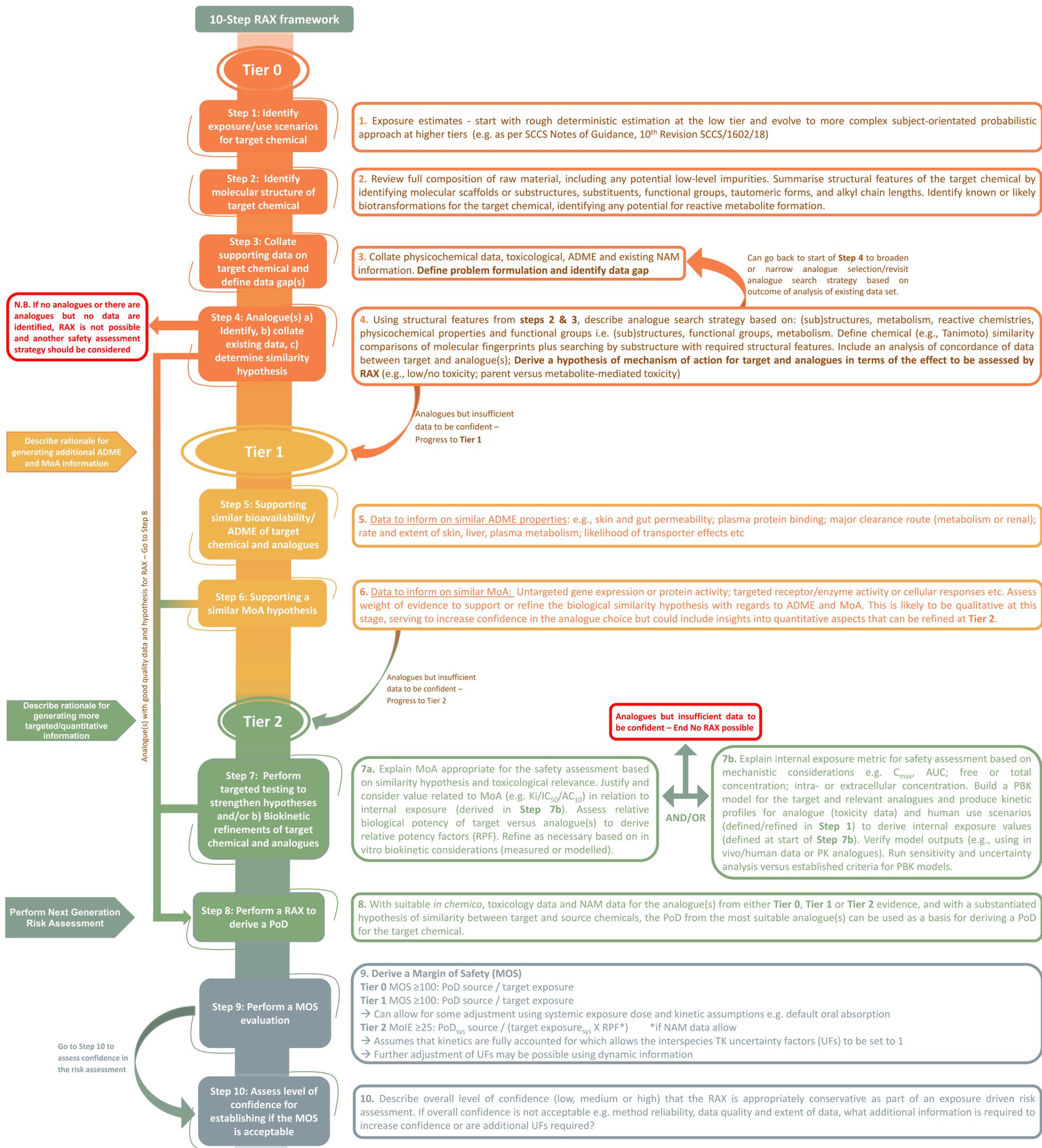


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In the context of Read-Across (RAX), new approach methods (NAMs) can help to strengthen the identification of suitable substances for RAX, increasing confidence in the analogue identification and the no observed adverse effect level (NOAEL) used as a point of departure (PoD) in a Next Generation Risk Assessment (NGRA). NAMs have also been used to inform on relative potency of analogue mode of action (MoA) and to predict internal exposure in both human and animal studies allowing for a risk assessment approach based on internal exposures without need to account for inter-species kinetic variability. To facilitate the implementation of RAX in a regulatory context, a framework to organise and report the information is needed to enable transparent, reproducible and scientifically defensible decision-making. We outline a 10-step framework for cases where a Threshold of Toxicological Concern (TTC) approach is not possible as exposure levels are not sufficiently low.



- This 10-step read-across (RAX) framework is proposed for use in cases where a TTC approach to cosmetics safety assessment is not possible. Two case studies based on this have been published in the OECD IATA project: parabens and caffeine (OECD <https://www.oecd.org/chemicalsafety/risk-assessment/iata-integrated-approaches-to-testing-and-assessment.htm>)
- RAX builds on established approaches by further substantiating hypotheses on toxicological similarity of substances, and integrating new approach methodologies (NAM) in the biological and kinetic domains.
- This is a robust approach to use RAX in regulatory risk assessment of cosmetics and could be considered for application to chemical assessment beyond cosmetics.