

CO-FORMULANTS DATA SUBMISSION BY THIRD PARTIES

- ⇒ During DAR/RAR preparation and/or peer review process information on the **full composition of the co-formulants** are normally requested by RMS/EFSA and it may be submitted directly by **the respective supplier/manufacturer as claimed confidential**.
- ⇒ Accordingly, these data shall be handled separately (e.g. **Volume 4 “not for the applicant”**)
- ⇒ Internal discussions are currently on-going at **EFSA/EC** level on this approach and its (legal) implications, e.g.:
 - **Accountability** for the dossier and its possible identified data gaps
Suppliers are **not our legal interlocutor**
 - **Sanitisation/Confidentiality** decision-making process

