



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

,Professor Keld Alstrup Jensen, Ph.D., cand.scient.

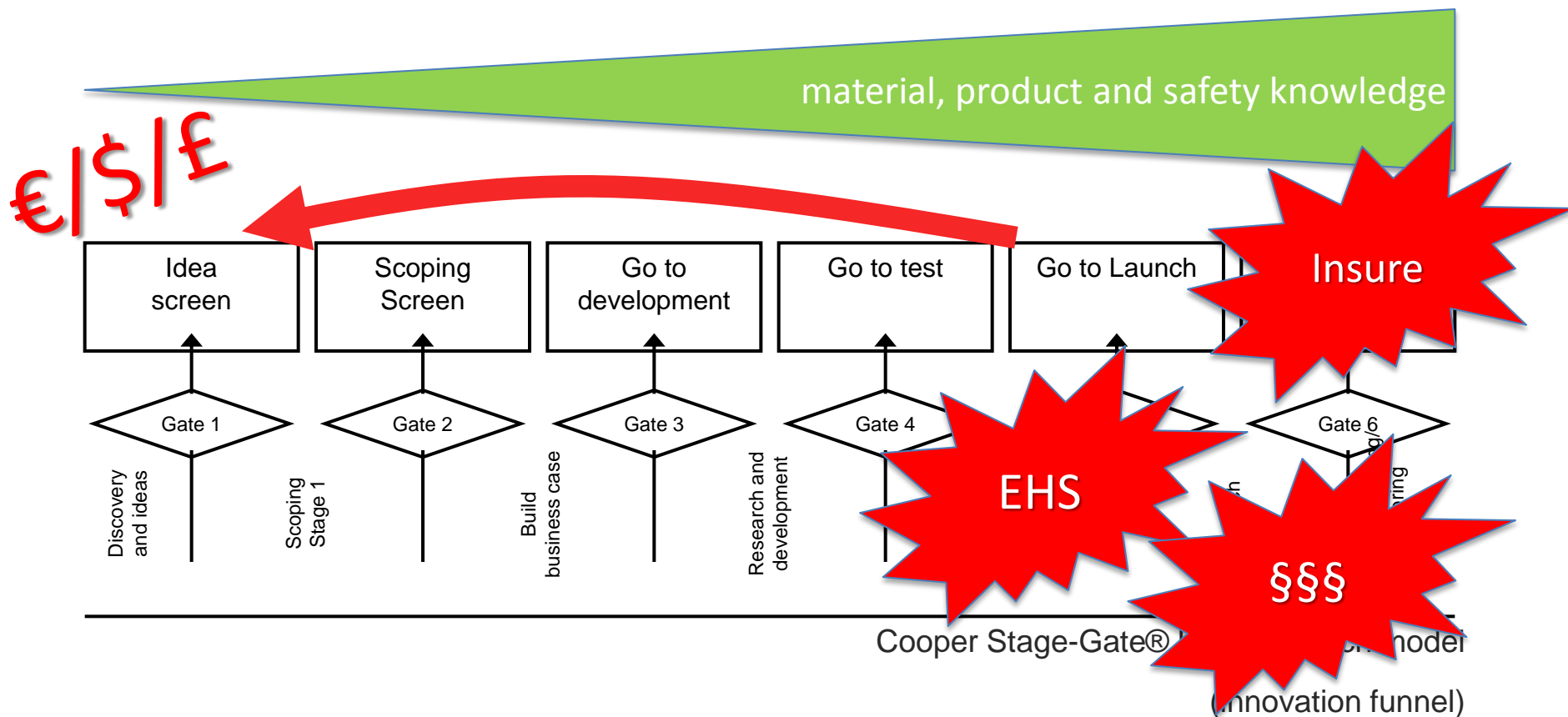
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National Research Centre for the Working Environment





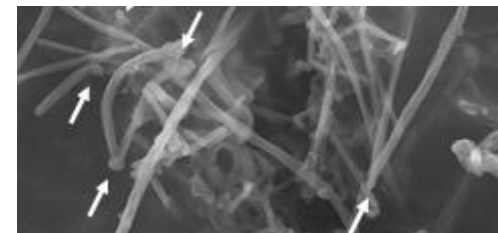
Materials and Product Innovation and Current Practice in Risk assessment and Management





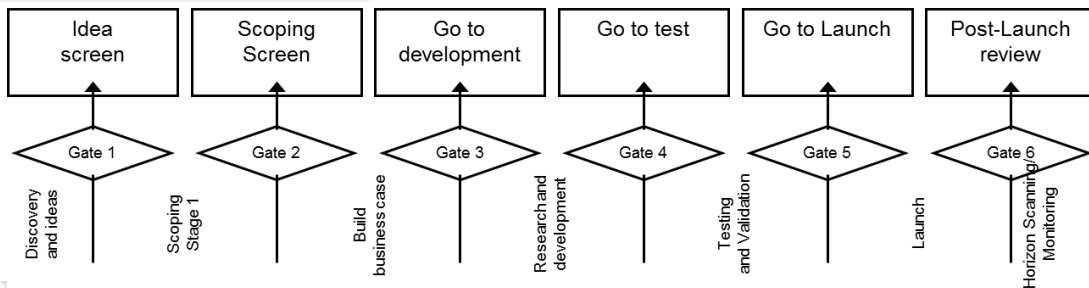
CNT as an Example!

Observed filaments/first structural data
Radushkevich and Lukyanovich Zurn Fisic Chim (1952)
Hillert and Lange Z Kristallogr (1958)
Baker et al. Carbon (1973); J. Catalysis (1973)



Patents CNT production 1980ies

Naming and TEM images
Iijima et al. Nature (1991)



Antifouling
Ca. 2007-2009

www.amcoat.no (closed)

Industrial Production



Application area	Uses in 2015
Electronics	Printed electronics (conductive ink)
Coatings	Conductive coatings (displays and touch screens) Anti-fouling coatings High-durability epoxy-paints
Energy	Li-ion batteries
Materials	Antistatic thermoplastics Conductive textiles Thin heating mats High performance sports goods Small windmills
Biomedical	Microscopy probes



CNT as an Example

Observed filaments/fibrils

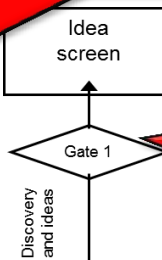
Radushkevich and Lukyanov (1998)

Hillert and Lange (2000)

Baker et al. Carbon (1975), J. Phys. Chem. (1976)

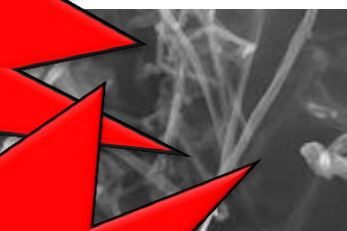
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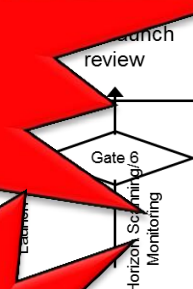
2004-2009

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



2009-2013

First Scientific OELs
(Pauluhn Reg.Tox.Sci (2009); JRC (2013),
NIOSH (2013)



2013

Bayer closes
Large new
plant

Antifouling
Ca. 2007-2009



www.amcoat.no (closed)

