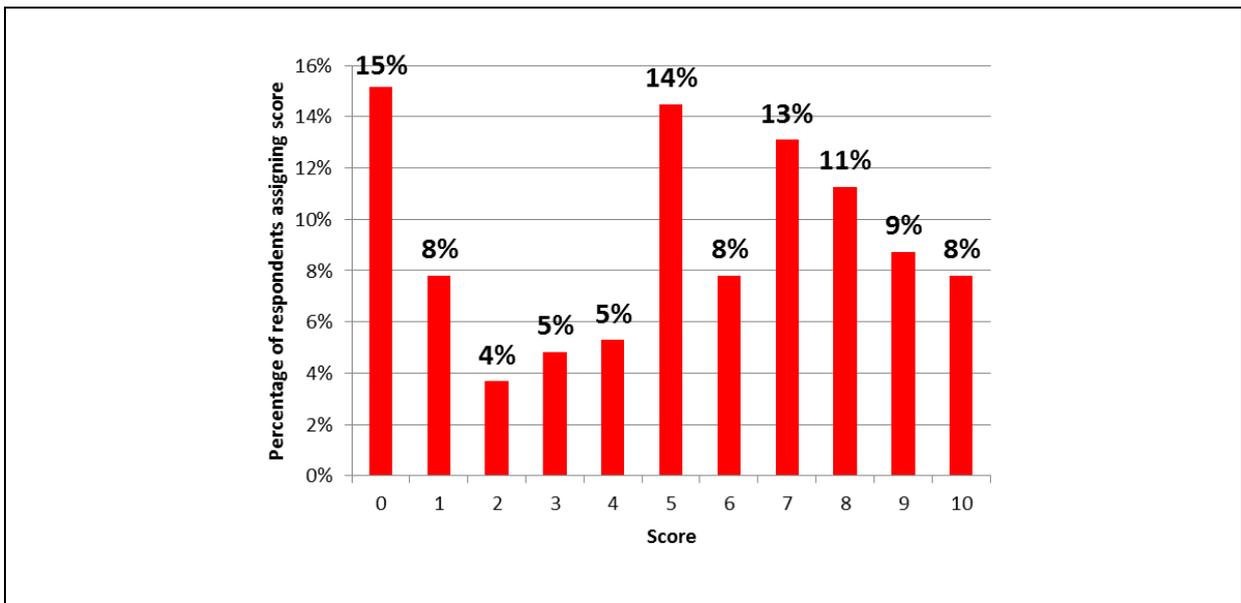


Figure 2-21: Chart showing results related to perceptions on how well trade associations represent their company's interests (n=435)

**Table 2-32: Number and percentage of respondents by how well trade associations represent their company's interests (n=435)**

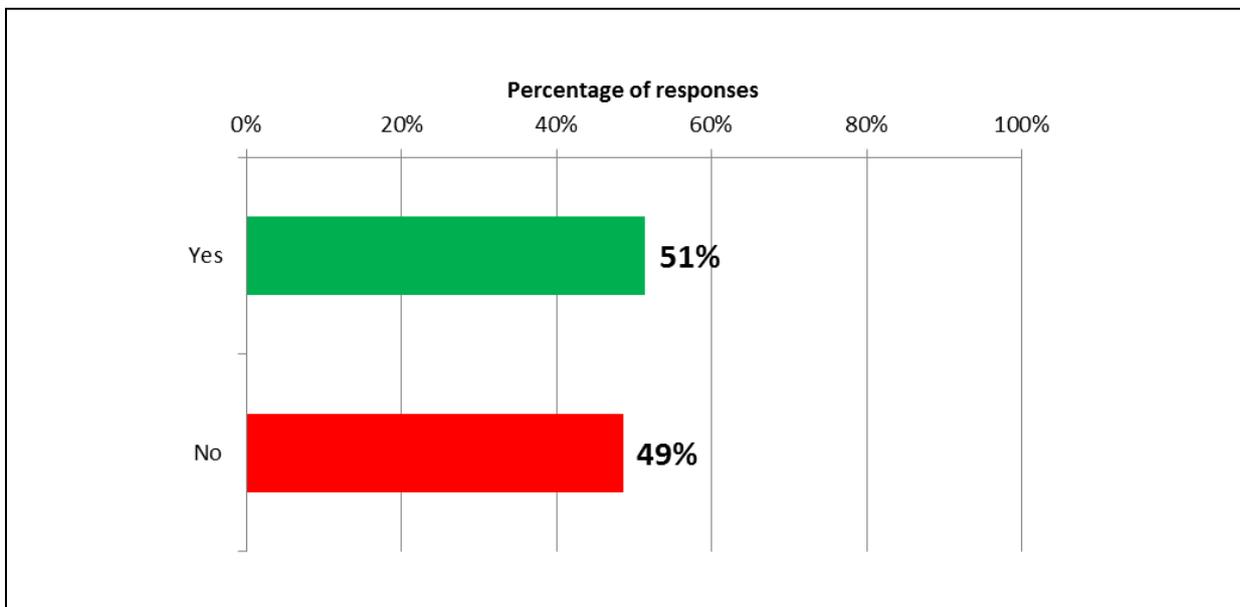
| Score          | Number of responses | % of all responses |
|----------------|---------------------|--------------------|
| 0 "Not at all" | 66                  | 15%                |
| 1              | 34                  | 8%                 |
| 2              | 16                  | 4%                 |
| 3              | 21                  | 5%                 |
| 4              | 23                  | 5%                 |
| 5              | 63                  | 14%                |
| 6              | 34                  | 8%                 |
| 7              | 57                  | 13%                |
| 8              | 49                  | 11%                |
| 9              | 38                  | 9%                 |
| 10 "Very well" | 34                  | 8%                 |

**Question 18: Advice Sought on Costs of Registration**

Question 18 asked respondents to indicate whether they had sought advice on the costs of registration and how to meet the costs. Respondents could reply 'yes' or 'no' to this question. In total, 477 responses were received. Figure 2-22 provides the proportion of respondents who answered 'yes' or 'no'. Table 2-33 gives the total number of responses and percentage answering 'yes' or 'no'.

**Table 2-33: Number and percentage of respondents by whether advice was sought on the costs of registration and how to meet the costs (n=496)**

| Response | Number of responses | % of all responses |
|----------|---------------------|--------------------|
| Yes      | 255                 | 51%                |
| No       | 241                 | 49%                |



**Figure 2-22: Chart showing results related to whether advice was sought on the costs of registration and how to meet the costs (n=496)**

**Question 19: Resources and Financial Budget Needed to Meet Registration Obligations**

Respondents were asked whether they already had in place the resources and financial budget needed to meet their registration obligations. Again, respondents could answer ‘yes’ or ‘no’. In total, there were 463 responses to this question. Figure 2-23 presents a chart showing the breakdown of responses. The number and percentage of responses is given in Table 2-34.

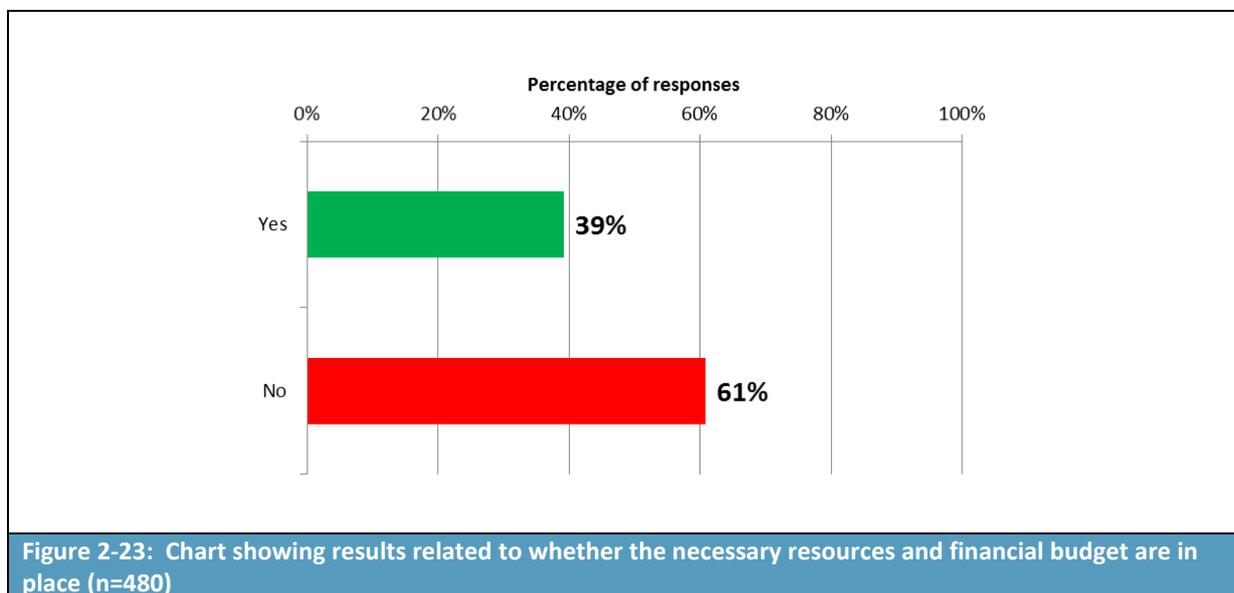


Figure 2-23: Chart showing results related to whether the necessary resources and financial budget are in place (n=480)

Table 2-34: Number and percentage of respondents by whether the necessary resources and financial budget are in place (n=480)

| Response | Number of responses | % of all responses |
|----------|---------------------|--------------------|
| Yes      | 179                 | 39%                |
| No       | 284                 | 61%                |

**Question 20: Impact of Resources and Financial Costs on Decision to Proceed with Registration**

Question 20 is focused on the extent to which resources and financial costs of registering chemical substances affected respondent’s decisions to proceed. A scale from 0 to 10 was used, where 0 is ‘in most cases, the cost of registration is not that significant compared to the commercial value of the substance’ and a score of 10 is ‘in most cases, there was a very significant cost impact compared to the commercial value of the substance’. There were 391 responses to this question, with an average score of 7.4. Figure 2-24 presents a chart showing the variation in results. Table 2-35 provides the full breakdown showing the number and proportion of respondents assigning each score.

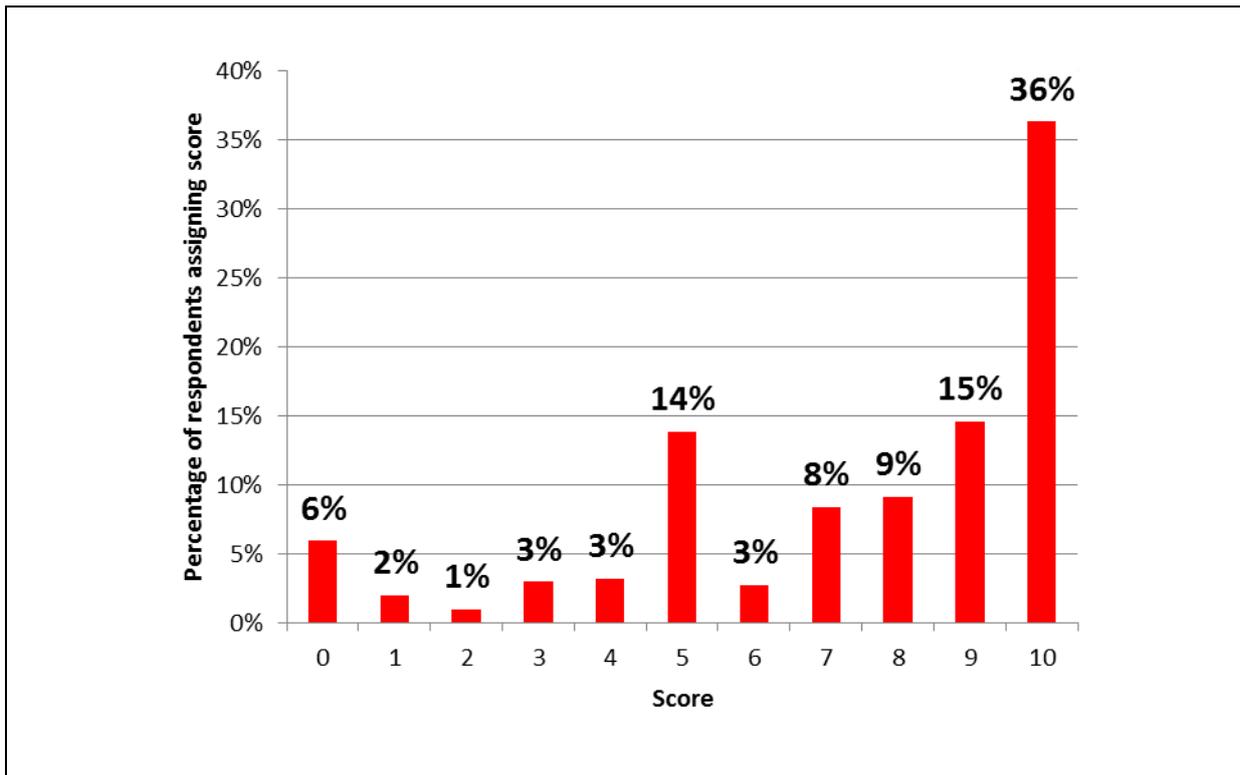


Figure 2-24: Chart showing results related to perceptions on how resources and financial costs affected their decision to proceed with registration (n=405)

Table 2-35: Number and percentage of respondents by how resources and financial costs affected their decision to proceed with registration (n=405)

| Score   | Number of responses | % of all responses |
|---|---------------------|--------------------|
| 0 "In most cases, the cost of registration is not that significant compared to the commercial value of the substance" | 24                  | 6%                 |
| 1   | 8                   | 2%                 |
| 2   | 4                   | 1%                 |
| 3   | 12                  | 3%                 |
| 4   | 13                  | 3%                 |
| 5   | 56                  | 14%                |
| 6   | 11                  | 3%                 |
| 7   | 34                  | 8%                 |
| 8   | 37                  | 9%                 |
| 9   | 59                  | 15%                |
| 10 "In most cases, there was a very significant cost impact compared to the commercial value of the substance"        | 147                 | 36%                |

**Question 21: Reasonableness of the Cost of the Letters of Access**

Question 21 asked respondents to indicate, using a score of 0 to 10, whether they thought the cost of Letters of Access was reasonable when considering the volume of substances that they deal with. A score of 0 represents 'very cheap compared with the commercial value' and a score of 10 represents 'very expensive compare to the commercial value'. There were 391 responses to this question, with an average score of 7.7. Figure 2-25 presents a chart showing the breakdown of responses. The number and percentage of responses who answered 'yes' or 'no' is given in Table 2-36.

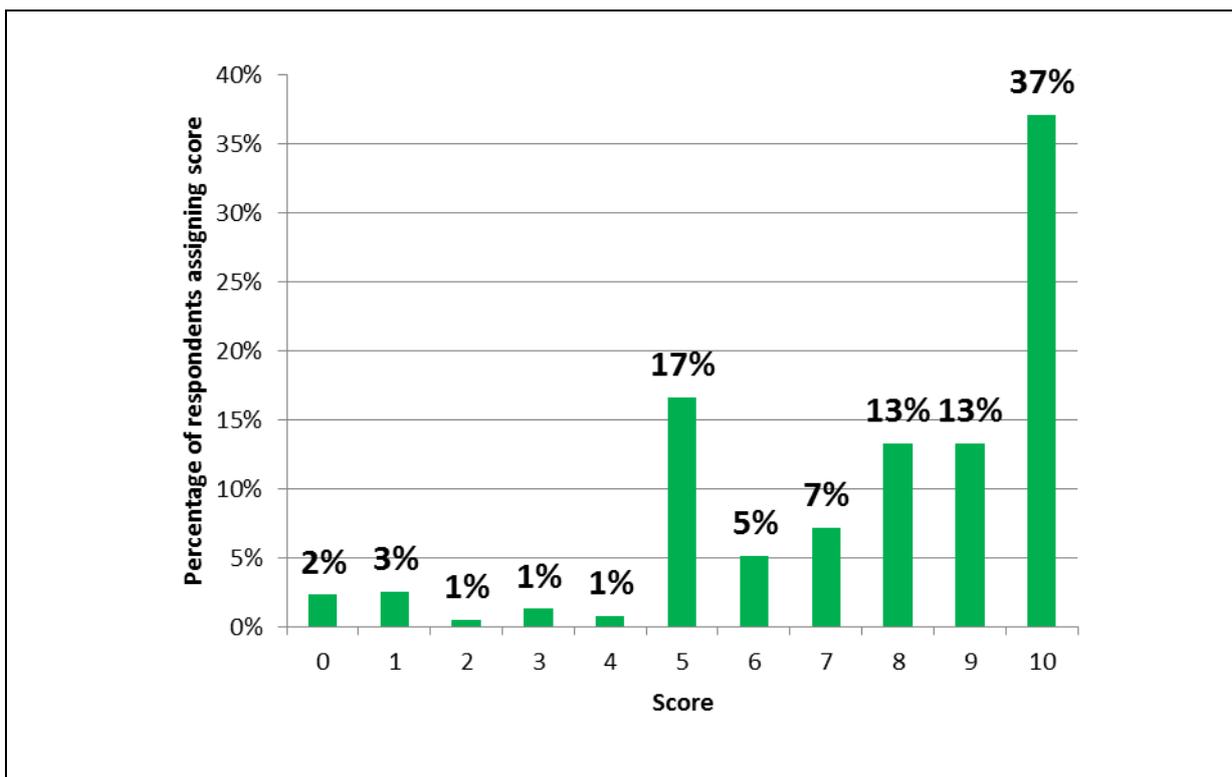


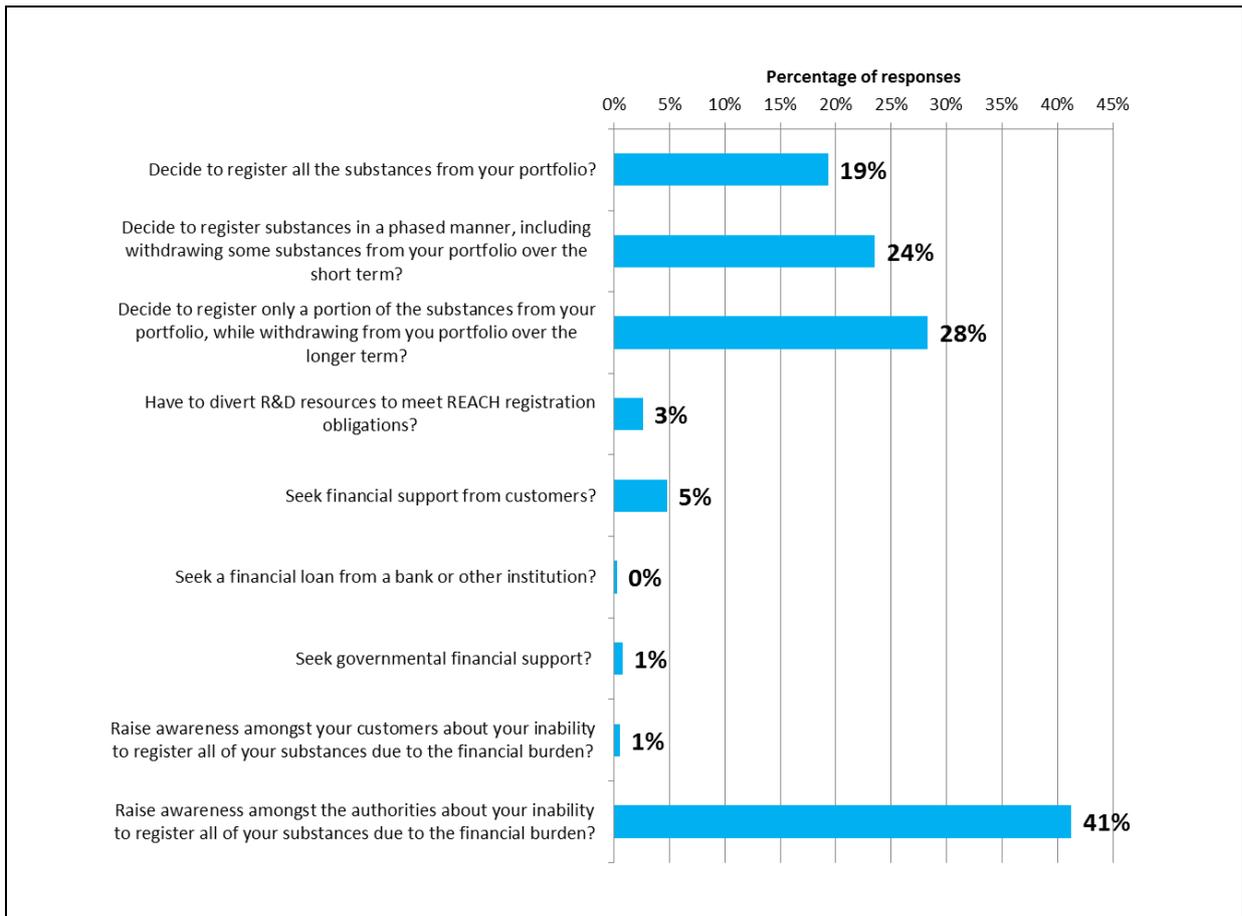
Figure 2-25: Chart showing results related to whether the cost of Letters of Access are considered reasonable (n=391)

Table 2-36: Number and percentage of respondents by whether the cost of Letters of Access are considered reasonable (n=391)

| Response   | Number of responses | % of all responses |
|--|---------------------|--------------------|
| 0 "Very cheap compared with the commercial value"    | 9                   | 2%                 |
| 1  | 10                  | 3%                 |
| 2  | 2                   | 1%                 |
| 3  | 5                   | 1%                 |
| 4  | 3                   | 1%                 |
| 5  | 65                  | 17%                |
| 6  | 20                  | 5%                 |
| 7  | 28                  | 7%                 |
| 8  | 52                  | 13%                |
| 9  | 52                  | 13%                |
| 10 "Very expensive compared to the commercial value" | 145                 | 37%                |

**Question 22: Response to Understanding to Time and Costs Associated with Registration**

Respondents were asked what their response was to understanding the time and costs associated with registering substances under REACH. Nine answers were suggested with space for respondents to indicate an 'other' response. Respondents could tick all of the responses that applied hence the total number of responses is greater than the number of respondents (364). Figure 2-26 presents a chart showing the proportion of responses that were undertaken. Table 2-37 provides the full breakdown of responses by number and percentage. Over 40% of the companies tried to raise awareness over their inability to register all of their substances due to the financial burden.



**Figure 2-26: Chart showing results related to response to understanding of time and costs required for registration (n=378)**

**Table 2-37: Number and percentage of respondents by understanding of time and costs required for registration (n=378)**

| Response  | Number of responses | % of all responses |
|---|---------------------|--------------------|
| Decide to register all the substances from your portfolio?  | 73                  | 19%                |
| Decide to register substances in a phased manner, including withdrawing some substances from your portfolio over the short term?    | 89                  | 24%                |
| Decide to register only a portion of the substances from your portfolio, while withdrawing from you portfolio over the longer term? | 107                 | 28%                |
| Have to divert R&D resources to meet REACH registration obligations?  | 10                  | 3%                 |
| Seek financial support from customers?  | 18                  | 5%                 |
| Seek a financial loan from a bank or other institution?   | 1                   | 0%                 |
| Seek governmental financial support?  | 3                   | 1%                 |
| Raise awareness amongst your customers about your inability to register all of your substances due to the financial burden?         | 2                   | 1%                 |
| Raise awareness amongst the authorities about your inability to register all of your substances due to the financial burden?        | 156                 | 41%                |
| Other   | 42                  | 11%                |

**Question 23: Percentage of Substances to be Withdrawn from the Market**

Respondents were asked to indicate the percentage of substances that they foresee withdrawing from their current substance portfolio. Possible answers ranged from 10% to 100% and were targeted just at those respondents that were considering withdrawing substances. In total, there were 236 responses to this question. Figure 2-27 shows the variation in responses. Table 2-38 presents the number of respondents who suggested each percentage and the proportion.

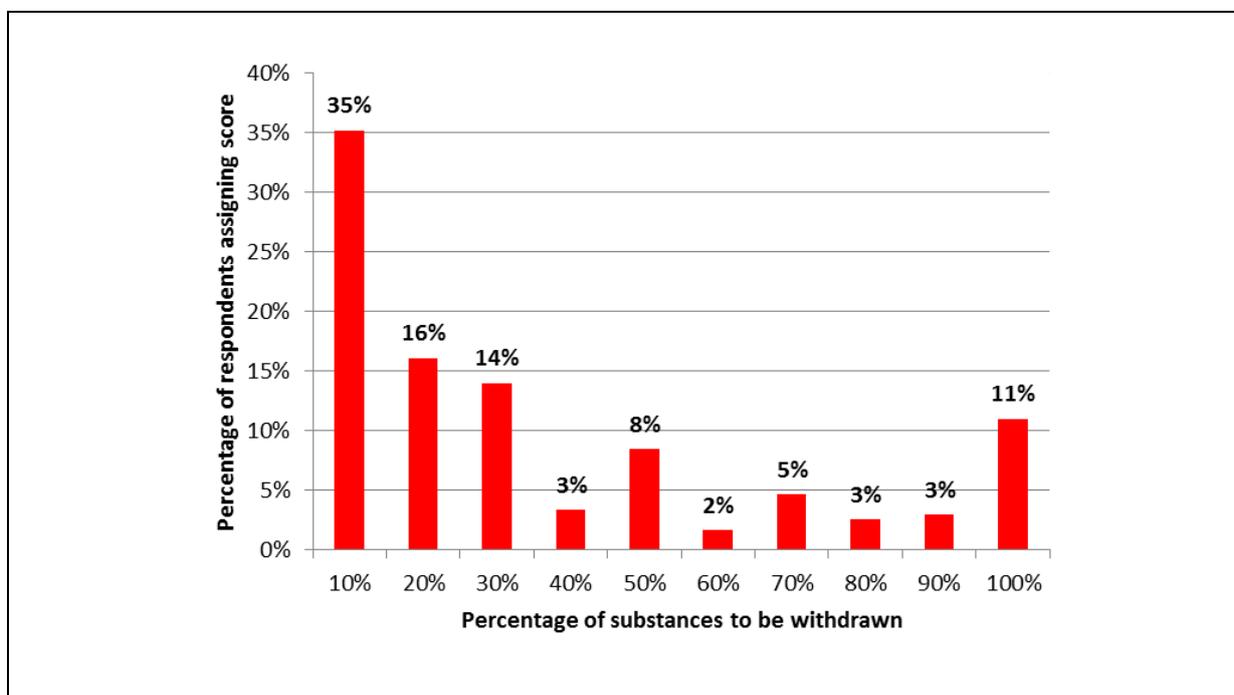


Figure 2-27: Chart showing results related to percentage of substances that respondents were considering withdrawing from the market (n=236)

Table 2-38: Number and percentage of respondents by percentage of substances that respondents were considering withdrawing from the market (n=236)

| Percentage of substance portfolio | Number of responses | % of all responses |
|-----------------------------------|---------------------|--------------------|
| 10%                               | 83                  | 35%                |
| 20%                               | 38                  | 16%                |
| 30%                               | 33                  | 14%                |
| 40%                               | 8                   | 3%                 |
| 50%                               | 20                  | 8%                 |
| 60%                               | 4                   | 2%                 |
| 70%                               | 11                  | 5%                 |
| 80%                               | 6                   | 3%                 |
| 90%                               | 7                   | 3%                 |
| 100%                              | 26                  | 11%                |

**Question 24: Customers ask for a Declaration of Compliance with REACH**

Question 24 asked respondents to indicate whether their key customers ask for the declaration of compliance with REACH. Respondents could answer ‘yes’ or ‘no’. There were 489 responses to this question. Figure 2-28 presents a chart showing the proportion of each answer. Table 2-39 provides full details of the responses by number and percentage.

