Seminar on Tips from 2010 Registration – Efficient Strategy for REACH registration in 2013/2018

- Part II REACH: Review, lessons learnt and recommendations -

Tokyo, 26 October 2011

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Agenda

Introduction

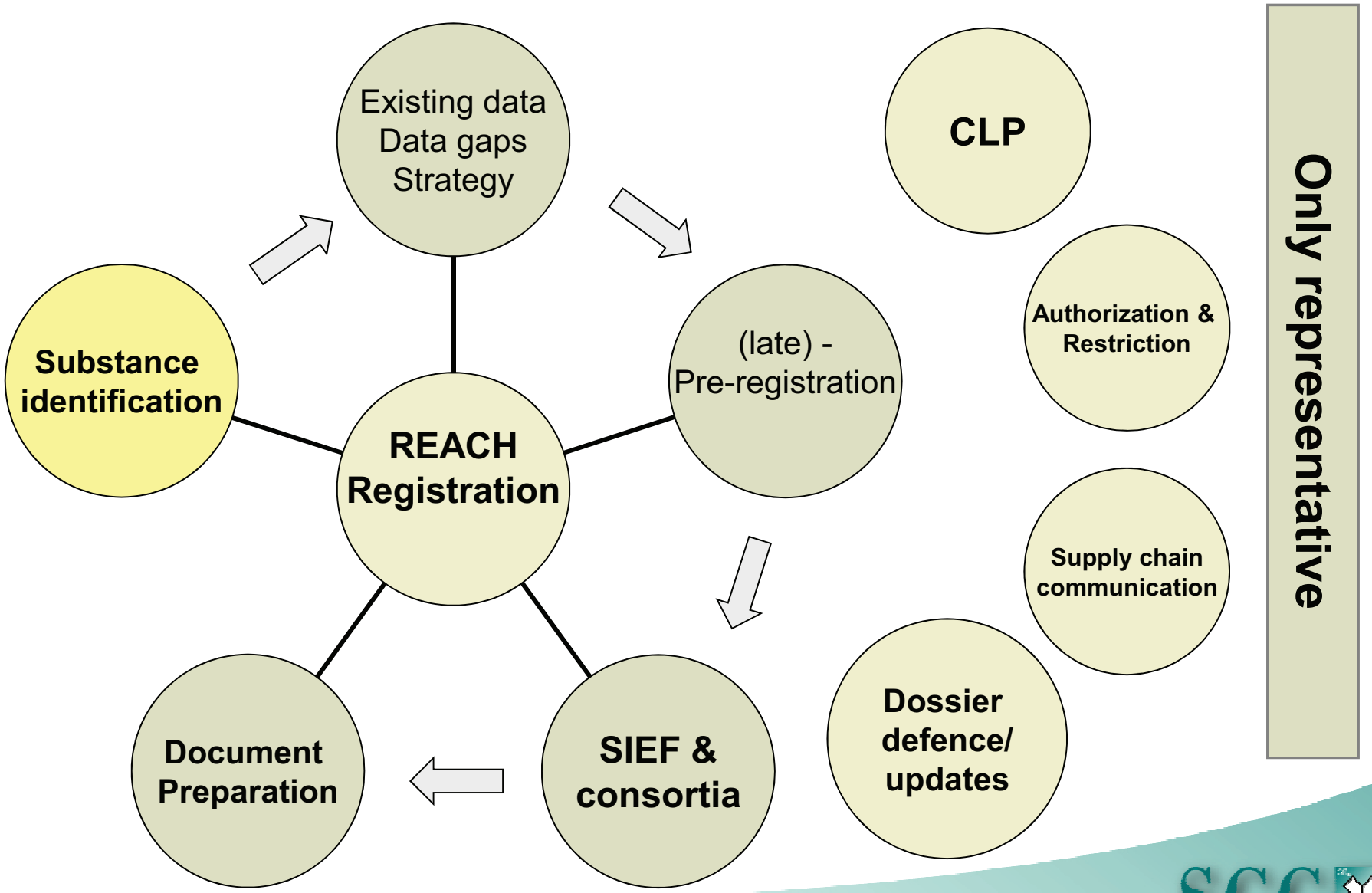
Part I - REACH & CLP: new developments in the EU

Part II - REACH: Review, lessons learnt and recommendations

Part III - CLP: Review, lessons learnt and recommendations

ANNEX

II The REACH Process – A Long Way to Compliance



II Substance Identification - Recommendations

- **Good analytical data and clear interpretation is a main key.**
- Start early to know your substance in detail.
- UV/Vis, IR, 1H-NMR and GC/HPLC are regarded as the absolute minimum requirements and need to be interpreted in the IUCLID dossier.
- Impurities and their analytics must not be neglected (sameness).
- UVCB is not a complimentary ticket for not providing analytics (significant experience from Notification of New Substances (NONS)).
  - General rule: substance > 10 % needs to be identified
- Confidential business information should be considered already at this early stage - data will be disseminated.
- First experiences made:
  - Isomers/ stereo-isomers are considered different substances
  - Generic EC-number = UVCB ≠ multi-constituent substance

