Regulatory application of science to Particles and Health - some introductory observations

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The Task is Complex

- **Regulators and their expert committees need to use the best available information to derive Evaluations and Opinions to inform both stakeholders and policy-makers to provide measures of protection for consumers, workers, and the environment by means of control measures (bans, restrictions, authorisations and various forms of limit values).**
- **Often, there is a balancing act between all players to permit the use and exposure of substances between any potential risks and societal needs.**
- **New information and new understanding of the models we use can change both Evaluations and Opinions**

Hazards, Risks and Control of Exposure

- ***For hazard identification*** **- which leads to classification all potential endpoints have to be considered and these are usually based on animal investigations, but all need to be addressed (data gaps).**
- ***For risks*** **- human data and animal data are used for establishing OELs in the workplace but these are often/usually based on one lead effect and for these are usually for the respiratory tract and lungs (assuming to be protective against all other effects) in the case of particles.**
- **The last decade has seen a shift more towards control of exposure by more use of hazard classification than by risk and this has somewhat altered the balance of the science/research/debate and, the underpinning regulatory policies.**

Sources of Information for Health and Toxicological Health Effects

- ***Human data*** **- best from well-conducted epidemiological studies but sometimes clear interpretation can be complicated by confounders (mixed exposures e.g. rubber workers, welders etc.) or biases (not enough years for long-latency diseases such as lung cancer)**
- ***Animal studies*** **– "apparently reliable" as all study factors controlled, but hard to find exact models to mimic human lung cancer, COPD, emphysema, chronic bronchitis, asthma, and inflammatory changes of both the respiratory tract and lung parenchyma (rats are not little humans and mice are not smaller versions of rats [discordancy in lung tumour studies].**
- ***In vitro*** **- new approach methodologies (NAMs) – rapidly developing for many key events and some close to getting OECD Test Guideline approval but, need to get insoluble particles inside cells.**