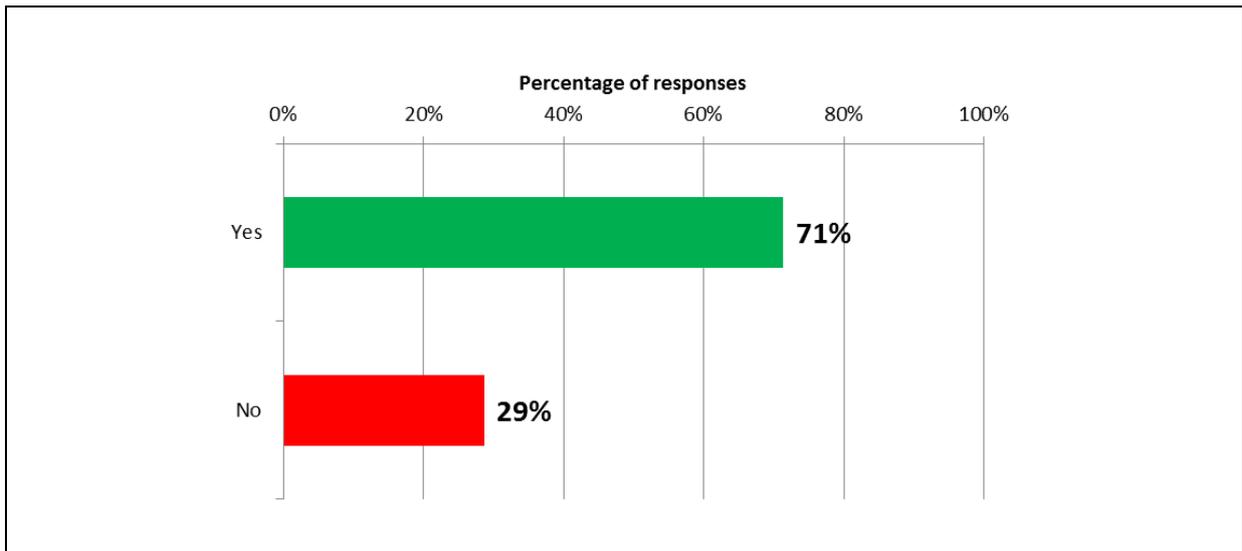


Figure 2-28: Chart showing results related to whether customers ask for a declaration of compliance (n=489)

Table 2-39: Number and percentage of respondents by whether customers ask for a declaration of compliance (n=489)

| Response | Number of responses | % of all responses |
|----------|---------------------|--------------------|
| Yes      | 349                 | 71%                |
| No       | 140                 | 29%                |

**Question 25: Assistance from the Supply Chain**

Respondents were asked whether customers in the supply chain offered assistance (including financial assistance) or expertise/data to help them to complete the registration process. There was a choice of 'yes' or 'no' responses. In total, there were 466 responses to this question. Figure 2-29 presents a chart showing the proportion of 'yes' and 'no' answers. Table 2-40 provides full details of the responses by number and percentage.

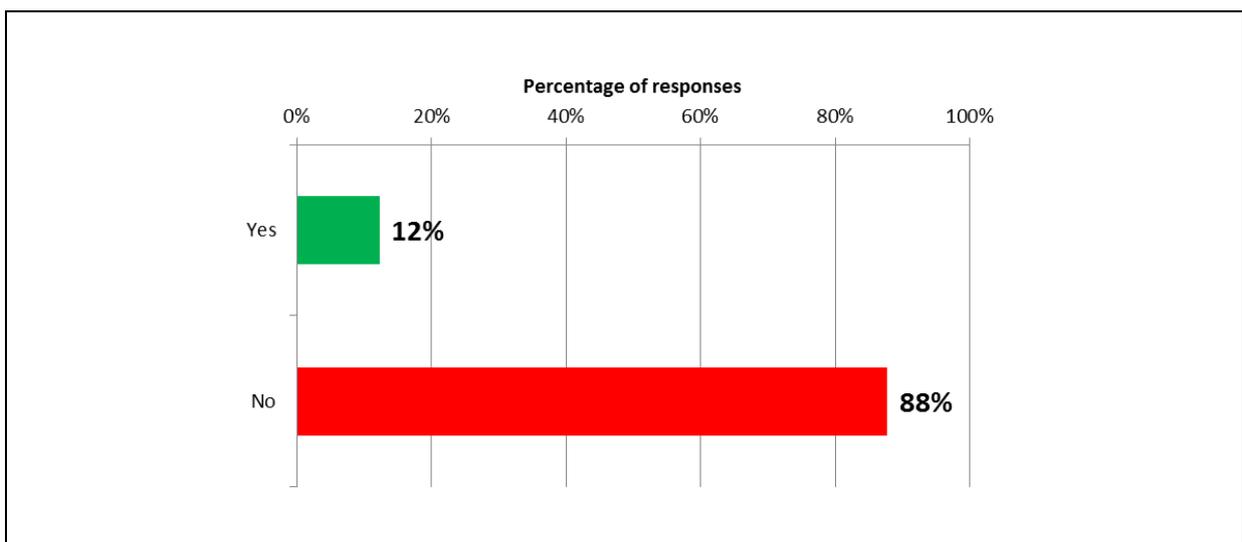


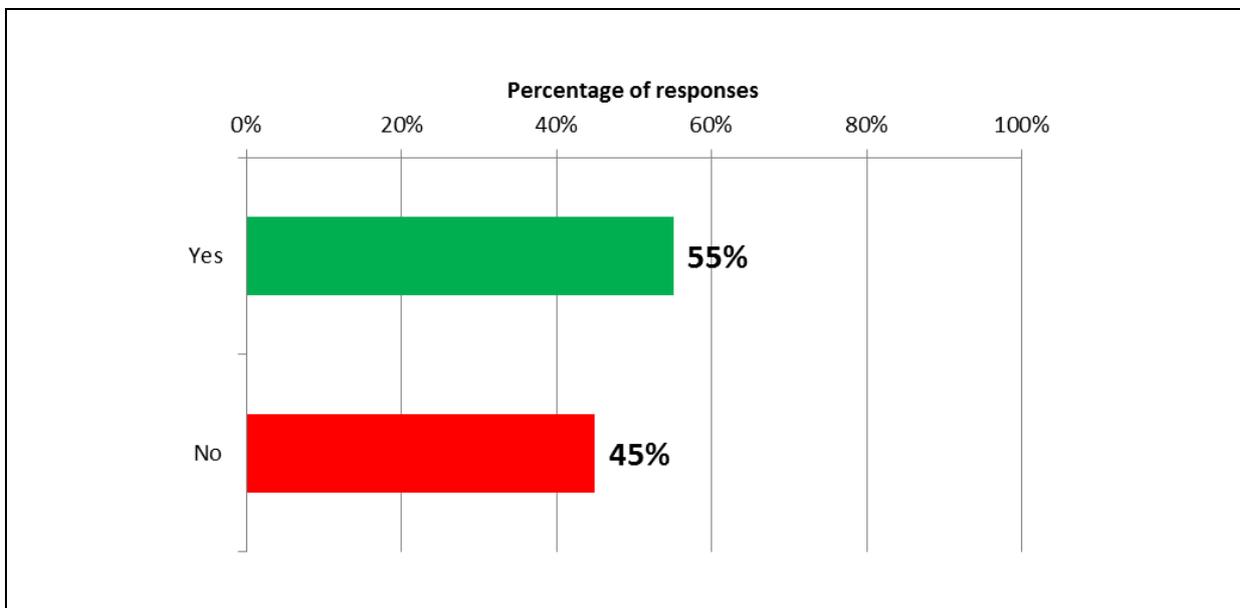
Figure 2-29: Chart showing results related to whether customers in the supply chain offered assistance to help them complete the registration process (n=466)

**Table 2-40: Number and percentage of respondents by whether customers in the supply chain offered assistance to help them complete the registration process (n=466)**

| Response | Number of responses | % of all responses |
|----------|---------------------|--------------------|
| Yes      | 57                  | 12%                |
| No       | 409                 | 88%                |

**Question 26: Investigation of Substitutes for Chemical Substances that may be Considered Hazardous**

Question 26 asked respondents to indicate if they actively investigate substitutes for chemical substances that may be considered hazardous or best avoided in the future. Respondents were able to choose from ‘yes’ or ‘no’. There were 463 responses to this question. Figure 2-30 provides a chart showing the proportion of ‘yes’ and ‘no’ answers. Table 2-41 gives full details of the responses by number and percentage.



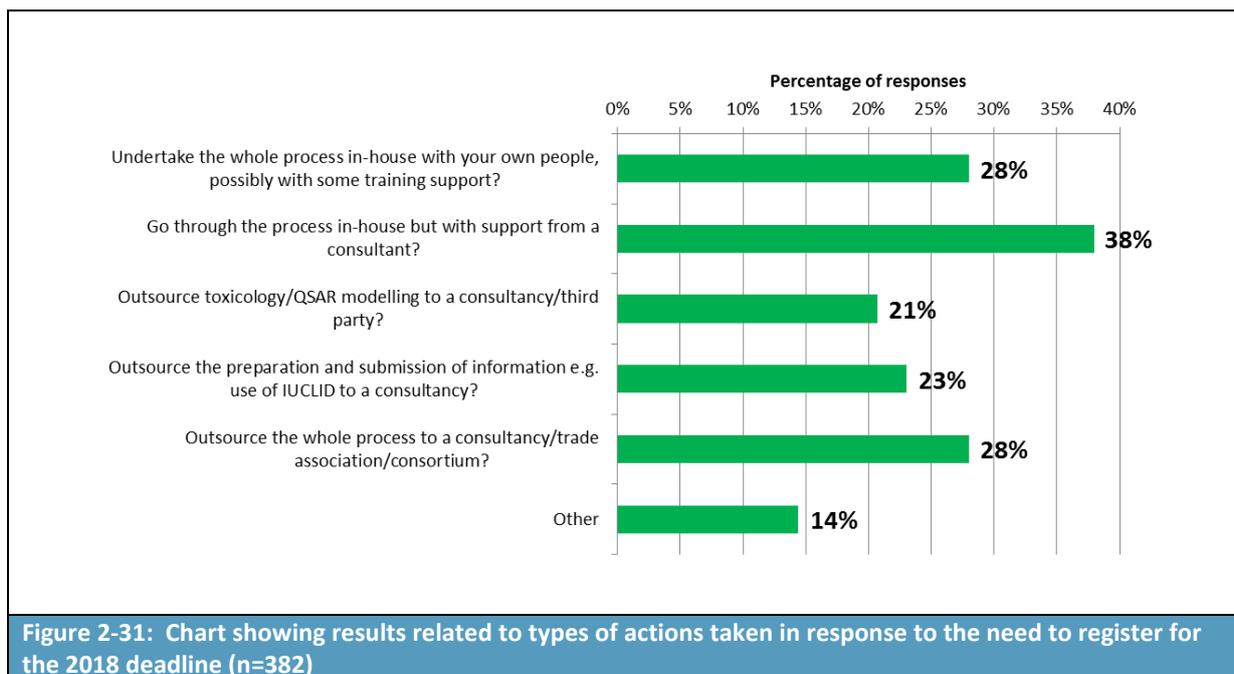
**Figure 2-30: Chart showing results related to whether they actively investigate substitutes for chemical substances that may be considered hazardous (n=463)**

**Table 2-41: Number and percentage of respondents by whether they actively investigate substitutes for chemical substances that may be considered hazardous (n=463)**

| Response | Number of responses | % of all responses |
|----------|---------------------|--------------------|
| Yes      | 255                 | 55%                |
| No       | 208                 | 45%                |

**Question 27: Actions They Will Take to Register Substances**

Question 27 asked which actions respondents would take if they have to register substances for the 2018 deadline. Five answers were suggested plus ‘other’. In total, there were 382 responses to this question. Figure 2-31 shows the variation in number of responses received by each answer. Table 2-42 provides full details of the number of percentage of respondents who indicated each approach. Respondents could tick more than one answer, so the total number of responses exceeds the number of respondents who answered this question.



**Table 2-42: Number and percentage of respondents by types of actions taken in response to the need to register for the 2018 deadline (n=382)**

| Action  | Number of responses | % of all responses |
|---|---------------------|--------------------|
| Undertake the whole process in-house with your own people, possibly with some training support? | 107                 | 28%                |
| Go through the process in-house but with support from a consultant?                             | 145                 | 38%                |
| Outsource toxicology/QSAR modelling to a consultancy/third party?                               | 79                  | 21%                |
| Outsource the preparation and submission of information e.g. use of IUCLID to a consultancy?    | 88                  | 23%                |
| Outsource the whole process to a consultancy/trade association/consortium?                      | 107                 | 28%                |
| Other   | 55                  | 14%                |

### Question 28: Interest in Using IUCLID

Question 28 asked respondents if they would be interested in using IUCLID (the software used to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances) on the cloud, lowering the cost for managing installations and hardware. Respondents could reply 'yes' or 'no'. If answering 'no', they were asked to provide information on why they had said no. There were 426 responses to this question. Figure 2-32 presents a chart showing the breakdown of responses. Table 2-43 identifies the number and percentage responding 'yes' or 'no', with further details also included for those who replied 'no'.

**Table 2-43: Number and percentage of respondents by whether they are interested in using IUCLID on the cloud (n=426)**

| Response | Number of responses | % of all responses |
|----------|---------------------|--------------------|
| Yes      | 244                 | 57%                |
| No       | 182                 | 43%                |

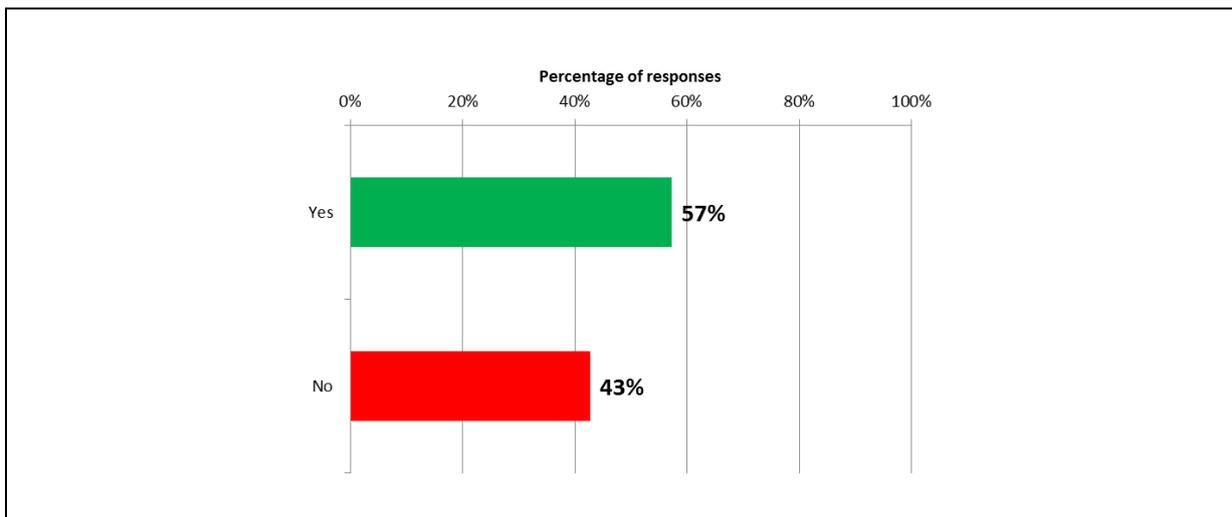


Figure 2-32: Chart showing results related to whether respondents are interested in using IUCLID on the cloud (n=426)

**Question 29: Already Registered Substances Under REACH**

Question 29 asked respondents whether they had already registered substances under REACH, with a choice of ‘yes’ or ‘no’ answers. There were 491 responses to this question. Figure 2-33 presents the breakdown by ‘yes’ and ‘no’ answers. Table 2-44 provides full details of number of respondents who replied ‘yes’ or ‘no’. Those respondents who answered ‘no’ to this question were not required to answer the remaining questions.

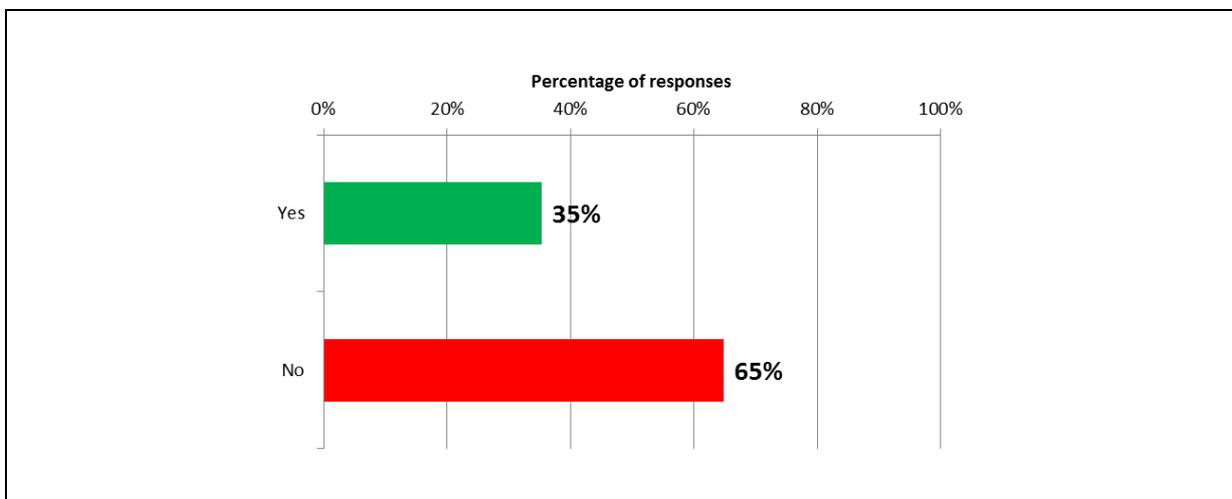


Figure 2-33: Chart showing results related to whether respondents had already registered substances under REACH (n=491)

Table 2-44: Number and percentage of respondents by whether they had already registered substances under REACH (n=491)

| Response | Number of responses | % of all responses |
|----------|---------------------|--------------------|
| Yes      | 173                 | 35%                |
| No       | 318                 | 65%                |

**Question 30: Ease of Undertaking Different Aspects of the Registration Process**

Respondents were asked to rate how easy they found eight different activities on a scale of 1 to 10, where 1 is 'very easy' and 10 is 'very difficult'. Respondents could also answer that they 'don't know'. There were 320 responses to this question. Figure 2-34 provides the average score for each activity. Table 2-45 presents the number of respondents allocating each score to each activity.

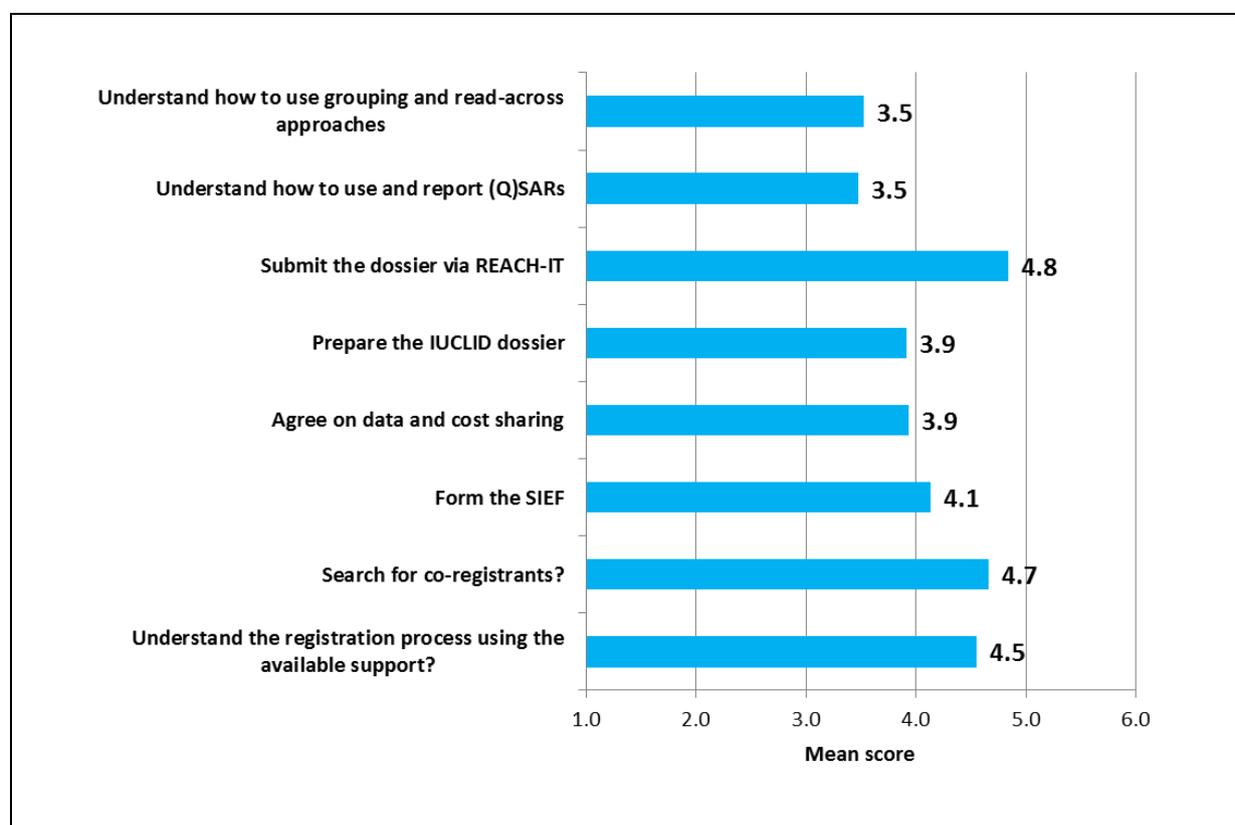


Figure 2-34: Chart showing results related to ease of undertaking each activity (n=320)

Table 2-45: Number of respondents by score assigned to ease of undertaking each activity (n=320)

| Activity   | Score assigned |    |    |    |    |    |    |    |    |    |            |
|--|----------------|----|----|----|----|----|----|----|----|----|------------|
|  | 1              | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 | Don't know |
| Understand the registration process using the available support? | 40             | 32 | 45 | 20 | 41 | 17 | 23 | 30 | 8  | 12 | 48         |
| Search for co-registrants?                                       | 40             | 28 | 28 | 33 | 36 | 16 | 20 | 26 | 7  | 17 | 58         |
| Form the SIEF  | 55             | 22 | 30 | 15 | 25 | 11 | 18 | 12 | 8  | 13 | 92         |
| Agree on data and cost sharing                                   | 55             | 34 | 27 | 22 | 20 | 13 | 15 | 12 | 8  | 11 | 87         |
| Prepare the IUCLID dossier                                       | 54             | 29 | 23 | 16 | 32 | 11 | 14 | 12 | 8  | 7  | 97         |
| Submit the dossier via REACH-IT                                  | 42             | 20 | 21 | 12 | 26 | 14 | 22 | 16 | 16 | 16 | 97         |
| Understand how to use and report (Q)SARs                         | 53             | 18 | 29 | 13 | 16 | 8  | 8  | 7  | 4  | 6  | 138        |
| Understand how to use grouping and read-across approaches        | 57             | 25 | 17 | 15 | 29 | 9  | 9  | 3  | 4  | 8  | 121        |

**Question 31: Ease of Use of IUCLID**

Question 31 asked respondents to rank their experience with IUCLID across seven factors from most important (1) to least important (7). There were seven factors to rank and 206 responses to this question. Figure 2-35 identifies the average rank assigned to each factor. Table 2-46 presents the number of responses that assigned each rank to each factor.

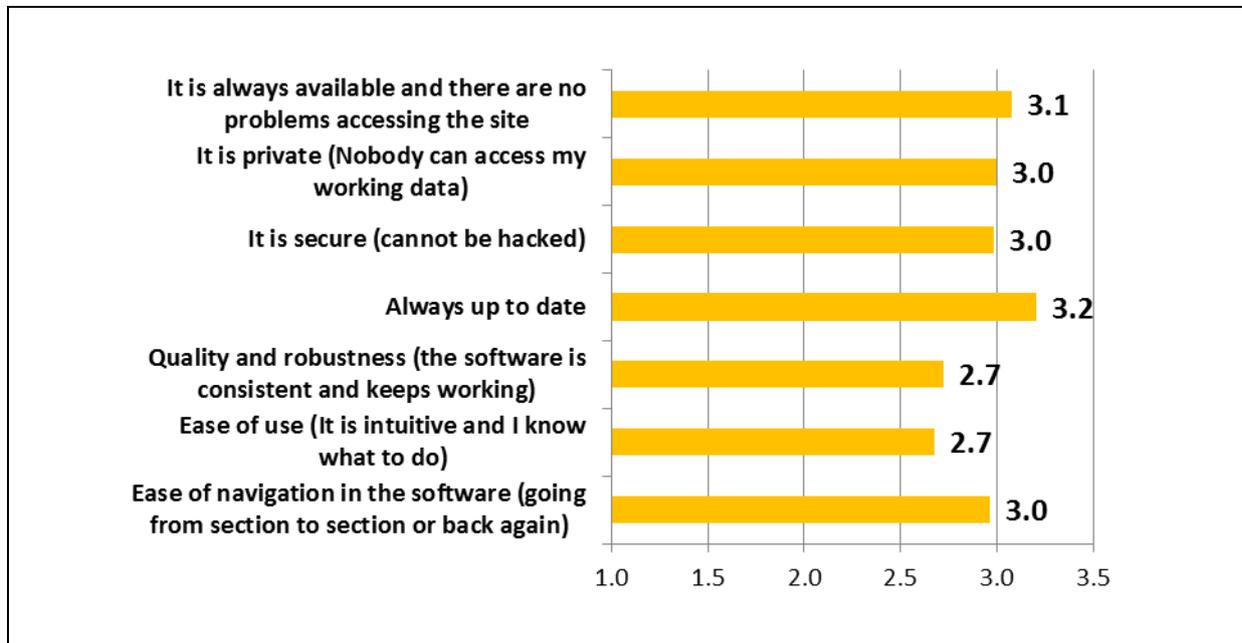


Figure 2-35: Chart showing results related to average rank of each factor associated with use of IUCLID (n=206)

Table 2-46: Number of respondents by rank of each factor associated with use of IUCLID (n=206)

| Activity   | Score assigned |    |    |    |    |    |    |
|--|----------------|----|----|----|----|----|----|
|  | 1              | 2  | 3  | 4  | 5  | 6  | 7  |
| Ease of navigation in the software (going from section to section or back again) | 56             | 48 | 31 | 26 | 11 | 11 | 18 |
| Ease of use (It is intuitive and I know what to do)                              | 72             | 48 | 21 | 28 | 6  | 8  | 16 |
| Quality and robustness (the software is consistent and keeps working)            | 70             | 43 | 29 | 29 | 9  | 4  | 17 |
| Always up to date  | 51             | 38 | 29 | 36 | 11 | 10 | 23 |
| It is secure (cannot be hacked)  | 71             | 29 | 24 | 30 | 12 | 14 | 18 |
| It is private (Nobody can access my working data)                                | 70             | 39 | 18 | 26 | 12 | 12 | 23 |
| It is always available and there are no problems accessing the site              | 55             | 43 | 27 | 31 | 14 | 7  | 22 |

**Question 32: Experience of Using IUCLID**

Question 32 asked respondents to rate their experience of using IUCLID across seven factors using a scale of 1 to 10 where 1 is 'very poor' and 10 is 'excellent'. Respondents could also select 'don't know'. In total, there were 228 responses to this question. Figure 2-36 presents the average score assigned to each factor. Table 2-47 present the number of respondents assigning each score.

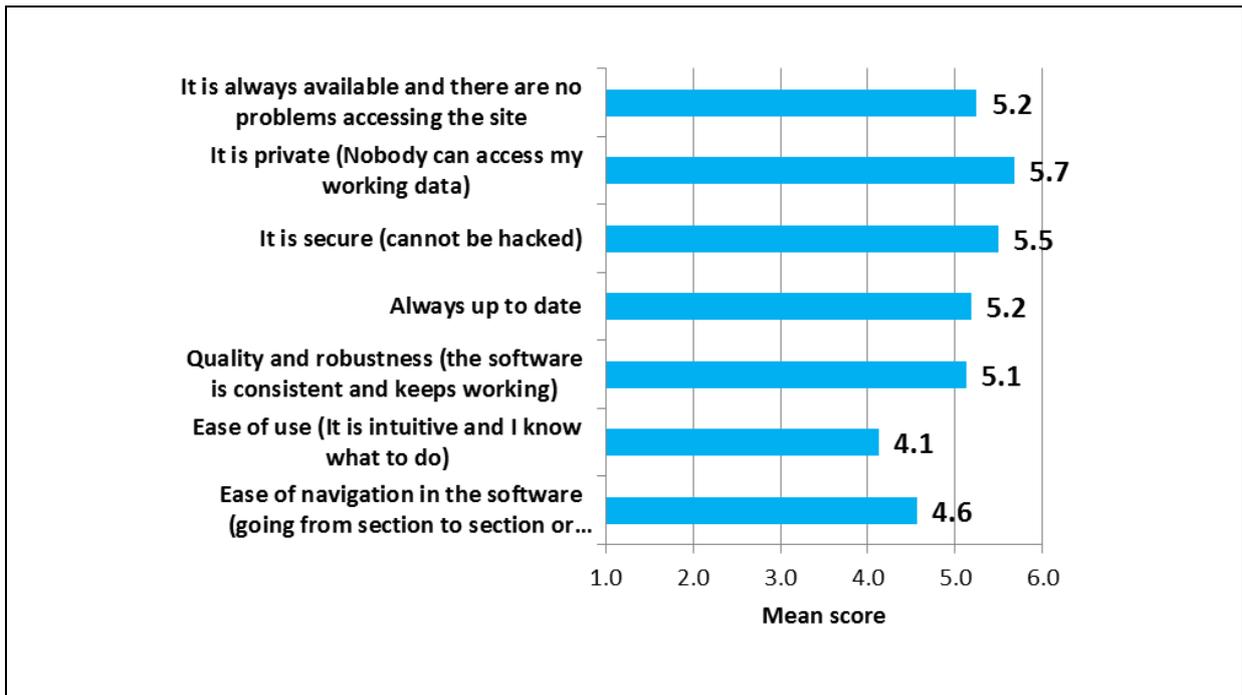


Figure 2-36: Chart showing results related to experience of using IUCLID (n=228)

| Table 2-47: Number of respondents by score assigned to experience of using IUCLID (n=228) |                |    |    |    |    |    |    |    |    |    |            |
|---|----------------|----|----|----|----|----|----|----|----|----|------------|
| Activity  | Score assigned |    |    |    |    |    |    |    |    |    |            |
|   | 1              | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 | Don't know |
| Ease of navigation in the software (going from section to section or back again)          | 24             | 12 | 24 | 14 | 18 | 19 | 12 | 17 | 4  | 4  | 78         |
| Ease of use (It is intuitive and I know what to do)                                       | 27             | 14 | 26 | 15 | 22 | 18 | 13 | 6  | 3  | 3  | 76         |
| Quality and robustness (the software is consistent and keeps working)                     | 15             | 8  | 20 | 13 | 23 | 16 | 17 | 14 | 8  | 6  | 83         |
| Always up to date   | 19             | 5  | 18 | 7  | 24 | 13 | 20 | 11 | 8  | 8  | 88         |
| It is secure (cannot be hacked)   | 12             | 2  | 10 | 5  | 21 | 11 | 10 | 8  | 9  | 7  | 124        |
| It is private (Nobody can access my working data)   | 13             | 4  | 7  | 7  | 19 | 11 | 15 | 10 | 10 | 9  | 115        |
| It is always available and there are no problems accessing the site                       | 13             | 9  | 19 | 9  | 22 | 20 | 14 | 9  | 11 | 8  | 85         |

### Question 33: Further Views

Question 33 provided a text box for respondents to note any other views they had on the REACH registration process and what they thought could be improved to make the registration process easier for them. Annex 3 provides the comments received. In total, 174 respondents provided further comments.