II Substance Identification - Recommendations

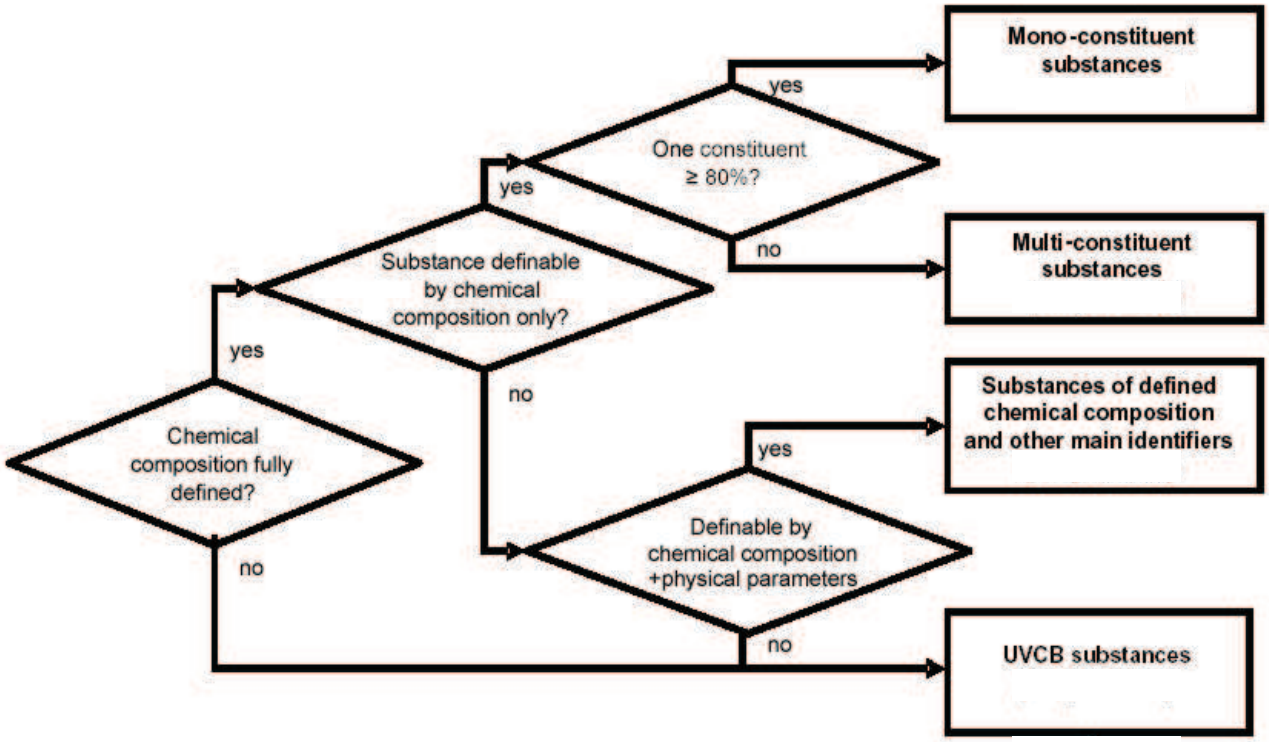
(continued)

- ECHA's first findings of 2010 dossiers: quality problems of many dossiers[1)]:
  - Ensure clear substance ID and unambiguous identification of the substance
  - Provide detailed information on the composition
  - Ensure the composition given is verifiable by qualitative and quantitative analytical data
  - Provide clear, concise description of quantitative analysis
- As a new REACH actor: prepare a substance inventory with all relevant information (ID codes, chemical name, tonnage, role under REACH etc.).
- **Substance identification is the first step to a successful registration.**

1) According to Leena Ylä-Mononen, ECHA-Director of Evaluation, Brussels, 23 Sept. 2011

II Substance Identification

Substance identification is supposed to be straightforward – according to ECHA*. Case by case it can be a real challenge under REACH and will have a huge impact on the joint registration approach!



Polymers

Isomers **(structural/optical)**

Additives/stabilizers

Confidential data

etc.

* ECHA: Guidance for identification and naming of substances under REACH

II Substance Identification – Reduced Requirements for Intermediates

- Substance use & handling/properties important to profit from reduced registration requirements such as isolated intermediates (according to Article 17 and 18 of the REACH Regulation).
- Intermediate concept is still a matter of interpretation (for details see ECHA-guidance* and position papers by CEFIC** / FECC***).
- Company decisions on intermediate use of a substance should be well-documented and kept available for inspection authorities.
  - Downstream users must support this claim by confirming strictly controlled conditions in the entire supply chain
- The REACH legal text should be the basis for this judgment in context with ECHA guidance.
- **Thorough identification in the beginning of the REACH process, less requirements/costs in the end.**

* ECHA: Guidance on intermediates, Dec. 2010
** Cefic: Briefing note revised ECHA guidance Intermediates under Strictly Controlled Conditions, June 2011 (http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/Final_QA-SCC_final%20for%20publication20110513.pdf)
*** Cefic, FECC: Position paper, Febr. 2011 (http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/)

II Existing Data, Data Gaps & Intelligent Testing Strategy: General Aspects

- Potential registrants are required to provide data on their substances as specified in the Annexes VI to X of REACH. Minimal data set Annex VI to VIII.
- New *in vivo* testing using experimental animals should be considered as a last resort (also required by REACH regulation, Annex VI).
- Several possibilities exist to waive/not carry out individual tests and should be carefully checked/taken into consideration (**Pros**: no animals, less expensive; **Cons**: extensive justification required by ECHA).
- Alternatives to testing:
  - *In vitro* methods
  - Grouping of substances and read-across
  - Quantitative Structure-Activity Relationship (QSAR) models (e.g. OECD toolbox)
  - Weight of evidence approach

II Existing Data, Data Gaps & Intelligent Testing Strategy: General Aspects

- Note that the quality and adequacy of information are not evaluated before a registration number is assigned; however, if ECHA identifies inadequate data, the missing information will be requested.
- Provide transparent, scientifically valid explanation & good documentation (as described in Annex VI of the REACH regulation).
- The acceptance of alternatively generated data by ECHA is still unclear but must be justified well in any case!
- ECHA's first findings of 2010 dossiers[1)]: "justifications provided for use of alternative methods fall short of REACH requirements"
- ECHA requires decent justification if data is being waived.

1) According to Leena Ylä-Mononen, ECHA-Director of Evaluation, Brussels, 23 Sept. 2011

II Existing Data, Data Gaps, Intelligent Testing Strategy – Initiation of Studies

- Consider that studies usually require more time and costs than expected.
  - Analytics are the biggest challenge
- Anticipate already before initiation the possible, maybe undesired, outcome of the study in your general strategy.
- Testing laboratory landscape in the EU underwent substantial changes in 2011 (closures of well-established laboratories; merges etc.)
- In principle, registrants have to submit a testing proposal for animal studies prior to undertaking testing (Annex IX).
- When designing the testing strategy for REACH, keep also in mind other regulatory EU and non-EU programs to make use of synergistic effects (global approach).
- The choice of guideline depends sometimes on the regulatory purpose and their acceptance; a careful selection is therefore a good guarantor for generating appropriate data and to minimise costs.

II Existing Data, Data Gaps, Intelligent Testing Strategy – Initiation of Studies

- Recommendation for the 2013 deadline:
  - Literature search and SIEF surveys should be completed first (still no guarantee for late responses)
  - Start with the required studies as soon as possible if not done yet!
  - Early start allows a sequential testing scheme thus cost minimisation!
  - Early start allows for additional studies in case of unexpected results!
  - Early start allows selecting the laboratory and not using the one an only which has capacities left....

II (Late)-Pre-Registration - Recommendations

- Companies may use the option of “late pre-registration” provided by Article 28(6) of the REACH Regulation if they manufacture or import chemical substances for the first time.
- Late pre-registration does not apply to companies that failed to meet the pre-registration deadline of 1 December 2008. These companies cannot continue producing or importing the substances before registration.
- When making a late pre-registration, you will need to be prepared to justify your reasons for the late pre-registration (e.g. new legal entity, new production...).
- To make use of the extended 2013 deadline, the last chance for a late pre-registration is six months from now, until 31 May 2012 (12 months before the relevant deadline)!

