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Report from the SME Visit Programme

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Key messages

The SME visits programme conducted between September and November 2015 provided 41 ECHA staff members with an opportunity to gain first-hand "real-life" insights into the businesses of SMEs subject to the EU chemicals legislation by visiting 39 companies in twelve EU member states. Staff participated enthusiastically and were hosted by selected SMEs that were keen on providing a beneficial learning experience. The programme targeted junior staff members without a previous work background in industry.

As a collateral benefit, the mission reports from visiting staff and a dedicated de-briefing session provided the ECHA Secretariat with useful feedback on SMEs' preoccupations. The ECHA Secretariat is sharing these insights with its main stakeholders as well as promulgating them more widely within the Agency.

Background

As a dedicated staff training and development project, the SME Visits Programme represented a considerable investment of the ECHA Secretariat and targeted junior staff members without previous working experience in industry.

As ECHA organised the programme with the help of the ECHA HelpNet, the European Enterprise Network and the Agency's Accredited Stakeholder Organisations representing industry the Secretariat selected enterprises with a more promising business profile from a total of 92 volunteers.

A whole-day briefing event kicked off the programme on 14 September 2015; a de-briefing meeting on 3 December allowed participants to share their insights with each other and with the Agency's managers. Between these two events, participants predominantly visited companies in countries of their own mother tongue which allowed them to better understand the business environment. Where no matching companies had volunteered, staff were hosted by SMEs in Ireland and the UK where they could conduct their conversations in English. In view of the mixed skills and work areas of the visitors, they mainly undertook their visits in small groups. More often than not, each such group visited a multitude of companies.

A list of visited companies is attached (Annex I).

Rationale

The main purpose of the SME Visits Programme was to allow participating staff members to gain "real life" first-hand SME experience and an opportunity to appreciate companies' efforts and challenges in complying with the EU chemicals safety regime. The programme enabled visitors to understand the relevance of their own ECHA work for the daily business of affected companies. Seeing how companies organise themselves to meet regulatory requirements, understanding their business practices as well as operational needs through insights on the

shop floor and in direct conversation with managers and employees, provided a valuable learning experience.

Apart from the above-mentioned de-briefing session, all visiting staff members provided mission reports. This had the beneficial side effect of allowing ECHA to harvest valuable feedback on issues preoccupying SMEs.

Insights gained from the visits are being promulgated within the Agency through various internal communications channels (ECHAnet interview series, etc.). The ECHA Secretariat is also informing the Agency's main stakeholders of the conduct of and outcome of this programme. These findings are summarised in Annex II.

Drawbacks

The enthusiasm that participating staff members displayed towards this programme reinforced the benefits they reaped from seeing chemicals' businesses in practice. As a learning experience, the programme encountered no drawbacks.

However, with regard to the findings compiled in Annex II, the programme has to be appreciated with two caveats:

- The composition of volunteering companies does not reflect a representative cross-section of SMEs, but was biased towards companies that actively interact with industry networks and are thus relatively better informed. Due to the keen support for instance of AISE, the visited companies also comprised a disproportionate number of formulators of detergents and similar products.

- In line with the purpose of providing valuable training experience to ECHA staff (with intelligence-gathering on SME concerns only a collateral by-product), the programme included a limited number of visited companies not qualifying as SMEs in accordance with the criteria of the Commission Recommendation (due to their size or ownership structure).

Attachments:

- Annex I: List of companies visited
- Annex II: Findings from the SME visits programme (for background reading)

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SME Visits Programme
Matching Companies and Staff
(Final list, 1 December 2015)