Industrial Production

2004	2007	2009	2011
65 tons	271 tons	500-1000 tons	1750-2500 tons

2017

Danish Worker
Authorities start
process for setting
nano-OEL



CNT as an Example

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

2009-2013

First Scientific Conference

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)

Industrial Production

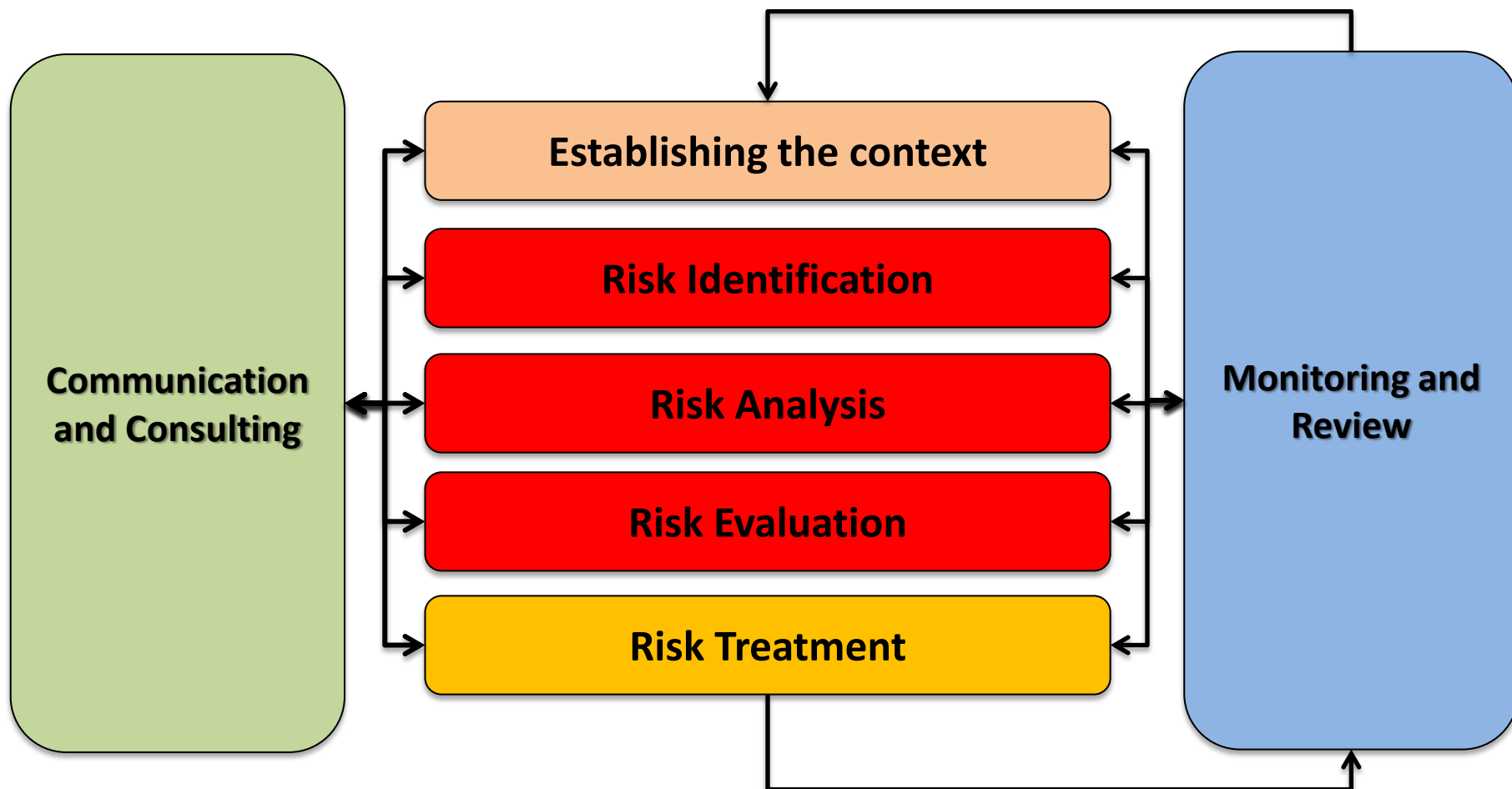
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2017
Danish Worker Authorities start process for setting nano-OEL



and Risk Management



ISO/IS/31000 (2009)



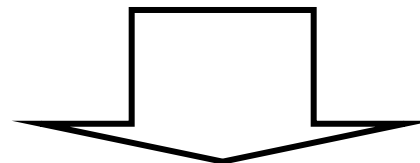
Current situation in the REACH

risk assessment approach

- REACH Tier 1 estimates
- ECETOC TRA
- EMKG EXPO Tool
- ConsExpo
- (Risk of Derm)
- Stoffenmanager
- Advanced REACH Tool
- ...



- No official exposure limits or DNEL's for NM
- No proper emission potentials for NM
- No default exposure scenarios in the tools
- Lack of product categories for nanoproducts
- Gaps in application domains



