

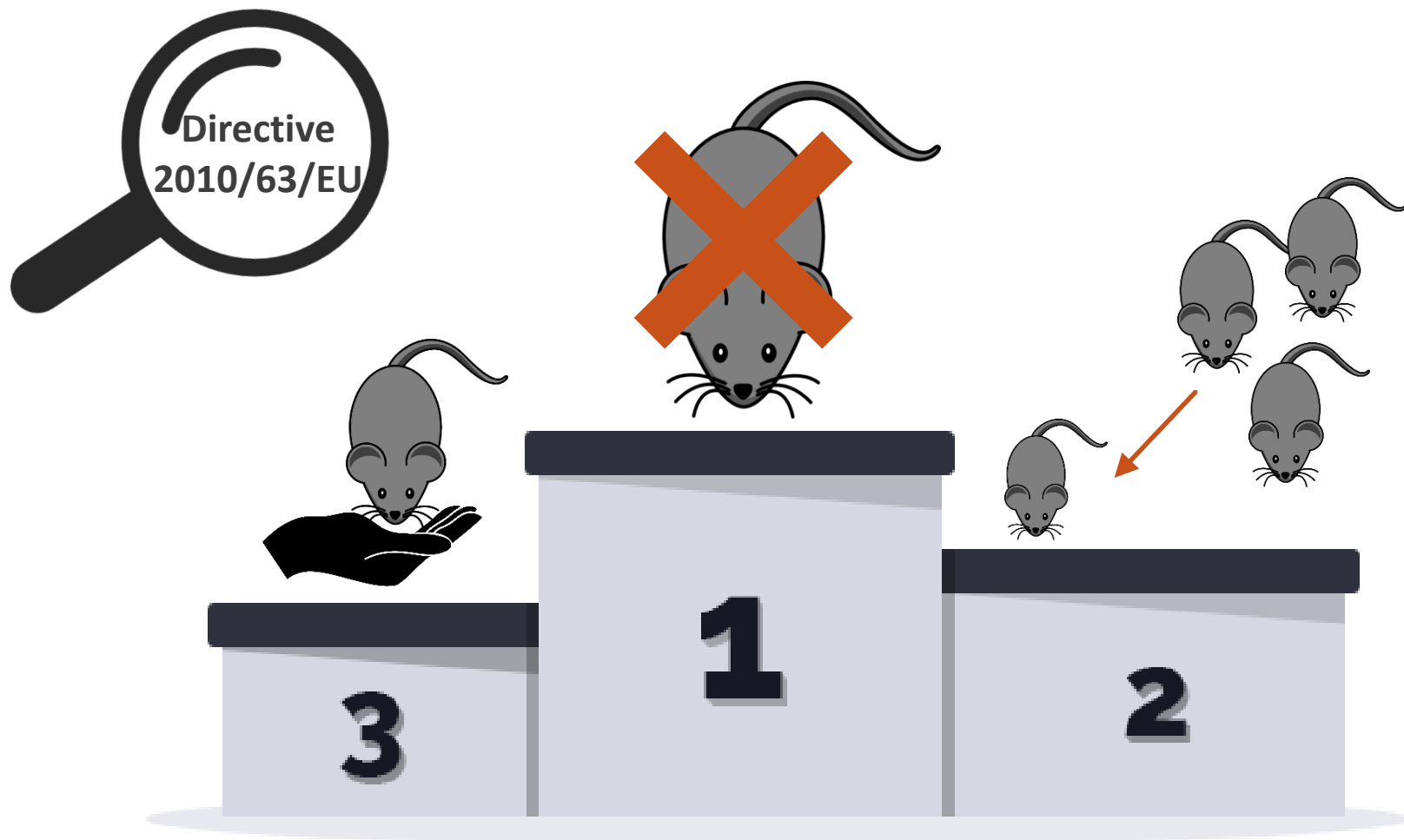
THE PARERE NETWORK IN BELGIUM: INCREASING AWARENESS ON NAMS AMONG REGULATORS

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Studiedag Leefmilieu Brussel / Bruxelles Environnement
Brussels, Belgium

European legislation



➔ Creation of EURL ECVAM and different European networks

'European Union Reference Laboratory for Alternatives to Animal Testing'



VALIDATION

Reliability - Relevance - Aim



COMMUNICATION

Between different stakeholders



DISSEMINATION

Active distribution of information

ICATM cooperation

Stakeholder dialogue

ECVAM Validation Process

Key documents

ICATM: Exchange Information on promising submissions. Select mode of collaborative activity.

ICATM: Technical aspects of VS. Propose VMG members. Second liaison members (=observers).

ICATM: Proposal of experts for the ESAC WG supporting the ESAC peer review.

ICATM: Harmonised recommendations of validated test methods (if feasible).

Relevance assessment:

- PARERE: regulatory relevance
- ESTAF: user relevance

Public input on planned Validation Study. Submission of existing information.

