ECEAE

THE EUROPEAN COALITION TO END ANIMAL EXPERIMENTS

The ADAPT principles for regulatory authorities

BUAV

campaigning to end animal experiments

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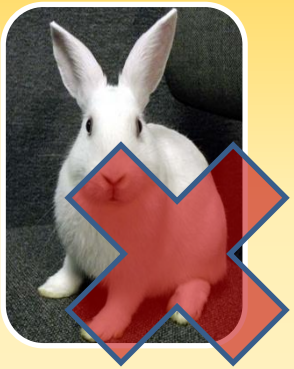
The ECEAE

- Formed in 1990, the European Coalition to End Animal Experiments (ECEAE) is made up of 24 member organisations across 22 member states

The path of an alternative method

Development → Validation → Formal test method → Regulatory acceptance → Legal acceptance



The various players

Developer	Validator	Test method formaliser	Regulator	Legislator
				Test Methods Regulation
ECVAM	ECVAM		ECHA	Member states
OECD	OECD			REACH text

2007 → 2013

Its not that simple!

- Many players
- Sector specific regulators and animal test regulators
- Not linear
- Path not the same even within same sector
- Path not defined

The ADAPT principles

These are the stages AFTER VALIDATION that regulators need to consider to ensure they are not holding up the successful implementation of alternative approaches

A ssessment

D ecision

A cceptance

P olicing

T ransparency

Assessment

What is needed:

- Assess whether the method is appropriate for each sector
  - Applicability domain of validation
  - Ability to classify
  - Substance specific issues with test method

Problems at this stage:

- Has to be done for each sector
- Regulator has to be proactive
- May be partly done during the validation/formal test method stage
- e.g. skin irritation but may also have reached an impasse there e.g EOGRTS

Decision

What is needed:

- Clarity on the point at which the regulator can make a decision about the use of the method - and that they do so!

Problems at this stage:

- Not always clear when regulator can decide
- Regulator can ‘hide’ behind other stages (international validation/formal test method, legislation)
- e.g. Skin irritation -OECD acceptance
- E.g. EOGRTS- Test Methods Regulation

Acceptance

What is needed:

- Formalisation of unequivocal acceptance. Removal of any remaining legal barrier to regulatory acceptance so that the method MUST be used.

Problems at this stage:

- Legal barriers- requirement for in vivo method in sector specific legislation e.g. REACH text- EOGRTS, skin irritation
- Requirements that alternative method cannot comply with in other sector specific legislation e.g. skin irritation
- Use of method in a testing strategy e.g. Skin corrosion/irritation
- No one 'body' collects everyone together
- Usually up to industry to identify these (and solve them)

REACH text

8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED		COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
8.1.	Skin irritation	
8.1.1.	*In vivo* skin irritation	8.1.1. The study does not need to be conducted if: — the substance is classified as corrosive to the skin or as a skin irritant, or — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or

COLUMN 1 STANDARD INFORMATION REQUIRED		COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
8.7.3.	Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex IX requirements	

Policing

What is needed:

- Monitoring of use of the alternative in sector specific regulatory submissions. Enforcement of non-compliance by sector regulator, prevention of occurrence by animal test regulator

Problems at this stage:

- No mandate –sector regulator
- Poor communication between sector regulator and animal test regulator
- Animal test regulator will not enforce until all sector regulators will accept (even internationally)

Transparency

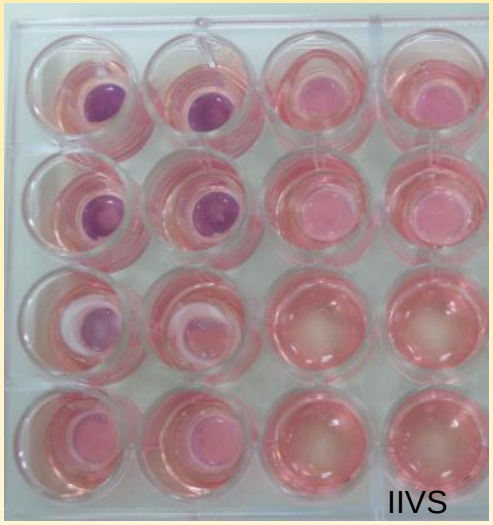
What is needed

- Sector and animal test regulators need to inform industry promptly when they have Decided and when they have Accepted

Problems at this stage:

- Lack of clarity over whether previous stages have been completed prevents effective communication
- Use of poor communication channels

e.g. Skin irritation use hidden in an ECHA report



How can we apply ADAPT?

- Validators need to present alternatives to regulators in a 'package' 
- Regulators need to have a process in place for each ADAPT stage that is proactive, not passive
- Legislators need to
  - Empower regulators when revising legislation
  - Avoid language in legislation that can act as a barrier