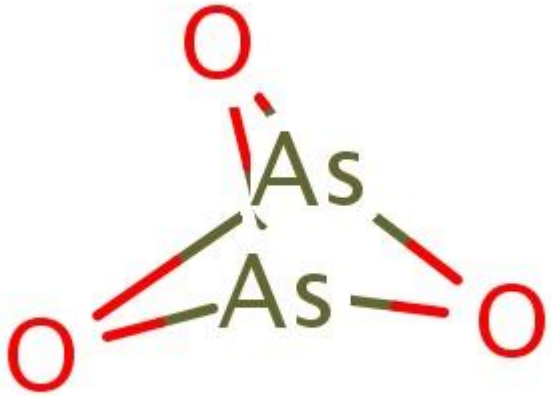
Experience in authorisation the As2O3 downstream user applicants: Linxens/Yara

Diarsenic Trioxide – As_2O_3



CMR 1A
Large
Intermediate use

Main AfA
Boliden &
Nordhammer

Smaller uses

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EPPA's involvement in AfA

- Substance prioritisation (various)
- Producers
  - ✓ Low Molecular Weight Phtalates (coordination of producers)
  - ✓ PY. 34 & PR.104 – AfA for DCC – SEA/AoA
- Downstream users
  - ✓ As_2O_3 for Linxens : SEA/AoA and PM
  - ✓ As_2O_3 for Yara: SEA/AoA and PM
  - ○ Trichlorethylene: Roquette: SEA/AoA and PM

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Two late and very different dossiers

Linxens

- Use of As_2O_3 3 as a grain refiner in electroplating
- Called 9 days before submission deadline
- Catastrophic failure of substitution process (technical issue and reclassification of alternative)
- Ca. 20 KG/Year

Yara

- Use of As_2O_3 as processing aid to activate the absorption and desorption of carbon dioxide by potassium carbonate in the production of ammonia
- Called 6 months after submission deadline
- Company undergoing major change
- Ca. 5T p/y needed until 2017

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Characteristics of the downstream user dossier

Literally 10 times easier than a producer's dossier

- Limited quantities of substance
- Availability of measured data
- Simpler CSR if RAC risk derivation accepted
- SEA economic costs ≈ costs for local economy
- AoA more specific and therefore convincing

Normal drafting time: 3 months – here 7&30days

Challenges:

- Measured data subject to medical secrecy
- Economic data can be patchy
- Alternatives sometimes not correctly researched

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What works well?

Interaction with ECHA – process not made harder

Trialogues – very important

- Linxens did not have one which was a shame.
- Yara did have one – gave confidence on measures

Interaction with RMIU

Simplifications already adopted

- CSR
- SEA

Dossier drafting is not as difficult or expensive as some people claim

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Positive outtakes for industry

Linxens:

- Even if your substitution fails you can get your AfA in
- Substitution work facilitates dossier drafting

Yara:

- Authorisation drove the AoA
- AfA led to the choice of Potassium Vanadate
- Better RMM for workers due to analysis for RAC

SEA cases are clear cut – factor 100,000 difference

Downstream user applications are not that onerous

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Difficulties

RAC:

- Measured data not always in format desired
- Focus too much on theoretical risk (dermal/Linxens)

SEAC

- Unawareness of importance of process technology
  - Legal/regulatory constraints to changes
  - Contractual constraints
- Fractions of a 1 EURO calculations in health cost

General

- Disproportionate demands from registrants
- Investment is high for single substance (≈250,000)

(both Linxens and Yara may need to apply again)

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Recommendations for future

Processing Aids

- Why a different position?
  - Not unlike intermediates
  - Used in industrial setting – more control
  - Not present in final product or article
  - Many used in high tech processes and are regulated
  - Use essential for efficiency – decider for investments
- What to change?
  - If measured data present – restrict dossier to that
  - Avoid inclusion of envi models for low volume
  - Demand only technical necessity c.q. sideline all classified alternatives

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