Public comment on ‘New ICCVAM Activities for 2021-2022’… and beyond

SACATM meeting 28-29 Sep 2021

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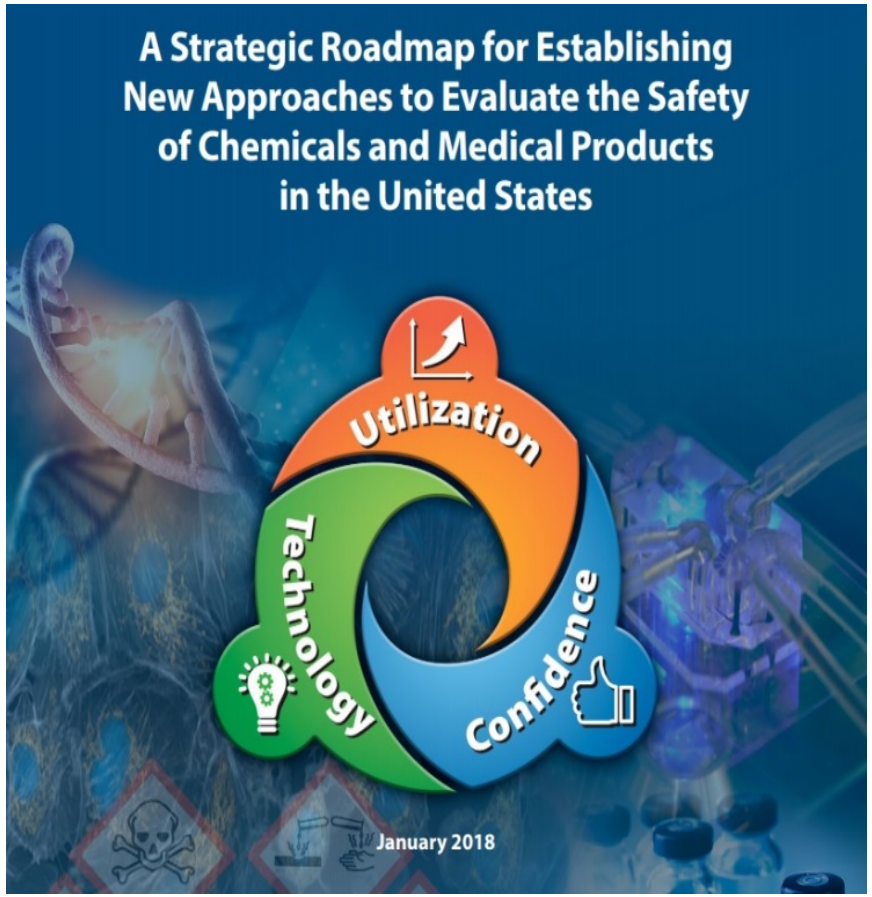
ICCVAM Strategic Roadmap



Goal 3: Encourage the adoption and use of new methods and approaches by federal agencies and regulated industries.

- Provide clear language regarding the acceptance of NAMs
- Collaborate with international partners to facilitate global harmonization and regulatory acceptance
- Explore processes to incentivize and promote the use of NAMs
- Identify appropriate metrics for prioritizing activities, monitoring progress, and measuring success.

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ICCVAM Public Forum – 27 May 2021

We presented a list 10 animal tests that could stop now in the US due to the availability of internationally accepted non-animal methods – part of our Making Alternatives a Priority campaign (MAP).

1 Skin irritation

2 Eye irritation

3 Skin sensitisation

4 Pyrogenicity

5 Botulinum toxin test

6 Antibody production

7 Leptospira vaccine potency test

8 Veterinary vaccines batch test

9 Abnormal toxicity

10 Shellfish toxins

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SACATM meeting – 02 Sep 2020

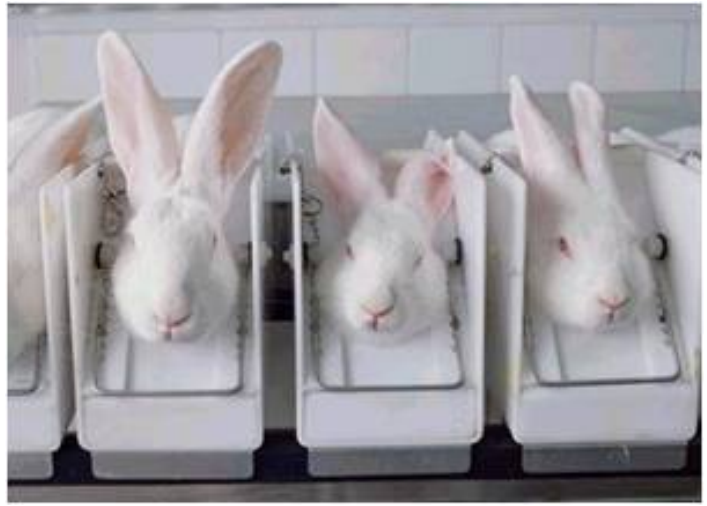
The following tests were identified by SACATM members during the last meeting as the "easiest" areas where animal replacement/reduction could be achieved.

