CURRENT TO NEAR-FUTURE RISK ASSESSMENT AND MANAGEMENT METHODS FOR MANUFACTURED NANOMATERIALS.

,

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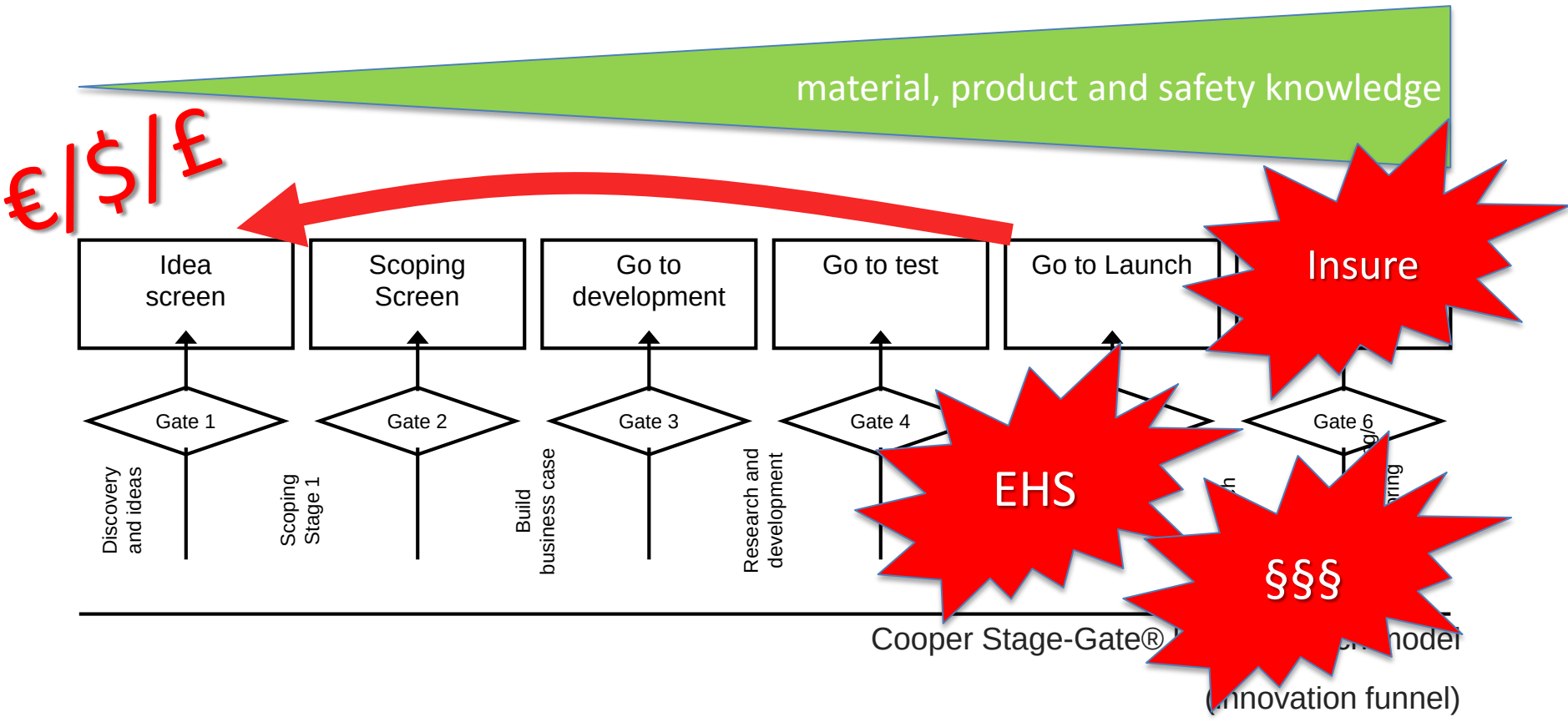
Materials and Product Innovation and Current Practice in Risk assessment and Management



CNT as an Example!

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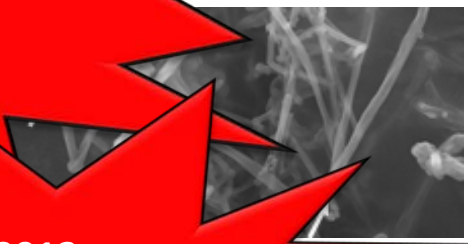
nano risk governance

2004-2009
Serious scientific health concern (e.g., Lam et al. Tox Sci. (2004), Poland et al. Nature (2008); Ma-Hock et al. Tox.Sci (2009)

Observed filaments/fir…
Radushkevich and Lu…
Hillert and Lange Z…
Baker et al. Carbon (1973), J. …

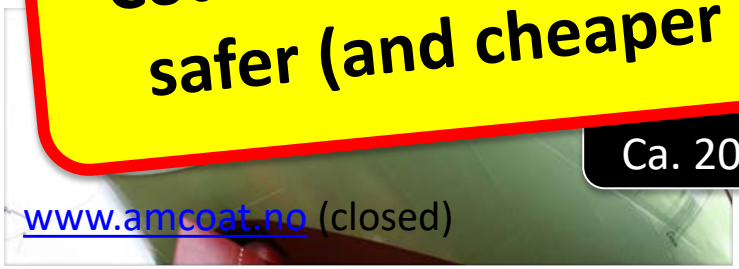


Patents CNT production 1980ies

Naming and TEM im…

2009-2013
First Sci… Hi…

Could this R&D and Launch process have been better, safer (and cheaper for the companies and society)?



Ca. 2007-2009

www.amcoat.no (closed)

Bayer closes
Large new plant

Electronics
Coatings
…nductive
…plays
…ch screens)
Anti…ling coatings
…rability epoxy-paints
…ce sports goods
…ppy probes

2017
Danish Worker Authorities start process for setting nano-OEL

Industrial Production

2004	2007	2009	201…
65 tons	271 tons	500-1000 tons	1750-2500 ton…

Jensen et al. Environmental project No. 1805 (2015)

Principal Risk Assessment and Risk Management

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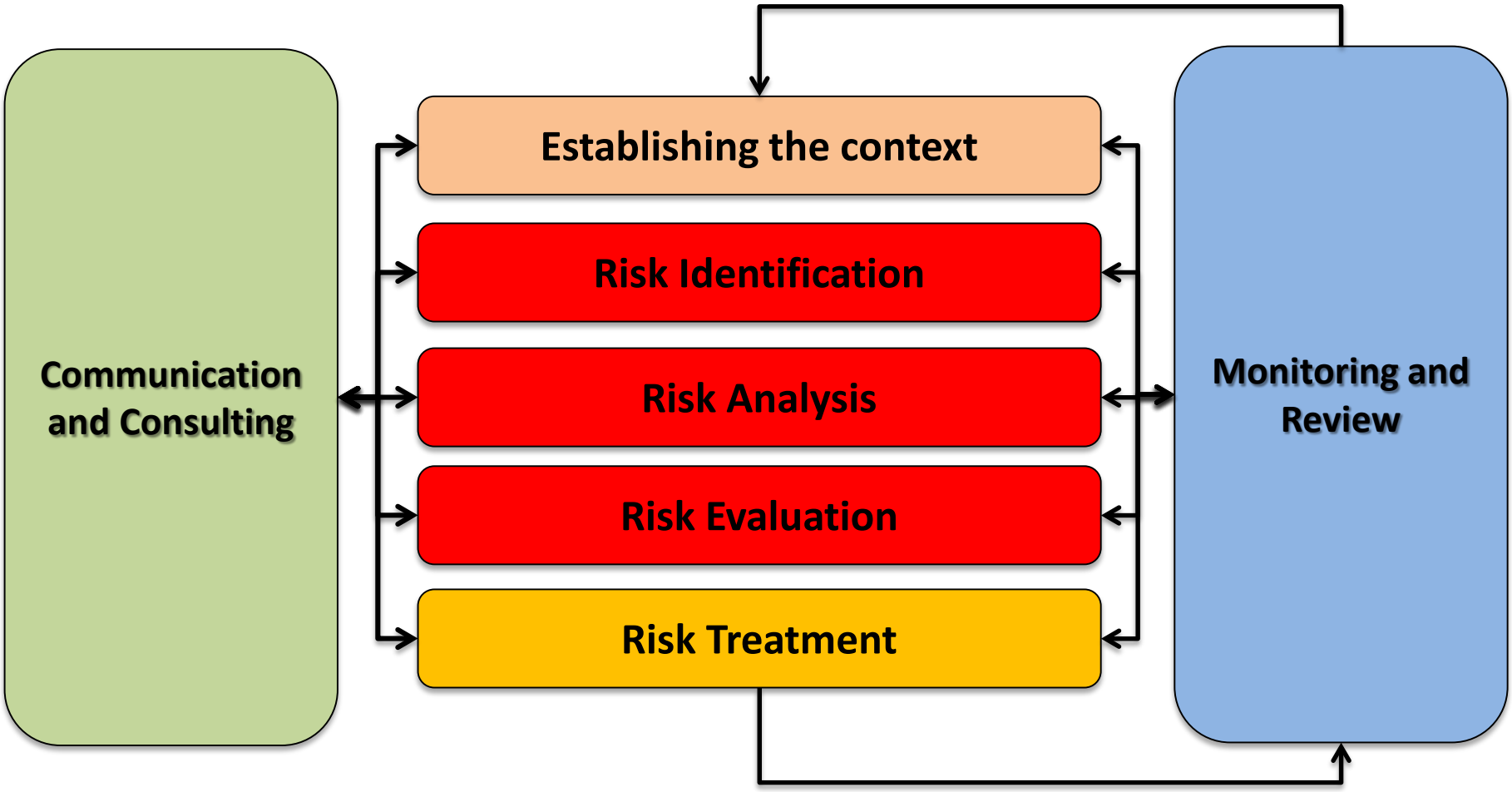

ISO/IS/31000 (2009)

From Risk Assessment to Emerging Risk Management (Governance)

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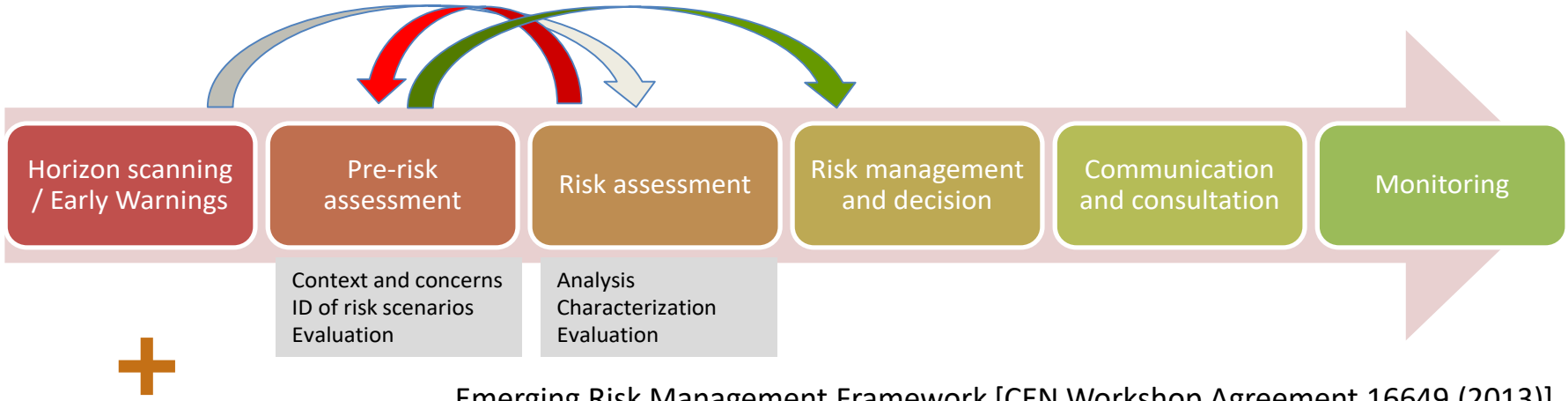
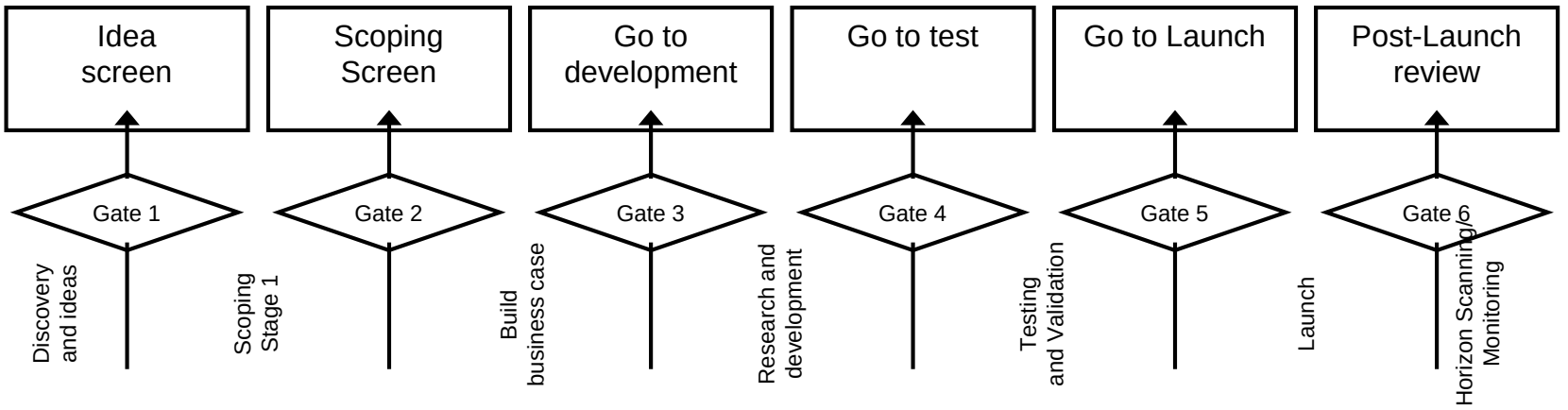