Annex I

AT	GAT Microencapsulation, 2490 Ebenfurth	Schultheiss, Kimerstorfer
AT	IVB Industrievertretung, 9074 Keutschach	Schultheiss, Kimerstorfer
CY	Chr. Kettis Trading Co Ltd.	Prevedouros
CY	Savvas Evagourou	Prevedouros
FR	Kleiberit Chimie, Reichstett	Dilhac, Phrakonkham
FR	Lavollee, Levallois-Paris	Dilhac, Phrakonkham
FR	Mauler, Soultz	Dilhac, Phrakonkham
DE	CU Chemie, Lahr	Yazgan, Trnka
DE	Lysoform, Berlin	Bräutigam, vom Brocke
DE	Organica, Bitterfeld	Bräutigam, vom Brocke
DE	Prisman, Lorsch	Yazgan, Trnka
GR	Cleanway , Athens	Prevedouros
IE	Arran Chemical Co, Roscommon, Athlone	Sosingot, Yasenov, Lefevre-Brevart
IE	Burgess, Dublin	Sosingot, Yasenov, Lefevre-Brevart
IE	Biocel, Cork	Sosingot, Yasenov, , Lefevre-Brevart
IT	Cifo, Bologna	Conti, Raffaelli
IT	Endura, Bologna	Conti, Raffaelli
IT	Farbotex, Cerrione, Biella, Piemonte	Ape, Lapenna
IT	Fila, Padova	Privitera, Gissi
IT	Giusto, Milano	Ape, Lapenna
IT	Manufattura Chim, Muggio, Monza/Brianza	Ape, Lapenna
IT	Morocolor, Campodarsego, Padova	Privitera, Gissi
IT	Zapi, Conselve (PD)	Privitera, Gissi
NL	Doedijns, Waddinxveen	Logtmeier, Balduyck
NL	Ravo, Alkmaar	Logtmeier, Balduyck
NL	Multinal Group, Duivendrecht (a new company organised by the local trade association ION)	Logtmeier, Balduyck
NL	KLM mainenance and repair (a new company organised by the local trade association ION)	Logtmeier, Balduyck
PL	Dragon-biz	Figiel, Sompolski
PL	Chamber of Commerce and Industry, Katowice[1]	Figiel, Sompolski
PT	Weber Saint-Gobain	Pedrosa, Lisboa
SK	Malzenice, Malzenice	Kubinakova, Zbihlej
SK	CMK, Zarnovica	Kubinakova, Zbihlej
ES	Betelgeux, Ador-Valencia	Quintana Sainz
ES	Francisco Aragon, Molina di Segura, Murcia	Rosello Villaroig, Sokolova
ES	Grupquisma, Madrid	Gonzalez Vida
ES	Jabonera, Las Torres de Cotillas, Murcia	Rosello Villaroig, Sokolova
UK	Coventry Chemicals, Coventry	Ajao, Pumpalaviciute, Kohtamäki, Sunajko
UK	John Hogg, Manchester	Ajao, Pumpalaviciute, Kohtamäki, Sunajko
UK	Syntor, Runcorn, Cheshire, nr. Liverpool	Torkkeli, Mak, Cioata
UK	Robinson Brothers, West Bromwich, West Midlands	Alasuvanto, Stoyanova, Vainio-Santos, Pirnar

[1] Due to a cancellation of the company “Dakis” a replacement visit was organised with an appointment with the representatives of the Chamber of Commerce and Industry.

Annex II (for background reading)

Findings from the SME Visits Programme

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Introduction

The **SME visits programme** conducted between September and November 2015 was a **training event targeting junior staff members** without a previous work background in industry. It provided 41 ECHA staff members with an opportunity to gain first-hand "real-life" insights into the businesses of SMEs subject to the EU chemicals legislation, by visiting 39 companies in twelve EU member states.

The visits familiarised ECHA staff with **companies working to a multitude of different business models** – from micro-traders to cutting-edge specialised German "Mittelstand" companies as well as their peers in other countries, from formulators to toll manufacturers, from companies with registration obligations to those mostly having to comply with the regulatory requirements for classification and labelling or communication in the supply chain.

In light of the purpose of the programme, it is therefore **a secondary benefit** that the mission reports from visiting staff and a dedicated de-briefing session provided the ECHA Secretariat with **useful feedback on SMEs' preoccupations**.

The findings also need to be read with a **caveat**: As ECHA had organised the programme with the help of the ECHA HelpNet, the European Enterprise Network and the Agency's Accredited Stakeholder Organisations representing industry, the composition of **volunteering companies does not reflect a representative cross-section of SMEs**, but was **generally biased** towards companies that actively interact with such

networks and are thus **relatively better informed**. The visited companies also comprised a disproportionate number of formulators of detergents and lubricants. Furthermore, the ECHA Secretariat selected enterprises with a more promising business profile from a larger pool of volunteers.

In some countries, representatives of **national authorities or EEN contacts accompanied ECHA staff** on some of their visits (e.g., France/Alsace; Netherlands); in others national authorities inquired with ECHA about details of the visits (UK); industry associations covered individual visits in their newsletters (e.g., the specialised German magazine "CPForum").

Main findings

A) Findings on the practical implementation of REACH & CLP

Sources of information

A high proportion of visited companies gave their **industry associations** as their main source of information as well as affiliated organisations, such as the Reach-Ready in the UK. Apart from receiving their newsletters, company staff also attends seminars organised by such associations which they also view as intermediaries towards public authorities. Companies generally feel better represented by their national associations than having an SME voice at EU level.

Some companies consult the webpages of their **national competent authorities**.

A Spanish company participates in a **WhatsApp chat group** on the BPR.

Overall, a number of visited companies prefer to receive information material and guidance in **English** as the language of their external trade or even their internal business language (e.g., visited companies in Austria and the Netherlands – please see also remarks on the translation of ECHA Guidance, below).

A number even of well-performing companies were found neither to be subscribing to the **ECHA e-news** nor consulting the **ECHA webpages**, possibly given the satisfactory support already provided by their industry association.

Internal organisation to meet regulatory tasks

Some visited companies have hired extra staff, sometimes combined with the function of quality manager, to meet their regulatory duties. However, it appears that the visited **companies have largely adjusted to REACH/CLP/BPR-related needs** and are dealing with them in a routinely manner.