II SIEF - Key Points for a Successful Work

- The main aim of the SIEF is the exchange of animal data, the agreement on sameness (problematic), the agreement on classification and labeling, and the successful registration of the substance.
- Lead Registrants and SIEF members are interdependent to a certain extent and cooperation among SIEFs is important for successful registration.
- What did not go well in the 2010 registration time:
  - Function of the SIEF formation facilitator (SFF) was blocked or not filled;
  - Lots of dormant members without any interest in the substance;
  - Lots of non-target, time-consuming communication;
  - Very low participation quote in surveys initiated by the SFF or the Lead Registrant;
  - REACH-IT no appropriate communication system; each SIEF has its own communication system.
  - Discussion on the value of “cheap” studies (cost driver for administrative costs)
  - Extensive contract negotiations
  - Calculation of Letter of Access (LoA) very difficult (divider of the total costs?)

II SIEF - Key Points for a Successful Work (continued)

Lead Registrants should:

- Be proactive and “lead” the SIEF members until registrations by providing the relevant information in a timely matter (e.g. surveys, time schedule, LoA costs and contents).
  - Sometimes calculation basis for LoA difficult to find
- Use an appropriate communication system depending on the SIEF member number (e.g. web based system).
  - REACH-IT message box does neither clearly show the substance nor the sender/importance of the message

II SIEF - Key Points for a Successful Work (continued)

SIEF members should:

- Watch the information provided by the Lead Registrant carefully and participate in surveys (e.g. data availability vs. initiation of vertebrate studies, cost calculation).
- Collect data on uses within the supply chain as early as possible.
- Keep sufficient resources - more work as expected.
- Ensure active communication.
- Have expertise not only with regard to REACH and CLP but also have some background for legal and scientific questions.
- Should recognise that the JOINT registration is the goal and everybody in the SIEF can contribute to a successful and efficient registration.
- As a SME which is especially dependent on the efficient SIEF functioning (to reduce investment of time and money) seek for immediate help if “problems” occur:
  - Contact the Lead Registrant;
  - Seek advice at helpdesks of MSCA, ECHA helpdesk and on the ECHA website, by industry associations, in seminars & workshops or from service providers).
  - Clarify your downstream user’s/client’s needs: REACH registration numbers become more and more a mandatory tool

II Consortia - Key Points for a Successful Work

The real work is done here if no single Lead is active

- Keep sufficient resources - more work as expected.
- Have expertise not only with regard to REACH and CLP but also have some background for legal and scientific questions.
- Decision makers should at least be present in the steering committee (if installed).
- Ensure a good communication and transparency within the consortia.
- Minimise administrative efforts and focus on the technical/scientific work (2010 deadline: some consortia assess administrative costs of over one million EURO for one substance! Consequently, the LoA was sometimes extremely costly).

II Consortia - Key Points for a Successful Work

(continued)

The real work is done here if no single Lead is active

- Collaborate with other consortia members - even though they are competitors.
- Consider that a cooperation with just a few companies is a suitable, easy alternative to a complex consortia as communication processes are streamlined and the entire SIEF will profit from low administrative costs.
- For SME, the cooperation is usually not the best solution. Reliance on the work of the experienced companies (prerequisite: well functioning) and purchase of the LoA within the SIEF.
- However, early contact is recommended as costs tend to increase for late joiners

II SIEF - Letter of Access and SIEF agreement - experience and recommendations

- Contract negotiations in 2010 were often time and money consuming.
- Standard contracts should be used (CEFIC contract* can serve as starting model; delete sections which do not apply).
- Costs for LoA have been increased often due to administration costs.
- Common practice: LoA for dossier instead of LoA for single studies (reduced administrative burden; can be a win-win situation for all parties).
- Costs for LoA may vary significantly.
- Clarify what you get besides the token: IUCLID, CSR...?

* Model Substances Information Exchange Forum Agreement

II SIEF - Letter of Access – Variability in Practice

- LoA example 1
  - Common monomer, 2,550 SIEF members
  - Lead provided token, analytics, CSR and dossier with summaries of all available studies
  - Tonnage band: 1 to 100 t/a — EUR 4,000
  - Tonnage band: 100 to 1,000 t/a — EUR 7,000
  - Tonnage band: >1,000 t/a — EUR 9,000
- LoA example 2
  - Common monomer, 888 SIEF members
  - Lead provided only token
  - Tonnage band: 1 to 100 t/a — EUR 30,000
  - Tonnage band: 100 to 1,000 t/a — EUR 30,000
  - Tonnage band: >1,000 t/a — EUR 30,000

II SIEF - Letter of Access – Variability in Practice

(continued)