Emerging Risk Management Framework [CEN Workshop Agreement 16649 (2013)]



Cooper Stage-Gate® Idea to launch model

Current situation in the REACH risk assessment approach

- REACH Tier 1 estimates
- ECETOC TRA
- EMKG EXPO Tool

- No official exposure limits or DNEL's for NM
- [illegible] application domains

No data and lack of validated REACH RA tools ⇒ Need for precautionary nano-specific Risk Assessment and –Management approaches

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

Is that critical? - Opinions among stakeholders

	Industry Representatives	*Academic Public Researchers*	*Policy makers Regulators Insurers*	*Users Society Representatives*
Adequacy of current regulation for nano-risk governance				
Importance of nano-risk assessment procedures				
Importance of specific disposal procedures for NMs				
Usefulness of DS (decision support) web-tools for nano-risk governance				

Color scale (from 1-very low to 5-very high)

Unpublished caLIBRAte results

From Risk Assessment to Emerging Risk Management (Governance)

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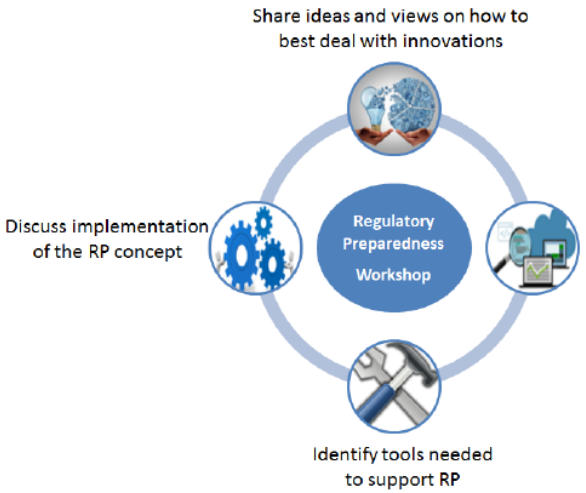
Horizon scanning / Early Warnings	Pre-risk assessment	Risk assessment	Risk management and decision	Communication and consultation	Monitoring
	Context and concerns ID of risk scenarios Evaluation	Analysis Characterization Evaluation			

