



Risk Assessment in Nanosafety

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Tools for Now and the Future

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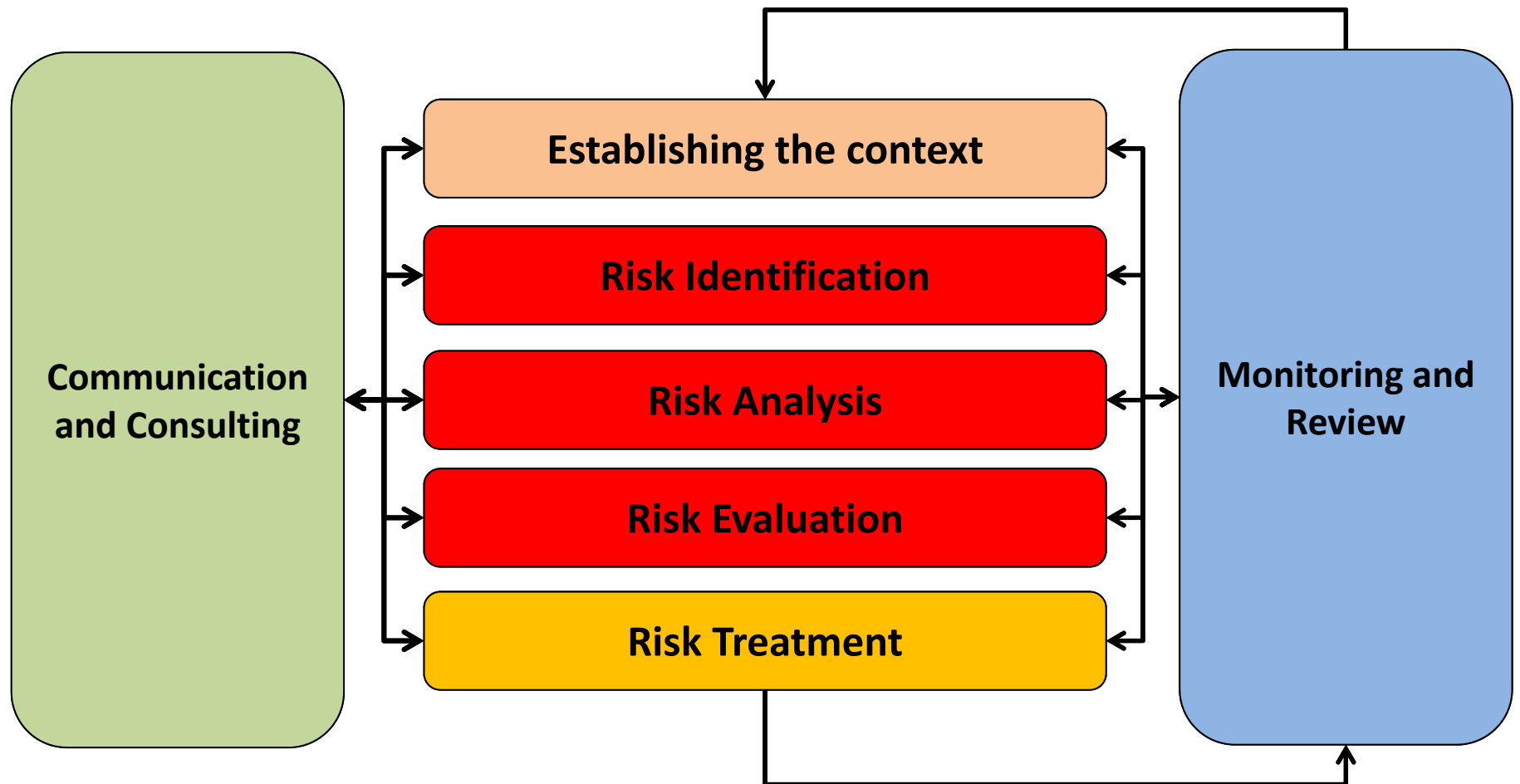
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Principal Risk Assessment

and Risk Management



ISO/IS/31000 (2009)



"Current" situation – Example

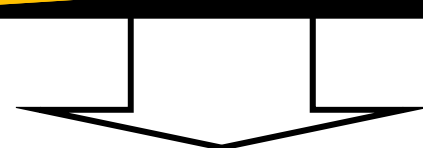
REACH risk assessment approach

- UHDFK #Wu# #hw p dwhv
- HFHWR F #UD
- HP NJ #H[SR #Wro
- FrqH{sr
- Ukn ri#Ghup ,

➤ No official OELs available - NM limits values are just slowly emerging (+grouping issues)

➤ No proper...

Need for suitable data and "validation" of existing or new nano-specific Risk Assessment and – Management approaches



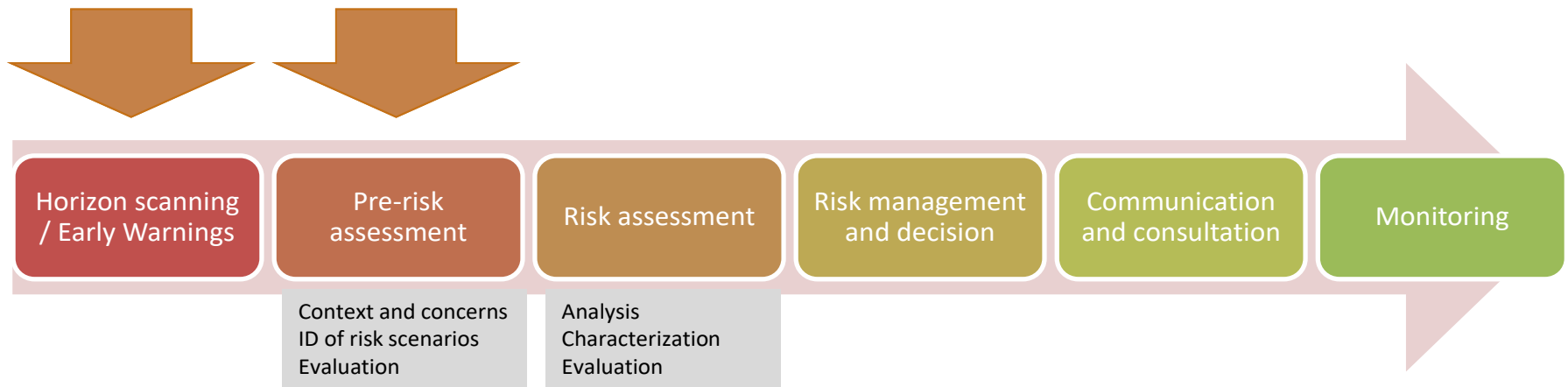
Reliable risk assessments with REACH model is either impossible or should be done with GREAT care!