## 3 The Market Segments

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### 3.1 Introduction

This Section presents the segmentation model and the market audit to be used for the development of a marketing plan and a communication strategy for ECHA, in order to raise awareness among SMEs of their registration duties, to offer the cloud services, and ultimately facilitate and maximise substance registration.

### 3.2 Definition of Terms

**Marketing** – The alignment of products and services to satisfy the requirements of a market.

**Market** – Defined as a set of organisations who share a common need that can often be satisfied by alternative solutions. For this project, the need is defined as being able to trade and use chemical substances in the EU. In this instance, the relevant organisations include manufacturers and importers of chemical substances. These organisations interact with other entities that influence their behaviour and attitudes towards regulatory compliance. Among these **influencers** there are downstream users (in particular key clients of the manufactures and importers) and **channel influencers** such as trade associations, local HSE help-desks, inspectors, consultancies, outsourcers and training providers. At a secondary level, this list may also include green pressure groups, financial institutions and individuals in terms of investors, loan providers and insurers.

It should be noted that organisations do have alternatives to registration: offshoring the manufacture of chemicals not to be imported or used on the EU market, using alternatives that are registered (for downstream users), withdrawing substances from the market and trading illegally.

**Segment** – A segment is defined as an aggregation of organisations and individuals in a market that seek similar or the same *benefits* at a particular time or within a particular department. These benefits can include ease of understanding the registration process, ease of implementation, ease of use of tools, cost reduction, etc. It is important to note that an organisation can belong to several segments depending on the context.

**Target population** – Population of SMEs in the European Economic Area subject to REACH registration duties for the 2018 deadline.

### 3.3 The Segments

#### 3.3.1 Overview

During the consultation of the stakeholders, it became apparent that IUCLID is only a component of the registration process and cannot be seen in isolation. Many of the SMEs will never use the software directly, rather outsourcing part or the whole registration process to specialist contractors. Therefore, the model developed illustrates the benefits sought by the actors in terms of the registration process as a whole, as well as those sought on the use of the IUCLID software.

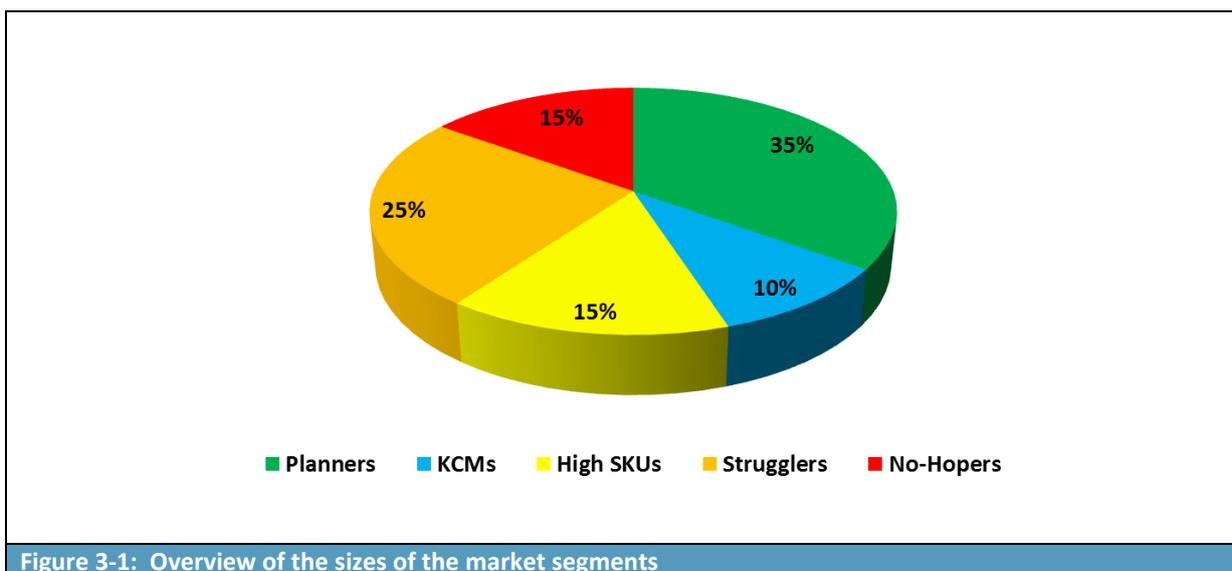
For the purposes of this project, we distinguished between three types of segments:

- **Product builder and supplier segments**, which manufacture and import chemical substances (products) and which therefore own registration duties. These have been further defined by their attitudes towards registration:
  - **Planners**. The Planners are companies that set aside resources for the registration of their substance portfolio;
  - **High Stock Keeping Units (SKUs)**. The High SKUs have their competitive advantage due to being able to supply a large range of products, at very short notice, to their customers;
  - **Key Component Manufacturers (KCFs)**. These companies manufacture and supply high value specialties. Clients are dependent on guaranteed supply and are willing to finance registration;
  - **Strugglers**. The Strugglers are all those companies that are still verifying whether they have to register. Typically they are smaller players which, historically, have not had any budget for regulatory purposes and these costs have never figured in their business model;
  - **No-Hoppers**. These are companies which have gone or will go out of business once they have verified and understood the cost of registration of their substances;
  - **Ignorers**. These companies either ignore the existence of the REACH Regulation or believe they do not have registration duties or have decided to take the risk because of lax enforcement.
  
- **Advice givers**, which assist and guide the above especially on whether there is a requirement to register. Further distinguished between:
  - Trainers
  - Advice givers
  
- **Experts**, further divided into:
  - **Service providers**, which can act as contractors for a part of the registration process (QSAR modelling, toxicology testing, IT services) or act as a “one stop shop” and undertake the whole process on behalf of the client (consultants, and sourcing and registration service providers<sup>11</sup>).
  - **In-house experts**, mainly amongst the Planners segment.

Figure 3-1 presents the size estimates of the product builder and supplier segments, in terms of the number of companies in the target population. The sizes of the segments have been roughly estimated on the basis of the responses to some key questions in the survey: Planners are all those SMEs that replied “Yes” to Q19 “Have you already put in place the resources and financial budget needed to meet your registration obligations?”. Key Component Manufacturers are all those companies that replied positively to Q25 “Did customers in your supply chain offer assistance (including financial assistance) to you or expertise/data to complete the registration process?”. High SKUs are all those companies that replied to have to register above 10 substances for the 2018 deadline (Q12 “How many chemical substances are you going to register for the 2018 deadline?”). Strugglers are all those companies that replied “No” to Q19 and that are still verifying their registration duties (Q10 “Do you believe you have REACH Registration duties?”). No-Hoppers are all those companies that replied negatively to Q19 and that are certain to have registration duties (replied “Yes, we verified that we have to register substances” to Q10).

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<sup>11</sup> Chemical distributors which import substances on client commission and offer registration services.



### 3.3.2 The Planners

#### Description

The Planners are companies that set aside resources for the registration of their substance portfolio over time (answered “Yes” to Q19 “Have you already put in place the resources and financial budget needed to meet your registration obligations?”).

However, even these companies may phase substance registration to smooth cash-flow and EBIT<sup>12</sup> impact. Typically, they have in-house regulation expertise and understand the registration process, either because they already registered substances for the previous deadline (over 60% declared to have registered substances before) or because they attended training organised by industry associations and public authorities. They may carry out the registration process in-house but many will outsource specialist components such as QSAR modelling, IT implementation and toxicology, either to access specialist expertise or due to limited in-house resources.

Planners tend to be medium-sized chemical manufacturers and distributors, with previous experience with registration of substances. Only around 36% of small enterprises declared already having a financial budget in place for the registration. The percentage goes further down (23%) when considering micro-enterprises with a financial plan ready.

|                    | Medium     | Small      | Micro      | Total                   |
|--------------------|------------|------------|------------|-------------------------|
| No                 | 62 (49%)   | 118 (64%)  | 89 (77%)   | 269 (63%)               |
| Yes                | 65 (51%)   | 67 (36%)   | 27 (23%)   | 159 (37%)               |
| <b>Grand Total</b> | <b>127</b> | 185 (100%) | 116 (100%) | <b>428<sup>13</sup></b> |

<sup>12</sup> Earnings Before Interest and Taxes.

<sup>13</sup> The grand total excludes the large companies and those that did not reply to Q19.

**Table 3-2: Planners by activity - Q19: Have you already put in place the resources and financial budget needed to meet your registration obligations?**

|             | Chemical distributors | Chemical manufacturers | Other distributors | Other manufacturing sectors | Other sectors | Not disclosed | Grand Total |
|-------------|-----------------------|------------------------|--------------------|-----------------------------|---------------|---------------|-------------|
| No          | 38 (62%)              | 87 (50%)               | 33 (69%)           | 91 (77%)                    | 19 (73%)      | 1 (100%)      | 269 (63%)   |
| Yes         | 23 (38%)              | 87 (50%)               | 15 (31%)           | 27 (23%)                    | 7 (27%)       | (0%)          | 159 (37%)   |
| Grand Total | 61                    | 174                    | 48                 | 118                         | 26            | 1             | 428         |

**Table 3-3: Planners by activity - Q19: Have you already put in place the resources and financial budget needed to meet your registration obligations?**

| Regions                  | No        | Yes       | Total |
|--------------------------|-----------|-----------|-------|
| Benelux                  | 17 (53%)  | 15 (47%)  | 32    |
| Eastern Europe           | 38 (84%)  | 7 (16%)   | 45    |
| France                   | 59 (68%)  | 28 (32%)  | 87    |
| Germany                  | 23 (51%)  | 22 (49%)  | 45    |
| Italy                    | 25 (57%)  | 19 (43%)  | 44    |
| Japan                    | 1 (100%)  | (0%)      | 1     |
| Malta                    | 1 (100%)  | (0%)      | 1     |
| Multiple locations       | 12 (52%)  | 11 (48%)  | 23    |
| Poland and Baltic States | 20 (74%)  | 7 (26%)   | 27    |
| Portugal and Spain       | 33 (63%)  | 19 (37%)  | 52    |
| Scandinavia              | 20 (69%)  | 9 (31%)   | 29    |
| Switzerland              | 2 (100%)  | (0%)      | 2     |
| UK and Ireland           | 18 (45%)  | 22 (55%)  | 40    |
| Grand Total              | 269 (63%) | 159 (37%) | 428   |

Around 50% of the SMEs operating in the Benelux, Germany, the UK and Ireland, and companies operating in multiple locations tend to have already budgeted for registration.

Planners are fully aware of the REACH Regulation and their registration duties (over 99% replied “Yes” to Q5 and Q7), having become aware mostly thanks to ECHA and national trade associations. Around 86% sought advice as to what they had to do to comply with their registration duties, mainly referring to consultants, ECHA and national help-desks.

**Table 3-4: Planners - Source of advice about registration duties (Q9)**

| Entity                           | No. | %   |
|----------------------------------|-----|-----|
| ECHA Help-desk                   | 62  | 39% |
| National help-desk               | 58  | 36% |
| National or regional authorities | 31  | 19% |
| European trade association       | 19  | 12% |
| National trade association       | 46  | 29% |
| Suppliers                        | 20  | 13% |
| Peers                            | 24  | 15% |
| Customers                        | 8   | 5%  |
| Consultancy                      | 80  | 50% |
| Other                            | 0   | 0%  |
| Total                            | 159 | -   |

Around 77% of the Planners already verified their registration duties (against 66% of the general sample), with 67% certain to have substances to register for the 2018 deadline and 10% declaring to have verified not having substances to register.

| Table 3-5: Planners by REACH role (Q11)   |     |     |
|---|-----|-----|
| Role  | No. | %   |
| Manufacturer of chemical substances   | 73  | 46% |
| Importer of chemical substances or mixtures   | 88  | 55% |
| Formulator of mixtures  | 47  | 30% |
| Industrial or professional users of chemical substances, on its own or in a mixture, in professional or industrial activities (end users) | 25  | 16% |
| Distributor of chemical substances or mixtures  | 50  | 31% |
| Suppliers (manufacturers/importers/wholesalers/retailers) of articles   | 16  | 10% |
| Only representative   | 16  | 10% |
| Grand Total   | 159 | -   |

Most of the planners declared multiple roles, with around 55% declaring to be importing chemical substances or mixtures and around 46% to be manufacturing chemical substances in the EU.

Only 12% of the planners declared not to yet know how many substances in the different tonnages they are going to register for the 2018 deadline; mainly because they are still carrying out the cost benefit analysis or because it is unclear whether the substances will be registered by their suppliers. Some also indicated that they are still checking whether the 1 tonne threshold is exceeded. None declared that they are still unclear whether the substances they deal with need to be registered.

Around 65% of the planners belong to a trade association and are moderately satisfied with the way trade associations represent their interests (average score given in response to Q17 is 6).

Around 78% sought advice on the costs of registration and, on average, scored the significance of the costs compared to the commercial value of the substances at 7.8 (on a scale from 0 to 10). The same average score (7.8) resulted from the responses to Q21, namely what they thought of the costs of the Letters of Access when compared to the commercial values of the substances (where 10 is “very expensive compared to the commercial value”).

| Table 3-6: Planners - Q22. As a result of understanding the time and costs associated with registering substances under REACH, did you: |     |     |
|---|-----|-----|
| Decide to register all the substances from your portfolio?  | 39  | 25% |
| Decide to register substances in a phased manner, including withdrawing some substances from your portfolio over the short term?        | 44  | 28% |
| Decide to register only a portion of the substances from your portfolio, while withdrawing from you portfolio over the longer term?     | 52  | 33% |
| Have to divert R&D resources to meet REACH registration obligations?  | 28  | 18% |
| Seek financial support from customers?  | 23  | 14% |
| Seek a financial loan from a bank or other institution?   | 10  | 6%  |
| Seek governmental financial support?  | 4   | 3%  |
| Raise awareness amongst your customers about your inability to register all of your substances due to the financial burden?             | 25  | 16% |
| Raise awareness amongst the authorities about your inability to register all of your substances due to the financial burden?            | 9   | 6%  |
| Other   | 28  | 18% |
| Grand Total   | 159 | -   |

Over 50% of the Planners will register their entire portfolio or will register substances in a phased manner. However, over 30% will also withdraw some substances from their portfolio over the longer term (less than 20% of their portfolio)<sup>14</sup>.

Over 65% of the Planners will either undertake the whole registration process in-house or with the support of a consultant. Around 1 in 4 will outsource the whole process and as many will outsource the toxicology and/or the IT submission. However, from the scores assigned by the companies to the various aspects of the registration process, even among the Planners there is the perception that there is margin for improvement.

| <b>Table 3-7: Planners - Q30: How easy did you find the following:</b> |          |          |          |          |          |          |          |          |          |           |            |
|--|----------|----------|----------|----------|----------|----------|----------|----------|----------|-----------|------------|
|  | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> | <b>5</b> | <b>6</b> | <b>7</b> | <b>8</b> | <b>9</b> | <b>10</b> | <b>Av.</b> |
| <b>Understand the registration process using the available support</b> | 6        | 14       | 19       | 12       | 18       | 9        | 11       | 16       | 4        | 3         | <b>4.9</b> |
| <b>Search for co-registrants</b>                                       | 11       | 8        | 17       | 13       | 18       | 10       | 9        | 13       | 4        | 6         | <b>5.0</b> |
| <b>Form the SIEF</b>   | 14       | 7        | 18       | 7        | 12       | 7        | 9        | 7        | 4        | 8         | <b>4.8</b> |
| <b>Agree on data and cost sharing</b>                                  | 18       | 15       | 17       | 9        | 11       | 10       | 7        | 7        | 4        | 3         | <b>4.2</b> |
| <b>Prepare the IUCLID dossier</b>                                      | 15       | 18       | 9        | 9        | 17       | 6        | 8        | 7        | 4        | 2         | <b>4.2</b> |
| <b>Submit the dossier via REACH-IT</b>                                 | 7        | 12       | 10       | 4        | 13       | 7        | 12       | 9        | 9        | 8         | <b>5.5</b> |
| <b>Understand how to use and report (Q)SARs</b>                        | 15       | 8        | 16       | 6        | 9        | 5        | 6        | 5        | 1        | 2         | <b>4.0</b> |
| <b>Understand how to use grouping and read-across approaches</b>       | 16       | 12       | 10       | 9        | 15       | 7        | 6        | 3        | 2        | 2         | <b>4.0</b> |

| <b>Table 3-8: Q31 Rank the following factors in order of importance</b> |  |
|---|--|
| <b>1</b>  | Quality and robustness (the software is consistent and keeps working)            |
| <b>2</b>  | Ease of use (It is intuitive and I know what to do)                              |
| <b>3</b>  | It is secure (cannot be hacked)  |
| <b>4</b>  | It is private (Nobody can access my working data)                                |
| <b>5</b>  | Ease of navigation in the software (going from section to section or back again) |
| <b>6</b>  | It is always available and there are no problems accessing the site              |
| <b>7</b>  | Always up to date  |

| <b>Table 3-9: Q32 Current experience with IUCLID</b>                                    |          |          |          |          |          |          |          |          |          |           |            |
|---|----------|----------|----------|----------|----------|----------|----------|----------|----------|-----------|------------|
|   | <b>1</b> | <b>2</b> | <b>3</b> | <b>4</b> | <b>5</b> | <b>6</b> | <b>7</b> | <b>8</b> | <b>9</b> | <b>10</b> | <b>Av.</b> |
| <b>It is private (Nobody can access my working data)</b>                                | 3        | 1        | 3        | 2        | 8        | 8        | 11       | 6        | 6        | 3         | <b>6.3</b> |
| <b>It is secure (cannot be hacked)</b>  | 2        | 1        | 3        | 2        | 10       | 9        | 7        | 5        | 5        | 3         | <b>6.1</b> |
| <b>It is always available and there are no problems accessing the site</b>              | 2        | 3        | 5        | 4        | 12       | 11       | 8        | 6        | 8        | 4         | <b>6.0</b> |
| <b>Quality and robustness (the software is consistent and keeps working)</b>            | 2        | 3        | 9        | 6        | 13       | 12       | 9        | 5        | 6        | 2         | <b>5.6</b> |
| <b>Always up to date</b>  | 5        | 3        | 7        | 3        | 14       | 8        | 10       | 4        | 6        | 2         | <b>5.5</b> |
| <b>Ease of navigation in the software (going from section to section or back again)</b> | 3        | 7        | 11       | 6        | 10       | 13       | 11       | 2        | 3        | 2         | <b>5.0</b> |
| <b>Ease of use (It is intuitive and I know what to do)</b>                              | 3        | 8        | 11       | 6        | 16       | 11       | 6        | 2        | 2        | 1         | <b>4.7</b> |

Around 60% declared to be interested in using IUCLID on the cloud. Quality and robustness of the software, ease of use, security and privacy are the aspects of IUCLID that are ranked the highest.

<sup>14</sup> Q23 “If you are considering withdrawing some of your substances from the market, what is the percentage of the foreseen withdrawal from your current substance portfolio?”

Companies belonging to this segment are fairly happy with the performance of the current version of IUCLID with regard to privacy and security of the data (average scores of 6.3 and 6.1). However, offering IUCLID functionalities on the cloud may bring uncertainty over these aspects.

### **Audit**

By definition, Planners highly value all the information that allows them to develop plans for the medium to long-term. A major problem with the registration process is that it is not possible to find out the cost upfront without engaging in the actual process. Planners are mostly companies with experience in registering substances for the previous deadlines and most of them have at least one regulatory officer dedicated to deal with the REACH obligations. They prepared for the REACH Regulation deadlines in advance and they trained their personnel accordingly. However, Planners seek external support (consultants), as the knowledge required and the burden of registering multiple substances exceeds their available resources.

Once they are part of the Substance Information Exchange Fora (SIEF) and they find out about the cost of Letters of Access (lead registrants are often large enterprises), they have already incurred substantial costs. Moreover, the consulted stakeholders have indicated costs for the LoAs starting from €10,000 - 25,000 to over €250,000. When facing these costs, even Planners are forced to withdraw part of their substance portfolio, especially when they were not able to properly plan the use of their resources for registration.

Therefore, they value support on developing use maps and exposure scenarios for their substances, so that they can determine the precise information required for the registration. Planners would also benefit from a smooth registration execution.

Table 3-10 and Figure 3-2 show ECHA’s performance as perceived by the Planners, in relation to four defined Critical Success Factors (CSF). For illustrative purposes, ECHA’s performance is scored against a benchmark, representing how an ideal organisation should have to score, realistically, in order to achieve the objectives of collecting high quality information used by SMEs for improving safety with regard to human health and the environment, without causing financial stress amongst the SME registrants. Further discussion on the CSFs is provided in Section 4.

| <b>Table 3-10: ECHA’s performance on Planners’ CSFs against the benchmark</b> |               |             |                  |
|---|---------------|-------------|------------------|
|   | <b>Weight</b> | <b>ECHA</b> | <b>Benchmark</b> |
| <b>Use maps and exposure scenarios</b>  | 0.3           | 5           | 7                |
| <b>Any other planning information</b>   | 0.3           | 4           | 8                |
| <b>SIEF fair price</b>  | 0.3           | 3           | 7                |
| <b>Registration execution</b>   | 0.1           | 6           | 8                |
| <b>Average</b>  |               | <b>4.2</b>  | <b>7.4</b>       |

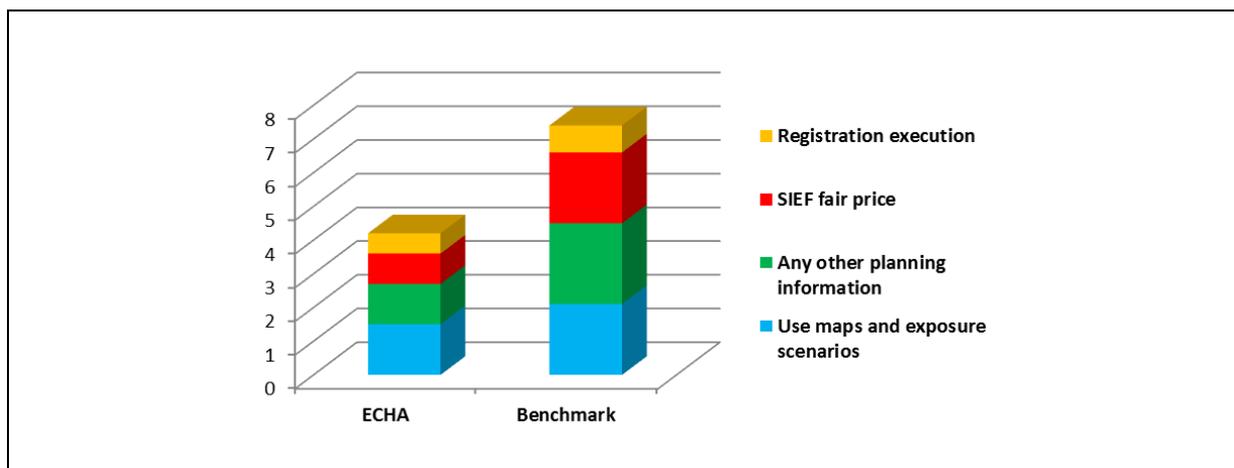


Figure 3-2: ECHA's performance on Planners' CSFs against the benchmark

### 3.3.3 The Key Component Manufacturers

#### Description

The Key Component Manufacturers (KCFs) tend to be innovative companies (over 65% carry out research on safer alternatives)<sup>15</sup> supplying specialty chemicals with a high added value that are not easily sourced. Their clients are dependent on guaranteed supply and will therefore subsidise or pay for registration. Most of the KCFs (around 60%)<sup>16</sup> do not have previous experience with the registration process, mainly supplying substances in low tonnages. Typically, they are medium-sized chemical manufacturers found in sophisticated and complex supply chains (e.g. aerospace, automotive).

Around 20% of the Italian SMEs participating in the survey declared having received assistance from their clients. The project team's best estimate is that, across the European Economic Area, KCFs constitute 10% of the SME target population.

Table 3-11: KCFs by size – Q25: Did customers in your supply chain offer assistance (including financial assistance) to you or expertise/data to complete the registration process?

|                    | Medium   | Small     | Micro     | Total     |
|--------------------|----------|-----------|-----------|-----------|
| <b>No</b>          | 97 (77%) | 164 (93%) | 103 (93%) | 364 (88%) |
| <b>Yes</b>         | 29 (23%) | 12 (7%)   | 8 (7%)    | 49 (12%)  |
| <b>Grand Total</b> | 126      | 176       | 111       | 413       |

Table 3-12: KCFs by activity - Q25: Did customers in your supply chain offer assistance (including financial assistance) to you or expertise/data to complete the registration process?

|                    | Chemical distributors | Chemical manufacturers | Other distributors | Other manufacturing sectors | Other sectors | Not disclosed | Grand Total |
|--------------------|-----------------------|------------------------|--------------------|-----------------------------|---------------|---------------|-------------|
| <b>No</b>          | 53 (90%)              | 143 (83%)              | 45 (94%)           | 103 (93%)                   | 20 (87%)      | (-)           | 364 (88%)   |
| <b>Yes</b>         | 6 (10%)               | 29 (17%)               | 3 (6%)             | 8 (7%)                      | 3 (13%)       | (-)           | 49 (12%)    |
| <b>Grand Total</b> | 59                    | 172                    | 48                 | 111                         | 23            | 0             | 413         |

<sup>15</sup> Q26 "Given your market and supply chain, do you actively investigate substitutes for chemical substances which may be considered hazardous or best avoided in the future?"

<sup>16</sup> Q29 "Have you already registered substances under REACH?"

| Table 3-13: KCFs by activity - Q25: Did customers in your supply chain offer assistance (including financial assistance) to you or expertise/data to complete the registration process? |                  |                 |            |
|---|------------------|-----------------|------------|
| Regions   | No               | Yes             | Total      |
| Benelux   | 28 (90%)         | 3 (10%)         | 32         |
| Eastern Europe  | 39 (93%)         | 3 (7%)          | 45         |
| France  | 71 (88%)         | 10 (12%)        | 87         |
| Germany   | 43 (86%)         | 7 (14%)         | 45         |
| Italy   | 32 (78%)         | 9 (22%)         | 44         |
| Japan   | 1 (100%)         | (0%)            | 1          |
| Malta   | 1 (100%)         | (0%)            | 1          |
| Multiple locations  | 16 (80%)         | 4 (20%)         | 23         |
| Poland and Baltic States  | 24 (92%)         | 2 (8%)          | 27         |
| Portugal and Spain  | 43 (83%)         | 9 (17%)         | 52         |
| Scandinavia   | 25 (93%)         | 2 (7%)          | 29         |
| Switzerland   | 2 (100%)         | (0%)            | 2          |
| UK and Ireland  | 39 (100%)        | (0%)            | 40         |
| <b>Grand Total</b>  | <b>364 (88%)</b> | <b>49 (12%)</b> | <b>428</b> |

As for the Planners, KCFs are fully aware of the REACH Regulation and their registration duties (100% replied “Yes” to Q5 and Q7), having become aware mostly thanks to ECHA and national trade associations. Around 80% sought advice as to what they had to do to comply with their registration duties, mainly referring to ECHA and national help-desks and consultants.

| Table 3-14: KCFs by REACH role (Q11)  |           |          |
|---|-----------|----------|
| Role  | No.       | %        |
| Manufacturer of chemical substances   | 22        | 45%      |
| Importer of chemical substances or mixtures   | 23        | 47%      |
| Formulator of mixtures  | 16        | 33%      |
| Industrial or professional users of chemical substances, on its own or in a mixture, in professional or industrial activities (end users) | 9         | 18%      |
| Distributor of chemical substances or mixtures  | 11        | 22%      |
| Suppliers (manufacturers/importers/wholesalers/retailers) of articles   | 6         | 12%      |
| Only representative   | 7         | 14%      |
| <b>Grand Total</b>  | <b>49</b> | <b>-</b> |

Most of the KCFs declared multiple roles, with around 47% declaring that they import chemical substances or mixtures and around 45% that they manufacture chemical substances in the EU.

