



Bayer CropScience

**New Pesticide Regulation:
Round Table discussion:
a selection of open questions
associated with new
requirements**

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Open questions associated with new requirements



- ❑ Comparative *in vitro* metabolism data (active substance) required:
 - No guidance provided on study design
 - What if human different from animals?
 - Further studies ? Then what type of studies?
 - How will those data be used (risk assessment, relevance, CLP)?

- ❑ Toxicokinetic / Blood concentration data should be included/considered in all (?) subchronic and chronic/carcinogenicity and reproductive toxicity studies:
 - What ? How ? When ?
 - How will those data be used (dietary exposure vs. gavage) ?

Open questions associated with new requirements



❑ Phototoxicity testing *in vitro*:

- many compounds will fall under the conditions of required testing
- What if a compound comes up positive ?
- How will those data be used (risk assessment, classification and labelling) ?

❑ Definition of what constitutes « negligible exposure » for CMRs

“ An active substance, safener or synergist shall only be approved, if, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans”

- ## ❑ Potential neurotoxic and immunotoxic effects and effects potentially related to change in hormonal systems must be carefully addressed (short term and developmental / reproductive studies): what? How? When? Consequences?

Open questions associated with new requirements



□ Litterature data:

- requires applicants to provide “**scientific peer-reviewed open literature**” published within last 10 years
- guidance provided on how to perform searches unclear (EFSA guidance in preparation)
- requires submission of full reports/publications (practical ? Copyright ?) with an analysis of pertinence, significance and possible incorporation into end points definitions

□ Definition of what constitutes an endocrine disruptor (I. Fegert)