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



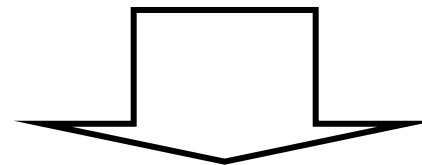
Current situation in the REACH

risk assessment approach

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

➤ No official exposure limits or DNEL's for NM

**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

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

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

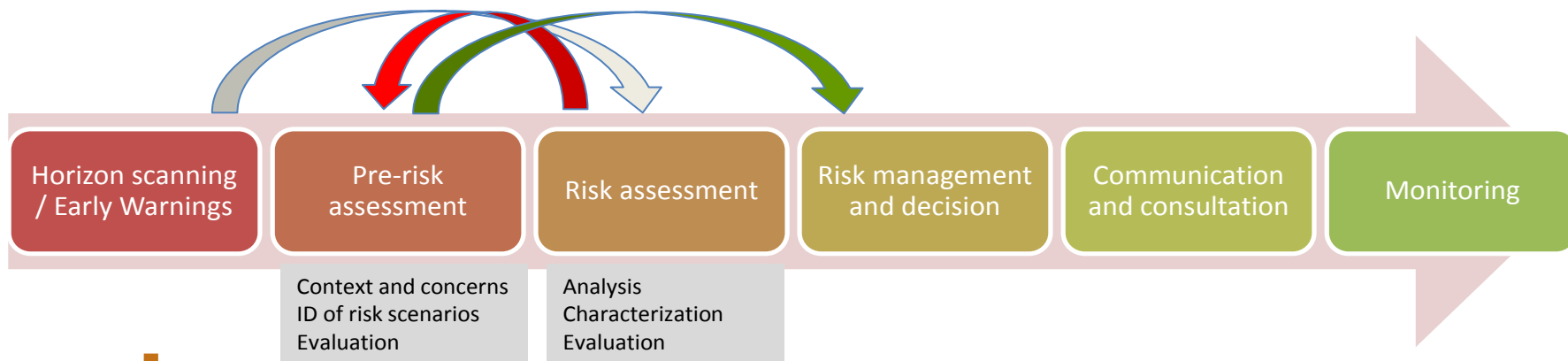


Unpublished caLIBRAte results

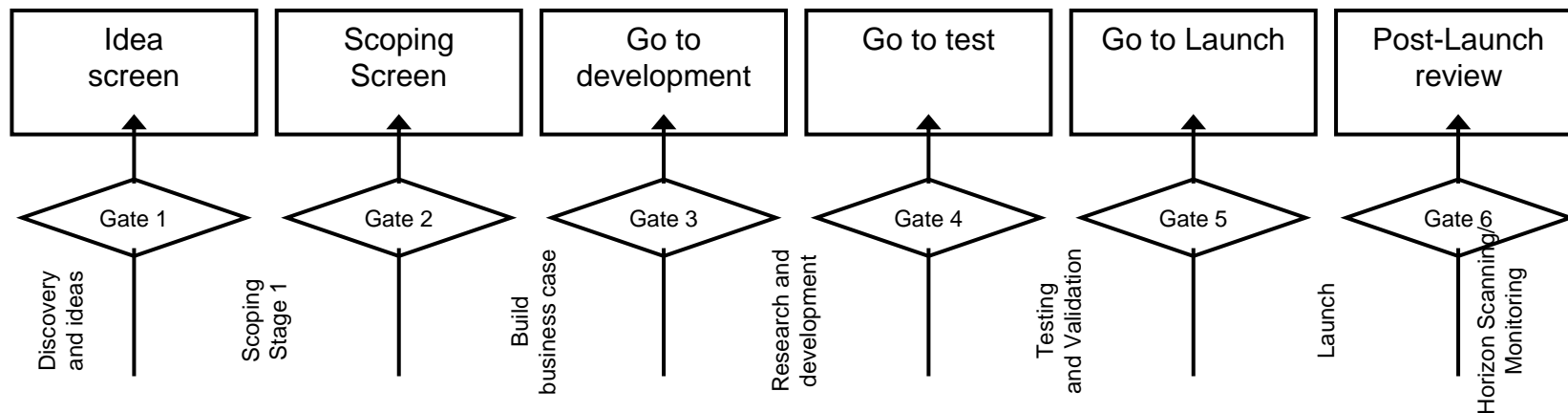


From Risk Assessment to

Emerging Risk Management (Governance)



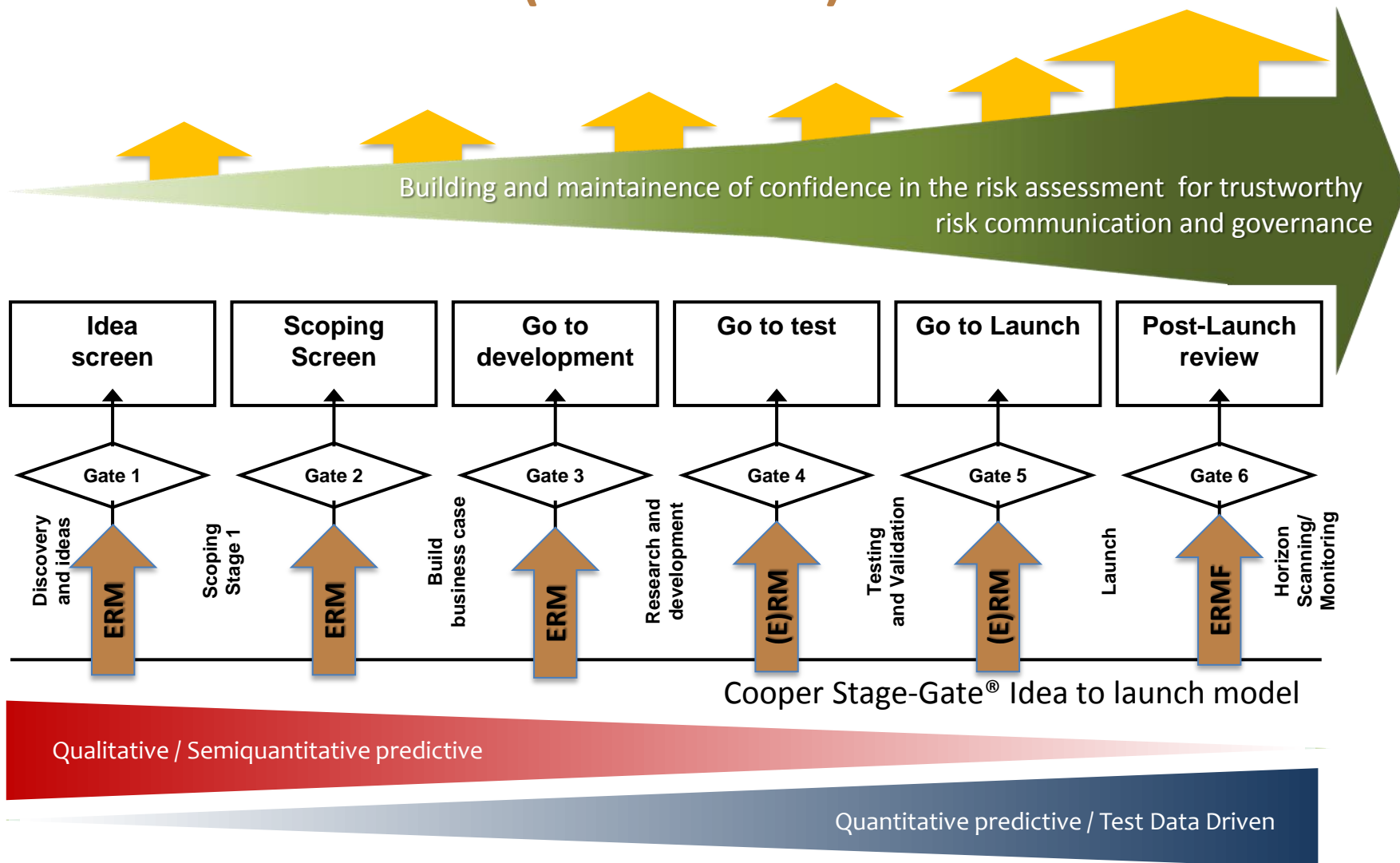
Emerging Risk Management Framework [CEN Workshop Agreement 16649 (2013)]