Ability to ID a new risk

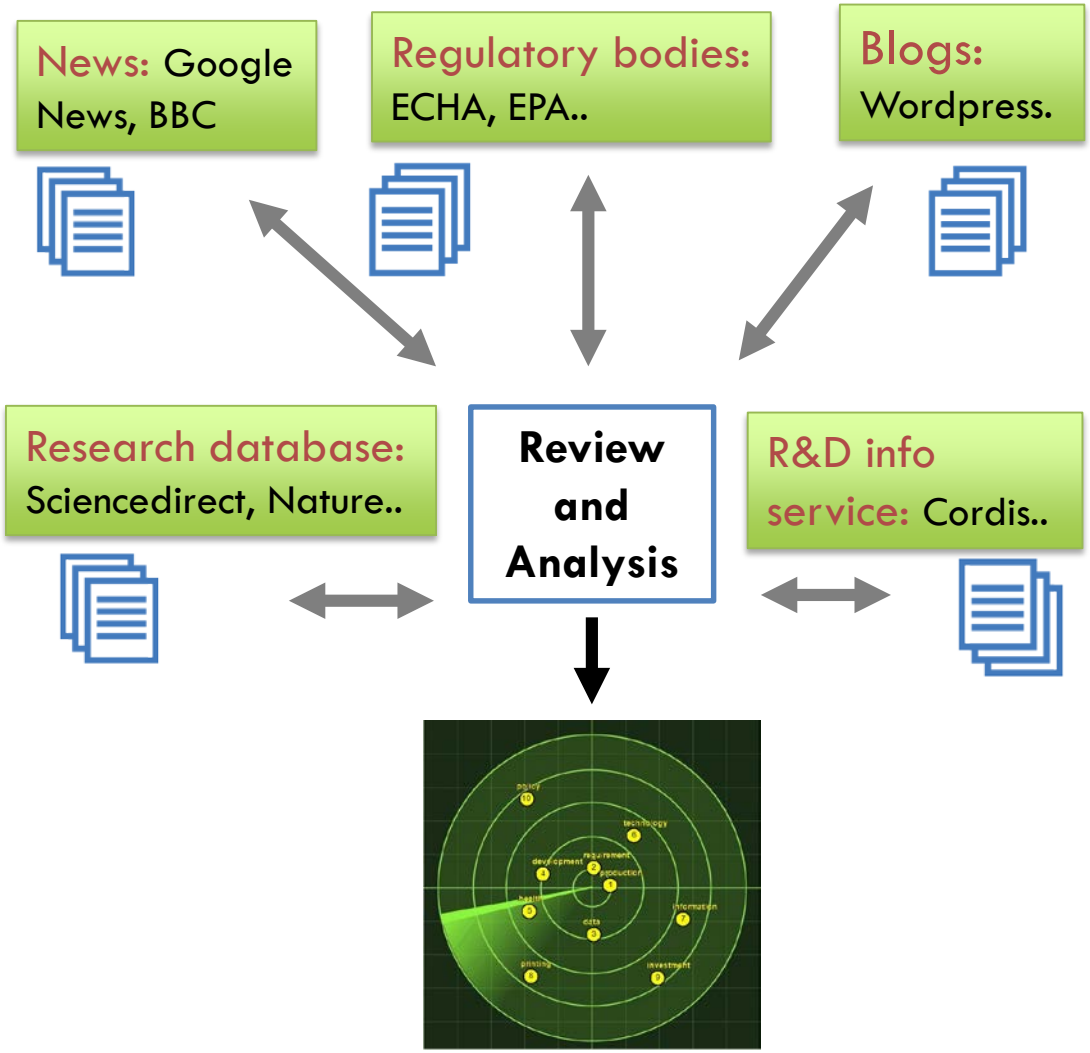
Different?; Unsafe? Regulation? …

Emerging Risk Management Framework [CEN Wor



Nano-Risk Radar: Horizon Scanning and Monitoring

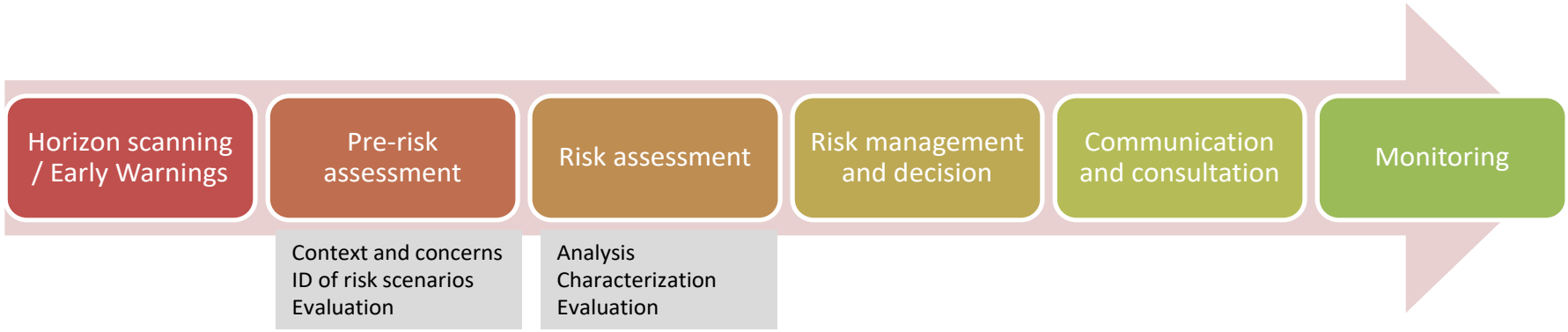
- Web-based tool
- Regular automatic search for "**Nano-safety**" related topics from online sources based on user-defined query.
- Analyses content using natural language processing techniques
- Ranks the results according to their relevance in graphical summary – The Radar



Jovanovic, Chakravarty, Jelic; R-Tech (Germany)
Klimek et al. *Scientometrics* (2016)

From Risk Assessment to Emerging Risk Management (Governance)

caLIBRAte nano risk governance



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

Ability to ID a new risk

Different?; Unsafe? Regulation? …

Applicable data or methods and tools

Methods, Measurement, Read-across, Grouping, ..

Applicable data knowledge

Efficacy of RMM, "risk-knowledge",..

Knowledge Applicable methods, tools, data

Methods, Systems, Data-bases,..

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

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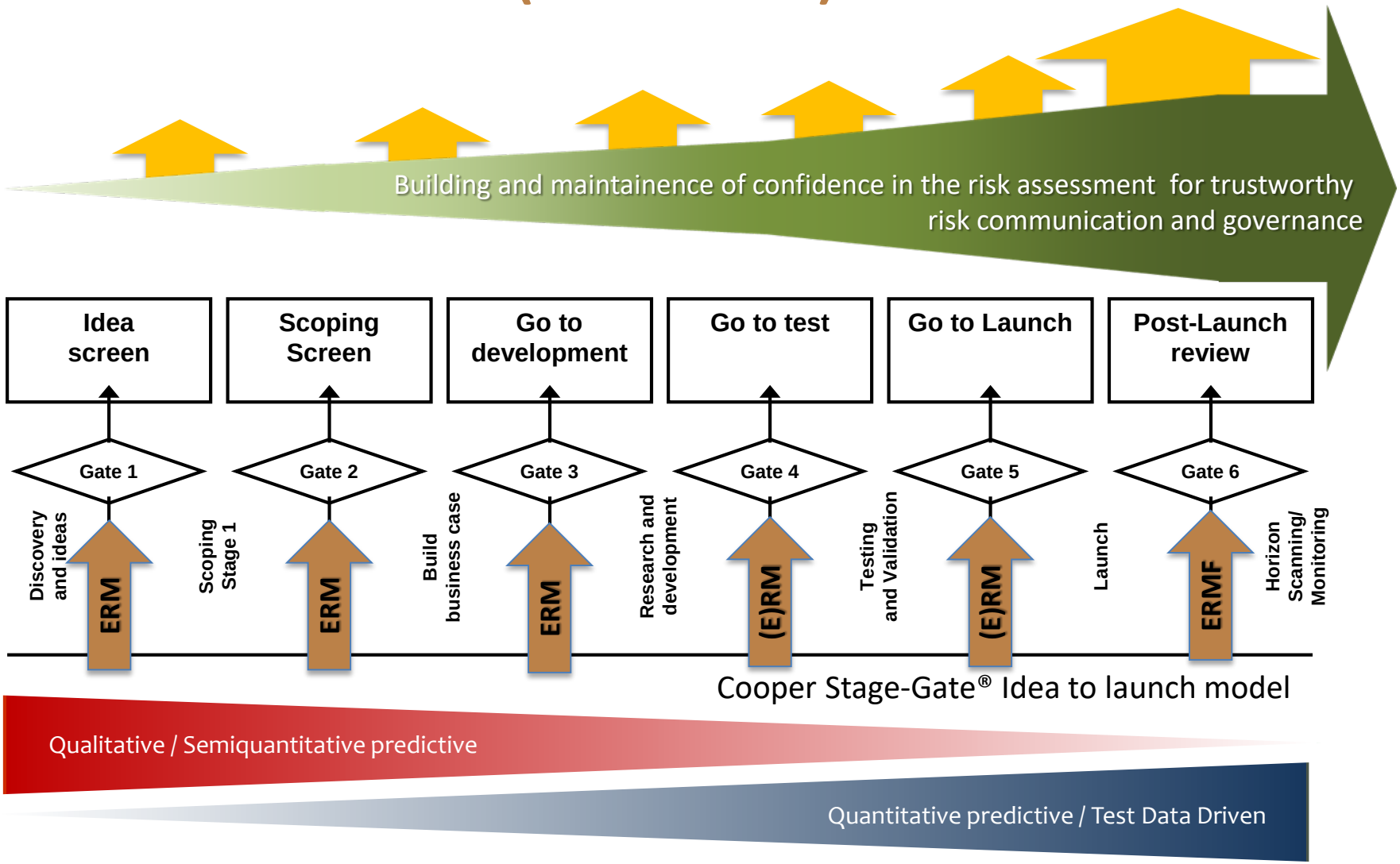

Users: industry, service providers, regulators, NGO's etc.

