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European Chemicals Agency

A study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers

Final Report

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Amec Foster Wheeler Environment
& Infrastructure UK Limited

Report for

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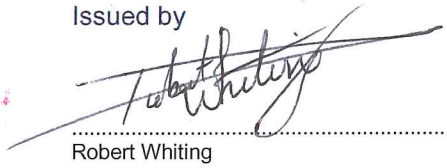

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Robert Whiting

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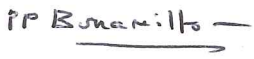

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Document revisions

No.	Details	Date
1	Draft final report	26/06/2017
2	Final report	14/07/2017

Executive summary

This report provides the findings of a study to gather insights into the drivers, barriers, costs and benefits for updating REACH registrations and CLP notification dossiers. The REACH regulation aims to provide a high level of protection for human health and the environment (whilst maintaining free movement of substances) through the safe management of chemical substances. This is achieved through requiring manufacturers / importers of chemical substances to develop dossiers of information covering chemical identity, physical properties, uses, hazards, and risks which are submitted to the European Chemicals Agency (ECHA). This safety critical information for hazardous substances is further disseminated across the downstream supply chain in the form of an extended safety data sheet (eSDS). To date there have been two dossier submission deadlines for phase-in substances, in 2010 and 2013, which covered the higher volume substances manufactured or imported into the European Union (>100 tonnes). Additionally one further deadline for phase-in substances (1 - <100) is planned for 2018. A review of the dossiers submitted to ECHA thus far has revealed a variable quality in the information held within submitted dossiers.

Article 22 of the REACH regulation places a mandatory requirement for a registrant, upon their own initiative to update their dossier without undue delay with new information. This will be particularly important given the quality issues that ECHA has identified within the dossiers reviewed thus far. However based on a review of the ECHA database it was identified that only a limited number of dossiers have been updated thus far, with concerns that a more concerted effort is needed on a wider basis by all REACH registrants in order to uphold the aims of the Regulation. The current study worked with REACH registrants to explore the issue of updating REACH dossiers to better understand the reasons why registrants do or do not update their REACH registration dossiers and CLP notifications.

The study methodology included a combination of targeted survey and stakeholder interviews. The first phase included the development of a questionnaire to explore benefits, drivers, obstacles and incentives for why an update does or does not occur. The questionnaire also included questions to better understand the update of C&L notifications under the CLP Regulation. The second phase included a series of follow-up telephone and face-to-face interviews to explore more deeply the trends identified from phase 1.

The results from both the questionnaire and interview phase highlighted key issues within the REACH registrant community that affect whether they update or otherwise. Briefly these issues can be summarised as follows:

- Many within industry have the perception that ‘registration’ is the end of a process and that no additional work is needed following this point. This issue is in part exacerbated by the mechanisms developed to manage REACH registrations, for example:
    - The letter of access fees for co-registrants is a onetime payment to aid registration. There is often no mechanism in place for lead registrants to secure financial contributions from SIEF members with update of the dossier.
    - Once registration has been completed and a REACH registration number provided, some registrants consider that the dossier is complete, and that no further action is needed.
    - Even for lead registrants this can be difficult as there needs to be a business case made for why a given company would spend additional funds and resources to update their dossier when they perceive that they are already compliant. This also reflects that the registrants do not always realise that Article 22 requires mandatory updates when new data is available.
- There were concerns expressed that the wording of Article 22 is vague. It places an obligation on the individual to decide when an update is needed based on ‘new information’ without ‘undue delay’. The respondents highlighted that the ethos of REACH is ‘one substance, one registration’, and that many registrations have been completed within SIEFs. This makes it ambiguous as to whom is responsible. Does the lead registrant take full responsibility alone? With the support of SIEF members? Or is it up to the individual?
- Communication was also highlighted as an issue. In particular the possibility for SIEFs to disband post registration and members to drop out of the process of keeping the dossier up-to-date. There

were also issues around roles and responsibilities and cost-sharing aspects of updating dossiers, again with SIEF members often finding it difficult to reach agreement. Additionally the results of the questionnaire phase highlighted that the majority of respondents (68%) answered that they had no system in place to help them monitor whether new data was available to assist with a REACH dossier update.

- A counter-point to this opinion was that the respondents highlighted the importance of CLP classifications. Changes affecting the CLP classification could be perceived as an important driver for update of dossiers within the REACH registrant population.
- There were strong concerns expressed that the financial costs of updating REACH dossiers were much higher than the benefits potentially provided from the updated information. In particular many of the SME registrants felt that for their businesses REACH represented only a regulatory burden with no benefits at all. There were also concerns expressed that the mechanisms for registration favoured larger companies who could use the cost sharing aspects of co-registration as a mechanism to force SMEs out of the market.
- These concerns also highlighted that respondents have only limited resources and at the time of the survey were often working to meet the 2018 phase-in registration deadline. Many companies commented that this, combined with data requests for REACH substance evaluations and the need to update dossiers places significant burdens on them, and they have to balance the different requests being made against the resources they have available.
- The respondents also highlighted a number of technical problems with updating their dossiers. These largely focussed on the IUCLID software used for dossiers. New versions of the software had created a lot of additional work, with the update from IUCLID 5.6 to 6.0 commented upon in particular. There were also comments raised around new manual checks of dossiers which had been applied inconsistently, meaning that some dossiers were rejected, even where similar dossiers were accepted. This meant that the registrants felt that even for minor changes updates could represent a lot of effort and that they were reticent about using the submission portal if checks were not done in a consistent fashion.
- For another category of registrant (trade associations and consortia), examples were provided of where efforts had been made to encourage their members to see registration as the beginning of a process, rather than the end. In these cases REACH registration had been integrated into a longer ongoing programmes of product stewardship. This included data management systems and programmes of work targeted to generate new data for update of dossiers. However this category of respondent also commented that the requirements of Article 22 were vague and that within their own work they had prioritised both which substances to update and what kind of data was needed.
- The responses from the respondents suggested a possible REACH fatigue within industry where a great deal of effort and cost had already been spent on the original registrations. According to some responses further update of the dossiers would need to be targeted with a strong case made for why such updates are needed.
- One further issue of importance was dissemination. The respondents highlighted that where a dossier acts as a ‘catch-all’ for all data for all possible users, it contains highly technical information possibly better suited to academics and regulators. This highly technical information is seen as of less use to downstream users, who instead tend to focus more closely on the CLP classification and exposure scenarios. The dissemination of information from the dossier is also closely linked to the perception of the value of the dossier. Many registrants see the dossier development as a one-off task completed at registration, and in such cases the further use and application of the data from the dossier can be limited. The use of eSDS as the dissemination tool for the dossier should provide DUs with valuable data to manage the health and environmental impacts of substances. The perceived value of eSDS by DUs has the potential for DUs to seek high quality eSDS from their suppliers (the registrants). This in turn would give the registrants the incentive to maintain an up to date dossier in order to meet the demands of their clients for good quality eSDS. However comments received suggested that the quality of eSDS (which contain exposure scenarios) is highly variable and that there was a lack of consistency in how they were developed and structured. This, in their view, undermines the inherent value of the dossier itself.

The conclusions of the study highlighted a complex situation with multiple issues affecting the REACH registrant community. Chiefly however this breaks down to perceptions over how the registration process should work and when it concludes; obligations and in particular lack of clarity over who is responsible for updating which sections of the dossier and with help from whom; Limited resources (particularly with the approaching 2018 registration deadline); and a suggestion that update could include some or all of the sections of dossiers. The recommendations from the study are therefore structured around four simple steps:

- A clear definition on specifically what needs to be updated. This should be targeted to maximise the benefits and limit burden on registrants as far as possible.
- Clear definition of who is responsible for updates. This should make clear the roles of lead registrant and co-registrant in the update process.
- A regulatory mechanism to improve compliance with the mandatory need to update dossiers. (Note that update of dossiers according to Article 22 is already a mandatory requirement. However further specific detail is needed, and a fixed temporal cycle with clear deadlines would help to improve the rate of dossier update).
- An improved understanding of why the updates are important. This should make clear that the update has an impact in protecting health and the environment. For example where the new information changes the CLP classifications or exposure scenario conclusions and this needs to be communicated to the DUs.

The recommendations have been made taking the four steps detailed above into consideration. The recommendations have been grouped into three categories. Firstly those actions that can be taken directly by ECHA; secondly recommendations for the trade associations supported by ECHA; and finally recommendations that would require new policy measures. The inclusion of actions for trade associations reflects the key role that trade associations have for setting good industry standards and dissemination of information across the industry.

Table 1 below provides the final recommendations from the study.

Number	Recommendation	Description	Issue addressed	Consequence
Actions to be undertaken directly by ECHA without regulatory change				
1	Investigate how the available material provided by ECHA can be better accessed by registrants looking for information on guidance on roles and obligations for dossier update.	A review of the ECHA website and guidance documents is recommended to ensure that key information is being identified and used by registrants that are trying to update their dossiers. This will be particularly important after the last registration deadline as the material is branded '2018 registration'. This should also investigate how to facilitate registrants to make better use of the existing information.	Lack of clarity over roles and obligations between lead registrant and co-registrants disrupt the process. Can lead to breakdown in communications, cost-sharing disputes, or SIEF members dropping out. Lack of clarity on exactly what information needs to be updated and separate lead registrant (LR) from co-registrant (CR). Comment from ECHA has highlighted that there is already useful guidance on these topics, but apparently the respondents were unaware of this.	Improved understanding of obligations by registrants.
2	Direct instructions from ECHA to Improve clarity over requirements of Article 22.	This recommendation is to provide clear and simple instructions on who is responsible for update of which sections and under what	Lack of clarity over roles and obligations between lead registrant and co-registrants disrupt the process. Can lead to	Further clarification of obligations will make clear what is expected and

Number	Recommendation	Description	Issue addressed	Consequence
		circumstances of the dossier. This could be communicated as a news article within the ECHA newsletter for example.	breakdown in communications, cost-sharing disputes, or SIEF members dropping out. Lack of clarity on exactly what information needs to be updated and separate LR from CR. The respondents highlighted a lack of understanding on who is responsible for updating which sections of the dossier. Furthermore there is ambiguity over which sections of the dossier should be targeted.	make enforcement of non-compliance less complicated.
3	Provision of additional support measures for SMEs to encourage update of dossiers	Additional technical support to help SME registrants understand their obligations. To help support and minimise this burden we would recommend considering a package of measures: i) Guidance on how to identify inappropriate lead registrant behaviour and clear overview of their rights. ii) ECHA to co-ordinate further support at national level through discussions with MSCAs.	SMEs were identified as having very limited resources and often little regulatory expertise in REACH. There were also comments around the administrative burden on this group of registrants.	Better support for SME registrants means that they will be much more likely to complete updates and remain compliant.
4	Develop a system to identify where reviews have been completed but an update of the dossier is not needed.	Possible development within the REACH-IT website to request registrants to provide indication of where a review has been completed but an update not triggered. This could work via one of two options: i) A tick-box system within REACH-IT. This should include a caveat explaining the legal obligations of updating dossiers in REACH. ii) A system within REACH IT to indicate a review has taken place including provision of evidence to demonstrate that a review has taken place.	Some registrants highlight that they check for new data but that it does not trigger an update. This is not captured by ECHA.	It is currently unclear how many registrants are conducting reviews of dossiers which do not result in an update. A mechanism to provide such information would limit burden for unnecessary updates and help ECHA have a more complete picture.
5	Expansion of the published update programme for IUCLID (updates are done twice a year), with clear details of what is included and why an update is planned in order to improve	ECHA already has fixed windows for updates which are communicated in the public domain (spring and autumn updates).	Updates of IUCLID have been recognised as creating significant extra work for registrants and many respondents identified this as a major barrier to updating	Limiting updates of IUCLID would in turn limit impact on registrants to complete migration of dossiers, and

Number	Recommendation	Description	Issue addressed	Consequence
	clarity and stability over planning for industry	However it is clear that effort is needed to limit updates to only where necessary and that good transparency is needed on what is planned. The existing plans could therefore include additional information on the scope of the update, and if new data needs are included, why they are needed.	dossiers. Greater control and transparency over updates is needed.	manual checking for errors post update.
6	ECHA to use the enforcement forum to make clear the obligations of Article 22 and work with national enforcement agencies to integrate compliance checks on updates with other REACH compliance checks.	This recommendation is for ECHA to use the enforcement forum with national enforcement agencies to focus future enforcement activities to integrate checks on dossier updates with other compliance checks.	The registrants that took part in the questionnaire and interview phases highlighted concerns that there is not a level playing field and that REACH is not enforced evenly across the EU in terms of checking that registrations are in place and up to date. This has a negative impact on the willingness of registrants to commit resources to REACH tasks. Companies are less likely to keep dossiers updated if this is not being enforced.	Increased consistency in enforcement will provide greater incentives to ensure dossiers are up to date.
Actions through trade associations with support of ECHA				
7	Facilitate increased awareness of benefits of updating dossiers and risks of not updating, through trade associations.	Communicate benefits of updating (ensuring safe use, product stewardship) and risks of not updating (harm to health/environment, potential non-compliance with legislation) to trade associations. Encourage trade associations to disseminate this information to members. Point to existing guidance where appropriate. As part of this dissemination trade associations and consortia also have a role to play in highlighting best practice for managing SIEFs post-registration as part of an ongoing product stewardship programme.	Mis-perception over the role of the dossier and registration as the end of a process.	Increased awareness of need to update dossiers.
8	Trade associations to work with ECHA to provide guidance to industry on what eSDS should look like and further interaction with DUs on how to make use of eSDS.	To address the perception of the dossier having limited benefit to the registrants, the recommendation targets the DUs as end recipient of the data (in the form of an eSDS). This would mean that the registrant's customers have a strong understanding of REACH and are requesting the best quality data from their suppliers. There is already an ongoing body of work to look at eSDS and the consistency and quality	Communication of the hazards, risks and risk management measures across the supply chain is key to the functioning of REACH. However comments made on eSDS suggested that the clarity and quality of communication could be variable. Additionally where work on dossiers is perceived as a one-off	The results of the questionnaire and interviews highlighted that the benefits of an up to date dossier are not well defined. Improved perception of the value of dossiers would lead pressures from DUs for up-to-date eSDS and in turn more up-to-

Number	Recommendation	Description	Issue addressed	Consequence
		of how to develop a good eSDS. However this work could be continued and further strengthened. This recommendation is therefore three-fold. i) Further engagement with industry on what a good eSDS should look like. Best practice and support to industry for consistent approach. ii) Work with DUs on how to get best use of eSDS. iii) Development of 'how to' documents showing how information in the eSDS comes from specific data sets in the dossier If DUs hold the eSDS in high regard they will demand high quality documents from their suppliers (the registrants). In turn this puts pressure on the registrants to keep dossiers up to date to generate the eSDS.	task, the use of the dossier for other tasks particularly dissemination is less. This reduces the perceived value of the dossier and benefit of why a registrant would want to update their dossier.	date registration dossiers.
Recommendations actioned through new policy measures				
9	Require mandatory periodic update of dossiers (and system for registrants to provide evidence of continued validity / completed reviews where update is not needed).	The recommendation would be to have mandatory deadlines on a temporal basis (e.g. every 3 years) with a clarification that if new data becomes available sooner an update is triggered immediately without undue delay. This would still also uphold the one substance; one registration philosophy meaning that SIEFs should be maintained as part of a product stewardship process after the 2018 phase-in registration deadline. This would require a regulatory change to require registrants to issue an updated registration dossier every 3 years (or similar). If there is no data to be updated, the registrant would be required to confirm that the data remains correct, and up-to-date. This could perhaps be best achieved through a clarification or update of the requirements under Article 22, which might be feasibly done through an Implementing Regulation.	While update according to Article 22 is already mandatory, there is uncertainty among registrants over what is intended and who should act. The mechanics of REACH mean that SIEFs can break down following registration and that necessary planning for updates as part of a product stewardship programme does not happen in many cases.	Increased level of dossier update. Improved confidence in effective management of risks to health and environment. Improved clarity on when a dossier update is needed.

Contents

1. Introduction

1.1 Background and objectives

Background to the study

The Regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH (EC 1907/2006)) aims to provide a high level of protection of human health and the environment from the use of chemical substances; allow the free movement of chemical substances on the EU market; and enhance innovation in and competitiveness of the EU chemicals industry.

Under the REACH regulation, manufacturers, importers or only representatives of non-EU companies must submit registration dossiers to the European Chemicals Agency (ECHA) for the substances they produce and sell. Companies are also obliged to update REACH dossiers with any relevant new information, without undue delay. While many registrants pro-actively manage their dossiers to ensure that they are up to date and as accurate and complete as possible, this is not always the case.

ECHA has also identified, based on analysis of those registration dossiers submitted, that the quality of REACH registration dossiers submitted can be of variable quality. This further underlines the need for update of REACH dossiers to ensure that they are complete, accurate and provide high quality information in order to aid the Regulation's aims for a high level of protection for human health and the environment. However the reasons behind why registrants update their dossiers or not are highly complex, reflecting the diverse nature of the European chemicals industries. There is an imperative need to better understand the drivers and obstacles behind why registrants do or do not update their dossiers. This topic is of particularly high interest given the approaching final phase-in deadline for REACH dossiers in May 2018, and ongoing work on the REFIT evaluation of the REACH regulation and the parallel fitness check on the most relevant chemicals legislation excluding REACH.

Equally, alongside the REACH regulation, the regulation on classification, labelling and packaging of chemicals (CLP (EC 1272/2008)) places obligations on industry to submit their classifications for substances and mixtures to the C&L inventory held by ECHA. This activity has also seen a variable response rate with divergences in classifications of given substances notified to ECHA. Therefore, there is also a need to better understand the drivers and obstacles to updating notifications for this process.

Amec Foster Wheeler and project partner Peter Fisk Associates were contracted by ECHA in February 2017 to conduct a study to explore these issues through engagement with a wide variety of stakeholders. This study report provides the findings of an extensive consultation (based on a questionnaire) and series of interviews with contacts in different industry settings to explore the issues around update of REACH registration dossiers and CLP notifications. This study report provides the results of these activities in chapter 2 and 3 with overall conclusions and recommendations in chapter 4 and 5 respectively.

Objectives of the study

The study objectives have been defined within the Terms of Reference (ToR), as:

- To gather insights, through engagement with stakeholders, into the current drivers, incentives, costs, challenges and benefits for companies to regularly update their REACH registration and CLP notifications dossiers. This should focus in particular on the analysis of best practice regarding dossier updates. The study will also explore sectoral differences and working methods within the SIEFs (Substance Information Exchange Forum).
- To provide recommendations for ECHA to encourage and incentivise REACH registrants and CLP notifiers to engage with best practice for regularly updating their dossiers, by drawing on the insights identified in the first objective.

1.2 Methodology

Introduction

To meet the study objectives detailed within section 1.1 a mixture of stakeholder engagement processes have been used to make contact with a diverse range of stakeholders across Europe. This includes representatives of companies that manufacture and import chemicals into the EU, including both large-sized companies and SMEs. It has included contact with consultants who fulfil the only representative or third party representative roles. Contacts at trade associations and representatives of organisations who lead consortia for named substances within the REACH registration process were also included.

The methodology was based on two phases. The first phase involved development of a questionnaire which was sent to industry contacts and made publically available via a website. Then subsequently to the conclusion of the questionnaire phase, the results of the questionnaire outputs were used to form the basis for targeted interviews with key contacts from amongst questionnaire respondents. This second phase allowed a deeper exploration of results and development of final conclusions and recommendations on possible options to promote the proactive update of REACH registration dossiers and CLP notifications where needed.

Phase 1 – Questionnaire survey

Phase 1 of the study covered the development and execution of a questionnaire designed to explore the topics covered by the study objectives. The starting point for the questionnaire involved discussion between ECHA and the consultants to discuss key areas to be covered. The resulting questionnaire covered 34 questions, with an estimated time for respondents to complete of 25 minutes. A copy of the final questionnaire used is provided within Appendix A.

The questionnaire covered questions based on the following structure:

- Admin section: Covering details of the respondent (name, company, location, and role within REACH i.e. manufacturer, importer, only representative). The admin section also included questions regarding company size (based on REACH criteria), and industry sector (based on NACE codes).
- REACH registration: The questions on REACH registration updates were broadly grouped to assess the role of the respondent in the process, i.e. lead registrant, co-registrant, or independent. This section also covered the number and type of registrations completed and explored whether they had already completed an update to the registration. The rest of this section grouped questions based on:
    - Benefits of updating registrations;
    - Drivers behind why updates were completed;
    - Obstacles experienced in conducting updates; and
    - Incentives that could persuade more registrants to conduct updates.
- Submissions to the C&L inventory: The questions in this section initially asked whether respondents had submitted an update of their notification to the C&L inventory. They then explored the drivers and obstacles to updates, whether respondents had witnessed divergence in the classification for the same substance, the reasons behind the divergence and what could be done to address this.

Following initial review by the steering group, the development of the questionnaire also included a pilot testing phase where a draft version of the questionnaire was provided to five experts based within European trade associations related to the chemical industries for comment. This pilot testing helped to ensure that the structure and format of the questionnaire was robust, clear and that any missing questions/amendments were captured.

The finalised questionnaire was then uploaded to a survey site (survey monkey) which was readily accessible via the internet. The questionnaire was launched on 3 April 2017 with a duration of six weeks, and closed for responses on 12 May 2017.

ECHA provided the project team with a contact list based on organisations that had previously submitted REACH registration dossiers. This included around 5,700 contacts based at companies across Europe, including manufacturers, importers and only representatives. Amec Foster Wheeler drafted a brief introductory letter (see Appendix A) and made contact with these respondents by email to draw their attention to the questionnaire. A reminder email was also circulated approximately three weeks into the duration of the survey to help prompt further responses.

ECHA also placed details of the survey within the weekly ECHA newsletter which has a circulation of around 15,000. A reminder message was also placed in the ECHA newsletter in the week commencing 24 April 2017. Again this was intended to help prompt further responses to the questionnaire.

At the conclusion of the questionnaire phase 322 responses were received covering a wide range of industry types and companies with different roles under REACH. A further discussion of the results from phase I is provided within chapter 2 of this report.

Phase 2 – Interview phase

The completion of phase I provided the project team with a valuable set of data to help with analysis of the main benefits, incentives, drivers, and obstacles to promoting the proactive update of REACH dossiers and CLP notifications. The questionnaire also included a request for respondents to volunteer to take part in a telephone or face to face interview lasting around 1 hour. Those that provided positive responses to this question were then reviewed by the project team to select an audience with as broad a range of stakeholder representation as possible. This included a mixture of company sizes, both large-sized companies but also SMEs. It included manufacturers, importers, consultants, trade associations and consortia under REACH. It also included a broad range of industry sectors covering everything from the oil and gas sector to construction materials and soaps and detergents.

The analysis of the questionnaire results also allowed the project team to identify early trends within the data and areas where further exploration of the topic was needed. Based on this analysis a background paper was developed covering questions spanning four relevant themes:

- Benefits and incentives;
- Drivers;
- Obstacles; and
- Technical issues.

In total 20 respondents were included within the interview phase.

Prior to the interview taking place the interviewees were sent a copy of the background paper as a means of preparation. The background paper was also used by the interviewers to help guide the discussion and cover important points identified from the questionnaire phase. A copy of the background paper that was used is provided within Appendix B.

Upon completion of each interview, the interviewer produced a set of draft notes which were provided to the interviewee for comment. This was done as part of the project's quality control procedures to make sure that the details recorded during the interviews had been taken correctly and that the notes taken presented a true reflection of the discussion.

Upon completion of the interview phase the project team collated the responses provided by the interviewees. These were used alongside the results from the questionnaire, to identify and draw out the key results which have been reported in the study conclusions. These conclusions were used in turn as the basis for development of recommendations (see chapter 5). Further discussion of the interview phase is provided within chapter 3.

2. Results of phase I - questionnaire survey

2.1 Introduction

This section includes a discussion of the results of the survey undertaken between 3 April and 12 May 2017. In order to provide a comprehensive but condensed summary, the analysis has been structured in the following sub-sections:

- **Demographics of the respondents**
- **Questions related to the update of REACH dossiers**
- **Questions related to the update of C&L notifications**

2.2 Demographics of respondents

Notification of the questionnaire was sent by email directly to a contact list of 5,700 possible respondents (provided by ECHA). The questionnaire was also advertised in the ECHA newsletter with a circulation of approximately 15,000 readers. The questionnaire was launched on 3 April and closed on 12 May. In the six weeks that the questionnaire remained open, 322 responses were received.

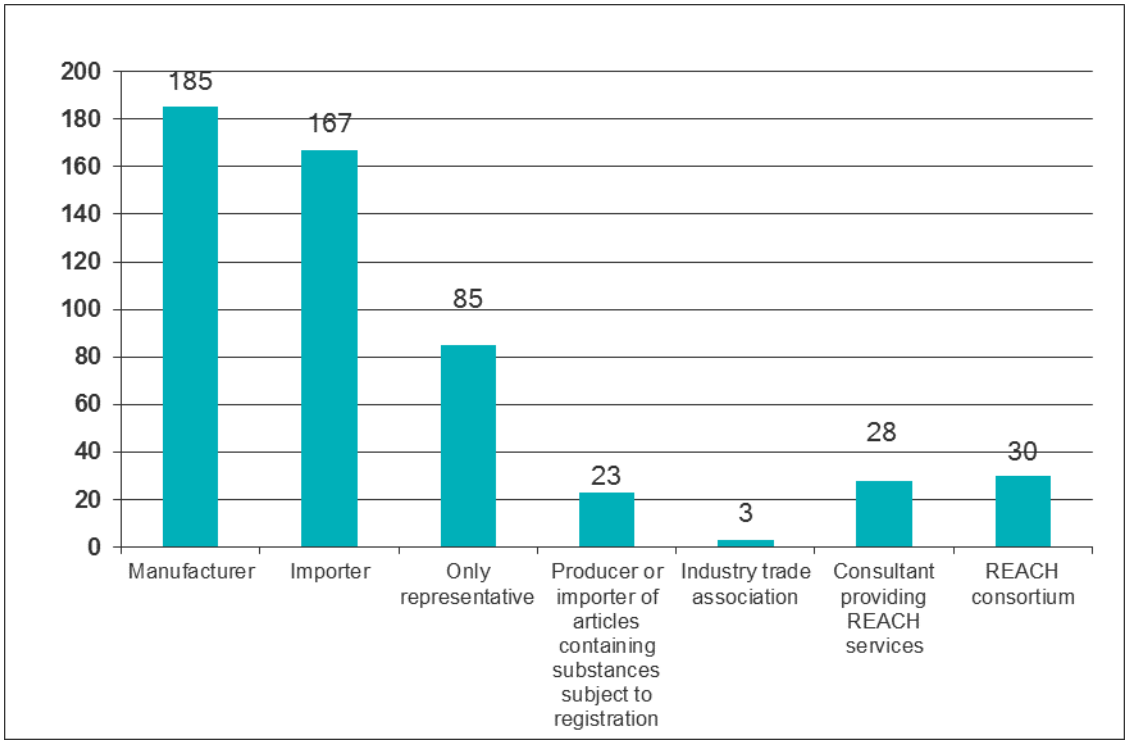
This sample size while small compared to the potential number of respondents, illustrated a good spread of demographics (company size, geographic location, industry sector), and therefore confidence that the results reflect a good cross-section of what is a diverse chemicals industry. One potential bias in the results that was identified relates to question 14 which asked whether the respondent had completed an update to their REACH registration dossier. 74% of respondents stated that they had updated their dossier whereas the proportion of total registrants that have updated registration dossiers is much lower. In fact, according to the report on the Operation of REACH and CLP (ECHA, 2016), 64% of the registrations submitted since 2008 have never been updated. One possible explanation for this bias is that the questionnaire focuses on updates of REACH dossiers and could therefore attract respondents who had already had some involvement in this process.

This sub-section provides an overview of the administrative section of the questionnaire covering questions 3-6.

Role of the company

Question 3 asked respondents to define the role of their company within the REACH regulation. This question allowed the respondents to pick multiple answers where for example they may act as both a manufacturer and an importer. 309 responses were received to this question. The majority of respondents indicated that they are manufacturers (185 respondents, 60%), importers (167 respondents, 54%) and/or ‘only representatives’ (85 respondents, 28%). Figure 2.1 provides a breakdown of the responses received.

Figure 2.1 Role of the companies (respondents) under REACH (values are number of respondents)*



Number of responses: 309. Note: * Since respondents can act in more than one role the total adds up to more than 309.