Only 12% of the KCFs declared not to yet know how many substances in the different tonnages they are going to register for the 2018 deadline, mainly because they are still checking whether the 1 tonne threshold is exceeded. None declared that they were still unclear whether the substances they deal with need to be registered.

Around 65% of the KCFs belong to a trade association and are moderately satisfied with the way trade associations represent their interests (average score to Q17 is 6).

Even KCFs assigned an average score of 7 (where 10 is “very expensive compared to the commercial value”) to both the significance of the costs of registration and of the costs of the LoAs when compared

to the commercial values of the substances. They will rationalise their portfolio, withdrawing the least valuable substances from the market.

Around 60% declared to be interested in using IUCLID on the cloud.

**Audit**

Critical Success Factors for this segment are:

- Protection of Intellectual Property Rights (IPR);
- Customer confidentiality.

KCFs are mainly concerned about protecting their IPR and confidentiality around their customer base. Table 3-15 and Figure 3-3 show ECHA’s performance as perceived by the KCFs against the benchmark.

| Table 3-15: ECHA’s performance on KCFs’ CSMs against the benchmark |        |          |           |
|--|--------|----------|-----------|
|  | Weight | ECHA     | Benchmark |
| Customer confidentiality   | 0.5    | 5        | 9         |
| Protection of IPR  | 0.5    | 5        | 9         |
| <b>Average</b>   |        | <b>5</b> | <b>9</b>  |

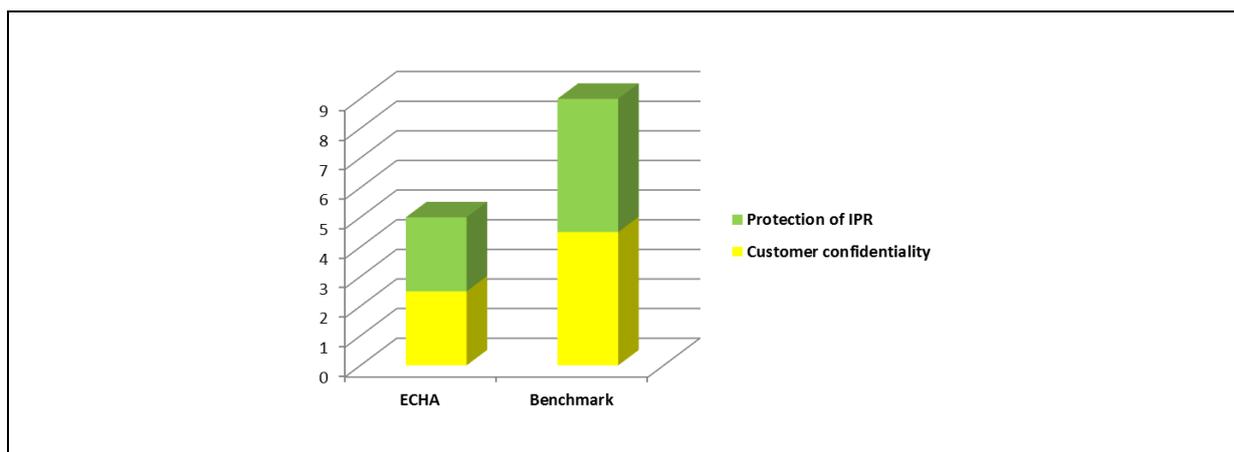


Figure 3-3: ECHA’s performance on KCFs’ CSMs against the benchmark

### 3.3.4 The High SKUs

**Description**

The High Stock Keeping Units (SKUs) have their competitive advantage on being able to supply a large range of products, at very short notice, to their customers. They tend to be small and medium-sized manufacturers and distributors of chemical products. The segment captures enterprises with a deep understanding of their customer and product applications (typically, formulators such as dye importers) and companies that operate as chemical distributors in localised chemical clusters, which may or may not have the same deep knowledge of customers’ applications. The project team’s best estimate is that they represent between 15 - 25% of the SME target population, overlapping with the Strugglers segment.

High SKUs are perfectly aware of the REACH Regulation and of the registration duties (100% replied “Yes” to Q5 and Q7), having become aware mostly through national trade associations and regional authorities and inspectors.

| Table 3-16: High SKUs – Q6. How did you become aware of the REACH Regulation? Thanks to: |     |     |
|--|-----|-----|
| Entity   | No. | %   |
| Customers  | 3   | 7%  |
| European Chemicals Agency (ECHA)   | 7   | 16% |
| European trade association   | 2   | 5%  |
| National or regional authorities/inspectors  | 10  | 23% |
| National trade association   | 14  | 32% |
| Other: Press   | 2   | 5%  |
| Peers  | 3   | 7%  |
| Suppliers  | 2   | 5%  |
| Grand Total  | 44  | -   |

Around 90% of these companies sought advice on how to comply with the Regulation, mostly from public authorities and consultancies. Around 75% of High SKUs are certain to have to register substances for the 2018 deadline, but one in four is still verifying its duties.

| Table 3-17: High SKUs - Source of advice about registration duties (Q9) |     |     |
|---|-----|-----|
| Entity  | No. | %   |
| ECHA Help-desk  | 21  | 48% |
| National help-desk  | 17  | 39% |
| National or regional authorities  | 9   | 20% |
| European trade association  | 5   | 11% |
| National trade association  | 15  | 34% |
| Suppliers   | 1   | 2%  |
| Peers   | 4   | 9%  |
| Customers   | 2   | 5%  |
| Consultancy   | 20  | 45% |
| Total   | 44  | -   |

Around 70% of High SKUs are a member of a trade association, but they are not particularly satisfied with the way they are represented (average score 5.6). Around 75% sought advice on the costs of registration, considering these and the costs of the LoAs disproportionate when compared to the commercial values of the substances to be registered (average scores of, respectively, 8.3 and 8.1).

| Table 3-18: Planners - Q22. As a result of understanding the time and costs associated with registering substances under REACH, did you: |    |     |
|--|----|-----|
| Decide to register all the substances from your portfolio?   | 7  | 16% |
| Decide to register substances in a phased manner, including withdrawing some substances from your portfolio over the short term?         | 17 | 39% |
| Decide to register only a portion of the substances from your portfolio, while withdrawing from you portfolio over the longer term?      | 13 | 30% |
| Have to divert R&D resources to meet REACH registration obligations?   | 3  | 7%  |
| Seek financial support from customers?   | 12 | 27% |
| Seek a financial loan from a bank or other institution?  | 1  | 2%  |
| Seek governmental financial support?   | 1  | 2%  |
| Raise awareness amongst your customers about your inability to register all of your substances due to the financial burden?              | 9  | 20% |

| Table 3-18: Planners - Q22. As a result of understanding the time and costs associated with registering substances under REACH, did you: |    |     |
|--|----|-----|
| Raise awareness amongst the authorities about your inability to register all of your substances due to the financial burden?             | 6  | 14% |
| Grand Total  | 44 | -   |

### Audit

High SKUs are in crisis because of the number of different substances they put on the market and the rapid turnover of products. There is a high rate of annual churn, often seasonal<sup>17</sup>. The registration cost is forcing them to reduce their product portfolio with consequent impact on competitive viability and company size. Companies within this segment are often family-owned businesses that have been run conscientiously and which would try to be legally compliant. They are complaining vociferously about the costs of registration to all authorities at European and National level and they are very bitter about the REACH Regulation.

They fear “whistle-blowing” will happen more and more, with competitors black-mailing and asking other companies to pay for the LoAs if they do not want to be visited by the enforcement authorities. They will also report any competitor whom they believe is avoiding registration.

Their major concerns all relate to costs of the registration:

- Impact on the cash-flow;
- Indirect overheads;
- SIEF costs.

Table 3-19 and Figure 3-4 show the performance of ECHA perceived by the KCFs against the benchmark.

| Table 3-19: ECHA’s performance on High SKUs’ CSMs against the benchmark |        |            |            |
|---|--------|------------|------------|
|   | Weight | ECHA       | Benchmark  |
| Impact on the cash-flow   | 0.35   | 2          | 6          |
| Indirect overheads  | 0.15   | 4          | 6          |
| SIEF costs  | 0.50   | 1          | 7          |
| <b>Av.ge</b>  |        | <b>1.8</b> | <b>6.5</b> |

<sup>17</sup> For example, dye importers are subject to the seasonality and trends of the fashion industry.

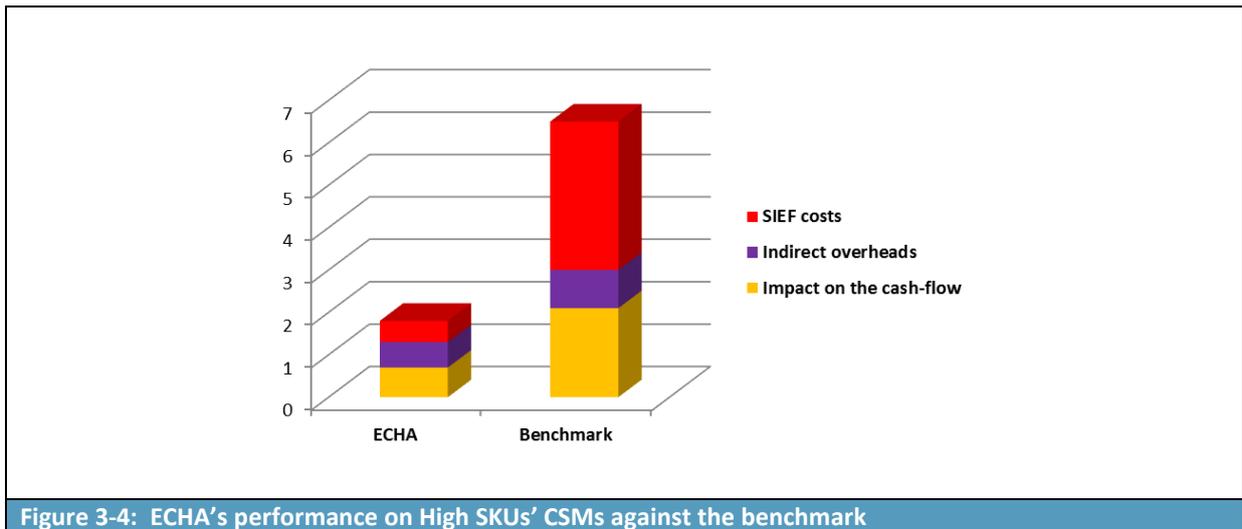


Figure 3-4: ECHA's performance on High SKUs' CSMs against the benchmark

### 3.3.5 The Strugglers

**Description**

The Strugglers are all those companies that are still verifying<sup>18</sup> whether they have to register their substances<sup>19</sup> and did not set apart resources for registration purposes (Q19). Typically, they are microenterprises and small companies (Figure 3-5) which, historically, have not had any substantial budget for regulatory compliance and these costs have never figured in their business model. Over 50% of Strugglers operate in industries that are not classified as chemical activities (Table 3-20). Thanks to the initiatives of ECHA and of national and regional authorities, they are aware of the REACH Regulation (over 90% replied positively to Q5 on awareness of REACH) but, alarmingly, over 15% were still not aware at the moment of the survey that all substances manufactured or imported into the EEA in quantities between 1 and 100 tonnes per year need to be registered by 31 May 2018. The project team's best estimate is that they represent between 25-30% of the SME target population, overlapping with the No-Hoppers segment.

<sup>18</sup> As of May 2017.

<sup>19</sup> Replied that they are still verifying their duties to Q10.

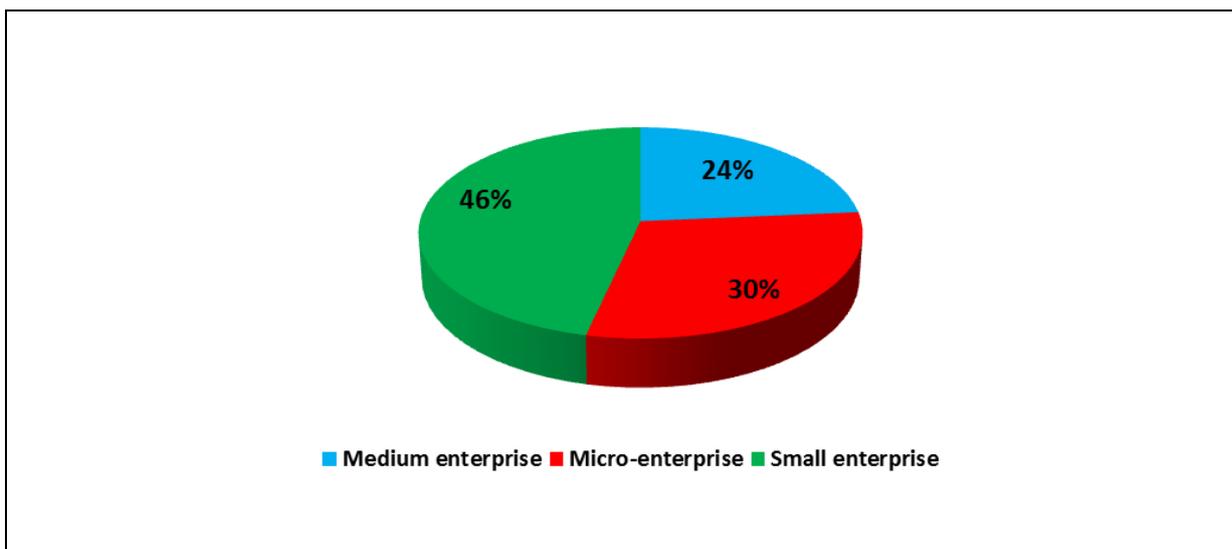


Figure 3-5: Proportion of micro-, small- and medium-sized enterprises within the Strugglers segment

| Role                        | No. | %   |
|-----------------------------|-----|-----|
| Chemical distributors       | 13  | 10% |
| Chemical manufacturers      | 46  | 36% |
| Other distributors          | 19  | 15% |
| Other manufacturing sectors | 40  | 31% |
| Other sectors               | 9   | 7%  |
| Grand Total                 | 127 | -   |

These companies are slowly becoming aware of their registration duties and are overwhelmed by the knowledge burden. They often have little understanding of customer uses of their products. Many (over 35%) are still verifying whether the substance(s) need(s) to be registered or are unclear whether the 1 tonne threshold is exceeded. They are shocked when they discover the costs of registration and soon realise they do not have the in-house skills and capacity.

### **Audit**

Strugglers are grudge purchasers of 'one stop shop' consultancy services. The registration cost is forcing them to reduce their product portfolio or shrink volumes to below one tonne per year. As soon as they clarify their registration duties and understand the associated costs, they seek help from all authorities at European and National level. As for the High SKUs, they are very bitter about the REACH Regulation and, in particular, about the requirement of registering substances in low production volumes. They see the Regulation as a device to help multinationals and large companies at the expense of SMEs. They point in particular to the unfairness and non-proportionality of the costs when manufacturing or importing quantities just above one tonne per year, when compared to the incidence of the same costs on higher tonnages.

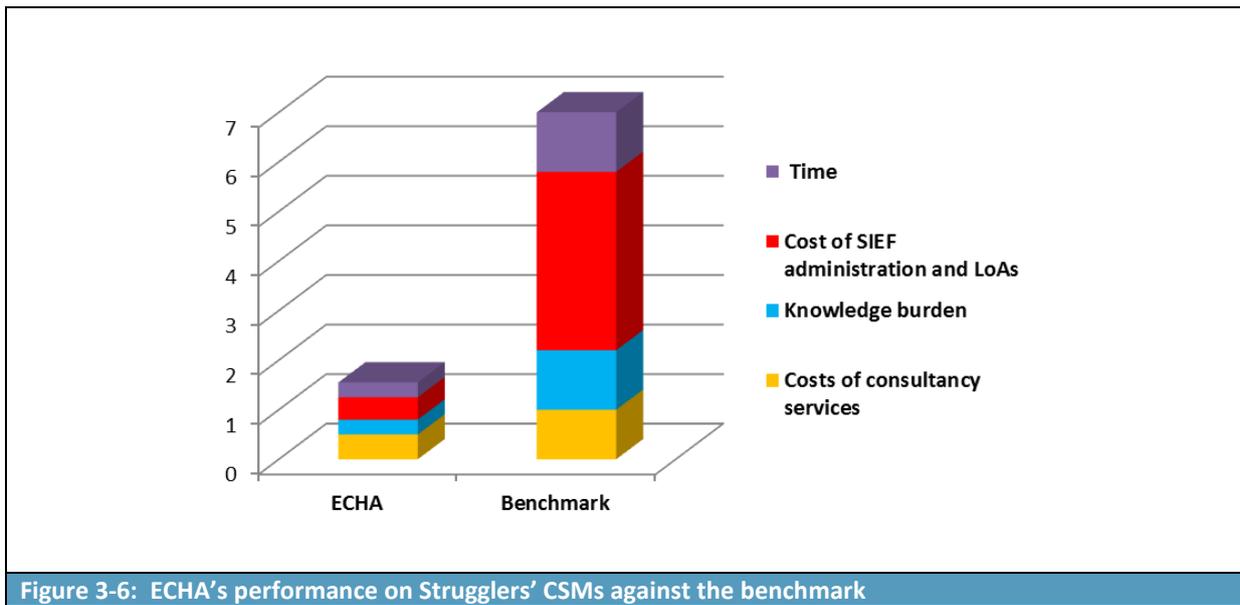
The Critical Success Factors for this segment are:

- Costs of consultancy services;
- Knowledge burden;
- Cost of SIEF administration and LoAs;

- Time.

Table 3-21 and Figure 3-6 show ECHA’s performance as perceived by the KCFs against the benchmark.

| Table 3-21: ECHA’s performance on Strugglers’ CSMs against the benchmark |              |             |           |
|--|--------------|-------------|-----------|
|  | Weight       | ECHA        | Benchmark |
| Costs of consultancy services  | 0.25         | 2           | 4         |
| Knowledge burden   | 0.15         | 2           | 8         |
| Cost of SIEF administration and LoAs                                     | 0.45         | 1           | 8         |
| Time   | 0.15         | 2           | 8         |
|  | <b>Av.ge</b> | <b>1.55</b> | <b>7</b>  |



### 3.3.6 The No-Hoppers

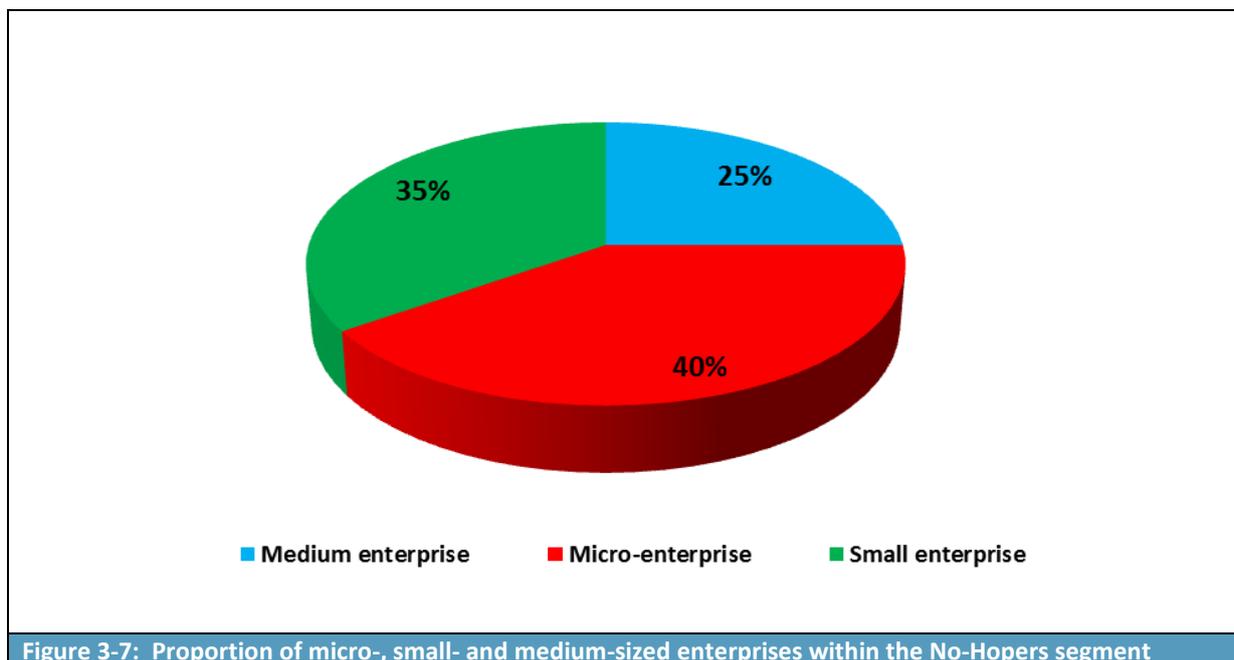
The No-Hoppers are all those companies that have just clarified having registration duties (Q10) but do not have a budget for the registration of the substances (Q19). There are Strugglers that:

- Will liquidate or moth ball their business once they have verified and understood the cost of registration;
- Have already liquidated or sold their business to larger competitors, usually at a discount price;
- Reduced product quantities to below one tonne per year;
- Will, or have already, dramatically cut their substance portfolio.

Some importers and distributors will survive by ceasing imports from outside the EU, replacing these with imports of (usually more expensive) substances from the EU.

Companies in the No-Hoppers segment tend to be microenterprises and small companies, evenly distributed amongst the industrial sectors and across the EEA. They often do not currently or have never belonged to any trade associations (around 70% are not affiliated) as they believe these are run

by large companies and do not defend SMEs' interests (average score to Q17 is 2.4). These were often prudently run family businesses and they blame the European Union for hitting them with a sledge hammer designed for large organisations.



The project team's best estimate is that, at the moment, they constitute around 15% of what was the SME target population. The final size of this segment, in June 2018, will be determined by the effectiveness of the actions taken by, not only ECHA, but also the European Commission and the national and regional authorities.

### 3.3.7 The Ignorers

The Ignorers are all those companies that either ignore their registration duties (examples may be charcoal traders or small waste management companies recovering substances from waste and putting them on the market) or have decided not to register and incur the risk of being discovered. Typically they serve relatively unsophisticated local supply chains that are usually populated by small players who have little or no understanding or knowledge of the REACH Regulation (e.g. corner shops and independent fuel stations selling charcoal). If they serve customers with knowledge of the Regulation, these will only ask for the registration number rather than for any evidence of validity. It is not possible to size this segment with even one order of magnitude of accuracy, as these are companies invisible to ECHA, national and regional authorities and national trade associations and which do not reply to surveys. They may be in the thousands.

### 3.3.8 The Trainers

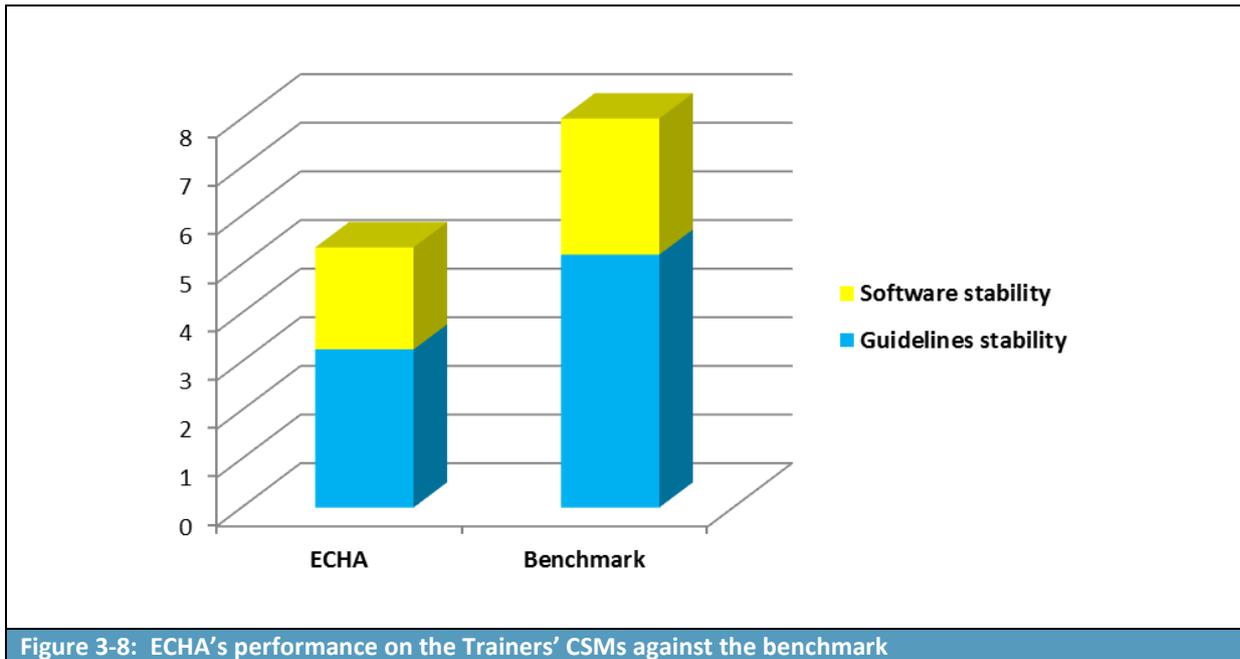
#### *Description*

The Trainers are typically trade associations and consultancies that provide competence to execute the registration process. They mostly serve planners and High SKUs.

**Audit**

Trainers are mainly interested in the stability of the ECHA guidelines and software.

| Table 3-22: ECHA’s performance on the Trainers’ CSMs against the benchmark |        |      |           |
|--|--------|------|-----------|
|  | Weight | ECHA | Benchmark |
| Guidelines stability   | 0.65   | 5    | 8         |
| Software stability   | 0.35   | 6    | 8         |
|  | Av.ge  | 5.35 | 8         |



**3.3.9 The Advice Givers**

**Description**

The Advice Givers are typically trade associations, consultancies and local enforcement authorities. They serve a very large number of Strugglers, some of whom may become No-Hoppers, which seek the following top level benefits:

- Guidance on whether they need to register;
- Guidance on what to do if they do need to register; and
- Guidance on cost to register.

Advice Givers provide support in determining the regulatory obligations and sign posts to seek further assistance.

**Audit**

Advice Givers are mainly interested in the stability of ECHA’s guidelines and in the pragmatic interpretation of the Regulation.

**Table 3-23: ECHA’s performance on the Advice Givers’ CSMs against the benchmark**

|  | Weight | ECHA     | Benchmark |
|--|--------|----------|-----------|
| Guidelines stability                       | 0.5    | 5        | 8         |
| Pragmatic Interpretation of the Regulation | 0.5    | 5        | 8         |
| <b>Av.ge</b>                               |        | <b>5</b> | <b>8</b>  |

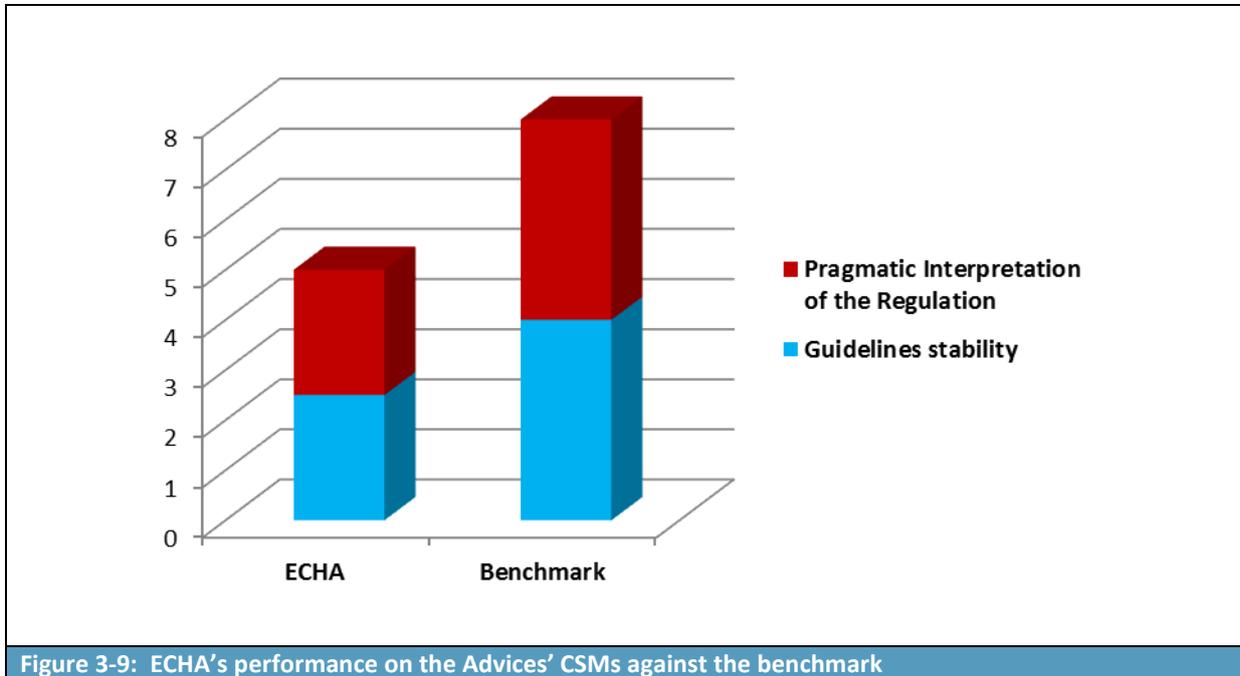


Figure 3-9: ECHA's performance on the Advices' CSMs against the benchmark

### 3.3.10 The Experts

#### Description

The Experts include consultancies, contractors and in-house experts amongst the Planners.

