



The Cricket And The Ant



Antimony Trioxide (ATO)

□ EU Risk Assessment: 2000-2008

- human tox and environmental studies
- cost shared → i2a

□ REACH registration: 2010

- most data from EU Risk Assessment (i2a)
- scientific efforts (i2a)
- Joint Registration: i2a membership or LoA



Italian Trader



☐ contacted i2a for LoA

- disagreement to contribute retroactively to EU RA data
- trader did not initiate 'cost sharing dispute'

☐ separately registered ATO

- OSOR violation
- 'Box ticking' – poor quality, old data, errors
- Some critical endpoints from i2a studies – data ownership violation (disseminated data from EU web sites)

☐ No corrective actions to date



Status

□ GENERAL

- not unique
- new TCC – can no longer happen

□ ATO / i2a members

- competitive disadvantage = no constructive message
- 2018 registrants ?
- additional data generation post registration: more ‘free riders’ ?



Seeking Help From ECHA / COM

- ❑ To drive (also retroactively) level playing field and fair-play
 - **Compliance Checks** on registrations that may violate OSOR
 - No data no market
- ❑ To drive fair data cost sharing among all who benefit

Data sharing implementation regulation

We appreciate that this is taken seriously and thank ECHA for the opportunity to share this experience in today's meeting.

