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What U.S. Companies Need to Know to Prepare for REACH 2018 and Beyond

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Today's Presenter

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REACH Registration Dossier: Content of the Individual Company Part

Structure of the Registration Dossier

- Need to distinguish between different aspects of the Registration obligations:
  - The Joint Data Dossier (Annex VII/VIII data)
  - The Test Plan for Annex IX/X Data
  - The Chemical Safety Report
  - **The Annex VI Individual Company Dossier**
  - The Administrative Fees

Composition of the Joint Dossier

- The Lead Registrant for a substance submits, on behalf of the other registrants (non-Lead members), the following information:
  - Robust study summaries and study summaries
  - The classification and labeling (C&L) of the substances
  - Testing proposal(s), if needed
  - Guidance for safe use of the substance;* and
  - The Chemical Safety Report (CSR)*

** No obligation to submit jointly*

Composition of the Non-Lead Member Dossier

- Once the Lead Registrant submits the joint part of the registration dossier, he will provide the other registrants with the **name of the joint submission** and a **security token** to be used in REACH-IT to identify themselves as part of the joint registration.
- As an individual registrant, you will need to submit the following so called REACH Annex VI information:
  1. information on the identity of the EU manufacturer or importer or Only Representative (OR);
  2. information on the identity of the substance; and
  3. information on manufacture and uses of the substance.

Information on the Identity of the EU Manufacturer or Importer or Only Representative

1.1. Registrant information

1.1.1. Name, address, telephone number, fax number and e-mail address

1.1.2. Contact person

1.1.3. Location of the registrant's production and own use site(s), as appropriate

Information on the Identity of the EU Manufacturer or Importer or Only Representative *Cont'd*

1.2. Joint submission of data

- In this section, you will need to indicate:
  - which parts of the registration are submitted by the Lead Registrant; and
  - mention the submission token.

1.3. Third party appointed under Article 4:

- (this only applies if you have appointed a third party representative to interact on your behalf in the Substance Information Exchange (SIEF).
- 1.3.1 Name, address, telephone number, fax number and e-mail address of that representative
- 1.3.1. Contact person

Information on the Identity of the Substance (1/3)

The information given in this section must be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)
2.1.2. Other names (usual name, trade name, abbreviation)
2.1.3. EINECS or ELINCs number (if available and appropriate)
2.1.4. CAS name and CAS number (if available)
2.1.5. Other identity code (if available)

Information on the Identity of the Substance(2/3)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including Smiles notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

Information on the Identity of the Substance(3/3)

2.3. Composition of each substance

2.3.1. Degree of purity (%)
2.3.2. Nature of impurities, including isomers and by-products
2.3.3. Percentage of (significant) main impurities
2.3.4. Nature and order of magnitude (… ppm, … %) of any additives (e.g. stabilising agents or inhibitors)
2.3.5. Spectral data: ultra-violet (UV), infra-red (IR), nuclear magnetic resonance (NMR) or mass spectrum (MS)
2.3.6. High-pressure liquid (HPLC) and gas chromatogram (GC)
2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (impurities and additives)

Information on Manufacture and Use(s) of the Substance(s) (1/2)

3.1. Overall EU manufacture and/or imports in tonnes per registrant per year in the calendar year of the registration (estimated quantity)

3.2. In the case of an EU manufacturer or producer of articles with a substance intended to be released during use: Brief description of the **technological process** used in manufacture or production of articles.

3.3. An indication of the **tonnage used** for one's own use(s)

Manufacturing Process

If your substance is a UVCB, you need to describe the manufacturing process, as the chemical composition alone is not sufficient to identify this type of substance. The level of detail depends on the type of process.

Typically, you should provide information on the following points:

identity of starting materials and/or source, including their ratio;

reaction type and scheme (identification of each individual process or synthesis step);

any relevant process parameters, such as temperature, pressure or pH values;

purification and isolation steps;

"end of reaction" values, such as pH-value, viscosity, iodine number or acid number.

Information on Manufacture and Use(s) of the Substance(s) (2/2)

3.4. Form (substance, preparation or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in mixtures made available to downstream users and quantities of the substance in articles made available to downstream users.

3.5. Brief general description of the identified use(s)

3.6. Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses

3.7. Uses advised against where applicable and why (i.e. recommendations by supplier). This need not be an exhaustive list.