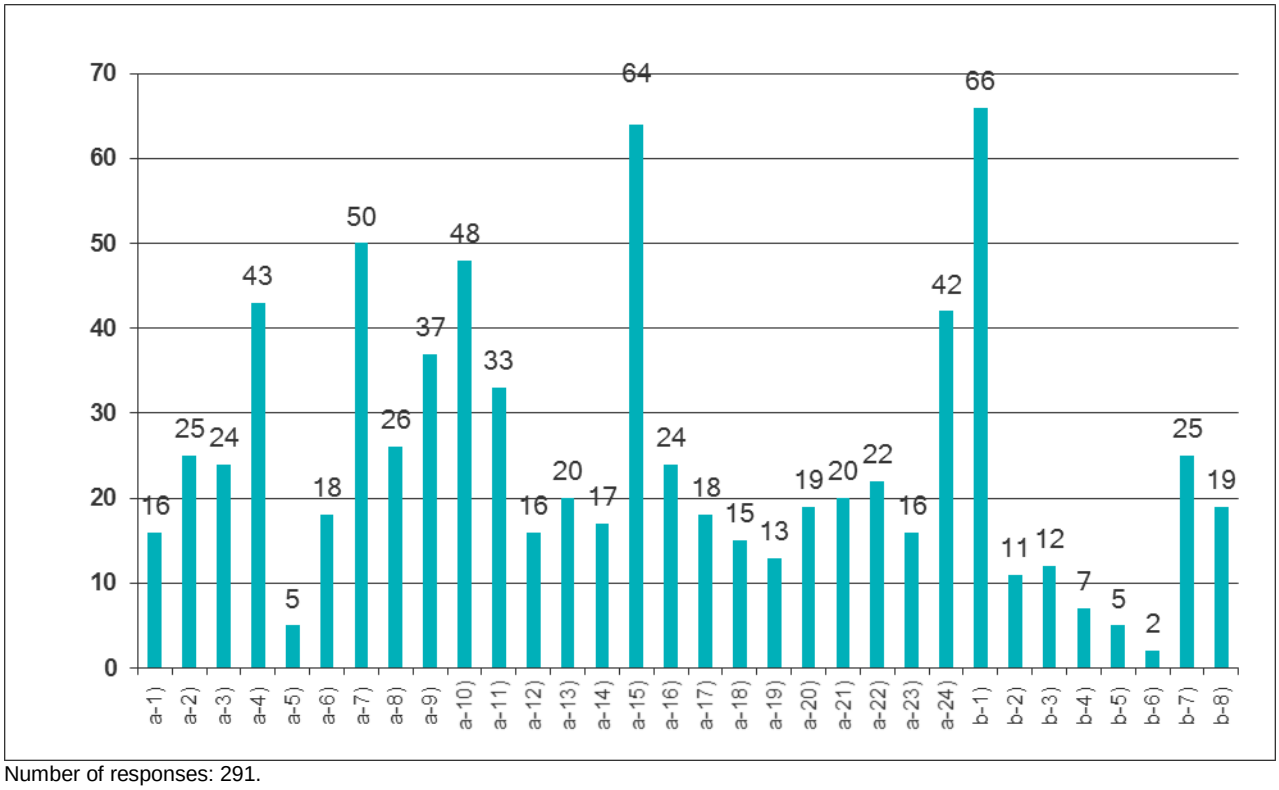
Product group

Question 4 asked the respondents to define the industry sector to which they belonged, with categories defined by NACE codes. Additionally the categories allowed both manufacturing activities and also trade of goods that had been produced. As with question 3, respondents were able to pick multiple responses if for example they both manufactured chemicals for sale, but also imported/distributed goods for sale.

There were 291 responses to this question. There was a broadly even distribution of industry categories amongst those selected by the respondents, although the majority of responses (76%) corresponded to manufacturers (18%: sales and distribution and 6%: other).

In the case of manufacturers, the most common groups were “basic organic chemicals”, “other inorganic mineral compounds” and “solvents and alcohols”. In the case of “sale and distribution”, the most common group was “sale and distribution of chemicals”. Figure 2.2 provides a breakdown of these details.

Figure 2.2 Main product groups of the substances the respondents have registered or helped register under REACH



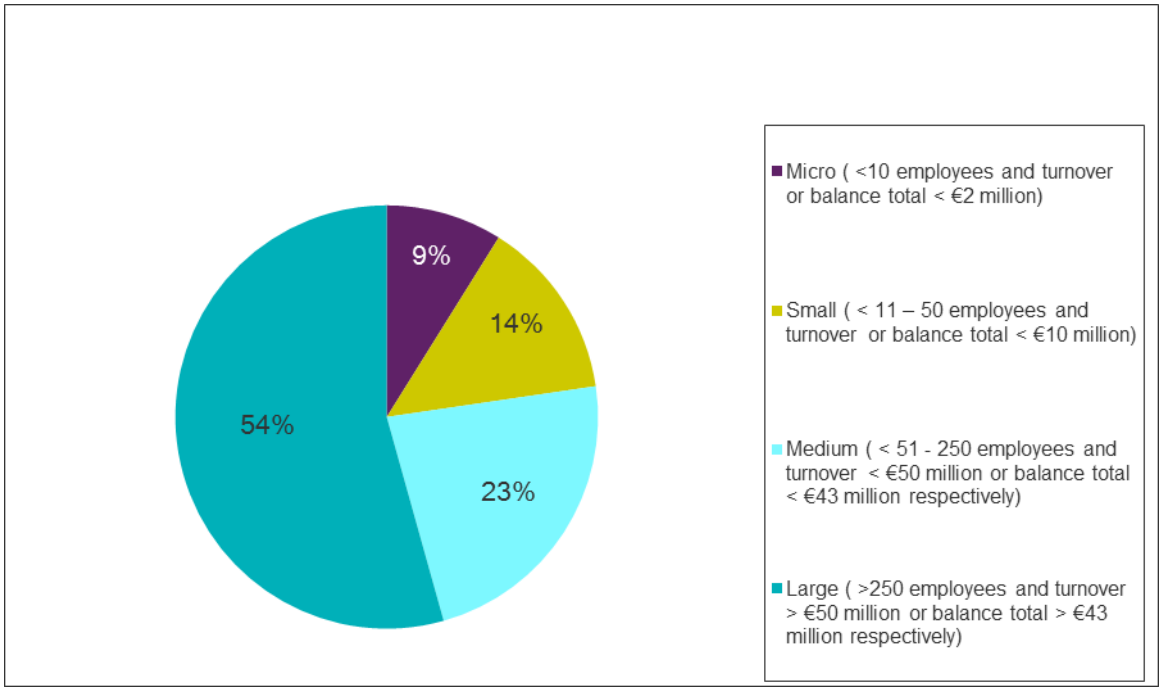
Number of responses: 291.

Guide to sectoral codes: a-1) Industrial gases (NACE 20.11 - Manufacture of industrial gases), a-2) Dyes and pigments (NACE 20.12 - Manufacture of dyes and pigments), a-3) Metals (Ferrous, and Ferro alloys) (NACE 24.1 – Manufacture of iron and steel), a-4) Metals (Non-Ferrous) (NACE 24.4 – Manufacture of non-ferrous metals), a-5) Glass based products (NACE 23.1 – Manufacture of glass), a-6) Cement, lime and concrete (NACE 23.5 – Manufacture of cement and lime), a-7) Other Inorganic mineral compounds (NACE 20.13 – Manufacture of basic inorganic chemicals), a-8) Inorganic acids, peroxides and halogens (NACE 20.13), a-9) Basic inorganic chemicals not listed above (NACE 20.13), a-10) Solvents and alcohols (NACE 20.14 – Basic organic chemicals), a-11) Fuels, oils, and lubricants (NACE 20.14 + 20.59 - Other), a-12) Rubber and rubber products (NACE 21.1 – Manufacture of Rubber), a-13) Plastic and plastic based products (NACE 21.2 – Manufacture of plastic), a-14) Organic Acids, enzymes and reagents (NACE 20.14), a-15) Basic organic chemicals (not listed above) (NACE 20.14), a-16) Fertilisers, pesticides and agrochemicals (NACE 20.15 Manufacture of fertilisers and nitrogen compounds + NACE 20:20 – manufacture of pesticides and other agrochemical chemicals), a-17) Paints, varnishes and inks (NACE 20.30 - Manufacture of paints, varnishes, and printing ink), a-18) Soaps and detergents (NACE 20.41 - Manufacture of soap and detergents, cleaning and polishing), a-19) Perfumes and toiletries (NACE 20.42 – manufacture of perfume and toiletries), a-20) Glues and adhesives (NACE 20.52 – manufacture of glues), a-21) Catalysts (NACE 20.59), a-22) Water treatment chemicals (NACE 20.59), a-23) Construction industry chemicals (NACE 20.59) , a-24) Other, b-1) Sale and distribution of chemicals (NACE 46.75 – wholesale chemicals), b-2) Sale and distribution of fuels (NACE 46.71 – Wholesale of liquid and solid fuels), b-3) Sale and distribution of metals, (NACE 46.72 – Wholesale metals), b-4) Sale and distribution of construction chemicals (NACE 46.73 – Wholesale construction goods), b-5) Sale and distribution of household products (NACE 46.49 – Wholesale household goods), b-6) Sale and distribution of Home maintenance goods (NACE 46.74 – Wholesale hardware, plumbing and heating), b-7) Sale and distribution of intermediates (NACE 46.76 – Wholesale intermediates), b-8) Other.

Company size

Question 5 asked the respondents to provide information on their company size. This was based in the REACH definitions of SMEs and large size companies. This question was answered by 305 respondents. The distribution of the sample size indicated that the large companies were the biggest category of respondents, with 54% of the respondents being large companies and the rest being SMEs. Among SMEs, half were medium size enterprises, 30% of the SMEs were small companies and 19% of the SMEs were micro companies. Figure 2.3 provides a breakdown of the responses to this question.

Figure 2.3 Company size breakdown of respondents



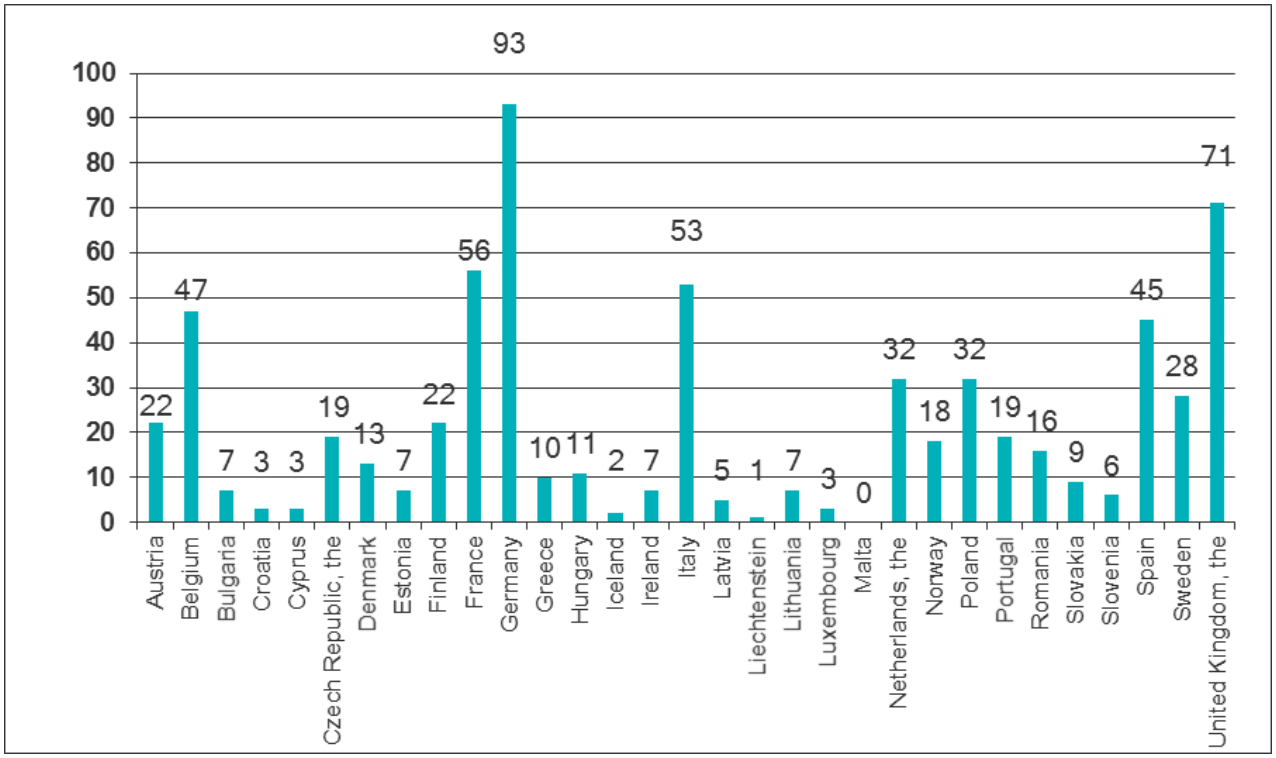
Number of responses: 305

Geographical coverage

Question 6 asked the respondents to provide details of where their company was based. As with previous questions the respondents were able to pick multiple answers. In the case of multi-national companies that operate in multiple Member States they were able to select all countries where they were active. In total 309 responses were obtained in this question. Although the geographical coverage of the sample is relatively heterogeneous, the most frequently selected countries were from Belgium, Germany, France, Italy, Spain and the United Kingdom. These five countries make up over half of the responses[1]. Figure 2.4 provides a breakdown of the responses to this question.

[1] This does not mean that it was also half of the respondents, as several companies operate in more than one country

Figure 2.4 Geographical coverage of respondents



Number of responses: 309

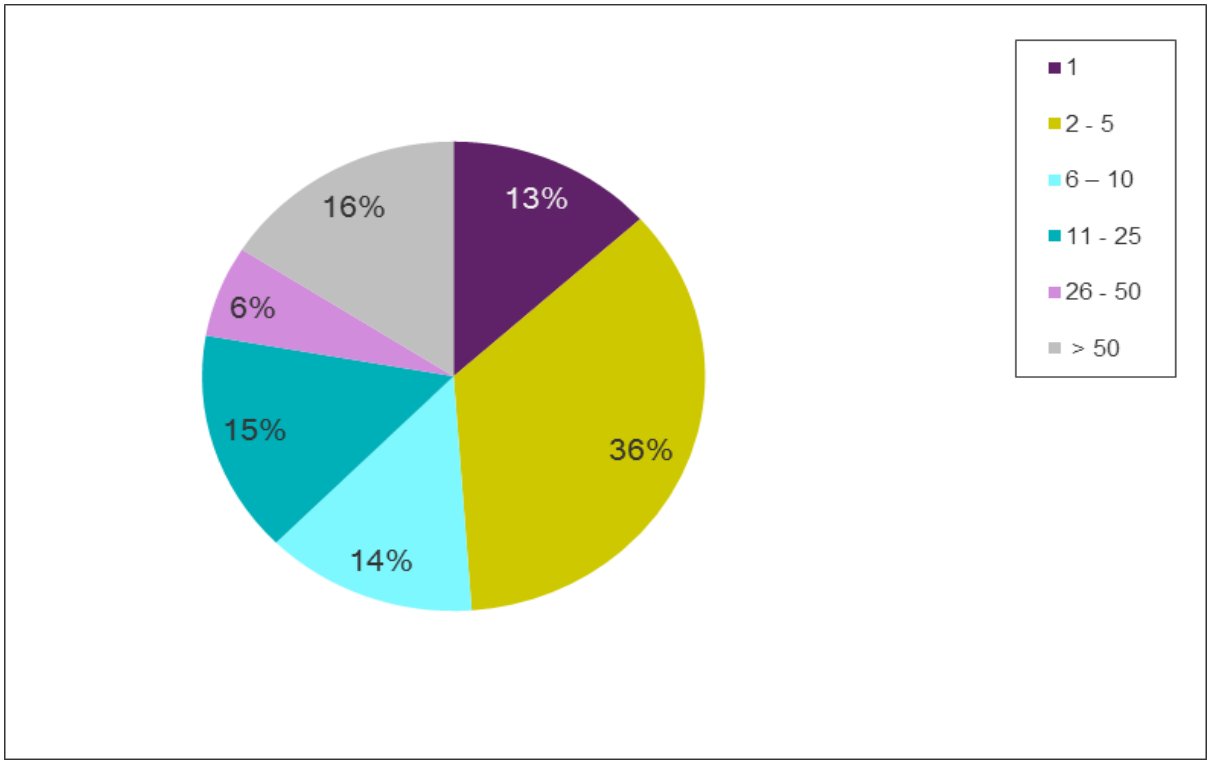
2.3 Results of REACH update questions

This sub-section includes the questions relating to REACH dossier update, covered by questions 7-24 in the questionnaire (see Appendix A).

Number and type of registrations

The first question (question 7) within this section aimed to assess how many registrations had been completed by the respondents as a measure of how many substances were being managed. Figure 2.5 illustrates that most (62%) of the companies that responded to the questionnaire have registered 10 or fewer substances. More than half of these registered 2-5 substances, which was the most common answer overall (36% of all responses). There is also a relatively high percentage (16%) of respondents that have registered over 50 substances, which related to larger companies and only representatives. Question 9 asked what kind of registrations had been submitted with the majority of respondents (88%) having completed full substance registrations, and 12% having completed registrations of intermediates.

Figure 2.5 Number of registrations



Number of respondents: 301

The data has been analysed further to establish whether there are trends related to the demography of the population. Table 2.1 and Table 2.2 include a matrix comparing the number of substances registered to company size and role under REACH.

As can be observed in Table 2.1, the majority of companies that have registered more than 50 substances are large companies. However, company size cannot be considered a determining factor in the number of registrations as the dataset was dominated by large companies. However, smaller companies are less likely to have >50 registrations as reflected in the table below.

Table 2.1 Comparison of results matrix. Substances registered vs company size (Number of companies)

Substances registered	Large	Medium	Small	Micro
> 50	30	5	8	2
26 - 50	17	0	2	0
11 – 25	33	8	1	4
6 – 10	25	10	3	3
2 – 5	46	33	16	10
1	11	12	9	7

Number of responses: 295. Note: This table presents number of companies in each size group. It is worth nothing that some companies have multiple roles in the process of registering substances under REACH, as reflected in Table 2.2 below

In the case of company roles, only representatives are the group with the highest number of companies with over 50 substances registered under REACH. Only Representatives are an EU based legal entity or natural person able to take on the role of the registration obligations for a non-EU company. While in some cases Only Representatives can be EU divisions of a multi-national company that also has divisions in non-EU

countries, they also often consultants acting on behalf of many non-EU companies. This may help to explain why the Only Representative category have a high number of registrations already completed.

There were 15 respondents that stated that they acted as only representatives, importers and manufacturer. From these 15, one company also selected “Producer or importer of articles containing substances subject to registration” and two selected “REACH consortium”). Furthermore, 11 respondents that stated that they are ‘only representatives’ also stated that they are ‘consultants providing REACH services’.

Also, based on the analysis there was not a clear trend when comparing manufacturers with importers.

Table 2.2 Comparison of results matrix. Substances registered vs role under REACH (Number of companies)

Substances registered	Manufacturer	Importer	Only representative	Total number of companies responding to both questions (i.e. substances and role)
> 50	26	26	32	**48**
26 - 50	16	14	5	**19**
11 – 25	33	28	12	**46**
6 – 10	23	27	14	**41**
2 – 5	64	60	17	**107**
1	19	21	3	**40**

Number of responses: 301. Since respondents can have more than one role, the totals in each row and the grand total add up to more than the number of companies that responded to these two questions.

Role in joint submissions (question 8)

Within the REACH registration process it is possible for registrants to act as lead registrant developing the dossier with support of a SIEF; as a member of a SIEF supporting the lead and making registration through purchase of a letter of access; or acting independently as a sole registrant.

Question 8 allowed the respondents to select the frequency with which they held these different roles across the substances that they had registered. Table 2.3 provides a breakdown of these findings, with the most frequent response being that the respondent acted as a member of a SIEF completing REACH registration as a co-registrant. Fewer respondents commented that they had held the lead registrant role on a frequent basis, with the least common response being that the respondent acted as an independent registrant.

Table 2.3 Role in the joint submissions for REACH registrations (number of responses received)

Answer Options	Frequently	Sometimes	Rarely	Never	Response Count
Lead registrant	47	59	39	75	220
Member registrant	205	51	19	9	284
Individual registrant (No co-registrants)	14	33	56	79	182

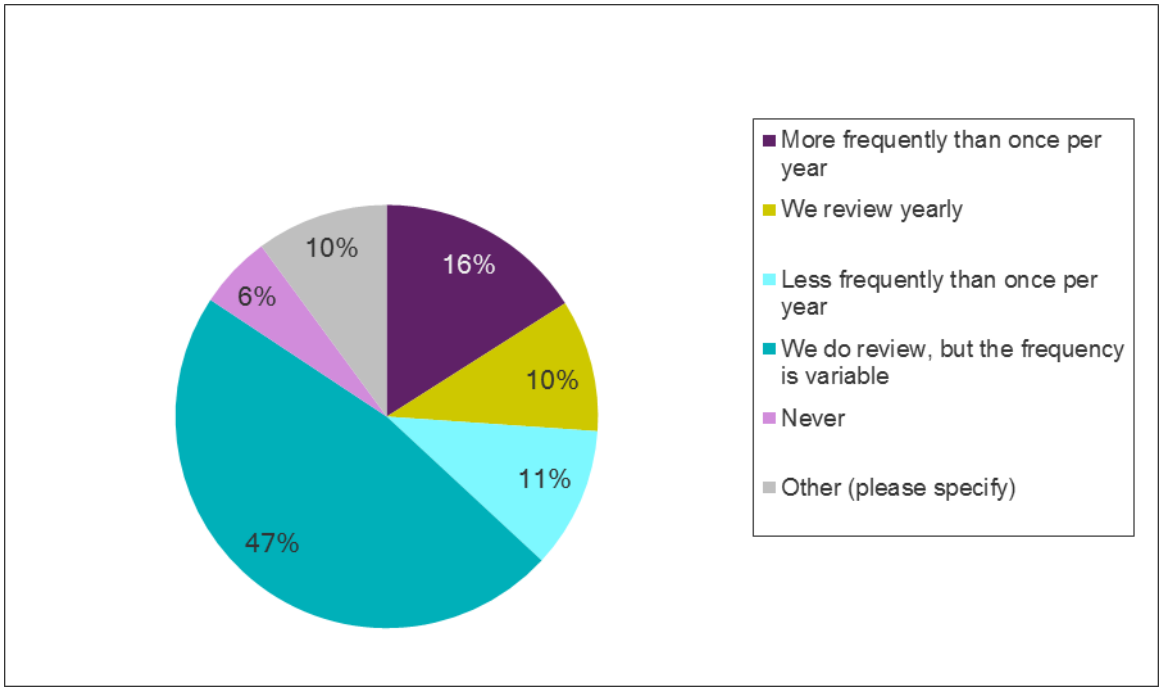
*Total number of responses received 295

Review of information to keep the dossiers up to date

An important part of maintaining REACH registration dossiers is to review the information within the dossier for any potential weaknesses and to conduct updates when new information becomes available. Question 10 asked respondents to comment on how often they checked for relevant information that could be used for updating dossiers. According to the questionnaire, the majority of respondents (47%) review information to keep the dossiers up to date on a variable frequency with no particular fixed intervals. Instead reviews are done on an ad-hoc basis, likely after being triggered by a driver (see the sub-section on drivers below).

Figure 2.6 illustrates that, aside from the 47% that conduct reviews on an ad-hoc basis, a further 37% have some formal periodic programme of review for information. 16% review information more than once a year, with other frequencies being evenly distributed (approximately 10% each). A further 6% of respondents commented that they never review the information relevant to their dossier. Of those that responded other', the majority of the comments received highlighted that reviews were done on an ad-hoc basis for a number of reasons linked to drivers such as direct requests from ECHA or lead registrants.

Figure 2.6 Frequency of review of information to keep dossiers up to date



Number of responses: 287

The replies to question 10 were assessed in combination with the replies to other questions to identify possible trends. The data analysis included an assessment on whether the answers to question 10 were influenced by the role of the companies in the registration process (lead, member, individual registrant).

The comparison between lead and member registrants in this respect is difficult due to the high number of member registrants completing the survey, compared to lead registrants or individual registrants. As can be seen in Table 2.4, the proportion of lead registrants that have some kind of periodical review in place is 42%, which is higher than for members and individual registrants, where the proportion of companies that review with a variable frequency is higher than those that do it at a specific frequency.

Table 2.4 Frequency of review of information vs role in the registration process under REACH (Number of companies)

Answer Options	Lead	Member	Individual
Review more frequently than once per year	10 (10%)	29 (12%)	6 (14%)
Review yearly	20 (20%)	41 (17%)	8 (18%)
Review less frequently than once per year	12 (12%)	23 (9%)	4 (9%)
Do review, but the frequency is variable	42 (42%)	119 (49%)	22 (50%)
Never	3 (3%)	9 (4%)	1 (2%)

Answer Options	Lead	Member	Individual
Other	14 (14%)	24 (10%)	3 (7%)
Response count	101	245	44

Number of responses: 282 Notes: The companies considered "lead", "member" or individual member" are those that have replied that they take each role "frequently" or "sometimes". The number of total responses in the table is higher than 282 because companies could select more than one response (if they have had different roles).
The percentages (%) refer to the proportion of companies in each role (lead, member) that chose a specific answer in question 10. For example: 10% of companies that stated to be lead registrants frequently or sometimes review more frequently than once per year.

As for company size, there are clearer trends (Table 2.5). In order to analyse whether the size of the company had influence on the frequency of review, the proportion of companies of each size (large, medium, small, micro) that selected each of the possible responses to question 10 was assessed. Large companies are more likely than companies of a smaller size to have a review process without an established frequency (53% of large companies). This percentage decreases with company size (48% for medium, 37% for small and 23% for micro).

A different result of this comparison is that the proportion of companies that review information yearly or more frequently. Table 2.5 suggests that in particular the micro sized companies had a number of respondents indicate annual or more frequent checks, with a bigger percentage portion of the size category compared to other size brackets. However closer examination of this category also highlighted a number of consultants / only representatives and a trade association. Therefore some care is needed in reviewing these data to draw comparisons.

One interesting point to consider from this analysis in comparison with the earlier questions is that consultants/Only Representatives can meet the REACH definitions to be considered an SME but will work on REACH full time. Conversely for manufacturers and importers REACH is only part of their job and day-to-day activities. Note that Table 2.2 highlighted the highest majority of manufacturers and importers had registered between 2-5 substances.

Table 2.5 Frequency of review of information vs company size

Answer Options	Large	Medium	Small	Micro
Review more frequently than once per year	12 (8%)	7 (11%)	7 (20%)	4 (15%)
Review yearly	22 (14%)	11 (17%)	5 (14%)	8 (31%)
Review less frequently than once per year	16 (10%)	6 (9%)	5 (14%)	2 (8%)
Do review, but the frequency is variable	82 (53%)	31 (48%)	13 (37%)	6 (23%)
Never	7 (4%)	4 (6%)	2 (6%)	3 (12%)
Other	17 (11%)	5 (8%)	3 (9%)	3 (12%)
Response count	156	64	35	26

Number of responses: 281

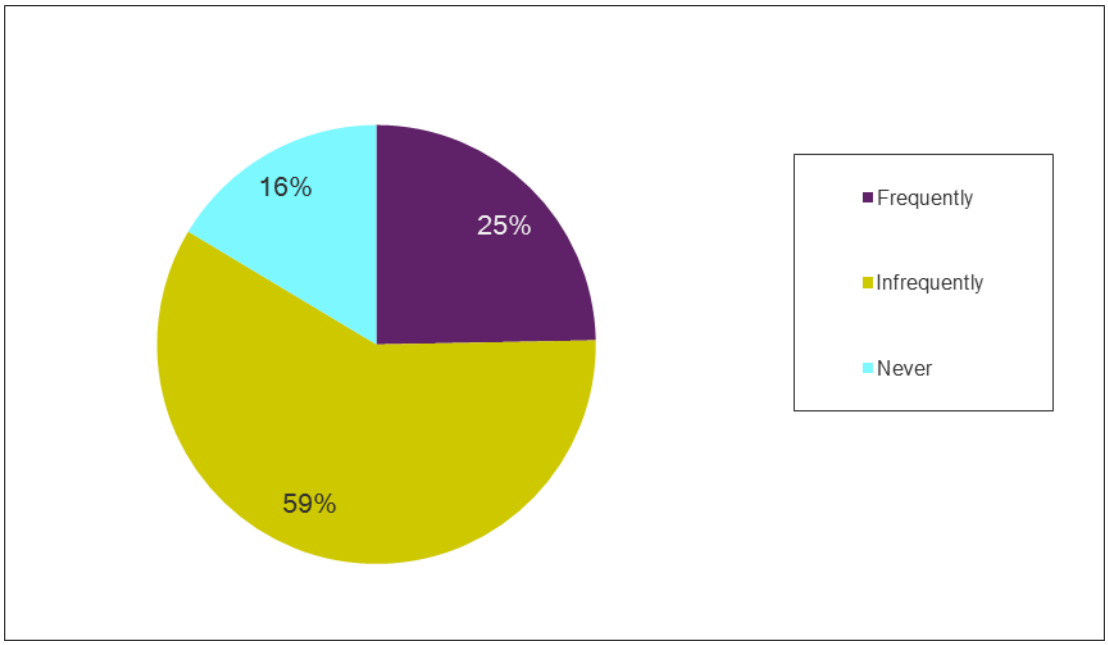
A follow on question (question 13) asked the respondents whether they made use of a system for monitoring whether an update was necessary and if new data had become available. The majority of respondents (68%) answered that they had no system in place to help them monitor whether new data was available to assist with a REACH dossier update.

When exploring whether this proportion changes for large companies as opposed to SMEs, it was found that the general trend (33% yes vs 68% no) remains for large and SMEs (aggregated). If medium, small and

micro entities are assessed as individual groups, there are small variations caused mainly by the small number of small and micro companies that responded this survey.

Furthermore question 11 asked respondents the question 'how often does a review of information result in a need to update a registration?' Figure 2.7 illustrates that respondents indicated that the review of information does not usually identify the need of updating the dossier. The responses to this question highlighted that 25% commented that a review for relevant data frequently resulted in a need to update registrations. One caveat to the results for this question would be that it is down to the individual to decide whether an update is required or otherwise (this follows the approach described in Article 22). It is possible therefore that the respondents use different criteria to decide whether an update is needed or not.

Figure 2.7 How often did a review of data result in a need to update registrations?