Nonetheless, it is clear that **regulatory compliance officers** (or departments) are facing an **increased workload** as well as respective **training needs**, compared to some years ago, necessitating SMEs either to hire staff specifically for this job or to deviate capacities away from R&D which was found to be quite intensive in some more specialised companies that ECHA staff visited. Regulatory compliance staff is often recruited for their **IT skills** and their ability to do **business in English**. This contributes to such staff members generally being younger than the average experienced chemists.

Communication in the supply chain, downstream users, SDS

Overall, visited companies acknowledged the **importance of communication** in the supply chain. Their experiences with SDSs to date are mixed, with an **encouraging**

groundswell of ongoing improvement.

Positive trends:

- The **quality of SDSs has noticeably improved** since REACH came into force;
- Some companies **train their staff and help their suppliers** in this regard to raise awareness for its usefulness and the respective legal requirements. A company, for instance, also conducts weekly meetings between its sales and technical departments;
- Some also **train their distributors on ADR** requirements;
- Not surprisingly, cooperation in establishing **SDS** seemingly works **better with larger companies** than with smaller suppliers;
- Some companies professed always to request the SDS for their raw materials, thereby checking its indications against the ECHA website to ascertain themselves of their registration (by **counter-checking the registration number**); they also have discontinued purchasing from non-compliant suppliers;
- Visited companies regularly update their SDSs and have installed sophisticated **data bases** for their own use; they also communicate the uses of their products by means of the **use-descriptor system**; such in-house **software** is also used to handle the portfolio, in some companies using a decision-tree **to manage the risks** or limit the sale of substances subject to REACH processes;
- Thereby, companies use **commercial IT products** to establish SDSs;
- A company reported that it individually adapts SDSs for its workforce, compressing information into such a **one-to-two-page "adapted SDS"**.

Prevailing challenges:

- Whilst SDSs have often improved, this is not the case with **Exposure Scenarios**;
- **SDSs are often not updated**; for instance, the new CLP pictograms are not yet inserted into the SDSs (Comment: due to an ongoing transition period, this is not yet mandatory);
- SDSs are **not correctly or consistently translated** (sometimes the necessary languages are missing; the texts may be translated, but even the translated versions refer to contact details of toxicology centres or national legislation of the country of production instead of the country in which the product is marketed);
- Sometimes, the SDS are **not translated** into the language of the market, at all;
- At least one of the visited companies stopped exporting a substance due to the **cost of translating** the SDS;
- Companies often see reason to **mistrust information** (substance properties, exposure scenarios) **from non-EU suppliers**; in some cases, third country providers declare the identity of their innovative substances confidential, impeding their classification; in more extreme cases, foreign suppliers make references to fake norms;
- At least one company found it difficult to calculate **PNEC/DNEL values** for their safety assessment;
- **Occupational exposure limits** varying between national jurisdictions (OEL/NDS) further complicate the picture;
- The **size of some SDSs (800 pages!)** render them useless for all practical purposes;
- **Many e-SDS** apparently contain **repetitions** which confuse their readers and extend their length;
- Some companies **correct the SDSs** of their suppliers;
- Some SMEs have chosen to **outsource the preparation of SDSs**;
- Others and their suppliers remain puzzled on how to develop **exposure scenarios for mixtures**;
- There is also confusion to what extent **information from ECHA's dissemination portal** can be used to compile SDSs, as the data published on

the portal is not validated by ECHA; the SDS Guidance is interpreted as allowing this to be done. (Comment: It appears that some national helpdesks encourage companies to make use of data disseminated by ECHA, even though the Agency's Dissemination Portal contains legal advice on the IPR ownership of this data.)

(Comment: These persisting challenges underline the relevance of ECHA's Downstream User communications effort which foresees numerous information products in 2016).

Classification and labelling

Visited companies generally accepted the value of C&L.

- Some companies highlighted the **(very) positive effects** of the **CLP** Regulation improving communication about hazard information; the labelling obligations have markedly improved communication in the supply chain;
- The CLP Regulation has **reduced** the **possibility** for some **to "hide" hazardous properties**;
- The CLP Regulation was seen as having **empowered companies** to demand detailed SDSs from their suppliers;
- **Distributors with strong market power** (e.g., large wholesalers or retailers) are creating pressure to be "ahead of the game" by proper labelling according to the CLP system (even ahead of the expiry of valid transition periods);
- Companies are therefore increasingly aware that proper C&L behaviour impacts on the **reputation of their brands** A number of companies have invested – often quite considerable – in **printing machines** for CLP labels or labels as such; one company even purchased a contingency amount of back-up printers; formulators of mixtures with frequently changing recipes tend to invest into such printing machines and therefore use **blank labels**, whereas companies with more constant production lines tend to purchase stocks of **pre-printed labels**; both models require **considerable investment**.

However, they mentioned a number of shortcomings, too.