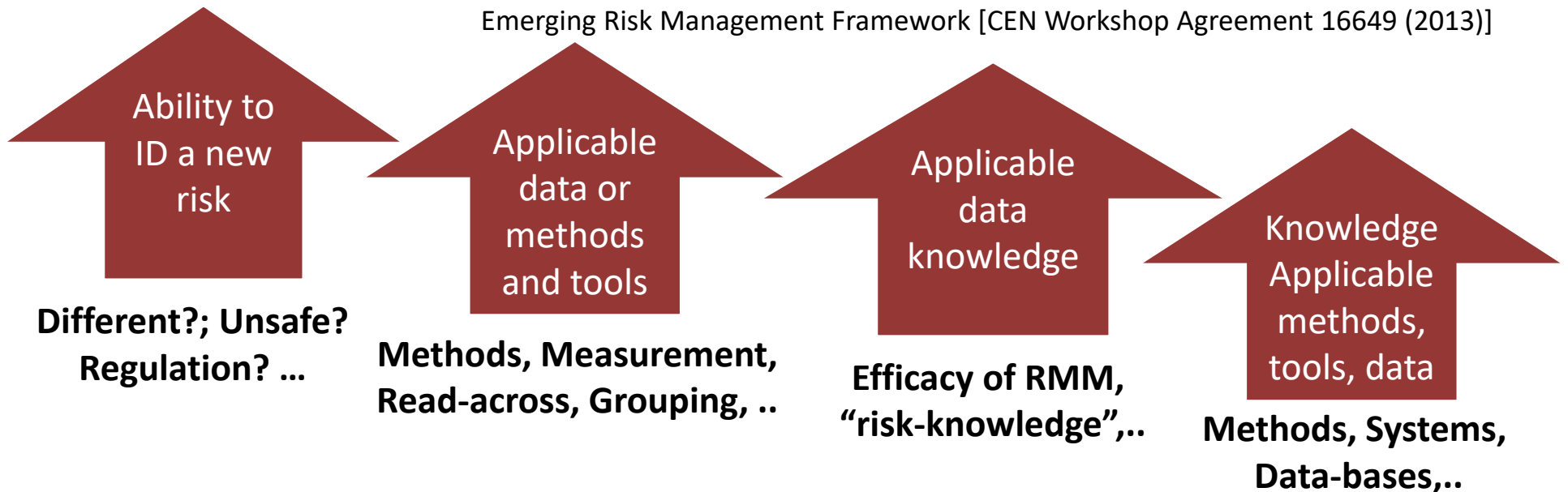
From Risk Assessment to Emerging



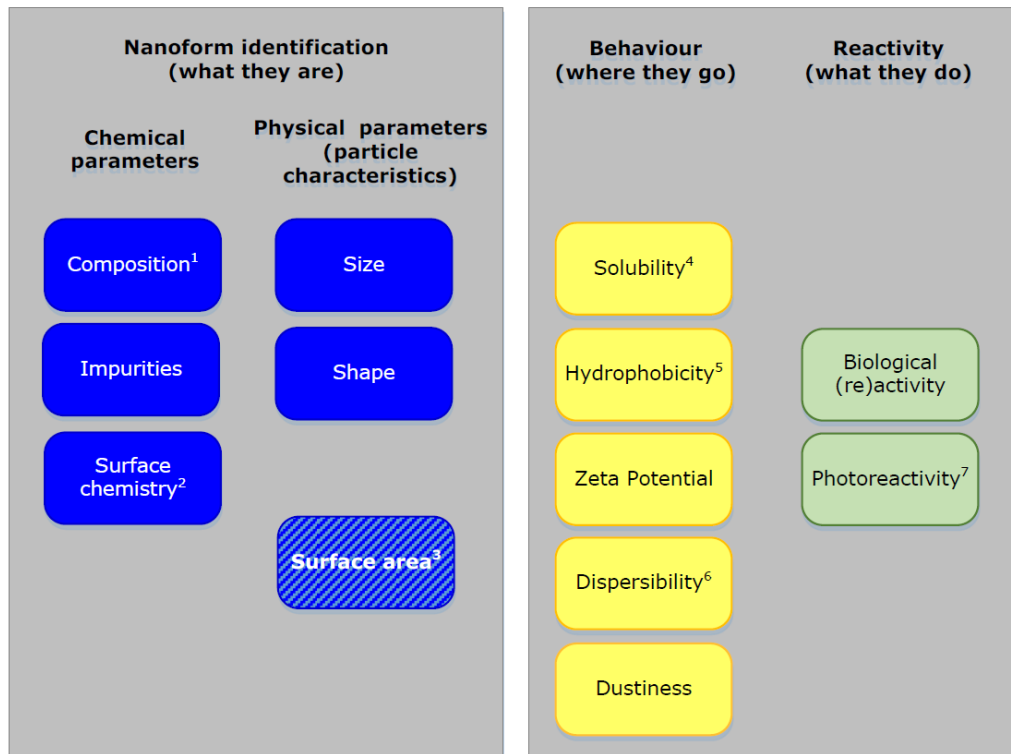
Risk Management and Governance



Emerging Risk Management Framework [CEN Workshop Agreement 16649 (2013)]