Comments on draft recommendation:

- PARERE
- ESTAF

Public input on draft ECVAM recommendations

1. Assessment of submitted test method
Scientific aspects. Stakeholder relevance (priority setting). Optimisation (if necessary).

2. Planning & conduct of (Pre-)Validation Study (VS). → Test method evaluation.

3. ESAC review of (1) VS conduct (2) VS conclusions → (3) **ESAC opinion** on test method's validity for purpose.

4. Draft ECVAM Recommendations on validated test method.

5. 'Right to be heard' process.

6. Public Commenting

7. Finalisation of ECVAM recommendations (ER). Publication of ER + ESAC opinion + VSR.

Test Submission

PARERE report / ESTAF View

Validation Project Plan (VPP)

Validation Study Report (VSR)

ESAC Request

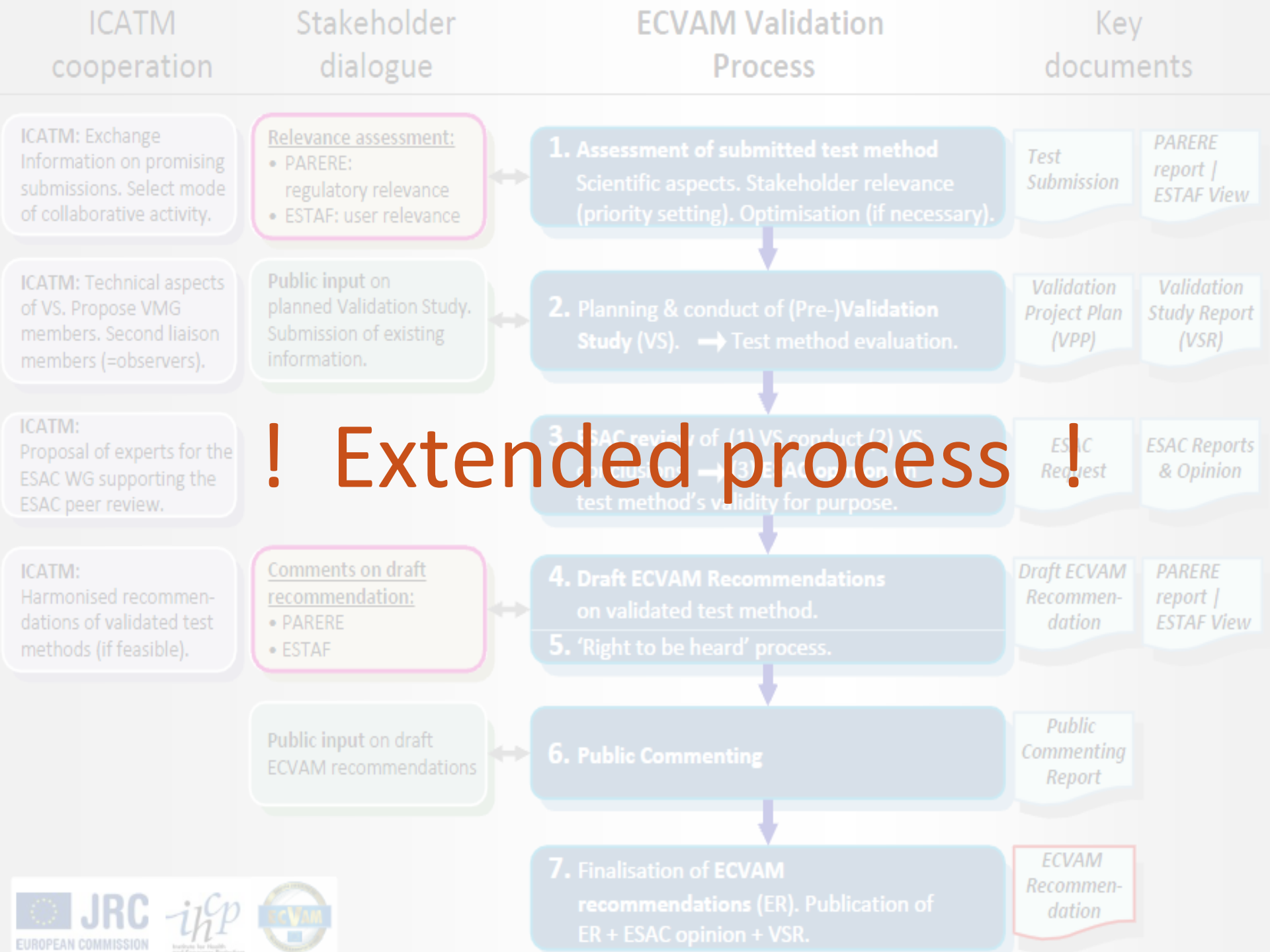
ESAC Reports & Opinion

Draft ECVAM Recommendation

PARERE report / ESTAF View

Public Commenting Report

ECVAM Recommendation



EU-NETVAL

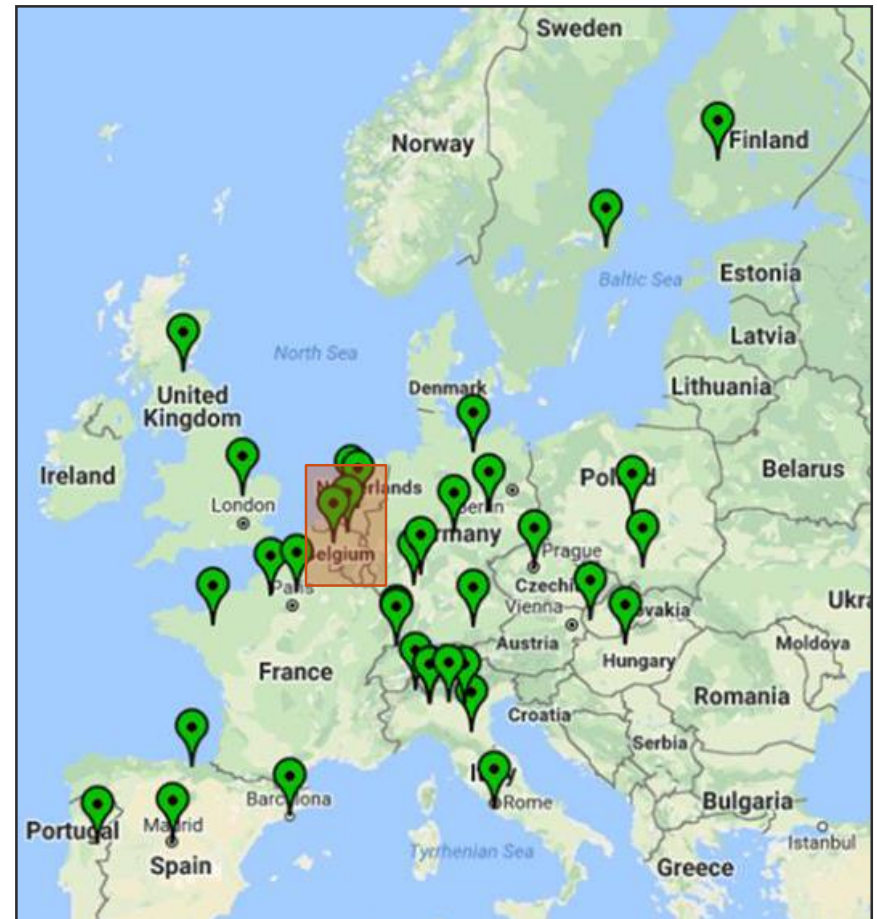
‘EU Network of Laboratories for the Validation of Alternative Methods’

AIM: Support validation studies of EURL ECVAM

COORDINATION: EURL ECVAM with DG Environment and the NCPs

MEMBERS: 35 (last call 09/2015)

1. Sciensano – Quality of Vaccines and Blood Products
2. VITO-ABS – Research team Applied Bio & molecular Systems



PARERE network

‘Network for Preliminary Assessment of Regulatory Relevance of alternative methods and approaches’



PARERE representative in
30 EU member states
(BE: *Sciensano*)



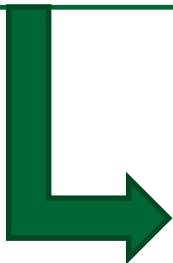
