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Society for Chemical Hazard Communication Fall Meeting

Data available under REACH and Global Impact of that Data

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Overview

- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Data
- Data Sharing and Compensation
- Liabilities for Use of REACH Data within REACH and for Other Registration/Advocacy Purposes
- What Companies Can Do to Limit Liability

Data Submitted under REACH

- Core REACH principle -- “no data, no market”
- Registration entails the generation of, or citation to, substance-specific health and safety data, the results of which are set forth in a technical dossier
- For substances manufactured or imported in quantities of ≥10 metric tons/year, a Chemical Safety Report (CSR) is required that includes results from the Chemical Safety Assessment (CSA)

How Companies Generate/Share Data under REACH -- SIEFs

- The purpose of Substance Information Exchange Forums (SIEF) is to facilitate the sharing of existing data on the substance, the collective identification of data gaps, and cost sharing with respect to the generation of any new data
- Participation in a SIEF is mandatory for those entities specified in REACH Article 29 (*i.e.,* registrants, certain downstream users, and third parties that have submitted information to the European Chemicals Agency (ECHA))
- One SIEF per substance

How Companies Generate/Share Data under REACH -- SIEFs (cont'd)

- Only SIEF members of a substance have access to the SIEF via REACH-IT, *e.g.*, pre-registrants, late pre-registrants, and Data Holders can view other SIEF members
  - Non-SIEF members cannot view members of a SIEF

- Within a SIEF, several different roles are assigned
  - Some SIEF members are performing self-nominations in key roles
  - It is important to know your role, rights, and responsibilities, *e.g.*, Lead Registrant and SIEF Formation Facilitator (FF) can be very active while a Joint Registrant typically has a more passive role

How Companies Generate/Share Data under REACH -- Consortia

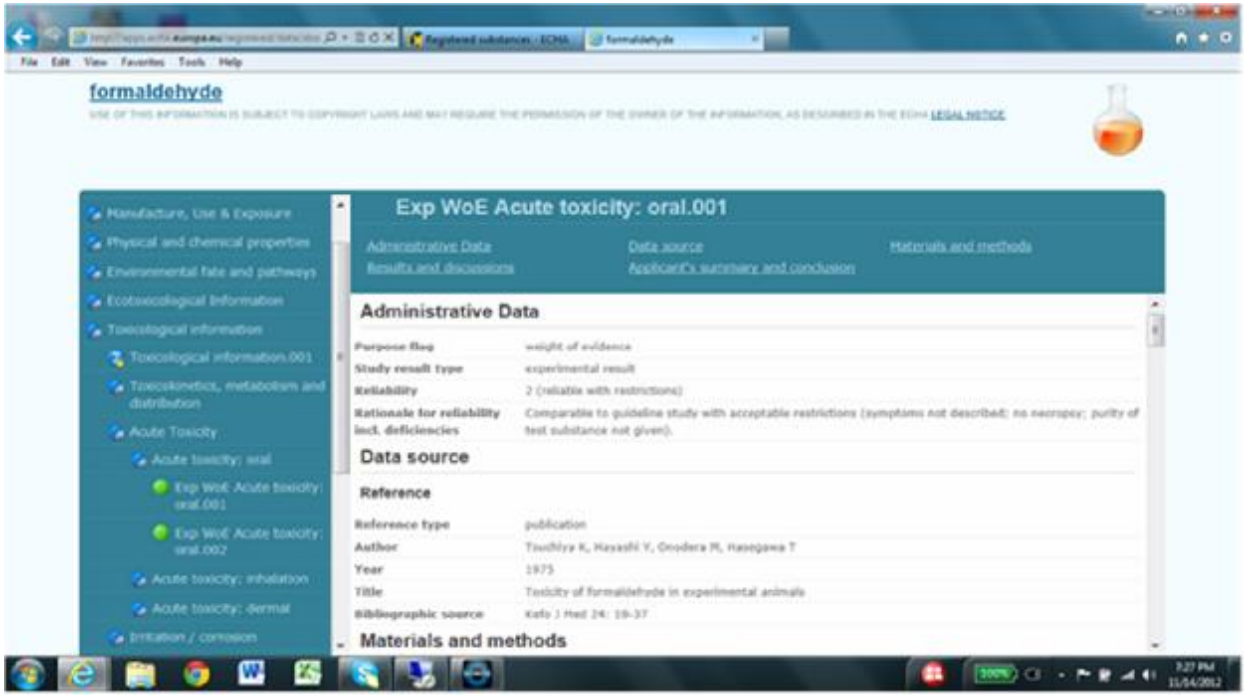
- Membership in a consortium or any other form of cooperative data sharing agreement is voluntary
- Consortia are a more formal type of cooperation among registrants established to provide practical help with SIEF data sharing and compensation obligations and the preparation of registrations
- It is possible that one consortium could cover registrants from different SIEFs, *e.g.*, in the case of categories/related substances

REACH Data Availability

- The Lead Registrant performs the Lead Registration that contains data compiled by the SIEF and/or consortium, and submits to ECHA
- ECHA is obligated to disseminate certain data contained within the technical dossier (data endpoints) submitted under REACH
  - The technical dossiers are available online

REACH Data Availability (cont'd)