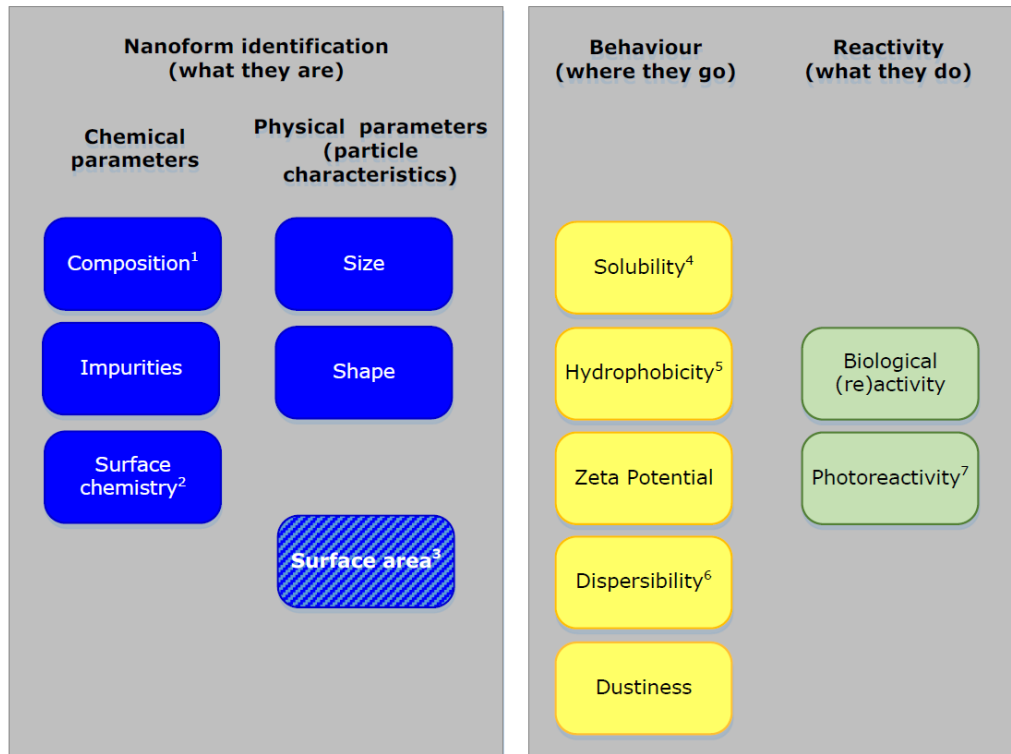


Essential for ID of new risks in REACH

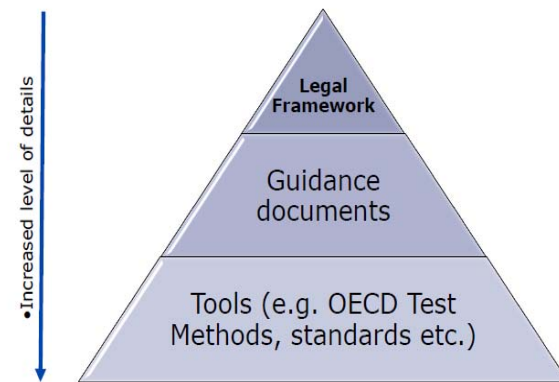


 **Substance identification and grouping:** 

Essential for ID of new risks in REACH



Test methods/standards underpin the implementation of legal frameworks

