The use of epidemiological data for pesticide risk assessment

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Presentation outline

- 1. Industry's contribution to assessing human health risk from exposure to PPP's
- 2. Industry's perspective on the existing epidemiological literature on PPP's and health
- 3. Industry's perspective on using epidemiology for regulatory risk assessment

1. Industry's contributions

- **Industry has conducted retrospective cohort studies on production workers, eg chlorpyrifos, triazine, paraquat, atrazine, 2,4-d, alachlor.**
  - Production workers are higher and longer exposed than applicators
  - Exposure during production is not as complex as in agriculture
  - These studies all had a specific protocol and were all published
- **Farm family exposure field study funded by Croplife USA**
  - Studies were mainly aimed at providing data on exposure and handling of PPP's

1. Industry's contributions

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-ECPA's industry epidemiologists have reviewed the epidemiologic literature on PPPs, including on:

- Cancer in farmers, neurological effects (adults, children), prostate cancer, childhood cancer, reproductive outcomes, Non-Hodgkin Lymphoma, respiratory disease, Parkinson's disease
- ECPA and it's member companies continue to monitor new publications

-ECPA established an external epidemiology advisory panel in 2012 consisting of 8 external epidemiologists, to

- review the epidemiologic literature on PPPs, and provide recommendations to ECPA for areas of further work
- Conclusions will be available in mid 2015

1. Industry's contributions

Developed two frameworks to integrate toxicological and epidemiological evidence for Risk Assessment (Adami et al 2011 and ECETOC 2009)

1. collect relevant studies
2. assess their quality
3. evaluate their weight of evidence
4. assign scalable conclusion (in terms of reliability)
5. assess causality
6. use data if association is deemed causal

2. Industry's perspective on the existing epidemiological literature on PPP's

- There is a huge number of epidemiology studies on PPP's
- Exposure assessment is the weakest point
- Exposure to PPP in agriculture is extremely complex and conventional study designs may have reached their detection limits
- Questionnaire data on PPP exposure suffer from information bias, as in studies on other topics
- Most studies suffer from the multiple comparison pitfall and lack a specific hypothesis
- Studies on "pesticide exposure" in general are not informative
- The relatively sparse studies on a single molecule show negative or inconsistent results
- Search strategies used in Systematic Reviews tend to miss entirely negative studies

2. Industry's perspective
How can studies be improved?

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- Improving and validating Exposure Assessment Methodology
- Using Human Biomonitoring data for exposure assessment
- Use early markers of effect for diseases with long latency
- Avoid the multiple comparison pitfall by defining a specific a priori hypothesis and statistical analysis

2. Industry's perspective
Negative outcome studies

- Provided PPP's are handled as recommended we are convinced they pose no health risk.
- So epidemiology studies will be negative (show no risk)
- Studies should be designed to avoid data are endlessly analyzed until a positive association is achieved
- There must be a procedure to integrate negative epidemiology studies (or systematic reviews) into the regulatory process

3. Industry's perspective on using epidemiology for risk assessment of PPP's

- If reliable and reproducible, human data should be given precedence over animal data
- However, the quality and transparency of many epidemiology studies are a cause of concern
- In order to improve epidemiology studies on pesticide exposure and health industry makes the following recommendations:

Industry's recommendations for epidemiologic research on PPP's

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- Develop reliable methods for exposure assessment
- Only studies/analyses that measure exposure on the level of a specific compound should be conducted
- Studies should have a specific hypothesis (compound and endpoint specific). If not, they are of an explorative character of which there are enough by now
- Studies must have a protocol that is followed by the researchers methodology, including confounder selection and statistical analysis and avoid the multiple comparison pitfall
- Preferably, there must be a plausible mechanism for the association under investigation
- Industry is committed to good stewardship and responsible and safe use of PPPs. It has acted to improve safe crop protection in the past and will continue to do so

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Thank you for your attention