Toxicity studies: waivers, read-across studies, protocols

Criteria to waive toxicity studies

AMFEP appreciate EFSA's clear guidance re.:

Waiving of toxicity studies for production strains complying with QPS qualifications, e.g.:

- No cytotoxicity (*Bacillus*)
- No safety concerns identified elsewhere in the assessment process
- For GMMs: No concerns from genetic modifications

AMFEP further suggests:

Waiving of toxicity studies when no enzyme/TOS is transferred into the final food (no MoE calculation), e.g. in production of:

- Glucose syrup, Distilled alcohol, De-gummed oil

Does EFSA agree to these criteria?

Criteria for read-across toxicity studies

It is AMFEP's understanding that read-across toxicity studies may be used when:

The production strain is developed from the same (or closely related) recipient strain

No concern arising from the genetic modifications

The enzyme production process is essentially the same, e.g. similar:

- raw materials
- process steps
- temperature and pH conditions

Can EFSA confirm our understanding?

Former OECD guidelines/other guidelines

AMFEP emphasizes the validity of toxicological studies performed according to former versions of the OECD guidelines – or other applicable guidelines – performed at the time of development of the food enzyme

Only in specific situations additional data/quality requirements may be needed

Can EFSA help clarify such situations?