Exchange of knowledge on NAMs with regulators

BE PARERE network

Link between the PARERE contact point, the **National Coordinator of the OECD Test Guidelines Programme (NC)** and the National Contact Point for implementation of Directive 2010/63

Convention entre l'Institut Scientifique de Santé Publique (ISP), la Région flamande, la Région wallonne et la Région de Bruxelles-Capitale concernant la désignation d'un point de contact unique chargé de fournir des conseils sur la pertinence réglementaire et l'opportunité des approches alternatives proposées pour validation (le point de contact PARERE).

Overeenkomst tussen het Wetenschappelijk Instituut Volksgezondheid (WIV), het Vlaamse Gewest, het Waalse Gewest en het Brussels Hoofdstedelijk Gewest betreffende de aanduiding van een contactpunt dat advies uitbrengt over de relevantie van regelgeving en de geschiktheid van alternatieve benaderingen die ter validering worden voorgesteld (het PARERE contactpunt).



DEPARTEMENT
OMGEVING



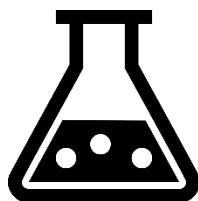
leefmilieu
brussel
.brussels



Wallonie
service public
SPW

BE PARERE network

BE experts from different regulatory domains



Role of PARERE has evolved – type of experts needed has changed

In practice

- 1 Coordination of advice from Belgian experts and the Belgian participation in EU-NETVAL
- 2 Organisation of 2 meetings of the BE PARERE network and 1 with the NCPs
- 3 Preparation and participation to the yearly PARERE/ESTAF meeting



Contact

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