- **Formulators** need to adapt their recipes more frequently and quickly than the CLP regime assumes (e.g., they need to keep up with fast evolving formulations of their mixtures by frequently re-formulating their labels);
- Given the **investment needs for labels** (e.g., a company producing specialised chemicals in a highly flexible customer-oriented way stocks 3000 different labels), the two-year **transition periods** of the CLP are regarded as impracticably short, given the stocks of products and/or labels;
- Furthermore, the **transition periods** are seen to be **unfair**: whilst one company has labelled its product as an irritant under the CLP Regulation, a competitor is still marketing an equivalent mixture under the DSD, without any pictogram, at all; this necessitated a company's sales personnel to invest a lot of effort into customer education to explain the new legal regime;
- Numerous SMEs raised the problem of **wasted expenditure** (for instance, to the tune of € 25,000 in one case or of 5,000 printed labels or labels for 750 unique products in others) **on labels** that subsequently needed to be changed; (Comment: ECHA's SME Ambassador, in his function as Chairman of the HelpNet Steering Group, has been consistently appealing to national helpdesk correspondents to argue for a more acceptable approach to be taken by MSCAs; changes due to ATDs and harmonised classification should be imposed at predictable and more affordable intervals);
- Companies are struggling to find practical means to **affix labels to small products**, tubes or curved packages, with pictograms and translated texts, etc.; one company mentioned difficulties in affixing translated labels to tubes of glue, instead of only onto the outside package;

- The quantity of **information** on labels **varies between countries**;
- In another case, the **re-classification** of a mixture was perceived to be too stringent, forcing the SME to change its CLP labels at **considerable cost** when, for instance, a mixture that used to be considered as an irritant was re-classified as corrosive, even though their pH value does not exceed 7-8;
- Several companies remain **confused** on how to **classify mixtures**, overall;
- **Non-harmonised classification** adds to their confusion;
- Some products have needed to be repeatedly **reformulated due to recurring re-classification under the CLP**;
- **Suppliers still do not always provide accurate C&L information**;
- Furthermore, national authorities and industry groupings promote **differing classification criteria**; instructions regarding re-classification are being interpreted differently; one company opined that its national association had misinterpreted relevant criteria; another complained that the authorities in their neighbouring country were not a stringent as in their own;
- One company commented that new **pictograms have changed customer behaviour** even if there was no change in the product (for instance, the change from the St. Andrew's Cross to the corrosion pictogram increased product rejection);
- A company shared its concern that the new **Unique Formula Identifier** for poison centres (UFI) that may need to be placed on labels in the next years would result in the need to maintain two separate data bases;
- One company thought that the **CLP Regulation** should have been combined with the European Agreement concerning the International Carriage of Dangerous Goods by Road **(ADR) rules**. **Inconsistencies** between both legislations result, in some cases, in manually having to label secondary packaging needed solely for transport;
- Exporting companies see **deviations between the GHS and the CLP** regime;
- More anecdotally, one company reported that it had to change its corporate design, at quite some expense, to adapt to the new CLP pictograms as it had matched its **colours** with the old ones.
- Companies generally indicated that, in contrast to large company that exercise customer power, **consumers** neither have enough knowledge nor interest in the labels; they tend to **take note of the pictograms** and often **ignore the precautionary statements**, with their consumer behaviour more driven by pricing and product appearance; some companies appear to question their efforts to fit these statements and their translations onto small labels;
- With regard to end-user awareness, companies' experience **differences between professional and general consumer users**. Companies encouraged further public awareness campaigns to be conducted.

Preparedness for the 2018 REACH registration deadline

(Comment: A **considerable proportion of visited companies** are not preparing registrations for the deadline as they are **formulators**. None of these, however, were contemplating to submit their own registration in case their supplier would fail to do so.)

Some **companies with registration obligations** are still undertaking a cost-benefit analysis to determine if they should even consider registering whereas others reported that their business partners and suppliers had **not yet made up their minds** in this regard, even in cases in which their registration is likely to require a CSA/R. Market uncertainties and doubts about the reliability of non-EU suppliers contribute to **deferring their decisions on 2018 REACH registrations**.
The **high costs** of preparing a dossier (e.g., € 80,000 for the relatively standard data set, or up to € 700,000 for a 28-day repeated dose toxicity study by inhalation, or € 30,000 for having a IUCLID dossier prepared by a consultant), combined with **difficulties in SIEF-communication** (very low response-rates in pre-SIEFs, for

instance) or in accessing data altogether had already forced some of the visited companies to **discontinue parts of their portfolios**. Some SIEFs were seen to have been "taken over" by consortia, putting their SME members at a disadvantage.

One company facing registration obligations of numerous substances **for their 2018 registrations**, indicated that it will **need to make a triage between substances** in its portfolio, as it could not afford to register all of them, given the very high testing costs of £ 250,000 per each of their small volume, niche application substances. The company professed its fear that it would need to **lay off staff** in this context.

