



Ministerie van Infrastructuur
en Waterstaat

Validation a common good

Resources

Organization

Long-term assurance

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Take-away messages session 1

- Safe use of chemicals only with relevant, reliable and reproducible information on hazards
- New methods still needed for: new endpoints, new types of materials, more relevance, quicker, cheaper, no lab animals
- Scientific readiness : Sufficiently described?
- Validation readiness: Test conditions? Relevance for hazard?
- Regulatory readiness: Harmonisation, Test Guidelines, Test Guideline Regulation
- **Validation is essential for regulatory purposes**



Take-away messages session 2

- Method developers lack understanding of regulatory needs
- Validation activities are not funded by funding organisations
- Protocols for development, validation and test guideline preparation are needed
- A planned approach for development, validation and test guideline development is needed
- **Conditions for developers to provide validation-ready methods are understood but not well met**



What's the problem?

- Many illnesses contributed to chemicals but no test available that confirms or clears chemicals including pesticides.
- Example: link between Parkinson and exposure to pesticides:
La relation entre la maladie de Parkinson et le métier d'agriculteur, très exposé aux pesticides, est bien documentée dans la littérature. Depuis 2012, la maladie de Parkinson peut, sous certaines conditions, être reconnue comme maladie professionnelle chez les agriculteurs.
- Also ethic reasons for new test methods, example:
Commission acts to accelerate phasing out of animal testing in response to a European Citizens' Initiative



So, why don't we solve it?

- General recognition that the current test methods are insufficient
- Several programs at EU level to accelerate development of new test methods
- Additional incentives from side of public demand for animal free testing
- There seem to be many initiatives to develop new test methods but ...
- Validation of test methods is key but often fails due to insufficient interest, insufficient financing



Validation principles

Relevant

Regulatory
relevant and
useful for
end-users

Predictive
capacity
(biological
and
mechanistic
relevance)

Applicability
and
limitations

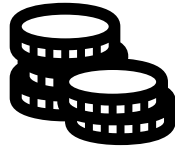
Reliable

Scientifically
sound

Reproducible



Validation in numbers



- > R&D to pre-validation: €200.000 – 2 million
- > Validation: €200.000-800.00*

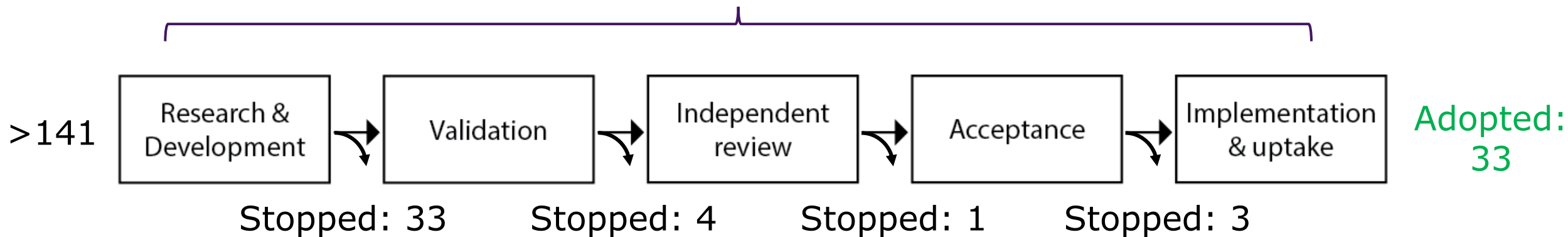


- > Where does R&D ends and validation starts?
- > Years – decades
- > If efficient test method optimisation: 1-3 years



Alternative method database - TSAR

Total 141
35 ongoing



→ Validation is key for acceptance



Funding of validation

Public funding for development of NAMs/NGRA
(New Approach Methods and Next Generation Risk
Assessments):

~€ 500 million 2016-2026



Validation and acceptance of NAMs/NGRA
lagging behind!



So, what's next?

- We need a system in which governments, risk assessors, scientific institutes, industry and other relevant stakeholders cooperate to identify the gaps and select projects to move forward.
- That will require a coordinated approach
- Preferably at EU level
- And it will need funding



Towards a pragmatic solution

- Extend portfolio of test methods to meet regulatory needs
- Inventory by regulatory risk assessors
- Priorities funding method development most needed from risk assessors' perspective
- Cease funding method development where good methods are already available
- Redirect funding from development to validation
- **Develop a balanced, long-term strategy, covering all phases**
- **Agree a rolling action plan to effectively and jointly implement the strategy**



Fund regulatory ready and needed methods

- Most funding provided by governments and national research funding organisations (NRFOS), limited funds by EC (amongst others PARC but not validation part).
- Mandated to fund research = method development \neq method validation
- But public funding should optimally benefit society
- Valorisation of method development through inclusion of validation
- Mandates of DG-RTD and NRFOS need to be changed, budgets not per se increased
- **Change budget provisions DG-RTD through Multi-annual Financial Framework**
- **Budget decisions are made in unanimity, when any is uncertain nothing changes**



Plan, coordinate, cooperate over entire chain

- EU to develop a [European Test Method and Validation Strategy](#)
- Ensure adequate staffing, funding and mandate for validation efforts
- Coordinate with (inter)national, existing and future, public or private activities
- Coordinate with academia to develop education and training in validation
- Collect, distribute and apply best practices like PEPPER
- Develop validation protocols based on work such as in PARC



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Become an agent of change

- PEPPER good example: dedicated funds for validation, dedicated solutions
- Help explain the importance of validation, maybe less spotlights but more impact!
- Extend PEPPER-like to other area's, especially neurodegenerative and immunotoxic effects
- Promote changing the Horizon Europe budget conditions to include validation through your Finance Ministries
- **Support the development of a European Test Method and Validation Strategy**
- Watch the animation (2 minutes)



Thank you for your attention!

Help with an EU strategy to improve validation
at the policy conference 22-23 of January

Register here:

