Epidemiological outcome: some key questions of regulatory managers

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Who are the "risk managers" (EU)?

Active substances approval

PPP-use authorisation

Regulation (EC) No 1007/2009
Regulatory context:

- Dossier submission
- Epidemiological data
- Full scientific risk assessment of AS / PPP
- Authorisation of PPP use (risk management decision)
- Monitoring
- PPP-use (good agricultural practice + integrated pest management)
- Only if no effects on HH and no unacceptable effect on the environment
- May include risk mitigations and "ad-hoc" monitoring

SU Directive 2009/128/EC
National Action Plans
Professional use → training
• **5.9.4. Epidemiological studies**, Relevant epidemiological studies shall be submitted, where available.

• **5.9. Medical data**
  ... Data ...relevant to the effects of human exposure, where available, shall be used to confirm the validity ... with respect to target organs, dose-response relationships, and the reversibility of adverse effects. Such data may be generated following accidental, occupational exposure or incidents of intentional self-poisoning...
- **Recital 13:**

For ethical reasons, the assessment of an AS or a PPP *should not be based* on tests or studies involving the *deliberate administration* of the AS or PPPs to humans ... Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for AS or PPPs.
RM questions

- when designing epidemiological studies
- when analysing results of epidemiological studies
generalities...

basics

→ representativity (no of samples ?)
→ plausibility (correlations?)

to keep in mind → RM decisions based on:
- single AS or PPP use
- under specific conditions of use (e.g. restrictions, maximum levels, protective equipments)
When designing epidemiological studies...

- the link observed effect – exposure is crucial
- prioritisation vs. Broad scope?
- if prioritisation:
  • Which AS? (e.g. candidates for substitution? AS prioritised via National Action Plans (SUD)?...)
  • To focus on which population groups? (e.g. kind of exposure, age, ....?)
When analysing results...

- link to particular (group of) active substances
  - Approved/non approved AS?
- exposure
  - Over time: single exposure, repeated exposure, levels of exposure, how did exposure change over time? (AS taken off the EU market in last 20 years)
  - Which kind of PPP-use? Authorised? Accidental?
  - Key exposure route via PPP use? (some AS may have also other uses, adding further exposure routes)