The need not only to **register** substances being put onto the market, but also **intermediates**, was also regarded as triggering **unaffordable expenditure** (e.g., whilst registering six substances could be done for € 300,000, registering also the intermediates associated with this six substances as full registrations, instead of merely intermediate registrations, would drive the overall cost up to € 1.5 million). This questions ECHA's interpretation of strictly controlled conditions as a precondition for registering intermediates as such, and not as full registrations (see also remarks on ECHA Guidance, below).

A number of SMEs struggle to find suitable test **laboratories**. SMEs are also facing difficulties in affording the laboratories' charges, not least for needs under the BPR. Laboratories were said to charge € 5000 solely for the development of an analytical method. Only highly-performing visited companies have sufficiently qualified analytical laboratories in-house to conduct quality control and to ensure compliance. One visited company thought that ECHA should publish a list of GLP-accredited laboratories.

Similarly, some indicated that they could not afford specialised **REACH consultants**.

Companies realise that they will **need to re-train** their regulatory officers **in the use of submission IT tools** as these have considerably evolved since their previous work with them for the 2010 and 2013 REACH registration deadlines.

The **management of SIEFs**, the often **"ridiculously high" costs of Letters of Access**, the behaviour of Lead Registrants trying to squeeze SMEs out of their markets, were critically mentioned by numerous visited companies. One company specifically thought that registering well-known substances had been made unnecessarily complicated, expensive and time consuming. ECHA staff got the impression that the OSOR principle (one substance – one registrant) would not be adhered to for some substances (e.g., antimony). Companies reported of **SIEF agreements without re-calculation clauses** and leaving members uninformed of the cost calculation formulae.

However, **some companies** professed to have encountered **smooth** pre-SIEF and **SIEF management and communication**.

However, some are encountering **problems with post-registration follow-up**, typically with SIEF communication continuing with members, but the **Lead Registrant ceasing further contact**. One company reported of the Lead Registrant having unilaterally updated the classification of the substance to a less sever category without informing the SIEF members.

Registration costs particularly hit companies frequently changing their regular product portfolio to flexibly satisfy customer needs in **small tonnages**, rendering such **production unprofitable**.
Also, some confusion exists on the effects of **pre-registration**. Can it be withdrawn? A number of visited companies face the legacy of having pursued a "full portfolio pre-registration strategy".

With some companies, ECHA visitors also noted **some quite basic ignorance of the registration requirements**, namely who actually has to register and how to achieve a fair agreement on **data sharing**.

Companies tend to see all costs (registration fees, administrative charges, expenditure for studies, and in-house resource investment) as a **cumulative regulatory overhead expenditure**, **not distinguishing between ECHA fees and other costs**.

Enforcement

Some companies advocated further **harmonising criteria for inspections**. The **perception of an "uneven playing field"** was reported by a number of companies. Inspectors are believed to generally follow **national enforcement agendas**. A voice was heard, stating that the authorities of one member state are swift to take cases to court. Another mentioned that **inspectors** interpret the SDSs for mixtures by assuming the higher concentration of a hazard; they are seen to be **more knowledgeable when checking pure substances**.

Other issues

Feedback received also mentioned the **PPORD requirements** being too stringent for SMEs undertaking a lot of research, in particular for intermediate uses, to swiftly and flexibly satisfy their customers' needs. They also render research less affordable for SMEs.

One company aired the concern that alternatives to **Chromium VI** of equivalent quality would not be available whereas another was more confident in that regard.

Two visited companies were typical of the **Italian dye sector**, needing to register hundreds of substances for dyes and mixtures of which the recipes have to flexibly react to the needs of the Italian fashion industry, interest in using read-across, etc. (Comment: The ECHA Secretariat has been in direct contact with representatives of this particular sector.)

The **national helpdesks** of some countries were not held in high esteem, their services being perceived as slow and sometimes inappropriate for resolving specific questions. Quite a number of companies professed never to have contacted their national helpdesk. ECHA staff gathered the impression that a number of less experienced of the visited companies would have received answers to their rather basic questions if they had simply approached their helpdesks.

B) Findings on ECHA's support activities

Information provided by ECHA

Companies overwhelmingly commented that the **ECHA website is overloaded with information** which therefore is **difficult to navigate**, all the more as the website's search function is hardly helpful.
(Comment: This feedback coincides with the results of ECHA's recent customer insight survey which is being taken as input for re-designing the structure of ECHA's website.)

Various interlocutors **suggested** that ECHA's e-news could more clearly **distinguish between** information related to the **different pieces of legislation**, i.e. BPR, CLP and REACH.
(Comment: ECHA is foreseeing such a change already).

Another **desired more sector-specific information**.

One company ventilated the idea of ECHA **summarising legislative and guidance updates** in specific semi-annual communiqués. A few appreciated the website without any reservation.

A company particularly **praised ECHA's webinars**, mentioning that they had watched all of them, and had found the Q&As very useful.

One feedback deemed ECHA's **social media** information to be less relevant for companies than for other audiences.