- LoA example 3

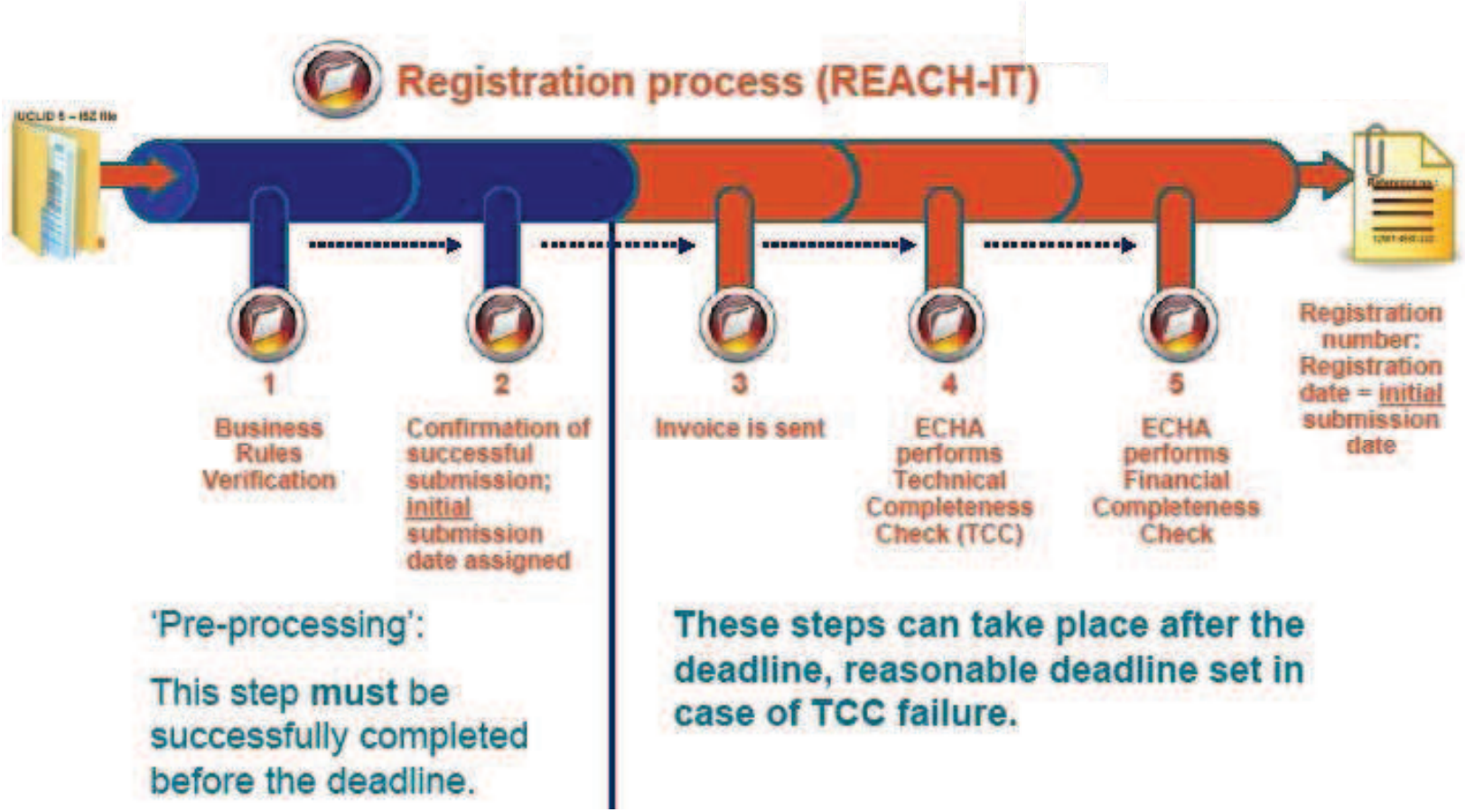
  - Common chemical substance, > 3,500 SIEF members
  - Tonnage band: 1 to 10 t/a EUR 30,000
  - Tonnage band: 10 to 100 t/a EUR 50,000
  - Tonnage band: 100 to 1,000 t/a EUR 180,000
  - Tonnage band: >1,000 t/a EUR 200,000

  - Although this LoA-fee seems exorbitant, the regular SIEF members have simply no chance or bargaining power to negotiate the price down.
  - Legal actions difficult!
  - But costs are still significantly lower than the generation of all data and the respective dossier alone!
  - So far, no concrete recommendation by national and international authorities.

II Document Preparation - Recommendations

- Especially problematic: document preparation for monomers if only polymers are imported.
- Also the technical dossier requires sometimes time-consuming efforts.
- Each SIEF member needs to complete the individual substance/company specific information in sections in the IUCLID dossier (sections 1, 3, 4, 11, and 13).
- Complete these sections as early and as much as possible before receiving the Lead Registrants dossier (sections 2, 5-10, 12).
- For the submission of your dossier to ECHA, information from the Lead Registrant (token and joint registration name) are required.
- It is strongly recommended to check dossiers through the dissemination plug-in tool provided by ECHA.
- Also, tools are available for the fee calculation.
- ECHA sends just one invoice reminder (only via REACH-IT) for an unpaid invoice. Make sure that you respect the extended due date as your REACH submission will otherwise be rejected.

II After submission of the Dossier in REACH-IT



II Statistics of the 2010 Registration

(Source: ECHA, 01 Dec. 2010)

1. Number of Submissions

Dossier type	Accepted for Processing		Successfully Completed	
	Total*	For the 2010 deadline**	Total*	For the 2010 deadline**
Registration	19 702	17 174	14 265	12 312
Transported Isolated Intermediate	3 544	2 692	2 699	1 979
On-Site Isolated Intermediate	1 429	857	1 037	492
Total	**24 675**	**20 723**	**18 001**	**14 783**

*Total includes dossier updates during the period.

**Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

2. Breakdown of Submissions

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

* Includes individual submissions for non-phase in substances

** Number of Member Registrants for every Lead Registrant

5. Dossiers by Company Size

Company size	Accepted for Processing For the 2010 deadline*
Large	86%
Medium	9%
Small	4%
Micro	1%

* Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

ad 1: Dossiers submitted by an Only Representative: 19 %

II Estimations for the 2013 Registration

(Source: ECHA, 23 Sept. 2011)

- Registration obligation for substances > 100 tonnes per year (if pre-registered): by 31 May 2013
- Around 3500 substances are expected to be registered in 2013
- Around 15000 dossiers are estimated to be submitted.
- As oppose to the first registration deadline in 2010, more small and medium sized enterprises (SME) are expected to be active under REACH now.
- The first time REACH activities of SME will be a big challenge for everybody (resources, know-how, language etc.).
- ECHA started awareness campaigns, provides some support also for SME (ECHA website; overview guidance documents like fact sheets, guidance in a nutshell etc.).

II Status of dossier evaluation

- Evaluation of 5 % (at a minimum) of the registered dossiers (approximately 1,000 dossiers from over 20,000 lead and member dossiers for the 2010 deadline)

- Evaluation methods of the dossiers:
  - Technical Completeness Check, TCC (ECHA)
  - Compliance check (ECHA)
  - Testing proposals (ECHA)
  - Detail evaluation of prioritised substances (Member States Competent Authorities (MSCA)) (Community Rolling Action Plan)
  - Detailed evaluation of NONs more likely by ECHA only.

II Technical Completeness Check - ECHA

- Automatic computerised check of technical issues (all dossiers).
- Check of business rules (some to be checked manually by ECHA).
- Registrants can perform the technical completeness test with a plug-in tool in IUCLID before submission via REACH-IT (new TCC less demanding than former version).
- Feedback from ECHA within one hour after submission.
- Issue of invoice by ECHA within one day.
- Pay submission fee within two weeks.

Submission Report - [redacted]

Passed Tasks

No.	Task	Remark	Result
1.	Virus check	-	Succeeded
2.	File format validation	-	Succeeded
3.	Check XML structure	-	Succeeded
4.	Enforce Rules	-	Succeeded
5.	Store Dossier	-	Succeeded
6.	Create Substance Identity	-	Succeeded
7.	Assign MSCAs	-	Succeeded
8.	Technical Completeness Check	-	Succeeded
9.	Pay Submission Fee	-	Started
10.	Overall Completeness Check	-	Started
11.	Issue Reference Number	-	Not Performed Yet
12.	End of Pipeline Activities	-	Not Performed Yet
13.	Data Dissemination	-	Not Performed Yet
14.	Trigger WorkFlow	-	Not Performed Yet

II Compliance Check - ECHA

- Compliance check mainly on substance ID
- Check done by ECHA prior to evaluation of testing proposal
- Tight deadline for comments (4 weeks)
- Main issues
  - Decision between mono-constituent/multi-constituent/UVCB substance
  - Large concentration ranges for constituents and stabilizers not warranted by ECHA (substance ID of whole SIEF)
  - Detailed analytics
- Tight deadline for submission of dossier update (2 weeks)
- NONS are handled differently.
- Now direct exchange (via phone) with ECHA possible and highly recommended (but be aware: discussions are not legally binding).