Cooper Stage-Gate® Idea to launch model

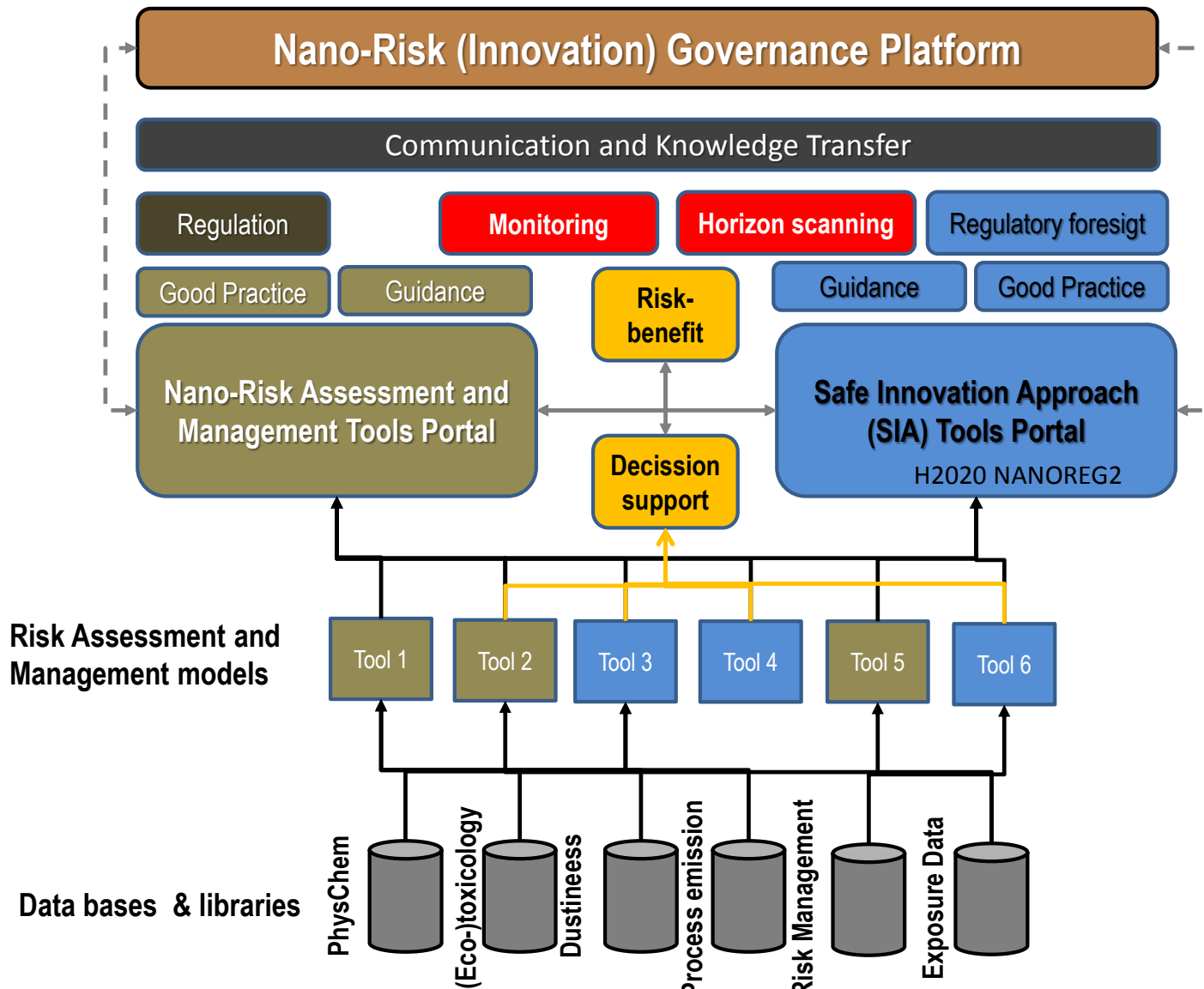


From Emerging Risk Management to Nano-risk (innovation) Governance





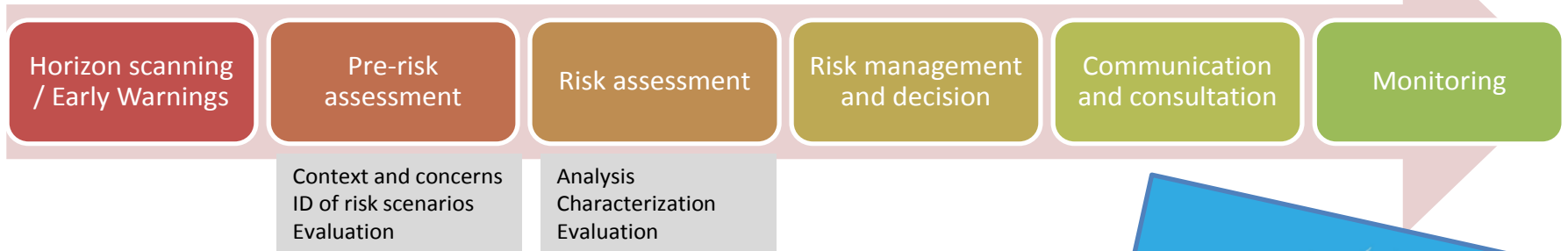
Users: industry,
service providers,
regulators, NGO's etc.





From Risk Assessment to

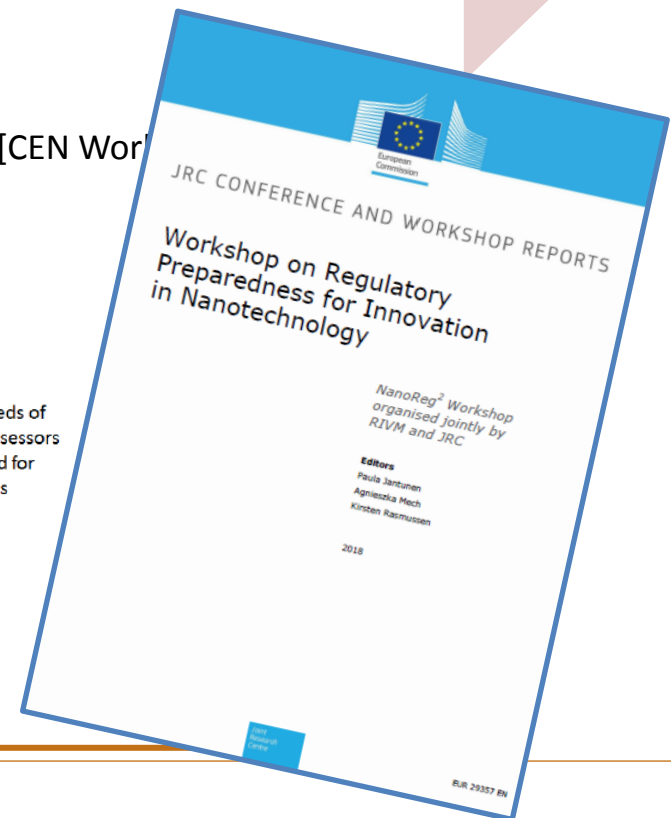
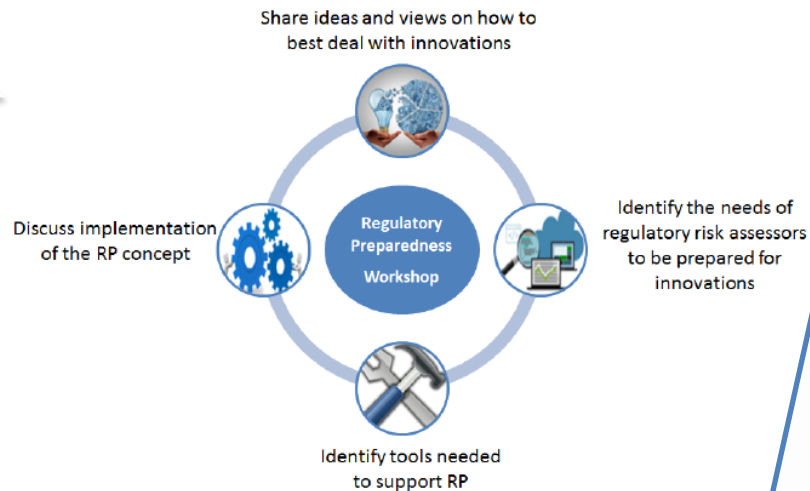
Emerging Risk Management (Governance)



Emerging Risk Management Framework [CEN Work]