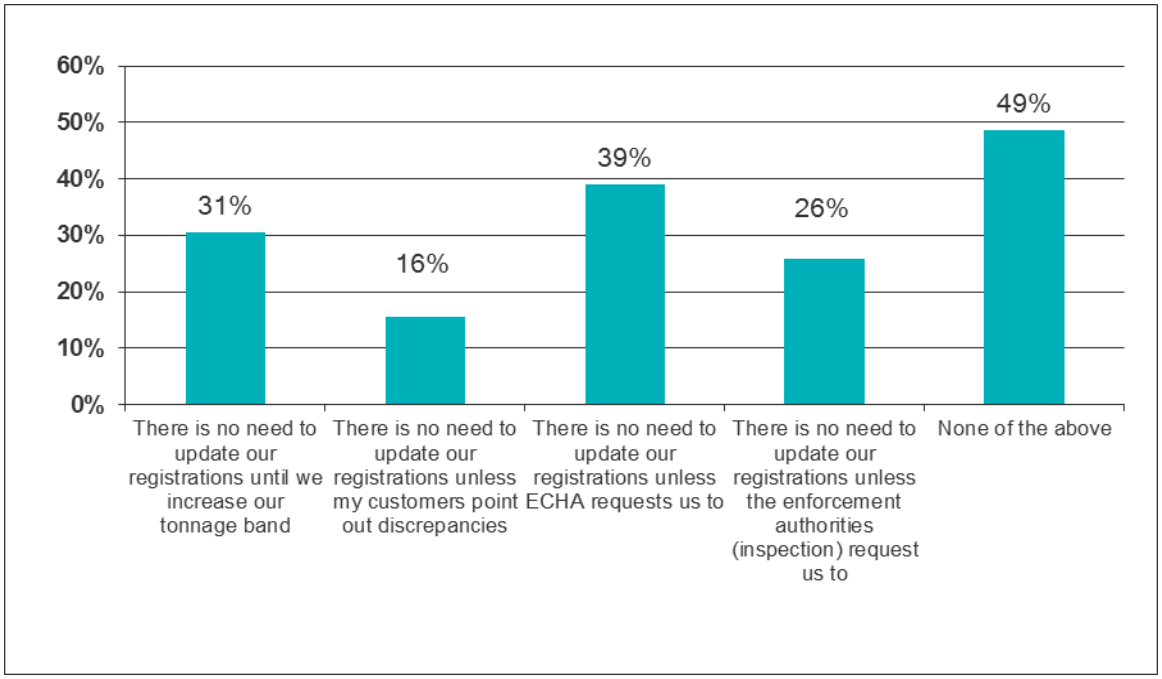


Number of responses: 287

Linked to the question above, the respondents were asked whether they agreed with a set of statements around when an update to registrations should be triggered (question 12). Figure 2.8 provides an overview of the responses provided. The responses generally agreed that the main driver was direct contact from ECHA, with contact from the member state competent authority or the client's request update the dossiers less frequently cited. The main response however (49%) was that the respondents did not agree with any of the statements provided at all, and that other factors were likely attributable to when an update should be triggered. It should be noted that as with other questions the respondents could choose multiple answers. However, based on a review of the responses none of the respondents that chose "none of the above" selected any other options, which suggests that they referred to other factors not proposed in question 12.

The selection of the 'none of the above' answer denotes that the respondent disagreed with all of the other possible answers provided. Interpreting what this means is also a question of how the original respondent interpreted the question. This could be in one of two ways, firstly it is possible that the respondents felt that there was no need to update the dossier and disagreed with the 'prompts' suggested in the other answers. The alternative possibility is that the respondents felt that there could be many reasons to update a dossier and that the possible answers reflected only some of these options. Ergo by selecting 'none of the above', the respondent was suggesting that they felt the situation was more complex and simply one or two options.

Figure 2.8 When should a REACH registration update be triggered (respondents to mark all statements with which they agreed?)



Number of responses: 282

The fact that the most frequent response selected was 'none of the above' posed an interesting question as to why the responds felt this way. During the interim meeting with ECHA the matter was discussed further and it was agreed to complete additional analysis on this particular question to see whether there were any trends within the different sub-groups or category of respondent.

Therefore, the responses of these companies to other questions were analysed in detail to identify possible trends or characteristics that would differentiate them from the rest of the respondents. The following were assessed: company size, role in REACH, countries of operation, number of substances, lead/member registrants, type of registration, frequency of reviews and sector (see detailed analysis in **Error! Not a valid bookmark self-reference.**).

It was found that in general, the characteristics of the companies responding "none of the above" (proportion of companies in each size range, proportion of companies in each role in REACH, proportion of activity in each country, among others) are in line with the overall average responses indicating no specific trends in the underlying data.

Table 2.6 Characteristics of the companies that responded none of the above compared to the total number of respondents

Answer Options	Companies responding 'none of the above' to question 12	All companies responding to the survey
Proportion of companies in each size group	Large (56%), Medium (23%), Small (12%), Micro (10%)	Large (54%), Medium (23%), Small (14%), Micro (9%)
Number of substances registered	>50 substances (19%), 26-50 substances (7%), 11-25 substances (18%), 6-10 substances (14%), 2-5 substances (30%), 1 substance (12%)	>50 substances (16%), 26-50 substances (6%), 11-25 substances (15%), 6-10 substances (14%), 2-5 substances (36%), 1 substance (13%)
Sector	Very similar proportion of companies in each group to that of the total 'population' of companies responding to the survey. The split between manufacturers and importers and the 'rank' of the 10 most common sectors are almost identical	

Answer Options	Companies responding 'none of the above' to question 12	All companies responding to the survey
Countries of operation	Very similar proportion of companies operating in each country when comparing the companies responding "none of the above" in question 12 to the total number of companies	
Proportion of companies that have acted as lead registrants	Frequently (24%), sometimes (26%), rarely (18%), never (32%)	Frequently (21%), sometimes (27%), rarely (18%), never (34%)
Proportion of companies that have acted as member registrants	Frequently (74%), sometimes (17%), rarely (7%), never (3%)	Frequently (72%), sometimes (18%), rarely (7%), never (3%)
Proportion of companies that have acted as individual registrants	Frequently (7%), sometimes (18%), rarely (33%), never (42%)	Frequently (8%), sometimes (18%), rarely (31%), never (43%)
Type of registration	Full registration (88%), registration of intermediates (12%)	Full registration (88%), registration of intermediates (12%)
Frequency of reviews	More frequently than once per year (11%), We review yearly (16%), Less frequently than once per year (9%), they do review, but the frequency is variable (48%), Never (4%), Other (12%)	More frequently than once per year (11%), We review yearly (16%), Less frequently than once per year (10%), they do review, but the frequency is variable (47%), Never (6%), Other (10%)
Has the company already updated at least one dossier?	Yes (80%), No (20%)	Yes (74%), No (26%)

The key message provided from the responses to questions 10-13 illustrated that the majority of respondents do not necessarily pro-actively manage and look for new relevant information to update REACH dossiers, rather they are prompted to do so by an underlying driver. Furthermore it was relevant to note that 6% of the respondents do not look for new relevant information related to their dossiers at all (Figure 2.6). The reason for this could be linked to the perception by registrants that registration is the end of the process and therefore no further work is needed. The responses suggest that the respondents were unclear when and why an update should be triggered, and more importantly what would be the benefit of deploying resources to complete such an update.

The responses therefore suggest that in this case pro-active work to identify and update dossiers is not the main reason for dossier update. Rather the responses suggest that in the majority of cases industry takes its cue from ECHA[2] and updates dossiers when directed or prompted to do so because of a related work stream initiated by ECHA, for example dossier evaluation activities.

Dossier updates

Role and responsibilities

Question 14 asked the respondents whether they had updated their dossier, with 74% of the 211 who answered this question stating that they had updated at least one dossier. For this particular question there may be some bias in the response given the focus of the questionnaire is on REACH updates; the survey may therefore have attracted respondents with an interest in this topic and/or with a track record of having updated dossiers.

The questionnaire results highlighted that the percentage of large companies that have updated at least one dossier is higher (84%) than for SMEs, and the proportion reduces with company size. This suggests that it is more common for large companies to update their dossiers at least once than it is for SMEs. This is also

[2] ECHA, 2016, 'Report on the Operation of REACH and CLP 2016', ECHA-16-R-08-EN

reflected when comparing the distribution of companies that responded 'yes' to this question compared to the total number of companies (Table 2.7).

Table 2.7 Company size distribution for companies that updated the dossier compared to the total (%) number of respondents

Answer Options	One or more dossiers updated (Number of YES)	% among all companies that updated one or more dossiers	Number of companies responding to the survey	%
Large	128 (84% of large companies)	62%	153	55%
Medium	42 (65% of medium companies)	20%	65	23%
Small	20 (57% of small companies)	10%	35	13%
Micro	16 (64% of micro companies)	8%	25	9%

With regard to the sector to which the companies that responded 'yes' to question 14 belong, the proportion of manufacturers that responded 'yes' to question 14 (82%) was almost the same as the proportion of manufacturers within the total number of respondents (81% manufacturers, 18% sale and distribution). As for individual sectors, the 10 sectors with the highest number of companies among those that responded 'yes' to question 14 was not different to the 10 sectors with the highest number of companies overall (i.e. among all the companies responding to the survey).

This shows that the sectoral profile of the companies that have updated one of more dossiers is not different to that of the companies that responded to the survey.

As can be seen in Table 2.8, the proportion of companies that have updated at least one dossier in each sector is above 70% in most cases. As stated above, this could be caused by the fact the survey may have attracted respondents with an interest in this topic and/or with a track record of having updated dossiers. There are a few sectors where the proportion of respondents that have updated at least one dossier is significantly lower than the average of 74%. These are manufacturing of cement, lime and concrete (56%), 'sale and distribution: other' (58%) and 'sale and distribution of metals' (67%).

Table 2.8 Sector distribution for companies that updated one or more dossiers compared to the total (%) number of respondents

Sectors	Number of companies that have updated one or more dossiers	Total number of companies reported in that sector	% of companies that updated one or more dossiers in each sector
a-1) Industrial gases (NACE 20.11 - Manufacture of industrial gases)	12	16	75%
a-2) Dyes and pigments (NACE 20.12 - Manufacture of dyes and pigments)	18	25	72%
a-3) Metals (Ferrous, and Ferro alloys) (NACE 24.1 – Manufacture of iron and steel)	18	24	75%
a-4) Metals (Non-Ferrous) (NACE 24.4 – Manufacture of non-ferrous metals)	37	43	86%

Sectors	Number of companies that have updated one or more dossiers	Total number of companies reported in that sector	% of companies that updated one or more dossiers in each sector
a-5) Glass based products (NACE 23.1 – Manufacture of glass)	5	5	100%
a-6) Cement, lime and concrete (NACE 23.5 – Manufacture of cement and lime)	10	18	56%
a-7) Other Inorganic mineral compounds (NACE 20.13 – Manufacture of basic inorganic chemicals)	39	50	78%
a-8) Inorganic acids, peroxides and halogens (NACE 20.13)	23	26	88%
a-9) Basic inorganic chemicals not listed above (NACE 20.13)	30	37	81%
a-10) Solvents and alcohols (NACE 20.14 – Basic organic chemicals)	34	48	71%
a-11) Fuels, oils, and lubricants (NACE 20.14 + 20.59 - Other)	24	33	73%
a-12) Rubber and rubber products (NACE 21.1 – Manufacture of Rubber)	14	16	88%
a-13) Plastic and plastic based products (NACE 21.2 – Manufacture of plastic)	19	20	95%
a-14) Organic Acids, enzymes and reagents (NACE 20.14)	16	17	94%
a-15) Basic organic chemicals (not listed above) (NACE 20.14)	52	64	81%
a-16) Fertilisers, pesticides and agrochemicals (NACE 20.15 Manufacture of fertilisers and nitrogen compounds + NACE 20:20 – manufacture of pesticides and other agrochemical chemicals)	21	24	88%
a-17) Paints, varnishes and inks (NACE 20.30 - Manufacture of paints, varnishes, and printing ink)	15	18	83%
a-18) Soaps and detergents (NACE 20.41 - Manufacture of soap and detergents, cleaning and polishing)	15	15	100%
a-19) Perfumes and toiletries (NACE 20.42 – manufacture of perfume and toiletries)	12	13	92%
a-20) Glues and adhesives (NACE 20.52 – manufacture of glues)	17	19	89%
a-21) Catalysts (NACE 20.59)	18	20	90%
a-22) Water treatment chemicals (NACE 20.59)	19	22	86%
a-23) Construction industry chemicals (NACE 20.59)	13	16	81%
a-24) Other	32	42	76%
b-1) Sale and distribution of chemicals (NACE 46.75 – wholesale chemicals)	50	66	76%

Sectors	Number of companies that have updated one or more dossiers	Total number of companies reported in that sector	% of companies that updated one or more dossiers in each sector
b-2) Sale and distribution of fuels (NACE 46.71 – Wholesale of liquid and solid fuels)	9	11	82%
b-3) Sale and distribution of metals (NACE 46.72 – Wholesale metals)	8	12	67%
b-4) Sale and distribution of construction chemicals (NACE 46.73 – Wholesale construction goods)	7	7	100%
b-5) Sale and distribution of household products (NACE 46.49 – Wholesale household goods)	5	5	100%
b-6) Sale and distribution of Home maintenance goods (NACE 46.74 – Wholesale hardware, plumbing and heating)	2	2	100%
b-7) Sale and distribution of intermediates (NACE 46.76 – Wholesale intermediates)	23	25	92%
b-8) Other:	11	19	58%

Number of responses: 268. Note: Some companies belong to more than one sector. Therefore, the total number of companies reported in this table is higher than 268

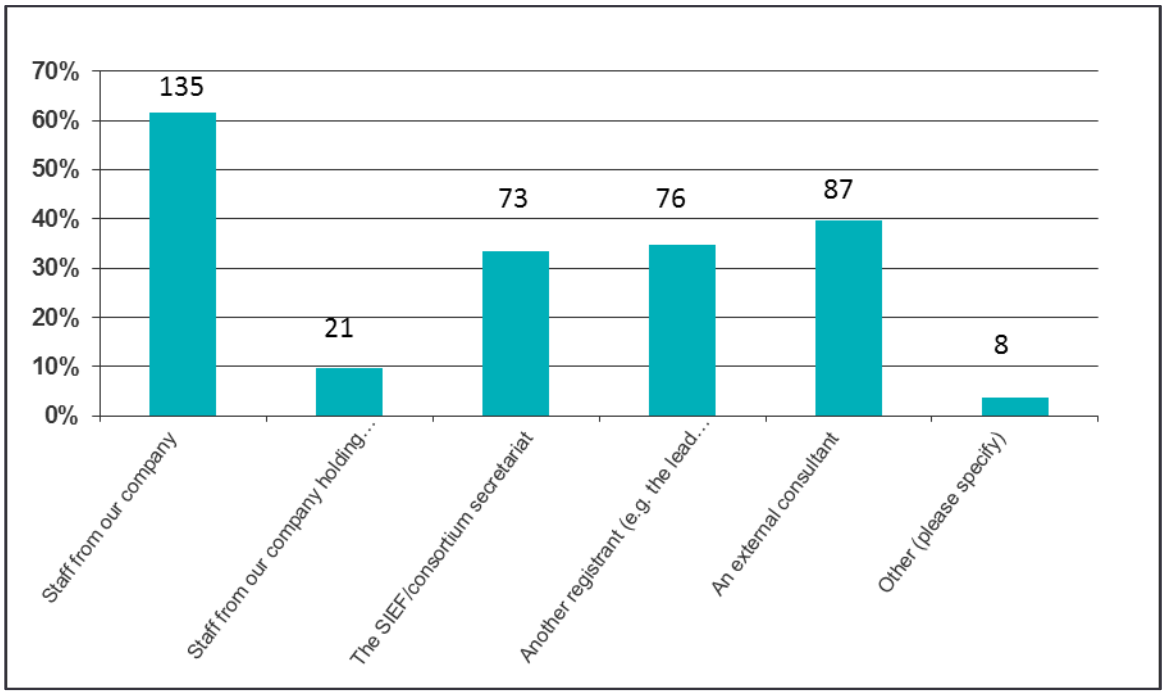
A follow up question (question 14-b) asked the respondents to provide details of what role they had taken within the REACH process (lead registrant, member registrant, independent) for the updates that had been completed. This was a similar question to question 8 regarding roles for the original submission. Table 2.9 illustrates that question 14-b elicited a similar response to question 8 with the majority of respondents taking the member registrant role within a SIEF. The lead role was second most frequent and independent was the least frequent response provided.

Table 2.9 Role in dossier updates

Answer Options	All	Most	Some	Few	None	Response count
Lead registrant	33	40	29	19	43	164
Member registrant	60	39	49	26	14	188
Individual registrant (No co-registrants)	7	12	19	17	73	128

Question 15 then asked who was responsible for the update of the REACH dossier. Figure 2.9 identifies that around 72% of the responses (156 out of 219 response counts) identified that staff from the company or the company holding that had been used as the primary resource to update the information, but the responses also highlighted that it was common for other stakeholders (the consortium secretariat, the lead registrant or consultants) to also have a role in updating dossiers. Note that where multiple stakeholders can be involved in updating a dossier the respondents were allowed to choose more than one answer. Hence the totals exceed 100%.

Figure 2.9 Who updated the dossiers?



Number of responses: 219

This trend was not influenced by company size. The responses to question 15 were dominated by large companies in all cases. This was mainly caused by the fact that there are more large companies that responded to the survey overall (Table 2.10).

When analysing the distribution of responses in each individual company size range, the trends were the same for all groups: staff from the own company was the most preferred option in all cases, followed by external consultant, consortium/another registrant, staff from the company holding and 'other' (

Table 2.11).

Table 2.10 Company size profile of companies responding to who updated their dossiers

	Number of companies			
	Large	**Medium**	**Small**	**Micro**
Staff from own company	86	25	13	9
Staff from holding	14	4	2	
Consortium secretariat	50	10	7	5
Another registrant (e.g. the lead registrant)	50	11	7	5
External consultant	53	17	10	6
Other	4	4		

Note: L: Large, M: Medium, S: Small

Table 2.11 Vertical distribution (%) of the responses to question 15 in each company size group

	Number of companies			
	Large	**Medium**	**Small**	**Micro**
Staff from own company	33%	35%	33%	36%
Staff from holding	5%	6%	5%	0%
Consortium secretariat	19%	14%	18%	20%
Another registrant (e.g. the lead registrant)	19%	15%	18%	20%
External consultant	21%	24%	26%	24%
Other	2%	6%	0%	0%
Sum	100%	100%	100%	100%

Note: L: Large, M: Medium, S: Small. Vertical distribution refers to the proportion of companies that responded to each option (Q15) within each company size group. Example: 33% of large companies responded that staff from their own company updated the questionnaire

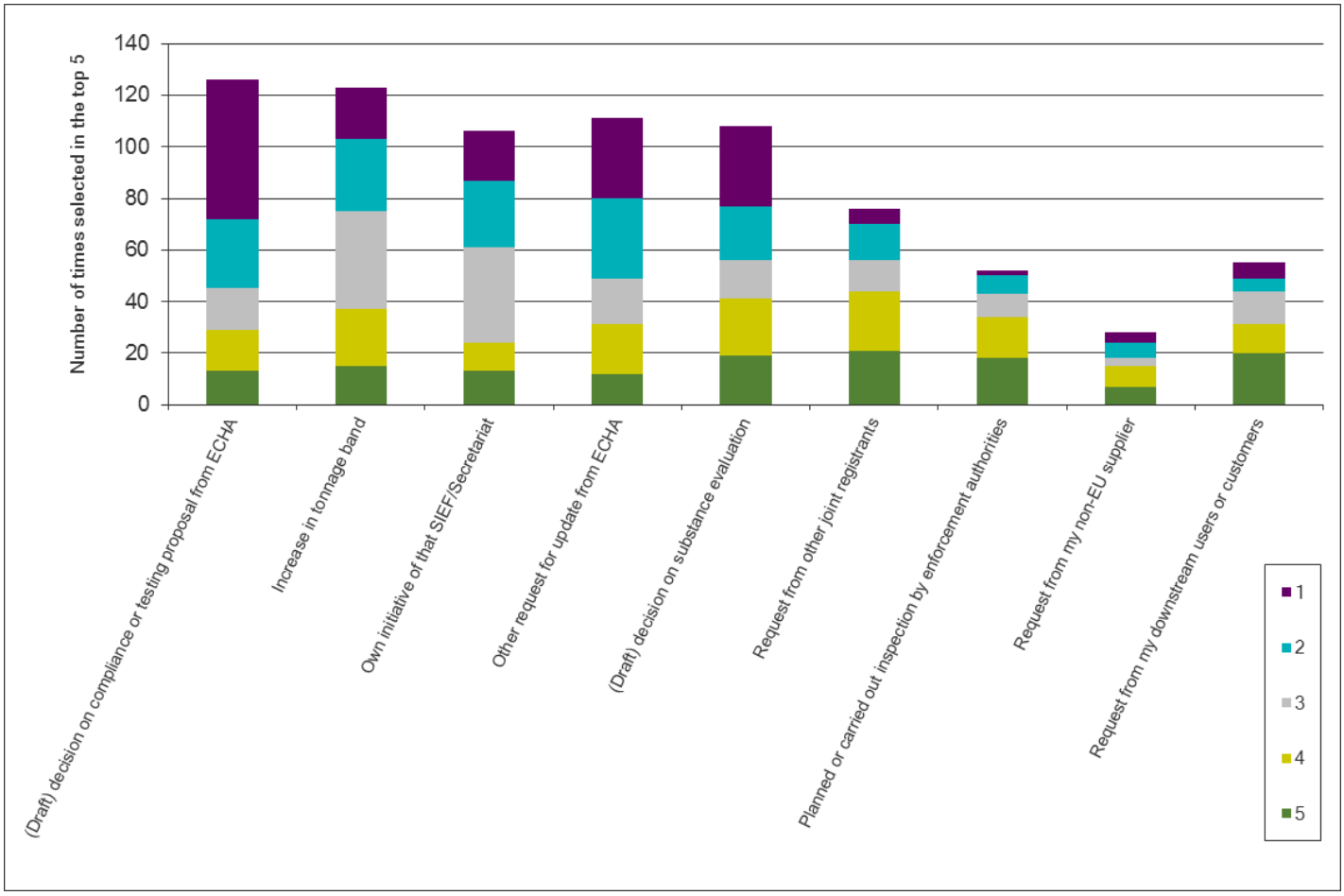
Drivers

Figure 2.11 demonstrates that, based on the information submitted as part of the questionnaire, in terms of the most significant drivers for the updates, these are mainly direct contact with ECHA (decisions on compliance or testing proposals, decisions on evaluations or other requests). Another key driver related the need to update due to increase in tonnage bracket[3]. The response also highlighted requests from other registrants, non-EU suppliers or inspections were reported to have less influence.

Those that responded 'other' mentioned a change in the legal entity, updates to IUCLID, update to occupational risk data, and various others. One respondent stated that there had been a different reason each time and that they did not keep track of what each reason was over the years.

[3] Update of tonnage bracket is a mandatory requirement of the REACH regulation in order to remain compliant. Ergo it has the potential to act as a stronger driver than voluntary update of dossier to remain compliant with Article 22.

Figure 2.10 Drivers for the updates (question 16) [Respondents were asked to select their 'top 5', with '1' being the most significant driver and '5' the least significant]



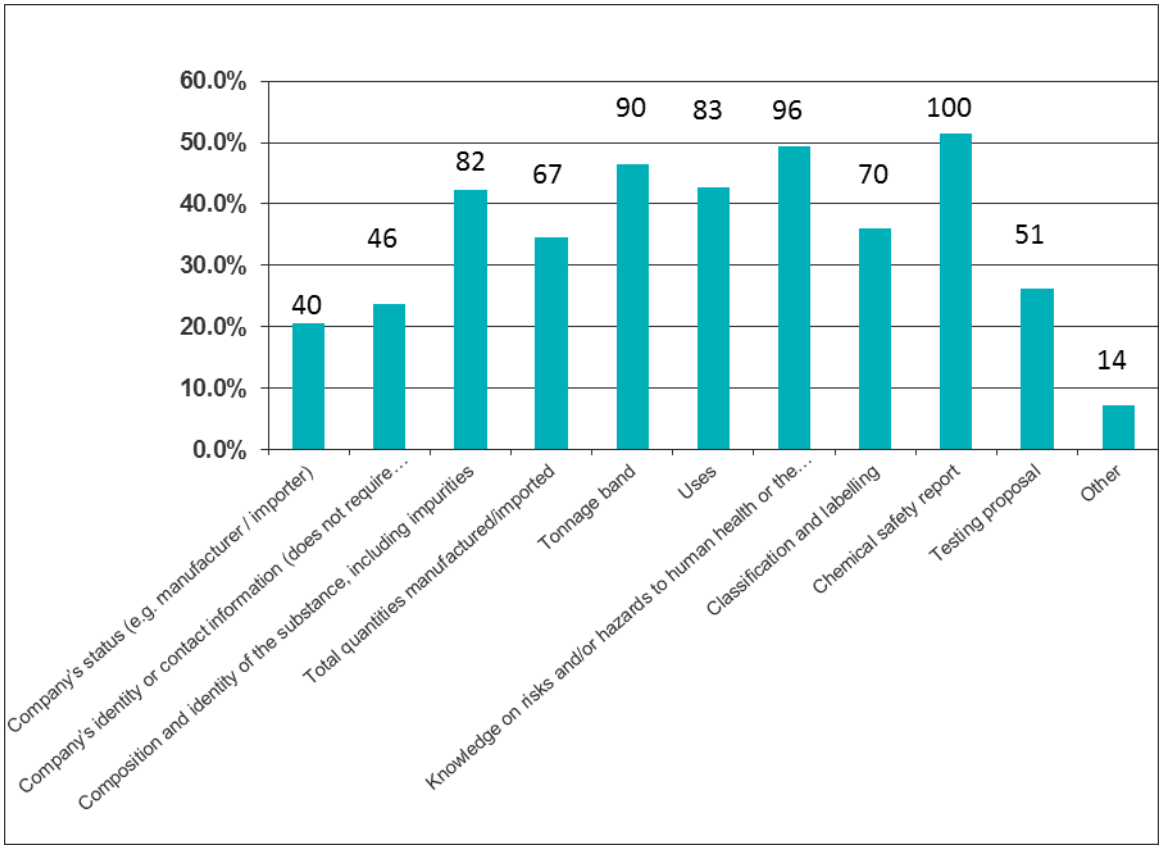
Number of responses: 186. Note: Respondents were requested to rank their top 5 drivers only. The numbers reflect the number of times companies selected each driver in their top 5

The key message from this question was that while pro-active work from industry within the SIEF was seen as an important driver, the main drivers for REACH update of dossiers come primarily from the activities of ECHA and direct contact between ECHA and registrants to request action. It is also relevant to take note of the drivers seen as being of lower priority; for example, inspections from enforcement authorities was seen of relatively low importance. It could be hypothesised that this is the case because the quality of dossiers and REACH compliance is already seen as good by the authorities; but it can equally be hypothesized that the frequency of targeted inspections is low meaning the respondents did not feel it was an important driver.

Information updated

Question 17 asked the respondents what sections of the REACH dossier were updated when an update was carried out. The breakdown of responses for this question is provided in Figure 2.11. The results highlight that there are five of the possible categories that were selected over 40% of the times. The most common updates were to the chemical safety report, knowledge on risks, tonnage band, uses and composition and identity of the substance.

Figure 2.11 Information updated



Number of responses: 194. Respondents were allowed to select all that applied. As a result, the sum of the percentages is higher than 100% and the sum of responses is higher than 194

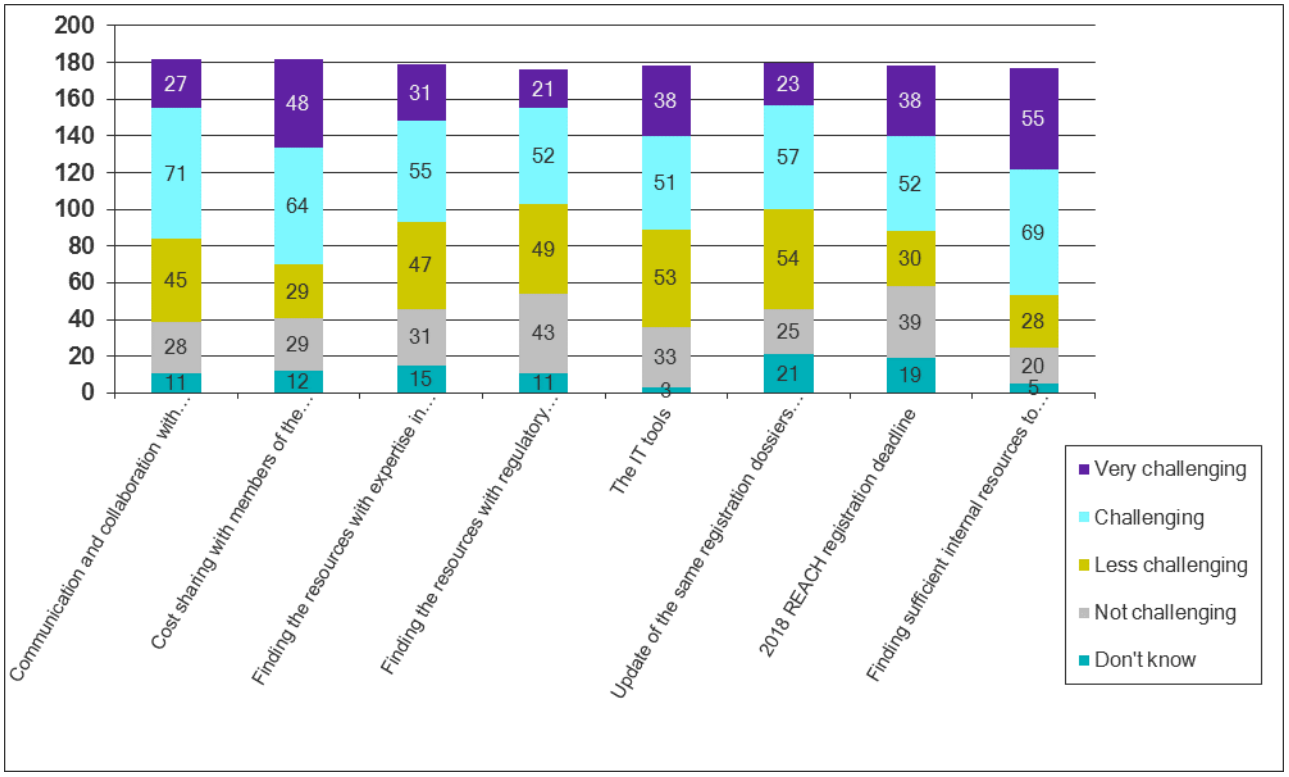
Challenging and barriers to updating the dossiers (Questions 18 and 24)

Figure 2.12 provides a breakdown of the responses to question 18, on what challenges had been faced by the respondents when they had conducted an update of the REACH dossier. The figure illustrates that, in all cases, 40% or more of the stakeholders found that all mentioned aspects of updating the dossiers were challenging or very challenging.