II Compliance Check – ECHA: Draft Decision

ECHA
European Chemicals Agency

Helsinki, 14 -09- 2011
GB/ab/D(2011)3843

[redacted]
Germany

Communication number: [redacted]
Last submission number: [redacted]

Registration number: [redacted]
Latest submission date: 27/10/2010

NOTIFICATION OF A DRAFT DECISION ON A COMPLIANCE CHECK UNDER REGULATION (EC) NO 1907/2006

The European Chemicals Agency (ECHA) has examined your registration dossier of [redacted] in a compliance check pursuant to Article 41 of Regulation (EC) No 1907/2006 (REACH Regulation). Subsequently ECHA has prepared a draft decision according to Article 41(3) of the REACH Regulation.

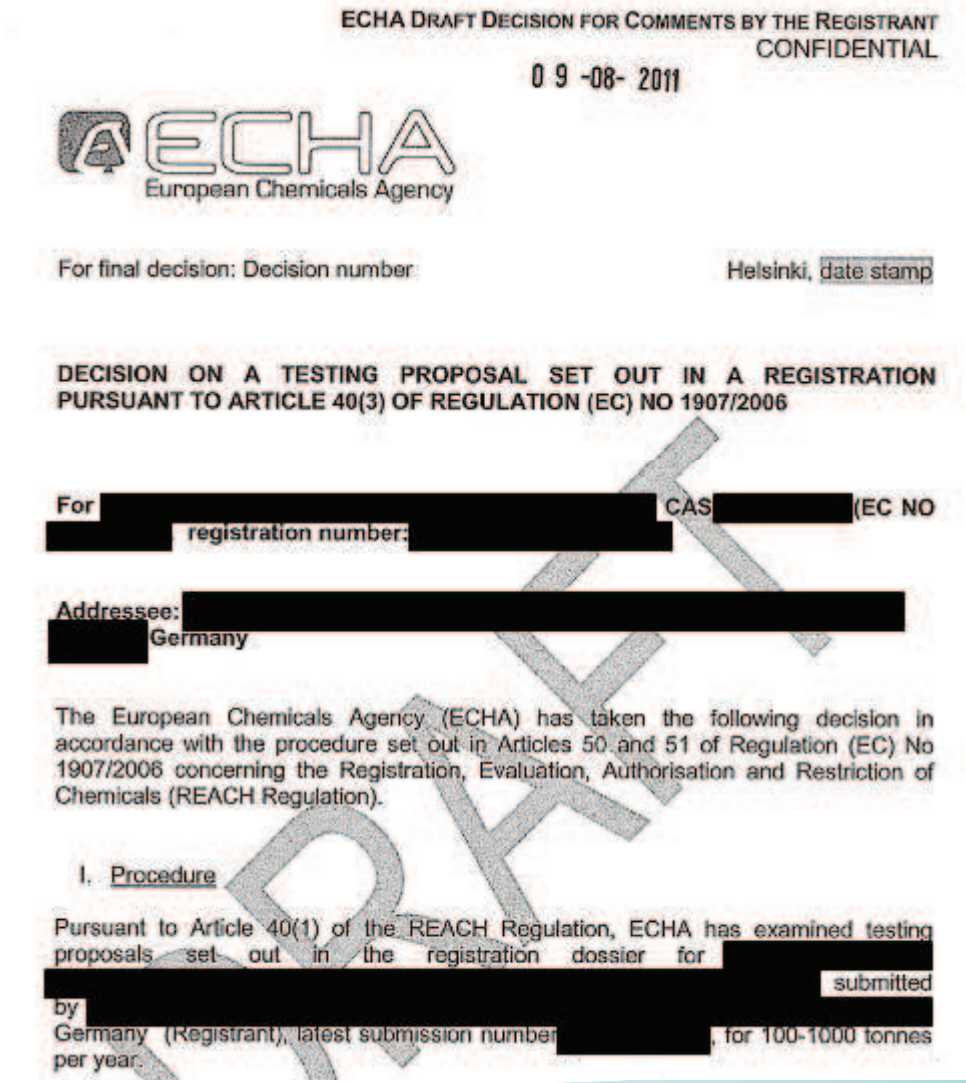
Please note that ECHA initiated the present compliance check of your registration dossier in order to request missing information that are necessary for evaluating the testing proposal included in your registration dossier.

II Testing proposals - ECHA

- Testing proposals have to be submitted for higher tier ecotoxicology and toxicology tests (Annex IX and X REACH)
- All testing proposals will be evaluated by ECHA
- Deadlines for ECHA feedback on testing proposals
  - 01.12.2012 for all registrations from 01.12.2010
  - 01.06.2016 for all registrations from 01.06.2013
  - 01.06.2022 for all registrations from 01.06.2018
- Public consultation phase for 6 weeks

  http://echa.europa.eu/consultations/test_proposals/test_prop_cons_en.asp
- Draft decision by ECHA sent via REACH-IT only! Ensure REACH-IT on a frequent and regular basis.
- Short deadline for comments (4 weeks). If no comments are provided in time, acceptance of the ECHA request.

II Testing proposals – ECHA: Decision on a Testing Proposal



ECHA DRAFT DECISION FOR COMMENTS BY THE REGISTRANT
CONFIDENTIAL

09 -08- 2011

ECHA
European Chemicals Agency

For final decision: Decision number

Helsinki, date stamp

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For [redacted] CAS [redacted] (EC NO [redacted] registration number: [redacted]

Addressee: [redacted] Germany

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined testing proposals set out in the registration dossier for [redacted] submitted by [redacted] Germany (Registrant), latest submission number [redacted], for 100-1000 tonnes per year.

