35TH **PESTICIDES STEERING NETWORK MEETING**
12 MAY 2026

ALTERNATIVES TO ANIMAL TESTING IN RELATION TO DATA REQUIREMENTS UNDER REGULATION (EC) NO 1107/2009

EUROPEAN FOOD SAFETY AUTHORITY

CONTEXT AND ISSUE

- The origin of the case was plant extracts where the RMS has requested for **all the data requirements to be addressed by studies under Reg. 283/2013**
- EFSA suggested to the applicant to consider alternatives in the data requirements for animal studies, such as waivers based on Weight of Evidence considering
  - public literature on compound transformation/degradation relevant to the a.s. ingredients,
  - bridging from other regulatory studies and assessments (e.g., other essential oil PPP dossiers, feed additives), or
  - PBTK modelling to estimate tissue concentrations upon livestock exposure for lead compounds,
  - PBTK read across from all available data and predictions

- However, the RMS did not accept this approach, noting:
  - Limited expertise and no guidance to assess alternative methodologies
  - Concerns that such approaches may not comply with current legal data requirements

LEGAL AND SCIENTIFIC CONSIDERATIONS

- For substances other than basic substances, the default legal position is that the applicant must submit a dossier **fully addressing the data requirements under Regulation (EU) No 283/2013.**
- **However, this is not absolute.**
- In view of **vertebrate testing**, well-supported waivers and non-testing approaches (including modelling), are already regularly accepted **case by case**, particularly where:
  - the information is not necessary owing to the nature of the substance/uses, which may clearly be the case for uses of plant extracts
  - According to Reg. 1107/2009 Article 62(1) first sentence "*Testing on vertebrate animals for the purposes of this Regulation shall be undertaken only where no other methods are available*." although the chapter is on data sharing, however, the intention to avoid unnecessary vertebrate testing is clear.

Reg. 283/2013 Annex Introduction 1.5 could be added to frame the proportionality of requirements, and acceptability of study waivers.

NAMS AND UPDATE OF THE DATA REQUIREMENTS (DRS)

- This is also supported by the updated Data Requirements (DRs) (*at advanced stage*)

- "Before undertaking *in vivo* studies, a weight-of-evidence analysis shall be performed on the existing relevant data. Where insufficient data are available, they can be developed through application of sequential testing, in which the testing strategy shall take into account validated non-animal approaches and testing e.g. bridging or read-across principles, *in silico* studies, *in vitro* study protocols."

- **Update of the DRs reinforce the use of NAMs.**

KEY NEED

The lack of expertise does not justify the inappropriate use of animals!

How could RMSs build familiarity with alternative methodologies??