The European Partnership
for Alternative Approaches to Animal Testing

ACUTE TOXICITY TASK FORCE QUESTIONNAIRE

EXPLANATORY STATEMENT

This questionnaire is conducted to support the EPAA Acute Toxicity Task Force investigation on the drivers for acute toxicity testing and the potential for waiving one of the routes of administration for regulatory purposes. It is directed to the following sectors: **chemicals, cosmetics, crop protection, and consumer products**.

The information is provided in confidence. Individual responses will not be released. The aggregated data will be published in the EPAA paper on drivers for toxicity testing and presented at a workshop with regulatory authorities. Respondents will be informed about the aggregated results.

Please ensure this questionnaire is forwarded to the most appropriate person in your company (responsible for acute toxicity studies). Completion of this questionnaire will take no more than 15 minutes.

COMPANY:

SECTOR:
Email of the respondent for any further questions:

Please answer the questions below based upon how your company conducts acute toxicity studies (for CRO's based upon your own policy and designs or experience of how clients want these studies conducted).

1) What is the standard acute toxicity package within your company? (*Please confirm whether any non-rodent studies are conducted*)

2) Is this agreed within your company as a global policy? Yes - No

3) Do you have a preferred OECD guideline (e.g. fixed dose, acute toxic class)? Yes - No
If yes, which one and why?

4) If you have a preferred OECD test method do you have any experience of this not being accepted in any region? (e.g. US, Japan)

5) Have you ever been requested to perform or to repeat an acute toxicity study to according to another OECD test method? Yes - No
If yes, what was the rationale?

6) In your company's view what is the objective of the acute toxicity studies? (*Please tick all that apply*)

☐ (a) Hazard assessment e.g. classification and labelling
☐ (b) To aid dose selection for repeat dose toxicity studies
☐ (c) To obtain preliminary information on target organ toxicity (please specify how this is assessed e.g. is micropathology performed?)

☐ (d) Risk assessment
☐ (e) None of the above – regulatory requirement only (please specify name or reference of Directive/Regulation etc)
☐ (f) Other, please specify:

7) Do you conduct acute toxicity studies by more than route of administration? Yes - No

If yes (*Please tick as appropriate*):
☐ (a) One route (*state which route*):
☐ (b) Using two routes (*state which routes*):
☐ (c) Using three routes (oral, dermal, inhalation)

8) Have you been successful in waiving one or more routes? Yes - No
If yes could you explain rationale used:

Number of animals used: Please complete the questions below

9) On average how many rodents are used per study?:

10) Please briefly describe the study design as you conduct it:

11) Do you take any opportunities for using "cut down" approaches (e.g. one sex)?

12) What is the post dose observation period?

13) What is the average group size *(specify)*?

14) Do you use different animals at each dose level? Yes - No

15) Do you carry out any pathological evaluation? (*Please tick as appropriate*)
☐ (a) Gross macroscopic observations but no microscopic pathology
☐ (b) Limited microscopic pathology on all animals *(specify what you mean by limited)*
☐ (c) Limited microscopic pathology on decedents only *(specify what you mean by limited)*
☐ (d) Full microscopic pathology on all animals
☐ (e) Full microscopic pathology on decedents only

16) If microscopic pathology is carried out is the objective to: (*Please tick as appropriate*)

☐ (a) Establish cause of death
☐ (b) Identify target organs

17) Do you carry out any toxicokinetic evaluation? (*Please tick as appropriate*)

☐ (a) Yes *(please specify what)*
☐ (b) Yes but limited *(please specify what)*
☐ (c) No

18) If toxicokinetic evaluation is carried out what is the reason for this? *(Specify)*

19) What data do you provide to the regulatory authorities? (*Please tick as appropriate*)

☐ (a) Minimum lethal dose
☐ (b) Maximum non-lethal dose
☐ (c) No adverse effect level
☐ (d) Dose-response

20) What is the limit dose in your tests? (*Please tick as appropriate*)

☐ 2g/kg
☐ 5 g/kg, please explain the rationale for 5g/kg if you use it

21) In the current regulatory climate what would you consider an ideal acute toxicity package?

22) Do you have any thoughts on opportunities for application of the 3Rs?

23) In your experience has a single dose acute toxicity study ever identified a target organ that hasn't been identified in longer term studies *(if yes please give an example)*:

24) Do you consider the provision of acute toxicity data is a critical part of any safety package? *If yes please explain why?*

25) Has your company ever submitted a regulatory dossier/file without any acute toxicity data?

26) If you were shown a data set of over 1000 chemicals that demonstrated high concordance of oral and dermal exposure data such that the case could made to regulators to waive dermal acute toxicity tests would your company stop conducting dermal acute toxicity tests? Yes - No

If not please explain the rationale:

THANK YOU FOR RESPONDING