DRAFT

II Testing proposals – SCC Example

- Submission of dossier including testing proposals in November 2010
- Public consultation in May/June 2011
- Draft decision in August 2011
- Testing proposals for
  - *In vivo* mammalian erythrocyte micronucleous test (OECD 474)
  - Sub-chronic repeated dose toxicity study (OECD 408) with additional parameters for reproduction toxicity
  - Pre-natal developmental toxicity study (OECD 414)
- Detailed evaluation of testing proposals by ECHA
- Specific modification of tests possible (e.g. additional parameters)
- Tight deadline (one year) for dossier update, incl. CSR
- Possibility to directly contact responsible person at ECHA (via email and for a short time now via phone) to discuss the requests.
- Check of capacities of laboratories.
- Initiate the studies after clarified framework conditions.
- Keep ECHA informed in case of delays, problems.

II Results of the first Dossier Evaluation – General

(ECHA, 2011)

- Substance identity was not clear and/or not consistent.
- If no standard procedure followed, scientific explanation was not at all or not transparently provided.
- The quality of robust study summaries was not optimal.
- Chemical Safety Assessments (CSA) were not optimal regarding transparency, consistency and completeness.
- Information related to intermediates were not sufficient.

- **Provide sufficient, transparent and consistent information as well as scientific explanation.**

II Results of the First Dossier Evaluations - SCC experience

Inquiries (NONS)

- All information according to Article 10 has to be provided, also for intermediates.
- HPLC- or GC spectra even for inorganic substances are potentially required in order to demonstrate the absence of organic impurities.
- Descriptions of analytical methods used for the determination of the substance purity and the concentrations of impurities have to be provided.
- Actual measurement data/ results of analysis need to be provided.
- Percentage of the main impurities with minimum and maximum value and typical concentration have to be provided (... sometimes an issue of “creativity”).
- Spectra have to be conclusive, even the arbitrary scales. Table of peaks containing retention times, areas and corresponding concentrations have to be provided.
- Successful inquiry on one substance (client 1) does not guarantee successful inquiry for the same substance (client 2). Evaluation at ECHA depends on person, experience and other factors.
- It may happen that 3 -4 submissions are needed to pass the evaluation at ECHA and to receive the Inquiry and EC number.

II Results of the First Dossier Evaluations - SCC experience (continued)

Hazard Assessment – Study data

- The IUCLID file is basis for ECHA evaluation – studies may be considered invalid based on data provided in the IUCLID, ECHA has no full study reports available.
- Basic and detailed information can/should be included in IUCLID file
- Data waiving needs sound basis, e.g. technical, scientific, exposure
- Additional study data may be requested by ECHA based on exposure assessment outcome, e.g. inhalation toxicity
- Aquatic toxicity – chemical analysis vs. test item directly weight into test vessel
- Difficult handling of insoluble substances (< 1 mg/L)
- Water accommodated fractions are less acceptable, especially for rapidly hydrolysing substances
- Generic EC-number = UVCB ≠ multi-constituent substance

II Results of the first Dossier Evaluation - Specific Topics (ECHA, 2011)

CSR issues

- Exposure calculations were not transparent.
- Exposure scenarios didn't cover all intended uses.
- Exposure assessment didn't cover all exposure routes, endpoints, life cycles.
- No transparent or no consistent relation between:
  - exposure assessments and risk description
  - use conditions and risk management measures

DNELs and PNECs

- Derivation rationale was not transparent.
- Explanation missing in case of deviation from the guidance documents.
- Wrong DNELs, PNECs derived - do not match to relevant exposure scenarios.
- Errors regarding the starting point of the derivation.

- **Provide transparent calculation rationales and cover all intended uses, exposure routes.**
- **Try to get the best (highest DNELs/PNECs) which can be scientifically justified!**

II SVHC Substances: Authorisation Process and Communication in the Supply Chain

Authorisation process

- Step 1: Identification of SVHC substances (by authorities; target: 135 by end of 2012; accelerated process requested by EU Commission)
  - Commenting possibility by **interested parties**
  - Outcome: **Candidate List (currently 53 SVHC substances; 7 new candidate substances)**
- Step 2: Prioritisation (by authorities)
  - Candidate substances prioritised
  - Commenting possibility by **interested parties**
  - Outcome: **Inclusion into Annex XIV** (REACH regulation)
- Step 3: Application for authorisation of Annex XIV substances (by industry)
  - Base fee EUR 50,000!
  - Documents to be provided: CSR, analysis on alternative substances
- Step 4: Granting of authorisation (by European Commission)
- Step 5: After a sunset date set, the use of the Annex XIV substance is prohibited!

Communication of SVHC in the supply chain

- Communication is already required for a candidate substance!
- Once a substance is listed on the candidate list, it will always stay on the list; Articles 31-33 (REACH regulation) apply!

II SVHC substances: authorisation and communication in the supply chain (continued)

List of substances subject to authorisation

- 1st amendment of Annex XIV* to the REACH regulation on 17 February 2011: six substances subject to authorisation:
  - 5-tert-butyl-2,4,6- trinitro-m-xylene (**Musk xylene**)
  - 4,4'-Diaminodiphenylmethane (**MDA**)
  - Hexabromocyclododecane (**HBCDD**)
  - Bis(2-ethylhexyl) phthalate (**DEHP**)
  - Benzyl butyl phthalate (**BBP**)
  - Dibutyl phthalate (**DBP**)
- Latest application deadline for authorisation of these substances: January 2013/2014.
- Sunset dates for these substances: July 2014/2015 (afterwards their use is prohibited!).
- Intermediates are not subject to authorisation.

* Commission regulation EU No. 143/2011 of 17 February 2011

II The extended SDS (eSDS) and the new REACH Format for SDS

- Extended SDS under REACH add relevant exposure scenarios based on chemical safety assessments performed according to registration requirements.
- Addition of exposure scenarios justify that certain uses of the substances have been considered and that potential exposure has been assessed (clear definition of allowed uses).
- Need to be concise and readable to the intended user; avoid complicated information - provide easy to follow text.
- Contents of the eSDS should reflect real use patterns.
- Readers of the eSDS should understand the key massages of the eSDS (e.g. use conditions, risk management measures).

II The extended SDS (eSDS) and the new REACH Format for SDS (continued)

- Currently, no agreed format (up to 1,000 pages of eSDS!)
- Automatic generation of the eSDS from the CSR is the only practical solution for the future (e.g. CHESAR).
- Translation necessary – use standard phrases so that they can be translated automatically.
- Feedback from DU will also determine the extent of the CSR/eSDS.
- A GAP exists between eSDS legal requirements (Article 31, Annex II) and expert knowledge in the supply chain evaluating/using eSDS.
- Different eSDS-approaches exist. No standard approach in place yet but tools are under development.
- Even the format of the basic SDS (not the annex) has substantially changed under REACH (e.g. defined sections, inclusion of the registration number(s), CLP classification for substances etc).