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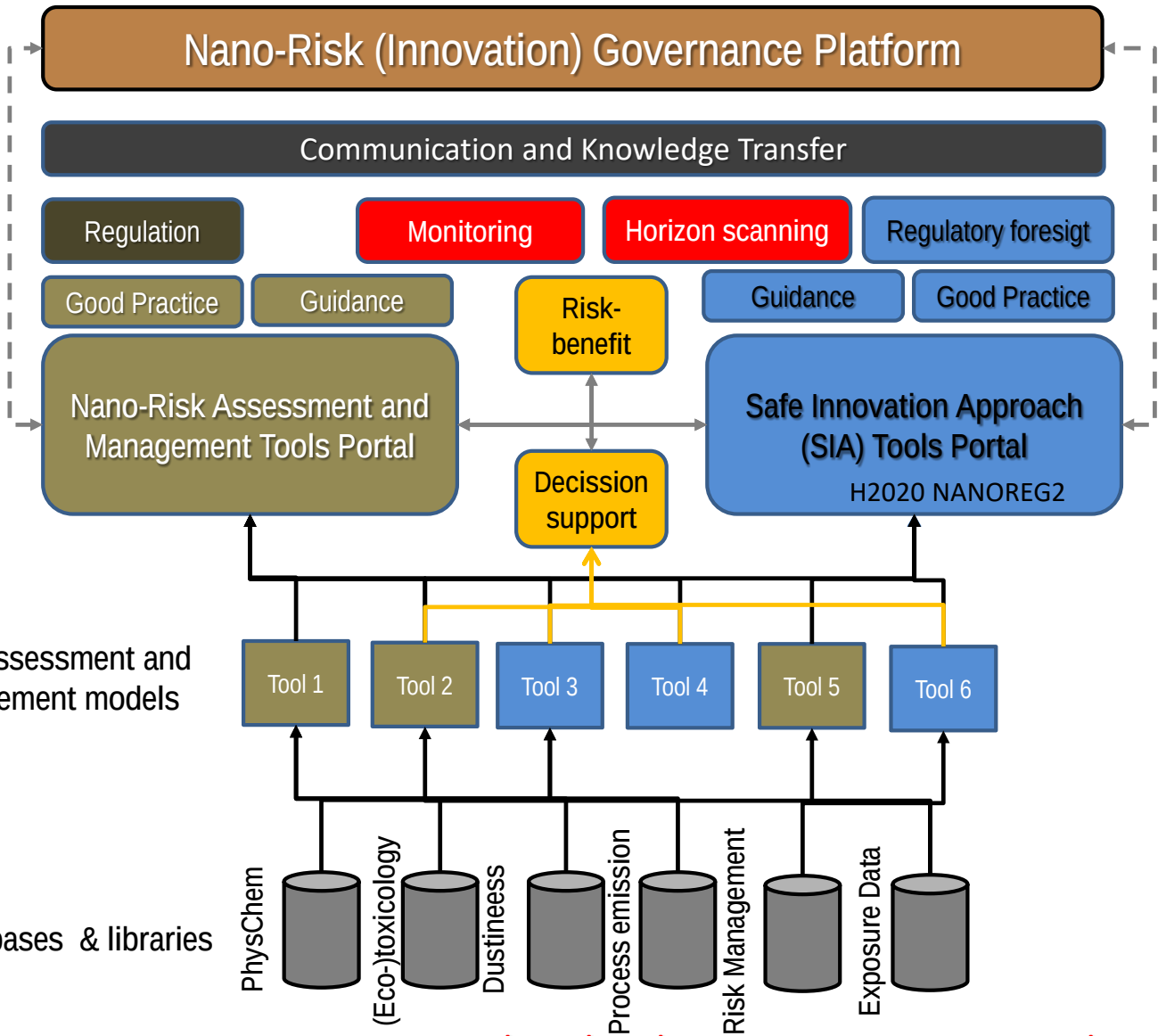

Further development in NMBP-13 and NMBP14 projects

When should nano-risk assessment procedures be performed?

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

Color scale (Number of counts)

Unpublished caLIBRAte results

Conceptual innovation risk governance framework

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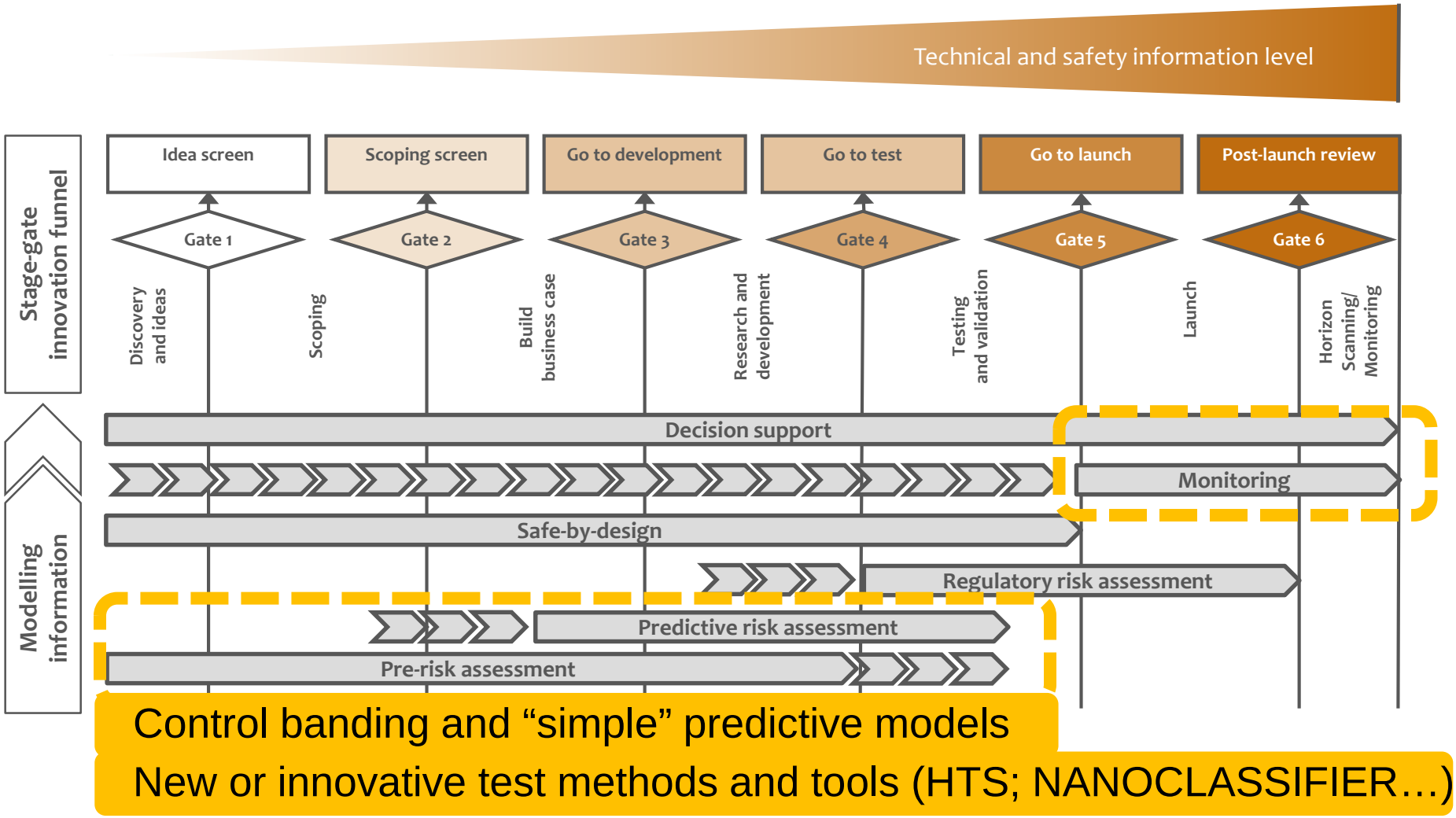

So, do we have the data and the tools?