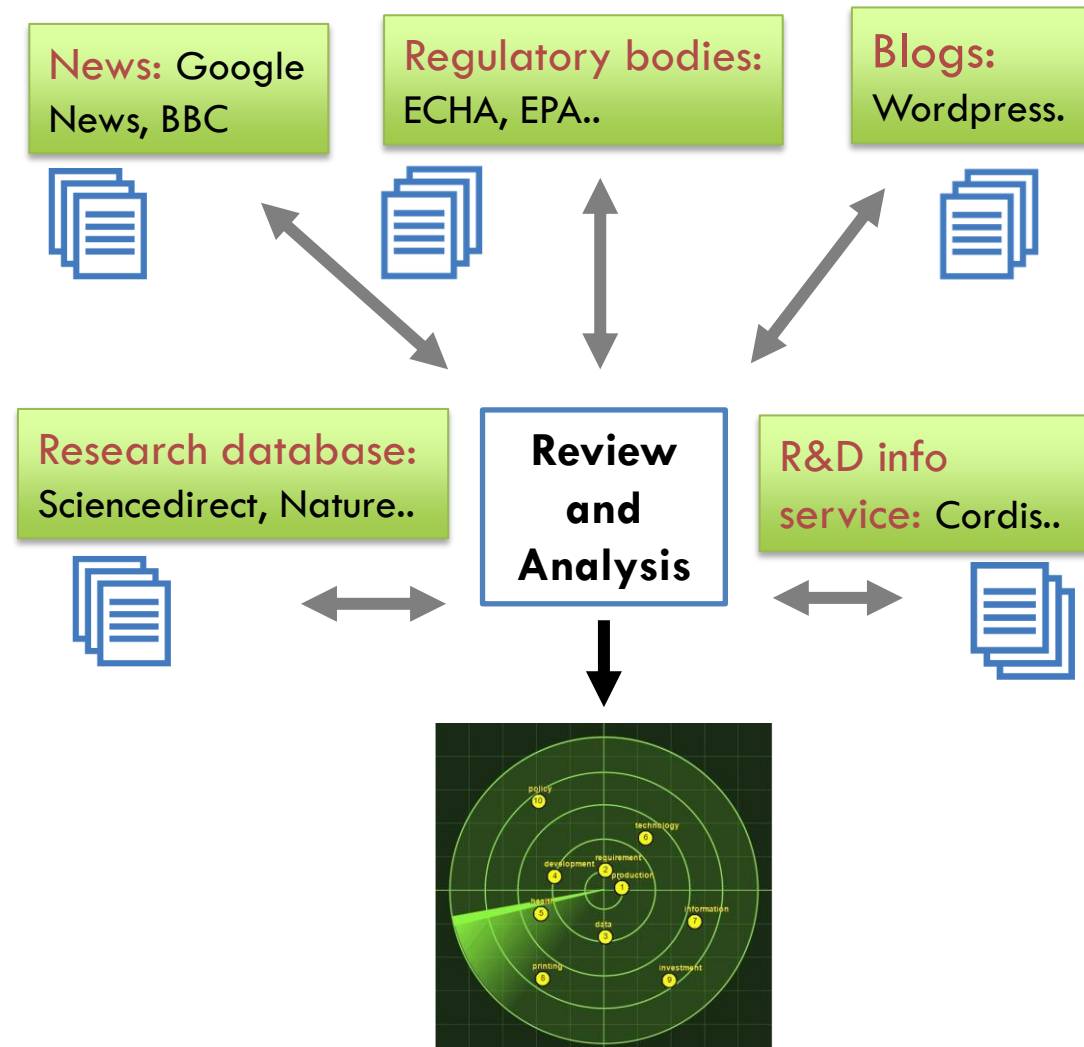


**Different?; Unsafe?
Regulation? ...**



Nano-Risk Radar: Horizon Scanning and Monitoring

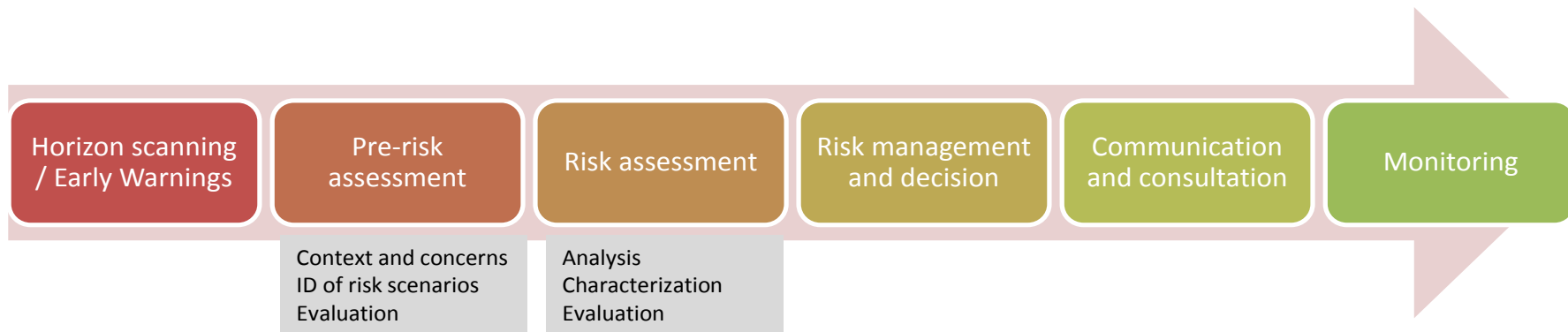
- Web-based tool
- Regular automatic search for "**Nano-safety**" related topics from online sources based on user-defined query.
- Analyses content using natural language processing techniques
- Ranks the results according to their relevance in graphical summary – The Radar



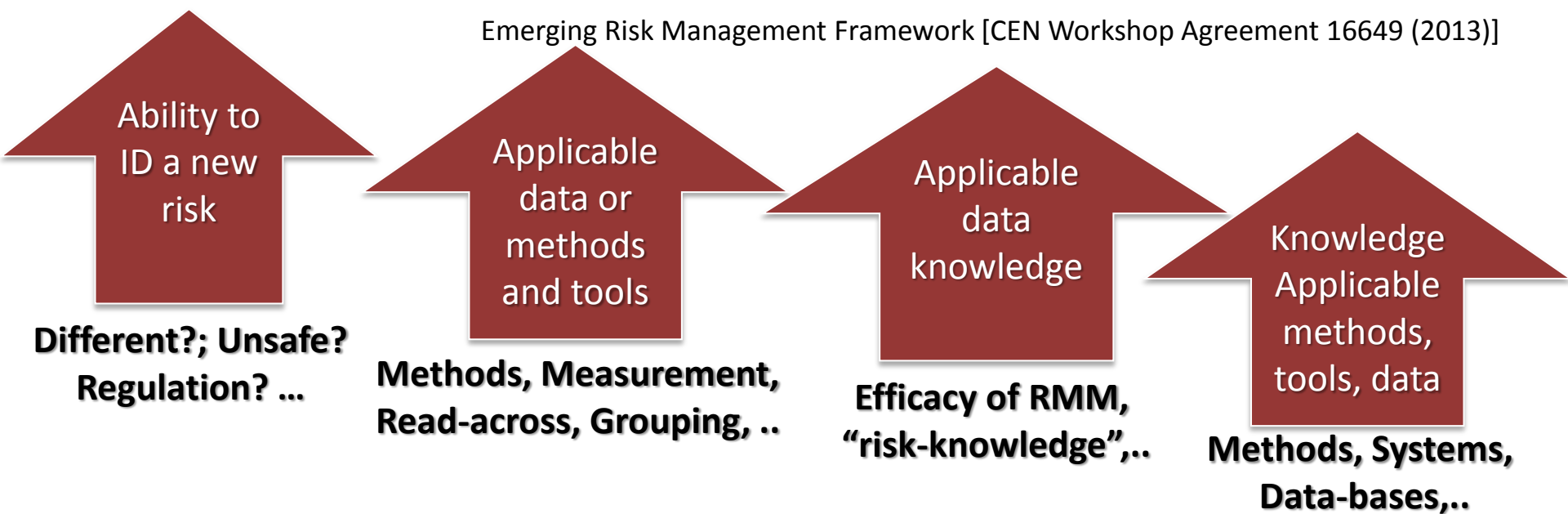


From Risk Assessment to

Emerging Risk Management (Governance)



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





When should nano-risk assessment procedures be performed?

