The need to **ADAPT** to new technologies

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Our experience with the chemicals, medicines and cosmetics sectors over the last 20 years has highlighted the complexity of the 'path to acceptance' and the many hurdles that are placed in the path of new methodologies that replace animal tests.

The path of an alternative method

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

Even simple, like-for–like replacements have struggled to gain acceptance and full implementation. Time scales from validation to adoption and replacement have been in excess of 10 years and for many are still not complete. This is due in part to a failing of regulatory authorities to take responsibility for identifying new methods, to assess the suitability for their sector and to then clearly notify industry of their decision. This has an impact on harmonisation worldwide if it is not even clear whether a region has accepted a new method or not.

Why do methods get stuck?

- Lack of awareness, availability and enforcement
- Desire for international harmonisation
- Need for in-house validation/proficiency testing
- Complicated regulatory processes;
  - Horizontal and vertical legislation
  - Several sectors - need for test methods and acceptance of test method by each regulator

A D A P T

Assessment

Does every relevant regulatory body have a proactive mandate to identify and assess the suitability of new methods for their sector?

Decision

Who has responsibility for deciding whether an alternative method is suitable and do they have a mandate to update their guidance/ legislation proactively?

Acceptance

Have all regulatory stages been identified for each sector and is there a body in charge of monitoring the progress of methods through these stages and accelerating them if necessary?

Policing

Do all relevant regulatory bodies monitor the use of alternatives and will action be taken if animal tests are done unnecessarily?

Transparency

Does the regulatory authority have a clear and appropriate mechanism for informing all stakeholders of their decisions at each stage?

Cruelty Free International has created the ADAPT principles to help regulatory bodies identify where changes in their policies and processes are needed to ensure the more rapid implementation of alternatives.

How can industry apply ADAPT?

Make sure that throughout your business there is awareness of and commitment to use these alternatives and waiving options.

Perform in–house validation of the alternative for your product, where necessary and update your licences.

Proactively evaluate the need for animal testing and take your results to the regulators.

How can regulators apply ADAPT?

Give all relevant bodies a clear mandate to replace animal testing with suitable alternatives as quickly as possible.

Ensure an individual or group within each regulatory body is given the task of implementing ADAPT.

Ensure there is regular dialogue between all relevant regulatory bodies to foster consistency and collaboration.

Future-proof legislation to avoid the need for continual updates to allow the use of new, alternative methods.

Conclusion

The situation will become even more complex and difficult in the new world of IATAs where like-for–like replacement is no longer an option and several testing strategies are possible.

It is vital that regulatory authorities take up the ADAPT principles now so that, as these new methodologies come into play, the framework is in place to rapidly evaluate and accept - or reject - them.

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