#### Audit

Experts seek clarification and expert opinion from ECHA and national authorities on interpretation of the Regulation and of the guidelines.

| Table 3-24: ECHA's performance on Experts' CSMs against the benchmark |        |             |           |
|---|--------|-------------|-----------|
|   | Weight | ECHA        | Benchmark |
| Pragmatic interpretation of the Regulation                            | 0.25   | 2           | 4         |
| Exposure Scenarios  | 0.15   | 2           | 8         |
| QSAR Guidance   | 0.45   | 1           | 8         |
| SIEF fair price   | 0.15   | 2           | 8         |
| <b>Av.ge</b>  |        | <b>1.55</b> | <b>7</b>  |

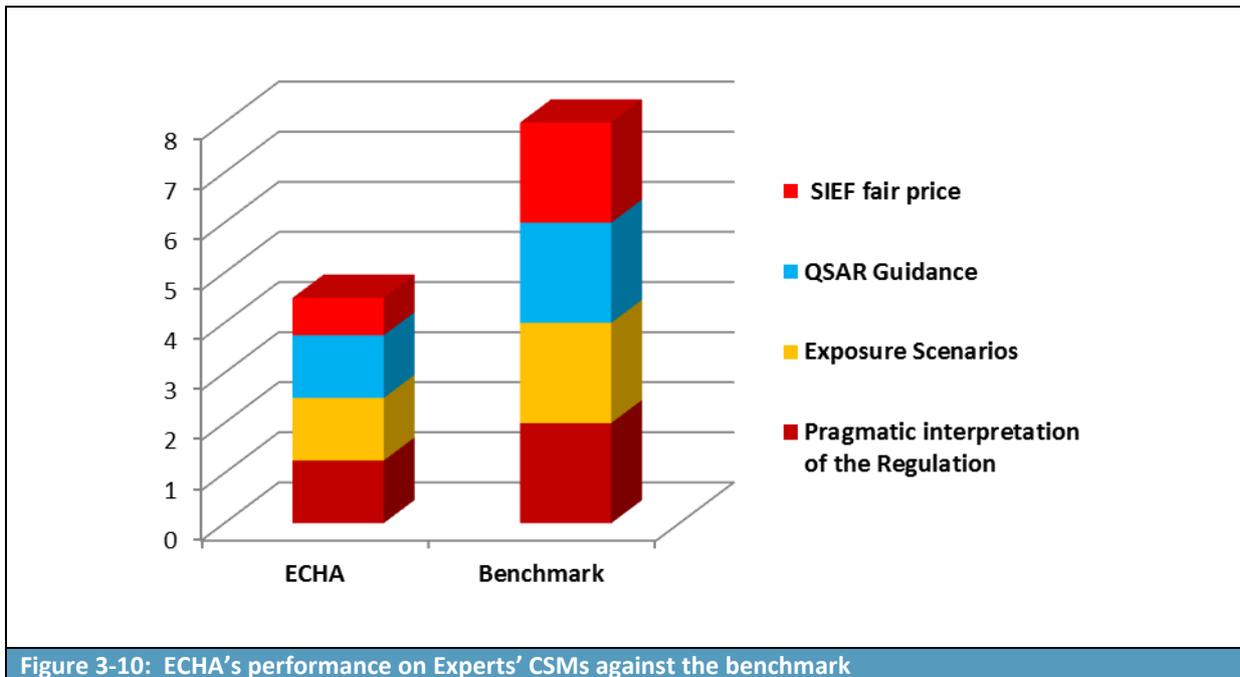


Figure 3-10: ECHA's performance on Experts' CSMs against the benchmark

## 4 Propositions and Recommendations

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### 4.1 Introduction

In developing a strategy based on market segmentation, the usual approach would be to develop financial and market share objectives by segment. Strategies are then actionable propositions that improve performance against the Critical Success Factors, such that competitive position is improved in that segment. Alternatively, the decision may be to withdraw from a segment as the position is too weak or is dying.

In the case of ECHA and the development and offer of IUCLID functionalities on the cloud, the objective is to facilitate the registration of substances, ultimately saving time and resources to SMEs. However, IUCLID is only a component of the registration process and, through the consultation of stakeholders, it has soon become apparent that part of the SME target population faces huge problems before even approaching the IUCLID software. Moreover, many SMEs outsource the preparation and submission of the registration dossiers to consultancies, never using IUCLID directly.

Therefore, it is necessary to consider the original objectives of the REACH Regulation and of the registration in particular, that is the collection of high quality information on the hazard properties of the substances on the market, so that this information can be used by companies to enhance their risk management measures for the improvement of the safety of their workers' health and, ultimately, of the safety of the general population and the environment. The concurrent objective is to ensure the free circulation of substances on the internal market, maintaining a level playing field and enhancing the competitiveness and innovation of European companies.

Indicators of success for such objectives are the number of substances that will be registered by May 2018 and the number of SMEs that will register. Unfortunately, the current figures on the number of expected substances that will be registered and the number of registration dossiers that will be received are only rough estimates and it will be difficult to assess any discrepancies, even *a posteriori*.

With regard to the awareness of SMEs of the REACH Regulation and of the need to register low production volume substances by May 2018, ECHA and the other stakeholders have run countless initiatives, and the effects are visible. Over 95% of the SMEs consulted were aware of their duties. Unfortunately, a sizeable number of SMEs has moved too late and will face tough decisions in terms of rationalisation of their substance portfolio.

There is also a considerable number of SMEs that duly took action on time, verifying their obligations and setting apart resources for the registration of their substances when possible (many SMEs operate with small margins). Even among these companies, the costs of registration, in particular in the presence of large substance portfolios, force SMEs to consider phased registration and withdrawal of substances in the long term. A major problem is that it is not possible to determine the costs of registration upfront without engaging in the process.

The cost of a Letter of Access ranges between €25,000 and €250,000, and the pricing and, more generally, the rules agreed within the SIEFs, are perceived as unjust by SMEs. Many of the SMEs consulted believe that it is the large groups that rule within the SIEFs and that these are making business of the substance information they hold. They would welcome a regulatory initiative fixing the cost of registration to the actual quantity manufactured or imported (€ per kg of substance). Any other pricing policy is disproportionate and severely impacts companies dealing with lower quantities (typically SMEs).

Apart from the costs, another major problem is the enforcement of the Regulation: the stakeholders consulted doubt that the authorities have the resources to perform extensive checks and, when faced with the registration costs, many SMEs may decide to get around the rules, fiddling, for example, with the quantities manufactured or imported or with the sameness criteria (e.g. asking different authorities until the most convenient answer is received).

Many of the SMEs consulted do not perceive any added value in registering substances and, often, do not have access to the information they bought or do not consult the information to make improvements to their own risk management measures. This is a major failure of the registration process and of its original intention.

Against this background, the project team distinguishes between propositions for the IUCLID cloud services and propositions for the registration process more generally.

## 4.2 Cost of Registration

### 4.2.1 Possible actions and key messages

The key issue for many SMEs is the cost of registration and, in particular, the cost of the Letters of Access and of participating in the SIEFs. ECHA has limited powers on this matter, but should raise awareness amongst the European Commission and the Member States Competent Authorities on the struggles that SMEs are facing for this registration deadline and on the potential impacts on competitiveness and employment.

There are two main Critical Success Factors which have the most impact on the defined segments:

- SIEF costs and fair pricing;
- Knowledge burden and cost of consultancies' services.

Although ECHA has limited power in regulating SIEFs, various possibilities, within ECHA's remit, are suggested:

- Encourage the European Commission and the Member States to mobilise resources to support the registration of substances by SMEs for the 2018 deadline;
- Provide information on available funding for compliance on the ECHA website, along with examples of completed successful applications;
- Discuss with the Commission the opportunity to allow for more flexible payment mechanisms. If a SME can show that the registration costs exceed a certain profit/cost ratio per substance, European funds could cover the initial one-off registration costs with these then repayable via loans to the companies of say 5-10 years, depending on the overall cost per substance. This would allow:
  - ECHA to check that the relevant data-sharing agreements adhere to the three principles of transparency, fairness and non-discrimination;
  - The maximisation of substances registered;
  - A level playing field within the EU market;
- Create a platform where manufacturers/importers can advertise the substances for which they lack the resources for registration and where downstream users can advertise the substances for which they are willing to offer partial or full financial support to registration (with ECHA verifying that the manufacturers/importers actually pre-registered the substance);
- Require notification of the SIEF costs with publishing of this information;

- Provide best practice examples of SIEF pricing;
- Provide successful stories of SMEs that challenged SIEF pricing;
- Provide examples of well-justified opt out cases;
- Improve communication on the ease of challenging SIEF pricing and on the possibility to opt out on the basis of the failure to adhere to the principles of fairness, transparency and non-discrimination defined in the Implementing Regulation on joint submission and data-sharing;
- Allow the use of data obtained from in vitro and in silico studies when these are not of an inferior quality to data obtained from in vivo studies;
- Provide best practice examples of consultancies pricing for registration services;
- Send the link to the Commission implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing to all companies (not only SMEs) in the process of registering substances. This can be done via email or in the form of a banner on REACH-IT;
- Pull out some key messages on the three principles of a sound SIEF management:
  - Transparency: Highlight that data-sharing agreements shall include the itemisation of the data to be shared, with cost, description and justification for each item. Highlight that all administrative costs should also be itemised and justified.
  - Fairness and non-discrimination: reinforce the message that registrants can only be asked to pay for the information they need to submit to the Agency to fulfil their registration requirements, and that this applies also to administrative costs;
- Clearly specify the information that registrants in lower tonnages are obliged to submit (further explained below);
- Add a message for the lead registrants but visible to all registrants: if there is a data-sharing dispute, the authorities reserve the right to start an investigation on anticompetitive practices or abuse of dominance in accordance with EU competition law and for the breach of Articles 101 and 102 of the Treaty on the Functioning of the European Union. This message has the double objective of deterring lead registrants in overcharging SIEF participants (effectively engaging in anticompetitive practices) and to show SMEs that the authorities will take action against anticompetitive behaviours.

The Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing sought to establish a fair and transparent system for data sharing including the itemisation of costs. A central principle in this regulation (and also intended in REACH) is that registrants participating in the SIEF should only be obliged to pay for information (and administration costs) that is required for their registration. So the preamble to the regulation (para 5) identifies that “*administrative costs and costs related to information requirements should only be shared where those costs are relevant to the information that a party is obliged to submit for registration*” and Article 2 (on Transparency) sets out the itemisation of the costs and other requirements to enable this to happen.

It appears to the study team that, particularly in relation to mutagenicity testing, there remain grey areas that will be of importance, particularly for registrants at 1-10t and, therein, SMEs. These relate to situations where any costs associated with further *in vivo* mutagenicity testing should or should not be shared with 1-10t registrants, which is not always clear. Consider the cases set out below.

### Case 1: A substance registered only at 1-10t

A registrant of a substance registered only at 1-10t requires data in relation to the Annex VII gene mutation test (GMBact). In the event of a positive result, additional data from Annex VIII and above are required. The general route followed by the ECHA *Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7a: Endpoint Specific Guidance* is one of undertaking relevant mutagenicity testing progressing up through Annex VIII and above to establish genotoxicity. So the guidance indicates that the following would be required in the event of a positive result for GMBact:

- either or both of CABvitro/MNT Vitro or GMvitro tests in Annex VIII as appropriate to the Integrated Testing Strategy set out in ECHA Guidance (ITS);
- Cytvivo or GMvivo<sup>20</sup> *in vivo* tests in Annex IX as appropriate to the ITS.

In this case it is obvious that sharing the significant costs of (particularly the *in vivo*) mutagenicity testing between all registrants would be a fair way to proceed.

### Case 2: A substance registered at both 1-10t and higher tonnages

For a substance registered (or to be registered) at a tonnage above 10t per year, registrants at the higher tonnage bands require:

- the Annex VII gene mutation test (GMBact); and
- either or both of CABvitro/MNT Vitro or GMvitro tests in Annex VIII as appropriate to the ITS.

In the event that one of these test returns a positive result, further testing is required in the form of Cytvivo or GMvivo *in vivo* tests in Annex IX (as appropriate to the ITS). However, whether these costs should or should not be shared with 1-10t registrants is not entirely clear and might depend on the outcome of the tests. This is illustrated in the Table below.

| Table 4-1: Should further mutagenicity costs be shared by 1-10t registrants? |  |   |   |  |
|--|--|---|---|--|
| Annex VII Information (GMBact)   | Annex VIII (CABvitro/MNT Vitro or GMvitro) | Annex XI (Cytvivo or GMvivo <i>in vivo</i> tests) | Should further mutagenicity costs be shared by 1-10t registrants? |  |
| Positive   | Positive/negative                          | Positive (genotoxic)                              | Yes   | As in Case 1, it would seem fair for the costs of all further mutagenicity testing to be shared between all registrants including those at 1-10t   |
| Positive   | Positive/negative                          | Negative (non-genotoxic)                          |   |  |
| Negative   | Positive                                   | Positive (genotoxic)                              | Probably  | There is a weak argument that, as the Annex VII test returned a negative result, a 1-10t registrant would not be liable for the costs of further testing. This argument would be based on the fact that, if the substance were registered only at 1-10t, no further mutagenicity testing would have been required so why should 1-10t registrants share the costs? As noted, this is a weak argument |

<sup>20</sup> GMBact: gene mutation test in bacteria (Ames test); CABvitro, in vitro chromosome aberration test; MNTvitro, in vitro micronucleus test; GMvitro:gene mutation assay in mammalian cells; Cytvivo:cytogenetic assay in experimental animals; GMvivo:gene mutation assay in experimental animals

| Table 4-1: Should further mutagenicity costs be shared by 1-10t registrants? |  |   |   |   |
|--|--|---|---|---|
| Annex VII Information (GMBact)   | Annex VIII (CABvitro/MNT Vitro or GMvitro) | Annex XI (Cytvivo or GMvivo <i>in vivo</i> tests) | Should further mutagenicity costs be shared by 1-10t registrants? |   |
| Negative   | Positive                                   | Negative (non-genotoxic)                          | Perhaps or perhaps not?   | <p>There is a strong(er) argument that, as the Annex VII test correctly returned a negative result, a 1-10t registrant should not be liable for the costs of further testing.</p> <p>Similar to the above this argument hinges on the fact that, if the substance were registered only at 1-10t, no further mutagenicity testing would have been required. Should registrants at 1-10t be liable for the further mutagenicity testing, that is the result of false positive results in testing under Annex VIII, particularly as this is a fairly likely outcome (95%) of the three battery test (see below)?</p> |

The difference between contributing simply to the costs of the Annex VII GMBact test (around €3,500 per substance) or having also to contribute to costs for further testing (around a further €30,000 to €68,000 depending on the combination of tests required by following the ITS) is likely to be very significant for registrants at 1-10t and especially for SMEs.

The influence of the three battery test on costs is also important. As we have identified in previous studies (most recently the REACH Economics study), for the battery of three mutagenicity tests that are currently applied in Annex VII and VIII, a positive result in any of these three tests triggers the need for further *in vivo* mutagenicity testing and the cost of this further testing is significant (in excess of around €40 thousand). However, the potential for false positive results from the three test battery is high. In 2011 the UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) published Guidance on a Strategy for Genotoxicity Testing of Chemical Substances<sup>21</sup>. This reviewed the effectiveness of testing strategies, comparing batteries of two versus three tests finding that:

- A two test battery is likely to correctly identify 73% of rodent carcinogens and 78% of *in vivo* genotoxicants;
- A two test battery is likely to falsely identify 88% of non-carcinogens as potential rodent carcinogens that would need to undertake further *in vivo* studies;
- Adding a third test (as in Annex VIII) increases the sensitivity marginally, correctly identifying 75% of rodent carcinogens and 79% of genotoxicants;
- At the same time, adding the third test (as in Annex VIII) is likely to increase the percentage of non-carcinogens falsely identified as potential carcinogens to 95%.

<sup>21</sup> The UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) (2011) Guidance on a Strategy for Genotoxicity Testing Of Chemical Substances. <http://www.iacom.org.uk/guidstate/documents/COMGuidanceFINAL.pdf>

On the basis of the lack of convincing evidence that the three test battery identifies more carcinogens/genotoxins than the two test battery combined, with the increase in the numbers of substances falsely identified under the three test system, the two test system is recommended by the UK COM.

Considering the impact of UK COM's conclusion on costs and cost sharing for 1-10t registrants, under the (current) three test battery in Annex VIII around 95% of substances will be identified as requiring further mutagenicity testing through Annexes IX and X. This means that, without clarification of the costs for which 1-10t registrants are liable, around 95% of the SMEs (and others) that are seeking to submit a 1-10t registration for a substance also registered at a higher tonnage band are likely to be asked to make significant contributions to costs for which they perhaps should not be liable. As such, it will be worth adding further clarification on when mutagenicity testing costs should and should not be shared with 1-10t registrants. In addition, the UK COM evidence suggests that this figure of 95% could be reduced to 78% by eliminating the third test from the (current) three test battery.

## 4.2.2 Communication channels

Apart from the Planners, all other product builder and supplier segments do not routinely check the ECHA website, and when they do they are deterred by the large amount of information. Even the ECHA newsletter is perceived by some as, although interesting, too dispersive, particularly for SMEs. The communication channels for these segments need to be pro-active:

- Emailing key messages using the REACH-IT pre-registration database, with links back to the ECHA or national help-desks;
- Through Trade Associations;
- Through national and regional enforcement authorities.

In addition, ECHA could ask for the cooperation of downstream users in promoting the cloud services, requesting that they pass the information upstream within the supply chains. Cefic, FECC, EASME and other major European downstream user associations may help ECHA in this task, requesting that national trade associations suggest to their members to pass the information about the cloud services availability for SMEs to their suppliers.

ECHA should be clear on its remit and on what can and cannot be done. The key problems faced by the SMEs should be mentioned and the relevant support (even if palliative) proposed.

## 4.3 IUCLID Specific CSFs and Strategies

When it comes to the current version of IUCLID, respondents to the survey (those who actually used the software) were sufficiently satisfied. For the IUCLID cloud version, ECHA will have to carefully consider how to improve the perception of privacy and security of the database, as these were the two factors highlighted by consultants as of particular concern.

In terms of privacy, companies should be given the opportunity of granting permission to ECHA to access pre-submission data. This could be done in the form of a confidentiality agreement. With regard to security, ECHA should communicate the key security features of its IT system (disaster recovering tests, reports of independent auditors and of internal audits on security features).

However, many of the companies with registration duties will never use the software directly, outsourcing the whole process or the submission of the information via IUCLID to specialist consultants for efficiency and effectiveness reasons.

Nevertheless, the IUCLID cloud version could be of use for the smaller entities in the SME target population, namely the micro-enterprises.

## Annex 1 Interview Guide

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Could you give us an overview of your company? Number of employees, turnover, client sectors, types of chemicals manufactured and imported.

Are you a manufacturer or importer?

When did you first become aware of the REACH Regulation?

Was it through industry associations, authorities, inspectors, peers?

Did you attend any training on the REACH Regulation? Organised by? Did you attend any specific training on registration?

Did you have to register substances for the previous deadlines?

How many substances do you have to register for the 2018 deadline?

Are you dropping any substances from your portfolio?

When did you start planning for the registration?

What is the cost per substance? Can you break the cost down (letters of access, testing, FET)

Do you have a dedicated person or team that is following the registration? Was this person or team assigned to other tasks before (e.g. R&D)? Was he hired just for dealing with REACH?

Did any of your client enquire about your intentions to register?

Did any of your client offer assistance (also financial) in registering substances?

Do your clients ask for the registration numbers of the substances you provide?

How long does it take to submit the information through IUCLID?

Did you have any problem with IUCLID in the past?

Would you be interested in using the IUCLID cloud service?

What do you think are the advantages (or disadvantages) of the cloud service?

What are the features you would like them to improve?

What could ECHA do to facilitate the registration of substances?

What is your perception in terms of the behaviour and attitudes of your competitors? Will they withdraw substances? Will they trade illegally because they think the Regulation will not be enforced or is not sufficiently enforced?

Do you see any added value in registering substances? e.g. better toxicological and ecotoxicological information, improved health and safety.

## Annex 2 Survey Questionnaire

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Invitation letter:

Email subject: ECHA Survey Registration 2018

\*\*\*\*\*

Dear Sir/Madam,

Risk & Policy Analysts Ltd has been contracted by the European Chemicals Agency (ECHA) to carry out a survey aimed at small and medium-sized enterprises and concerning the registration of chemical substances under the REACH Regulation. As your organisation may have to register chemicals manufactured or imported into the European Economic Area between one tonne and one hundred tonnes per year by the deadline of 31 May 2018, we would like to get your feedback on the registration process. ECHA will use this feedback to improve the process and to further help SMEs in the run-up to the deadline.

We will treat all replies in a confidential manner and only the aggregated results of the survey will be passed to ECHA.

The survey can be found at: <https://www.surveymonkey.co.uk/r/2018Registration-EN>

Please provide your responses by the **2<sup>nd</sup> of June 2017**.

Thank you.

Kind regards,

\*\*\*\*\*

### Information about your company

#### Q1. Please provide the following details:

|  |  |
|--|--|
| Company name*:                           |  |
| City/Town (optional):                    |  |
| Contact name (optional):                 |  |
| E-mail Address (optional):               |  |
| Your position in the company (optional): |  |
|  |  |

#### Q2. Please indicate the country in which your business is located (tick all that apply):

|                          |          |
|--------------------------|----------|
| <input type="checkbox"/> | Austria  |
| <input type="checkbox"/> | Belgium  |
| <input type="checkbox"/> | Bulgaria |
| <input type="checkbox"/> | Croatia  |
| <input type="checkbox"/> | Cyprus   |

|                          |  |
|--------------------------|--|
| <input type="checkbox"/> | Czech Republic                               |
| <input type="checkbox"/> | Denmark                                      |
| <input type="checkbox"/> | Estonia                                      |
| <input type="checkbox"/> | Finland                                      |
| <input type="checkbox"/> | France                                       |
| <input type="checkbox"/> | Germany                                      |
| <input type="checkbox"/> | Greece                                       |
| <input type="checkbox"/> | Hungary                                      |
| <input type="checkbox"/> | Iceland                                      |
| <input type="checkbox"/> | Ireland                                      |
| <input type="checkbox"/> | Italy  |
| <input type="checkbox"/> | Latvia                                       |
| <input type="checkbox"/> | Liechtenstein                                |
| <input type="checkbox"/> | Lithuania                                    |
| <input type="checkbox"/> | Luxembourg                                   |
| <input type="checkbox"/> | Malta  |
| <input type="checkbox"/> | Netherlands                                  |
| <input type="checkbox"/> | Norway                                       |
| <input type="checkbox"/> | Poland                                       |
| <input type="checkbox"/> | Portugal                                     |
| <input type="checkbox"/> | Romania                                      |
| <input type="checkbox"/> | Slovakia                                     |
| <input type="checkbox"/> | Slovenia                                     |
| <input type="checkbox"/> | Spain  |
| <input type="checkbox"/> | Sweden                                       |
| <input type="checkbox"/> | United Kingdom                               |
| <input type="checkbox"/> | Other. Please specify in the text-box below: |

**Q3. Please indicate which of the following best describes the size of your company. When answering this question please respond in line with the European Commission definition of what is a SME<sup>22</sup>:**

- Micro-enterprise: (staff < 10, turnover < €2 million, balance sheet total < €2 million)
- Small enterprise: (staff < 50, turnover < €10 million, balance sheet total < €10 million)
- Medium enterprise: (staff < 250, turnover < €50 million, balance sheet total < €43 million)
- Large enterprise: (staff > 250, turnover > €50 million, balance sheet total > €43 million)

**If you are an Only Representative, please refer to the size of the non-EU entities you are representing.**

|                          |                   |
|--------------------------|-------------------|
| <input type="checkbox"/> | Micro-enterprise  |
| <input type="checkbox"/> | Small enterprise  |
| <input type="checkbox"/> | Medium enterprise |
| <input type="checkbox"/> | Large enterprise  |

**Q4. Please select the NACE codes that best reflect your primary activities (tick all that apply).**

|                          |    |  |
|--------------------------|----|--|
| <input type="checkbox"/> | A1 | Crop and animal production, hunting and related service activities |
|--------------------------|----|--|

<sup>22</sup> For further details, please see:  
<http://ec.europa.eu/DocsRoom/documents/10109/attachments/1/translations/en/renditions/native>

|                          |   |   |
|--------------------------|---|---|
| <input type="checkbox"/> | B5  | Mining of coal and lignite  |
| <input type="checkbox"/> | B6  | Extraction of crude petroleum and natural gas   |
| <input type="checkbox"/> | B7  | Mining of metal ores  |
| <input type="checkbox"/> | B8  | Other mining and quarrying  |
| <input type="checkbox"/> | B9  | Mining support service activities   |
| <input type="checkbox"/> | C10.4   | Manufacture of vegetable and animal oils and fats   |
| <input type="checkbox"/> | C11   | Manufacture of beverages  |
| <input type="checkbox"/> | C12   | Manufacture of tobacco products   |
| <input type="checkbox"/> | C13   | Manufacture of textiles   |
| <input type="checkbox"/> | C14   | Manufacture of wearing apparel  |
| <input type="checkbox"/> | C15   | Manufacture of leather and related products   |
| <input type="checkbox"/> | C16   | Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials |
| <input type="checkbox"/> | C17   | Manufacture of paper and paper products   |
| <input type="checkbox"/> | C18   | Printing and reproduction of recorded media   |
| <input type="checkbox"/> | C19   | Manufacture of coke and refined petroleum products  |
| <input type="checkbox"/> | C20   | Manufacture of chemicals and chemical products  |
| <input type="checkbox"/> | C21   | Manufacture of basic pharmaceutical products and pharmaceutical preparations  |
| <input type="checkbox"/> | C22   | Manufacture of rubber and plastic products  |
| <input type="checkbox"/> | C23   | Manufacture of other non-metallic mineral products  |
| <input type="checkbox"/> | C24   | Manufacture of basic metals   |
| <input type="checkbox"/> | C25   | Manufacture of fabricated metal products, except machinery and equipment  |
| <input type="checkbox"/> | C26   | Manufacture of computer, electronic and optical products  |
| <input type="checkbox"/> | C27   | Manufacture of electrical equipment   |
| <input type="checkbox"/> | C28   | Manufacture of machinery and equipment n.e.c.   |
| <input type="checkbox"/> | C29   | Manufacture of motor vehicles, trailers and semi-trailers   |
| <input type="checkbox"/> | C30   | Manufacture of other transport equipment  |
| <input type="checkbox"/> | C31   | Manufacture of furniture  |
| <input type="checkbox"/> | C32   | Other manufacturing   |
| <input type="checkbox"/> | C33   | Repair and installation of machinery and equipment  |
| <input type="checkbox"/> | D35.2   | Manufacture of gas; distribution of gaseous fuels through mains   |
| <input type="checkbox"/> | E36   | Water collection, treatment and supply  |
| <input type="checkbox"/> | E38.2   | Waste treatment and disposal  |
| <input type="checkbox"/> | F41   | Construction of buildings   |
| <input type="checkbox"/> | F42   | Civil engineering   |
| <input type="checkbox"/> | F43   | Building completion and finishing   |
| <input type="checkbox"/> | G46   | Wholesale trade, except of motor vehicles and motorcycles   |
| <input type="checkbox"/> | G46.1.2   | Agents involved in the sale of fuels, ores, metals and industrial chemicals   |
| <input type="checkbox"/> | G46.4   | Wholesale of household goods  |
| <input type="checkbox"/> | M72   | Scientific research and development   |
| <input type="checkbox"/> | M75   | Veterinary activities   |
| <input type="checkbox"/> | Q86   | Human health activities   |
| <input type="checkbox"/> | Other. Please specify in the text-box below (you can find other activities and the corresponding NACE codes at:<br><a href="http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&amp;StrNom=NA_CE_REV2&amp;StrLanguageCode=EN&amp;IntPckKey=&amp;StrLayoutCode=&amp;IntCurrentPage=1">http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&amp;StrNom=NA_CE_REV2&amp;StrLanguageCode=EN&amp;IntPckKey=&amp;StrLayoutCode=&amp;IntCurrentPage=1</a> ): |   |