Important References

- Guidance for identification and naming of substances under REACH and CLP: http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf
- Data Submission Manual 18 – How to report the substance identity in IUCLID 5 for registration under REACH http://echa.europa.eu/documents/10162/13653/substance_id_report_iuclid_en.pdf
- REACH-IT Industry User Manual – Part 11 (Online dossier creation and submission for inquiries): http://echa.europa.eu/documents/10162/13654/reachit_online_dossier_creation_inquiry_en.pdf
- Data Submission Manual 5 – How to complete a technical dossier for registrations http://echa.europa.eu/documents/10162/13653/dsm5_tech_dossier_en.pdf

2018 Registration Costs

Registration Deadline

- For 1-100 tonnes per annum (tpa) pre-registered phase-in substances the deadline is May 31, 2018
- In practice you should submit well ahead of time in case your dossier fails the completeness check
- It will be more difficult to pass the completeness check then it was in 2010 and 2013

Registration Cost Factors

- Tonnage band
- Intermediate v. Full Registration
- Simple Chemical Safety Report (CSR) vs Exposure Scenarios
- Data in the Joint Dossier
- Number of 2010 and 2013 Registrants and 2018 Projection
- Individual Registration Preparation Costs
- Registration Fee

Registration Fees

- Fees are set out in Commission Implementing Regulation No. 2015/864 at http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02008R0340-20150625
- You get 30 days to pay and you get one reminder
- Registration fees for 1-10 tpa (Joint Registration) range from €1304 to €65 depending on size of company
- Registration fees for 10-100 tpa (Joint Registration) range from €3506 to €175 depending on size of company
- Fees for intermediates under Strictly Controlled Conditions (Joint Registration) range from €1304 to €65 depending on size of company.
- For Only Representatives (ORs), fee reduction for Small and Medium and Micro Sized Enterprises (SMEs) is determined by the relevant data of the non-EU manufacturer, including relevant information from linked and partner companies of that enterprise.
- 1-10 tpa fee can be waived if all Annex VII data submitted

Determining SME Status

Enterprise category	Headcount	Turnover or Balance sheet total	
medium-sized	< 250	≤ 50 million euro	≤ 43 million euro
small	< 50	≤ 10 million euro	≤ 10 million euro
micro	< 10	≤ 2 million euro	≤ 2 million euro

Complex Financial Test

- Ownership structure at the time of the submission
- Account closure and years of reference
- Headcount of staff
- Audited financial accounts and/or consolidated financial accounts
  - Follow instructions at http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category

SME Verification by ECHA

- Can happen at any time.
- Most SME declarations to be checked.
- If wrong fee is paid, you will need to pay the correct fee plus an administrative fine.
- Administrative fine can be as much as 2.5 times the fee avoided.
- If you fail to pay, your registration is revoked.

Intermediate vs Full Registration

- Before joining a registration for an intermediate substance, confirm that you are actually producing an intermediate.
- Below 1000 Tonnes, intermediate registration does not require data.
- 1000+ Tonnes only requires Annex VII data.

Nomenclature and Sameness

- No value in paying for the joint registration of a substance that you do not produce.
- Be careful about Isomers, Stereoisomers, etc.
- Review Lead Registrant's Substance ID Profile (SIP) carefully.

Registration Updates (1)

- The following updates to a registration involve a fee
- Increase in tonnage band
- Requests for confidentiality
- Change in legal entity

Registration Updates (2)

The following updates to registrations are free:

- Higher to lower tonnage band;
- Registrant details, where the legal entity is not affected;
- Composition of the substance;
- New uses/uses advised against;
- New risks or hazard information;
- Changes to the chemical safety report;
- Changes to Guidance on safe use;
- Notification that an Annex IX or X test must be developed;
- Requests to make previously confidential information accessible;
- Changes in classification and labeling.

New Developments

- ECHA plans to roll out “Cloud Services for SMEs” in 2017; essentially an on-line version of IUCLID for declared SMEs.
- Reduced ability to conduct in-vivo studies for eye and skin irritation and sensitization.