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances



Letter of Access -- Data Sharing Mechanism

- When compiling the technical dossier, the Lead Registrant (or SIEF FF or consortium) must obtain access/permission to cite the data contained within the technical dossier to address the relevant endpoints from the Data Holder or publisher (*e.g.,* copyright)
- This right, referred to as a "Letter of Access" (LOA), permits a Data Holder to make relevant study data available by granting access to the data, typically following a data compensation structure
- A Data Holder is typically requested by the Lead Registrant for the right to "sub-license" data citation rights to other legal entities that may in the future need data citation rights, *e.g.,* Joint Registrants from the same SIEF
- In most cases, sub-licensing is granted, but if a Data Holder does not agree to sub-license, each registrant must negotiate directly with the Data Holder

Data Compensation Issues

- REACH does not specify a data compensation scheme -- only that costs of sharing information required for registration are determined in a fair, transparent, and non-discriminatory way
- Some standards have been developed:
  - Fleischer system for determining replacement study cost values
  - ECHA *Guidance on data sharing* principles (April 2012 version 2.0)
  - CEFIC model for data sharing
- Even with these standards, there are variables and complications in determining what is “fair” compensation

Data Liabilities for Use of Data for REACH Purposes

- Lead Registrants (and possibly others in SIEF core groups or with joint registrations) are liable towards:
  - ECHA/authorities for the content of their own registration
  - Other registrants (within or outside a SIEF) (*e.g.,* misrepresentations related to the ownership of studies or information, the quality of studies or information, the stated relevance of studies or information for read-across purposes)
- Data Holders, Lead Registrants, and other SIEF participants must be mindful of property rights and quality issues when making representations and granting rights on studies available to them

Data Liabilities for Use of Data for REACH Purposes (cont'd)

- A Lead Registrant, consortium, or core SIEF group and/or its members can be jointly liable towards third parties
  - Respective liability of consortium or core SIEF group members between themselves can be organized in a respective consortium/SIEF agreement
- If a party does not have access to the full study reports, as is the case in many scenarios, those parties would not be held to the same standard as Lead Registrants and/or Data Holders that make representations about the data

Data Liabilities for Use of Data for REACH Purposes (cont'd)

- If a company that is not a member of a SIEF or consortium seeks access to REACH data for REACH purposes, *e.g.*, read-across purposes, the data sharing and compensation standards and issues would apply -- determining compensation and rights in a "fair, transparent, and non-discriminatory" manner

Data Liabilities for Use of Data Outside of REACH

- If a company that is not a member of a SIEF or consortium seeks access to REACH data for non-REACH purposes:
  - Data Holders/Lead Registrants can decide to restrict use for REACH purposes only thus restricting purposes beyond supporting a REACH registration
  - If Data Holders/Lead Registrants do not restrict rights, there are opportunities for additional data compensation
  - With certain REACH data publicly available, Data Holders/Lead Registrants could face issues despite efforts to restrict data uses

Data Liabilities for Use of Data Outside of REACH (cont'd)

- If other companies, countries, agencies, or organizations seek data submitted under REACH, or rely on data information publicly available, issues to consider include:
  - Risk of Data Scrutiny and Inconsistencies: Since the purposes of a REACH dossier can be different from other regulatory purposes, there is the potential for scrutiny and complaints by non-REACH entities regarding the completeness of the database, selection of key studies, etc. In addition, companies or agencies using REACH and non-REACH data may obtain different conclusions based on conflicting data results
  - Confidentiality Can Be Compromised: If a full study report is requested by and thereafter submitted to a competent authority outside of the European Union (EU), *e.g.*, the U.S. Environmental Protection Agency (EPA), confidentiality protections can be compromised, *e.g.*, mandatory publication of data submitted to EPA, so know the disclosure obligations

Data Liabilities for Use of Data Outside of REACH (cont'd)

- Compensability Period Limited: REACH's 12 year rule for compensability may impact the value and usefulness of data globally
- Regulatory Implications: Study results can create other regulatory obligations (*e.g.,* Toxic Substances Control Act (TSCA) Section 8(e) reporting)
- Risk of Data Misuse: The purposes for which data were generated under REACH will not be the same as another regulation and can create issues
  - Data can selectively be taken out of context and used to develop snap shot priority lists outside the scope of regulatory criteria

What Companies Should Do to Limit Potential Liabilities

- Be aware of data submitted under REACH for substances of interest
- When entering into data sharing agreements, determine limitations on data rights beyond REACH and ensure that Data Holders are made liable for the data they are sharing, *e.g.,* study reliability and robust study summaries
- Protect/never share full study reports -- copyright results if possible
- Be specific about study ownership -- study reports should contain the names of study sponsors/owners (*e.g.,* the consortium (if applicable) as well as individual companies/consortium members)

- Biocide Product Regulation (BPR) -- The newly enacted BPR includes a data compensation scheme similar to REACH but there are several differences (*e.g.,* length of data protection, mandatory data sharing) that could increase liability issues
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) -- Data submitted under FIFRA are entitled to some protection and subject to a very specific data compensation scheme that varies from REACH
  - If there is a dual-use substance with pesticide and non-pesticide uses, determining data rights and liabilities can be problematic

THANK YOU

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