Most of the respondents (70%) marked finding sufficient internal resources to update the dossiers and communication as “very challenging” or “challenging”.

Other challenging aspects were around the cost sharing aspects with other members of the SIEF or consortium and the upcoming 2018 REACH registration deadline. Additionally, the IT tools used for developing and submitting information were also identified as a challenging aspect that hindered update of dossiers. This aspect was included as a theme for inclusion in the phase II interviews. The interviews highlighted further in particular difficulties with new versions of IUCLID and the need to migrate dossiers which created significant additional work. This was particularly problematic for the IUCLID 5.6 to 6.0 migration. There were also comments made regarding infrequent use of IUCLID meaning migration was not possible and that it was necessary to transcribe or re-build dossiers that were more than one version out of date.

Figure 2.12 Challenging aspects (Question 18)

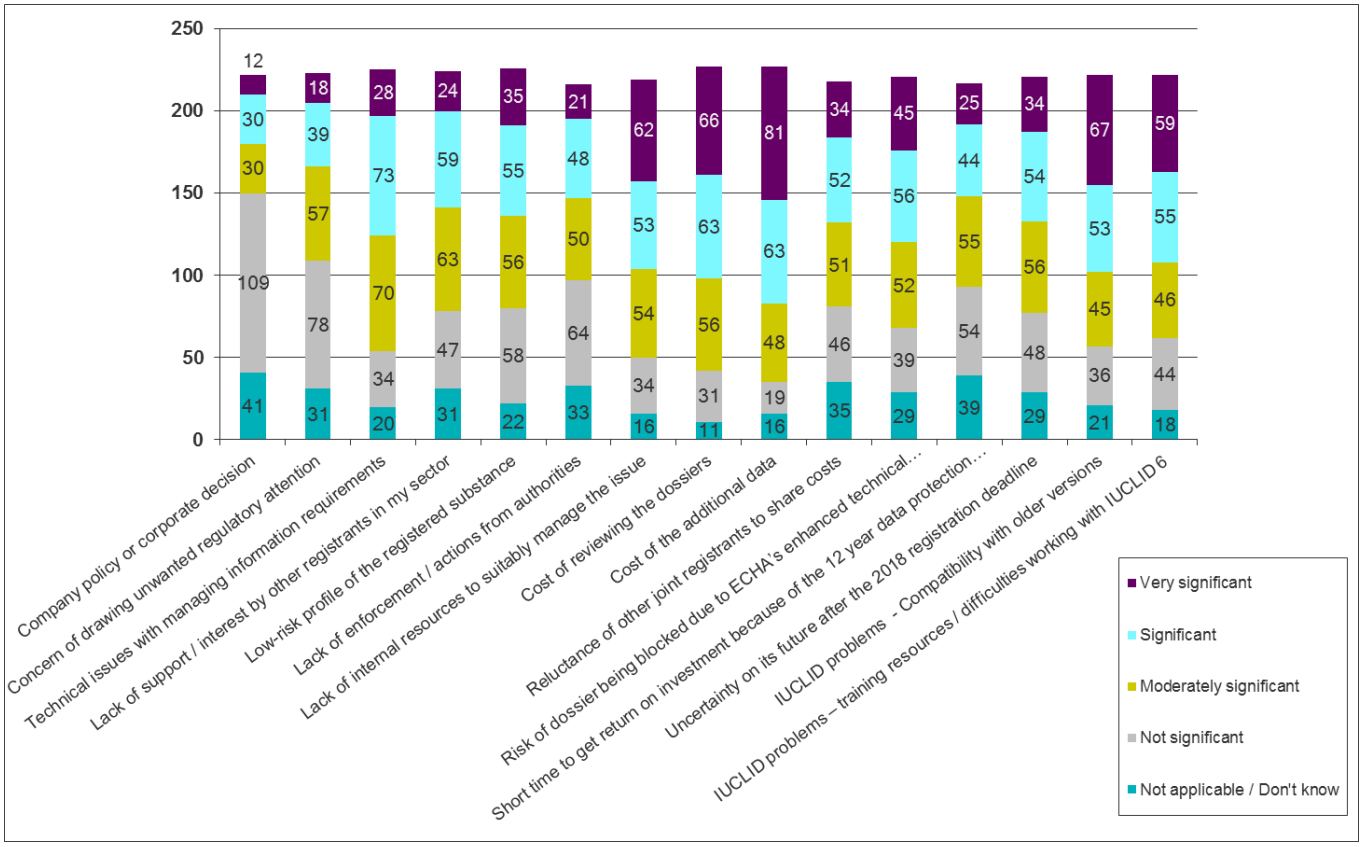


Number of responses: 186. Respondents were allowed to select several aspects, hence why the total number of responses reflected in the figure is higher than 186

Question 24 touched upon a related topic and asked the respondents what they saw as the main barriers to updating REACH registrations. Figure 2.13 provides a summary of the responses. The most significant barriers identified related to costs and time: the cost of the additional data, the cost of reviewing the dossiers and the lack of internal resources to update the dossiers in a timely manner. Problems with IUCLID were also highlighted, especially related to the compatibility of older versions. This was an issue specifically targeted as part of the interview phase with further commentary provided in section 3.5.

There were other barriers that were not marked as being a ‘very significant’ or ‘significant’ barrier as often as those described in the paragraph above: Company policies (e.g. requesting or incentivising not to update), concerns with drawing unwanted attention or lack of enforcement from authorities.

Figure 2.13 Main barriers for updating the dossiers



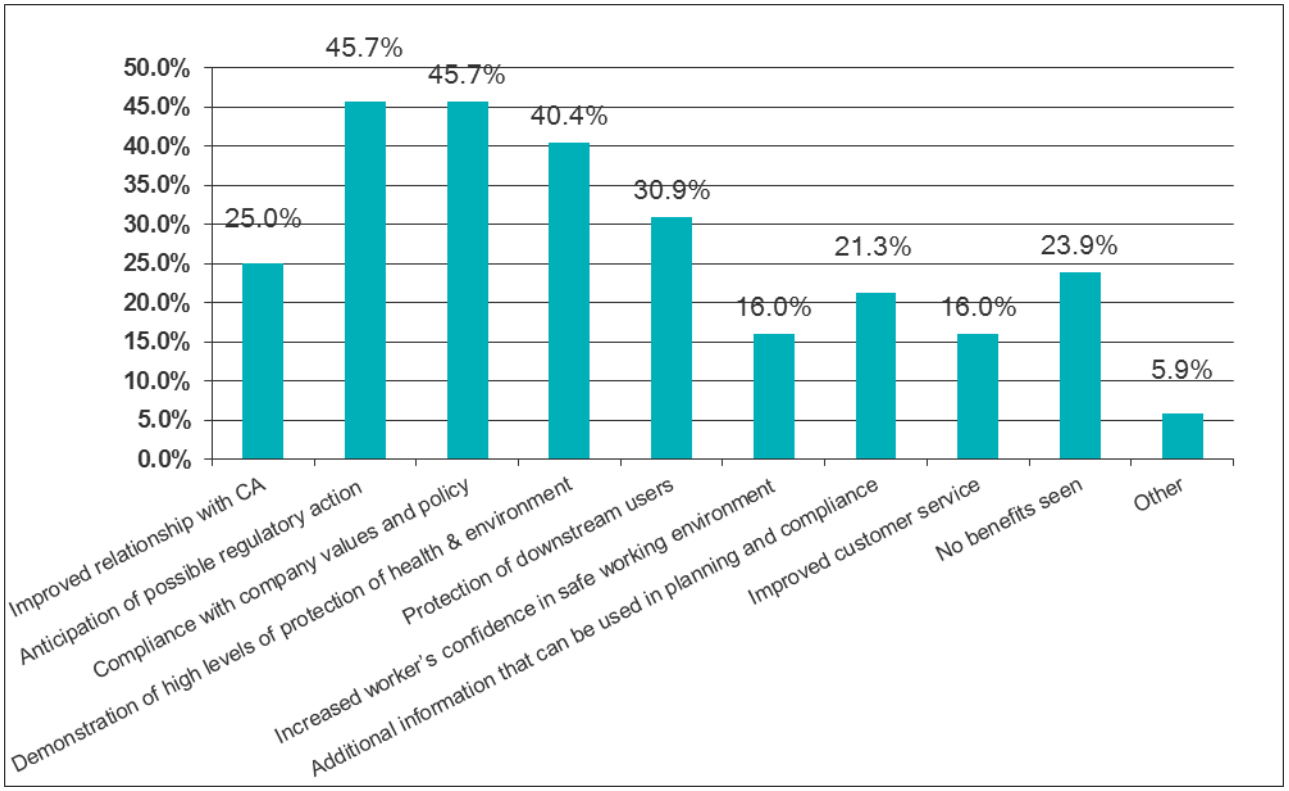
Number of responses: 241. The sum of responses in each barrier is lower than 241 because not all companies selected an option (very significant, significant, moderately significant, not significant or not applicable) for every one of them

Benefits (Question 19)

The respondents were asked to select what they saw as the key benefits of updating REACH dossiers where new relevant information was identified. Figure 2.14 provides a summary of the responses to this question. The highest two responses provided indicated that the main benefits expected were to assist in anticipating regulatory actions (46%), compliance with their own company values and policy (46%) and in order to demonstrate high levels of protection of health and the environment (40%). Conversely just under 24% stated that they do not see any benefit to updating their REACH dossiers.

The comparison between the benefits (24% who commented that they see no benefit to REACH updates) and challenges (40% of all respondents who marked all categories as challenging or very challenging), would suggest that there was a significant amount of the respondents that took part in the survey that the efforts to update their REACH dossiers was not matched by the benefits of doing so.

Figure 2.14 Benefits



Number of responses: 188. Respondents were allowed to select all that applied (i.e. the sum is higher than 100%)

When assessing the profile of those who responded that they do not see any benefit in updating the dossiers, it was found that over 50% are large companies. However, this was not considered significant statistically because the distribution of the companies that responded between large, medium, small and micro companies is very similar to the distribution found in the answers of question 19 (i.e. more than 50% of the companies that responded the survey are large companies, so the fact that above 50% of the companies that responded that there is no benefit are large is just a reflection of the demographics of the respondents). As regards SME, the conclusion is the same.

Another possibility that was assessed was the proportion of companies that do not see any benefit would change depending on the size (Table 2.12). As can be observed in the table below, the proportion of SMEs that do not see a benefit in updating their dossiers is higher than in the case of large companies.

Table 2.12 Number and proportion of companies in each company size group that do not see any benefit in updating their registrations

	Number of companies that see no benefit	Total number of companies that answered to both questions (i.e. size and question 19)	%
Large	23	115	20%
Medium	12	36	33%
Small	6	19	32%
Micro	4	15	27%

With regard to the sectoral distribution, the sectors with the highest number of companies among those that see no benefit in updating the dossiers are: “manufacture – other”, “sale and distribution of chemicals”, “basic organic chemicals”, and “other inorganic mineral compounds”. These are some of the sectors with the

largest amount of companies within the respondents to the survey. Therefore, there does not seem to be a clear trend in this respect (Table 2.13).

However, there are some results that are worth noting. Although the proportion of companies that do not see a benefit was relatively low (below 13% in more than three quarters of the sectors), there were a few sectors for which this was not the case: “Manufacturing – Other”, “Sale and distribution – Other”, “Sale and distribution of fuels”, Sale and distribution of household products”, and sale of distribution of chemicals” had all above 15% of companies responding that updating the dossiers has no benefit for them.

Table 2.13 Sector profile of companies responding that they see no benefit in updating their registrations

	Number of companies that do not see a benefit	Number of companies in the sector	%
a-1) Industrial gases (NACE 20.11 - Manufacture of industrial gases)	1	16	6%
a-2) Dyes and pigments (NACE 20.12 - Manufacture of dyes and pigments)	2	25	8%
a-3) Metals (Ferrous, and Ferro alloys) (NACE 24.1 – Manufacture of iron and steel)	2	24	8%
a-4) Metals (Non-Ferrous) (NACE 24.4 – Manufacture of non-ferrous metals)	4	43	9%
a-5) Glass based products (NACE 23.1 – Manufacture of glass)	0	5	0%
a-6) Cement, lime and concrete (NACE 23.5 – Manufacture of cement and lime)	0	18	0%
a-7) Other Inorganic mineral compounds (NACE 20.13 – Manufacture of basic inorganic chemicals)	5	50	10%
a-8) Inorganic acids, peroxides and halogens (NACE 20.13)	1	26	4%
a-9) Basic inorganic chemicals not listed above (NACE 20.13)	3	37	8%
a-10) Solvents and alcohols (NACE 20.14 – Basic organic chemicals)	4	48	8%
a-11) Fuels, oils, and lubricants (NACE 20.14 + 20.59 - Other)	4	33	12%
a-12) Rubber and rubber products (NACE 21.1 – Manufacture of Rubber)	1	16	6%
a-13) Plastic and plastic based products (NACE 21.2 – Manufacture of plastic)	1	20	5%
a-14) Organic Acids, enzymes and reagents (NACE 20.14)	1	17	6%
a-15) Basic organic chemicals (not listed above) (NACE 20.14)	6	64	9%
a-16) Fertilisers, pesticides and agrochemicals (NACE 20.15 Manufacture of fertilisers and nitrogen compounds + NACE 20:20 – manufacture of pesticides and other agrochemical chemicals)	1	24	4%
a-17) Paints, varnishes and inks (NACE 20.30 - Manufacture of paints, varnishes, and printing ink)	2	18	11%

	Number of companies that do not see a benefit	Number of companies in the sector	%
a-18) Soaps and detergents (NACE 20.41 - Manufacture of soap and detergents, cleaning and polishing)	2	15	13%
a-19) Perfumes and toiletries (NACE 20.42 – manufacture of perfume and toiletries)	1	13	8%
a-20) Glues and adhesives (NACE 20.52 – manufacture of glues)	0	19	0%
a-21) Catalysts (NACE 20.59)	1	20	5%
a-22) Water treatment chemicals (NACE 20.59)	0	22	0%
a-23) Construction industry chemicals (NACE 20.59)	1	16	6%
a-24) Other	12	42	29%
b-1) Sale and distribution of chemicals (NACE 46.75 – wholesale chemicals)	10	66	15%
b-2) Sale and distribution of fuels (NACE 46.71 – Wholesale of liquid and solid fuels)	2	11	18%
b-3) Sale and distribution of metals (NACE 46.72 – Wholesale metals)	0	12	0%
b-4) Sale and distribution of construction chemicals (NACE 46.73 – Wholesale construction goods)	1	7	14%
b-5) Sale and distribution of household products (NACE 46.49 – Wholesale household goods)	1	5	20%
b-6) Sale and distribution of Home maintenance goods (NACE 46.74 – Wholesale hardware, plumbing and heating)	0	2	0%
b-7) Sale and distribution of intermediates (NACE 46.76 – Wholesale intermediates)	3	25	12%
b-8) Other:	4	19	21%

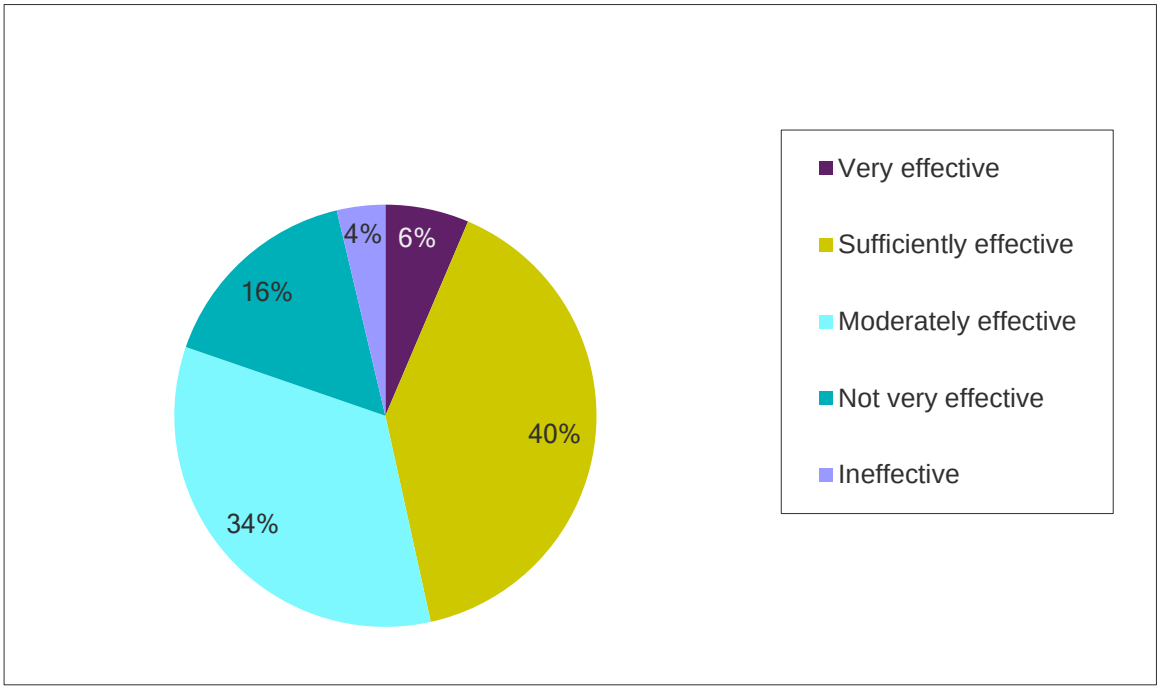
Number of responses: 188. The sum of responses in the table is higher than 188 because respondents were allowed to select more than one sector

Joint registrations

Communication within the SIEF (question 20)

The majority of respondents (80%) commented that communication within the SIEF is at least moderately effective, with 46% of the total number of responses indicating that it is sufficiently effective or very effective (Figure 2.15). Conversely, comparison with question 18 on challenges highlighted communication as one of the biggest challenges. This was an issue explored further within the interview phase to look at specific issues (see section 3.4). SIEFS by their very nature can be diverse and varied; however there were clear issues identified over clarity of roles and obligations of the SIEF members, particularly at update stage after a REACH registration number had been issued.

Figure 2.15 How effective is the communication and cooperation among joint registrants regarding dossier updates?



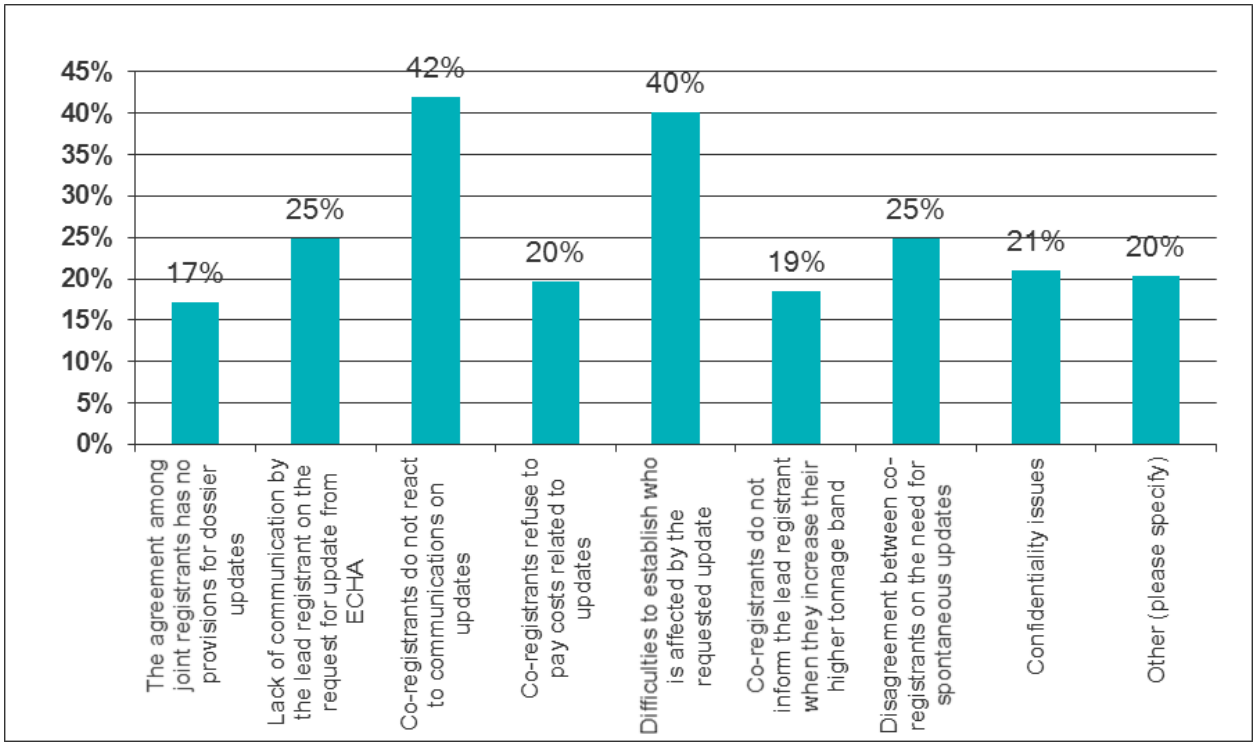
Number of responses: 187

Issues encountered with joint registrations (Question 21)

Question 21 asked the respondents to comment on what issues they had experienced when working in SIEFs as a member registrant. Figure 2.16 provides a summary of the responses provided. These responses highlighted that the main issues are establishing who is affected by the update, the lack of reaction from co-registrants with regard to updates and lack of communication from the lead registrants.

The issues highlighted by the respondents pose further questions outside of the scope of the questionnaire. Namely what happens to the SIEF after the original registration is completed? How frequently does the SIEF communicate for potential update activities? Who is responsible for monitoring for relevant information to update the REACH dossier? Is this the lead registrant, the SIEF as a group or individual registrants under their own efforts?

Figure 2.16 Issues in updating joint registrations



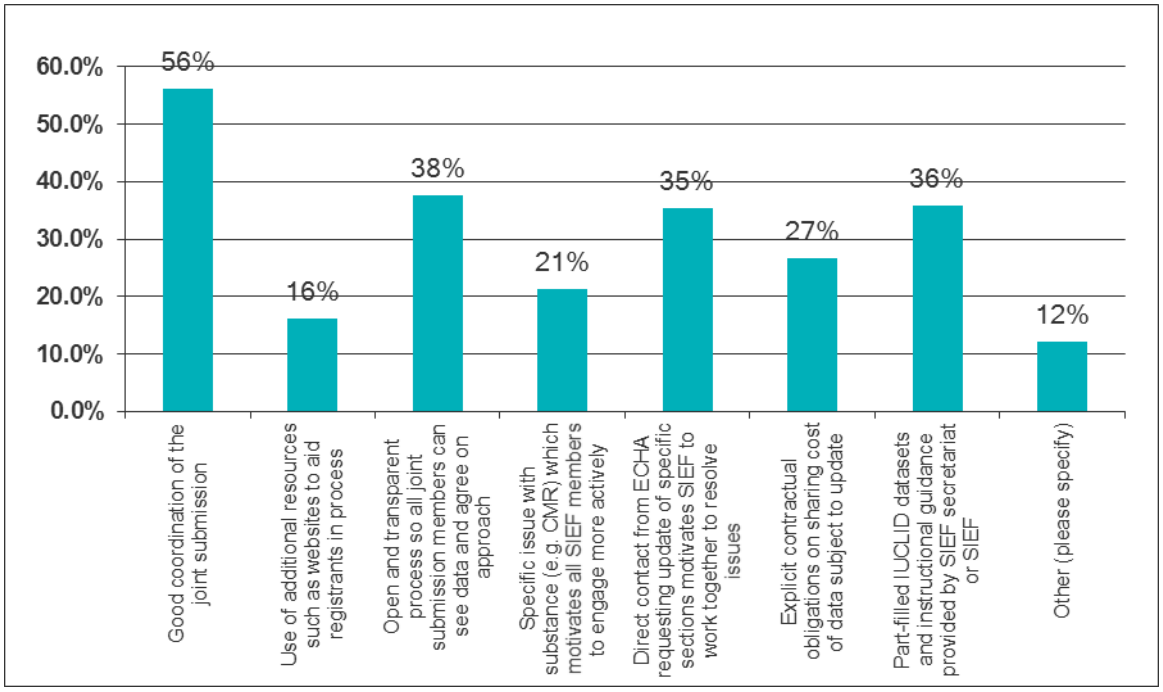
Number of responses: 157. Respondents were allowed to select all those that applied (i.e. the sum of percentages is above 100%)

Methods to improve collaboration (Question 22)

Question 22 provided a follow-on to the previous questions, and asked the respondents what positive actions they had experienced which had facilitated better collaboration. Figure 2.17 highlights the responses to this question. The highest frequency responses were that good communication (56% of respondents) and open and transparent processes (38%) were of key importance to help improve collaboration. However it is also interesting to note that one of the options that was selected less frequently (16% of respondents) indicates that the use of external websites to manage REACH registrations is not seen as important as any of the other suggested options.

The key message from this question seems to be that the important issues are a clear delineation of roles and understanding of who is affected by the REACH update process, and who is responsible for managing the update. Good communication and direction on these matters is of high importance to the respondents to aid this process and fully engage with others to complete their REACH update.

Figure 2.17 Good practice for successful dossier updates in joint registrations



Number of responses: 173. Respondents were allowed to select more than one option. As a result, the sum of percentages is above 100%

Incentives (Question 23)

Question 23 asked the respondents to rank the importance of a selection of possible incentives which would make them more likely to update their REACH registration dossiers. Each option could be ranked from having a high importance to no importance, as well as an option to state that the level of importance was unknown. Table 2.14 provides the summary of responses received to this question.

The option which respondents highlighted as having the highest importance as an incentive was easy to use IT tools. Other incentives which were ranked as of high importance included direct financial incentives, such as discounts on administrative fees for updates as well as greater awareness raising of the obligation to update in Article 22.

However, it is also of interest to note that mandatory updates received much fewer 'high importance' responses. Mandatory updates of REACH registration dossiers also received the highest number of responses in the 'no importance' category suggesting that the respondents did not favour this option.

Table 2.14 Possible incentives for updating the dossiers

Answer Options	High importance	Fair importance	Low importance	No importance	Don't know
1 Reputational options					
1a) Blame and shame; more visibility on ECHA's website	43	59	49	44	30
1b) Further recognition of those that pro-actively update; case study stories on ECHA's website	33	66	64	41	22
2 Awareness raising options					
2a) Greater awareness raising for Article 22 of the REACH Regulation (obligation to update)	52	85	44	23	20

Answer Options	High importance	Fair importance	Low importance	No importance	Don't know
2b) Voluntary programmes and commitments, certainty that the members of the joint submission will follow	22	80	68	31	18
3 Financial options					
3a) Direct economic incentives (e.g. discounted fees when updating to a higher volume with a compliant dossier)	69	75	40	21	18
3b) Penalties for failing to update registrations (e.g. where ECHA needs to place a direct request for update of dossiers)	44	70	50	29	28
3c) Use of a token system to control access to dossier updates	36	52	49	31	53
4 Regulatory options					
4a) More strict enforcement of Article 22 by Member State Authorities (obligation to update)	38	71	47	28	34
4b) Mandatory obligation to update on a periodic basis added in the REACH Regulation	29	62	41	58	31
4c) Easier-to-use IT tools for dossier updates, e.g. the ability to submit only the new and updated information, not have to re-submit the whole package. This could be offered online in REACH-IT, to save the IT burden of IUCLID.	122	63	23	14	12

Total number of respondents: 243. Note: number of responses, not percentages

2.4 Results of C&L inventory update questions

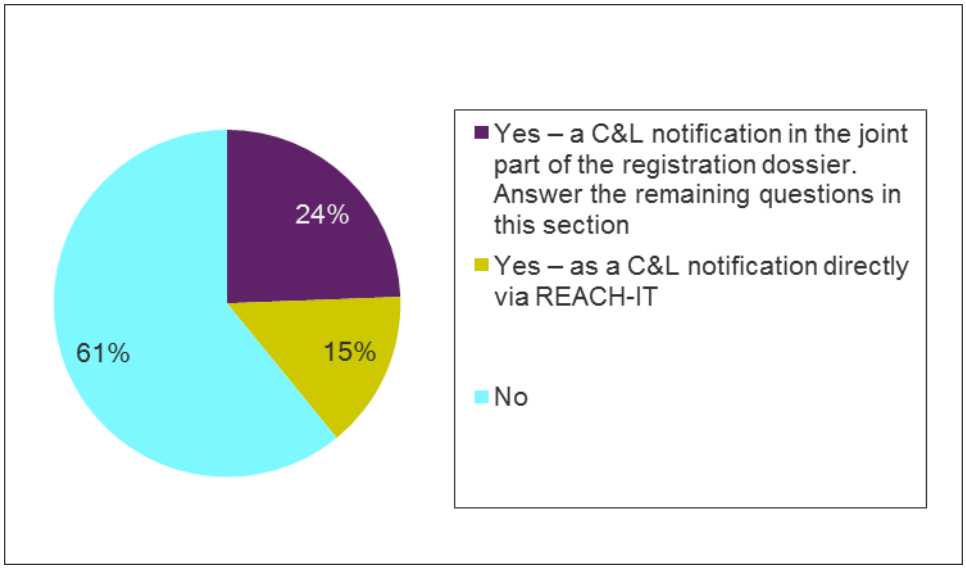
The second half of the questionnaire focused on the CLP regulation. Under CLP there is an obligation upon companies to notify their classifications for substances and mixtures to the C&L Inventory. As with REACH updates it is also possible for CLP classifications to change when new data becomes available allowing a re-assessment. C&L notification updates can be submitted as follows:

- Directly via the REACH-IT portal (ECHA website); and
- In the joint part of the registration dossier.

Questions 25-30 of the questionnaire focussed on issues relating to update of the C&L inventory.

Question 25 began by asking the respondents whether they had conducted an update to their C&L notifications. The response to this question illustrated that 61% of the respondents to this survey stated that they have not been involved in a C&L notification update. From those that have been involved, almost two thirds (24% of the total) were involved in submitting a C&L notification in the joint part of the REACH registration dossier. The rest (15%) submitted a C&L notification update directly via REACH-IT as illustrated by Figure 2.18.