Substance Information Exchange Forum (SIEF) Interaction

SIEF in Concept

- Potential Registrants agree on how to work together
- Potential Registrants select the Lead Registrant
- Potential Registrants gather the data
- Potential Registrants agree on Classification and Labeling
- Potential Registrants share the costs

SIEFs in Practice

- Major Producer or Small Group of Major Producers Take Responsibility
- Communicate with SIEF Members either by Email or through IT-Platforms such as SIEF IT
- Provide Summary Information
- Ask for Response by Certain Date and if Response is Not Provided Than Agreement is Assumed

SIEFs in Practice (2)

- Sometimes there is no producer willing to take charge
- Service Providers step in to fill the void
- Sometimes this is organized such as REACH Orphan Substances Consortium (ROSC) formed by ARCHE, Chemservice, and KV Consulting Services. http://www.kvconsultings.com/reach-2018-orphan-substances-consortium/
- In some cases the Service Provider is questionable. See, e.g., ECHA Alert Dated Feb 22, 2016 “Be aware of false invitations - check that the lead registrant is credible”

False Lead Registrants

- Some companies have been claiming to be the lead registrant in situations where their nomination has not been agreed between the co-registrants, where another lead registrant has already been selected, or even where a joint REACH registration has been already submitted to ECHA.
- Check whether your substance has already been registered through the *Information on chemicals* section on ECHA's website. http://echa.europa.eu/information-on-chemicals/registered-substances
- If not, check whether a Lead Registrant has identified themself to ECHA at http://www.echa.europa.eu/regulations/reach/registration/data-sharing/sief/active-lead-registrants

Minimum Due Diligence

- If a candidate lead registrant contacts you and you are not familiar with the Company
  - Ask for details on the identity of the substance to establish substance sameness.
  - Ask for evidence that they have the consent of the co-registrants to act as a lead registrant.
  - Ask for evidence that they have sufficient information for a compliant dossier.
  - Offers from leads that are not respecting the REACH rules might seem less costly. However, in many cases, the quality of the dossier might not be adequate, which may create serious legal consequences and additional costs to all registrants.
  - If your company is experiencing difficulties in verifying the validity of the lead registrant, you can contact the ECHA Helpdesk for further advice and possible intervention.

Remember

- One Substance One Joint Registration is Mandatory
- All Co-registrants are responsible for the legal sufficiency of the Joint Registration Dossier
- There are No Cheap Options
- Due Diligence Can Not Be Avoided

How to Negotiate Data Access in SIEFS

Core Principles – Data Sharing Under REACH (1)

- Data sharing is one of the core principles of the REACH Regulation.
- Primary aim is avoidance of unnecessary vertebrate animal testing.
- Central to One Substance – One Registration Principle.
- Potential registrants have the obligation to request that studies on the same substance involving vertebrate animals are shared.
- Potential registrants have the option to request the sharing of data not involving testing on vertebrate animals.

Core Principles – Data Sharing Under REACH (2)

- REACH allows the owner of data to be able to claim compensation for a period of 12 years from potential registrants.
- This “12 year-rule” applies to any data which has been submitted in the framework of a REACH registration, either to ECHA or to national competent authorities (under the former dangerous Substance Directive 67/548/EC).

Core Principles – Data Sharing Under REACH (3)

- The potential registrant and the previous registrant(s) must make every effort to reach an agreement on the sharing of the data and of its costs under fair, transparent and non-discriminatory conditions.
- As an example, sharing would be considered as being:
  - **not fair**, if the data owner requests the full cost of the study he paid where there are several other registrants;
  - **not transparent**, if the data owner requests the payment of a generic fee for the data contained in the joint registration dossier, without providing detailed information on the costs;
  - **discriminatory**, if the costs of the same study would be different for different EU manufacturers or importers or only representatives.
- ECHA will not assess whether the data compensation claim (costs or conditions under which sharing is proposed) is justified.

Core Principles – Data Sharing Under REACH (4)

- A registrant need only pay for the data he needs to register at his tonnage band.
- It is possible to opt-out of parts or most of the joint dossier if:
  - it would be disproportionately costly for him to submit this information jointly; or
  - submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
  - he disagrees with the lead registrant on the selection of the information.
- Any opt-out has to be fully justified and in principle an opt-out will be prioritized for compliance check.

Core Principles – Data Sharing Under REACH (5)

- It is not possible to opt-out entirely from the Joint Submission
- However it is possible to opt out from all of the information in the joint dossier
- Individual registrations cannot co-exist with joint registrations for the same substance.

Core Principles – Data Sharing Under REACH (6)

- Under REACH, only registrants of the same substance have data sharing (and joint submission) obligations.
- Hence, it is not mandatory for participants in different SIEFs to share data.
- Every request for access to studies across different SIEFs has to be negotiated on a case by case basis by the concerned companies.

