

## U.S. and European Acceptance of Alternative Methods 1998-2008<sup>1</sup>

No.	Method	ICCVAM BRDs and Peer Review	U.S. Regulatory Acceptance/Endorsement	OECD Adoption	EU Regulatory Acceptance/Endorsement <sup>2</sup>
1	CORROSITEX Skin Corrosivity Test	ICCVAM peer review and report; recommended in 1999	Yes, accepted by U.S. in 2000; as OECD TG 435 in 2006	OECD Test Guideline (TG) 435 (2006)	Yes, via OECD
2	Local Lymph Node Assay for skin sensitization	ICCVAM peer review and report; recommended in 1999	Yes, accepted by U.S. in 1999; as OECD TG 429 in 2002	OECD TG 429 (2002)	Yes, via OECD
3	Up and Down Procedure (UDP)	ICCVAM peer review and report; recommended in 2001	Yes, accepted by U.S. in 2003; as OECD TG 425 in 2003	OECD TG 425 (2006)	Yes, via OECD
4	Fixed Dose Procedure (FDP)	ICCVAM Working Group (WG) contributed to TG development	Yes, as OECD TG 420 in 2001	OECD TG 420 (2001)	Yes, via OECD
5	Acute Toxic Class Method (ATC)	ICCVAM WG contributed to TG development	Yes, as OECD TG 423 in 2001	OECD TG 423 (2001)	Yes, via OECD
6	EpiSkin Skin Corrosivity Test	ICCVAM review and report; recommended in 2002	Yes, as OECD TG 431 in 2004	OECD TG 431 (2004)	67/548/EEC
7	EpiDerm Skin Corrosivity Test	ICCVAM review and report; recommended in 2002	Yes, as OECD 431 in 2004	OECD TG 431 (2004)	67/548/EEC
8	SkinEthic Skin Corrosivity Test	ICCVAM contributed to U.S. OECD TG review	Yes, as OECD 431 in 2004	OECD 431 (2004)	Yes, via OECD
9	Rat TER Skin Corrosivity Test	ICCVAM review and report; recommended in 2002	Yes, as OECD TG 430 in 2004	OECD TG 430 (2004)	67/548/EEC
10	3T3 NRU Phototoxicity Test	ICCVAM contributed to U.S. OECD TG review	Yes, as OECD TG 432 in 2004	OECD TG 432 (2004)	67/548/EEC
11	3T3 NRU Phototoxicity Test: Application to UV Filter Chemicals	ICCVAM contributed to U.S. OECD TG review	Yes, as OECD TG 432 in 2004	OECD TG 432 (2004)	Yes, via OECD
12	<i>In vitro</i> dermal absorption methods	ICCVAM contributed to U.S. OECD TG review, expert consultation meetings	Yes, as OECD TG 428 in 2004	OECD TG 428 (2004)	Yes, via OECD
13	Use of Humane Endpoints in Animal Testing of Biological Products	ICCVAM agency initiative	Yes, 9 CFR 117.4e		
14	Rabies Vaccine, Humane Endpoints	ICCVAM agency initiative	Yes, 9 CFR 117.4e		
15	Bovine Corneal Opacity and Permeability (BCOP) Test Method	Yes, peer review and report; recommended in 2007	Yes, acceptance in 2008	<i>(Draft TG in preparation)</i>	
16	Isolated Chicken Eye (ICE) Test Method	Yes, peer review and report; recommended in 2007	Yes, acceptance in 2008	<i>(Draft TG in preparation)</i>	
17	Acute Toxicity <i>In Vitro</i> Starting Dose Procedure, 3T3 cells	Yes, 2001 workshop report; 2006 peer review and report; recommended in 2008	Yes	OECD TGs 420 (2001), 423 (2001), 425 (2006)	Yes, via OECD
18	Acute Toxicity <i>In Vitro</i> Starting Dose Procedure, NHK cells	Yes, 2001 workshop report; 2006 peer review and report; recommended in 2008	Yes	OECD TGs 420 (2001), 423 (2001), 425 (2006)	Yes, via OECD
19	ELISA Test for Batch Potency Testing of Erysipelas Vaccines (refinement)				Published in European Pharmacopeia

<sup>1</sup> Updated August 6, 2008

<sup>2</sup> Information provided by Executive Secretary, ESAC (European Centre for the Validation of Alternative Methods Scientific Advisory Committee), April 13, 2008

No.	Method	ICCVAM BRDs and Peer Review	U.S. Regulatory Acceptance/ Endorsement	OECD Adoption	EU Regulatory Acceptance/ Endorsement <sup>2</sup>
20	Relevance of the Target Animal Safety Test for batch safety testing of vaccines for veterinary				Published in European Pharmacopeia
21	ELISA Test for Batch Potency Testing of Human Tetanus Vaccines refinement				Published in European Pharmacopeia
22	ToBI Test for Batch Potency Testing of Human Tetanus Vaccines refinement				Published in European Pharmacopeia
<b>Totals</b>		<b>18</b>	<b>18</b>	<b>12</b>	<b>16</b>