II Only Representative (OR) – Special importer

- Non-EU companies cannot fulfill the requirements of REACH themselves: either the EU importer or an appointed OR (covering all EU importers) is liable under REACH.
- The OR is the EU focal point for the non-EU manufacturer and EU companies as well as for authorities and has in principle the same legal obligations as an importer.
- The OR is responsible for the registration dossier and number. The importer covered by this OR is not obligated to register under REACH, but is being considered a downstream user only. The OR model is considered the exception and not the rule.
- The OR is the legally responsible entity for the registration and hazard communication for the specified substance and should have the qualification needed.
- Work for the OR does not end when the registration is made (updates of the dossier, communication tasks, volume tracking etc.).

II Only Representative – Supply Chain Communication

- Communication with supply chain members cannot always be done by the non-EU-manufacturer due to EU competition law (need of an independent third party, trustee or other tools).
- Cooperation by all supply chain members cannot be expected. Communication with non-EU supply chain members can be a challenge as they do not have direct legal obligations under REACH and confidential business information play a big role.
- The supply chains for chemical substances can be very complex:
  - Different countries involved
  - Different roles of actors (manufacturers, preparation producers, articles producers, downstream users)
  - Processing of the substance (substance on its own, in preparations, in articles)
  - Volume tracking
- Enforcement audit: the OR is the legally responsible European entity.

II REACH Implementation Status – REACH-EN-FORCE-1*

- REACH-EN-FORCE-1 = 1st EU-wide REACH audit
- The first control audits by Member State Authorities took place in 23 EU countries plus Island and Norway.
- Emphasis of the audits in 2009/2010 on:
  - Pre-registration
  - Registration
  - Safety Data Sheets (only formal criteria, no qualitative checks)
  - Branches: mainly manufacturers of chemicals, whole sale & retail
- Harmonised audits in the EU countries (not a 100 % identical audit but standardised & electronic documentation)
- Goals of audits:
  - Implementation of REACH goals, information of companies
  - Harmonised approach
  - Avoidance of competition law issues

* Source: Ministry for work; Germany

II REACH-EN-FORCE-1 - Number of Audits*

Tab. 1: REACH-EN-FORCE 1 Audits 2010 (numbers in brackets = all audits including audits not part of statistical evaluation)

EU country	Number of audits	Number of audits per 1 million inhabitants
Estonia	75	57.7
Island	11	36.7
Cyprus	29	36.3
Bulgaria	137	18.0
Hungary	123	12.3
Slovakia	59	10.9
Malta	3	7.5
Ireland	31	7.4
Poland	268	7.0
Latvia	14	6.1
Belgium	59	5.6
Spain	220	4.8
Sweden	40	4.3
Norway	15	3.1
Germany	**257 (279)**	**3.1 (3.4)**

EU country	Number of audits	Number of audits per 1 million inhabitants
Finland	14	2.6
Greece	28	2.6
Slovenia	5	2.5
Austria	20	2.4
Denmark	13 (37)	2.4 (6.7)
Netherlands	34	2.0
United Kingdom	99	1.6
Romania	19	0.9
Portugal	2	0.2
France	14 (297)	0.2 (4.6)
Total	**1589 (1918)**	

* Source: Ministry for work; Germany

II REACH-EN-FORCE-1 - Status of the audited companies*

- Main focus in 2009: Manufacturers, importers and downstream users
- Main focus in 2010: even more on downstream users

Tab. 2: Status of the audited companies in Europe and Germany (double role possible)

Status	Number in Germany, 2010	Number in Germany, 2009	Total Number in Europe, 2009
Manufacturer	38	127	878
Importer	56	133	666
Only Representative	15	25	83
Downstream User	115	201	858

* Source: Ministry for work; Germany

II Non compliance results of REACH-EN-FORCE-1*

Germany:

- 2009: 3 of the 279 companies (ca. 1.1 %) were not compliant
- 2010: 2 of the 150 companies (ca. 1.3 %) were not compliant

EU:

- 2009: 2.6 % were not compliant

Tab. 3: Number and type of sanction measures in Europe and Germany

Sanction measures	Germany, 2010 (total: 150)	Germany, 2009 (total: 279)	Number in Europe, 2009 (total: 1589)
Information of the public („blame and shame“)	0	0	3
Letter	24	31	96
Order/ prohibition	1	3	169
Penalty	0	0	12
Complaint of an offence	0	1	3
Others	4	13	121

* Source: Ministry for work; Germany

II REACH-EN-FORCE 2*

A 2nd EU-wide REACH audit started with the emphasis on:

- Downstream users
- Communication within the supply chain
- Cooperation with customs

Topics to be checked during REACH-EN-FORCE 2 audits:

- REACH regulation (EC 1907/2006):
  - Registration obligation
  - Restrictions, no placing on the market
  - SDS
  - Information regarding articles
  - Risk assessment and risk minimisation measures
  - Data access and record keeping
- CLP regulation (EC 1272/2008):
  - Information regarding C&L and record keeping according to Article 49
  - Title V (harmonisation of the C&L, C&L Inventory)
  - C&L notification according to Article 40

* Source: Ministry for work; Germany

II REACH-EN-FORCE 2 - First Results

- As REACH-EN-FORCE 2 has just started this year, no final report yet available.
- First results (1 and 2) in Germany (state of Baden-Württemberg*):
  - Audited companies were in general well prepared
  - Still a need for consulting due to complex REACH requirements
  - In single cases violation of the registration obligation (especially by importers not by manufacturers)
    - Incorrect distinction of article versus substance
    - OR: qualification not fulfilled (“sufficient background in the practical handling of substances and the information related to them”)
  - Precautionary pre-registrations (not required, e.g. non-phase in substances)
  - Inadequate safety data sheets
  - Internal communication to be improved (“REACH interfaces” between purchasing, production and EHS)
- Auditors made the experience that REACH lead to a change of suppliers and caused a supply bottleneck.

* Regierungspraesidium Freiburg, 4 May 2011

II REACH-EN-FORCE 2 - RIPE

- Major difference to REACH-EN-FORCE 1 is – besides the topics to be checked – the availability of **RIPE**.
- RIPE is a new web portal for REACH and CLP inspectors and stands for **R**EACH **I**nformation **P**ortal for **E**nforcement and was launched on 27 June 2011.
- RIPE facilitates enforcement activities in the EU by providing key REACH and CLP information online (not be available to the general public).
- Online available information is related to the dossier submissions to ECHA and includes details on the submitting legal entity, date of submission, tonnage band, production and uses sites, intended uses, information on C&L, and guidance on safe use.
- Furthermore, key information on physico-chemical, toxicological and ecotoxicological properties can be accessed by around 2,500 inspectors in the EU Member States, Norway, Iceland and Liechtenstein.
- The new online tool is expected to facilitate the work of enforcement authorities significantly and will thus most likely lead to a better compliance with the REACH and CLP provisions. On the other hand it will lead to a more stringent control of REACH actors and thus more challenges by industry.