A number of companies suggested that ECHA should **make FAQs available in translation** too.
(Comment: ECHA has already foreseen under its 2016 Work Programme).

A company suggested targeting information on REACH requirements more intensively to **Only Representatives** as a means to improve information on substances imported from abroad. (Comment: this concurs with the results of the REF-3 project conducted by the ECHA Forum). Another company mentioned that it is often unclear whom an Only Representative actually represents.

Use of ECHA guidance, IT tools and contacts with helpdesks

Companies generally found the **ECHA Guidance** documents (including Guidance in a Nutshell) to be useful; others thought them to be too complicated and lengthy. Due to their length, some SMEs prefer to read the British HSE guidelines (of normally 10 to 12 pages), instead. Quite evidently, the degree of specialisation and expertise of the company determined these varied opinions on the guidance ("you have to be a chemist to understand the guidance"). The frequent changes of guidance related to the Information Requirements, particularly for the BPR guidance (comment: related to frequent ATPs = Adaptations to Technical Progress) were criticised. In the past, some guidance updates had been published too close to relevant deadlines. (Comment: something on which ECHA has improved over the last years). Guidance documents were criticised for repeating too much of the legal texts. Practical examples were found to be particularly useful in providing guidance.

ECHA's **SDS Guidance** was particularly appreciated, but companies also realise that, even being comprehensive and of **good quality**, it cannot take into consideration all aspects that SMEs may face.
As mentioned above, some companies raised their reservations against the **stringent definition of Strictly Controlled Conditions (SCCs)**, especially with regard to the rigorous containment. These conditions impact critically on the business of SMEs involved in the flexible production of small-scale and solid substances. In this context, **ECHA's Guidance on Intermediates** and its interpretation of SCCs was questioned. Some companies thought that the Guidance had taken the interests of large companies into consideration, but not comments provided on behalf of SMEs.

Numerous interlocutors indicated errors in the **translation of guidance** into their languages; some therefore chose to read the original versions in English. For the same reason of better understanding, a Spanish company, for instance, consults the webpages of the British HSE.

Visiting ECHA staff also noted a desire for **sector-specific guidance**.

Generally, companies having addressed it, perceived the **ECHA Helpdesk** positively.

One company expressed its wish for an **"online instant chat box"** to seek quick help from peer companies.

The more experienced companies that ECHA staff visited provided generally very positive feedback on **ECHA's IT tools** (IUCLID, REACH-IT). Those who are using them do so regularly and expressed their overall satisfaction with the tools. (Comment: as mentioned in the introduction, the sample of visited SMEs comprised more experienced companies; ECHA will roll out an entirely new generation of more user-friendly IT tools by mid-2016). However, **downloading and installing** these tools required **IT skills** which companies found difficult to muster. When explained to companies, the forthcoming **new REACH-IT interface** was well received. Wherever visited companies are not submitting registrations to ECHA, they were found to be rather ignorant of respective IT tools.

It was also remarked that IUCLID does not contain all fields needed for BPR purposes. **IUCLID plug-ins** were found to be helpful. The **length of IT manuals** was criticised. Interlocutors in visited companies unsurprisingly stated that a key challenge resulted from **using ECHA's IT tools only occasionally**; obviously, **routine matters**. When questioned, a company also showed interest in ECHA's plans for a **"IUCLID as a service"**, however with the caveat of not feeling entirely comfortable with ECHA hosting their data before being convinced of adequate security measures being in place. Some companies mentioned the **inconvenience of frequent software upgrades**.

Feedback on **Chesar** indicated that it was useful, but for specialists, only.

Numerous companies appreciated ECHA's **Dissemination Portal**. A company is already keenly awaiting ECHA's new **InfoCards**.

In this context, some companies were confused by the **discrepancies** between the C&L published on the ECHA website and that undertaken by their suppliers.

Equally, ECHA having **separate Article 95 lists from the Dissemination Portal** was seen to be disadvantageous.

The **R4PP3 and SPC Editor** tools are seen to be complicated.

Whilst some companies found it **difficult to understand** the registration process due to its complexity, one company particularly highlighted **inquiries' process** in this regard.

One company expressed a desire for more **support material on QSAR**. Others would appreciate **more information** on how ECHA evaluates specific endpoints when **alternative methods** are used for filling data gaps (comment: the company appeared not be aware of respective information already published by ECHA).

A company would have found it useful to know who was behind an **Access to Documents** request submitted to ECHA to be able to benefit from respective background information.

Another company thought the ECHA's **data sharing dispute mechanism** was not attractive as the company did not consider it advantageous to "go to war" against a competitor on which they depend in other contexts.

Some companies wished the **regulatory logic of** some **ECHA scientific opinions** to be better explained to the public: a company has decided to discontinue producing a disinfectant which it has been continuously manufacturing since 1900 of which an active ingredient may now be identified as a SVHC even if an alternative acting against certain pathogens has not yet been found. Another company mentioned that it was unclear to

them why sodium ortho-borate was considered to be toxic whilst potassium salt was not.