Data sharing process

- Once a data sharing request for studies submitted less than 12 years ago has been made, both the previous and potential registrants must make every effort:
  - to reach an agreement on the sharing of the information requested by the potential registrant;
  - to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.

Process where Data Sharing Negotiations Fail

- If the data owner and the potential registrant fail to reach an agreement, the potential registrant must inform ECHA of this failure.
- The potential registrant must also notify the data owner that they have informed ECHA.
- The potential registrant will receive from ECHA permission to refer to the vertebrate animal data, if ECHA considers that the data owner has not made every effort to share the data and its costs in a fair, transparent and non-discriminatory way, although the potential registrant has made such efforts.

Process where Data Sharing Negotiations Fail (2)

- Strong and complete documentary evidence is needed.
- The data requester must have requested clear information, challenged the answers which were unsatisfactory to him, made reasonable proposals to resolve the disagreements and granted reasonable time to the other party to address his arguments and proposals.
- The applicant will have to provide ECHA with all the correspondence and supporting documents (e.g. SIEF agreement) available at the time of the claim to ECHA, and will have to describe the situation to the Agency.
- The applicant must have offered the other party the opportunity to discuss all the concerns he may have on the data sharing conditions.

Process where Data Sharing Negotiations Fail (3)

- To initiate the process, information on the dispute is to be provided to ECHA using a webform available at: https://comments.echa.europa.eu/comments_cms/article302.aspx
- ECHA will then request that the previous registrant(s) provide within 10 working days evidence of the arguments and justifications they used during the negotiations with the potential registrant, if any.
- ECHA will then perform an assessment of whether a party has breached its obligation to make every effort on the basis of the documentation provided by both parties.
- In the case of no response to requests for data sharing ECHA will consider the efforts on the basis of different criteria, including the number of attempts to contact the other parties and the quality of these attempts (e.g. registered letter, acknowledgement of receipt, …).

Process where Data Sharing Negotiations Fail (4)

- ECHA will make a decision whether or not to grant permission to refer within one month after having received complete information from both parties.
- If ECHA decides to allow the potential registrant to register without submitting animal vertebrate data the potential registrant still needs to provide the non-vertebrate animal data.
- The previous registrant will have a claim against the potential registrant for an equal share of the cost of the vertebrate animal data before a national court. Requires that a copy of the full study report be shared.

Process where Data Sharing Negotiations Fail (5)

- The potential registrant or the previous registrant(s) may lodge an appeal before the ECHA Board of Appeals against the ECHA decision to grant permission, or not to grant permission, to refer to the data.
- Note, the potential registrant must obtain a decision from ECHA granting permission to refer to the data BEFORE submitting the registration.
- The owner of the study who has refused to provide either proof of the cost or the study itself is subject to penalties.

SIEFS and Phase-In Substances

Sameness Discussion in the SIEF

- Wherever a phase-in substance has an EINECS number, this will normally mean that one SIEF will be formed for one EINECS entry.
- However, one EINECS entry may also correspond to several substances or several EINECS entries may correspond to one and the same substance
- In the case for complex substances, substance sameness becomes a critical issue.

Sameness Discussion in the SIEF(2)

- Refusal to share data within SIEFs may, under certain circumstances, lead to inability to register the substance.
- Failure to split one EINECS entry into several substances, where necessary, may result in invalid registrations, the need to prepare and resubmit registration dossiers for all concerned substances and to pay the registration fee again.
- Therefore, in case of doubt, ECHA recommends that SIEF members share data as widely as possible within one EINECS entry (even if this is not strictly required by REACH) and, at the same time, interpret the substance definition narrowly, i.e. to submit several separate dossiers.
- Wherever a decision is taken not to split EINECS entries, care should be taken that the data submitted are appropriate for all variants and forms of the substance.

A Few Tips For The 2018 Registration Tier

Offers to Prepare Low Cost Dossiers

- Be careful!!
- It is permissible to use (Q)SAR to satisfy certain data requirements but
  - The (Q)SAR model should be associated with a defined endpoint.
  - The (Q)SAR model should be expressed in form of an unambiguous algorithm.
  - The (Q)SAR model should be associated with a defined domain of applicability.
  - The (Q)SAR model should be associated with appropriate performance of the model (the statistical “goodness” of the model, robustness and predictability).
  - The (Q)SAR model should be associated with a mechanistic interpretation for human health and ecotoxicological endpoints, if possible.
- Similar constraints apply to the use of read-across, weight of the evidence, etc.