## The REACH Regulation

### Q5. Are you aware of the EU REACH Regulation?

|                          |     |
|--------------------------|-----|
| <input type="checkbox"/> | Yes |
| <input type="checkbox"/> | No  |

**Q6. If yes, how did you become aware? Thanks to:**

|                          |  |
|--------------------------|--|
| <input type="checkbox"/> | European Chemicals Agency (ECHA)             |
| <input type="checkbox"/> | National or regional authorities/inspectors  |
| <input type="checkbox"/> | European trade association                   |
| <input type="checkbox"/> | National trade association                   |
| <input type="checkbox"/> | Suppliers                                    |
| <input type="checkbox"/> | Peers  |
| <input type="checkbox"/> | Customers                                    |
| <input type="checkbox"/> | Other. Please specify in the text-box below: |
|                          |  |

**Q7. Are you aware that all existing chemical substances manufactured or imported into the EEA between 1 and 100 tonnes per year need to be registered by 31 May 2018?**

|                          |     |
|--------------------------|-----|
| <input type="checkbox"/> | Yes |
| <input type="checkbox"/> | No  |

**Q8. Did you seek advice as to what you had to do to comply with your registration duties?**

|                          |     |
|--------------------------|-----|
| <input type="checkbox"/> | Yes |
| <input type="checkbox"/> | No  |

**Q9. If yes, who did you contact for advice? Please tick all that apply.**

|                          |  |
|--------------------------|--|
| <input type="checkbox"/> | ECHA help-desk                               |
| <input type="checkbox"/> | National help-desk                           |
| <input type="checkbox"/> | National or regional authorities             |
| <input type="checkbox"/> | European trade association                   |
| <input type="checkbox"/> | National trade association                   |
| <input type="checkbox"/> | Suppliers                                    |
| <input type="checkbox"/> | Peers  |
| <input type="checkbox"/> | Customers                                    |
| <input type="checkbox"/> | Consultancy                                  |
| <input type="checkbox"/> | Other. Please specify in the text-box below: |
|                          |  |

**Q10. Do you believe you have REACH Registration duties?**

|                          |   |
|--------------------------|---|
| <input type="checkbox"/> | Yes, we verified that we have to register substances  |
| <input type="checkbox"/> | Yes, we think we may have to register some substances, but we are still verifying our duties (e.g. checking the quantities, consulting the national helpdesk) |
| <input type="checkbox"/> | No, after verification, we are certain we do not have to register any substance   |
| <input type="checkbox"/> | No, we think we do not have to register any substance, but we are still verifying our duties (e.g. checking the quantities, consulting the national helpdesk) |

**Q11. How would you describe your organisation’s activities in the EEA regarding chemical substances? Please tick all that apply.**

|                          |   |
|--------------------------|---|
| <input type="checkbox"/> | Manufacturer of chemical substances   |
| <input type="checkbox"/> | Importer of chemical substances or mixtures   |
| <input type="checkbox"/> | Formulator of mixtures  |
| <input type="checkbox"/> | Industrial or professional users of chemical substances, on its own or in a mixture, in professional or industrial activities (end users) |
| <input type="checkbox"/> | Distributor of chemical substances or mixtures  |
| <input type="checkbox"/> | Suppliers (manufacturers/importers/wholesalers/retailers) of articles   |
| <input type="checkbox"/> | Only representative   |
| <input type="checkbox"/> | Other. Please specify in the text-box below:  |
|                          |   |

**If you answered “No, after verification, we are certain we do not have to register any substance” to Q10 (Do you believe you have REACH Registration duties?), you can skip all the remaining questions and submit your responses.**

**Planning for the registration**

**Q12. How many chemical substances are you going to register for the 2018 deadline?**

|                     | 1-10 tonnes per annum | 10-100 tonnes per annum |
|---------------------|-----------------------|-------------------------|
| 0                   |                       |                         |
| Between 1 and 5     |                       |                         |
| Between 6 and 10    |                       |                         |
| Between 11 and 20   |                       |                         |
| Between 21 and 50   |                       |                         |
| Between 51 and 100  |                       |                         |
| Between 101 and 500 |                       |                         |
| Over 500            |                       |                         |
| Don't know yet      |                       |                         |

**Q13. If you answered “Don’t know yet” to Q12, please clarify (tick all that apply):**

|                          |   |
|--------------------------|---|
| <input type="checkbox"/> | It is unclear whether the 1 tonne threshold is exceeded for the substance(s) we deal with |
| <input type="checkbox"/> | It is unclear whether the substance(s) need(s) to be registered                           |
| <input type="checkbox"/> | It is unclear whether our supplier(s) will register                                       |
| <input type="checkbox"/> | We are still carrying out the cost benefit analysis for each substance                    |
| <input type="checkbox"/> | Other. Please specify in the text-box below:  |
|                          |   |

**Q14. Substances used as intermediates under strictly controlled conditions benefit from reduced information requirements. How many substances will you register in full and how many will you register only as intermediates under strictly controlled conditions?**

|  | 1-10 tonnes per annum | 10-100 tonnes per annum |
|--|-----------------------|-------------------------|
|  |                       |                         |

|   |  |  |
|---|--|--|
| Full registration as an individual registrant     |  |  |
| Full registration as the lead registrant          |  |  |
| Full registration as member registrant            |  |  |
| Intermediate registration – individual registrant |  |  |
| Intermediate registration – lead registrant       |  |  |
| Intermediate registration – member registrant     |  |  |

**Q15. When do you plan to submit the registration dossiers for the 2018 deadline? Provide the indicative number per month.**

|                |  |
|----------------|--|
| May 2017       |  |
| June 2017      |  |
| July 2017      |  |
| August 2017    |  |
| September 2017 |  |
| October 2017   |  |
| November 2017  |  |
| December 2017  |  |
| January 2018   |  |
| February 2018  |  |
| March 2018     |  |
| April 2018     |  |
| May 2018       |  |
| Don't know yet |  |

**Your experience with the registration process**

**Q16. Do you belong to a Trade Association?**

|  |     |
|--|-----|
|  | Yes |
|  | No  |

**Q17. On a scale of 1 to 10, how well do Trade Associations represent the interests of companies like yours? 10 is 'very well' and 1 is 'not at all'.**

|   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

**Q18. Did you seek advice on the costs of registration and how to meet these?**

|  |     |
|--|-----|
|  | Yes |
|  | No  |

**Q19. Have you already put in place the resources and financial budget needed to meet your registration obligations?**

|  |     |
|--|-----|
|  | Yes |
|  | No  |

**Q20. How much have the resources and financial costs of registering your chemical substances affected your decision as to how to proceed? Give a score out of 10, where 10 is “in most cases, there was a very significant cost impact compared to the commercial value of the substance” and 0 is “in most cases, the cost of registration is not that significant compared to the commercial value of the substance(s)”:**

|   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

**Q21. Do you think the cost of Letters of Access is in most cases reasonable when considering the volume of the substances you deal with? Give a score out of 10, where 10 is ‘very expensive compared to the commercial value’ and 0 is ‘very cheap compared with the commercial value’.**

|   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|----|

**Q22. As a result of understanding the time and costs associated with registering substances under REACH, did you (tick all that apply):**

|                          |   |
|--------------------------|---|
| <input type="checkbox"/> | Decide to register all the substances from your portfolio?  |
| <input type="checkbox"/> | Decide to register substances in a phased manner, including withdrawing some substances from your portfolio over the short term?    |
| <input type="checkbox"/> | Decide to register only a portion of the substances from your portfolio, while withdrawing from you portfolio over the longer term? |
| <input type="checkbox"/> | Have to divert R&D resources to meet REACH registration obligations?  |
| <input type="checkbox"/> | Seek financial support from customers?  |
| <input type="checkbox"/> | Seek a financial loan from a bank or other institution?   |
| <input type="checkbox"/> | Seek governmental financial support?  |
| <input type="checkbox"/> | Raise awareness amongst your customers about your inability to register all of your substances due to the financial burden?         |
| <input type="checkbox"/> | Raise awareness amongst the authorities about your inability to register all of your substances due to the financial burden?        |
| <input type="checkbox"/> | Other. Please specify in the text-box below:  |
|                          |   |

**Q23. If you are considering withdrawing some of your substances from the market, what is the percentage of the foreseen withdrawal from your current substance portfolio?**

|     |     |     |     |     |     |     |     |     |      |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|
| 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100% |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|

**Q24. Do your key customers ask for a declaration of compliance with REACH?**

|                          |     |
|--------------------------|-----|
| <input type="checkbox"/> | Yes |
| <input type="checkbox"/> | No  |

**Q25. Did customers in your supply chain offer assistance (including financial assistance) to you or expertise/data to complete the registration process?**

|                          |     |
|--------------------------|-----|
| <input type="checkbox"/> | Yes |
| <input type="checkbox"/> | No  |

**Q26. Given your market and supply chain, do you actively investigate substitutes for chemical substances which may be considered hazardous or best avoided in the future?**

|  |     |
|--|-----|
|  | Yes |
|  | No  |

**Q27. If you have to register substances for the 2018 deadline, will you (tick all that apply):**

|  |   |
|--|---|
|  | Undertake the whole process in-house with your own people, possibly with some training support? |
|  | Go through the process in-house but with support from a consultant?                             |
|  | Outsource toxicology/QSAR modelling to a consultancy/third party?                               |
|  | Outsource the preparation and submission of information e.g. use of IUCLID to a consultancy?    |
|  | Outsource the whole process to a consultancy/trade association/consortium?                      |
|  | Other. Please specify in the text-box below:  |
|  |   |

**Q28. Would you be interested in using IUCLID (the software used to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances) on the cloud, lowering the cost for managing installations and hardware?**

|  |   |
|--|---|
|  | Yes                                       |
|  | No. Please clarify in the text-box below: |
|  |   |

**Q29. Have you already registered substances under REACH?**

|  |     |
|--|-----|
|  | Yes |
|  | No  |

If you answered “No” to Q29, you can skip all the remaining questions and submit your responses.

**Q30. How easy did you find the following: (Give a score out of 10, where 10 is ‘very easy’ and 1 is ‘very difficult’).**

|  |   |   |   |   |   |   |   |   |   |    |            |
|--|---|---|---|---|---|---|---|---|---|----|------------|
| Understand the registration process using the available support? | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Search for co-registrants?                                       | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Form the SIEF  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Agree on data and cost sharing                                   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Prepare the IUCLID dossier                                       | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Submit the dossier via REACH-IT                                  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Understand how to use and report (Q)SARs                         | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Understand how to use grouping and read-across approaches        | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |

**Q31. Based on your experience with IUCLID, please rank the following factors in order of importance (where 1 is 'most important' and 7 is 'least important').**

|  |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|
| Ease of navigation in the software (going from section to section or back again) | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Ease of use (It is intuitive and I know what to do)                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Quality and robustness (the software is consistent and keeps working)            | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Always up to date  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| It is secure (cannot be hacked)  | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| It is private (Nobody can access my working data)                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| It is always available and there are no problems accessing the site              | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Q32. Please score the following factors based on your current experience of using IUCLID (10 is 'excellent' and 1 is 'very poor').**

|  |   |   |   |   |   |   |   |   |   |    |            |
|--|---|---|---|---|---|---|---|---|---|----|------------|
| Ease of navigation in the software (going from section to section or back again) | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Ease of use (It is intuitive and I know what to do)                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Quality and robustness (the software is consistent and keeps working)            | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| Always up to date  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| It is secure (cannot be hacked)  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| It is private (Nobody can access my working data)                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |
| It is always available and there are no problems accessing the site              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Don't know |

**Q33. Please provide us with your views on the REACH registration process and what you think could be improved in order to make the registration process easier for your company.**

**Thank you.**



## Annex 3 Summary of Comments

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### A3.1 Additional Comments Received through the Survey

**Remove this huge registration fee! Why do we have to pay by forcing us to register to work? Products get more expensive and become non-marketable!**

Да се премахне тази огромна такса за регистрация! Защо трябва да плащаме като ни принуждават да се регистрираме за да работим? Продуктите се оскъпяват и стават не продаваеми!

6 - Bulgaria – Micro – Manufacturing not elsewhere classified – Supplier of articles Registration must be free of charge.

**Registration must be free of charge.**

Регистрацията трябва да бъде безплатно.

12 - Bulgaria – Micro – Manufacturer of chemical products

**We have only registered two substances under the regulations in force at that time, the whole process of registration extremely difficult, lengthy...**

zatím jsme pouze registrovali dvě látky v rámci předpisů, platných v té době, celý proces registrace nesmírně obtížný, zdlouhavý...

25 - Czech Republic – Micro – Importer and exporter of Chemicals

**Obligations are not clear and unambiguous at all, there is no one to advise a micro-business.**

Povinnosti vůbec nejsou jasné a jednoznačné, není kdo by poradil mikropodniku.

29 – Importer of chemicals or mixtures – Suppliers of goods

**It has become too expensive for small businesses because the big competitors decide what data will cost.**

Det er blevet alt for dyrt for små virksomheder, fordi de store konkurrenter beslutter, hvad data skal koste.

32 - Denmark – Small – Manufacturer of chemical products

**IUCLID 6 is easier than previous versions, however, readability has deteriorated (gray tones only). REACH-IT has become much more manageable to navigate in.**

IUCLID 6 er nemmere end de tidligere udgaver dog er læsevenligheden blevet dårligere (Kun gråtoner). REACH-IT er blevet meget mere overskueligt at navigere i.

33 - Denmark – Micro – Distributor of chemical products

**COST IS EXTREMELY HIGH FOR SMALL BUSINESS AS OUR DYNAMICS**

ΤΟ ΚΟΣΤΟΣ ΕΙΝΑΙ ΥΠΕΡΒΟΛΙΚΑ ΥΨΗΛΟ ΓΙΑ ΜΙΚΡΕΣ ΕΠΙΧΕΙΡΗΣΕΙΣ ΣΑΝ ΤΗΝ ΔΙΚΙΑ ΜΑΣ

53 - Greece – Micro – Wholesale trader – Importer of chemical substances or mixtures

**We believe that legislation should provide for simplified procedures for small businesses as they manage smaller volumes of chemicals. For example, the range of quantities of 1-100 does not compare to 101-1000 or to over 1000 tonnes. In addition, SMEs are the backbone of the EU and must be maintained.**

Θεωρούμε ότι η νομοθεσία έπρεπε να προνοεί για τις μικρές επιχειρήσεις πιο απλουστευμένες διαδικασίες καθώς διαχειρίζονται μικρότερους όγκους χημικών. Π.χ, το εύρος των ορίων ποσοτήτων 1-100 δεν συγκρίνεται με το 101-1000 ούτε με το πάνω από 1000 τόνους. Επιπλέον οι ΜΜΕ αποτελούν την ραχοκοκκαλιά της Ε.Ε. και πρέπει να διατηρηθούν.

58 - Cyprus – Small – Producer of chemicals – Importer, mixer and distributor of chemicals

**Small companies are going to be extinguished since is impossible to bear the cost of registration, impossible to find capitals to go through registration, experts are asking too much for registration, we are hostages and weak to react to anything**

61 - Greece – Small – Textile manufacturer – Chemical manufacturer and distributor

**It is a process that is made for the sole purpose of destroying all small companies and benefiting the large multinationals**

Είναι μια διαδικασία που γίνεται με μοναδικό σκοπό να αφανιστούν όλες οι μικρές εταιρίες και να ωφεληθούν οι μεγάλες πολυεθνικές

62 - Greece – Micro - Manufacture of rubber and plastic products - Producer of domestic carbon filters

**The obligation of sharing the costs allows wealthy companies to take the lead and spend a lot of money to push SME out of business, registration of synthesis intermediates is a competitive handicap compare to companies which can manufacture outside EU.**

63 - France, Netherlands, USA – Medium - Manufacturer of chemicals and chemical products

**REACH/ECHA needs to understand the significant barriers to trade inflicted by REACH. The entry costs are exorbitant for an SME. This will result in a monopoly type situation where only a select number of entrants will be registered; The clarity of the regulations are poor; The clarity about costs is not transparent as it varies from product to product; It is unclear how many elements need to be registered for a single product; Consultants fees are also high.**

64 - UK - Wholesale trader – Importer of metals and minerals – Wholesale trader

**Guidance to be presented in a format and using language that is easier to understand.**

66 – UK – Medium - Wholesaler of household goods

**The costs for Letter of Access are unreasonable for our micro company**

68 – Sweden – Micro – Manufacturer of chemical products – Wholesaler of household goods

**Substances used in producing speciality chemicals (low volume) with sales volume up to 10MT/year should be exempt of Reach registration**

71 – Portugal – Small - Agents involved in the sale of chemicals – Distributor of speciality chemicals

**I am the opinion that it is NOT fair to treat all chemical industries equal. Manufacturers of specific substances have a small portfolio and all data available. Formulators (ink, paints, others) have a VERY large portfolio and not all data is available (majority of suppliers do not share their information/formulation due to confidentiality + any data to be provided can take 5 months easily (this will be a problem after May 2018!!)). I wish you read my comments since I would really like ECHA to think about it.**

74: Spain, France, Czech Republic, Italy, UK – Medium enterprise – Other manufacturing – Formulator of inks and paints

**Why is an OR allowed to claim to be a Lead Registrant but who has no intention other than to use it as leverage to extort money from genuine registrants who are better placed to be LR? Why does ECHA not remove their names and support companies with a genuine interest in being LR rather than using it as a money-generator.**

77- UK – Medium enterprise – manufacturer of chemical products – Chemicals for industrial use

**Far too expensive and will kill our business**

79 – UK – Micro – Wholesale trade – importer and distributor of chemical substances

**The lack of transparency re the costs for the LoA's and the hidden additional costs such as the yearly surcharges of 8 - 10% imposed by some Sief Managers. In some cases can double the LoA cost by 2018, even though substance has not yet been registered.**

80 – UK – Small - Importer and distributor of chemical substances

**Possibly the most difficult process we have ever been asked to complete, as we are not specialists in chemicals. A system designed to put small companies out of business, yet with no perceived benefit.**

81 –UK – Small - Toy manufacturer – Importer of chemical substances

**It is too expensive. It is virtually the same cost for a large company as a small company. So per kg it is very expensive for small company. Like most EU initiatives its effect is much more burdensome for a small company. It destroys small companies and therefore the economy**

85 – UK – Small - Chemical manufacturer – Importer and distributor of chemical substances

**REACH registration is designed around significant, established organisations. It is poorly conceived for small R&D outfits, for whom it is a "death knell".**

86 – UK – Micro – Manufacturer of chemical products – Scientific R&D on metal alloy powders

**More time, re-schedule June 2018 till June 2020**

90 – Italy, Netherlands, Spain – Large - Manufacturer of chemical products

**There appears to be little official understanding that for many low volumes chemicals sold by multiple vendors that the cost and difficulty in compiling dossiers will mean that many compounds will not be registered. This will mean that these products will not be available in the EU accelerating the movement of chemical operations to other countries. The cost of collating data and the substantial time consumed compiling a dossier is not recovered from LOA applicants which means that small companies are unwilling to become LR's. The system does not work and this has been ignored by ECHA**

92 – UK – Small - Agent involved in the sale of fuels, ores, metals and industrial chemicals

**FAR TOO COMPLICATED, VERY POOR EXPLANATIONS OF WHAT IS REQUIRED. IMPOSSIBLE TO UNDERSTAND**

94 – UK – Small - Manufacturer of chemical products - Manufacturer of essential oils

**I'd like to give you two examples where logic and practicality don't meet with REACH. 1. PHMB CAS No. 27083-27-8 - this raw material is capable of being used at substantial dilutions in America for a variety of applications. In Europe in category P1 it has been prohibited. We have developed and patented a water based hand disinfectant capable of killing C.Difficile on patients hands within 60 seconds. The PHMB content of this product is less than 1%. Interestingly, in the UK more people die in hospitals of C.Difficile than die in accidents on the road. Our sporicidal hand disinfectant was the only product on the market in the world that kills spores. Most frustratingly no one and I mean no one wanted to hear the views of an SME. 2. We are a worldwide manufacturer of fire fighting chemicals and have spent over one million pounds on researching new firefighting foams that do not breakdown to PFOS or PFOA. We took our lead from the EPA and found a way of meeting the environmental requirement and comply with the EPA by September 2014. We have waited until February 2017 for ECHA to make up their mind on this subject. They first of all came in with a target of 1ppb, which they withdrew when they found out it couldn't be measured and then offered a derogation of 3 years if we, as a manufacturer, could meet a target of 1ppm, which our industry says it probably can do. You have to ask why the EPA in America got their decision out in 2014 and ECHA got theirs out in 2017. Indecision like this costs small companies lots of money, time and resources. Even now that ECHA have issued a decision, they are still publishing advice notes that fluorine free foam is just as good as foam with fluorine which is patently not true and**

**backed up by significant trials done in Europe and America by fluoroprotein manufacturers. I think I can give you another 4 or 5 examples of how difficult it is to work in the environment you've created and how very expensive it is and how very uncertain it is and how anybody can develop new products in this environment I fail to understand. I will be astounded if anybody replies to these comments in a sensible way. I have written to several European ministers who sent replied back full of platitudes that they have a sympathetic understanding of our plight but haven't found anybody who was able to do anything about it.**

97 – UK – Small – Formulator of mixtures

**For small companies the tonnage bands are too wide eg if slightly over 100t the costs escalate too much. Registration requirements will lead to many niche products being unavailable**

99 – Finland, UK – Small - Manufacturer of chemical products - Manufacturer of chemical substances

**It will put many SME's out of business. Far too costly and unnecessary. Testing is cost prohibitive causing long term development to be aborted and investment (money) lost. No provision has been made for this circumstance.**

100 – UK – Small - Manufacturer of chemical products – Manufacturer and distributor

**Difficult process, very expensive. Very small companies should be exempt. Too much work.**

101 – UK - Micro – Importer of Alumina chemicals

**Originally we understood that if you would need to only register small quantities and "bought" into the existing information, then we would only have to make a pro rata payment. It now seems that the payment is just based upon the number of registrants rather than the relative volume. It is for this reason that we will only supply products that have been registered by suppliers or that are exempt. The costs are simply prohibitive for a company of our size. This will affect new product development for all companies.**

104 – UK – Micro – Manufacturer, mixer and importer of chemical substances

**We would like to be informed as to the registration process please.**

105 – UK – Small – Importer of chemical substances - Fire extinguisher manufacturer

**Poorly communicated and poor job at enforcing the large players to cooperate with the intentions of the sieff**

111- UK – Micro - Importer of chemical substances or mixtures – Manufacturer of wooden boat kits

**Scrap it - it's pointless and destroys all innovation in the EU**

115 – UK – Small - Manufacturer of chemical products - Importer of chemical substances or mixtures

**Need to know the outcome from Brexit before registration of any more substances**

118 – UK – Medium - Importer of non ferrous alloys and minerals

**It reduces Europe's ability to compete with other growing markets. The cost is a burden and the regulation too complex and confusing. There are too many grey areas. Many smaller companies will slip through the net and may never comply.**

129 – UK – Large Enterprise – Manufacturer and importer of chemical substances

**Process is complex, burdensome and expensive. As an importer costs can only be recovered by increasing customer prices. Thus we are either uncompetitively priced and do not achieve sales, or we increase raw material costs for chemically based products consumed in Europe.**

122 – Germany, Spain, UK – Medium - Manufacture of chemicals and chemical products – Agent involved in the sale of fuels, ores, metals and industrial chemicals

**1) When logging in, cannot find a list of previously pre-registered substances.**

**2) Very slow response from helpdesk (asked about Nano form substance classification)**

124 – Norway – Micro - Manufacture of chemicals and chemical products - Manufacturer of chemical substances

**Please show the leader registrant and contact through Reach-IT.**

129 – UK – Medium - Manufacture of chemicals and chemical products

**The whole REACH registration process is an absolute disgrace and a significant technical barrier to trade with no benefits visible in it's aim to protect human health and the environment. It is a sledgehammer to crack a nut and makes a mockery of the Lisbon treaty to make the EU a leader in innovation. This legislation has cost the chemical industry billions of Euros and GBP's and has made the industry less competitive versus our international competitors. Technical innovation in the chemical industry is virtually non existent due to the onerous nature of this legislation. I have copied a paragraph from the Lisbon treaty and this obviously is diametrically opposed to this noble aim. ECHA isn't even allowing read across to be used and forcing consortia to spend huge amounts on generating unnecessary data.**

**These surveys also make no difference to ECHA and it's approach. To say I'm unhappy with REACH is an understatement and CEFIC and the national trade bodies have let the industry down. The promotion of scientific and technological advance in its own right has become a specific objective of the Union for the first time. Previously, the Community aimed to promote research activities deemed necessary to support the competitiveness of industry and/or by virtue of other chapters of the Treaty. For the first time, the Lisbon Treaty defines the distribution of competences between the EU and the Member States in the areas of research, technological development and space as a shared competence.**

131 – UK, USA – Medium - Manufacture of chemicals and chemical products - Importer of chemicals Substances and terminal

**In my view reach is a pointless exercise that will be detrimental to the economy.**

133 – UK – Micro - Manufacture of basic pharmaceutical products and pharmaceutical preparations - Manufacturer of chemical substances

**All we need to do is give the CAS No to register with reach with a fixed fees for each product. This will be the easiest way to do, no need any further testing. Keep it easy and simple.**

138 – UK – Small - Manufacturer of chemical substances

**Appears complicated, we are subsidiary of a large MNC, but undertook this jointly with another SIEF member, outside of MNC. It is not straightforward and is very expensive**

139 - UK – Large - Manufacture of basic pharmaceutical products and pharmaceutical preparations

**It is a system designed by a committee of big organisations for big organisations. It is virtually impossible for one person to understand. For a piece of legislation which has not changed since its introduction the guidance provided has been constantly updated. The total amount of guidance now runs into several thousand pages. How anyone can claim this is designed in any way for small companies is dreaming. So the one way to make it easier is to make it simpler. Remember the expression KISS, keep it simple stupid.**

140 – UK – Medium - Manufacture of chemicals and chemical products

**A considerable resource issue for small companies which will result in a reduced wholesale supply of chemicals to business.**

141 – UK – Small – Wholesale trader - Importer of chemical substances

**It is unfair to smaller companies - costs of letters of access are not transparent, very expensive, no discount for smaller businesses. We have had to stop supplying products or find alternative suppliers and it has affected our competitiveness in the market. Also major concerns over what will happen with REACH if the UK leaves the EU therefore any investment is potentially on hold or put at risk until it is decided how this will work - a complete nightmare for us. We are micro in terms of balance sheet and number of employees but turnover is more thsn €2m euros. No support and help for SME's for complicate even if we wanted to. We simply cannot afford it so the larger companies will increase their market share and price us out of the market**

142 – UK – Small – Wholesale trader – Importer and distributor of chemical substances

**The Chemical Safety Assessment and chemical safety report are extremely difficult to prepare. Exposure scenarios are formulaic and do not always describe the real environment where a substance is used. The chemical safety report is extremely difficult to read because each page looks very similar with the same stock phrases repeated time after time. If you pick a page at random it is difficult to tell which section it is in without looking at the section heading.**

145 – UK – Small – Manufacture of chemicals and chemical products – Chemical manufacturer

**It is missing completely the intention, is only a limitation to the trade and a matter to be able to afford spending large amounts of money**

146 – Belgium, UK – Medium – Manufacture of chemicals

**For SMEs (micro), there should be ECHA-financed consultants who will take over the registration formalities.**

Für KMUs (Micro) sollte es ECHA finanzierte Consultants geben, die die Registrierungsformalitäten übernehmen.

148 – Germany – Micro - Manufacture of chemicals and chemical products

**SMEs (<50 employees) are clearly organized (use of employees and time), with a lot of effort, which can not be applied to the prices of the product compared to the global competition, and the content (thousands of pages of regulations) And elaborate / complex computer programs for registration and calculations) are often totally overwhelmed. We have already made these experiences at REACH-AfA.**

KMU's (<50 Mitarbeiter) werden mit dem gesamten Verfahren eindeutig organisatorisch (Einsatz von Mitarbeitern und Zeit), betriebswirtschaftlich (viel Aufwand, der nicht auf die Preise für das Produkt im Vergleich zur globalen Konkurrenz umgelegt werden kann) und inhaltlich (tausende Seiten an Regularien und aufwendige / komplexe Computer-Programme für Registrierung und Kalkulationen) häufig total überfordert. Wir haben diese Erfahrungen bereits bei der REACH-AfA gemacht.