Figure 2.18 Involvement in C&L notification updates



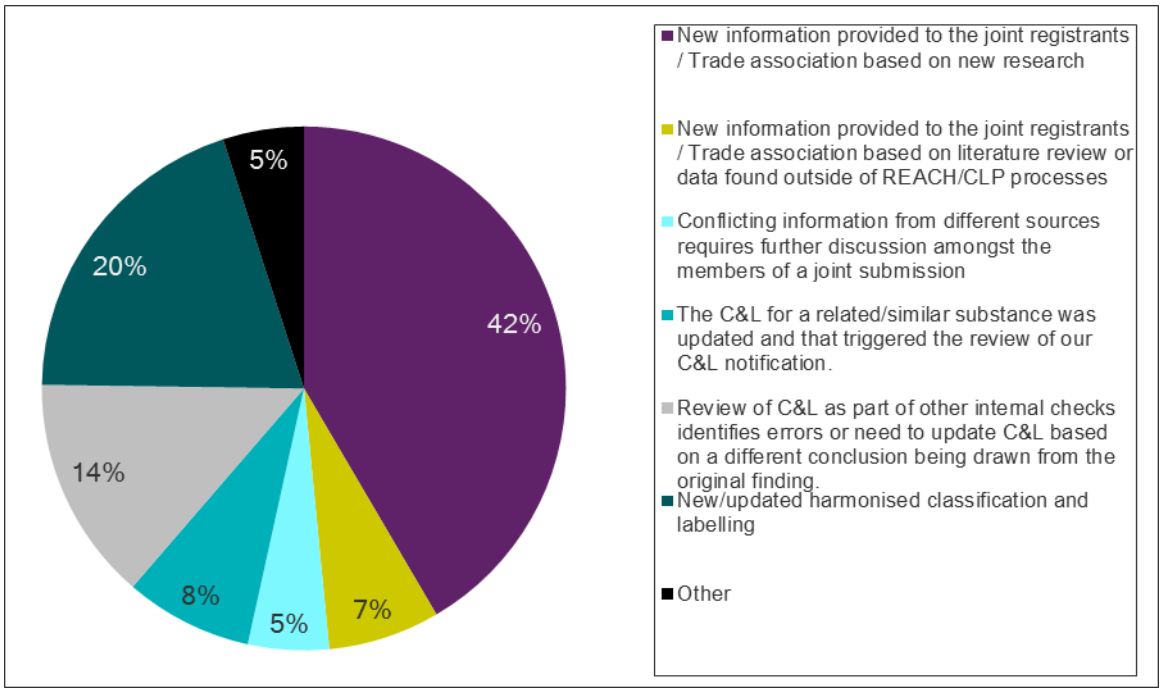
Number of responses: 238

Drivers for update of C&L notifications (question 26)

The respondents were then asked what they believed were the main drivers for why an update of the C&L notification would be needed. The main driver for these updates was, in most cases, new information provided to the joint registrants, either based on new research (e.g. following the results of testing proposals) or literature review/other data outside of REACH/CLP processes (49%) which affected the CLP classification.

Other drivers with a relatively high proportion of responses were new harmonised classification/labelling (20%), and review of the notifications as part of other internal checks and changes to other similar substances (14%).

Figure 2.19 Drivers for CLP updates



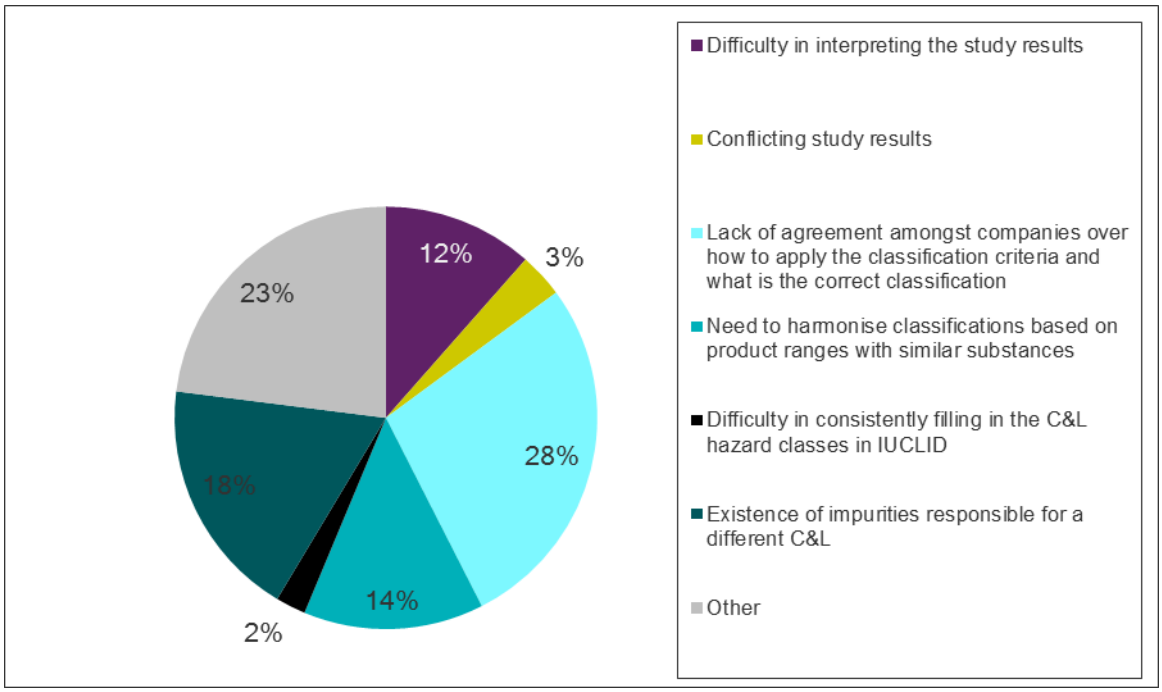
Number of responses: 101

Divergences for classification of the same substance (Question 27 and 28)

A significant proportion of respondents (59%) stated that they had seen divergences in the C&L inventory for classification of the same substance (question 27).

Based on these responses, the main reason for these divergences was the lack of agreement amongst companies over how to apply the classification criteria and what is the correct classification (28%). The rest gave a variety of other reasons, including the need to harmonise classifications based on product ranges with similar substances, existence of impurities or difficulties with the study results. A significant proportion of respondents selected 'other'. Among these, the variability of reasons specified was high. Some of the reasons included were: lack of knowledge and real data; lack of knowledge from notifiers about changes in the regulatory criteria; lack of interest in changing the CLP classification if there is new information; and that C&L notifications may be done by companies that have no data on the substance. Figure 2.20 provides a summary of this information.

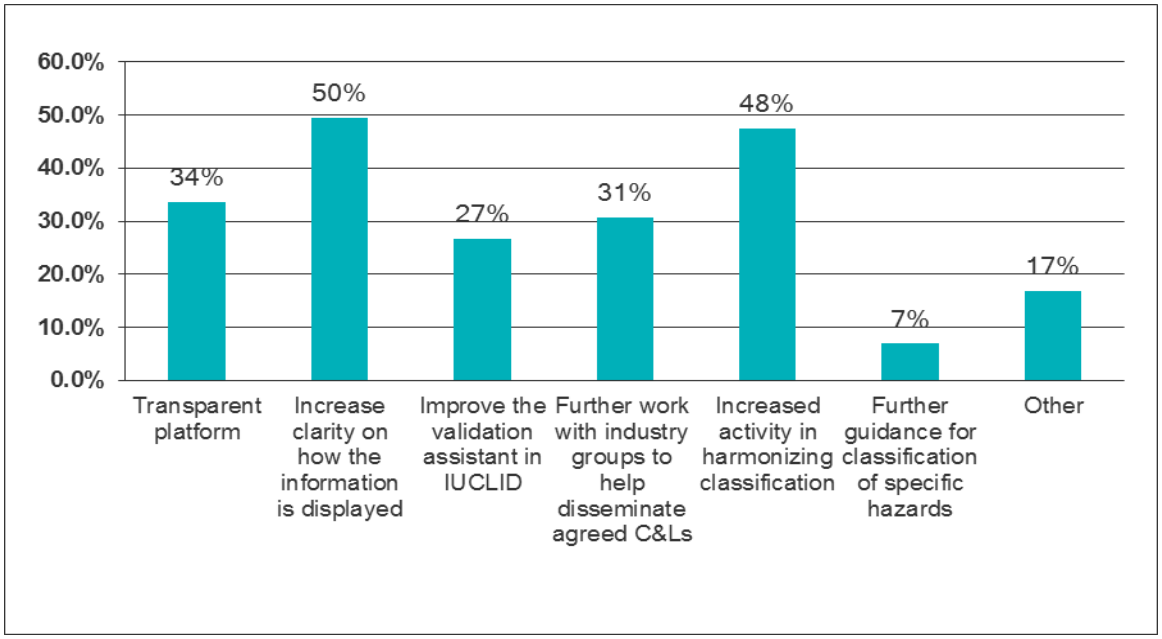
Figure 2.20 Reasons for divergences in CLP



Number of responses: 87

When asked about measures that could be used to tackle these divergences (question 29), responses suggested that the most useful measure would an increased activity in harmonising classifications and to improve the clarity of how the information is displayed in the C&L inventory. Also, a significant amount of respondents (34% of responses) suggested the provision of a transparent platform for notifiers of the same substance could be used to allow greater comparison of data. Very few of them considered that further guidance is needed. Figure 2.21 provides a summary of the responses to question 29.

Figure 2.21 Which measures would you consider to have the most potential to reduce the divergence in C&L notifications amongst registrants?

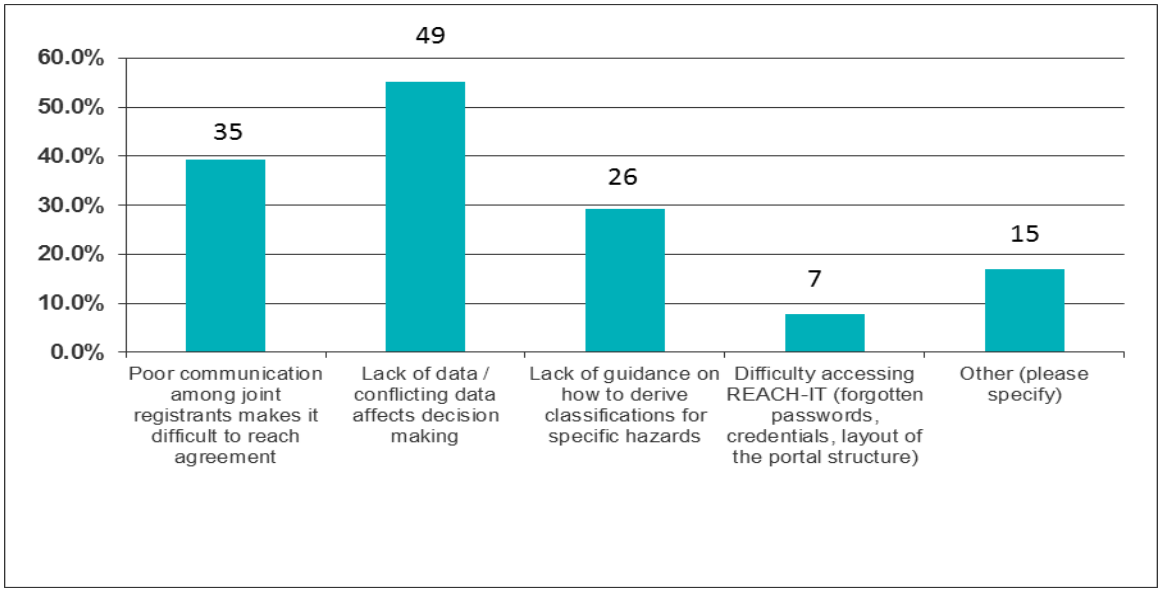


Number of respondents: 101. Respondents were allowed to select more than one option. Therefore, the sum of percentages is higher than 100%

Barriers to C&L inventory updates (question 30)

The majority of respondents highlighted three main barriers for providing updates to the C&L inventory, with the majority of the respondents mentioning the lack of data or the existence of conflicting data (55%), affecting decision making. They also mentioned poor communication or the lack of guidance (although few of them considered that guidance was needed to tackle divergences, as stated above). The difficulty to access REACH-IT was not perceived as a major issue. Those that responded 'other' (17%) provided a variety of barriers, but several of them mention the lack of agreement due to the presence of impurities. A summary of the responses is provided in Figure 2.22.

Figure 2.22 Barriers to CLP updates



Number of responses: 89. The figure indicates the number of times a company selected an option. The total number is higher than 89 because they could select more than one option. The percentages represent the proportion of companies that selected than option. As they could select more than one, the percentages will be above 100%

3. Results of phase II – stakeholder interviews

3.1 Introduction and overview

This section includes the feedback from the interview phase of the study. The development of the questionnaire (see Appendix A) from the first phase included questions giving the respondents the opportunity to volunteer to be included within the telephone interview phase. Following the completion of the questionnaire phase, the results were analysed and respondents were selected for interview taking into consideration a mixture of company size, role within the REACH regulation (manufacturer, importer, consultant, trade association, or consortium), geographic location and industry sector. This was done to maintain as wide a diversity of respondents as possible. In total 20 telephone interviews were conducted during May and June 2017.

As preparation for the telephone interviews a thorough analysis of the questionnaire results was completed. The overall study methodology intended to use the telephone interview phase to explore more deeply the trends and key messages that emerged during the questionnaire phase. Following the analysis of the questionnaire results and discussion with ECHA, a background paper was developed (see Appendix B). The background paper centred on four key themes from the questionnaire results:

- Benefits and incentives;
- Drivers;
- Obstacles; and
- Technical issues.

The background paper was provided to each of the respondents in advance of the interview to allow for preparation. The questions from the background paper were also used as a guide to help steer the discussion during the interviews together with the completed questionnaire for each individual. As part of the interview process it was also agreed with the respondent that the details of the interview would be anonymised and aggregated with all responses. This was done specifically to encourage an open and candid discussion to fully explore all of the issues that had been identified from the questionnaire phase.

The results within this section have been divided into the four main themes from the background paper with a discussion of the key issues and subject matter based upon the responses received. Each sub-section begins with a general discussion of the points raised which are salient to all respondents. Subsequently each sub-section also includes further parts detailing the issues which are relevant to specific categories of respondent, covering manufacturers and importers for both large companies and SMEs, and a category covering other stakeholders (consultants, trade associations and consortia). These further sub-sections are intended to help explore specific issues which face companies within different groups, in particular the SME category.

The discussion from the interview phase of the study has also been used to support the overall study conclusions (see Chapter 4) and recommendations (Chapter 5). A further breakdown of the respondents included within the interview phase is provided within Table 3.1.

Table 3.1 Breakdown of interview respondents

Company Size	Role within REACH regulation	Geographic location	Industry sector
13 Large sized companies. 4 SME companies. 3 Trade associations (representing multiple companies of different size).	10 Both Manufacturers and Importers 3 Manufacturers only 1 Importer only 2 Consultants 3 Trade associations 1 Consortium lead	Most respondents operated in multiple member states, but had head offices in: Austria, Belgium, France, Germany, the Netherlands, and the United Kingdom	Variety of industry sectors covered including: Oils and fuel; Metals; inks and dyes; solvents and organic chemicals; soaps and detergents; agrochemicals;

Company Size	Role within REACH regulation	Geographic location	Industry sector
			construction materials and water treatment chemicals.

3.2 Benefits and Incentives

General findings

This sub-section provides a commentary of the interview results for both the 'benefits' of maintaining an up to date REACH registration dossier, as well as the 'incentives' identified by the respondents for completing an update of the data within dossiers. This section also provides feedback provided by the respondents on options that could be used to further help incentivise REACH registrants in to updating dossiers on a more frequent basis.

Benefits

The results of the questionnaire phase of the study suggested that there was trade-off between the benefits of maintaining an up to date REACH dossier and the necessary effort and financial costs to do so (i.e. some registrants perceive that updates are needed only when there is either a commercial need or regulatory driver such as a direct request from ECHA). Therefore the interviews began by exploring the benefits of REACH registration and maintaining an up to date dossier through updates. Many of the respondents struggled to directly point to a strong financial benefit that had been received because of completing and updating a REACH registration. However there were a number of softer benefits which were identified by the respondents largely linked to improved health and safety and control of the substances that they manufactured or used. Table 3.2 provides a summary of the main benefits provided by respondents followed by a narrative that goes into more detail.

Table 3.2 summary of main benefits identified by interview respondents

Type of benefit	Description	Relation to REACH update
Improved health and safety – Data	Better data on substances to help understand the hazards and manage risks	An update dossier ensures all relevant data is included, particularly uses.
Improved health and safety - users	Greater visibility of end-users allows direct supply of relevant health and safety data.	Feedback relationship between users and manufacturer/importer to maintain dossier.
Improved health and safety - eSDS	Exposure scenarios within eSDS are of high importance. Improving the quality of dossiers means that the eSDS can also be better tailored.	New data can greatly affect the exposure scenarios, so a need for update is key to this process.
Substance control – impurities	Greater clarity on impurities and management of supply-chain as a result	Communication with suppliers on impurities within substances to update dossier.
Substance control - standardisation	Use of ECHA website to check classifications on goods provided by suppliers.	No specific relation to update. But if website is used in this way there would be pressure on registrants to make sure the classifications are correct and up to date.

One respondent highlighted that at the beginning of the REACH registration process, the data on their substance was poor. Working with others in the SIEF had been a rewarding process discussing with their counterparts and developing a definitive document for their substance. The process had greatly improved

the knowledge about the substance, including hazard and risk management. The respondent felt that the benefit to them was that they had a much greater understanding of the hazards and control of the associated risks. However, the same respondent also noted that a great deal of work and effort had gone into the development of the dossier which they now felt was quite complete. The respondent commented that they could see the need for updates but that these should be targeted and would likely occur on an *ad-hoc* basis. An annual updating process for example was considered as counter-productive and labour-intensive.

Another respondent identified similar benefits regarding knowledge and understanding. In this case the respondent came from a large sized company using distributors. The respondent commented that usually distributors are wary of passing on details of the downstream users for commercial reasons. The REACH regulation had allowed them much greater visibility of the downstream users and understanding of how their substance was being used. This aided dissemination of safety information and also meant that new uses could be identified. This would allow them to maintain the dossier with an accurate reflection of all uses, which was seen as being of high importance for health and safety as well as company reputation.

Other respondents commented on the benefits of REACH to manage the impurities within their substance. As part of the work of the SIEF and registration process there had been a great deal of discussion on manufacturing processes and impurities within their substance. Since the registration had been completed this was an issue on which they had continued to keep track. This included working with non-EU suppliers to review certificates of analysis and what impurities were present. The benefit of the dossier had therefore been that it had allowed them to identify where unacceptable impurities were present in their substance and put pressure on suppliers to rectify this issue. Updating of dossiers to keep track of these issues would therefore enhance this position and allow them a stronger bargaining position with non-EU suppliers.

Another of the respondents who worked for a company which both manufactured and imported chemicals gave a similar opinion. They stated that they had found the ECHA website (C&L Inventory) highly valuable to check the classifications on substances imported from outside the EU. This allowed them to work with non-EU suppliers to review and amend classifications where necessary. While a direct benefit of updating of dossiers could not be identified, the respondent suggested that there was a need for an up to date and accurate representation of the classifications on the ECHA website. In the cases where there was a wide variation in the CLP notifications, it was suggested that there should be removal of ‘incorrect’ classifications.

While the majority of the respondents were able to identify possible benefits from completing and updating a REACH registration, all agreed that these benefits were of lower priority or ‘nice to have’, rather than core to their day-to-day business functions. In part, this could make it difficult for health safety and environment (HSE) managers to convince their company directors to spend time and money completing an update. In other cases, the level of effort needed and difficulty to make an update, even for minor changes, meant that the respondents could be reticent in conducting such an update. Further discussion on technical difficulties is provided within section 3.5, but a number of respondents highlighted that they struggled with the REACH software (IUCLID) and that changes to the submission process (manual checks) had exacerbated this situation.

One further point raised by a respondent based within a trade association related to how the data within the dossier is used. The respondent noted that the REACH registration dossier can be seen (by ECHA and Member State Competent Authorities (MSCAs) as a ‘catch-all’ for all relevant health and safety data. Therefore, it is intended (by ECHA and MSCAs) that the dossier could be used by a wide range of stakeholders with different interests. Many parts of the dossier are highly technical, such as toxicological data on an end-point by end-point basis. This kind data is of value to researchers and regulators but for those working in industry, particularly SMEs (that have fewer resources) and downstream users, the data are presented in a way that is too technical and therefore meaning the data is not clear. To these stakeholders, it can be understood why they might not see the value or benefit of a dossier that is not useful to them directly. In these cases, the CLP classifications and exposure scenarios are of the highest value, because they make clear the hazards and risks in simple language. However, the quality of exposure scenarios is highly variable, and in many cases the full exposure scenarios are provided without tailoring (i.e. they are not summarised). This can create a situation for DUs where they do not understand the implementation of safe use in the supply chain, because the information they are presented with (in an eSDS) is too complex for them to use and understand, which can greatly undermine the whole process.

The respondent suggested that more could be done to 'sign-post' the dossier and make clear which sections would benefit which stakeholder groups. This way a wider audience could usefully access the dossiers and understand why updated data were needed.

A different respondent also picked up on this point with a further clarification. The respondent who is a manufacturer, noted that REACH is a substance focussed piece of legislation. However, they manufacture 'products' (i.e. their customers are buying named commercial products that can be essentially a single substance or a mixture of substances). Their customers are often formulating products and thus need to use data on all the substances in their product (which may be from different manufacturers) to create their own safety information (e.g. CLP for their product). The respondent felt that this was a great deal of work and effort and wished to reflect that options to make this process simpler should also be explored. Any update to a dossier affecting the chemical safety report, even if only a minor change can create a lot of additional work. This is a disincentive to dossier update.

The respondents also raised questions regarding when and why an update should be triggered. One respondent, representing a trade association commented that REACH had been integrated into their wider product stewardship duties. The use of a standardised approach to managing hazard and risk was greatly appreciated and this was seen as a key benefit of the regulation. However as part of the organisation's product stewardship duties they had a routine scientific analysis programme which ran on a four year cycle. This would produce new data on a periodic basis which could be added to the dossier. However, it could also be argued that the new data generated would not actually affect the results or conclusions, with the data having very similar values to what was already in the dossier. Therefore it posed the question of what additional benefits might be gained from updating a dossier. In cases where new data changed the conclusions, exposure scenarios or classifications a clear mandate for needing an update was obvious. However in other situations where this was not the case, the cost and effort to update the dossier would provide very little additional benefit other than a change of date on the dossier.

The same respondent also highlighted that where there was an ongoing product stewardship programme, these efforts would not be recognised by ECHA unless it resulted in an update. They commented that, to some extent this could be seen as unfair where the only indicator of data reviews was an updated dossier. Therefore, a registrant actively and thoroughly checking his dossier may conclude that an update is not necessary, while a much less thorough registrant might update their dossier with some relatively trivial information. To the outside world it would look like the less thorough registrant is more active in checking his dossier.

Incentives

The majority of respondents highlighted that they considered compliance with REACH as of high importance with many incorporating REACH into their health and safety management systems. The respondents also indicated a willingness to maintain and update REACH dossiers, chiefly for compliance issues, however all of the respondents indicated that they felt the financial costs and efforts to update REACH dossiers greatly outweighed any benefits their business might receive from maintaining updates. The incentives therefore typically related to cost and technical issues. Table 3.3 provides a summary of the incentives identified, with further commentary after the table.

Table 3.3 Summary of incentives

Type of incentive	Description	Relation to REACH update
Greater enforcement	Greater enforcement of the regulation to provide a level playing field	Respondents felt it hard to justify the costs of update when competing businesses did not act and were not penalised for non-compliance.
Brand recognition	Creation of a 'good compliance' scheme with a badge or logo that companies could use on marketing materials.	Following on from the point above, it was suggested a good compliance scheme could mark out those that do not make the effort to be compliant.

Type of incentive	Description	Relation to REACH update
Financial incentives	Suggestion of a rebate scheme based on ECHA admin fees for completing updates	Financial incentive to make the update process more appealing.
Letter of Access costs	Mechanism to limit or manage LOA costs, e.g. cap on toxicological data beyond a certain age	Costs and staff effort were identified as a barrier with the logical incentive to lower costs.
Guidance – dossier	A suggestion that part of the reason for why registrants do not see the dossier as an asset relates to accessibility and understanding of the data. The dossier could be made more accessible by 'sign-posting' which sections are most relevant to which parties	This would be a value building option, with the need to update as an indirect benefit of greater value attached to the dossier.
Guidance – eSDS	Quality of eSDS highly variable. A standardised template or examples of 'gold standards' could get more out of the dossier, enhancing value	This would be a value building option, with the need to update as an indirect benefit of greater value attached to the dossier.

The respondents raised an interesting point regarding compliance. There was a concern that REACH is not enforced in the same way across the EU, with some respondents feeling penalised that they had made efforts to be compliant where their competitors had not. This point was difficult to substantiate but multiple respondents pointed to an uneven playing field and felt that they would be more likely to make the effort to update dossiers if others in the same market were forced to do likewise. As an example one respondent from a multi-national company highlighted that the authorities in one Member State regularly complete site visits and checks for REACH compliance (and had checked that their dossiers were up to date). The authorities in a neighbouring Member State do not complete such checks, at least in the opinion of the respondent.

One respondent suggested that ECHA could create an endorsement scheme to highlight those that were compliant similar to a quality management system standard. For example, a 'REACH compliant' symbol could be used on company material (emails, letter heads etc) to reflect that registrants had duly made the necessary efforts to provide dossiers of high quality that were well maintained. However, how such a scheme could be implemented would need further consideration.

Other respondents highlighted that ECHA could adopt a scheme whereby the registrants get part of their ECHA registration fees returned if they complete an update within a certain period.

Other respondents highlighted that more focus and onus needed to be given to the roles within REACH, particularly around lead registrants and co-registrants. The respondent commented that it was well known in some cases that firms had tried to exploit the joint registration system by taking a lead role in the SIEF and becoming LR producing a poor quality dossier, which SIEF members had no choice in having to use and pay for. This meant that co-registrants were seemingly exploited by lead registrants with no or little intervention by ECHA. The respondent highlighted a good incentive for update would be to ensure that lead registrants were conducting business in the correct fashion, and for ECHA to take action where this was not the case.

Other respondents highlighted that Article 22 focuses on the obligations of the individual, whereas the REACH philosophy for "one substance, one registration (OSOR)", meant that the obligations for update were intended to be shared, with different roles between lead and co-registrants. A good incentive would be to simplify the update process for co-registrants, who would then only need to update tonnages, uses, or legal entities. On the other hand a manufacturer who had taken the lead role for a number of substances, noted that as a lead registrant, there are more obligations to update, than co-registrants, but that the SIEF were meant to support the lead registrant in that role. They had experienced problems with communications and some SIEF members were apparently no longer participating in the SIEF following registration. The respondent felt a good incentive would be either be an indication on the ECHA website to show which registrants had supported the update, or a token system where co-registrants could only claim access to the dossier if they had supported the update.

The following subsection summarises findings in terms of specific groups larger, namely firms that are manufacturers and importers, SMEs, and other stakeholders, such as trade associations and consultants.

The purpose of this is to focus on concerns for different enterprises for that may have access different resources and information and have a different perspective on dossier updates.

Comments from large sized manufacturers / importers

- Difficulty in identifying tangible benefits with a mixed set of responses from the respondents.
- Benefits identified tended to be 'soft' benefits such as improved understanding and visibility in the supply chain.
- In a number of cases the respondents highlighted the high costs of developing dossiers, even for what were perceived as low hazard substances.
- The respondents questioned specifically what kind of updates might be needed and the value of completing an update. While some respondents agreed that there was a need to maintain a high quality dossier, particularly if new data changed the conclusions, others highlighted that it was considered of lower priority.
- One point of interest highlighted already was that for at least one respondent they highlighted that within their role as a HSE manager they were keen to remain compliant and update the dossier wherever they could. However where his company had already spent millions of Euros developing the original set of dossiers, and where a REACH registration number had been obtained (denoting compliance). It was very hard for him to make the case to his executive board that they should allocate further funds to complete such an update.
- The main difference between the large and SME category stakeholders related to the available resources. For the large size companies there was possibly greater pressure to be compliant and to show that efforts were being made. However cost and effort to maintain such an update together with what were perceived as more limited benefits, made it difficult to make significant process. One respondent at a large chemical company highlighted that significant resources and man-power is given over to chemical compliance and health and safety. However REACH was only one component of the tasks dedicated to this department and therefore again it was a question of competing resources even within REACH, including the 2018 phase-in deadline, evaluations and need to update dossiers.

Comments from SME manufacturers / importers

- The SME category of stakeholder made up a smaller group of the total respondents involved within the interviews. However all four respondents within this category provided similar responses.
- Respondents indicated that they saw no benefits from REACH and that it only served to provide regulatory burden to their businesses.
- Difficulties in managing updates at the same time as the 2018 deadline, because of resource constraints.
- Reliance on consultants to help with REACH updates. Concerns that consultants seem to create work and that the process could be endless. There was a perception that it was better to wait for direct contact from ECHA to prompt them on defined aspects of the dossier to limit scope of work for update.
- Concerns that REACH is an anti-competitive piece of legislation. One respondent stated that it was often the case that larger companies took on the role of lead registrant because of the costs involved. They were then at liberty to charge inflated letter of access fees forcing smaller companies out of the market. The same respondent stated that for his business if the cost of being compliant with REACH was more costly than the profits made from selling his goods, he would simply stop selling those goods. This he believed was exactly what the larger companies wanted.

- As means of substantiating this claim the respondent pointed to a case where a letter of access fee included high costs for toxicological data that was 20 years old. Including inflation to current day prices. They felt the best incentive that would aid their position would be to make all toxicological data free after a set time period such as 12 years; this had not been done in their experience.