II Recommendations to efficiently tackle the next REACH challenges

Preparation Phase

- Correct **substance identification** is the first step to a successful and cost-efficient registration.
- Establish a **substance inventory** containing also of relevant business information
- Carry out a **GAP analysis** based on the actual REACH requirements (e.g. UN physico-chemical methods).
- Define clearly your role.
- Clarify the status of your raw material suppliers with regard to REACH.

Testing

- Development of an **intelligent testing & registration strategy** taking into account available data, read-across, category approach, data waiving options etc.
- Limit **experimental tests** to a minimum as they are time & money consuming, and the results are uncertain/unforeseeable (current guidelines!).
- Take new *in vitro tests* into account to avoid testing on vertebrates (e.g. skin irritation).
- Keep track of ECHA acceptance of new guidance (e.g. extended one generation guideline, see also Report from the Directors' Contact Group, 20 Sept. 2011).
- Initiate required tests as soon as possible for the 2013 deadline.

II Recommendations to efficiently tackle the next REACH challenges (continued)

Dossier preparation

- Provide transparent, scientifically valid and thorough explanation/justification (e.g. waiving, alternative testing methods)

SIEF and Consortia

- Promote **active SIEF communication** (as a lead and as a SIEF member) to have a clear schedule of upcoming milestones fixed as soon as possible.
- Evaluate carefully the need for a consortium membership or other forms of cooperation or the acquirement/conditions of the Letter of Access.
- Select a cooperation solution based on the individual requirements of your company to minimise administrative and legal costs; put the emphasis on the required technical REACH work.
- Act in time with regard to your and your client's needs.
- Consider cooperation with your EU-clients/downstream users (cost sharing or other models).

II Recommendations to efficiently tackle the next REACH challenges (continued)

Extended Safety Data Sheets

- Use tools for automatic generation and translation of the eSDS (e.g. CHESAR 1.2) as soon as available and valid.
- Consult new relevant guidance documents currently being reviewed by ECHA as soon as they are published.

SVHC, candidate list, authorisation procedure

- Monitor the ECHA website with its' various lists updated by ECHA (registry of intentions, candidate list etc.).
- Communicate candidate substances in the supply chain (internal processes established?).
- Be aware of authorisation process and check Annex XIV of the REACH regulation and/or the amendments, respectively.
- Be aware of restrictions in Annex XVII of the REACH regulation!

II Recommendations to efficiently tackle the next REACH challenges (continued)

General recommendations

- If a standard procedure does not apply, find a pragmatic solution and provide thorough explanation.
- Contact the Member State Helpdesks, the ECHA Helpdesk and ask for clarification/confirmation.
- Document all activities (retention time up to 10 years of last manufacture/import!).
- As a EU company: be prepared to be audited by EU authorities.
- Be prepared for an evaluation of your dossier by ECHA – 30 days time to respond (Article 50 of the REACH regulation).
- REACH has an impact also on internal business processes (e.g. communication in the supply chain).

II Recommendations to efficiently tackle the next REACH challenges (continued)

General recommendations

- Be prepared that the REACH process will keep you busy besides registration obligations (defense work; update on new information; new ECHA requirements like for example PBT assessment in Annex XIII)
- Be aware of several reports mandated by REACH (1 June 2012) and any follow-up actions:
  - **ECHA (Art. 75 (2)):** "The Agency shall be subject to a review by 1 June 2012."
  - **General report (Art. 117 (4)):** "Every five years, the Commission shall publish a general report on: (a) the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and; (b) the amount and distribution of funding made available by the Commission for the development and evaluation of alternative test methods. The first report shall be published by 1 June 2012."
  - **Scope of REACH (Art. 138 (6):** avoidance of overlaps with other relevant Community provisions e.g. RoHS; legislative proposal may be presented.
  - **Low tonnage (Art. 138 (3)):** "On the basis of that review, the Commission may present legislative proposals to modify the information requirements for substances manufactured or imported in quantities of one tonne or more up to 10 tonnes per year."

ご静聴有難うございました。

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Annex: Tools

- **IUCLID** (Dossier tool) and REACH-IT
  - Latest IUCLID version 5.3 released in March and REACH-IT 2.2 in April 2011
  - New dissemination plug-in available since February 2011 (for registration dossiers based on category approach)
  - Latest Technical Completeness Check (TCC) plug-in (5.3.1) available since Aug. 2011; includes substance identity checks for inquiry dossiers
  - Next update expected in summer 2012
- **CHESAR** (plug-in to IUCLID): to support the Chemical Safety Assessment; to facilitate the generation and updating of Chemical Safety Reports; compile the annex to the SDS
  - Latest version: Chesar 1.2 enables the users to generate the exposure scenarios for communication to downstream users. These exposure scenarios can then be annexed to the extended Safety Data Sheet
  - Next update scheduled for 2012: further functionalities regarding exposure assessments (new tools may be included: e.g. ART, ConsExpo, EMKG, Riskofderm...)
- **OECD toolbox**: to use Quantitative Structure-Activity Relationship ((Q)SAR) methodologies to group chemicals into categories and to fill data gaps by read-across.
  - Latest version: 2.2

Annex: List of abbreviations

- CEFIC: European Chemical Industry Council
- CLH: Dossier with proposal for harmonised classification and labelling
- CLP: Classification, Labelling and Packaging
- CSR: Chemical Safety Report
- ECHA: European Chemicals Agency
- EHS: Environmental Health and Safety
- eSDS: extended Safety Data Sheet
- DNEL: Derived No-Effect Level
- DPD: Dangerous Preparations Directive
- DSD: Dangerous Substances Directive
- GPS: Global Product Strategy
- LoA: Letter of Access
- MSCA: Member States Competent Authorities
- NONS: Notification of New Substances Regulations; Substances notified under Directive 67/548/EEC
- OR: Only Representative
- PNEC: Predicted No-Effect Concentration
- QSAR: Quantitative Structure Activity Relationship
- RoHS: Restriction of Hazardous Substances Directive
- SCC: Scientific Consulting Company GmbH
- SIEF: Substances Information and Evaluation Forum
- SFF: SIEF Formation Facilitator
- SME: Small and medium sized enterprise
- SLOJ: SCC Liaison Office Japan
- SVHC: Substances of Very High Concern
- TCC: Technical Completeness Check
- UVCB: Substances of unknown variable composition, complex reaction products or biological materials
- VCI: German chemical industry association