

To the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

Comments from the Institute for In Vitro Sciences (IIVS) on the need for clear statements of acceptance of new approach methodologies from agencies

Dear committee members,

As a contract research organization (CRO) serving a variety of industries, IIVS staff are often asked about the regulatory acceptance of new approach methodologies – particularly in vitro approaches. Our staff rely on a variety of resources to inform our clients about regulatory acceptance including the OECD Health Effects and NICEATM information portals. However, the clearest guidance comes from the agency itself. A good example of such clear guidance is the science policy released by the EPA OPP regarding the ‘Alternate Testing Framework for classification of Eye Irritation Potential of EPA-Regulated Pesticide Products.’ The guidance is easily found on the EPA website, provides background supporting information for the guidance and clearly states the purpose for which the described methods may be used (i.e., “thus the testing scheme can be used to satisfy the in vivo data requirement for eye irritation in 40 CFR Part 158W for antimicrobial cleaning products.”).

We encourage agencies to continue to strive to provide clear guidance on the official use and acceptance of alternative test strategies so that industry and CROs may use them to the fullest extent possible.

We thank you for taking these comments into consideration and appreciate the time and effort the committee makes to expand the use of alternative methods.