	<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>			
<i>Scoping screening; Basic research</i>			
<i>Go to development; Applied research/proof of concept</i>			
<i>Go to test; Production/engineering/testing</i>			
<i>Go to launch; Go to market</i>			
<i>Post launch review; On the market</i>			
<i>In all stages</i>			

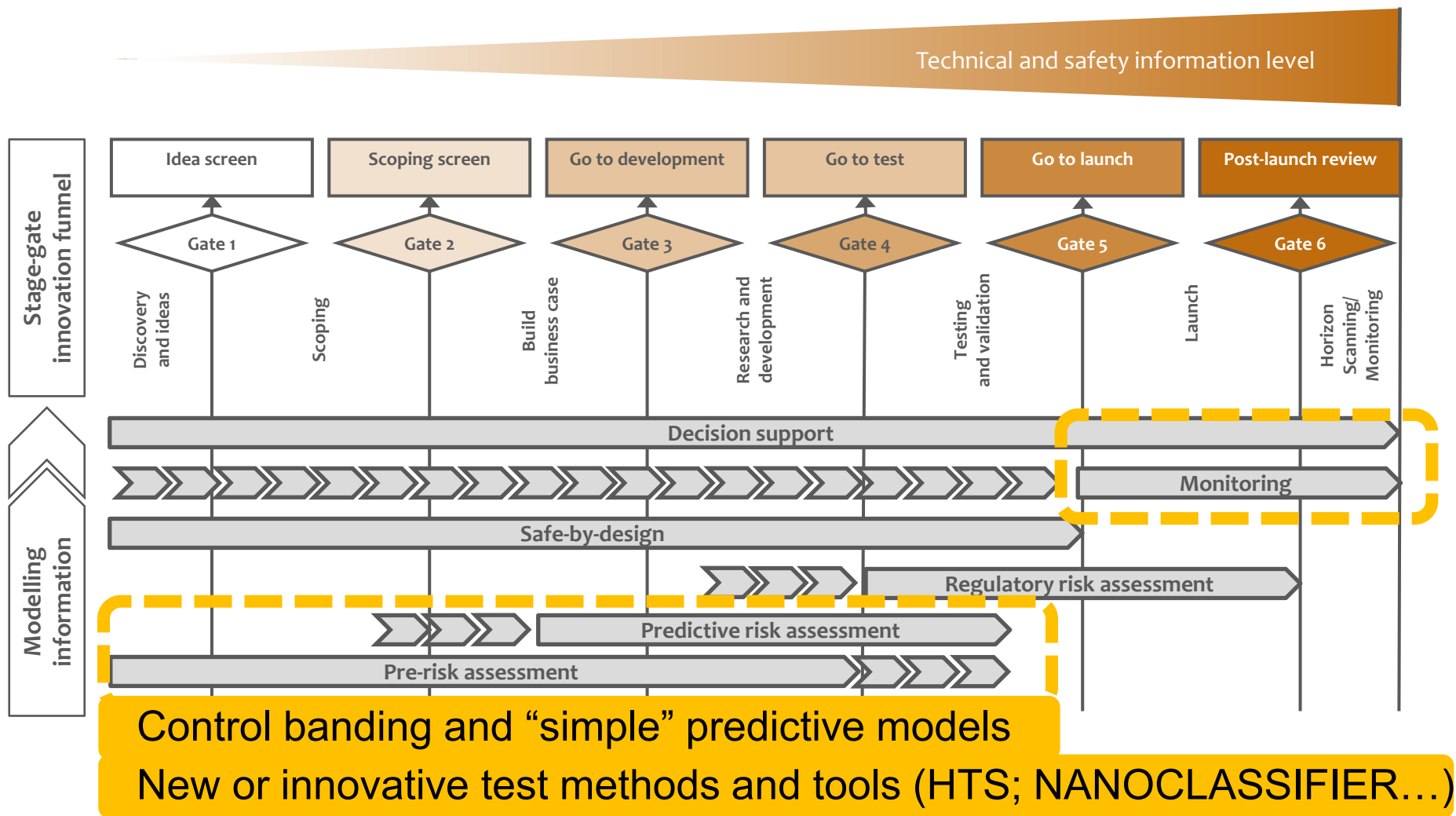
Color scale (Number of counts)