Batch testing for biologicals – responsible for largest use of animals. "*No current plans or agenda for biologicals but open to suggestions*"**.**

Antibody production – dedicated session on non-animal-based antibodies: "*the technology is there; we just need to figure out how to get people to use it*".

Marine biotoxin testing – "*alternatives not being applied consistently*".

Pyrogenicity testing – "*alternatives not being applied consistently*".



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What are the barriers?

Lack of global harmonization (e.g. batch testing for biologicals)

Lack of regulatory enforcement (e.g. marine biotoxin testing)

Product specific validation required (e.g. pyrogenicity)

Availability of the alternative (e.g. antibody production)

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Suggested new activities for ICCVAM

We recommend that ICCVAM establishes the following ad hoc workgroups:

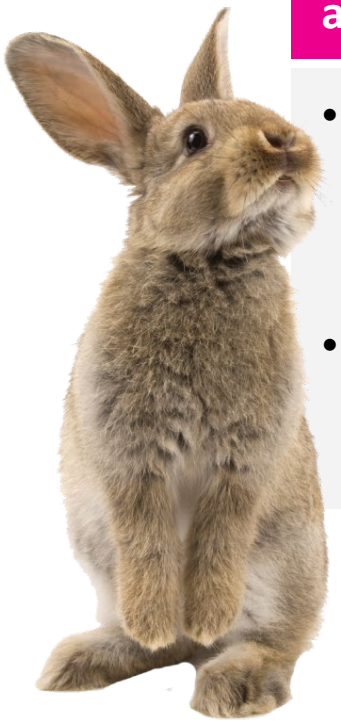
Topic	Recent progress in US	Suggested WG activities
Batch testing for biologicals	• TABST and LABST waivers accepted as per VICH guidelines since 2013 and 2019, respectively. • ATT no longer required since 2015. • USDA published exemption to hamster potency test for lepto vaccine in 2013. 60% of companies have transitioned to ELISA.	• Seek deletion of TABST and LABST from legal requirements (e.g. both were deleted from EU Ph. In 2012 and 1997, respectively). • Set deadline for companies to remove ATT from their product licences. • Prepare strategy to phase out animal batch tests, identify priority areas (e.g. lepto, rabies) and set targets (e.g. GSK target: 75% reduction by 2025).
Antibody production	• Events have been held by NICEATM and ICCVAM in 2020 to discuss the advantages of moving away from animal-based antibodies.	• Publish recommendation on use of non-animal-based antibodies (e.g. ECVAM recommendation in the EU) • Set up workshops/training webinars to tackle misconceptions and identify benefits of non-animal antibodies. • Create national resource to identify providers of non-animal antibodies.
Pyrogenicity testing	• FDA issued in 2012 guidance stating that the MAT or rFC can be used after product-specific validation.	• Seek deletion of rabbit pyrogen test from legal requirements (e.g. RPT to be deleted from all EU. Ph. monographs within the next 5 years). • Conduct nationwide survey to scope use of RPT (e.g. EPAA survey in EU) • Set up workshops/training webinars to tackle misconceptions and encourage use of non-animal methods.
Marine biotoxin testing	• In 2014, Maine became the first state in the US to receive FDA approval to use the HPLC method.	• Conduct nationwide survey to scope use of mouse bioassay. • Set up workshop to discuss costs/limitations and identify areas where improvements are needed.

Skin sensitization – guinea pig tests

US rejected recent OECD proposal to delete Buehler test.

In 2020 the FDA announced that they no longer recommend the LLNA test due to "limitations of the assay" and the guinea pig tests are preferred.

Non-animal methods and associated defined approaches are accepted by some US agencies but animal tests are still often preferred and/or required.



- Why has the FDA changed its position in favor of the guinea pig tests? What are the limitations of the LLNA? Where is the scientific evidence that the guinea pig tests are predictive of human responses?

- We strongly encourage ICCVAM to **reactivate its skin sensitization workgroup** and work towards the full deletion of the guinea pig tests from US and international regulatory requirements and widespread adoption of non-animal approaches.

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