Comments from other stakeholders (trade associations, consortia, and consultants)

- The remaining stakeholders include trade associations, consortiums and consultants. For the former two stakeholder categories the responses received highlighted a strong understanding of REACH and the aims of REACH. This had included the development of product stewardship programmes around REACH, management of substances and proactive efforts to identify new data where needed to update dossiers. In this case all four sets of respondents highlighted that there had been some prioritisation on the efforts to identify/develop new data towards high hazard substances.
- A common theme to the responses also questioned when and why an update was needed. The general consensus among the trade associations and consortiums was that new data which changed the conclusions of a dossier were of the highest value and should be prioritised.
- The consultant stakeholder group largely reflected the opinion of the large size manufacturers/importers. However one further point made was that there needed to be greater clarity in order to improve the benefit. In their opinion the ECHA website needed to reflect not only when an update had been completed but also which sections of the dossier had been updated. The same respondent also commented that the quality of eSDS can be highly variable and that more guidance was needed on what a 'gold standard' eSDS should look like, or default templates provided by ECHA.

3.3 Drivers

General findings

This sub-section provides commentary on the drivers which influence registrants in updating their REACH dossiers. Table 3.4 provides a summary of the key issues which came up during the interview phase. A further discussion about these key points is provided after the table.

Table 3.4 Summary of key points for drivers

Type of driver	Description	Relation to REACH update
Safety in the workplace – CLP classifications	A high level of importance was given to CLP classification. The respondents felt that this was the most relevant piece of information for DSU	The need to agree on a harmonised CLP classification for given substances was seen as important. On the same basis new data that may alter the CLP classification could also be seen as a higher importance than other sections of the dossier.
Safety in the workplace – Exposure scenarios	Safety was seen by many respondents as being the key objective of REACH. That can act as a justified reason for updating dossiers.	The relationship between dossier, chemical safety report and eSDS is not always clear. Different stakeholders attach value to different components of the dossier depending on their role. However safety was seen as high priority by all and therefore closer ties between the dossier update process and use of outputs is needed to justify updates.
Commercial drivers – imperative to update	There needs to be a strong business case to warrant the deployment of funds and resources to complete updates.	This partly ties into the results from the questionnaire with respondents perceiving registration as the end of the

Type of driver	Description	Relation to REACH update
		process. An update has to be justified to warrant expending resources.
Commercial drivers - compliance	For some respondents updating a dossier would only be important if it was a compliance issue.	All of the respondents indicated a willingness to be compliant and work with the regulation. However a number, particularly SMEs, felt that the regulation is too burdensome for the rewards it might provide. Therefore updates would only be completed as a compliance issue, not a proactive management system.
Commercial drivers – prioritisation of resources	Respondents highlighted resource constraints; they will prioritise which substances they feel are most important.	Competing issues of the 2018 deadline, evaluation and need to update means that registrants indicated they would likely take a targeted approach and prioritise what they believed to be important.
ECHA intervention	Direct contact from ECHA as part of evaluations, authorisations, restrictions etc. was seen by a key driver by many. The SME group in particular rely on consultants and highlighted that they could not always justify expenditure unless it had a commercial and financial driver. They wait to be prompted by ECHA before acting.	One of the key drivers is direct contact from ECHA to request an update. For some respondents they see this as a cost effective way of managing REACH as ECHA will identify specifically what needs to be updated and in what timescales.
New scientific data	Proactive management programmes that look for new research data (e.g. scientific journals or industry data) or develop their own data as part of a product stewardship programme.	A number of the larger companies, trade associations and consortia had active programmes of work to track new data, or in some cases carry out new research based on identified weaknesses in the dossier.

A key driver for update of REACH dossiers that came through very strongly was update of classification and labelling (CLP). This was seen as a very important reason to update a dossier. New information that would affect the CLP classification was considered important since this is key and highly visible information on substances passed down the supply chain. This contrasted with the communication in eSDS which was generally viewed as important, but widely perceived to be generally ignored and not understood by DUs (especially small DU firms).

Nevertheless, safe use of substances, was reported as an important driver for update, particularly safe use in the workplace. Larger firms are understood to integrate REACH with systems that are built to manage substance (product) information for a large number of regulatory areas. Firms running such systems (for example SAP[4]), are managing product information and regulatory compliance in a wider context and REACH is just one of a number of regulatory systems that has to be complied with. With regard to this, a key observation was that it should be remembered that firms are managing *products* rather than substances (this is particularly the case for DUs which are manufacturing products from a number for substances) and therefore information needs to be gathered from a number of dossiers (e.g. for classification of mixtures).

Compliance was noted as a feature of the need to update dossiers; for all firms the need to comply with REACH was viewed as very important for them and for their customers. New scientific information that would give better understanding of substance properties was identified, but there were problems with understanding the actual need for additional data and the costs of dossier update (see obstacles below).

It was strongly expressed that update with new data should be done on a priority basis, and that priority should be based on hazard. Given the resources needed and the expense of adding new data, they suggested that this should be done if this makes a difference to the safe use of the substance. It was clear that actors in the supply chain were asking for much more clarity from ECHA on when a dossier needs to be updated and why

[4] https://www.sap.com/uk/industries/chemicals.html

and how to prioritise that. This was coupled with the need for more explicit clarity of Article 22 itself or at least the interpretation of Article 22.

There was a perception of lack of fairness in dossier updating with some consortia and SIEFs spending considerable time and effort to update dossiers, while others appeared to not be doing so and 'getting away with it'.

There was a strong plea for ECHA to become more active and take a stronger and more interventionist line on registrants that are alleged to have used data without permission of the data owners. Registrants had observed companies appearing to exploit REACH for their own commercial gain by charging high access fees for poor quality dossiers and unnecessary updates (e.g. for which the data owner would get cost compensation for a study added (but not really needed)). It should be noted however that this situation of adding data for the sake of financial gain was refuted by others on the basis of the large amount of resource needed to update a dossier would make it not worth the effort (that of course would depend on the value of the data added of course).

Finally, it was a limited view (specific to those with substances that are or could be substances of very high concern (SVHC)) that dossier update was driven also by a need to provide the best possible and up to date data set in order to fully present the hazard profile and use pattern of substances that could be of high concern (the motivation being to avoid potentially being placed on Annex XIV or in a restriction proposal).

Comments from large sized manufacturers / importers

- Key driver is communicating compliance and CLP.
- The need to avoid further regulatory attention from ECHA (e.g. compliance check).
- Mostly a burden to make updates - there has to be a commercial driver.
- REACH has made a link between data and actual safety in the workplace.
- REACH has not made the EU industry more competitive, but it has delivered a value in safety.
- MSCAs and ECHA are asking for too much data and this is not helping the decision-making on safe use.
- More balanced communication from ECHA is needed (ECHA appears to only to criticise industry) – ECHA should praise the successes and should distinguish the bad dossiers from the generally good.
- A main motivation to dossier update should be the adequate supply of data in order to do the assessment – i.e.to show if the substance is safe or not.
- Firms also providing data for other regimes such as PPP and biocides are used to spending a lot of money to support studies, other companies do not necessarily do that.
- REACH generates lots of work for consultants who can always find additional things that need doing at additional cost. Communication from ECHA on what to update carries more weight and is motivating.

Comments from SME manufacturers / importers

- There is awareness of suppliers with no REACH registration at all. This appears to not be enforced.
- Smaller companies cannot manage all the obligations of REACH without the use of IT tools because it is too much work to do manually. It is too complex. SMEs really need access and training to use such tools.
- It is better to wait for ECHA to demand an update, as it targets the specific things that ECHA requires.

Comments from other stakeholders (Trade associations, consortia, and consultants)

- Maintaining and ensuring the quality of the dossiers helps with argumentation regarding the need for (or not for) Authorisation or Restriction.
- For importers, there may be a particular problem as the importer may rely on their manufacturer for new data, and perhaps the non-EU manufacturer is less aware or willing to look for or provide new data to the importer.
- Consultants can help by advising the clients on the best way to stay complaint.
- Better to act proactively within the consortium to update dossiers, particularly where the data are not so good or is older. Letters from ECHA which advise on update areas (e.g. screening check) to highlight issues that might need looking at are welcomed.

3.4 Obstacles

General findings

This sub-section provides commentary on the obstacles which act as a barrier to registrants updating their REACH registration dossiers. There are a number of overlaps and correlations between the obstacles described by the respondents and the drivers detailed in the previous sub-section. These overlaps provided some interesting further insights to the mechanisms used in motivating the registrants to take action. Table 3.5 provides a summary of the key issues which came up during the interview phase. A further discussion about these key points is provided after the table.

Table 3.5 Summary of key points for obstacles

Type of obstacle	Description	Relation to REACH update
Software – IUCLID 6 (see section 3.5 on Technical issues for further discussion)	Respondents raised the issue of problems using and working IUCLID on several occasions, particularly the migration from IUCLID 5.6 to 6.0	Difficulties in driving and managing IUCLID were seen by many as a barrier which made them reticent to complete updates even when new data was available due to excessive time and effort needed.
Administrative burden	Respondents, particularly SMEs, felt that the data demands were excessive and that REACH presented them with a significant administrative burden for minimum reward.	This obstacle is potentially a reputational issue. If the registrants perceive REACH as an admin task it can be envisaged that they do not see the value in the process or the data it provides. This means they are likely unwilling to update unless directly prompted by ECHA (see drivers)
SIEF interactions – poor communication	Co-registrants highlight cases of poor leadership by lead registrants including rogue LRs which hinder the process. Lead registrants highlight it can be difficult to motivate support from the SIEF with some members of the opinion that registration is the end of the process and any update is not their problem.	This obstacle was noted to have two effects. The general issue relates to SIEFs breaking down post registration. Continued communication can become difficult. Both co-registrants and lead registrants have highlighted problems with each other's roles and obligations and an ambiguity over who is meant to do what.
SIEF interactions - roles		
Cost sharing	One issue also related SIEFs was cost sharing and difficulties in getting SIEF members to agree to cost sharing for new data when a REACH registration was in place.	This issue creates a significant issue over working together in SIEFs and which registrants can update when. Discussions over cost sharing could delay updates and take significant resources for staff time.
Consultants	Respondents, particularly SMEs, were reliant on consultants to assist them. Some were seen as very good, while	This obstacle in part relates back to the drivers. Registrants will try and minimise costs by waiting for ECHA to prompt

Type of obstacle	Description	Relation to REACH update
	others could be expensive and this meant that registrants were at their mercy.	them. ECHA requests usually detail specifically what is needed, and this means that the registrants can ensure that consultants work to a defined scope rather than having a broad remit.
Lack of enforcement	The respondents highlighted that there is not a level playing field and that it can be difficult to justify spending money on REACH updates when competing companies do not, and no punitive action is taken by ECHA or the MSCAs.	The perception that there is not a level playing field creates an atmosphere of anti-trust, meaning registrants are unwilling to update dossiers unless they can see their competitors are also undertaking the same efforts.
Poor communication in the supply chain	Some respondents highlighted difficulties in confidently knowing how their substance is being used. This can affect the uses component of the dossier	One respondent highlighted the difficulty in removing obsolete uses from dossiers because of lack of visibility in the supply chain and fear that removing obsolete uses could create liability issues.
Lack of guidance from ECHA	Some respondents highlighted that Article 22 is aimed at the individual but that REACH registration works within the SIEF. This creates ambiguity over who should act when. Respondents indicated that they needed ECHA to provide guidance on what is needed by whom and by when.	This obstacle relates to other on communication and roles.

It was clear from all respondents that the administrative and resource burden of updating dossiers was a major obstacle to (regular) dossier update. Considerable effort and organisation is needed to coordinate efforts for even fairly minor dossier updates (some quantitative estimates were given, see below). In particular, respondents were very surprised (and even angry) that ECHA should choose to perform major updates to IUCLID during the phase-in process. Migration of data to updated versions of IUCLID was reported as time-consuming, difficult and unnecessary. It was the view of some that this (updating of IUCLID) was serving largely ECHA's desire for more and more data in a format that ECHA could automate, rather than helpful additions for registrants. While the utility of IUCLID was generally understood, updating (IUCLID) at a time when registrants are already very busy with dossier updates and also compliance (2018) deadlines was adding additional administrative burden onto generally small regulatory affairs teams that are already overburdened. This could suggest that there is greater need for transparency and explanation not only around the timetable for IUCLID updates; but also why the updates are needed and what purpose new data requirements fulfil.

Another obstacle raised by the respondents was over roles and obligations within the SIEF. One respondent highlighted that many co-registrants do not necessarily have additional useful information that they can share with lead registrants. In this case the co-registrants tend to only focus on tonnage data and legal entity issues. The opinion is therefore it is the lead registrant's duty to update all other sections of the dossier. Therefore, while the lead registrant's dossier may be updated, the co- registrants' dossiers are often not updated, e.g. in the case of >1000t substances where no tonnage band change occurs. Conversely lead registrants acknowledge this obligation but refer back to cost-sharing requirements and need for the SIEF to collaborate. Following registration communications can break down and it can be difficult to get co-registrants to support the update process either with new information or funds to support additional research as there is no regulatory driver to require them to do so.

It seemed that due to the technical needs of dossier preparation and update that technical consultants were being hired (indeed some of the respondents for this study representing registrants were consultants). It was commented that this is expensive and it was hinted that consultants can sometimes make work for themselves by suggesting work on dossiers that is not absolutely necessary (the other view expressed (although not as much) was that consultants have also helped to give good advice on dossier updates).

A concerning area was the apparent exploitation of REACH by some lead registrants, apparently pushing to take the lead on a substance to produce a poor-quality dossier for which a high LoA price was being charged

(the costs of pursuing unfair pricing was viewed by some as not worth the effort). In addition, it appeared that some LRs were suggesting the addition of studies (that were not necessarily required) apparently for financial gain (because they could charge the consortium for the data). As mentioned above, the use of data for which registrants did not have access rights was raised, as was the lack of response from ECHA to reported transgressions.

Some respondents have had difficulties with getting good information on uses from the supply chain (due to commercial confidentiality issues). There were also problems to get agreement to the removal of obsolete uses, and a frustration of SIEF leads to motivate co-registrants to act and supply relevant information. On the other hand, SIEF members could be frustrated by the lack of transparency on updates that they were having to make a financial contribution for, because they could not see how the dossier had been updated. This would be the case where the lead registrant owns the dossier and the co-registrants only have permission to quote that they are covered by the dossier for REACH registration. In some cases the registrants do not receive a copy of the dossier as part of LOA fees or update activities. The ECHA website indicates an update has taken place but does not provide further information on what the specific updates have been.

Comments from large sized manufacturers / importers

- Updating an intermediate dossier has no benefit for customers because there is no information being passed along the supply chain.
- Registrants are often dependent on the consortium for information on when and what to update - if communication is poor or not clear it makes it difficult.
- Implementing Regulation 2016/9 legislation means ORs challenge the LR for each and every cost for dossier update - this means hundreds of emails etc. that all require responses. Updating is very expensive and a large drain of resources - need consultants and lawyers – which is very expensive and is of little commercial value.
- Main obstacles identified to preventing update of dossiers were three-fold, firstly issues with finding sufficient internal resource, secondly with data-cost sharing and finally with communication between other registrants.
- For a full dossier, an update would take around 2 weeks, due to the need to check every end point, in the migration from IUCLID 5.6 – 6.0 this is a lot of work.
- Where there have been changes of classification and a need for a full review of the data this cost the co-registrants c. €30,000 in total. The reason being a change in classification also resulted in the need to update the CSR and all the exposure scenarios.
- Major problems with communication within the SIEF.

Comments from SME manufacturers / importers

- Reported a lack of guidance from ECHA on reasons to update.
- Problems with one or two companies staking the claim to be LR - but have little data and done no work – they control the cost for poor quality dossiers.
- IUCLID 6 - updating from version 5 to 6 has been very troublesome. ECHA assumes high level of knowledge in IT – e.g. editing the registry etc. is difficult. Many are having to employ consultants to help – which is an additional expense.
- Resource constraints due to changing the IUCLID software at the time when registrants are getting 2018 dossiers in order.

- Heavy demands for data on low hazard substances[5], this has a knock-on effect for supply and demand, because if the cost of registration is more expensive than the value of the substance, they simply will not register. This has serious consequences for the market.
- .Onerous data demands and animal testing stifle innovation and production of new substances.
- Resource and cost constraints. For 10 – 100 tonne substances, often a small SIEF size including SMEs with concerns on cost, They can use read across, but there is no guarantee that it will be accepted, if it is not accepted then they have to do the testing and this is can be really very expensive.
- Frustrated by the level of information requirements from ECHA on the one hand and by communication on LoAs for SIEF managers on the other.

Comments from other stakeholders (Trade associations, consortiums, and consultants)

- The wording of Article 22 is not clear (i.e. under what circumstances to update).
- Perception from respondents that the current system is unfair, because for those that make the effort to identify new data and update their dossier they usually have more scrutiny from ECHA, and more work is needed.
- Greater clarity and communication from ECHA is needed on how dossiers are selected for assessment.
- Persuading the co-registrants to delete uses once they become obsolete is important is because specific types of uses can be the deciding factor as to whether a given substance is added to the SVHC candidate list or not.

3.5 Technical issues

General findings

This sub-section provides commentary on the technical issues which hinder the REACH update process. While much of the discussion provided by the respondents focussed on IUCLID as the main software tool to develop and update dossiers; there was also a wider discussion on other REACH software tools, REACH-IT and data management systems. A summary of the main points raised by the respondents is provided within Table 3.6 with further commentary after the table.

Table 3.6 Summary of main technical issues which hinders REACH updates.

Type of technical issue	Description	Relation to REACH update
IUCLID – Migration issues	The respondents commented that new versions of IUCLID create a lot of work, with the migration from IUCLID 5.6 to 6.0 being particularly labour intensive	Respondents stated that level of effort and work required to do updates where a migration from 5.6 to 6.0 was needed had meant that they were reticent to do the update.
IUCLID – New data sections	Respondents commented that IUCLID 6.0 had a number of new data fields which required population. There was a concern raised that the data demands of IUCLID now go beyond what is set down in the regulation.	New data requirements make updates more difficult as not all respondents were aware of the new requirements before beginning an update.
New manual checks	New manual checks have been added to the REACH submission process. There	Alongside the automated dossier checks a new round of manual checks are

[5] The issue with 'low hazard substances' is complicated by the need to create a dossier and gather data in the first instance to define that a substance is in fact low hazard. Therefore there can be an issue where it is difficult to corroborate whether a substance is low hazard without having the data to make that judgement.

Type of technical issue	Description	Relation to REACH update
	were comments that these are applied inconsistently which makes registrants apprehensive about completing an update.	included. However there are concerns about compliance and inconsistency in checking.
IUCLID – Cloud services	The majority of respondents welcomed the new cloud based resource, but highlighted that with previous versions of IUCLID migration to new versions had warranted the need for manual corrections. Would this be the case for the cloud also?	The cloud based version of IUCLID should resolve previous issues with version control and migration of dossiers to newer versions.
Selection of IT tools	There was a suggestion that there could be too many different tools for REACH based activities, a need to simplify was highlighted to get the best out of existing tools.	While IUCLID is the main tool for dossier development and update, a range of other tools exist for related components. The suggestion was that there could be an overabundance of tools which complicates the process.
REACH-IT	The respondents spoke positively of REACH-IT v3.0, noting that it was a good improvement and easy to navigate. However there were questions on why the website was only available in business hours and why emails cannot be forwarded on to direct accounts.	The REACH-IT website allows some additional functionality not covered by IUCLID. The website was perceived as useful by all respondents.
Data management systems	Data management systems were highlighted as being of high value. However they work best for larger datasets (more substances). For SMEs with a limited number of substances other options may be more appropriate.	Data management systems may be needed to help identify new data and help track existing substances.

The results of the questionnaire highlighted that there was a delicate balance between the benefits and incentives for completing a dossier update vs the financial cost and staff effort needed to complete such an update. To encourage a more proactive response from REACH registrants, it was suggested that there needed to be a set of options to maximise the benefits and incentives while limiting the costs and staff effort as far as possible. The preceding section has already provided a detailed discussion of the obstacles and methodologies to avoid such obstacles. However based on the results from the questionnaire there was a clear need to include specific focus on technical issues as a separate theme. This was on the basis that technical issues were repeatedly raised by the respondents in the questionnaire results.

The respondents who took part in the interviews primarily focussed on technical difficulties with IUCLID. However the discussion was expanded to look at other technical issues also. For IUCLID the biggest technical difficulty raised by all of the respondents was the update of IUCLID to newer versions and the need to migrate dossiers. A large number of the respondents interviewed stated that the migration from IUCLID 5.6 to 6.0 in particular had created a great deal of additional work and staff effort for registrants when migrating their dossiers. This was in part because the structure of IUCLID 6.0 was very different to 5.6. Respondents also highlighted that the newer version also now included new data fields which had to be populated. One respondent raised a comment in this regard that they had concerns that the IUCLID 6.0 data requirements now went beyond what was required in the REACH regulation. This trend of increasing data requirements had eroded the confidence of the respondents interviewed, the consequence being that they now attached less value to the dossier. There was also a response from the SME stakeholders that the REACH dossier had become overly burdensome because of data demands which they felt were not necessary.

A different issue raised by a respondent at a large sized manufacturer and another at a trade association related to new ‘manual checks’ now included as part of any data submission. Previously the dossier submission process triggered automated checks which could be verified using the technical completeness checker before submission. However the new manual checks appeared to be applied inconsistently. One

respondent commented that they had submitted two similar dossiers within a few weeks of one another making use of the same waiver, where one had been accepted and the other rejected because it failed the manual checks. This lack of consistency meant that registrants were reticent about updating a dossier in case it failed on a check which could not be predicted before submission.

Another respondent at a large sized manufacturer highlighted that there had been many updates to the IUCLID dossier in the past few months, highlighting the switch to version 6.0 in particular. The respondent highlighted that the greatest thing needed by all stakeholders at this time was a period of stability. The respondent highlighted that the 2018 phase-in deadline would likely be very challenging for many people, particularly those in SMEs. He therefore asked that there should be no more IUCLID updates until after the 2018 phase-in deadline had passed.

As part of the same discussions all respondents were made aware of ECHA's plans to launch a cloud based version of IUCLID which would auto-update. This should alleviate the previous issues with version control and migration to newer versions of the software. The response from the respondents on the proposed cloud based system was met with mixed opinions. While some respondents welcomed the addition of a cloud based version, a particular merit being that it would no longer need to be hosted on a physical machine. Others highlighted that with previous new versions and migration of dossiers there had always been bugs which had to be manually fixed by the registrant post-migration. If a cloud based resource were used including automatic updates would there also be assistance for quality control checks?

One respondent from a trade association highlighted that the migration of IUCLID to newer versions had created a great deal of additional work and frustration from their members trying to update. It was suggested that ECHA could provide some kind of help desk, possibly with a telephone number people could call for support in the weeks or months following an update. Additional support from ECHA after an update had been completed could help alleviate much of the additional work and frustration of registrants.

The same respondent also raised a new issue regarding IT tools in general. As part of the REACH dossier development process ECHA has developed a tool called Chesar which can be used to help populate the chemical safety report from the dossier. In the respondent's opinion they found Chesar difficult to operate with a lot of manual edits required on top of the tool. Another respondent from a manufacturer commented that the new version of IUCLID did not work well with Chesar. They had preferred to use the Chesar from IUCLID 5.6 with the dossiers from IUCLID 6.0 and then manual edits afterward. The respondent from the trade association commented that in their opinion more specialist IT software solutions to manage REACH data are not always helpful. Care was needed to decide when an IT tool was really needed. A better solution could be simplified guidance to aid registrants develop what was needed.

During the same interview the point was raised that exposure scenarios within eSDS are highly variable in structure and quality, and this in part reflected a lack of harmonisation and understanding from registrants on what was expected. A more standardised approach through 'gold standard' examples of good eSDS or even standardised templates would be very useful and help reduce effort.

Another respondent commented that in their opinion the Chesar tool is really designed for organic chemicals and does not work very well for inorganics. In their opinion a tool called 'MEASE' was better suited for use with inorganic chemicals when developing the chemical safety report.

The respondents also commented on the REACH-IT website which had recently been migrated to version 3.0. The majority of the respondents commented that the new version of the website was an improvement and easy to navigate. Others however asked why the website was only available during business hours, being closed on weekends and public holidays which they felt was counter-intuitive to business. One respondent from the SME stakeholder group highlighted that REACH is only a small part of their work and so often they do not check the REACH-IT website to see if new messages had been received. A question was raised on why emails could not be sent directly as it would mean they were more likely to take action.

Alongside the REACH centric IT tools there was also a discussion around data management tools and how useful they were. The respondents were told that the results from the questionnaire noted only limited use of such systems. The response from respondents highlighted a clear split in opinions for larger companies, trade associations and consortia all felt that they were extremely important. This was on the basis that when working with large data-sets, either because of many substances to be registered, or when leading a SIEF with many members a data management system is needed. The SMEs felt the need for data management

systems would be overly expensive with only limited benefit given that they only had a small number of substances which needed to be tracked.

Comments from large sized manufacturers / importers

- The majority of the comments from large sized manufacturers and importers were on technical issues relating to IUCLID, particularly the migration from IUCLID 5.6 to 6.0.
- There was a call from one respondent for a period of stability and a promise not to update IUCLID again before the 2018 phase-in deadline as it was felt each new version of IUCLID had created a great deal of additional work and effort for the registrants.
- The main difference between the large sized companies and SMEs related to their respective roles in the REACH process. The majority of the large sized companies manufacturing or importing substances developed their dossiers in-house.
- The large sized companies highlighted significant efforts and possible technical difficulties in developing CSRs and eSDS. This also included further updates and revisions to CSRs and eSDS should the dossier be updated. This could be triggered even where there had been minor changes, for example one new toxicological study altering the toxicological endpoint could require the entire CSR to be amended for each and every use where the endpoint was relevant.

Comments from SME manufacturers / importers

- All of the SME respondents stated that they relied upon consultants to develop and update dossiers under REACH due in part to lack of technical capability but also time constraints.
- SMEs have only very limited resources and technical capability so rely on consultants to assist them.
- Many SME representatives commented that they found IUCLID too complex and difficult to drive themselves.
- External training on IUCLID would not benefit SME representatives as they would infrequently use the software and frequent updates to the software would mean training quickly became obsolete.
- Infrequent updating of dossiers usually created migration problems between old and newer versions of IUCLID and made the update much more difficult and costly.
- Concerns from SMEs that the complexity of the system favours large sized companies and creates an anti-competition situation where SMEs are ill placed to keep up with compliance compared to bigger companies.

Comments from other stakeholders (Trade associations, consortia, and consultants)

- Very similar responses to large sized manufactures and importers.
- One additional comment from this stakeholder group was a request for greater flexibility in the IUCLID dossier, particularly for toxicological data. In this case the respondent from a trade association noted that they had a lot of valuable legacy data they wished to include but the format and structure of IUCLID meant that had to carry out a great deal of extra work to get the data into a suitable format. The respondent suggested a possible button for legacy data which would then allow the IUCLID formats to accept data in a more flexible format.

4. Conclusions

4.1 Key results from the study

Introduction

This chapter provides a further discussion of the overall results from the study, including the identification of key issues which should be addressed by the recommendations (see chapter 5).

The basis of the questionnaire development and subsequent themes for the background paper (see Appendix A and B respectively) explored four main topics with the respondents, namely the benefits, incentives, drivers and obstacles to managing update of REACH dossiers.

These topic areas were targeted as part of the approach to address the study objectives and understand why registrants do or do not update their dossiers. The responses to the questionnaire which were further elaborated upon by the interviews has identified specific issues that fit within these topics, namely:

- The role of REACH registration, and perception of registrants on their obligations under REACH;
- The perceived benefits of the REACH regulation to the registrants and wider supply chain;
- Role of mandatory versus voluntary updates;
- The balance between cost and effort to complete updates versus the benefits of doing so;
- Identification of when and why an update is needed;
- Understanding of roles and obligations under REACH, including SIEF interaction, cost-sharing, and responsibility for updates;
- Resourcing available to contribute to REACH; and
- Technical issues which affect willingness to act.

The remainder of this chapter explores these issues under the context of benefits, incentives, drivers and obstacles.

Benefits and incentives of updating REACH registration dossiers

Introduction

Article 1 of the REACH regulation states that the aims of the regulation are:

> *"to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."*

Furthermore under the philosophy of "one substance; one registration", and creation of substance information exchange fora (SIEFs), there is a mechanism put in place to encourage registrants to work together to aid the development of the REACH registration dossier and have fruitful discussions on the nature of the substance under review including agreement on hazard classification and risk management measures under the Chemical Safety Report.

The tangible benefits of the REACH regulation to meet the aims of Article 1 are therefore two-fold. Firstly the development of information on chemical substances defining uses, hazards and risks as a collective group of manufacturers/importers within the SIEF. This would lead to a single representative registration per substance (save for out-opts).

The second tangible benefit of the REACH regulation to meet the aims of Article 1 is the application of this data-set as a dissemination tool across the supply chain (in the form of eSDS for hazardous substances

manufactured/imported in volumes of 10 tonnes or greater) so that downstream users actively using the substance can take the necessary actions to protect human health and the environment.

Therefore the imperative need to update dossiers would be to ensure that the dossier is accurate and of high quality so that all hazards are correctly identified and risks managed. This could be seen as being particularly important where the uses of a given substance may evolve over time.

Based on the results from the questionnaire phase and the interview phase it was clear that the respondents have mixed views and opinions on the role of the REACH dossier, its inherent benefits and why there would be a need to update the dossier. These mixed opinions highlighted that to some degree the aims of the regulation are not fully understood by all, and in particular for the second component on dissemination of the information in the dossier in an effective way does not always happen.

The role of REACH registration, and perception of registrants on their obligations under REACH.

The REACH regulation has put in place a mechanism to aid the development of substance dossiers and communication of the dossier to ECHA via dossier submission. This process in most cases involves the creation of a SIEF with a lead registrant to act as facilitator and co-registrants who support the lead with data for dossier development and cost-sharing aspects through the letter of access fees. The culmination of this process is the registration itself and issue of a REACH registration number to the registrant.