Unpublished caLIBRAte results



risk governance framework



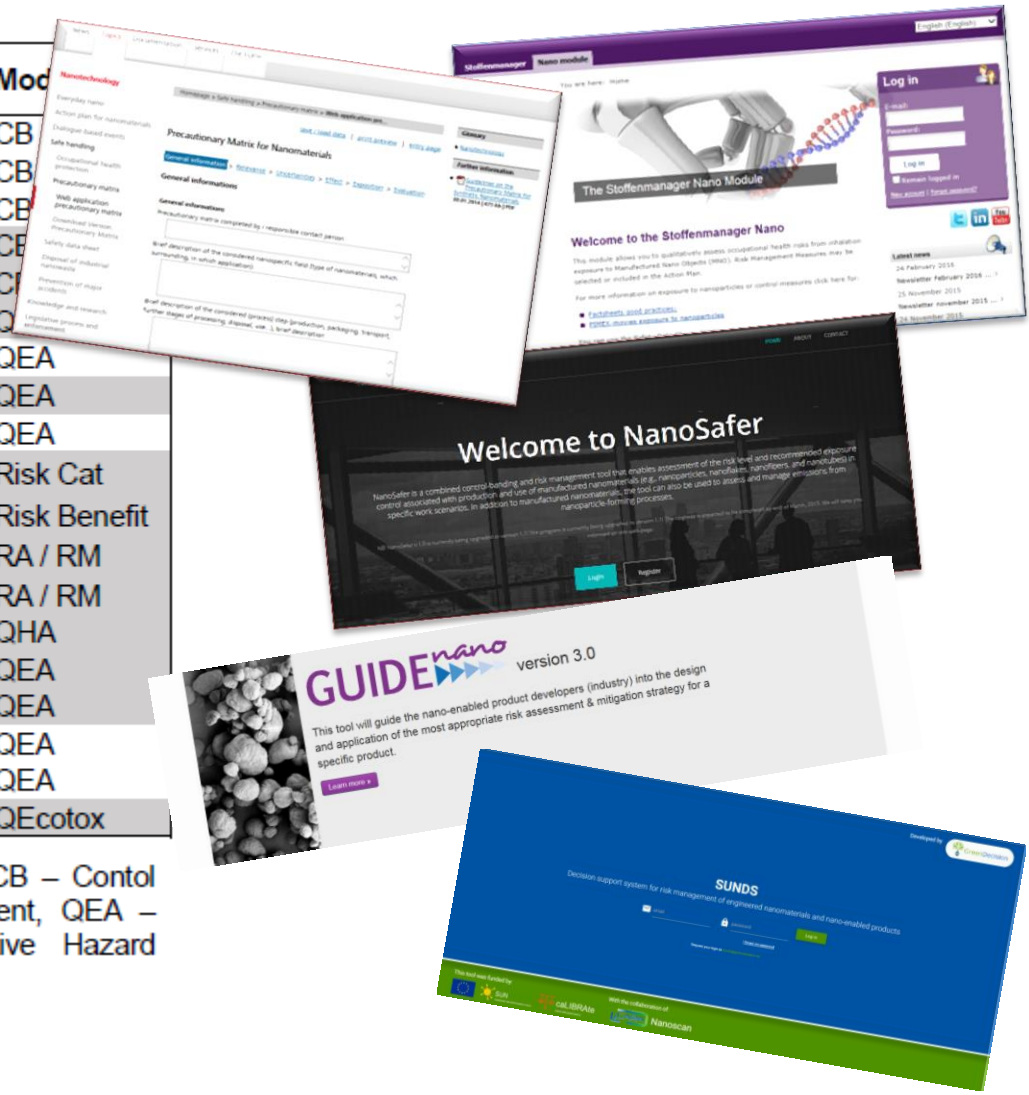


So, do we have the data and the tools?

Several different nano-specific tools

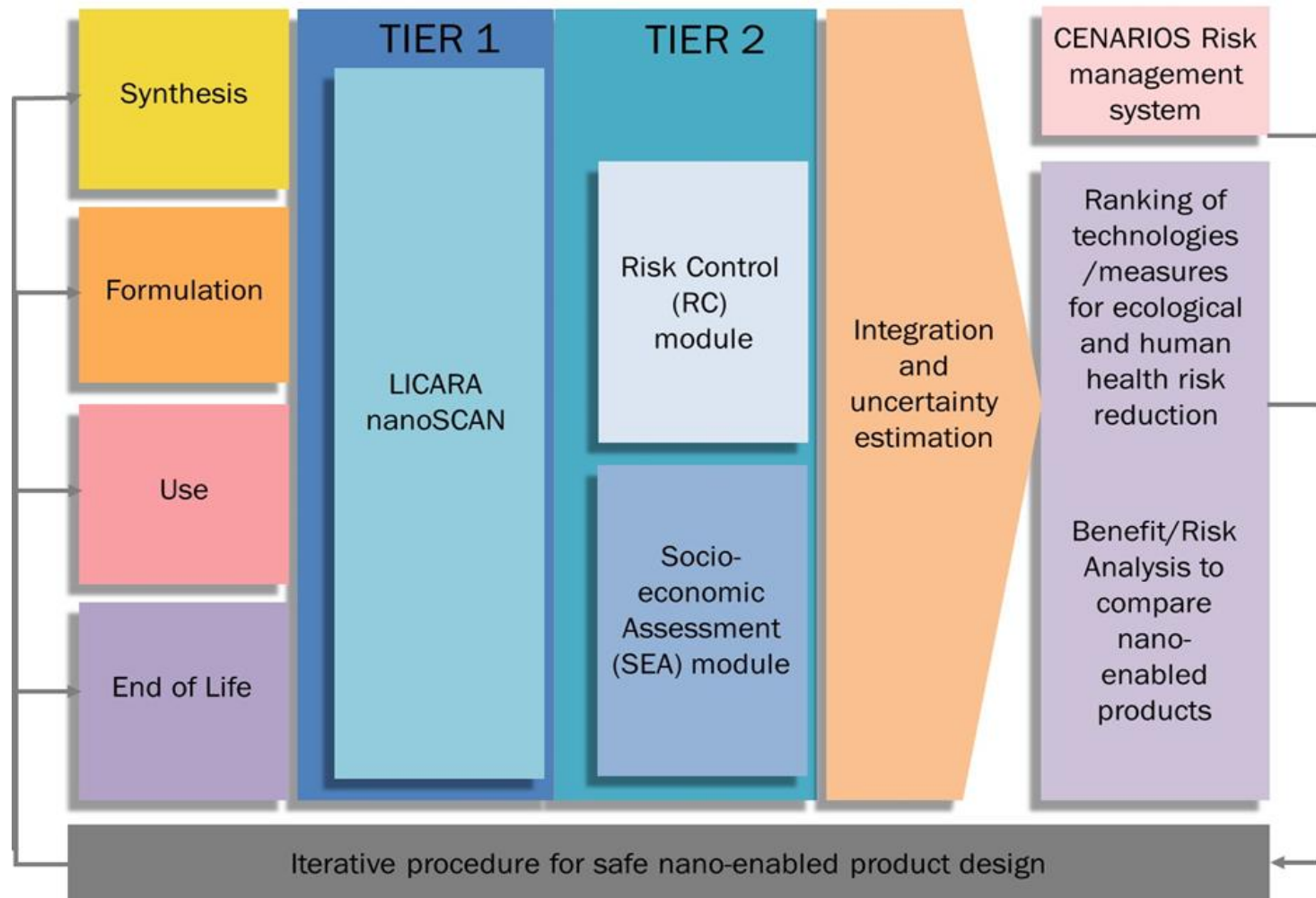
No.	Model name	Application area	Owner	Mod
1	ANSES tool	Work	ANSES	CB
2	ISO TS 12901 CB tool	Work	ISO	CB
3	US Nanotool	Work	LLNL (USA)	CB
4	StM Nano	Work	Cosanta (NL)	CB
5	NanoSafer CB	Work	NRCWE	CB
6	ConsExpo Nano	Cons	RIVM	QEA
7	BAUA SprayExpo	Work	BaUA (DE)	QEA
8	RiskofDerm	Work	TNO	QEA
9	IEAT	Work	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



