## 02.16 FOCUS



REACH ANNEXES AMENDED

## VitroScreen expertise on GLP compliant *in vitro* testing strategies

**REACH requirements** for skin corrosion/irritation, serious eye damage/eye irritation, acute dermal toxicity and skin sensitisation **are changing**, making **non-animal testing the default requirement.** 

**ECHA**, while updating its guidance on information requirements and its advice on the use of OECD test guidelines, **reminds registrants of their obligations to consider and, whenever possible, use alternative methods** in the following contexts:

• **chemical substances**, including starting material, reagents and isolated intermediates

VitroScreen

vitro science

registrants are requested to use Alternatives

- active substances for biocides and pesticides
- cosmetic ingredients

mixtures

E	ndpoint	Guidelines	Testing strategy
S	kin corrocion	OECD TG 431 <b>Episkin</b>	Stand alone test to discriminate corrosive and non- corrosive substances and mixtures.
S	Vin irritation	OECD TG 439 <b>RHE models</b>	Necessary to perform OECD TG 431 in case tissue viability results to be $\leq$ 50%.
S	erious eye amage	OECD TG 491 <b>STE</b>	Stand alone test to discriminate Cat. I from non classified. Initial test in a top-down approach or as follow up of OECD TG 492. Suitable for testing chemicals that are dissolved or uniformly suspended for at least 5 minutes in physiological saline, 5% DMSO in saline, or mineral oil.
		OECD TG 492 EpiOcular™ EIT and SkineEthic™ HCE EIT	To discriminate classified (Cat. 1 and Cat. 2) from non classified chemicals. Initial test in a bottom-up approach. Applicable to solids, liquids, semisolid and waxes (both substances and mixtures).
		OECD TG 442C <b>DPRA</b>	<i>In chemico</i> acellular test method. Neither stand alone nor applicable to lipophilic and unknown substances and mixtures.
_		OECD TG 442D <b>KeratinoSens™</b>	To be used as part of an integrated testing strategy. Applicable to test chemicals which are soluble and stable either in water or DMSO and with a cLogP < 5.
		OECD TG 442E <b>h-CLAT</b>	To be used as part of an integrated testing strategy. Applicable to all chemicals soluble or forming a stable dispersion in saline or medium or DMSO.
		<b>EpiCS</b> <sup>®</sup> based on IL-18 release	Applicable to liquids, viscous, solid and lipophilic test substances. The method can be adapted to screen finished products.