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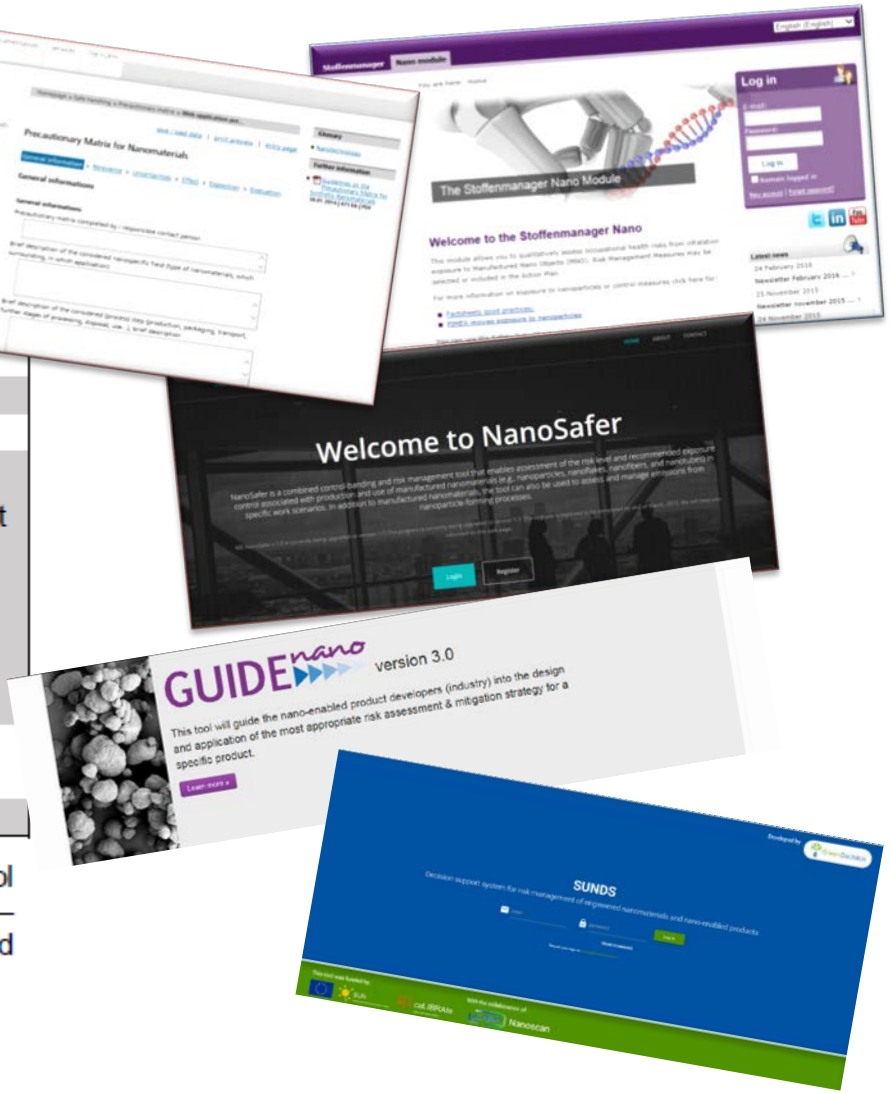
nano risk governance

Several different nano-specific tools

No.	Model name	Application area	Owner	Mod
1	ANSES tool	Work	ANSES	CB
2	ISO TS 12901 CB tool	Work	ISO	CB
3	US Nanotool	Work	LLNL (USA)	CB
4	StM Nano	Work	Cosanta (NL)	CB
5	NanoSafer CB	Work	NRCWE	CB
6	ConsExpo Nano	Cons	RIVM	Q
7	BAUA SprayExpo	Work	BaUA (DE)	QEA
8	RiskofDerm	Work	TNO	QEA
9	IEAT	Work	IOM	QEA
10	Swiss PM	Env/Cons/Work	FOPH (CH)	Risk Cat
11	LICARA NanoScan	Env/Cons/Work	EMPA/TNO	Risk Benefit
12	SUNDS	Env/Cons/Work	UNIVE / GD	RA / RM
13	GuideNano	Env/Cons/Work	LEITAT	RA / RM
14	nano-QSAR	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



SUN Decision Support

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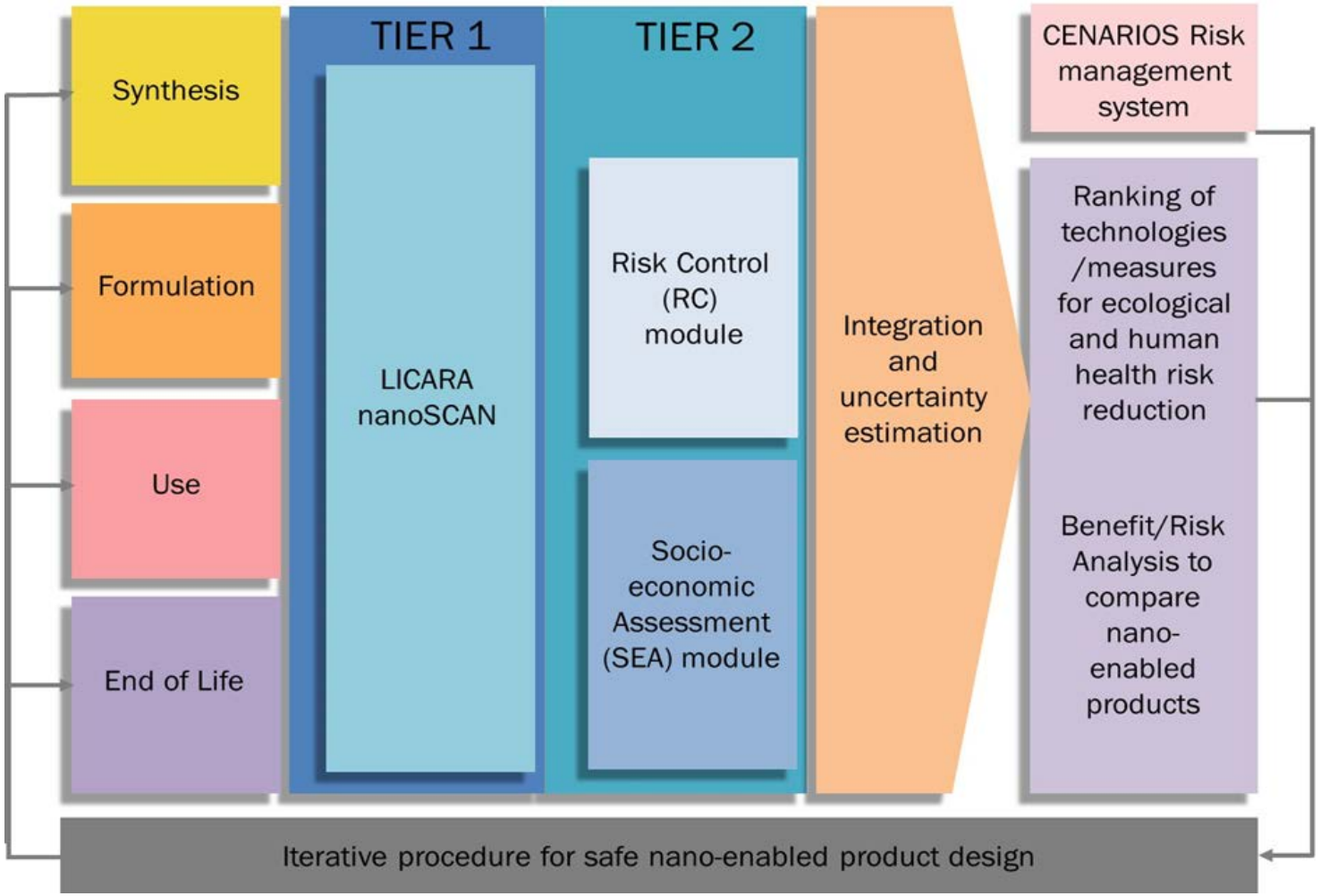