It was also thought that the **members of ECHA's scientific Committees** as well as MSCA rapporteurs or experts often **lacked sufficient knowledge of the uses** of a substance to be able to make a sound regulatory judgement on them.

Companies were generally **unaware of** the **criteria applied for fee reductions**. This was the case even with such companies that exceed the SME benchmarks due to their size or ownership patterns. It seems that managers who have to focus their attention on the business and operational needs of their companies do not have the "small print" of ECHA's criteria on their "radar screens". The SME visits showed that companies may comprehend the complex criteria better on the basis of presentations than of the already comprehensive website information. A company suggested that information on the SME criteria should not only be provided on the ECHA website, but also appear in the submission tool, itself.
(Comment: ECHA is already preparing this for the release of REACH-IT 3.1 in 2016).

One company sought more **transparency** on the background to the **level of BPR-related fees** charged by ECHA.

C) Findings related to the impact of EU legislation

Overall, ECHA visitors got the impression that this cumulative regulatory burden made companies perceive **legislation as the greater source of burden** than its implementation by ECHA or other public bodies.

Some companies thought that the wording of the **CLP Regulation** was **difficult to understand**, due to its legal jargon and inconsistent structure. One company suggested adding a summary of content, another to **include bookmarks** in the PdF version of the published CLP legislative text. Some wording in the Portuguese **translation** of the legal text was found to be incorrect.

Impact on the business environment

A recurring important conclusion from the company visits was to recognise the **cumulative regulatory burden** that SMEs are facing **as a result of overlapping pieces of legislation**. Numerous interlocutors did not perceive REACH as the most burdensome, but its combination with other EU and national legislation imposing obligations related to environmental protection, cosmetics, road transport safety, food safety, the marketing of detergents, VOCs, eco-labelling, occupational exposure levels, and either outdated or specific national legislation (e.g., national poison centres or nano-registries). They expressed a desire for closer harmonisation of relevant regulatory stipulations. One company also mentioned the ever-changing EU regulations for the marking of fuel as impacting on its business with solvents. Another, for instance, suggested exempting substances from REACH Authorisation if they had already been authorised under other EU legislation or making them subject of a lighter testing regimes (e.g., food additives).

Specialised companies described that they need to bear this burden against the background of the **intense competition** on their markets. As one company formulated it, the regulatory burden will make the **niches** disappear **on which SMEs depend**. Some companies see their **business models unduly threatened** and occasionally are already considering moving their production into fields subjected to lighter regulation.

(Comment: **Partly**, this perception of the legislation appears to have been **fuelled by frustrated expectations** that the REACH and Biocidal Products Regulations would simplify this "regulatory jungle").

This burden is aggravated by the need of various companies to take into consideration the regulatory obligations applied in **non-EU countries** into which they **export**.

Some companies criticised the legislation for not taking a sufficiently risk-based approach. The **hazard-orientation** of regulatory processes resulted in **unnecessary costs** to be borne by SMEs. For instance, the recent re-classification of formaldehyde or forthcoming one regarding ethanol were seen to be due to this bias. As another example, imposing too many CLP labels ("over-labelling") not only drove up the cost of printing and of administering labels, but also drove down the actual attention consumers pay to them.

Some visited companies fear for their **business continuity** with regard to **substances that may disappear from the market** wherever the **costs** linked to the **REACH registration** process exceed the market benefit. The related negative **impact on employment** was seen as a hidden cost of REACH. There is also an impact of reducing the wealth of recipes.

A number of SMEs visited mentioned the **prohibitive costs of increasing their production volume to a higher tonnage** band above 100 t/a. The legislation's volume thresholds were thought to put SMEs at a disadvantage. In this light, **many suppliers** of chemical substances produced in low tonnage bands are still **waiting until the last moment** to decide whether to register or not.

With regard to various substances, customers have not yet gained confidence in **alternatives**, preferring the continued supply of existing ones (however, see also feedback on alternatives under "effects of REACH", below).

In light of the regulatory needs, a number of companies saw a **risk of making failed investments** into the development of new substances for which they may not be able to find a commercially viable market, putting jobs and profits into jeopardy.

Visiting staff also learned of scepticism towards the **possible misuse of** substance-related **information** that ECHA makes publicly available by non-EU competitors.

One company expressed fears that the **TTIP** agreement would put EU companies at a disadvantage. (Comment: This could possibly be addressed by the Representations of the European Commission in EU member states increasing their awareness raising activities to point out that chemicals safety standards are not part of the negotiation).

The visits indicated that, as a result of REACH and CLP as well as due to growing operative experience, businesses generally give due regard to ensuring a **high level of worker protection**, having invested into related technology and personal protection equipment (PPE) as witnessed during the walk-arounds on the shop floor. One company also specifically highlighted its investment into training provided to its staff on personal protection and the safe handling of its chemicals. However, this could not equally be said of a minority of visited companies.