Special Rule for 1-10 tpa Phase-in Substance Registrations

- Registration of Phase-in Substances at 1-10 tpa only require physicochemical data (Annex VII) unless

  (1) it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1A or 1B CMRs or PBT/ vPvB; or

  (2A) there is dispersive or diffuse use(s), i.e., the substance is among other things used in consumer mixtures or incorporated into consumer articles; and

  (2B) it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the CLP classification criteria for any health or environmental hazard classes.

- This type of registration requires a fee to the ECHA whereas a full Annex VII dossier does not require a fee.

Intermediate Registration

- For registration of intermediates under strictly controlled conditions (SCC):
  - For transported isolated intermediate of >1000 tonnes/year under SCC, you are only required to pay for the test data you require for your registration (i.e. relevant to Annex VII of the REACH Regulation). Additionally, you may also be required to pay the costs relevant to the administration of the joint submission.
  - For transported isolated intermediates of <1000 tonnes/year, your data requirements are limited to any available information you have. You may only need to contribute to the costs relevant to the administration of the joint submission.

Post-Registration Data Sharing Obligations

- Article 22 updates
- Compliance Checks
- Substance Evaluation (CoRAP)

New Data Sharing Regulation

Regulation on Transparency and Cost-Sharing

- Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&qid=1453380621080&from=EN
- Objective is to ensure that the sharing and joint submission of information is determined in a fair, transparent and non-discriminatory manner.
- Serves to assist Small, Medium and Micro Enterprises (SMEs) in data sharing prior to the 2018 Registration deadline.

Transparency Obligation

- Cost-sharing model must be transparent to all potential registrants and existing registrants.
- Need itemized study costs and related administrative costs keyed to the specific REACH data requirements.
- Must justify how the data satisfies the information requirements and how the administrative costs relate to the registration process.
- Parties to an existing data sharing agreement may waive itemization but they must all do so in a signed written statement.
- Potential registrants not bound by this waiver but may also waive by written consent.

Transparency (2)

- The data owners need to document yearly any further administrative and study costs incurred in relation to the operation of the data-sharing agreement and any compensation received from subsequent registrants.

Transparency (3)

- Annual documentation must be kept for a minimum of 12 years following the latest submission of a study and must be made available, free of charge, upon request from any party to the data-sharing agreement or upon request from the Agency or a Member State.
- In the absence of detailed documentation of costs incurred or compensation received before 5 January 2016, data owners must make every effort to collate proof, or the best approximation, of such costs and compensation.
- This documentation must be made available free of charge upon request from any registrant or potential registrant within a reasonable time and in full consideration of applicable registration deadlines.

Fairness and Non-Discrimination

- Registrants must reach an agreement on a fair cost-sharing model that must apply to all registrants without discrimination, including future registrants.
- In agreeing on a particular cost-sharing model, consideration could be given to factors such as: the number of estimated potential registrants; provision for sharing any costs resulting from a potential substance evaluation decision; and the possibility of future additional data requirements for that substance.
- In the event that a cost-sharing model includes provisions to cover the possibility of future additional data requirements any compensation for this must be justified and indicated separately.

Reimbursement Mechanism

- A reimbursement mechanism must be included in every cost-sharing model and may take into account the following factors:
  - the possibility of future additional registration requirements for that substance;
  - a method of proportional redistribution to each party of their share of fees paid when a potential registrant joins that agreement in the future;
  - and the economic viability of certain reimbursements where the costs of reimbursement are higher than the amount to be reimbursed.
- Parties to a data-sharing agreement that already exists on the date of entry into force of the Regulation may waive their obligation to include a reimbursement mechanism in their cost-sharing model if all parties to that agreement give their signed consent to the waiver.

Assurance of One Substance – One Registration

- If an existing registrant refuses to enable a potential registrant to join the joint registration dossier, the ECHA shall permit the potential registrant to join the existing submission, subject to
  - the granting of a permission to refer to part or the entirety of the data concerned in accordance with Article 27(5) or 30(3) of the REACH Regulation and,
  - if necessary, subject to the demonstration that an agreement has been reached on the sharing of the remainder of data, or
  - subject to the demonstration that the potential registrant submits the information required in accordance with the opt-out provisions of REACH Regulation.