150 – Germany – Small - Manufacture of chemicals and chemical products - Importer

**It is still unclear what is meant by "registration".**

Es ist nach wie vor unklar, was unter "Registrierung" zu verstehen ist.

154 – Germany – Medium – Semiconductor manufacturer

**For co-registrants, the procedure is relatively simple and reliable, provided the LR provides data in the current version of IUCLID. As a rule, SME registrations can only be dealt with by external support. Here, more help would be given, which data gaps under certain circumstances can also be closed by statements, QSAR or expert knowledge. Testing proposals also in the low tonnage range would be useful if ECHA seriously examines the meaningfulness (also in view of the scarce laboratory resources).**

für Co-Registranten ist das Verfahren relativ einfach und zuverlässig, vorausgesetzt der LR stellt Daten in der aktuellen Version von IUCLID zur Verfügung. Eine federführende Registrierung können KMUs idR nur mit externer Unterstützung bearbeiten. Hier würde mehr Hilfestellung, welche Datenlücken unter welchen Umständen auch durch Statements, QSAR oder Expertenwissen geschlossen werden können. Testing Proposals auch im niedrigen Tonnagebereich wären sinnvoll, wenn ECHA die Sinnhaftigkeit ernsthaft prüft (auch angesichts der knappen Laborressourcen).

157 – Germany – Medium – Tobacco products

**Despite the information provided by the IKW, the registration procedure is difficult to understand. We are a small company that does not have the resources for this. Time consumed internally and externally.**

Uns ist das Registrierungsverfahren trotz Informationen hierzu vom IKW schwer verständlich. Wir sind ein kleines Unternehmen, das hierfür nicht die Ressourcen hat. Zeitaufwand intern und extern.

158 – Germany – Medium – Wholesaler of substances and mixtures

**Reach registration / editing should be done by authorities who want to manage the information. This will prevent the exchange of information to the competition.**

159 – Germany – Small - Manufacture of chemicals and chemical products

**This is still too complicated for SMEs. There are not enough professional staff in the companies and it is too expensive to outsource everything!**

Für KMUs ist das immer noch zu kompliziert. Es gibt zu wenig fachlich gutes Personal in den Firmen und es ist zu kostspielig alles auszulagern!

168 – Germany – Medium – Manufacturer of rubber and plastic products

**More active and more concrete cooperation between the authorities in the preparation, preparation and improvement (update work) of the dossiers. Particularly the dossiers submitted by SMEs; There is no scientific expertise or an overview of similarly assessed substances.**

Aktivere und konkretere Mitarbeit der Behörden bei der Vorbereitung, Erstellung und Verbesserung (Update-Arbeit) der Dossiers. Besonders der Dossiers eingereicht von KMUs; dort ist die wissenschaftliche Expertise und der Überblick über ähnlich bewertete Substanzen nicht gegeben.

181 – Germany – Medium - Manufacture of chemicals and chemical products

**Good and easy to handle!**

gut und einfach zu handhaben!

186 – Germany – Small Business - Manufacturer of rubber and plastic products

**Improving transparency: Pre-SIEF / SIEF Communication should be officially facilitated by the ECHA  
LOA costs should be available in advance (binding cost models should be assessed) Lead registrants  
should always be named and assigned to the Reg.No. (including current contact data)**

Verbesserung der Transparenz: pre-SIEF / SIEF Kommunikation sollte offiziell durch die ECHA moderiert werden LOA-Kosten sollten vorab verfügbar sein (verbindliche Kostenmodelle zur Abschätzung wünschenswert) Lead Registranten sollten immer genannt und der Reg. Nr. zugeordnet werden (inkl. aktuellen Kontaktdaten)

190 – Germany – Large – Wholesaler and importer of chemicals

**Improvement / development of alternative test methods (e.g., in vitro, QSAR, etc.). Costs and for  
OECD 421 or 422 (for tonnage 10 - <100 tonnes year according to ANNEX VIII) is much too high, and  
the duration is also problematic. No alternative methods available for OECD 421/422 yet.**

Verbesserung/Weiterentwicklung von alternativen Testmethoden (z.B. in-vitro, QSAR etc.). Kosten und für OECD 421 oder 422 (für Tonnageband 10 - <100 Tonnen Jahr gemäß ANNEX VIII) viel zu hoch, und auch die Zeitdauer ist problematisch. Bis jetzt noch keine alternativen Methoden für OECD 421/422 verfügbar.

204 – Germany – Small business – Wholesale trade

**The whole process is simply an organizational madness.**

Das ganze Verfahren ist schlichtweg ein organisatorischer Wahnsinn.

207 – Germany – Medium - Wholesale trader

**Review: Poor! Much too cumbersome, seems to be an exclusion project of Europe for foreign goods!  
Only good for European large conglomerates!**

Beurteilung: Mangelhaft! Viel zu umständlich, Scheint ein Aussgrenzungsprojekt von Europa fuer auslaendische ware zu sein! Nur gut fuer Europaeische Grosskonzerne!

208 – Germany, USA, Mexico – Small – Plastic and rubber manufacture

**We produce nanomaterials, of which 1 must be registered. The entire process is not designed for  
nanomaterials. There are too many uncertainties if you are not directly involved in the registration  
process. Especially with the establishment of innovative product business these registration fields  
+ SIEF data costs are necessary also if further registrations (with us biocide) are double-loading and  
not purposeful. Especially with the actual own data record. The opt-out option is much too  
neglected, and no consultant from the helpdesks can / will provide a binding answer.**

Wir produzieren Nanomaterialien, davon muss wohl 1 registriert werden. Der komplette Prozess ist nicht auf Nanomaterialien ausgelegt. Es gibt zu große Unsicherheiten, wenn man nicht direkt beim Erstregistrieren dabei ist. Gerade beim Aufbau von innovativem Produktgeschäft sind diese

Registrierungskosten + SIEF-Daten-Kosten wenn auch weitere Registrierungen (bei uns Biozid) nötig sind doppelt belastend und nicht zielführend. Vorallem mit dem eigentlichen eigenem Datensatz. Die Opt-Out option ist viel zu vernachlässigt, und kein Berater auch von den Helpdesks kann/will einem verbindliche Antworten geben.

220 – Germany – Small – Manufacturer of chemical substances

**Procedure is clear and comprehensible, unfortunately, a major problem is the hidden cost by filling necessary data gaps.**

Verfahren ist klar und verständlich, leider ist ein Hauptübel die versteckten Kosten durch notwendige Füllung von Datenlücken.

224 – Austria - Medium – Manufacturer of chemical substances

**The space in this field is not enough. Iuclid and Reach IT are made for employees of large companies who do nothing else. We will withdraw from the project business and will therefore be unable to support innovation from the laboratory to the production process. I'm curious how that looks in 6-8 years with new developments in the EU.**

Der Platz in diesem Feld reicht dazu wirklich nicht aus. Iuclid und Reach IT ist für Mitarbeiter grosser Firmen gemacht, die nichts anderes machen. Wir werden uns aus dem Projektgeschäft zurückziehen und können daher keine Innovation vom Labor in die Produktion mehr begleiten. Bin mal gespannt wie das dann in 6-8 Jahren aussieht mit Neuentwicklungen in der EU.

225 – Germany – Micro –Importer, Manufacturer of chemical substances

**Since completely outsourced, this question can unfortunately not be answered in detail. But without a general simplification of the process, only the outsourcing remains for smaller companies**

Da komplett ausgelagert, kann diese Frage leider nicht detailliert beantwortet werden. Aber ohne generelle Vereinfachung des Prozederes bleibt für kleinere Unternehmen nur die Auslagerung

226 - Germany – Medium - Manufacturer of chemical substances

**SMEs need to do exactly as much as multinationals have a complete department for them. Time and cost intensive!**

KMU Unternehmen müssen genau soviel Aufwand treiben als Multinationals die eine komplette Abteilung dafür haben. Zeit und Kosten intensiv !

228 – Germany – Medium - Manufacturer of chemical substances

**As an SME, you can not do anything yourself because there are no resources for such bureaucracy - apart from the fact that the purpose of REACH has still not been developed! Unfortunately, you are dependent on external consultants.**

Als KMU kann man gar nichts selber unternehmen, da keine Ressourcen für derartige Bürokratie vorhanden sind - abgesehen davon, dass der Sinn von REACH sich immer noch nicht erschlossen hat!!! Leider ist man dafür auf externe Berater angewiesen.

231 – Germany – Micro - Manufacturer of chemical substances

**It is a disaster for my company and a question of existence by what means the Chemielobby and the EU small and medium-sized family enterprises which have successfully produced and sold disinfectants for more than 95 years are pushing out of the market.**

Es,ist eine Katastrophe für meine Firma und eine Existenzfrage mit welchen Mitteln die Chemielobby und die EU kleine und mittlere Familienbetriebe die seit mehr als 95 Jahren mit Erfolg Desinfektionsmittel produziert und verkauft haben aus dem Markt drängen.

233 – Germany, Slovakia – Micro - Manufacturer of chemical substances

Without the help of UMCO consultations, we have problems with regard to the quantities of substances in our products. The recycles were registered with their monomers according to Article 2 (7d) and Articles 31 or 32.

Ohne die Hilfe von Beratungen durch die Firma UMCO haben wir Probleme in Bezug auf die Stoffmengen in unseren Produkten. Die Recyklate wurden mit Ihren Monomeren nach Artikel 2 (7d) und Artikel 31 oder 32 registriert.

236 – Germany – Medium – Plastic recycling

**We have been reading the REACH regulation for 5 years now and have only arrived on page 982. For this reason, it is not yet possible for us to make any constructive suggestions for improvement, which are expected to be submitted by May 31, 2017, due to a lack of knowledge of the REACH registration procedure. Because of the binding of financial and temporal resources, we must understandably adjust our production to this day.**

Wir lesen jetzt seit 5 Jahren die REACH Verordnung und sind erst auf Seite 982 angekommen. Uns ist es aus mangelnder Kenntnis des REACH -Registrierungsverfahrens daher noch nicht möglich konstruktive Verbesserungsvorschläge zu unterbreiten und werden diese voraussichtlich bis zum 31.05.2017 nachreichen. Unser Produktion müssen wir aufgrund der Bindung von finanziellen und zeitlichen Ressourcen bis zu diesem Tag verständlicherweise einstellen.

240 – Germany –Small - Manufacturer of chemical substances

**Due to the enormous administrative and cost costs, we will not register a substance as a distributor. Because of the large number of products that we move under the tonnage range below 100 mt, we would have to invest hugely in human resources and other resources, which is beyond our capabilities. Either our suppliers register from their side or the products will no longer be available after the last stage of the registrations. Since our products are mainly from the Asian region and a large proportion of our suppliers do not have an interest in registering due to the small quantities, it is already clear that most of our pre-registered products will no longer be available after the registration deadline has expired. This will mean that our customers will no longer be able to produce their follow-up products. Unfortunately, the original good idea of "making chemicals safer" has made a costly, bureaucratic giant, which is to be implemented and controlled by an extremely high administrative burden. The economic effects of this regulation have obviously been completely ignored. From today's point of view, it can be assumed that the chemical industry in Europe will cease production or relocate in non-European countries after implementation of REACH - some of this is already happening in our customer base. The handling of chemicals is not made safer by REACH, but more costly and labor-intensive. The benefit of this is more than questionable. SMEs will find it difficult to move into market niches in the future. This will support monopolistic structures in large-scale chemicals, which will have a detrimental effect on the consumer. The makers of REACH should think about this again intensively.**

Aufgrund des gewaltigen Verwaltungs- und Kostenaufwandes werden wir als Distributeur keinen Stoff registrieren. Aufgrund der Vielzahl von Produkten, die wir im Tonnageband unter 100 mt bewegen, müssten wir enorm finanziell in Personal und andere Ressourcen investieren, was unsere Möglichkeiten übersteigt. Entweder unsere Lieferanten registrieren von deren Seite oder die Produkte werden nach der letzten Stufe der Registrierungen nicht mehr verfügbar sein. Da wir unsere Produkte hauptsächlich aus dem asiatischen Raum beziehen und ein großer Teil unserer Vorlieferanten aufgrund der geringen Mengen kein Interesse an einer Registrierung hat, ist bereits jetzt schon abzusehen, dass die meisten von uns vorregistrierten Produkte nach Ablauf der Registrierungspflicht nicht mehr verfügbar sein werden. Dies wird dazu führen, dass unsere Kunden ihre Folgeprodukte nicht mehr herstellen können. Leider hat man aus der ursprünglichen guten Idee "den Umgang mit Chemikalien sicherer zu machen" einen kostspieligen, bürokratischen Giganten gemacht, der durch einen extrem hohen Verwaltungsaufwand umgesetzt und kontrolliert werden soll. Die volkswirtschaftlichen Auswirkungen dieser Regulierung hat man offensichtlich dabei vollkommen ignoriert. Aus heutiger Sicht ist davon auszugehen, dass die chemische Industrie in Europa nach der Umsetzung von REACH Produktionen einstellen bzw. in nichteuropäisches Ausland verlagern wird - z. T. findet dies in unserem Kundenkreis bereits jetzt statt. Der Umgang mit Chemikalien wird durch REACH nicht sicherer sondern kostenintensiver und arbeitsaufwendiger gemacht. Der Nutzen hieraus ist mehr als fragwürdig. KMU's werden es schwer haben sich auch zukünftig in Marktnischen bewegen zu können. Dadurch werden monopolen Strukturen in der Grosschemie unterstützt, die sich nachteilig für den Verbraucher auswirken werden. Hierüber sollten die Macher von REACH nochmals intensiv nachdenken.

243 – Germany – Small - Manufacturer of chemical substances

## **BASIC TRAINING**

FORMACION BASICA

262 – Spain – Large – Drinks Manufacturer

**IUCLID can be much improved**

El programa IUCLID es muy mejorable

263 – Spain – Medium - Manufacture of other non-metallic mineral products

**Facilities to create a registration file.**

Facilidades para crear un expediente de registro.

264 – Spain – Medium - Chemical Manufacturer

**It has improved since 2010.**

Se ha mejorado desde 2010.

266 – Spain – Large - Chemical Manufacturer

**- Simplification of registration for substances between 1-10 tonnes. - Regulatory grouping concerning REACH / CLP in a single regulation.**

**Reduce registration costs. We will be forced to withdraw products from the market with the losses they can cause to the company and the level of employment of the same. Our sector is fertilizers and the value added is very small. They are cosmetics or pharmaceutical products and the volumes that are handled are small.**

Disminuir los costes de registro. Nos veremos obligados a retirar productos del mercado con las pérdidas que pueden ocasionar a la empresa y al nivel de empleo de la misma. Nuestro sector son fertilizantes y el valor añadido es muy pequeño. Son cosméticos o productos farmacéuticos y los volúmenes que se manejan son pequeños.

269 – Spain – Small - Chemical Manufacturer

**Standardize study costs to facilitate data sharing. That ECHA should act as an intermediary in cost negotiations to make it an easier process.**

Estandarizar los costes de los estudios para facilitar el 'data sharing'. Que la ECHA hiciera de intermediario en las negociaciones de costes para que sea un proceso más fácil.

277 – Spain – Medium - Chemical Manufacturer

**It would be interesting that from the moment a guide is published, it is in all the languages of the European Union. Although we understand English, with the mother tongue is everything easier to understand.**

Sería interesante que desde el momento que se publica una guía, esta estuviera en todos los idiomas de la unión europea. Aunque entendamos el ingles, con la lengua materna es todo mas fácil de entender.

280 – Spain – Small – Inorganic chemical manufacture

**Economically assist micro and SMEs**

Ayudar economicamente a las micro y pymes

284 – Spain – Micro – Importer and formulator of chemicals

**It is a process designed and designed by large multinational companies with the main objective of slimming the market and reduce competition, and the secondary objective of improving the protection of health and the environment from the risks involved in the handling of chemicals, Leading to the development of R & D for the substitution of the highest risk substances.**

Es un proceso diseñado y pensado por las grandes empresas multinacionales con el objetivo principal de adelgazar el mercado y disminuir la competencia, y el objetivo secundario de mejorar la protección de la salud y del medioambiente de los riesgos que conlleva la manipulación de los productos químicos, llevando aparejado consigo como consecuencia de todo ello la potenciación del I+D para la sustitución de las sustancias de más alto riesgo.

285 – Spain – Medium – Chemical manufacturer

**Very well explained from the beginning. In my case, as a formulator, I just have to make sure that my suppliers comply with REACH**

Muy bien explicado desde el principio. En mi caso, como formador, solo debo asegurarme que mis proveedores cumplen con REACH

293 – Spain – Micro – Textile Manufacturer

**Translation to Spanish and FREE training courses**

Traducción a Español y cursos formativos GRATUITOS

298 – Spain – Small – Beverage manufacturer

**The process is expensive and costs, it requires companies and especially SMEs to invest a lot of resources.**

El proceso es caro y costos, requiere que las empresas y sobre todo las Pymes inviertan muchos recursos.

300 – Spain – Medium Chemicals manufacturer

**It is very complicated everything related to it and it is not very clear, you have to be a consultant or specialist to be able to do it correctly.**

Es muy complicado todo lo relacionado con ello y no está muy claro, tienes que ser un consultor o especialista para poderlo hacer de forma correcta.

305 – Spain – Medium – Domestic products

**VERY DIFFICULT. INABORDABLE FOR COMPANIES LIKE OURS, NOT IN THE CHEMICAL SECTOR**

MUY DIFICIL. INABORDABLE PARA EMPRESAS COMO LA NUESTRA, AJENA AL SECTOR QUÍMICO

314 – Spain – Medium – Metal products manufacturer

**The legislative idea and the objectives are very interesting and favorable, but the means to apply them seems costly, complex and not intuitive. Customers are not willing to pay an extra cost, which impacts us negatively. There is a lot of general ignorance. The manuals are not clear, simple and fast. The consultations are very expensive. Information is needed in local languages with telephone support or remote connections that solve problems as reliability and not just computer programs. The fines are exorbitant for legislation that varies so much and for which there is so much ignorance. The training videos are very clear. To solve it, consultants with remote connections are needed and the cloud idea is good too, but if it does not work, it is still more complex. Hope this questionnaire serves to have more help. Thanks for the attention, a greeting**

La idea legislativa y los objetivos son muy interesantes y favorables, pero los medios para aplicarlos nos parece costos, complejo y nada intuitivo. Los clientes no están dispuestos a pagar un coste extra, lo que nos repercute negativamente. Hay mucho desconocimiento general. Los manuales no son claros, sencillos y rápidos. Las consultorías son muy costosas. Se necesita información en idiomas locales con asistencia telefónica o por medio de conexiones remotas que solucionene lso problemas dado fiabilidad y no sólo programs informaticos. Las multas son desorbitadas para una legislación que varia tanto y de la cual hay tanto desconocimiento. Los vídeos formativos nos son muy claros. Para solventarlo se precisan asesores con conexiones remotas y la idea de cloud también es buena, pero si no funciona todavía es más compleja. Espera que este cuestionario sirva para poder tener más ayudas. gracias por la atención, un saludo

325 – Spain – Small Company – Chemical manufacturer

**I find it very complicated**

Lo veo muy complicado

343 – Spain – Medium – Metal products manufacturer

**Materials are often not translated into the national language. Text in English is hard to understand available, long and often legal - need a very good knowledge of the language. State aid is minimal (only base line), national-training does not. Smaller companies cannot afford to go very in expensive English language courses.**

Materjale tihti ei tõlgita rahvuskeelde. Inglise keelsed tekstid on raskelt aru saadavad, pikad ja tihti juriidilised - vajavad väga head keele tundmist. Riigi poolne abi on minimaalne (ainult tugiliin), rahvuskeelseid koolitusi ei ole. Väiksematele firmadele ei ole taskukohane käia väga kallitel inglise keelsetel koolitustel.

347 – Estonia – Medium - Distributor of chemical substances or mixtures

**I do not know whether it is necessary for us**

Ei oska öelda, kas see on meile vajalik

349 – Estonia – Micro – Wholesale trade

**Our subsidiary has been involved in REACH registration process and we gained experience. Costs were significant even though there were a lot of companies involved in the registration. The project consisted of a consultant who eventually made the registration itself. In the case of complex substances, registration becomes challenging and a small company does not have enough resources, especially when we do not really function in the chemical industry. The limit of 1 tonne is really low and undoubtedly makes it difficult for a small company operating in many chemical industries.**

Tytäryhtiömme on ollut mukana REACH-rekisteröintiprosessissa ja siitä saimme kokemusta. Kustannukset olivat merkittäviä, vaikka kyseisessä rekisteröinnissä oli paljon yrityksiä mukana. Projektissa oli konsultti, joka lopulta teki myös itse rekisteröinnin. Kun on kyse monimutkaisista aineista, rekisteröinnistä tulee haastavaa ja pienellä yrityksellä ei ole tarpeeksi resursseja, etenkin, kun emme toimi varsinaisesti kemianteollisuudessa. 1 tonnin raja on todella matala ja vaikeuttaa varmasti monen kemianteollisuudessa toimivan pienyrityksen toimintaa.

361 – Finland – Medium – Wholesaler and manufacturer of chemical substances

**Almost overwhelmingly bureaucratic and difficult to perceive.**

Lähes ylivoimaisen byrokraattinen ja vaikeasti hahmotettava.

362 – Finland – Small – Manufacturer of machinery

**Service in Finnish**

Palvelua suomen kielellä

363 - Finland, Sweden, Estonia - Small - Manufacture of ferroalloys

**The procedure is complicated and expensive. If someone else has already registered our own, we should have a "tick box" procedure to easily, quickly and cost-effectively track our records.**

Menettely on monimutkainen ja kallis. Jos joku muu on jo rekisteröinyt oman aineemme, pitäisi olla "rasti ruutuun" -menettely, jolla oma rekisteröintimme hoituisi helposti, nopeasti ja kustannustehokkaasti.

365 – Finland - Large - Manufacture of metal products

**As a final user of the substance, it is very difficult to assess the risk of non-registration (and hence obsolescence) of the substances used by our suppliers. The risk is still poorly understood today. No information was provided by our suppliers.**

En tant qu'utilisateur final de substance, il est très difficile d'évaluer le risque de non enregistrement (et donc d'obsolescence) des substances utilisées par nos fournisseurs. Le risque est encore aujourd'hui mal connu. Aucune information n'a été communiqué de la part de nos fournisseurs.

368 – Finland – Large company – Manufacturing

**The registration process is simple and IT tools are easy to use. \*\*\* Production is facing two difficulties: - The cost of LOA is not under control (between 0 and 15K€ for an intermediate registration) - The implementation of strictly controlled conditions requires a lot of investments for low tonnage intermediates.**

370 – France – Large - Plastics manufacturer

**Difficulties in identifying our substances to be recorded. Indeed, we only proceed with a physical operation and not with a chemical transformation of the waste that we receive. We therefore believe that the substances we have have been pre-registered by our suppliers but continue to check in spite of the lack of collaboration of our suppliers because they provide us with waste that does not fall within the scope of the REACH regulation. What to do in this case?**

Des difficultés à identifier nos substances à enregistrer. En effet, nous ne procédons qu'à une opération physique et non à une transformation chimique des déchets que nous recevons. Nous pensons donc que les substances que nous avons ont été enregistré au préalable par nos fournisseurs mais continuons de vérifier malgré le manque de collaboration de nos fournisseurs car ces derniers nous fournissent des déchets qui n'entrent pas dans le cadre du règlement REACH. Que faire dans ce cas?

385 – France – Micro – Consumer products manufacturer

**The response time of the INERIS Helpdesk by mail is a little too long. For example, I am still waiting for the answer of a question asked on 31 March.**

Le délai de réponse du Helpdesk de l'INERIS par mail est un peu trop long. A titre d'exemple, j'attends toujours la réponse d'une question posée le 31 mars dernier.

441 – France – Small – Manufacture of oils and fats

**An online registration would be much preferable. The IUCLID software is too complicated to install.**

Un enregistrement en ligne serait largement préférable. Le logiciel IUCLID est trop compliqué à installer.

441 – France – Medium – Chemicals manufacturer

It is a domain of hyperspecialises that in a general regulatory environment of safety and environment can only be entrusted to consultants for medium-sized companies (too complicated to maintain such a specialty for the registration of a few substances). It is not normal for a year of the deadline to be yet to be interpreted of the opinions and guides in English, whereas legally it is already not obvious to grasp all the senses in its own language (for example on The concept of article).

C'est un domaine d'hyperspécialises qui dans un contexte général réglementaire de sécurité et d'environnement ne peut être confié qu'à des consultants pour des entreprises de tailles moyennes (trop compliqué d'entretenir une telle spécialité pour l'enregistrement de quelques substances). Il n'est pas normal à un an de l'échéance d'être encore à interpréter des avis et guides en Anglais alors que juridiquement il n'est déjà pas évident d'en saisir tous les sens dans sa propres langue (par exemple sur la notion d'article).

446 – France – Medium – Chemicals industry

**Review the principle of SIEF implementation**

Revoir le principe de mise en œuvre des SIEF

448 – France - Large - Chemicals manufacturer

**It is a complicated, time-consuming process, expensive and unsuitable for small businesses.**

C'est un processus compliqué, long, cher et peu adapté à de petites entreprises.

461 – France – Medium – Wholesale trade of chemicals

**This questionnaire does not answer our activity as wholesaler distributor of pharmaceutical products for pharmacies**

Ce questionnaire ne répond pas à notre activité de grossiste répartiteur de produits pharmaceutiques pour pharmacies

478 – Belgium – Medium – Wholesale distributor of pharmaceutical products

**We have responded to a pre-registration questionnaire, but then we had no feedback or help or information on the subject outside our professional federation**

Nous avons répondu à un questionnaire de préenregistrement depuis nous n'avons eu aucun retour ni aide ni informations sur le sujet hors par notre fédération professionnelle

485 – France - Medium – Electricals manufacturer

**Have information about the REACH registration process clearer, and understandable.**

Avoir des informations sur le processus d'enregistrement au titre de REACH plus claires, et compréhensible.

504- France – Small – Metals manufacturer

**Stop changing IUCLID version without stopping, stop adding an intermediate file to attachment while most of the info is in the folder IUCLID (redundant)**

arrêter de changer de version IUCLID sans arrêt, arrêter d'ajouter un dossier intermédiaire en pièce jointe alors que la plupart des infos est dans le dossier IUCLID (redundant)

509 – France – Medium – Chemicals manufacturer

**It would require clear and concise instruction because at the moment we find only small pieces of information in many different places**

Il faudrait une instruction claire et concise, car pour l'instant on ne trouve que des petites parties d'information dans plein d'endroit différents

510 – France – Small – Wholesale trade of chemicals

**Surely very good for the environment and knowledge of products but very expensive and time consuming; Why do analyzes that may have already been done by other countries like USA and Canada; Why pay the same analyzes several times when buying a LoA; Some companies do business even if it is not in the status; Some LoA prices are very expensive; Recording a molecule is even more so;**

Surement très bien pour l'environnement et la connaissance des produits mais très onéreux et demande beaucoup de temps; Pourquoi refaire des analyses qui ont peut être été déjà faite pas d'autres pays comme USA et Canada; Pourquoi payer plusieurs fois les mêmes analyses lors de l'achat d'un LoA; certaines sociétés font du business même si ce n'est pas dans les status; Certain prix de LoA sont très cher; Enregistrer une molécule l'est encore plus;

515 – France – Medium – Chemicals manufacturer

**Long & complicated implementation for small structures. No or little support (especially DOM). Knowledge level in chemistry indispensable or rare in SMEs.**

Mise en oeuvre longue & compliquée pour les petites structures. Pas ou peu d'accompagnement (surtout DOM). Niveau de connaissances en chimie indispensable or rare en PME.

517 – France, Reunion - Plastics manufacturer

**The formulators have few means to demonstrate the safe use of their mixtures. The LCID approach is very good but inapplicable on 6000 products. The Bottom-Up approach is still somewhat theoretical and there is little practical training to apply it to mixtures. Plus, many empty data from suppliers, inconsistencies in classification, ... the purpose of SME formulators is to anticipate not to have to register and pay.**

Les formulateurs ont peu de moyens pour démontrer l'utilisation sûre de leurs mélanges. La démarche LCID est très bien mais inapplicable sur 6000 produits. La démarche Bottom-Up est encore un peu théorique et il y a peu de formation pratique pour l'appliquer aux mélanges. Plus, de nombreuses données vides chez les fournisseurs, des incohérences de classification, ... le but des PME formulatrices est d'anticiper pour de ne pas avoir à enregistrer et payer.

526 – France – Small - Manufacture of paints, varnishes and sealants

To the extent that we use very small quantities as end-user, I do not think we are subject, but our knowledge of REACH needs improvement

Dans la mesure où nous utilisons de très faibles quantités en tant qu'utilisateur final, je ne pense pas que nous soyons soumis, mais notre connaissance de REACH est à améliorer

530 – France – Small – Veterinary activities

**When the materials are paints - even non-toxic - made from polymers manufactured outside EU., going back to the sources of these polymers was "mission impossible" hence the shutdown of the corresponding business.**

Quand les matériaux sont des peintures -même non toxiques- fabriquées à base de polymères fabriqués hors U.E., remonter aux sources de ces polymères était "mission impossible" d'où l'arrêt du business correspondant.