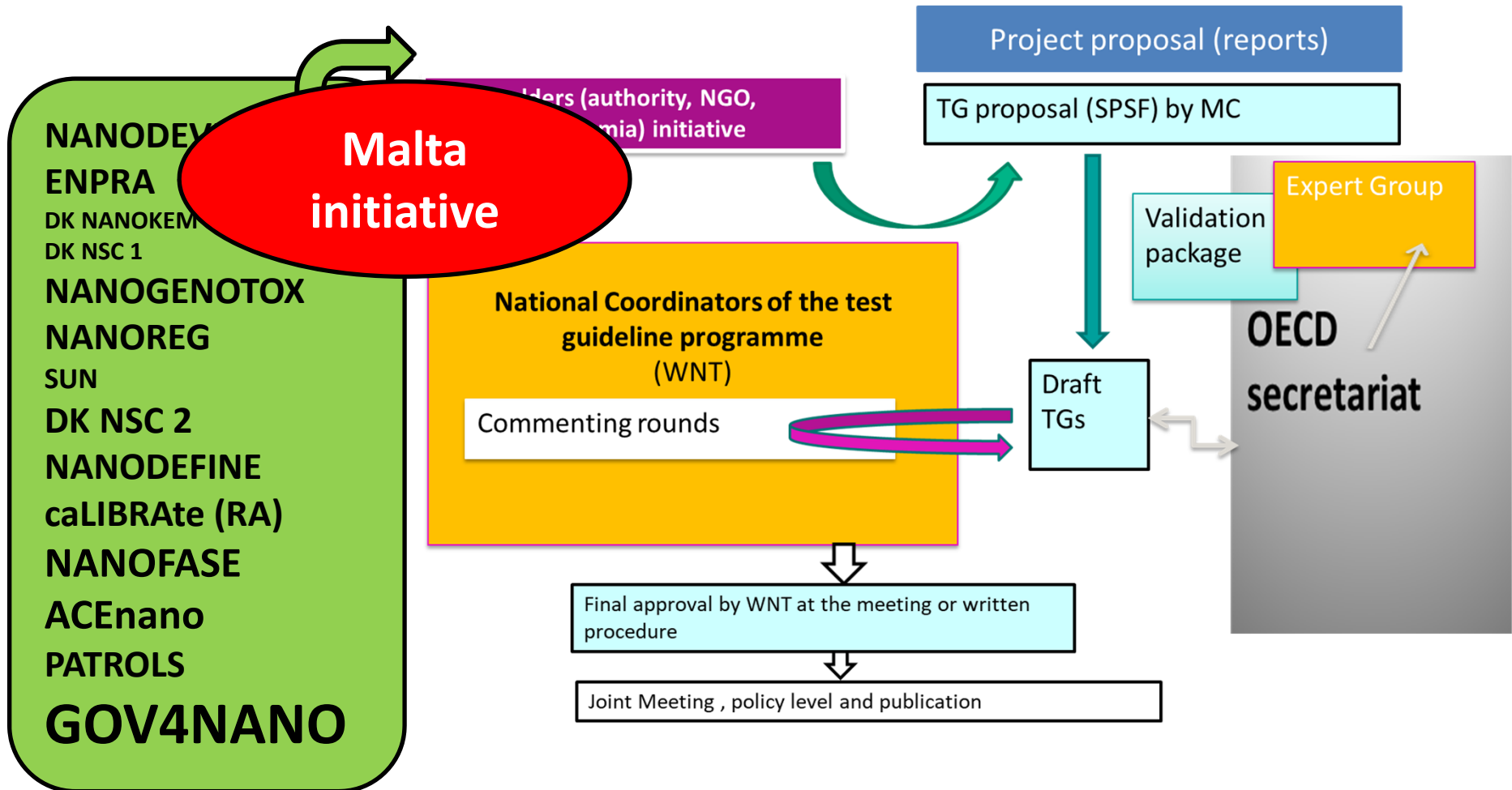




“Standards” takes *leaders, time, cost:*



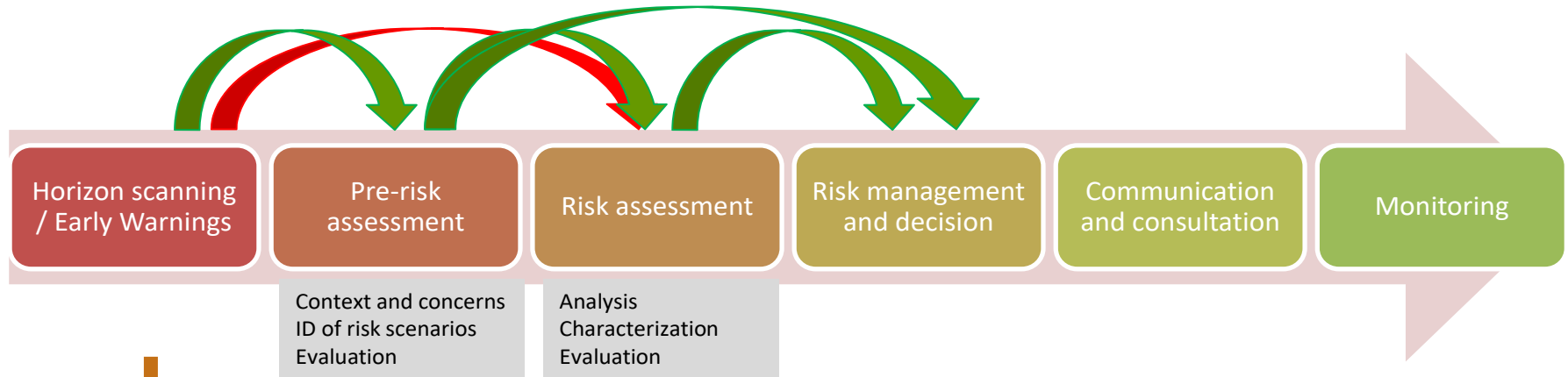
Leveraging on national and EU research results



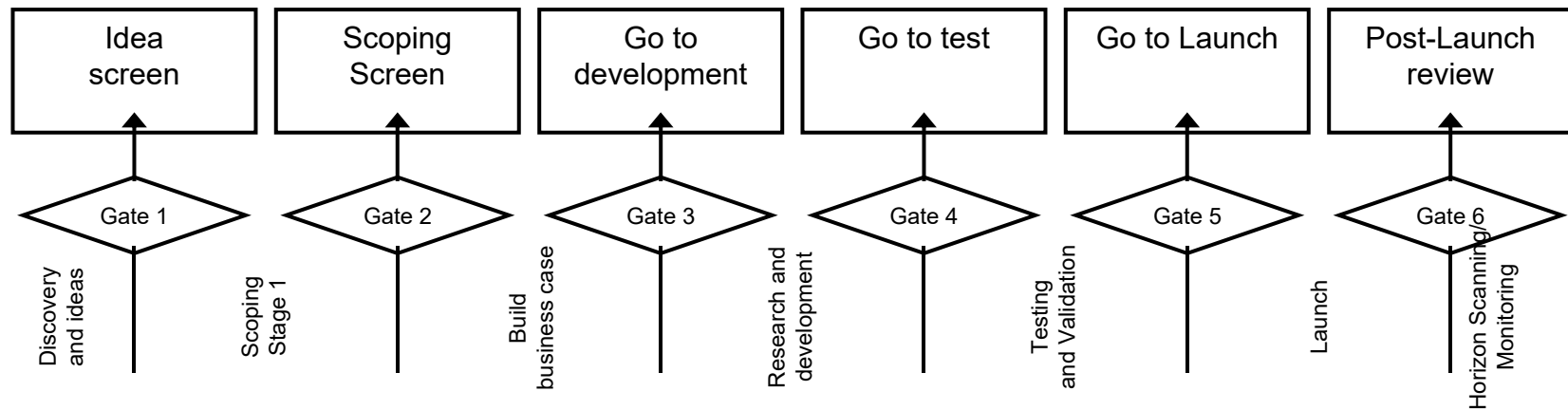
Modified from Jukka Ahtiainen og Mar Gonzales (OECD HQ, Paris)



