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Addressing regional needs in Latin America: Overcoming barriers to NAM adoption for local tolerance testing

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The use of animals for product regulation is an important ethical and scientific issue across the world, the desire to reduce and replace is shared by most countries. Latin America is composed of 20 countries, including ranges from North, Central and South Americas, and parts of Caribbean. The legislation of these countries is different from each other, and most still use toxicological tests on animals for the registration of their products. In addition, the lack of technical knowledge on the part of the evaluators associated with the input costs for the new approach methodologies (NAMs) makes their use challenging in Latin America. Validated OECD guidelines are currently available for important toxicological endpoints such as genotoxicity, sensitization and skin irritation/corrosion, as well as eye damage. However, only 6 Latin American countries are part of the OECD Mutual Acceptance of Data (MAD) system, consequently another challenge to be overcome for the adoption of NAMs in this region. The first Brazilian federal law on the scientific use of animals was approved in 2008 (Law 11794), which created the National Council for Animal Experimentation Control (CONCEA), responsible for issued several normative using NAMs and recognizing it in the country, subsequently. The regulatory framework was in 2019, especially for agrochemical, when the National Health Surveillance Agency (ANVISA) published RDC 294. The current legislation does clearly refer to the use of NAMs approved by CONCEA, OECD, or authorities with similar regulatory exigences in article 6°. Therefore, NAMs are accepted for registering products at ANVISA, if performed following validated protocols. In view of this, Brazil is at the vanguard of Latin America regarding regulatory acceptance and use of NAMs. To further promote the adoption of NAMs throughout the region, collaborative efforts focused on knowledge sharing, technical training, and the development of region-specific guidance are crucial. Besides, moving forward, a concerted effort is needed to expand the OECD MAD system to include more Latin American countries and to provide accessible training and resources to regulatory bodies throughout the region. By prioritizing the implementation of validated NAMs, Latin America can align with global best practices, reduce reliance on animal testing, and promote innovation in product development, and consequently foster both ethical and scientifically sound regulatory practices.

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ASPIS academy for sustainable toxicology through NAMs

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The evolution of chemical risk assessment has been marked by the emergence of New Approach Methodologies (NAMs), offering a transformative paradigm that replaces traditional testing approaches with more efficient and human-relevant methods. At the forefront of advancing NAMs for next-generation chemical risk assessment are Early-Stage Researchers (ESRs), whose development and support are critical for driving innovation in the field. Recognizing this critical need, the ASPIS Academy (AA) serves as a comprehensive networking initiative that brings together over 120 ESRs from three major H2020 European projects within the ASPIS cluster (ONTOX [1], RISK-HUNT*3R* [2], and PrecisionTox [3]). Through targeted initiatives encompassing training, mentorship, research group collaboration, laboratory exchange programs, outreach activities, and sustainability efforts, the AA is committed to fostering ESR professional development. These initiatives are coordinated by ESR representatives with guidance from experienced researchers. AA embraces diversity by fostering an inclusive environment that welcomes participants of varied backgrounds, beliefs, and identities, ensuring equal opportunities for emerging scientists to develop their ideas and aspirations. As a model for supporting early-career researchers, the AA demonstrates how to create an enabling environment while addressing challenges and pursuing continuous growth. This work advances the dialogue between AA and the broader community, demonstrating the contributions of ASPIS ESRs and illustrating the innovative capacity of emerging scientists.

References

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