The responses from both the questionnaire and the interview phase highlighted that, while a great deal of onus is placed on the registration and registration number as means of demonstrating compliance; many within industry see the registration as the end of the REACH process. This can mean that post-registration the SIEF breaks down and that communication between SIEF members ceases. Additionally based on the interview phase it was clear that different respondents have managed the issue of updates in different ways. For some the lead registrant planned for updates as part of the letter of access fees, for others such as trade associations and consortia there have been ‘top up fees’ and managed programmes of work to identify new data and complete updates.

However, while many in industry do perceive the registration as the end of the process, it has also created problems. The interview respondent’s highlighted cases where members of SIEFs had refused to provide further support for update because they already considered themselves compliant. Another respondent highlighted a case where acting in his role of HSE manager he had identified new data to aid an update but needed permission from his executive board. In the executive board’s perspective where considerable funds and time had been spent on the original dossier and a REACH registration number was in place, it was hard for the HSE manager to make a business case as to why further funds should be made on updating the dossier.

Interestingly there were also examples, primarily within the trade association / consortium stakeholder groups, where efforts had been made to encourage the view that registration is the beginning of the process, not the end. This included the development of product stewardship programmes which integrated REACH into that process and had planned programmes for update. It should be made clear that this would have required careful planning and resources. The SME respondents highlighted that they had very limited resources and therefore it is possible to understand how such product stewardship programmes would need to be led at SIEF or consortium level for the SME group.

The perceived benefits of the REACH regulation to the registrants and wider supply chain.

The questionnaire phase included questions on benefits, which were also further explored during the interviews. During the interview phase it was clear that the respondents struggled to identify tangible benefits of updating dossiers which would add direct value to their business. However a number of softer benefits were identified, including improved understanding of the substances they use, better visibility of the supply chain, particularly downstream users. The REACH regulation had also empowered some, giving them a stronger position to work with suppliers on impurities within substances (particularly SVHCs), as well as means of comparing the CLP classification on safety data sheets against a robust reference source.

However all of the respondents suggested these identified benefits of the REACH registration dossier were lower priority to their day-to-day business, and that the costs of REACH registration did not really justify the benefits received. This meant that the desire to complete updates of dossiers was somewhat diminished.

This position was exacerbated by a number of obstacles and technical difficulties (described in more detail later in this chapter), meaning that the potential for voluntary update of dossiers was less likely.

The SME category of stakeholders held a more negative position feeling that the process for them had been particularly burdensome with little or no obvious rewards from having been compliant. There was also a suggestion from one SME respondent that the mechanism created by REACH favoured bigger companies and that there could be an anti-competition issue where larger companies charged excessive fees for letter of access forcing SMEs out of the market.

Another key point raised regarding benefits was the role of the dossier itself. The point made was that the dossier acts as a catch-all of information for all possible stakeholder uses. It contains highly technical information which would be ideally suited to academics and regulators, for most downstream users this information is too detailed and too technical to be effective. For industry users and in particular the downstream users the CLP classification and exposure scenarios are of the highest interest because they detail clearly and simply the hazards, risks and risk management needed.

The interview results suggested to some degree that this aspect was partly lost with much of the focus on the dossier itself and the data demands to ensure a high quality dossier.

Role of mandatory versus voluntary updates

The questionnaire phase included questions on incentives to promote the update of dossiers. The results from this question suggested that the biggest incentives to aid update relate to financial incentives such as rebates on ECHA admin fees and stricter enforcement of the regulation to ensure a level playing field. The option to make updates mandatory on a fixed period basis was rated as a less desirable option. The interviews explored these topics in more detail.

The respondents indicated that they had concerns regarding a level playing field; highlighting that it was difficult to justify spending significant funds and efforts on updates when they could see competing business did not do this with no punitive measures implemented. A stronger enforcement of the regulation to create a level playing could encourage respondents to complete updates voluntarily. An example provided by one respondent at a multi-national company highlighted national authorities pro-actively completing site visits and checks that dossiers are in place and up-to-date, while the national authorities in a neighbouring Member State did not. However all of the respondents highlighted the efforts needed for updates and that the need would have to be justified to warrant them doing the work.

One interesting point was identified regarding mandatory updates. While the questionnaire suggested it was less desirable, the interview respondents highlighted that the biggest issue for them was two-fold. Firstly a clear and simple mandate to understand specifically why an update was needed and what should be updated. Secondly because all businesses need to manage cash-flow there is a need for sufficient warning to allow them to plan and set aside resources to meet their objectives. In this regard a mandatory deadline for updates could be beneficial as it sets a clear and simple message of what is needed and by when, with the possibility to plan for the work. Additionally where the REACH registration number denotes compliance against the regulation, there is no regulatory driver to enforce updates.

Summary

The responses provided within the questionnaire and interviews highlighted a number of difficulties and issues around how benefits of REACH registration dossiers are perceived and why update of dossiers is important. This included a perception that the registration is the end of the process. Difficulties in identifying roles and responsibilities of registrants to work together on updates, and focus on what tangibly might be the benefits to the individual. Notably the use of the dossier to disseminate health and safety information across the supply chain was more weakly identified. Some respondents highlighted better visibility of DUs and direct contact to provide health and safety information as being a benefit. However it was unclear whether they were actually using the data from the dossier in these communications. Additionally around the incentives issue the topic of mandatory updates was discussed (noting that update according to Article 22 is already mandatory). High importance was placed on the CLP classifications and dissemination of information. New data that changed the CLP classification could be seen as an important incentive for update. While the questionnaire results favoured other (e.g. financial) incentives, the interview phase suggested that a

mandatory update would help clarify what had to be done by when and allow registrants to set aside resources to plan for it. It would also add a regulatory driver to do updates where one did not currently exist.

Drivers

Introduction

The questionnaire phase of the study included questions on drivers and incentives to understand what motivated the registrants to complete an update. The results of the question highlighted that for the majority of the registrants an update was completed when prompted to do so by ECHA. Other cases where dossiers had been updated typically related to a change in tonnage bracket with the pro-active update of dossiers and non-regulatory mechanisms less prevalent.

The interview phase of the study expanded upon these topics with two key themes identified, one being a strong opinion that the costs and efforts needed to complete an update outweighed any potential benefits from doing so. These themes are discussed further below.

The balance between cost and effort to complete updates versus the direct benefits to the registrant of doing so.

The questionnaire phase of the study included a number of questions around drivers, incentives and obstacles, with a general trend in the responses being that there was a concern that the effort and cost required to update a dossier outweighed any potential benefit that might be gained. The interview respondents highlighted that developing the dossier had been a costly and complex process and that updating dossiers could be equally so. Many of the respondents focussed on technical issues (discussed further later in this chapter) highlighting that even for minor changes the level of effort could be significant. This meant that it was hard to justify expending such efforts to update the dossier.

Furthermore partly linked to the issues identified under the benefits theme, the respondents pointed to REACH registration being perceived as the end of the process. This meant that it was difficult to justify an update where a REACH registration number was already in place. Additionally the response from the SMEs highlighted a reliance on consultants which could be expensive. These two issues meant that in the majority of cases the registrants preferred to wait for ECHA to make contact and provide guidance on what should be updated. For the larger companies the direct contact by ECHA created a compliance issue which gave them impetus to act (i.e. the regulator was instructing them to update). For the SME companies direct contact by ECHA meant that a specific set of requests could be responded to providing a defined scope to consultants and thus limiting cost.

However the SME sub-category also highlighted a negative opinion of REACH, with the respondents highlighting the regulatory burden with little direct benefit. The costs and efforts needed meant they may be unlikely to act voluntarily unless additional support was provided.

The counter-point to this position was a number of cases particularly at trade association and consortium level where REACH registration has been treated as the beginning of the process, not the end. The creation of product stewardship programmes and managed systems to assess when new data was needed for update was included in an integrated approach. However the chief driver in these instances was to manage the substances covered in order to predict and manage future regulatory action. Therefore the main driver identified was the need to produce a high quality dossier for substances to detail how all of the hazards and risks were managed in order to avoid further actions such as authorisation or restriction.

Identification of when and why an update is needed.

The responses from the interview phase highlighted that the wording of Article 22 is perceived as vague and focussed on the individual, while dossier development is typically a group effort under SIEFs. This meant that the respondents had many questions around what should define the need for an update and requests that ECHA should also take into account the limited resources of registrants and competing demands of the 2018 phase-in deadline, evaluation and need for updates.

Other respondents highlighted that even when conducting minor updates such as tonnage data, the technical issues working with the software made this a significant task. Comments from the respondents highlighted that as part of their own planning highest priority was given to new data that may change either the CLP classifications or to revisit the outcomes of the exposure scenarios within the CSR. There were also comments around difficulties with cost-sharing and upon whom the obligations fall, i.e. who should conduct the update (described in more detail later in this chapter).

Summary

The responses from the questionnaire and interviews highlighted that the respondents have an opinion that the costs and efforts needed to complete an update outweigh the perceived benefits. In part this issue relates back to the perception of registration as the end of the process. There were also comments that Article 22 focusses on the individual whereas dossier update is often a group effort, or largely falls on the lead registrant. These issues meant that in majority of cases updates were generated as a result of direct contact by ECHA to request an update. This was due in part to the fact this contact created a compliance driver but also defined requests rather than a blanket approach for updating of all sections of the dossier.

Obstacles

Introduction

The responses from the questionnaire and interview phases highlighted a number of obstacles faced by registrants in updating their dossiers. Chiefly these related to either communications, data-sharing, resourcing or technical issues in developing and maintaining dossiers. Additionally spanning all of these related areas were issues surrounding roles and obligations and enforcement of those roles and obligations to maintain a level playing field. This sub-section provides a commentary on these aspects.

Understanding of roles and obligations under REACH, including SIEF interaction, cost-sharing, and responsibility for updates.

The issue of clear roles and obligations under Article 22 has been raised in previous sections, however the potential disputes and obstacles this issue creates warrants further discussion. The point was made that the bulk of the data within the dossier is held by the lead registrant, and that co-registrants are most likely to only need to update tonnage data, legal entity or use data. One respondent went further and suggested that one of the main reasons for a lack of updates was because there were many co-registrants who simply did not have any new data to provide the lead registrant. Therefore the co-registrants held the opinion that firstly update of the dossiers outside of sections 1 – 3, was the responsibility of the lead registrant as a solo activity. Secondly the co-registrants held the opinion that they were therefore only responsible for updating data primarily on tonnage, legal entity or uses. The respondents therefore felt that unless there was a change of tonnage bracket, the update of tonnage data had less importance and that the efforts needed to update dossiers with this information meant that the effort outweighed the benefit.

The respondents suggested that they held the opinion that the priority should be sections of the dossier linked to CLP classifications and that therefore tonnage data could be perceived of lower priority. This when combined with technical difficulties to complete updates and limited resources meant that updates were less likely to be completed. The respondents queried how important this information would be to ECHA and whether it makes any significant difference to the overall data in the dossier.

The lead registrants to some extent concurred with this position recognising that much of the data was actually under the control of the lead registrant. However these respondents also posed the question on what role the co-registrants have in supporting the lead update the dossier. Once a letter of access fee has been paid and a REACH registration number obtained, the co-registrants have no regulatory driver to force them to support the lead registrant either through top up fees or provision of data. Equally if the co-registrant has new data to complete an update if the lead registrant chooses not to act the only way to complete the update is to opt out which has its own implications.

Other respondent's highlighted problems with "rogue" lead registrants where the co-registrants were at the mercy of the lead registrant with little flexibility for managing the lead dossier update (see section 3.2). The

respondents commented that SIEF disputes such as those with rogue lead registrants failed to have useful enforcement or intervention from the regulator. This was perceived because the responsibility falls between ECHA and the MSCAs and so is treated as a grey area. There were also comments made regarding issues with cost-sharing where SIEFs were in dispute. These issues could potentially greatly delay an update. Other respondents highlighted a perverse incentive where registrants could generate new research data which was not needed and then over-charge the co-registrants insisting that an update was necessary.

These issues highlighted that Article 22 simply refers to 'new information' without defining why it might be needed and what would be the benefit to updating the dossier. The respondents suggested that further guidance was needed from ECHA to help prioritise when updates were needed and what data was important to include for updates.

Resourcing available to contribute to REACH.

The respondents highlighted that the development and subsequent update of REACH dossiers can be labour intensive depending on what needed to be updated. An example provided by one respondent was where a single new toxicology study could change the result for a specific end-point. This would require all of the exposure scenarios to be updated for every use and could potentially include a large number of uses, hence being very resource intensive. The arguments made both in the questionnaire phase and during interviews was recognition that resources were limited and competing deadlines for the 2018 phase-in deadline, evaluations and updates made it very challenging. The respondents suggested a phased approach should be considered to allow the 2018 deadline to pass before considering updates.

The SME subgroup also highlighted that the cost aspects of updates were particularly problematic and raised concerns that the nature of SIEF work favours big companies. One respondent raised concerns that this allowed bigger companies to overcharge for letters of access, which would force SMEs out of the market place.

Technical issues which affect willingness to act.

The questionnaire phase of the study highlighted that technical issues, particularly with software, were seen as a major obstacle in completing updates. This message was particularly strong in the results. Therefore for the background paper used in the interview phase, technical issues were included as a separate category from other obstacles.

The responses from respondents largely focussed on IUCLID as the main software used in dossier development and update. The respondents highlighted that release of newer versions of the IUCLID software and need to migrate dossiers were particularly problematic. This had been the case for the transition from IUCLID 5.6 to 6.0. There were also concerns raised regarding additional data requirements for IUCLID 6.0 with one respondent questioning whether the data requirements now exceed the minimums set in the regulation. Other respondents had concerns regarding new manual checks which were said not to be applied consistently and which raised concerns within the registrants and acted as a deterrent to update.

The use of a cloud based version of IUCLID to overcome update and migration issues was welcomed by the respondents, but there also concerns about how it would work in practice. This largely related to any bugs or data corruptions during auto-migration and need for manual corrections afterward.

The other key focus of the discussion on technical issues related to the development of CSRs and eSDS. This included comments that some registrants included all data with no tailoring in the eSDS leading to an overload of data situation for downstream users. Others commented that where they made products not substances, it could be challenging to develop an eSDS based on multiple CSRs and that no formal template or good example of what a completed eSDS should look like was believed to exist. This lea to inconsistent documents which undermined the dissemination of safety information to downstream users.

Summary

The results of the questionnaire and interview phase highlight a range of different obstacles. Broadly these can be grouped into issues relating to communication, data-sharing, resourcing and technical difficulties. Spanning all of these themes were issues related to identification of roles and obligations within the REACH process. In particular the differences between lead registrants and co-registrants were highlighted. There

was also ambiguity around responsibilities for organisations in these two roles which led to issues around communication, data-sharing, agreeing when an update was needed and how the process should be managed.

Another major issue raised by the respondents was their limited resources and competing demands of the 2018 phase-in deadline, evaluations and need for updates which made it challenging to meet all the expectations placed upon them.

Technical issues were also highlighted throughout the questionnaire results with IUCLID in particular acting as the focus of the comments received. Respondents felt difficulties with the complexity of using IUCLID combined with migration issues for old dossiers into new formats could make the effort of updating dossiers excessive, particularly if the update was a minor issue such as new tonnage data.

4.2 Summary table

This sub-section provides a table of summarised points from the conclusion.

Table 4.1 Summary of main study conclusions

Issue	Positive elements	Negative elements	Issue to be addressed
Role of the dossier	Improved knowledge on substances, particularly substances that were data poor. Improved understanding of substances, including impurities and supply chain. Role of trade associations and consortia to see registration as the beginning of the process and creation of product stewardship programmes to manage the onward update work.	▶ Many within industry see registration as the end of the process. Award of a REACH registration number denoting compliance means there is no regulatory driver to encourage further update. ▶ Breakdown of SIEFs post-registration and lack communication to help drive update. ▶ Perception of REACH dossier as a data gathering task without connection to direct benefits it may provide to human health and environment. ▶ Possible problems with the dissemination of eSDS due to quality / consistency of eSDS.	▶ Lack of regulatory incentive to drive dossier update. ▶ Mis-perception over the role of the dossier and registration as the end of a process. ▶ Lack of understanding for the role of dossier driving the development of exposure scenarios in eSDS, and importance of eSDS for dissemination. ▶ SME sub-group seemed particularly disenfranchised. May require additional technical support and guidance, particularly around 2018 deadline.
Mandatory vs voluntary updates	Some of the respondents highlighted the perception of REACH registration as the beginning of a process. Product stewardship programmes had proactively managed the need for update of dossiers. However this was largely driven by a regulatory need to ensure that substances were strictly controlled and avoid the need for further regulatory action such as authorisation.	▶ Perception by registrants that once they have obtained a REACH registration number no further work is required to update dossiers. Can be difficult to develop a business case when benefits are difficult to identify. ▶ Concerns over a lack of a level playing field and need for stricter enforcement. ▶ Questionnaire results favoured financial incentives, but interviewees suggested the biggest issue is lack of clarity over what is expected. A mandatory update requirement if given sufficient time to plan could work.	▶ Lack of clarity over expectations for what should be updated and by when. ▶ Perceived lack of level playing field has negative effects for registrants who which to remain compliant.
Effort versus reward	REACH registration has been beneficial for improved knowledge on substances, particularly those that were data poor at the beginning of the process.	▶ Broad nature of ‘update’ means that there is unwillingness to act because potential data needs (e.g. new toxicity data) for update of dossier seem too excessive. Registrants prefer to	▶ Lack of clarity over expectations for what should be updated and by when.

Issue	Positive elements	Negative elements	Issue to be addressed
	When used as the core data for the beginning of a new product stewardship process effort for updates can be suitably planned and managed allowing greater control over outputs.	wait for direct contact from ECHA as elements to be updated are usually more defined. ▶ Perception that registration is the end of a process means that registrants wait for ECHA to contact them and tell them the data needs update. ▶ Requests from DUs / suppliers / non-EU partners to update dossiers were much less frequent.	▶ Labour intensive efforts of updates mean registrants unlikely to act unless prompted to do so. ▶ Uneven implementation of enforcement or lack of enforcement has created a lack of a level playing field. This has meant registrants less willing to expend effort to be compliant.
Roles and obligations	Examples of well managed SIEFs where lead registrants take on the main role for update but are well supported by co-registrants. However the examples witnessed came from trade associations and consortia where membership was an important driver to be supportive.	▶ Article 22 focusses on individual while work done in groups by SIEFs. Makes the onus of obligations ambiguous. ▶ Poor SIEF communications a problem, either where lead poorly manages the process, or where co-registrants drop out of the process as they no longer have an incentive to support update (already compliant through REACH registration number).	▶ Lack of clarity over roles and obligations between lead registrant and co-registrants disrupt the process. Can lead to breakdown in communications, cost-sharing disputes, or SIEF members dropping out.
Resourcing	Some SIEFs are well organised with provisions set aside to manage the product stewardship and development of new data for dossier update.	▶ Concerns over competing resource demands between 2018 phase-in deadline, evaluations and updates. ▶ SME sub-group stated they are particularly hard hit and felt that the REACH mechanism favours big companies. Possible anti-competition issue where lead registrants have control over LOA fees.	▶ Need for phased approach to manage resource burden on registrants. ▶ Possible additional support needed for SMEs, particularly with 2018 deadline approaching.
Technical issues	Possibility of IUCLID cloud service providing significant benefits to limit the impact of IUCLID updates and need for migration of dossiers. However with previous updates there have been data bugs/corruption issues requiring manual edits after update. Unclear whether this would still be an issue.	▶ Update of IUCLID causes significant additional work. Update from IUCLID 5.6 to 6.0 particularly problematic. Request for stability ahead of the 2018 deadline. ▶ Other technical issues with development of CSRs and eSDS with consistency a problem.	▶ Further updates of IUCLID before 2018 to be considered carefully. ▶ More guidance needed on consistency and gold standard for eSDS.

5. Recommendations

5.1 Introduction

This chapter provides a set of recommendations aimed at addressing the issues identified in the far right hand column of Table 4.1. In developing these recommendations consideration has been given to whether the recommendation can be enacted directly by ECHA as a supporting action, whether it requires a new policy measure or whether industry with the support of ECHA is best placed to lead the recommendation.

All of the recommendations are to be further considered by ECHA and others involved in the REACH and CLP regulations, in terms of their expected impacts.

Based on a review of the conclusions and the issues identified within Table 4.1 all of the possible issues identified can be grouped into one of three categories:

- Lack of clarity on what specifically needs to be provided by whom and by when.
- Resourcing issues which limit capacity or willingness to act.
- Balance between efforts needed for update versus perceived benefits.

Therefore in developing the recommendations to address the issues identified it can be foreseen that there are four logical steps to how the recommendations should relate back to the issues identified, which can be defined thus:

- **Clear definition on specifically what needs to be updated.** The results and Table 4.1 suggest that the Article 22 definition is considered too generic and there is uncertainty within the registrant community on where efforts should be focussed. Specifically, what should be treated as high priority, with a justified reason for why that might be the case? Clear guidance on what is expected and over what timeframe would be very useful in this regard.
- **Who is expected to provide the data?** The results also suggest a disconnection between the individual requirements of Article 22 and group work in SIEFs. There also appear to a number of difficulties with the functioning of SIEFs relating to communications, cost-sharing, and regulatory drivers to save SIEF members dropping out of the process because they already have a REACH registration number. Clearly definitions of expectations backed up by enforcement may be needed here.
- **A regulatory mechanism to provide the update as a mandatory need.** Article 22 of the REACH regulation already places a mandatory requirement for registrants to update dossiers with new data without undue delay. However the existing mechanism for REACH registration and philosophy of one substance one registration places a great onus on the original registration. There is a perception of registration being the end of the process and receipt of the REACH registration number as an indication of compliance. Greater efforts are needed to improve understanding of the mandatory nature of Article 22, but there is also likely a need to go further with fixed temporal deadlines for update (unless data is available sooner).
- **Improved understanding of why updates are important.** The responses received across the questionnaire and interview phase suggested a perception that REACH registration is the end of a process. Others appeared to hold the opinion that REACH registration is a data gathering task to satisfy the needs of ECHA. Additionally where much of the focus is on developing the items for submission less thought is given to dissemination. Greater efforts need to be made to help make clear the link between a well maintained and up to date dossier and protection of human health and the environment. The use of eSDS as a dissemination tool for hazardous substances is particularly important. More focus on DUs to help make more use of eSDS together with work to help improve the quality and consistency of eSDS would in turn highlight the value and benefits of the dossier as the data source to underpin the development of eSDS.

In order to deliver these logical steps the recommendations provided include a number of approaches around guidance and support to registrants. It should also be considered that, if the intended outcome is to increase the frequency and quality of updates Article 22 may need strengthening as a regulatory driver. This could mean the need for fixed temporal deadlines for updating dossiers, to provide registrants with clear indication of what is needed and by when. This would also require the need for an 'opt out' mechanism where a review had been completed but an update was not triggered on that occasion. Above all the responses received highlighted the need for clear and simple messages which are applied by all, with sufficient time to allow businesses to plan and set aside resources.

A temporal mandatory update programme would need to be targeted, prioritise what data was important and ensure that it was enforced to maintain a level playing field as indicated by the respondents.

5.2 Recommendations actioned through ECHA as supporting actions

This sub-section provides details of the recommendations that can be actioned directly by ECHA without the need for amendment of the REACH regulation. Table 5.1 provides a summary of the recommendations with additional explanation after the table.

Table 5.1 Recommendations actioned through ECHA

Number	Title	Description	Issue addressed	Consequence
1	Investigate how the available material provided by ECHA can be better accessed by registrants looking for information on guidance on roles and obligations for dossier update.	A review of the ECHA website and guidance documents is recommended to ensure that key information is being identified and used by registrants that are trying to update their dossiers. This will be particularly important after the last registration deadline as the material is branded '2018 registration'. This should also investigate how to facilitate registrants to make better use of the existing information.	Lack of clarity over roles and obligations between lead registrant and co-registrants disrupt the process. Can lead to breakdown in communications, cost-sharing disputes, or SIEF members dropping out. Lack of clarity on exactly what information needs to be updated and separate lead registrant (LR) from co-registrant (CR). Comment from ECHA has highlighted that there is already useful guidance on these topics, but apparently the respondents were unaware of this.	Improved understanding of obligations by registrants.
2	Direct instructions from ECHA to Improve clarity over requirements of Article 22.	This recommendation is to provide clear and simple instructions on who is responsible for update of which sections and under what circumstances of the dossier. This could be communicated as a news article within the ECHA newsletter for example.	Lack of clarity over roles and obligations between lead registrant and co-registrants disrupt the process. Can lead to breakdown in communications, cost-sharing disputes, or SIEF members dropping out. Lack of clarity on exactly what information needs to be updated and separate LR from CR. The respondents highlighted a lack of understanding on who is responsible for updating which sections of the dossier. Furthermore there is ambiguity over	Further clarification of obligations will make clear what is expected and make enforcement of non-compliance less complicated.

Number	Title	Description	Issue addressed	Consequence
			which sections of the dossier should be targeted.	
3	Provision of additional support measures for SMEs to encourage update of dossiers.	Additional technical support to help SME registrants understand their obligations. To help support and minimise this burden we would recommend considering a package of measures: iii) Guidance on how to identify inappropriate lead registrant behaviour and clear overview of their rights. iv) ECHA to co-ordinate further support at national level through discussions with MSCAs.	SMEs were identified as having very limited resources and often little regulatory expertise in REACH. There were also comments around the administrative burden on this group of registrants.	Better support for SME registrants means that they will be much more likely to complete updates and remain compliant.
4	Develop a system to identify where reviews have been completed but an update of the dossier is not needed.	Possible development within the REACH-IT website to request registrants to provide indication of where a review has been completed but an update not triggered. This could work via one of two options: iii) A tick-box system within REACH-IT. This should include a caveat explaining the legal obligations of updating dossiers in REACH. A system within REACH IT to indicate a review has taken place including provision of evidence to demonstrate that a review has taken place.	Some registrants highlight that they check for new data but that it does not trigger an update. This is not captured by ECHA.	It is currently unclear how many registrants are conducting reviews of dossiers which do not result in an update. A mechanism to provide such information would limit burden for unnecessary updates and help ECHA have a more complete picture.
5	Expansion of the published update programme for IUCLID (updates are done twice a year), with clear details of what is included and why an update is planned in order to improve clarity and stability over planning for industry.	ECHA already has fixed windows for updates which are communicated in the public domain (spring and autumn updates). However it is clear that effort is needed to limit updates to only where necessary and that good transparency is needed on what is planned. The existing plans could therefore include additional information on the scope of the update, and if new data needs are included, why they are needed.	Updates of IUCLID have been recognised as creating significant extra work for registrants and many respondents identified this as a major barrier to updating dossiers. Greater control and transparency over updates is needed.	Limiting updates of IUCLID would in turn limit impact on registrants to complete migration of dossiers, and manual checking for errors post update.
6	ECHA to use the enforcement forum to make clear the obligations of Article 22 and work with national enforcement agencies to integrate compliance checks on updates with other REACH compliance checks.	This recommendation is for ECHA to use the enforcement forum with national enforcement agencies to focus future enforcement activities to integrate checks on dossier updates with other compliance checks.	The registrants that took part in the questionnaire and interview phases highlighted concerns that there is not a level playing field and that REACH is not enforced evenly across the EU in terms of checking that	Increased consistency in enforcement will provide greater incentives to ensure dossiers are up to date.

Number	Title	Description	Issue addressed	Consequence
			registrations are in place and up to date. This has a negative impact on the willingness of registrants to commit resources to REACH tasks. Companies are less likely to keep dossiers updated if this is not being enforced.	

The results from the questionnaire and interview phase highlighted a strong opinion that the level of effort and cost to complete an update outweighed the perceived direct benefits of such an update. Part of the concerns voiced by the respondents around these issues was that even minor updates can require a lot of effort. There was also a perception from the respondents that registration is seen as being the end of a process and there were questions as to what is the exact role of the dossier (i.e. is it a data file to aid ECHA develop a known library of information or is it an industry document for use in health and safety practices). It is of high importance that ECHA is able to provide clear and simple instructions to the registrant population both in order to make clear what the priorities are and why the update process is important.

Recommendations for addressing the perception of the role of REACH dossiers and eSDS to aid the safe management of chemicals and protect human health and environment are included under section 5.3 for actions by trade associations with ECHA's support. However on the data requirements this action can be led by ECHA.

The results do suggest that where much effort has been focused on registration and attaining a REACH registration number, that there is a lack of a strong regulatory driver for updates. This is despite the fact that Article 22 carries a mandatory obligation to update dossiers for registrants. The multiple issues discussed within this study report suggests that guidance alone may not be fully effective at generating a motivation to update proactively. Therefore a temporal mandatory update programme with fixed deadlines may be need to be carefully considered. Recommendations for this option are discussed in section 5.4.

Recommendation 1 addresses issues identified with engagement and motivation of industry to work within the REACH process. The results of the study have highlighted that there is ambiguity over roles and obligations for REACH registrants within different contexts. While ECHA has developed guidance on registration, updates to registration and the roles of lead and co-registrants the results of the study suggest that this ambiguity still exists. Based on discussion with ECHA there is a concern that many within industry do not read the guidance or visit the ECHA website to seek help on these topics. In the past ECHA has tried a number of approaches to engage and work with industry on topics related to update of registration dossiers. Therefore there is a need to identify an approach to reach these members of industry that are difficult to engage with and help provide support to improve understanding of what needs to be updated.

Recommendations 2, 3, and 5 are intended to improve clarity over what is expected from registrants to help make obligations clearer. Recommendation 2 includes clear instructions on what Article 22 means, including ECHA's expectations and roles and obligations of lead and co-registrants. This could be communicated as part of the ECHA newsletter and used in combination with recommendation 9 on an implementing regulation for further clarifying the duties of registrants under Article 22. Recommendation 3 covers further support for the SME category of registrant. The results of the study suggested that the administrative burden for this group in particular could have significant impacts. Steps to minimise the burden of completing and updating registrations for this group is therefore a key message. Recommendation 5 covers potential impacts created by IUCLID updates. The results suggested that updates of the software had the potential create significant additional work for registrants, particularly around migrating of dossiers to newer versions. While updates are unavoidable, ECHA has aimed to limit updates where possible and it is hoped that the cloud based version of IUCLID will further limit the impacts of migrating to newer versions. Additionally further clarity on the scope of the updates, and in particular where new data requirements are added to the IUCLID template, why these additional fields are needed are key to help industry prepare for updates. This information also improves clarity and understanding within the registrant population on why the update is needed.