Conceptual framework

Several different nano-specific tools

No.	Model name	Application area	Owner	Model ty
1	ANSES tool	Work	ANSES	CB
2	ISO TS 12901 CB tool			
15	SimpleBox4Nano	Env	RIVM	QEA
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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

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

Conceptual innovation risk governance idea

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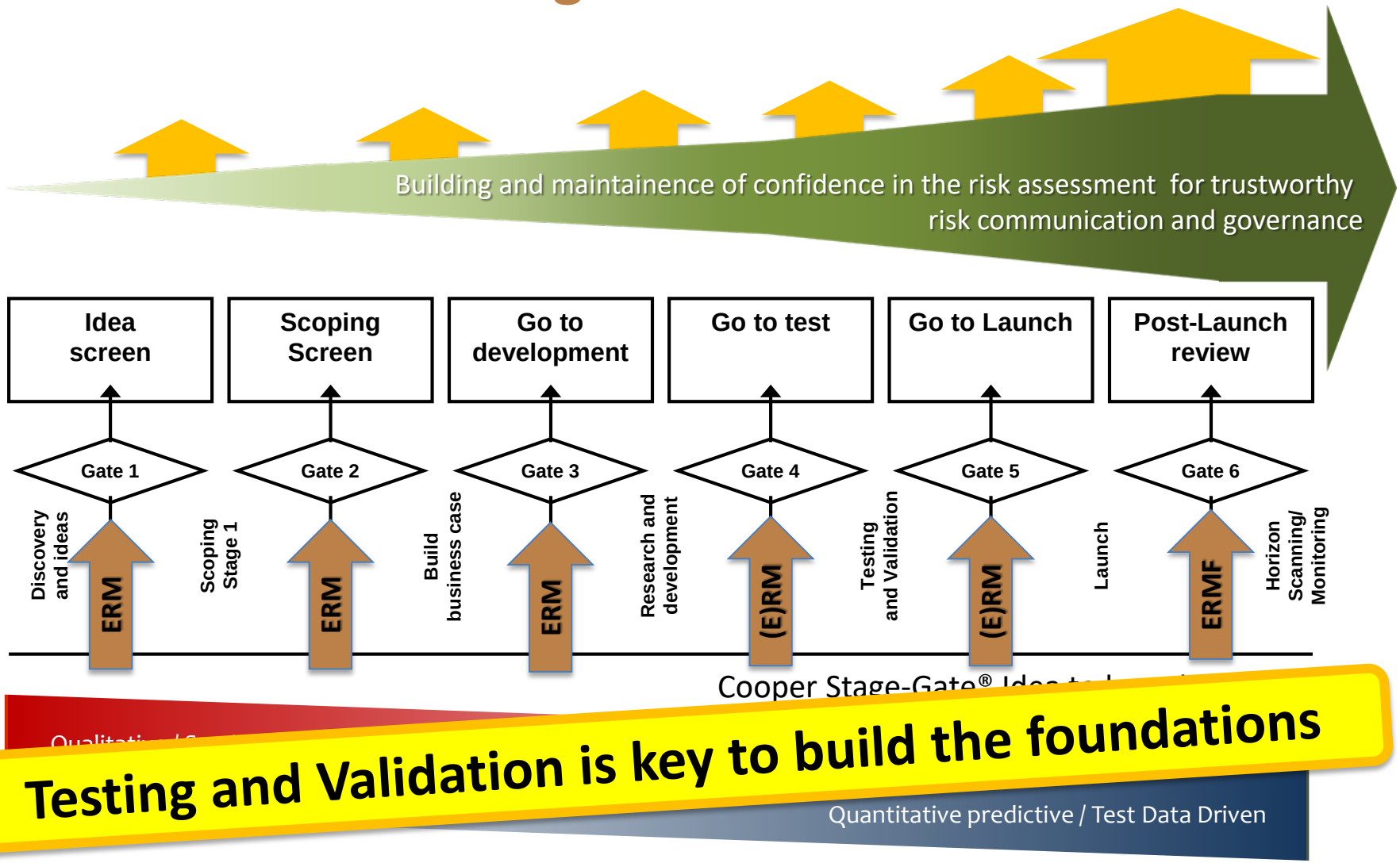

Ongoing in H2020 caLIBRATe: Validation by sensitivity and performance testing

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Pouring 700g CuO under a fume hood

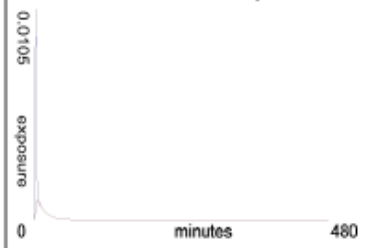
ASSESSMENT BY TIER 2

NanoSafer v 1.1

Result of assessment

Estimated hazard level 0.2
The hazard level is estimated based on
High aspect ratio material: No
A high volume specific surface area of 97.50 m2/cm3
OEL of analogue bulk material: 1 mg/m3
Solubility: Insoluble (< 1 g/L)
Presence of surface coating: No
Known hazards of analogue bulk material

Estimated time-resolved exposure index



Near-field Acute	Near-field Daily	Far-field Acute	Far-field Daily
0.0025	0.0000	0.0002	0.0000
EB1: Very low exposure potential	EB1: Very low exposure potential	EB1: Very low exposure potential	EB1: Very low exposure potential

NF=1.5 µg m^{-3} < $M_{NF\ real\ work\ environment}$ (9.2 µg m^{-3})

Toxicity / Exposure	0.76-1.00	0.51-0.75	0.25-0.50	0.00-0.25
>1.00	RL5	RL5	RL5	RL5
0.51-1.00	RL5	RL5	RL4	RL4
0.26-0.50	RL5	RL4	RL4	RL3
0.11-0.25	RL4	RL4	RL3	RL2
< 0.11	RL4	RL3	RL2	RL1

RL1: Very low toxicity and low exposure potential

$$OEL_{nano} = OEL \cdot \frac{30}{SSA_{nano}} \cdot \frac{1}{\delta}$$

Specific density of the nanomaterial (g/cm³)