From Emerging Risk Management to Nano-risk (innovation) Governance



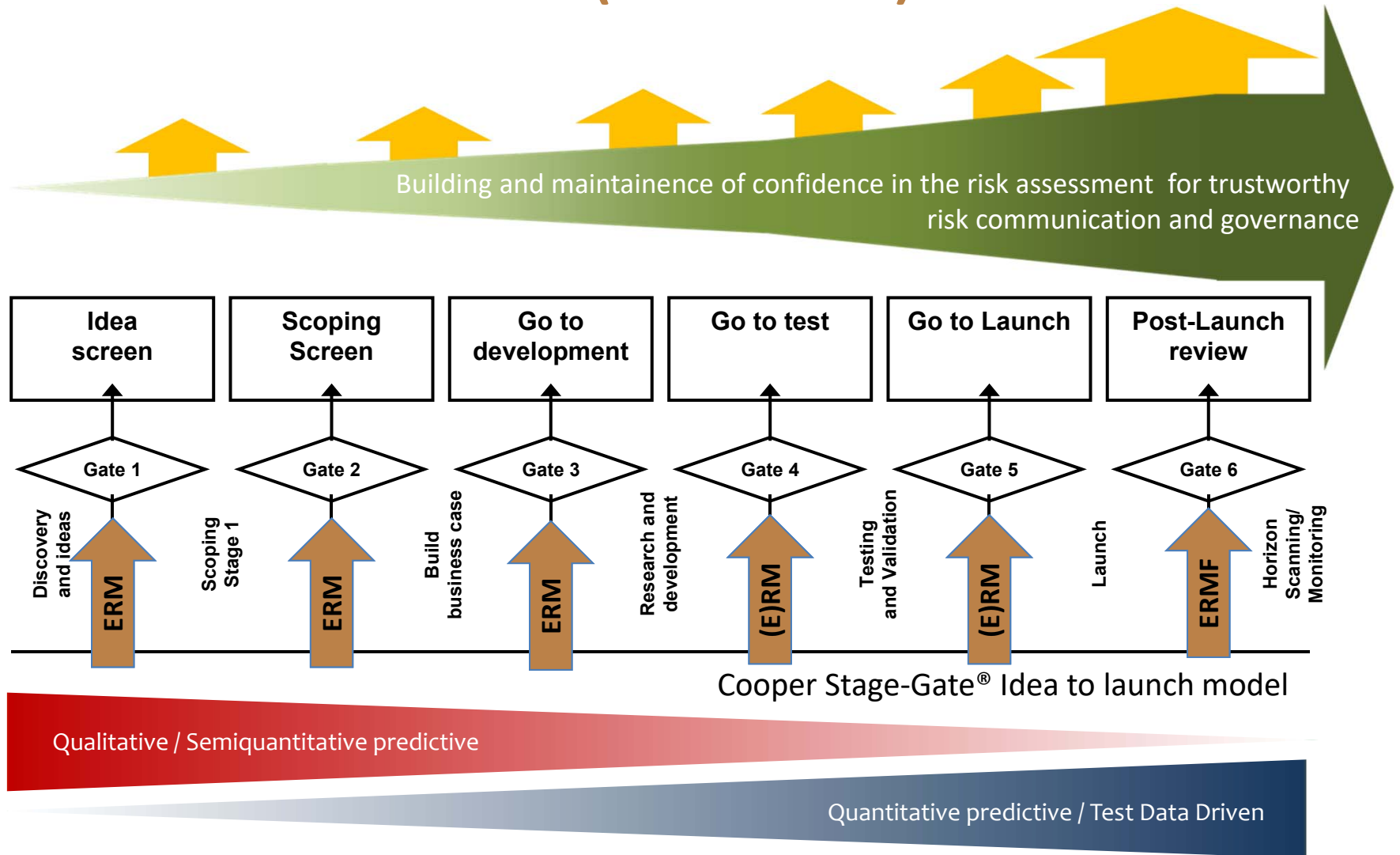
Emerging Risk Management Framework [CEN Workshop Agreement 16649 (2013)]



Cooper Stage-Gate® Idea to launch model



From Emerging Risk Management to Nano-risk (innovation) Governance





In line with stakeholder opinions!



	<i>Industry Representatives</i>	<i>Academic Public Researchers</i>	<i>Policy makers Regulators Insurers</i>
<i>Idea screening; Early planning stage of R&I</i>	Light green	Dark green	Light green
<i>Scoping screening; Basic research</i>	Light green	Dark green	Light green
<i>Go to development; Applied research/proof of concept</i>	Dark green	Dark green	Dark green
<i>Go to test; Production/engineering/testing</i>	Dark green	Dark green	Dark green
<i>Go to launch; Go to market</i>	Dark green	Light green	Light green
<i>Post launch review; On the market</i>	Light green	Light green	Light green
<i>In all stages</i>	Dark green	Dark green	Light green

Color scale (Number of counts)



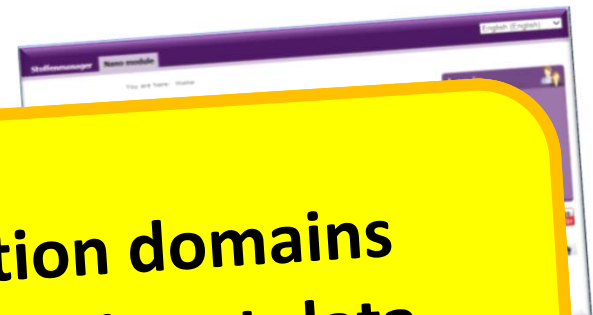
Unpublished caLIBRAte results



Do we already have the

nano-specific Risk Assessment tools?