547 – France – Micro – Wholesale of chemicals

**I think Reach is fictional to feed a useless bureaucracy that tunes into multinational corporations.**

smatram da je Reach izmišljen da se nahrani beskorisna birokracija koja ugađa multinacionalnim korporacijama .fuj.....

574 – Croatia – Micro – Manufacture of chemicals

**It should be simpler, clearer and more transparent.**

Egyszerűbb, egyértelműbb és átláthatóbb folyamat kellene.

584 – Hungary – Small – Chemical manufacturer

**The Bank, importing raw gold for sale to goldsmith companies, has decided to suspend the service pending further details on the REACH-IT system**

La Banca, importando oro grezzo per la vendita alle aziende orafe, ha deciso di sospendere il servizio in attesa di approfondimenti in merito al sistema REACH-IT

596 – Italy – Large – Metal importer

**The company imports gold to supply goldsmiths but currently we are evaluating whether to cease the activity**

L'AZIENDA IMPORTA ORO PER FORNITURA A IMPRESE ORAFE ED E' IN CORSO LA VALUTAZIONE PER LA DISMISSIONE DEL SERVIZIO

597 – Italy – Large – Metal importer

**I cannot express my opinion because for SIEF management operations, dossier preparation and registration we have always supported specialist consulting companies**

Non posso esprimere parere perchè per le operazioni di gestione dei SIEF, preparazione dossier e registrazione ci siamo sempre appoggiati a società di consulenza specializzate

601 – Italy – Large - Pharmaceutical manufacturer

**Improve the understandability of the REACH-IT portal**

Migliorare la comprensibilità del portale REACH-IT

606 – Italy – Small – Chemicals Manufacturer

**Facilitate mechanisms for reducing the costs of substance dossiers**

609 – Italy – Medium – Chemicals manufacturer

**A much simpler, more accessible and quick tool.**

Uno strumento molto più semplice, accessibile e rapido.

610 – Italy – Small – Chemicals manufacturer

**We used an external consultant for the entire registration, so we are not in a position to give you any guidance.**

Ci siamo avvalsi di un consulente esterno per tutta la registrazione, quindi non siamo in gradi di darVi delle indicazioni.

611 – Italy – Small – Wholesale of Chemicals

**We do not have enough information regarding the registration process. As a result, we do not know how to answer this question.**

Non abbiamo abbastanza informazioni per quanto riguarda la procedura di registrazione. Di conseguenza non sappiamo rispondere a questa domanda.

613 – Italy – Medium - Wholesale of chemicals

**We believe that the REACH regulation, as and how it was thought, did not have the slightest consideration of the business fabric of small and medium businesses. Where the overall objectives can be shared, at operational level, and in this case in the economic costs and in the complexity of the practical registration process, the entire process is far too expensive for small businesses operating below 10 tonnes and Brings with it the survival of the company.**

Riteniamo che il regolamento REACH, tale e come è stato pensato, non abbia minimamente tenuto in considerazione il tessuto aziendale delle piccole e medie aziende. Laddove gli obiettivi possano nel loro complesso essere condivisibili, a livello operativo, e nella fattispecie nei costi economici e nella complessità dell'iter pratico di registrazione, l'intero processo è assolutamente troppo dispendioso per piccole aziende che operano al di sotto delle 10 tonnellate e porta con sé la sopravvivenza dell'azienda.

615 – Italy – Small – Manufacture of chemicals

**Procedures, constraints, and complexity do not allow Reach recording autonomously. The management of consortia and Sief can not be done by a small and medium company. All REACH construction is based on little chemicals for a company (focused on 5 to 10 products) Small and medium sized companies that manage (manufacture and import) more than 100 chemicals can not support Reach both as a skill and as a finance. The cost of a LoA of 10-15 k € is sometimes 6-8 years of net margin per 1000kg of production.**

Procedura, vincoli e complessità non permettono la registrazione Reach in modo autonomo. La gestione di consorzi e Sief non può essere fatta da una piccola e media azienda. Tutta la costruzione Reach si basa su poco chemicals per azienda (reach focalizzato su 5-10 prodotti) piccole e medie aziende che gestiscono (produzione ed importazione) più di 100 chemicals non possono sostenere il Reach sia come competenze che come finanze. Il costo di una LoA di 10-15 k€ a volte corrisponde a 6-8 anni di margine netto su 1000kg di produzione.

617 – Italy – Small – Manufacture of chemical additives

**Too expensive and complex. Reduce costs and limit the required tests.**

Troppo onerosa e complessa. Ridurre i costi e limitare i test richiesti.

626 – Italy – Small – Chemical Manufacturer

**To improve data retrieval from the submitted dossier to repopulate the IUCLID.**

Da migliorare il recupero dati dal dossier inviato per ripopolare lo IUCLID.

627 – Italy – Medium – Importer and trader of chemicals

**The registration costs of many substances are not absolutely compatible with the margins allowed by the market, often Reach costs are several times the revenue related to the product ...**

I costi di registrazione di molte sostanze non sono assolutamente compatibili con le marginalità permesse dal mercato, spesso il costo Reach è diverse volte il fatturato collegato al prodotto...

629 – Italy – Medium – Chemicals manufacturer

**Totally inefficient, everything should be changed and made accessible to micro enterprises**

Totalmente inefficiente, bisognerebbe cambiare tutto e renderla accessibile alle micro imprese

633 – Italy – Micro – Wholesale of chemicals

**It might be useful to implement dossier verification functions before sending**

potrebbe essere utile implementare le funzioni di verifica del dossier prima dell'invio

647 – Italy – Small – Manufacture of coke and refinement of petroleum

**Join Submission often receives emails about Dossier updates without knowing where it has been updated, at least the points where it has occurred, because they often only know the Lead and are no up-to-date updates for other participants. This is to avoid unnecessary requests to the Lead or Secretariats.**

Facendo parte di Join Submission spesso si ricevono mail relative ad aggiornamenti del Dossier senza però sapere ove sia stato aggiornato, almeno i punti ove si è intervenuti, anche perché spesso lo sa solo il Lead e sono aggiornamenti non fondamentali per gli altri partecipanti. Questo per evitare richieste inutili al Lead o alle segreterie.

654 – Italy – Small - Chemical manufacturer

**We necessary in constant contact with the consultant explanations, training**

Mums nepieciešām pastāvīgs kontakts ar konsultantu skaidrojumiem, apmācības

664 – Latvia – Small – Chemical manufacturer

**It was very difficult to make a registration, because everything is in English, and a lot of information for which there is no understanding**

Ļoti grūti bija veikt pirms reģistrāciju, jo viss ir angļu valodā un ļoti daudz informācijas par kuru nav izpratnes

666 – Latvia – Micro – Chemical vendors

**We are no longer our own borders chemical substances**

M'ghadniex nimpurtaw sustanzi kimici

667 – Malta – Micro – Wholesale of household goods

**Reach is a major barrier for (smaller) importers of commodities to continue business or develop new ones.**

Reach is voor (kleinere) importeurs van grondstoffen een zeer grote barriere om zaken voort te zetten, danwel nieuwe te ontwikkelen.

672 – Netherlands – Small - Wholesale of chemicals

**Excessively complex. Frequently, data is requested that is publicly available for decades (Merck Index, Handbook of Chemistry and Physics, etc., etc.). Some SIEFs are not cost-transparent and opt-out capabilities are limited. An even bigger problem is that the costs have an end-to-end structure which will allow further research questions to expire after 2018 without being clear when the end is in sight. This is reinforced by the precautionary principle that calls for further investigation of potential risks of substances. In addition, it is absolutely unclear to what extent REACH will contribute to greater public health and cleaner environment. The replacement strategy, implicit in REACH, may trigger new chemical hazards that may lead to new precautions. For now, REACH does not seem to be an unnecessary cost item.**

Overmatig complex. Veelal wordt om data gevraagd die al decennia lang openbaar beschikbaar is (Merck Index, Handbook of Chemistry and Physics, enz. enz.). Een aantal SIEFs zijn niet kostentransparant en opt-out mogelijkheden zijn beperkt. Een nog groter probleem is dat de kosten een op-einde structuur hebben waardoor bij nieuwe onderzoeksvragen kosten na 2018 verder op kunnen lopen zonder dat duidelijk is wanneer het einde in zicht is. Dit wordt versterkt door het vigerende voorzorgbeginsel dat bij potentiële risico's van stoffen verder onderzoek kan oproepen. Daarnaast is het volstrekt onduidelijk in hoeverre REACH zal gaan bijdragen aan een grotere volksgezondheid en schoner milieu. De vervangingsstrategie, impliciet in REACH, kan nieuwe chemische risico's oproepen die vervolgens tot nieuwe voorzorgsmaatregelen kunnen leiden. Vooralsnog lijkt REACH niet meer dan een onnodige kostenpost.

675 – Netherlands – Large – Wholesale of consumer goods

**The process is inefficient, an Excel tool that can be linked to the registration system could facilitate this**

Het proces is inefficiënt, een Excel tool welke gekoppeld kan worden aan het registratiesysteem zou dit kunnen vergemakkelijken

676 – Austria, Belgium, Finland, Italy, Luxembourg, Netherlands, Spain – Large - Wholesale of consumer goods

**All information in Dutch**

Alle informatie in het Nederlands

681 – Netherlands, Switzerland – Medium - Wholesale and import of polymers

**Distributor who lets his suppliers register does not have a notion of this, I think so.**

Distributeur die z'n leveranciers laat registreren heeft hier geen notie van, denk ik zo.

685 – Netherlands – Small – Wholesale of chemicals

**The process can be made clearer by improving information on the internet. The government could also better inform the companies**

Het proces kan duidelijker worden gemaakt door verbetering van de informatie op internet. Ook zou de overheid de bedrijven beter kunnen informeren

687 – Netherlands - Small business – Chemical manufacturer

**Lower cost, much more extensive read-access capability Simple requirements in terms of reach legislation Postponement of end date from May 2018 to 2025 Maximization of LOA prices etc. etc.**

Lagere kosten Veel uitgebreidere mogelijkheid van read-across Eenvoudigere eisen zijdens de reach wetgeving Uitstel van de einddatum van mei 2018 naar 2025 Maximalisering van de prijzen van de LOA etc. etc.

689 – Netherlands – Medium - Wholesale of chemicals

**To clarify which substances to be registered and where to buy with a LOA**

Het nog duidelijker maken welke stoffen geregistreerd moeten worden en waar met een LOA kan kopen

692 – Small – Netherlands - Chemicals manufacturer

**The REACH registration did not advance the competitiveness position. All costs that must be incurred for this registration are borne by the companies themselves, this share may be substantial. The objective of safety has not been achieved in practice.**

De concurrentie positie is door de REACH registratie niet op vooruit gegaan. Alle kosten die gemaakt moeten worden voor deze registratie worden door de bedrijven zelf gedragen, dit aandeel kan aanzienlijk zijn. De beoogde veiligheid is er in de praktijk niet op vooruit gegaan.

693 - Medium – Netherlands - Pharmaceuticals manufacturer

**A major commercial practice where SMEs suffer, especially for products registered by more than 500 companies**

een grote commerciële oefening, waar MKB dupe van is, met name voor producten die door meer dan 500 bedrijven gepre-registreerd zijn

705 – Netherlands – Micro – Distributor of chemicals

**No experience with the REACH registration process because no registrations need to be done.**

Geen ervaring met het REACH registratieproces omdat er geen registraties hoeven te worden gedaan.

706 – Netherlands – Large – Chemical manufacturer

**The REACH registration process is absolutely unworkable for SMEs. The decision to register a substance must be based on costs that are only partially known (for example, placing on a SVHC list, etc. may cost more than doubling). This combined with the fact that REACH does not know the dynamics of the market, ie through competition etc. I can also lose my market for a substance after registration, REACH makes a casino model. The SME needs to gamble, instead of taking a well-considered business-economic decision. The only workable alternative is to introduce a lumpsum per volume bandwidth so that an SME company knows what the exact cost of a registration is. Only then can a SME make a decent business decision. That is one, we are not talking about Objective Two: European business is becoming more competitive by REACH. Yes? If there are fewer suppliers per fabric, the price for that fabric is guaranteed up in Europe, but not in the rest of the world. So far no one has been able to explain how this strengthens the competitiveness of European business. But enough sour, no one has listened to this criticism for 10 years now.**

Het REACH-registratieproces is absoluut onwerkbaar voor het MKB. De beslissing om een stof te registreren moet je baseren op kosten die slechts deels bekend zijn (immers bij het plaatsen op een SVHC-lijst e.d. kunnen de kosten meer dan verdubbelen). Dit gecombineerd met het feit dat REACH de dynamiek van de markt niet kent, m.a.w. door concurrentie etc. kan ik ook na registratie mijn markt voor een stof kwijtraken, maakt REACH een casinomodel. De MKB'er moet gokken, ipv dat hij een weloverwogen bedrijfseconomische beslissing kan nemen. Het enige werkbare alternatief is het introduceren van een lumpsum per volume bandbreedte zodat een MKB bedrijf weet wat de exacte

kosten van een registratie zijn. Pas dan kan een MKB'er een fatsoenlijke bedrijfseconomische beslissing maken. Dat is één, dan hebben we het nog niet over doelstelling twee: het Europese bedrijfsleven wordt meer concurrerend door REACH. Ja?, als er minder leveranciers per stof zijn gaat de prijs voor die stof gegarandeerd omhoog in Europa, maar niet in de rest van de wereld. Tot nu toe heeft niemand mij uit kunnen leggen, hoe dit de concurrentiekracht van het Europese bedrijfsleven versterkt. Maar genoeg gezeurd, er luistert al 10 jaar niemand naar deze kritiek.

708 – Netherlands – Small business – Importer and wholesaler of chemicals

**Overall unclear, you do not know what when and why something should be registered.**

Totaal onoverzichtelijk, men weet niet wat wanneer hoe en waarom iets geregistreerd moet worden.

709 – Netherlands – Medium – Wholesale of consumer goods

**Gibberish for the ordinary man**

Ronduit belabberd voor de gewone man

710 – Netherlands – Micro – Pest control manufacturer

**The procedure for asking questions and / or disagreements is cumbersome and it takes too long to get answers. Also, the asker is sent back and forth between ECHA and the national government (REACH agency at the RIVM).**

Ik heb geen idee wat IUCLID is, hoe je er aan komt, laat staan hoe te gebruiken of waar het voor dient. Ik weet wel dat REACH heel veel geld heeft gekost, dat er met het geld een gigantische organisatie is opgezet maar het volledig onbegrijpelijk is en dat er stompzinige enquêtes worden zoals deze. Wat is deze enquête verschrikkelijk slecht opgezet. Te droevig voor woorden.

712 – Netherlands – Micro – Other

**I do not know what IUCLID is, how you get it, let alone how to use it or what it serves. I know REACH has cost a lot of money, that a huge organization has been set up with the money, but it is completely incomprehensible and that there are stupid surveys like this. What was this survey terribly badly set up? Too sad for words.**

Ik heb geen idee wat IUCLID is, hoe je er aan komt, laat staan hoe te gebruiken of waar het voor dient. Ik weet wel dat REACH heel veel geld heeft gekost, dat er met het geld een gigantische organisatie is opgezet maar het volledig onbegrijpelijk is en dat er stompzinige enquêtes worden zoals deze. Wat is deze enquête verschrikkelijk slecht opgezet. Te droevig voor woorden.

713 – Netherlands – medium – wholesale of chemicals

**The language barrier of documents should be available in Polish**

bariera językowa dokumentów powinny być dostępne w języku Polskim

717 – Poland – Small - Crop protection products

**Complete lack of information for small businesses and astronomical costs**

Kompletny brak informacji dla małych firm i astronomiczne koszty

720 – Poland – Micro – Wholesale of chemicals

**Drastically reduce or eliminate the cost of registration. The registration system prefers only big companies and will destroy and eliminate micro and small businesses from the market.**

Drastycznie zredukować lub całkowicie wyeliminować koszty rejestracji. System rejestracji preferuje wyłącznie wielkie koncerny i zniszczy oraz wyeliminuje z rynku mikro i małe przedsiębiorstwa.

724 – Poland – Small – Wholesale of raw materials

**Lack of information**

Brak informacji

727 – Poland – Large – Chemical Manufacturer

**The full registration process is done by our suppliers**

Procesu rejestracji pełnej dokonują nasi dostawcy

740 – Poland – Medium – Wholesale and import of chemicals

**REDUCE THE DESCRIPTION OF THE PRODUCT DESCRIPTION !!!!!!!!!!!!!!!!!!!!!!!**

OBNIŻCIE CENĘ OPISU PRODUKTU !!!!!!!!!!!!!!!!!!!!!!!

741 – Poland – Medium - Packing of charcoal

**At this time, we have been waiting for more than a year to clarify LEAD registrant about sharing cost and LOI, so we are afraid that the lack of information will delay the registration process.**

Neste momento, estamos há mais de um ano a aguardar esclarecimentos do LEAD registrant sobre os sharing cost e LOI, pelo que estamos receosos que a falta de informação nos atrase o processo de registo.

746 – Portugal – Small – Chemical manufacturer

**Focus more on technical training at IT level by carrying out official (ECHA) training in Member States because it is not easy for SMEs to have the money and human resources to send staff abroad to have much needed training in IUCLID, Which is always being updated in new versions that are not always compatible with each other. It is not easy to keep up to date or prepared.**

Apostar mais na formação técnica a nível de IT, levando a cabo formações oficiais (da ECHA) nos Estados Membros, porque para as PME não é fácil dispôr de verba e recursos humanos para enviar pessoal para o estrangeiro para ter formação tão necessária em IUCLID, o qual está sempre a ser atualizado em novas versões que nem sempre são compatíveis entre si. Não é fácil mantermo-nos atualizados, nem preparados.

747 – Portugal - Medium – Chemical manufacturer

**Make it cheaper**

Torná-lo mais barato

772 – Portugal – Micro – Chemical distributor

**It's a complicated process of noticing your guiding line. We are trying to make the process without resorting to the help of consulting companies that were born around this regulation since the consultancy in this area is expensive. The fear of making a mistake in a submission is high since from what we perceive we will not have many chances of making a mistake without cost. The local authorities provide very limited support. It is a time consuming process and has human and financial resources.**

É um processo complicado de perceber a sua linha condutora. Estamos a tentar fazer o processo sem recorrer à ajuda de empresas consultoras que nasceram à volta deste regulamento uma vez que a consultoria nesta área é cara. O receio de errar numa submissão é elevado uma vez que pelo que se percebe não teremos muitas hipóteses de errar sem acarretar com custos. As autoridades locais prestam apoio muito limitado. É um processo consumidor de muito tempo e recursos humanos e financeiros.

770 – Portugal – Micro – Chemical manufacturer

**It's not necessary**

Nu este cazul

781 – Romania - Small - Manufacture of non metallic mineral products

**We do not consider it useful to compare the properties of our substance and the reference substance. We do not understand the usefulness of this comparison.**

Nu consideram util sa facem comparatie intre proprietatile substantei noastre si ale substantei de referinta. Nu intelegem utilitatea acestei comparatii.

784 – Romania - Small – Chemical manufacturer

**I cannot judge, the process is still waiting for us**

neviem posúdiť, proces nás ešte len čaká

789 – Slovakia – Micro – Chemical manufacturer

**We are not aware of.**

Nismo seznanjeni.

792 – Slovenia – Small – Manufacture of metal products

**It would be necessary to make clear instructions and an overview of the company liable.**

Potrebno bi bilo narediti jasna navodila in pregled katere firme so zavezanci.

795 – Slovenia – Small - Plastic manufacturer

**background materials should be publicly available,**

dosjeji snoveh bi morali biti javno dostopni,

797 – Slovenia – Micro – Sale of ores, fuels, metals and chemicals

**hat IUCLID was web-based and as easy to use as REACH-IT.**

Att IUCLID var webbaserat och lika enkelt att använda som REACH-IT.

801 - France, Sweden, Netherlands, USA – Medium – Chemical manufacturer

**To get access to the "Lead registrants" dossier, it costs far too much per tonne imported so we can even consider the case. Would take about 6 years to get profitability again. In addition, we think that the chemical concept throughout the REACH Regulation is far too wide and that minerals should not be regarded as chemicals but are exempted in their entirety.**

För att ta del av "Lead registrants" dossier kostar det alldeles för mycket per importerat ton för att vi ens ska överväga saken. Skulle ta ca 6 år att få lönsamhet igen. Dessutom tycker vi att kemikaliebegreppet i hela REACH förordningen är alldeles för brett och att mineraler inte borde betraktas som kemikalier utan undantas i sin helhet.

808 – Sweden – Small - Manufacture of other non-metallic mineral products

**It should not cost money**

Det ska inte kosta pengar

814 – Sweden – Small - Metal trader

## A3.2 Additional Comments Received by Email

(...) Below are some of the points / criticism's raised:

> Cost of Registration

- a.) It is a very costly process for an SME
- b.) It is difficult to quantify the costs of registration as it fluctuates from Consortium to Consortium
- c.) Consultants are charging high fees
- d.) It is unclear how the funds are to be re-allocated if there is a larger number of registrants

> Clarity

- a.) Costs are not uniform or clear
- b.) Difficult to work out which products require registration
- c.) Difficult to know which elements per product require registration

> Burden of Costs

We find customers unwilling to share the burden

We find it strange that by providing a service to the industry we are having to pay tens of thousands of Euro for the service we provide.

> Confidentiality

An importer does not wish to disclose his sources of materials to co-registrant who are often competitors;

As the software is unfamiliar it is difficult to get guidance how much confidentiality can be preserved

> Technical barriers

Having briefly skimmed through several registration pages and guides for registering, one is easily put off by the jargon and systems used for registering.

It is unclear why there needs to be a different consortium/SIEF per product.

The lack of uniformity is a tremendous barrier in an age where software is designed for single entry ...

>We have spoken to contemporaries in different industries who are holding back from supplying to Europe or definitely will hold back in 2018 as they have no clarity on the regulations.

This means that come 2018, the European market place will be significantly undersupplied, with less competition and resulting higher prices.

This could be what the EU wishes, but lower supply usually equals higher prices. (...)

### **United Kingdom – Small – Distributor of metals and minerals**

I wanted to mention that a lot of companies in Poland produce charcoal or import and are not registered in ECHA. Is there an institution that can force companies to register or stop production in such a company?

### **Poland –Small – Manufacturer of charcoal**

(...) Formerly I worked as General Manager for a Manganese Sulphate Manufacturer (...) in China and one of my tasks was to try to apply for Reach on behalf of our Company. That process was incredibly

difficult for a Chinese Manufacturer and costs were way above what we could afford and totally out of line if you were really an SME the S in SME meaning small. Everything would be just fine if you were a huge multinational with an army of people there to answer endless questions but we were not. We were a small business and I was the only person capable of handling endless bureaucracy. In the end we never managed to succeed with REACH, money was part of that problem, and finally we went out of business (...)

#### **China – Small - Manufacturer**

(...) I hereby wish to inform you that our company has decided not to complete any REACH registration as a result of pre-registrations in activities. We will overthrow this process because of costs that are not commercially justified. We will therefore only acquire REACH registered companies for the products we are interested in (...)

#### **Italy – Small – Distributor**

(...) At the time we pre-registered a series of products with some difficulty due to the complexity of the regulation and the fact that it is in English. For this, it was hired a person who was dedicated to this subject exclusively. We would now need to be able to hire the help of a person or company that would dominate the registration process and guide us through every step that is needed (...)

#### **Spain – Micro – Manufacturer**

(...) Would it be possible to get in touch with "someone who counts" in order to discuss the situation of the SMEs that are heavily penalized by the regulation in comparison to large companies? (...)

#### **Italy – Small – Importer**

(...) We only imported 2 container loads of (...) that is last year and the previous. It was HELL trying to import this chemical with our local authorities. We had to pay hefty sums of money as it would not be released by customs as we needed this and that, whoever we had to speak to was never at the office. To this affect we think we will not go through this again as it is impossible to works in this way. Unfortunately! (...)

#### **Malta – Small – Downstream user (and importer)**

(...) We had the opportunity a few years ago, in contracts for the equipment (...), to buy in Europe and export chemicals subject to registration under the REACH regulation. We now simplify things by simply removing any substance of this type from our contracts. (...)

#### **France – Small – Distributor**

Europe kills all societies; I do not want to answer your questions. Fortunately I buy the substances. You will not help anyone, especially SMEs. We go straight into the wall and nothing will stop that.

#### **Belgium – Micro – Downstream user**

(...) REACH is a cost question for us. We deal with / deal with 10-15 elements / subject. If we are to pay to the respective topic consortium EUR 10-70,000 per element / because different elements cost

different, in order to register REACH, we will probably add down business. It's our reality with REACH!!  
(...)

#### **Sweden – Medium-sized – Distributor of metals**

(...) Because we consider that import costs to the EU are unfair in relation to our sales for the products. Due to the fact that five substances are to be registered at a cost of EUR10,000 / substance we are forced to terminate imports from Japan to the EU at the end of this year. (...)

#### **Sweden – Micro – Distributor**

(...) It is over 30 months now since I stopped the application process so I have probably forgotten more than I can remember but it is important you hear how registration is almost impossibly difficult - and almost impossible for all but rich large companies. At every single stage, the REACH application process proved extremely difficult. My company was started from nothing and owned by my wife and I. The Co employed two staff, myself and my son so you can see we were a tiny company, none the less we became successful and grew sales every month. Right from the start we endeavoured to be compliant with all legislation and rules - a fact our customers demanded -. We contacted REACH without being asked to do it; you can see we did not want to hide or operate illegally. At first I asked my son to register our application for REACH registration but he could make no progress. I then tried and I also failed - I have an honours degree in Civil Eng from (...) University so am not without a decent education -. At every stage in the process, you are referred to a separate guidance note and when you start reading the guidance note it becomes clear you need guidance to read the guidance notes. Eventually I had 2 shelves full of plastic A4 folders containing thousands of A4 sheets printed out to read. It became clear I could not make this application on my own, so I hired an IT expert, who also had a very very hard time trying to use the REACH registration process. We had to buy a computer programme from the USA just so we proceed. Eventually we achieved preliminary registration and actually began to progress to sections which had questions in. Progress was painfully slow due to the difficult IT process involved - my IT consultant was still being paid to do the input work whilst I supplied the answers. We had limited help from a consultancy and progress continued. We then received e-mails from the (...) Consortium in Holland demanding we pay around £200,000 to proceed with our application. We were also advised additional sums of money would be needed as the application processed deeper. If I was to pay such sums, the company's cash flow would have become negative and we could have had to cease operations within weeks - become bankrupt. I objected to this and sought UK government help to fight my appeal case. I also recall now that the nature of questions about my (...) products became increasingly difficult and then even more difficult. I have over 25 years of training and experience in (...) so understand my (...) products extremely well. Even so I found the REACH process asking questions about (...) that I have never heard before and questions I judged to be irrelevant to (...). The UK government advisor helping me advised I had a very strong case for appealing against the huge joining fee demanded by the (...) Consortium so I did appeal. The appeal process was not easy at all but I won the appeal and received the go ahead to proceed with only minimal and affordable joining fees. I also received technical information to help answer the product technical questions asked by REACH. By this point I was stressed to the maximum by the pressure to be REACH compliant and this was affecting my health. So even with the appeal won and the technical help, I was no longer to continue with my REACH registration. Can you imagine that I had won my appeal but could not face continuing with the REACH process? Well I can tell you it is extremely difficult to work through each REACH stage. I had had enough and was not willing to trade illegally so decided to sell my Co. Not being REACH approved reduced the value of my company and limited the potential buyers to current (...) companies. My memory may not be so good but I clearly remember feeling that the Tech questions and the financial input required looked suspiciously like the whole process had

been heavily influenced by existing European (...) companies. In my view, I am not a novice in (...), the whole process and cost had been influenced by these companies to make it almost impossible for new market entries. The (...) consortium members had contrived a system to prevent new (...) companies enter their market place. This feeling and view was reinforced by the comments and attitude via communication with the (...) consortium spokesperson in Holland, (...). So the construing won, the resistance to my application and the massively difficult task involved in working through REACH was too much: the REACH process serves to protect the current historical European suppliers and to prevent outsiders or new companies entering the market. One day this will be proven and those involved should be prosecuted. I started a new Co, grew the Co year on year and clearly wished to be REACH compliant. Yet even after spending lots of time and money processing my registration, even after winning my appeal, I still decided against going on and was compelled to sell my Co. Surely this goes same way to demonstrate how ineffective REACH is in helping new company formation. I am now part retired and REACH is a bad memory.

**United Kingdom – Micro – Manufacturer**

If we would like to proceed with the registration on our behalf of the 3 pre-registered substances in the Annex, what would be the costs?

**Italy – Medium-sized – Distributor of metals**

The EU organization and its organizations like you  
Should finally disappear from this wonderful Europe  
How well we could live without that disgusting organization!

**Germany – Small – Manufacturer of paints, varnishes and similar coatings, printing ink and mastics**





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