Recommendation 4 is also intended to improve transparency and limit the burden on industry. The registrants highlighted that where reviews of dossiers are completed this does not always trigger the need for an update. Currently there is no mechanism to illustrate that a review has been completed. The only way registrants can illustrate that a review has been completed is by submitting a dossier with no new changes. The creation of an option in REACH-IT to provide information that a review has been completed without an update needed would improve visibility of where ongoing work was taking place.

Recommendation 6 relates to comments made by registrants on a fair and level playing field for REACH. The recommendation would suggest that ECHA works closely with national enforcement agencies to integrate the compliance checking for dossier updates with the other checks completed by national enforcement agencies. If this can be done in a consistent fashion it would help create a level playing field for updates within the registrant population.

5.3 Recommendations actioned through industry with ECHA support

This sub-section provides details of the recommendations that can be actioned with the support of the trade associations in combination with ECHA, again without the need for amendment of the REACH regulation. Table 5.2 provides a summary of the recommendations with additional explanation after the table.

Table 5.2 Recommendations actioned through trade associations with ECHA's support

Number	Title	Description	Issue addressed	Consequence
7	Facilitate increased awareness of benefits of updating dossiers and risks of not updating, through trade associations.	Communicate benefits of updating (ensuring safe use, product stewardship) and risks of not updating (harm to health/environment, potential non-compliance with legislation) to trade associations. Encourage trade associations to disseminate this information to members. Point to existing guidance where appropriate. As part of this dissemination trade associations and consortia also have a role to play in highlighting best practice for managing SIEFs post-registration as part of an ongoing product stewardship programme.	Mis-perception over the role of the dossier and registration as the end of a process.	Increased awareness of need to update dossiers.

Number	Title	Description	Issue addressed	Consequence
8	Trade associations to work with ECHA to provide guidance to industry on what eSDS should look like and further interaction with DUs on how to make use of eSDS.	To address the perception of the dossier having limited benefit to the registrants, the recommendation targets the DUs as end recipient of the data (in the form of an eSDS). This would mean that the registrant's customers have a strong understanding of REACH and are requesting the best quality data from their suppliers. There is already an ongoing body of work to look at eSDS and the consistency and quality of how to develop a good eSDS. However this work could be continued and further strengthened. This recommendation is therefore three-fold. iv) Further engagement with industry on what a good eSDS should look like. Best practice and support to industry for consistent approach. v) Work with DUs on how to get best use of eSDS. vi) Development of 'how to' documents showing how information in the eSDS comes from specific data sets in the dossier. If DUs hold the eSDS in high regard they will demand high quality documents from their suppliers (the registrants). In turn this puts pressure on the registrants to keep dossiers up to date to generate the eSDS.	Communication of the hazards, risks and risk management measures across the supply chain is key to the functioning of REACH. However comments made on eSDS suggested that the clarity and quality of communication could be variable. Additionally where work on dossiers is perceived as a one-off task, the use of the dossier for other tasks particularly dissemination is less. This reduces the perceived value of the dossier and benefit of why a registrant would want to update their dossier.	The results of the questionnaire and interviews highlighted that the benefits of an up to date dossier are not well defined. Improved perception of the value of dossiers would lead pressures from DUs for up-to-date eSDS and in turn more up-to-date registration dossiers.

The recommendations within this sub-section relate to the involvement of the trade associations. The trade associations have been identified in particular due to the close relationship with industry and how the REACH data has been used in practice. The recommendations here relate specifically to the dual role that trade associations can play in helping disseminate information to industry and help develop best practice for how REACH updates can be managed. This is particularly important for encouraging the perception of registration as the beginning of a process not the end, and how SIEFs can be maintained post-registration.

The recommendations also give focus to the role of the eSDS in driving registrants to update dossiers. The results from the questionnaire and interviews highlighted that the benefits of updating dossiers while useful were considered more 'nice to have' than integral to the core function of business. The eSDS has a key role to play in dissemination of information on hazardous substances to DUs to protect health and the environment. However there have been concerns raised that the quality and consistency of eSDS, particularly exposure scenarios, are highly variable. This also includes variability between eSDS from different registrants. The variability of eSDS affects the accessibility and understanding of the information for DUs and according to some respondents undermines the effectiveness of the entire REACH process.

Further work both with DUs to understand the benefits of eSDS but also with registrants to help develop a consistent and easily understood format would greatly improve dissemination. Furthermore if DUs held the

eSDS in higher regard they would be more likely to not only request provision of eSDS more often but that the quality of the eSDS be maintained at a high standard. These requests from DUs as clients to registrants would act as a driver to give impetus to registrants to maintain their dossiers as a source of up-to-date information to help develop eSDS.

Recommendation 7 highlights the first role of dissemination. This would include working with ECHA to ensure that the message regarding the mandatory nature of Article 22 was disseminated. This would include the importance of completing updates, the consequences of non-compliance and why an update is important. As part of this recommendation it will also be key for trade associations to help set best practice on how SIEFs can be maintained post-registration and how the relationship between lead and co-registrants can work to facilitate the flow of information and identification of what data needs to be updated.

Recommendation 8 highlights the second role, focussing on development of eSDS as a means to both aid dissemination as well as acting as a driver to encourage update of REACH dossiers. Work is already ongoing by ECHA to look at the approach to best practice for developing eSDS and what a good eSDS should look like. This recommendation would urge that this work continues but also provides further recommendations to strengthen this work, with particular focus on DUs. This should explore how DUs make use of eSDS and what can be done to improve the accessibility and usefulness of these documents as far as possible.

5.4 Recommendations actioned through new policy measures

This sub-section provides details of the recommendations that can be actioned through the use of new policy measures. This would most likely work through the development of an implementing regulation based upon the existing text of Article 22 of the REACH regulation. Table 5.3 provides a summary of the recommendations with additional explanation after the table.

Table 5.3 Recommendations actioned through new policy measures

Number	Title	Description	Issue addressed	Consequence
9	Require mandatory periodic update of dossiers (and system for registrants to provide evidence of continued validity / completed reviews where update is not needed).	The recommendation would be to have mandatory deadlines on a temporal basis (e.g. every 3 years) with a clarification that if new data becomes available sooner an update is triggered immediately without undue delay. This would still also uphold the one substance; one registration philosophy meaning that SIEFs should be maintained as part of a product stewardship process after the 2018 phase-in registration deadline. This would require a regulatory change to require registrants to issue an updated registration dossier every 3 years (or similar). If there is no data to be updated, the registrant would be required to confirm that the data remains correct, and up-to-date. This could perhaps be best achieved through a clarification or update of the requirements under Article 22, which might be feasibly done through an Implementing Regulation.	While update according to Article 22 is already mandatory, there is uncertainty among registrants over what is intended and who should act. The mechanics of REACH mean that SIEFs can break down following registration and that necessary planning for updates as part of a product stewardship programme does not happen in many cases.	Increased level of dossier update. Improved confidence in effective management of risks to health and environment. Improved clarity on when a dossier update is needed.

The final recommendation relates directly to the wording of Article 22 and possible need for a further policy measures, such as an implementing regulation. It is important to make clear that update of dossiers

according to Article 22 is already a mandatory requirement of the REACH regulation. However as has been discussed in the earlier chapters there is a perception within industry that registration marks the end of a process. After this time it is possible for SIEFs to break down and communication cease. There is then ambiguity on who specifically is responsible for the update of the dossier. This includes the possibility for SIEF disputes over cost-sharing, and situations where data is available but the updates fail to happen because of communication problems or disputes over obligations.

Recommendation 2 aimed to address some of these issues through direct instruction provided by ECHA (possibly through the ECHA newsletter) in terms of what is expected under Article 22 and the roles and obligations of registrants under different circumstances. Recommendation 9 is intended to go further by providing a stronger regulatory driver for update. This would take the form of periodic deadlines by which time an update should have been made, this would include the caveat that if data (according to Article 22) is available sooner an update is triggered immediately without undue delay. The recommendation would stress the need to uphold the one substance; one registration philosophy and continuation of SIEFs post the 2018 phase-in deadline. This recommendation would also mark a need for recommendation 4, which would create a means for registrants to indicate cases where a review had been completed but an update was not triggered.

All of the above recommendations are intended to be considered further by ECHA and others before implementation.

Appendix A
Survey Questionnaire

An introductory letter provided to respondents

A study to gather insights on the updating of REACH registration dossiers and CLP notifications – Introductory Note

The questionnaire will go live on Monday 3rd April

Background to the study

Under the REACH regulation (EC 1907/2006) manufacturers, importers or only representatives of non-EU companies must submit registration dossiers to the European Chemicals Agency (ECHA) for the substances they produce and sell. Companies are also obliged to update REACH dossiers with any relevant new information, without undue delay. While many registrants pro-actively manage their dossiers to ensure that they are up to date and as accurate and complete as possible, this is not always the case.

ECHA would like to better understand the main obstacles and drivers for registrants in providing updates to their REACH registrations dossiers. This will enable ECHA to help support registrants in this process and ensure that the quality of dossiers submitted is of a good standard.

Equally, ECHA would also like to understand the obstacles and drivers to providing information on C&L notifications, updates to notifications and also why there is often divergence in classifications notified for the same substance.

Amec Foster Wheeler has been contracted by ECHA, and is working with Peter Fisk Associates Ltd, to explore this topic.

Why do we need your input?

The aim of this consultation is to capture the views and opinions of a large number of the companies involved in registration under REACH and notification under CLP. Specifically ECHA would like to better understand the key obstacles to updating information within different sectors, company sizes, geographies and roles within the SIEF[6]. What key drivers prompt registrants to take action in providing updates to their REACH registrations and CLP notifications?

The questionnaire that has been distributed with this message gives you the key opportunity to express your opinion on this topic and to ultimately aid ECHA's own planning and decision making to address how implementation of the legislation might be improved.

Answering all questions should take about 20 minutes.

What happens next?

The questionnaire will open to respondents for 6 weeks. On closure of the consultation the responses will be collated and analysed and an unbiased summary of the results will be presented to ECHA. Interviews will be conducted with a selection of respondents that indicated they would be interested in providing further detail on the topics discussed in this questionnaire. Conclusions and recommendations will then be synthesised from the questionnaire and interviews by Amec Foster Wheeler and presented to ECHA.

Any opinions or insights collected as part of this study will be handled and presented confidentially. They will be used for research purposes only and will not be reviewed by ECHA in a regulatory capacity. No reference to company names or individuals will be made in the reporting to ECHA.

[6] Substance information exchange forum

Questionnaire to investigate the drivers and obstacles to updating of REACH registration dossiers and C&L notifications.

I Information concerning the respondent

1) Name of individual:

Text box to provide response

2) Name of your company:

Text box to provide response

3) Role of your company or organisation under REACH? Select all the options that apply:

- ☐ Manufacturer
- ☐ Importer
- ☐ Only Representative
- ☐ Producer or importer of articles containing substances subject to registration
- ☐ Industry trade association
- ☐ Consultant providing REACH services
- ☐ REACH Consortium

4) Main product groups of the substances your company has registered or helped register under REACH? Select all the options that apply:

Manufacture (*Select from this list if the goods you produce are manufactured in the EU*)

- ☐ Industrial gases (NACE 20.11 - Manufacture of industrial gases)
- ☐ Dyes and pigments (NACE 20.12 - Manufacture of dyes and pigments)
- ☐ Metals (Ferrous, and Ferro alloys) (NACE 24.1 – Manufacture of iron and steel)
- ☐ Metals (Non-Ferrous) (NACE 24.4 – Manufacture of non-ferrous metals)
- ☐ Glass based products (NACE 23.1 – Manufacture of glass)
- ☐ Cement, lime and concrete (NACE 23.5 – Manufacture of cement and lime)
- ☐ Other Inorganic mineral compounds (NACE 20.13 – Manufacture of basic inorganic chemicals)
- ☐ Inorganic acids, peroxides and halogens (NACE 20.13)
- ☐ Basic inorganic chemicals not listed above (NACE 20.13)
- ☐ Solvents and alcohols (NACE 20.14 – Basic organic chemicals)
- ☐ Fuels, oils, and lubricants (NACE 20.14 + 20.59 - Other)
- ☐ Rubber and rubber products (NACE 21.1 – Manufacture of Rubber)
- ☐ Plastic and plastic based products (NACE 21.2 – Manufacture of plastic)
- ☐ Organic Acids, enzymes and reagents (NACE 20.14)
- ☐ Basic organic chemicals (not listed above) (NACE 20.14)
- ☐ Fertilisers, pesticides and agrochemicals (NACE 20.15 Manufacture of fertilisers and nitrogen compounds + NACE 20:20 – manufacture of pesticides and other agrochemical chemicals)
- ☐ Paints, varnishes and inks (NACE 20.30 - Manufacture of paints, varnishes, and printing ink)
- ☐ Soaps and detergents (NACE 20.41 - Manufacture of soap and detergents, cleaning and polishing)
- ☐ Perfumes and toiletries (NACE 20.42 – manufacture of perfume and toiletries)
- ☐ Glues and adhesives (NACE 20.52 – manufacture of glues)
- ☐ Catalysts (NACE 20.59)
- ☐ Water treatment chemicals (NACE 20.59)

☐ Construction industry chemicals (NACE 20.59)
☐ Other

Sale and Distribution (*Select from this list if you do not directly manufacture goods in the EU, but import and sell goods*)

☐ Sale and distribution of chemicals (NACE 46.75 – wholesale chemicals)
☐ Sale and distribution of fuels (NACE 46.71 – Wholesale of liquid and solid fuels)
☐ Sale and distribution of metals (NACE 46.72 – Wholesale metals)
☐ Sale and distribution of construction chemicals (NACE 46.73 – Wholesale construction goods)
☐ Sale and distribution of household products (NACE 46.49 – Wholesale household goods)
☐ Sale and distribution of Home maintenance goods (NACE 46.74 – Wholesale hardware, plumbing and heating)
☐ Sale and distribution of intermediates (NACE 46.76 – Wholesale intermediates)
☐ Other

Text box to provide response

5) Size of your company, or company assisted with completing REACH registrations (excluding other members of the company holding): (Manufacturers / importers / only representatives only)

☐ micro (<10 employees and turnover or balance total < €2 million)
☐ small (< 11 – 50 employees and turnover or balance total < €10 million)
☐ medium (< 51 - 250 employees and turnover < €50 million or balance total < €43 million respectively)
☐ large (>250 employees and turnover > €50 million or balance total > €43 million respectively)

6) Country your company is located in: Please select all that apply.

☐Austria
☐Belgium
☐Bulgaria
☐Croatia
☐Cyprus
☐Czech Republic
☐Denmark
☐Estonia
☐Finland
☐France
☐Germany
☐Greece
☐Hungary
☐Iceland
☐Latvia
☐Liechtenstein
☐Lithuania
☐Luxembourg
☐Malta
☐Netherlands
☐Norway
☐Poland
☐Portugal
☐Romania
☐ Slovakia
☐Slovenia
☐Spain
☐Sweden

☐Ireland ☐United Kingdom

☐Italy

II Experience with REACH registration and dossier updates

Registration context

7) How many substances has your company registered?

☐ 1
☐ 2 - 5
☐ 6 – 10
☐ 11 - 25
☐ 26 - 50
☐ > 50

8) What is your role in the joint submission for those registrations?

Lead registrant	frequently/sometimes/rarely/never
Member registrant	frequently/sometimes/rarely/never
Individual registrant (no co-registrants)	frequently/sometimes/rarely/never

9) What is the type of registration done?

☐ Mostly full substance registration (standard requirements)
☐ Mostly registration of intermediates

Company policy regarding dossier updates

10) Does your organisation review the information that is relevant to keep the registration up to date on a regular basis?

☐ Yes, we review yearly
☐ Less frequently than once per year
☐ More frequently than once per year
☐ Yes, but the frequency is variable
☐ No
☐ Other:

Text box to provide response

11) How often does a review of registrations result in a need to update the registration?

☐ frequently
☐ infrequently
☐ Never

12) Mark all statements you agree with

☐ There is no need to update our registrations until we increase our tonnage band
☐ There is no need to update our registrations unless my customers point out discrepancies
☐ There is no need to update our registrations unless ECHA requests us to
☐ There is no need to update our registrations unless the enforcement authorities (inspection) request us to
☐ None of the above

13) Has your company implemented a management system for checking if a situation triggering an obligation to update your registration occurs?

☐ Yes
☐ No

Comments/Description:

Text box to provide response

Experience with updates

14) Has one of your company's registrations already been updated?

☐ Yes
☐ No -> please skip to section on incentives question 23 onwards.

If yes, please provide details on whether this was as a lead, member, or individual:

Lead registration dossier	all/most/some/few/none
Member registration dossier	all/most/some/few/none
Individual registration dossier(no co-registrants)	all/most/some/few/none

15) Who updated the information? Select all that apply:

☐ Staff from our company
☐ Staff from our holding (mother/daughter/sister/partner company)
☐ The SIEF/consortium secretariat
☐ Another registrant (e.g. the lead registrant)
☐ An external consultant
☐ Other:

Drivers

16) What were the drivers for the dossier updates? Rank the 5 main ones (1 is the most frequent driver)

Aspect	Rank
(Draft) decision on compliance or testing proposal from ECHA	
Other request for update from ECHA	
(Draft) decision on substance evaluation	
Increase in tonnage band	
Own initiative of that SIEF/Secretariat; taking account of new information on hazards, uses or exposure	
Request from other joint registrants	
Request from my downstream users or customers	
Request from my non-EU supplier	
Planned or carried out inspection by enforcement authorities	

☐ Other

Text box to provide response

17) Which information was updated? Select all that apply:

- ☐ Company's status (e.g. manufacturer / importer)
- ☐ Company's identity or contact information (does not require update of the dossier)
- ☐ Composition and identity of the substance, including impurities
- ☐ Total quantities manufactured/imported
- ☐ Tonnage band
- ☐ Uses
- ☐ Knowledge on risks and/or hazards to human health or the environment
- ☐ Classification and labelling
- ☐ Chemical safety report
- ☐ Testing proposal
- ☐ Other:

Text box to provide response

18) How challenging are the following aspects of updating the registration dossier?

Aspect	Very relevant	Relevant	Less relevant	Not relevant	Don't know
Communication and collaboration with members of the SIEF/consortium					
Cost sharing with members of the SIEF/consortium					
Finding the resources with expertise in chemistry/(eco)toxicology					
Finding the resources with regulatory expertise					
The IT tools					
Update of the same registration dossiers several times					
2018 REACH registration deadline					
Finding sufficient internal resources to provide an update in a timely fashion					

☐ Other:

Text box to provide response

Benefits

19) What benefits do you feel your company has gained from updating its registrations to ensure a high quality, completeness and accuracy? Select all that apply:

- ☐ Improved relationship with Competent Authority

- ☐ Anticipation of possible regulatory action (compliance check, substance evaluation, risk management options)
- ☐ Compliance with company values and policy (product stewardship)
- ☐ Demonstration of high levels of protection of human health and the environment to customers and shareholders
- ☐ Protection of downstream users by improved recommended risk management measures
- ☐ Increased worker's confidence in safe working environment
- ☐ Additional information that can be used in planning and compliance for other legislation
- ☐ Improved customer service
- ☐ No benefits seen
- ☐ Other:

Text box to provide response

Cooperation in ongoing joint registrations)

20) How effective is the communication and cooperation among joint registrants regarding dossier updates?

- ☐ Very effective
- ☐ Sufficiently effective
- ☐ Moderately effective
- ☐ Not very effective
- ☐ Ineffective

21) Which issues have you encountered when working with joint registrants on updates of the registration? Select all options that apply.

- ☐ The agreement among joint registrants has no provisions for dossier updates
- ☐ Lack of communication by the lead registrant on the request for update from ECHA
- ☐ Co-registrants do not react to communications on updates
- ☐ Co-registrants refuse to pay costs related to updates
- ☐ Difficulties to establish who is affected by the requested update
- ☐ Co-registrants do not inform the lead registrant when they increase their higher tonnage band
- ☐ Disagreement between co-registrants on the need for spontaneous updates (need to satisfy the minimal requirements vs need to continuously provide all available information)
- ☐ Confidentiality issues
- ☐ Other:

Text box to provide response

22) Which working methods in your joint submission have resulted in effective collaboration on dossier updates?

- ☐ Good coordination of the joint submission
- ☐ Use of additional resources such as websites to aid registrants in process
- ☐ Open and transparent process so all joint submission members can see data and agree on approach
- ☐ Specific issue with substance (e.g. CMR) which motivates all SIEF members to engage more actively
- ☐ Direct contact from ECHA requesting update of specific sections motivates SIEF to work together to resolve issues
- ☐ Explicit contractual obligations on sharing cost of data subject to update
- ☐ Part-filled IUCLID datasets and instructional guidance provided by SIEF secretariat or SIEF

☐ Other

Text box to provide response

Incentives

23) Which incentives could increase the frequency and quality of dossier updates in your company (or your joint submission)? Rank the following options in order of importance:

Aspect	High importance	Fair importance	Low importance	No importance	Do not know
1 Reputational options:					
Blame and shame; more visibility on ECHA's website					
Further recognition of those that pro-actively update; case study stories on ECHA's website					
2 Awareness raising options:					
Greater awareness raising for Article 22 of the REACH Regulation (obligation to update)					
Voluntary programmes and commitments, certainty that the members of the joint submission will follow					
3 Financial options:					
Direct economic incentives (e.g. discounted fees when updating to a higher volume with a compliant dossier)					
Penalties for failing to update registrations (e.g. where ECHA needs to place a direct request for update of dossiers)					
use of a token system to control access to dossier updates					
4 Regulatory options:					
More strict enforcement of Article 22 by Member State Authorities (obligation to update)					
Mandatory obligation to update on a periodic basis added in the REACH Regulation					
Easier-to-use IT tools for dossier updates, e.g. the ability to submit only the new and updated information, not have to re-submit the whole package. This could be offered online in REACH-IT, to save the IT burden of IUCLID.					

What other possible options could be important?

Text box to provide response

Barriers

24) Which barriers to updating your dossiers are most significant?

Aspect	Very significant barrier	Somewhat significant barrier	To some extent a barrier	To no extent a barrier	Not applicable/ Don't know
Company policy or corporate decision to minimise updates					
Concern of drawing unwanted regulatory attention to a dossier					
Technical issues with managing information requirements, such as data gaps and read across approaches					
Lack of support / interest by other registrants in my sector					
Low-risk profile of the registered substance					
Lack of enforcement / actions from authorities to ensure that everyone is compliant					
Lack of internal resources to suitably manage the issue in a timely fashion					
Cost of reviewing the dossiers					
Cost of the additional data					
Reluctance of other joint registrants to share costs					
Risk of dossier being blocked due to ECHA's enhanced technical completeness check					
Short time to get return on investment because of the 12 year data protection period					
Uncertainty on the future of SIEFs, REACH and ECHA after the 2018 registration deadline					
IUCLID problems - Compatibility with older versions					
IUCLID problems – training resources / difficulties working with IUCLID 6					

Or if not included in the table above please detail below and indicate the scale of the barrier.

Text box to provide response

III Experience with Classification & Labelling (C&L) notification updates

25) Has your company been involved in updating a C&L notification?

☐ Yes – a C&L notification in the joint part of the registration dossier → answer the remaining questions in this section
☐ Yes – as a C&L notification directly via REACH-IT → answer the remaining questions in this section
☐ No – don't answer the remaining questions in this section, please move on to section IV

26) What was the main driver for updating your C&L notification?

☐ New information provided to the joint registrants / Trade association based on new research e.g. completed testing proposal generate new data which affects classification and/or labelling
☐ New information provided to the joint registrants / Trade association based on literature review or data found outside of REACH/CLP processes which affects classification and/or labelling
☐ Conflicting information from different sources requires further discussion amongst the members of a joint submission regarding a particular aspect of classification and/or labelling to reach agreement
☐ The C&L for a related/similar substance was updated and that triggered the review of our C&L notification.
☐ Review of C&L as part of other internal checks identifies errors or need to update C&L based on a different conclusion being drawn from the original finding.
☐ New/updated harmonised classification and labelling
☐ Other

Text box to provide response

27) Have you noticed any particular divergence in the C&L for substances you have submitted a notification to the CLP inventory?

☐ Yes
☐ No

28) Do you have any particular perspective on the reasons for divergence of substances?

☐ Difficulty in interpreting the study results
☐ Conflicting study results
☐ Lack of agreement amongst companies over how to apply the classification criteria and what is the correct classification
☐ Need to harmonise classifications based on product ranges with similar substances
☐ Difficulty in consistently filling in the C&L hazard classes in IUCLID
☐ Existence of impurities responsible for a different C&L
☐ Other

Text box to provide response

29) Which measures would you consider to have the most potential to reduce the divergence in C&L notifications amongst registrants?

☐ Providing a transparent platform (e.g. visible contact details) for notifiers of the same substance to discuss and agree on C&L for that substance
☐ Increase clarity on how the C&L information is displayed in the C&L inventory. (For example additional supporting information on how C&Ls were derived)
☐ Improve the validation assistant in IUCLID to guide the notifier in selecting the appropriate Hazard class/hazard statement pair.

☐ Further work with industry groups to help disseminate agreed C&Ls for particular substances, with support to industry to aid classification of such substances.
☐ Increased activity in harmonizing classification
☐ Further guidance for classification of specific hazards (if yes, which?)

Text box to provide response

☐ Other

30) Which (if any) of the following barriers to CLP updates have you encountered or do you perceive?

☐ Poor communication among joint registrants makes it difficult to reach agreement
☐ Lack of data / conflicting data affects decision making
☐ Lack of guidance on how to derive classifications for specific hazards
☐ Difficulty accessing REACH-IT (forgotten passwords, credentials, layout of the portal structure)
☐ Other

Text box to provide response

IV Follow up

This survey aimed at investigating drivers, incentives as well as hurdles in relation to updates of REACH registrations and CLP notifications. Is there anything you would like to add to this topic?

Text box to provide response

Are you willing to participate in a phone-/video-interview (up to 30 minutes) to discuss your views regarding REACH registration or C&L notification updates in more detail?

☐ Yes – please answer the remaining questions in this section
☐ No

31) Contact email:

Text box to provide response

32) Contact phone number (including country code)**:**

Text box to provide response

Thank you for completing this survey

Appendix B
Background paper for interviews

REACH – Drivers and obstacles to dossier update – Background paper

Theme 1: Benefits of updating REACH dossiers

- Other than directly for the registration of a substance, in what other ways do you, or could you, use the REACH dossier or data from the dossier (for example - for supplying data to your customers, global safety data sheets, other regulatory regimes, complying with other EU or national legislation)?
- How useful has the REACH dossier been to better understand the substances you manufacture / import? (I.e. has the information generated for the REACH dossier enabled you to do anything you would not have otherwise been able to do, for example improve product design, facilitate R&D etc.)?
- Have you had any feedback from downstream users within your supply chain on how useful the REACH registration dossiers are for them? For example, to what extent do they make use of the exposure scenarios from the chemical safety report/extended safety data sheet?
- Has the REACH registration process had any other positive impacts on your business (e.g. improved communication and collaboration with other companies in your sector)?
- What incentives or changes could help make the REACH dossier or data therein a more valuable company asset? (E.g. are there ways in which shaping the data would make it easier to use for other tasks?)

Theme 2: Drivers behind why REACH dossiers are updated

The results from the questionnaire suggested that the key drivers most frequently came from direct intervention by regulatory bodies (e.g. direct requests from ECHA) rather than from industry activities (e.g. SIEF discussions, client requests, internal work).

- What level of importance does your company place on ensuring the information within REACH dossiers is complete and accurate?
- Do you think a level playing field exists between those that are compliant and non-compliant?
- Do you believe that enforcement of the REACH regulation should be more coherent among Member States?
- What kind of new (not mentioned in the survey) type of drivers you can envisage in the future?
- What mechanism do you use to help identify where updates to REACH dossiers might be needed? I.e. are you part of a consortium which helps identify issues? A follow-on registrant that takes their cue from the lead registrant etc?
- If a regular update scheme would be imposed, applying to all dossiers or some dossiers (e.g. based on hazard data, tonnage or uses), under which conditions would you see this work? Economic, technical or societal drivers that could make it work?

One of the potential benefits identified from ensuring dossiers were complete and accurate was compliance with company values and product stewardship.

- How has the REACH regulation been integrated into your business model/ company strategy?
- How has your company made use of the REACH update process to demonstrate a high regard for safety and compliance against REACH?

Theme 3: Obstacles to successfully completing REACH dossier updates

The main obstacles identified to preventing update of dossiers were three-fold, firstly issues with finding sufficient internal resource, secondly with data-cost sharing and finally with communication between other registrants.

- Where data sharing issues have arisen as part of the update, how have these been resolved?
- Are you constrained in your dossier updating activities by consortium agreements that set out the circumstances under which as dossier may be worked on (i.e. updated)? If so, how?
- Do you feel that there is a clear understanding of the roles everyone needs to take within joint-registration and therefore it is clear who is affected by REACH updates? If this is not the case can you explain why?
- If you feel that communication has been a particular obstacle which has prevented you being able to update dossiers easily, can you explain the kind of issues that have presented and how these could be resolved?

Theme 4: Technical issues relating to management of data, and software tools (IUCLID and REACH-IT)

The survey results highlighted that there were potential issues with data management, which also included a number of issues when working with the software tools for REACH.

- How important do you feel it is to have a management system to track your REACH registrations? And if one is not used, how do assess what relevant new information may exist for your registrations?
- During the development of the original dossier were there any sections that you felt could be improved but that data was not available at that time? If this was the case did you put in place any plans to check for new data on a periodic basis or to generate such data?
- How much burden do you feel is created by IUCLID updates? Do you feel the IUCLID cloud service could make updates easier and therefore more likely to happen?
- How have you integrated the use of the REACH-IT portal into your other routine regulatory work? (I.e. is it someone's role to check the REACH-IT portal once a week for example)?