No.	Model name	Application area	Owner	Model type
1	ANSES tool	Work	ANSES	CP
2	ISO TS 12004			



Common for all!
Often restricted to specific application domains
Users often have challenges in finding input data
Limited use and low general knowledge about them
NOT VALIDATED

14		Human/Env.	Tomas Puzyn	QHA
15	SimpleBox4Nano	Env	RIVM	QEA
16	Mendnano	Env	UCAL (USA)	QEA
17	NanoDuFlow	Env	WA (NL)	QEA
18	RedNano	Env	UCAL (USA)	QEA
19	n-SSWD	Env	UNIVE	QEcotox

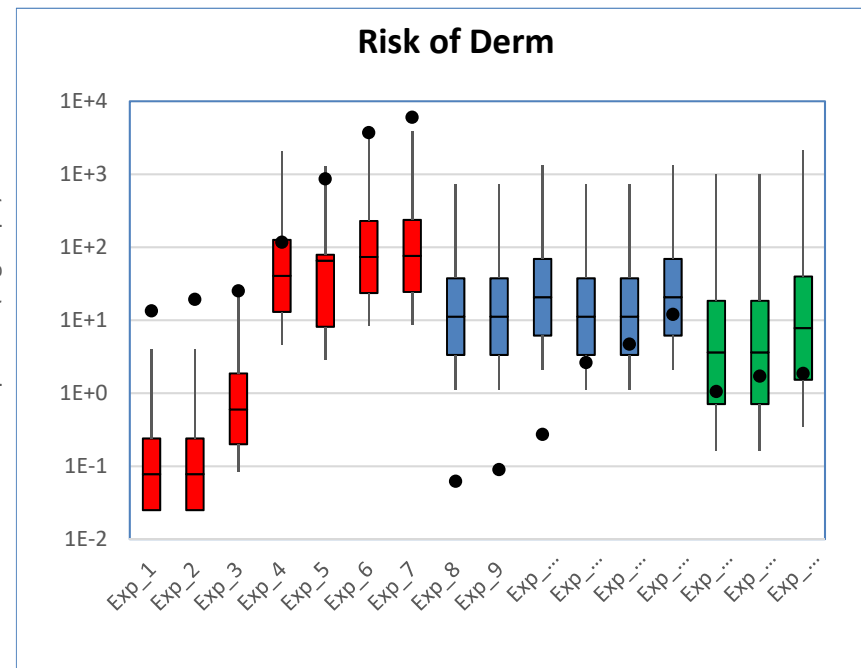
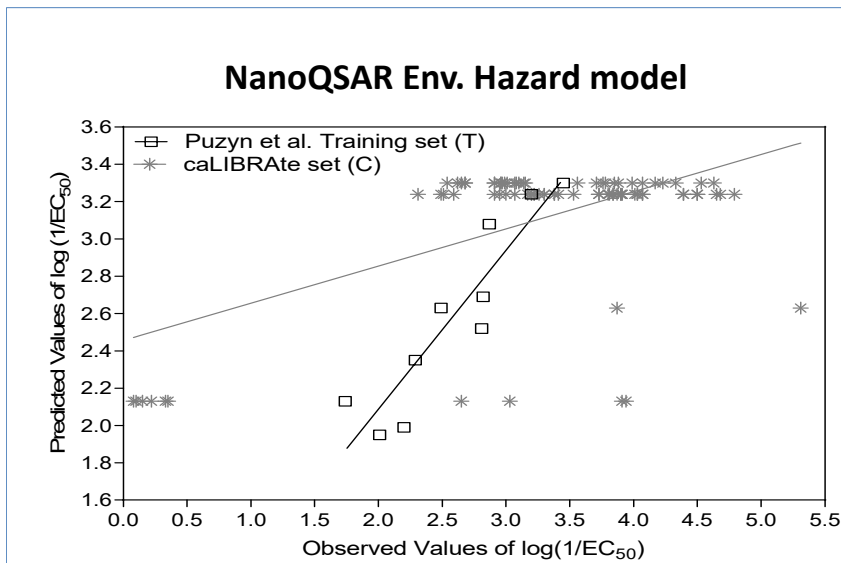
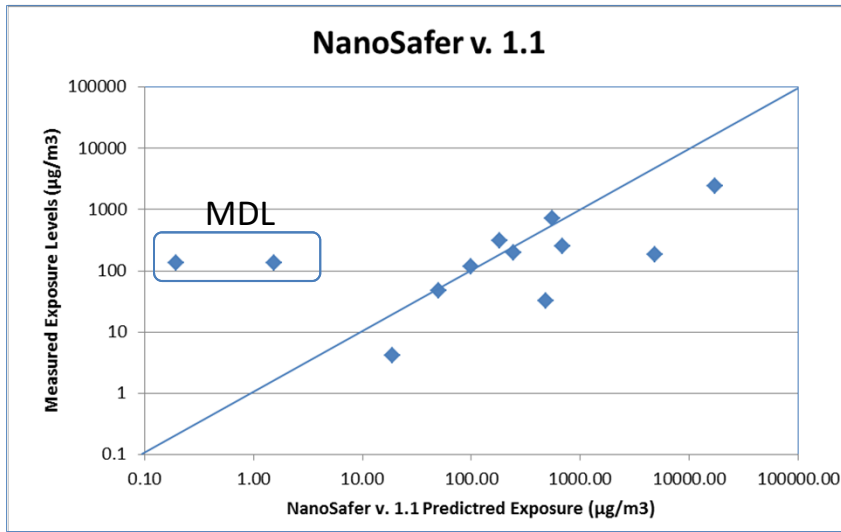
Abbreviations: Env - environmental, Cons - consumer, CB – Contol Banding, RA – Risk Assessment, RM –Risk Management, QEA – Quantitative Exposure Assessment, QHA – Quantitative Hazard assessment, Risk Cat – Risk Categorization





Performance testing for validation:

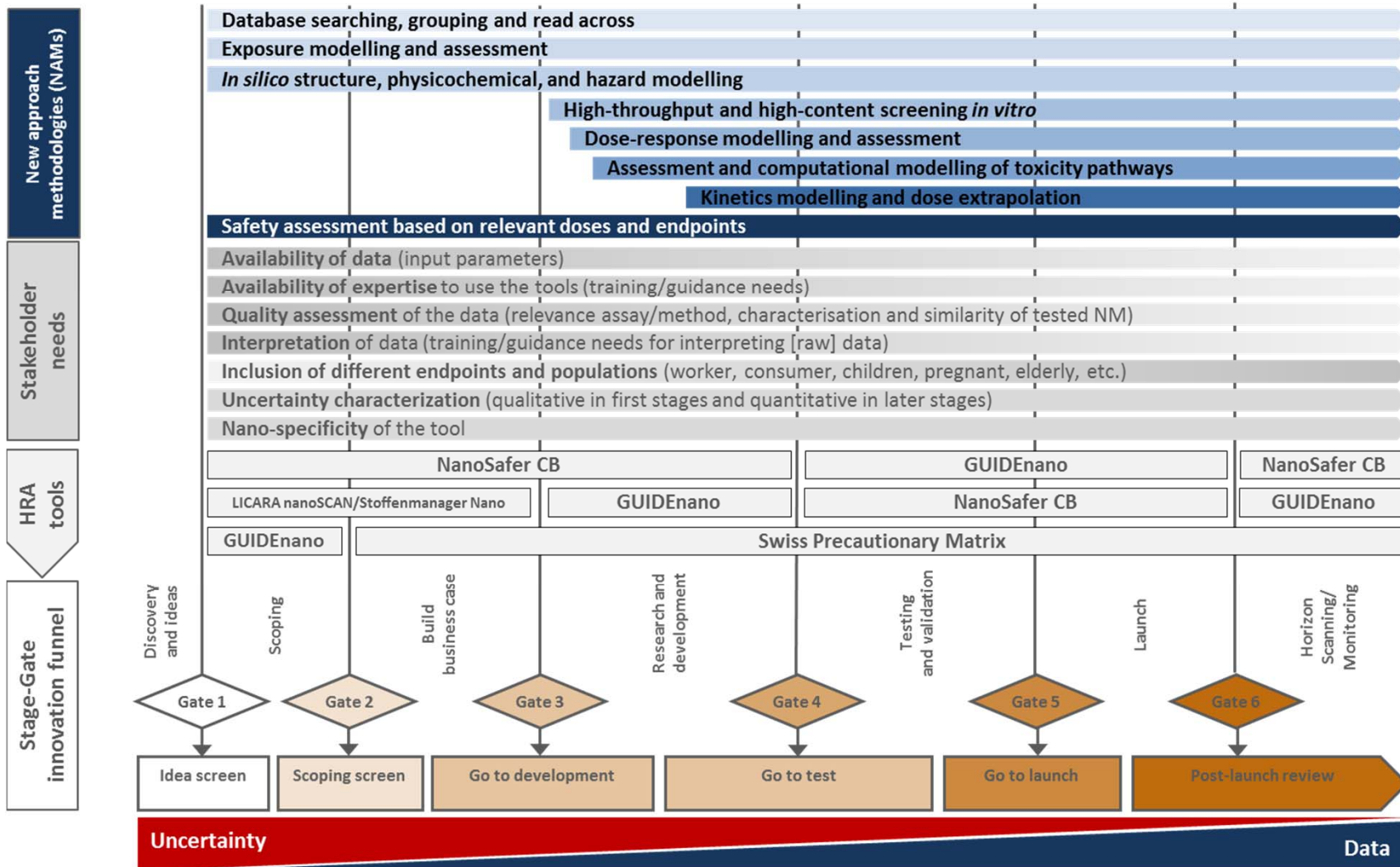
Ongoing work





Future steps: Include new approach

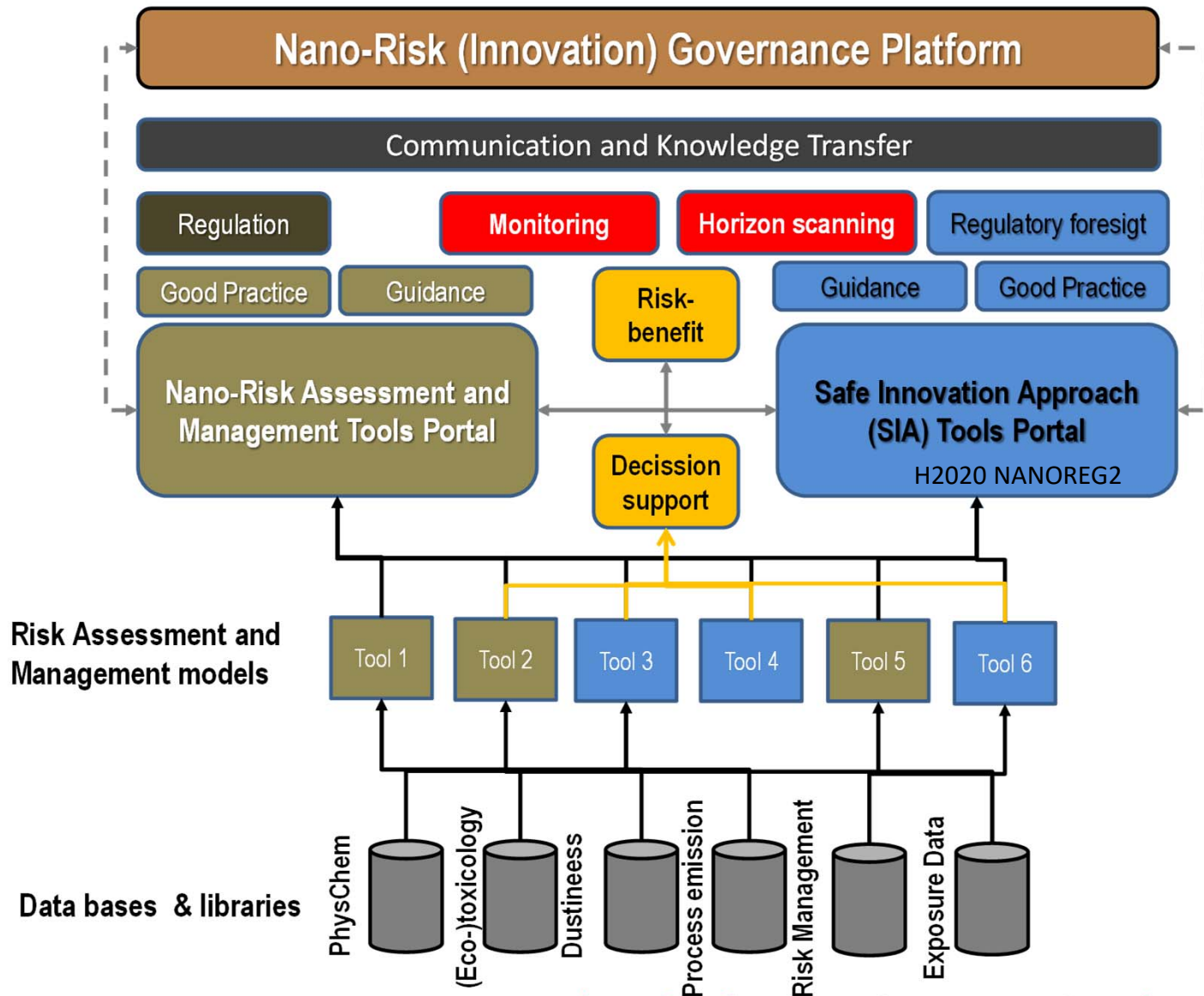
methodologies (NAMs) MN Risk Assessment



Nymark et al. Applicability of new approach methodologies to innovation and safety assessment of nanomaterials. In preparation



Users: industry,
service providers,
regulators, NGO's etc.

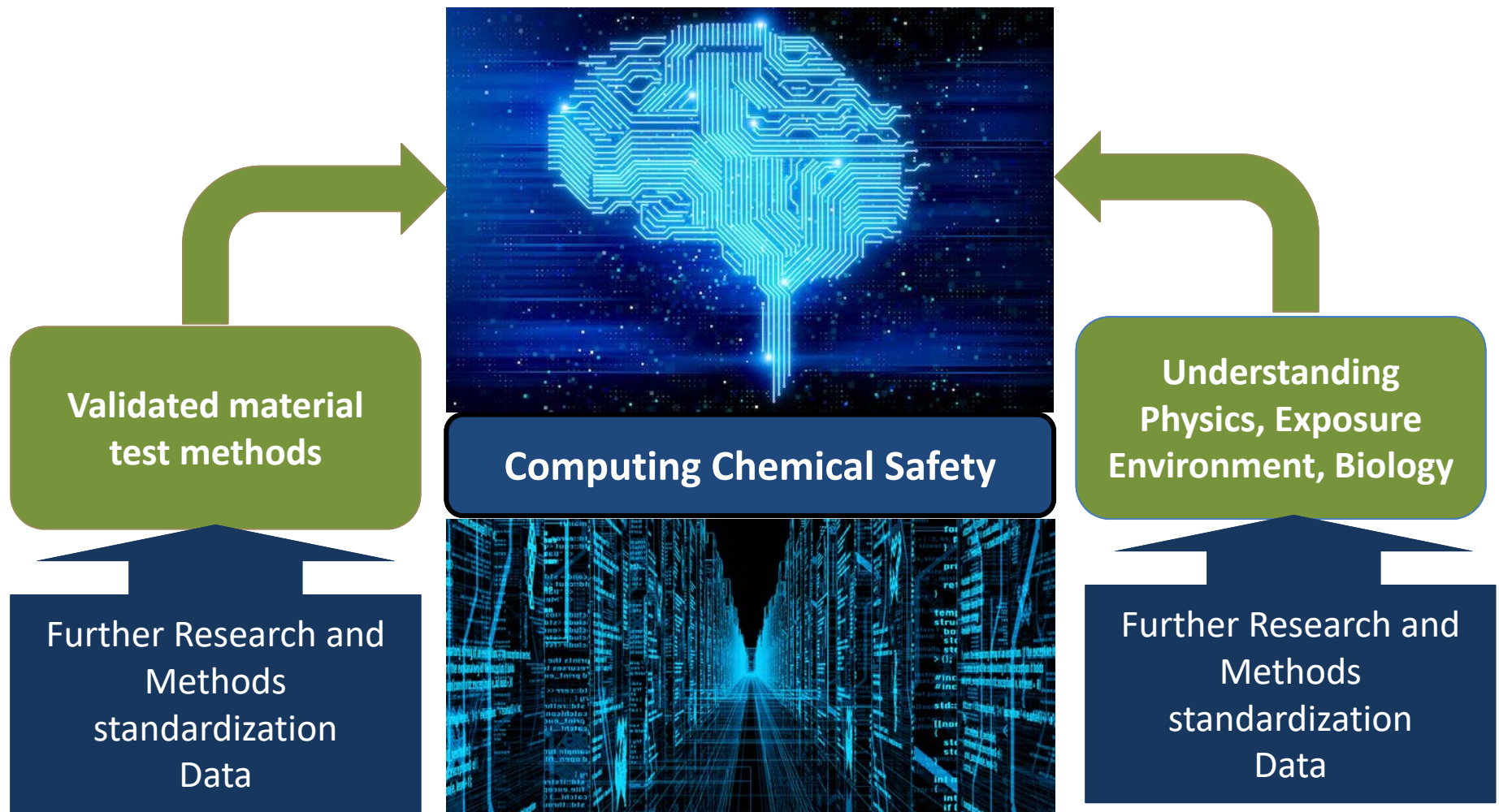




Far Future: We may reach >90%



Predictive “Chemical” Risk Assessment



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Welcome

We are a interdisciplinary group of researchers, risk assessors, test facilities, and industry developing tools that manufacturers, authorities and companies can use to manage workplace risks during innovation, production and use of manufactured nanomaterials. Together, we are the caLIBRAte project.



Thank you for your attention

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