Case Study: Substance Identity

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Outline - Substance ID

- Why is it important?
- Issues?
- Case Studies
- Conclusions

Substance Identity

- REACH Information Requirement
  - Art 10 a ii, Annex 2 (2 – 2.3.7)
- ECHA page - https://echa.europa.eu/regulations/reach/substance-identity
  - Explanation and Guidance
- IUCLID
  - Section 1.2 - Composition
  - Section 1.4 - Analytical data

Substance ID - Why it is important

- Starting point for any REACH discussion
  - What is the substance?
    - Chemical Composition / Physical form
    - Substance type
      - Mono, multi, UVCB
      - One Substance One Registration (OSOR)
- Link to intrinsic hazard data
  - Grouping / Read Across / Alternatives

Some issues encountered (not exhaustive!)

- "Historical" positions
  - EC List and global Inventories
  - Availability of analytical data
- Complexity of different UVCBs*
- Relationship with salts and isomers

*Unknown, of Variable Composition, or of Biological Origin

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Renewable Fuels Consortium

- Manufactures of novel fuels via co-processing with non-traditional feedstocks: vegetable and animal oils
- For many fuels, existing EC names reflect feedstock
  - Also included process description
- Addition of non traditional feedstock to the process results in the existing substance name being inaccurate

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Renewable Fuels Consortium

- Resolution
  - Investment in extensive analytical work on all member substances
    - Pilot and production
  - Analytically similar substances “grouped” together
  - Early discussion with ECHA Substance ID unit on naming
  - Development of new names and process descriptors that reflect emerging industry practice

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Renewable Fuels Consortium

- Subsequent actions
  - Each Member company
    - Enquiry process to ECHA
  - Pre discussion allowed for quick response and approval
    - Basis for OSOR
    - Lead registrants agreed in RFC
  - Dossier development on basis of analytical data and enquiry process
    - Allowed clear read across to existing data
  - ✓ Registration by Lead and Co-registrants

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H4R CONSORTIUM

Hydrocarbon Resins & Rosin Resins REACH Consortium

- Manufactures of Rosins and Rosin derivatives
  - UVCBs - Complex chemistry
    - Diterpenic monocarboxylic acids
    - Neutral fraction
  - No single constituents present at concentration > 10 %
- Thousands of potential component structures
- Different categories of derivative depending upon treatment

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H4R CONSORTIUM

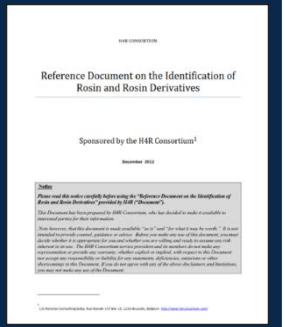
Hydrocarbon Resins & Rosin Resins REACH Consortium

- 28 Substance registrations in 2010
- ECHA 2011
  - Questions on Substance ID and read across of data
- H4R
  - Appreciation that the Substance ID was critical to plausibility of a category approach for read across
- How to approach when it is so complex?

H4R CONSORTIUM

Hydrocarbon Resins & Rosin Resins REACH Consortium

- Resolution - H4R developed a common position on identification methodology
  - Reviewed available technologies, made recommendations
  - Gave detailed model spectra and structures
  - Common reference substances for classes
- Provided the basis for
  - Individual registrant analysis
  - Common text and interpretation for use in updating dossiers for all registrants
  - Substance Information Profiles (SIP)
- Published on SIEF information pages
- Allowed development, with other biological data and discussion with ECHA, consistent and plausible test strategy



Reference Document on the Identification of Rosin and Rosin Derivatives

Sponsored by the H4R Consortium[1]

December 2012

Reference Document on the Identification of Rosin and Rosin derivatives

H4R CONSORTIUM

Executive Summary

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Observations on Substance ID

- Good quality data and practices critical to success - not just for registration
  - SIEF / Joint Registration communications / understanding
  - Registration (OSOR)
  - Test and read across strategies
- Registrant / SIEF led - cooperative working is key
  - Data led - agree on what is required
  - All need to be able to work to the same standard – not exclusive
  - Needs to be understood - over complexity excludes - but some complexity may be necessary!
  - Fit for purpose
    - Supports confidence in the intrinsic hazard data
      - Current data and any testing plans
  - Use the tools and help that is available

Thank You

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