Specific surface area of the nanomaterial [SSA]; m²/g

$$EXP_{Acute} = \frac{C_{Acute}}{2 \cdot OEL_{nano}} \qquad EXP_{8-hour} = \frac{C_{8-hour}}{OEL_{nano}}$$

(From AS Fonseca)

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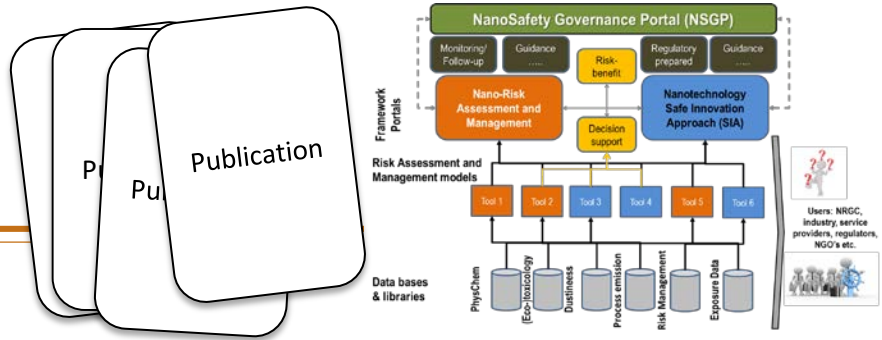
Year	Framework development	Aligning with stakeholders	Model development and testing	Database development
			Collecting models	Collecting of existing data
1	Conceptual framework development	Stakeholder consultation Interviews and surveys	Alignment with Cooper Stage Gate® and stakeholder needs	Operational database and structure development
			Sensitivity analysis and performance testing	Primary test databases
2	Development of guidance documents	User testing of models	Refinement and next generation methods	Filling data gaps and new case studies
3	Model integration into the SoS Framework		Sensitivity analysis and calibration	Final comprehensive databases
3.5	Demonstration using database case studies	Implementation and stakeholder training		



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

Nano-Risk (Innovation) Governance Platform

Comm

Regulation

Regulatory foresigt

Good Practice

Guida

Good Practice

Nano-Risk Assessmer
Management Tools P

vation Approach
Tools Portal

H2020 NANOREG2

Risk Assessment and Management models

Tool 1

Tool 6

Data bases & libraries

PhysChem

(Eco-)toxicology

Dustineess

Process emissio

Risk Manageme

Exposure Data

https://laughingsquid.com/

Further development in NMBP-13 and NMBP14 projects

caLIBRAte nano risk governance

- Webpage: www.nanocalibrate.eu
- See also: www.researchgate.net/profile/Keld_Jensen

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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

www.nanocalibrate.eu

www.researchgate.net/profile/Keld_Jensen

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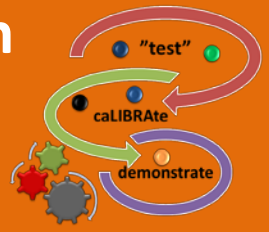

Applicability of new approach methodologies (NAMs) for innovation and safety assessment of MN

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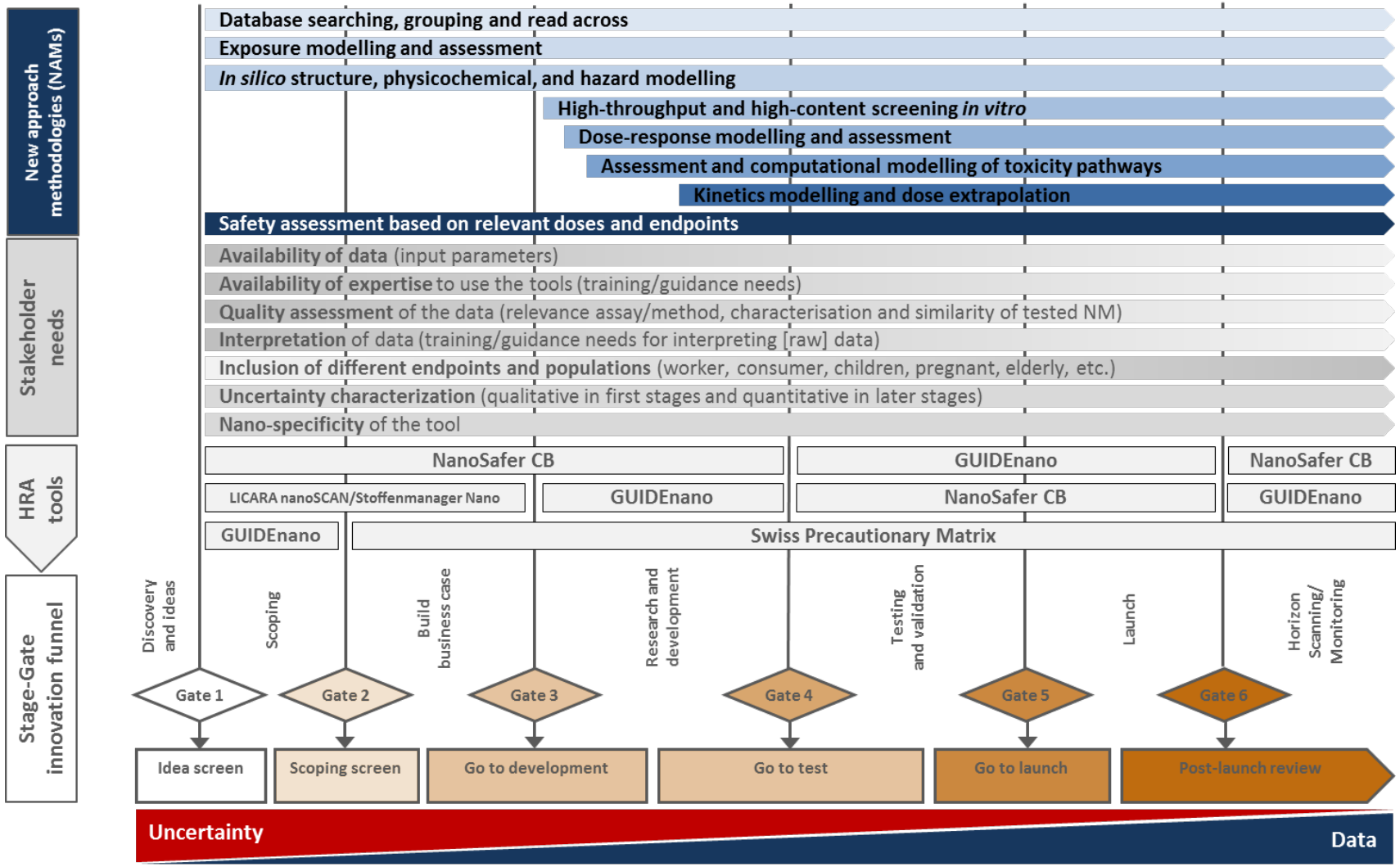

Nymark et al. Applicability of new approach methodologies to innovation and safety assessment of nanomaterials. In preparation