Feedback from companies producing Biocidal Products

Visited companies producing biocidal products generally complained about the **high costs** that the BPR imposes, **fearing to be forced out of the market**. Many are already observing **market concentration effects**. Some even spoke of "monopolisation". One company thought that all biocides business would even stop in the country where it is seated. Even middle-sized companies informed that their production of active substance was **only commercially viable due to cross-financing** from other fields of the businesses. For some substances, producers appear to be

contemplating qualifying them as medical products to “save themselves” from the BPR. Others are considering moving more into the cosmetics market, even if this means investing quite considerably into re-tooling their production sites and re-designing their production processes. Thus, the BPR is also contributing to **market distortions**.

A company preparing a dossier for an active substance is getting widely varying offers from **consultants** for creating a dossier (from £ 25,000 to £ 300,000!). In another case, a consultant was asking € 400,000 for data-sharing work without even defining the scope of his offer. In addition to such **uncertainties regarding the total regulatory expenditure**, further costs will arise for one of these companies adapting their production site to Lower Tier COMAH criteria, probably to the tune of £ 50,000 (drainage, site emergency provisions, and registration with the authorities). Such expenditure evidently represents a substantial burden for SMEs.

Companies also qualify the **costs of data sharing** as **prohibitive**. Overall, **data-sharing** does not appear to be as developed under the BPR as under REACH.

Contrary to REACH, the SME visits showed some companies complaining not to find any equivalent support from their **business associations** on the BPR.

A company observed **abusive market practices** by companies that do not declare their biocidal products.

One company mentioned that it could not use a certain active substance as the **companies holding the authorisation** for use in the respective country were either **not providing it** or impose unacceptable conditions for its use.

Another company specifically appreciated the **benefit** that the BPR requires a **detailed assessment of toxicity**.

By contrast, it deemed the **heavy “bureaucratic” BPR processes** to be on the downside, even **disastrous** for SMEs. Applying for **Union Authorisation** was perceived to be **prohibitively expensive**. Even only applying for a **National Authorisation** was considered **unaffordable** for some companies, due to the high costs of dossier preparation, for instance of skin sensitisation tests, **forcing them to stop production**.

According to one company, the **number of active substances on the market has already considerably decreased** due to the BPR. As remaining active substances apply similar modes of action, this would lead to resistances developing in the longer run.

Having to buy **raw materials** solely from companies registered under Article 95 BPR has already driven up the **cost** of such supplies.

One company mentioned that it could not use a certain active substance as the **companies holding the authorisation** for use in the respective country are either **not providing it** or impose unacceptable conditions for its use.

A company also mentioned the inconvenience of **differing BPR interpretations** by various public authorities and **different national requirements**.

(Comment: The frustration with the BPR may also be connected to expectations that may have been held that the **change from the BPD to the BPR** would bring about a simplified system, but companies having to realise that they **still quite widely fall under national jurisdiction**, e.g., having to meet the requirements for national authorisation in a neighbouring member state to which they export).

Feedback on the benefits of the legislation (REACH /CLP / BPR)

A **considerable portion of visited companies** stated **already tangible positive effects** of REACH:

- **Workers' understanding of the chemicals portfolio and of its risk management needs** has increased;
- When competitors stopped the production of certain substances due to the new regulation, this **triggered the development of alternatives**;
- Some of the visited companies have **abandoned producing certain substances**, such as CMRs;
- Some companies have **developed new substances in response to the classification needs under CLP**;
- Some visited companies request their suppliers to provide annually updated **information on the SVHC content** of their products and are subsequently working on substituting these;
- SME visitors found a number of **examples of successful substitution**, for instance of an industrial laundry detergent, thereby not only moving to a less hazardous substance, but also achieving an alternative that does not increase their production costs;
- Some companies **switched to EU suppliers** to be sure of **REACH conformity** (on the other hand, some visited companies still fear the relocation of chemicals production outside the EU); on the other hand, one company reported that their suppliers would in practice sign any statement of compliance only to get awarded the contract;
- **When changing suppliers** for commercial reasons, companies **check on the substance** having been registered and its uses being covered;
- REACH was also seen as having **aligned the quality standards in handling chemical portfolios** at national levels and thus contributed to a **more balanced market**;
- In spite of persistent shortcomings, REACH has **triggered better communication in the supply chain**;
- Summarily, these developments tend to indicate that REACH has contributed to **improving competitiveness**.
- Registrations under REACH have **increased the confidence** in products as well as raw materials;
- Companies have intensified and **improved their cooperation with industry associations**.

SMEs with evidently little experience still find **REACH** to be **difficult to understand and very complicated**. Some visited companies notice that their less experienced business partners are not clearly informed of their obligations.

Some companies indicated their impression that **toll manufacturers** are **not aware of their legal obligations**.

Some companies thought that the biggest drawback of **REACH** had been to create a **lucrative business around data ownership**, starkly reducing the availability of such data. Due to their limited time and pecuniary resources, **SMEs** are often **not in a position to negotiate** with financially more powerful companies.