

EPAA Partners Forum

14 November 2022, Brussels



The European Partnership
for Alternative Approaches to Animal Testing

Flash Report on EPAA's «Exposure Considerations in Human Safety Assessment» Partners' Forum, Part II, 14th November 2022

On 14 November 2022, the European Partnership for Alternative Approaches to Animal Testing (EPAA) held the second hybrid Partners Forum (PF) on “Exposure Considerations in Human Safety Assessment”. The PF was attended by 46 invited experts (29 present in person and 17 virtually) representing 8 industry sectors (16 companies and 6 industry associations), regulatory agencies (ECHA, EFSA, EMA & US EPA), SCCS, and the European Commission (DG ENV, DG GROW, DG JRC and DG RTD). The PF sought to build on findings and conclusions from a previous PF on this topic (in May 2022), specifically to agree key conclusions for the regulatory acceptance of exposure assessment approaches; cross-sector synergies and to rationalise the remaining research needs; and priority areas for further research investment.

The PF reviewed summaries of the opportunities for the use of exposure-based frameworks, exposure tools and exposure information in human safety assessment from eight sectors (agrochemicals, chemicals, cosmetics, detergents, foods, fragrances, medicines and veterinary medicines), with contributions from both industry and regulators. From the contributions and subsequent discussions first in 4 Break Out Groups and later in plenary, the PF concluded that collaboration across all industrial sectors, as well as exchange with regulators, has considerable potential and value for the incorporation

of exposure information into human safety assessment. A number of areas where opportunities for the development of approaches were identified including: exposure-based waiving; threshold of toxicological concern; physiologically-based kinetics, as well as skin and oral absorption modelling; better guidance on the use of New Approach Methodologies (NAMs), validation of NAM-based strategies and assessment of exposure with NAMs in Classification, Labelling and Packaging; development of the Minimum Anticipated Biological Effect Concentration (MABEL) and / or bioactivity level; use of aggregate exposure and biomonitoring; as well as an inventory of available exposure tools.

A number of “next steps” were agreed: the break out group leaders will review the outcome slides and identify priority actions where EPAA could make a significant contribution to the use of exposure data in human safety assessment, with an aim to address specific regulatory needs. The proposal will invite input by the PF participants and presented later for discussion with the EPAA Steering Committee. The overall findings from the two PFs on Exposure will be published as a report in a peer-reviewed journal. As well as capturing the current state-of-the-science for ‘Exposure Considerations in Human Safety Assessment’, the report will list the remaining research needs and propose synergies across sectors as areas for potential collaboration.

About EPAA

EPAA is a Public-Private Partnership across seven industry sectors and between European Commission and Industry stakeholders. Launched in 2005, it gathers 38 companies, 8 European trade federations and 5 Directorates-General of the European Commission.

Further information is available on https://ec.europa.eu/growth/sectors/chemicals/european-partnership-alternative-approaches-animal-testing_en

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