BREXIT and CHANGING an OR

BREXIT

- Will Not Happen Until 2019
- This Means that U.S. Companies with U.K. Affiliates will Need to Register in 2018
- Various Models (Norwegian model and Swedish model) have required buy-in of Free movement of people
- If you have a U.K. OR assume you will need to change OR post-BREXIT.

Change of Legal Entity

- Registrations, pre-registrations and notifications under the REACH and CLP regulations cannot be traded. They can however be transferred.
- Changes of legal personality include:
  - Mergers (absorptions, joining of equals);
  - Company splits (spin-offs, de-mergers);
  - Asset transfers;
  - Changes of Only Representative (OR).
- If you use an OR then the change of OR is what is relevant.
- If you have EU affiliates, then corporate changes are relevant.
- Change fees are based on the size of your company as declared in REACH-IT and range from €1631 to €82 depending on the size of the company.
- One Fee for All Registrations.

Change of Only Representative

- ORA is the only representative of non EU manufacturer LEA. ORA has registered substance X for LEA.
- LEA wishes to replace ORA with ORB as its only representative
- Consequences under REACH
  - There is a change of legal personality, because the identity of the registrant has changed.
  - ORB will need to update this change in REACH-IT
  - ORB will need to provide evidence of (i) the agreement of LEA appointing him as its OR, and (ii) the agreement of ORA to the transfer of the registration to ORB.
  - ORB will be charged the fee for change of legal personality. The fee is determined by the size of LEA.

ECHA Guidance

- REACH-IT Industry User Manual: Part 17 - Legal Entity Change http://echa.europa.eu/documents/10162/13654/legal_entity_change_en.pdf
- Practical Guide 8 – How to Report Changes in Legal Entities

http://echa.europa.eu/documents/10162/13643/pg_8_legal_entity_change_en.pdf

REACH Enforcement

ORs

- According to a report published by the ECHA Enforcement Forum in December 2015, a third of inspected ORs are not in compliance, compared to just 15% of substance importers and 6% of manufacturers.
- The Report urges the European Commission to revise Article 8 and:
  - explicitly define the duty for an importing DU to keep documents for the relevant substances, with annual tonnages confirmed by the ORs;
  - stipulate that only an importing DU, keeping such documentation, is released from the registration duties of an importer; and
  - define a new duty for the OR to send the information on covering the registration duties for the importing DU for a specific substance, including the annual imported quantities of the substance, to the importing DU.

ORs(2)

- The Commission, it says, should also:
  - clarify the conditions for relying on the REACH provisions exempting re-import from the registration obligation;
  - create a single database for all REACH-relevant import declarations to enable better targeting of inspections. Currently, says the report, this data is maintained by national customs authorities, making it difficult to trace all imports covered by a single OR if they occur in several countries; and
  - make it mandatory for ORs to submit information on covered importers in their registration file. This, it says, “would be helpful for the ORs and importing DUs and related inspections” and would allow ECHA, during the registration dossier completeness check, to make sure the information is in the registration dossier.

What Happens After mid-2018?

Only Representative Coverage

- Non-EU Manufacturer must maintain an OR as long as REACH is in effect.
- If you are relying on OR Coverage from your supplier that coverage will need to continue past 2018.

Introducing New Products into the EU After Mid-2018

- Pre-registrations are no longer valid after March 31, 2018.
- Must submit an Inquiry dossier under Article 26 REACH and wait for the Inquiry number to issue. http://echa.europa.eu/regulations/reach/registration/data-sharing/inquiry
- Must register at 1 tonne/ yr or more and wait 21 days before entering the market.
- This is true whether the substance is new or existing (phase-in).

Dossier and Substance Evaluation

- Dossier Evaluation (Compliance Check) can take place at any time. http://echa.europa.eu/regulations/reach/evaluation/compliance-checks
- List of Substances Potentially Subject to Compliance Check. http://echa.europa.eu/documents/10162/13628/substances_compliance_checks_en.pdf
- Substance Evaluation can take place at any time. http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
- These Evaluation processes will increase the price of the LOA.

Future Plans

- Registration of Polymers?
- CSR for substances at 1 tonne per year or more?
- More requirements for registration of nano-materials?
- More substances subject to Authorization
- SVHCs in Articles subject to Restrictions

THANK YOU

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