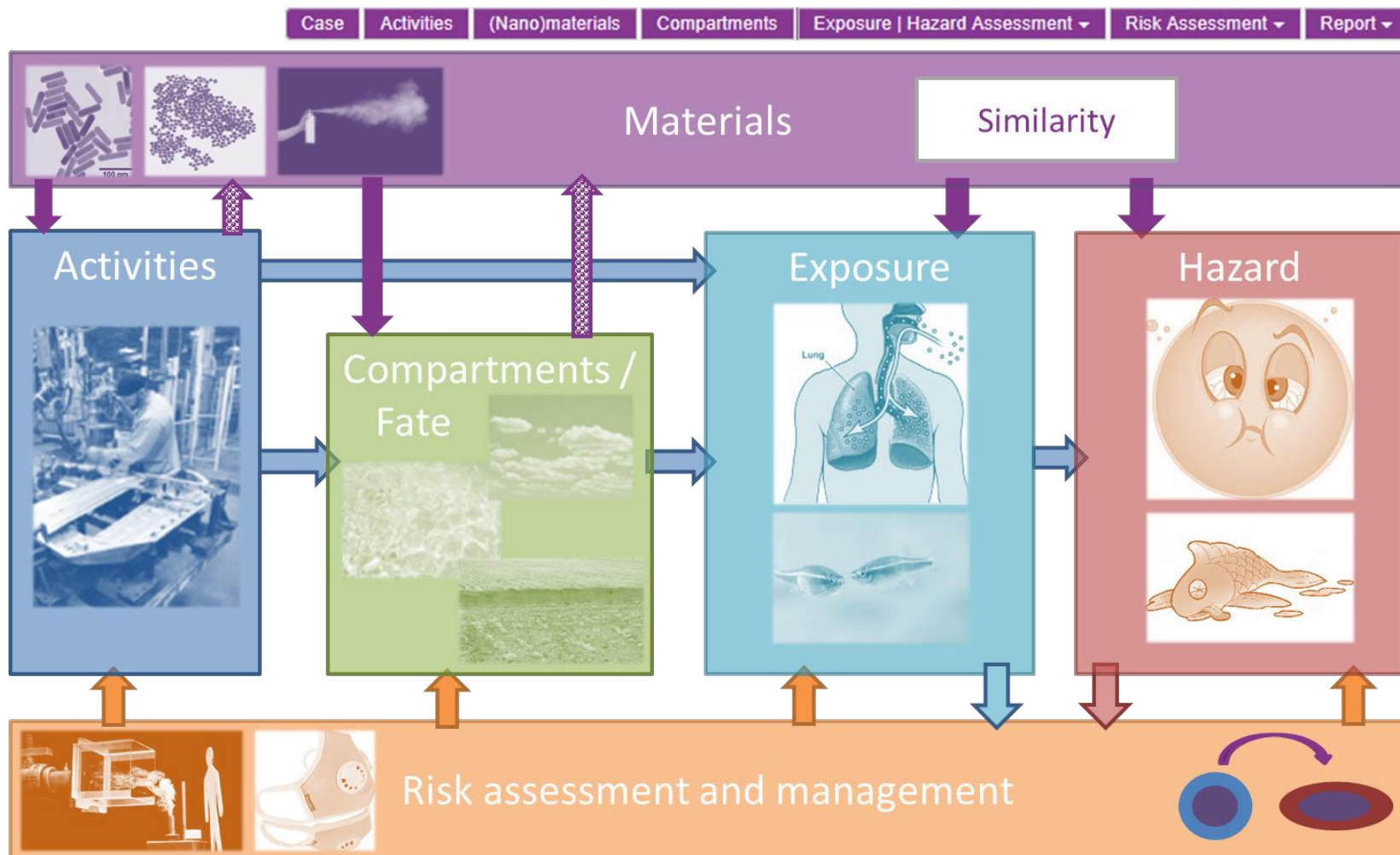


SUN Decision Support





Conceptual framework



Several different nano-specific tools

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

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
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19	n-SSWD	Env	UNIVE	QEcotox

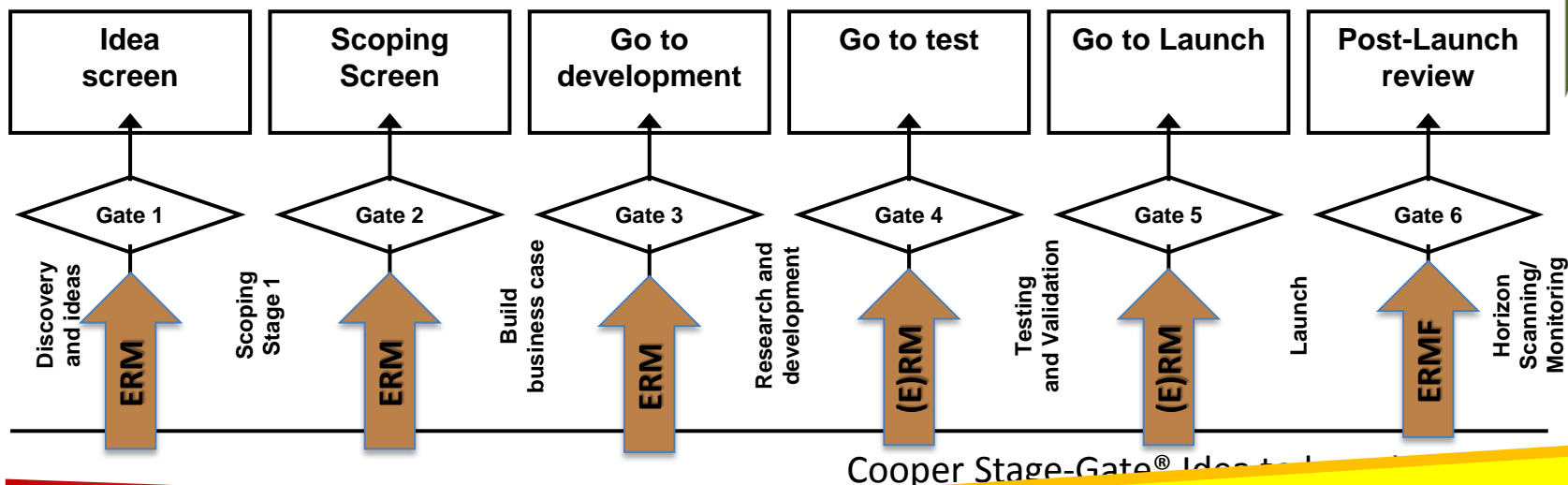
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Conceptual innovation

risk governance idea



Testing and Validation is key to build the foundations

Quantitative predictive / Test Data Driven

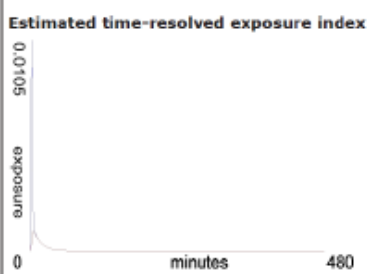
Validation by sensitivity and performance testing

Pouring 700g CuO under a fume hood

ASSESSMENT BY TIER 2

NanoSafer v 1.1

Result of assessment

<p>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</p>		<p>Estimated time-resolved exposure index</p> 	
<p>Near-field Acute 0.0025 EB1: Very low exposure potential</p>	<p>Near-field Daily 0.0000 EB1: Very low exposure potential</p>	<p>Far-field Acute 0.0002 EB1: Very low exposure potential</p>	<p>Far-field Daily 0.0000 EB1: Very low exposure potential</p>

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

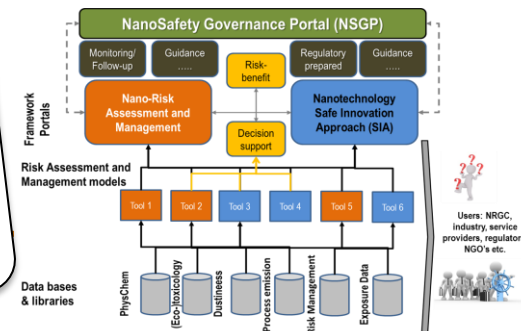
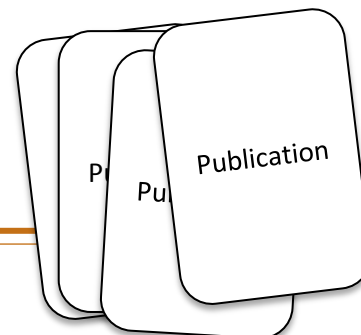
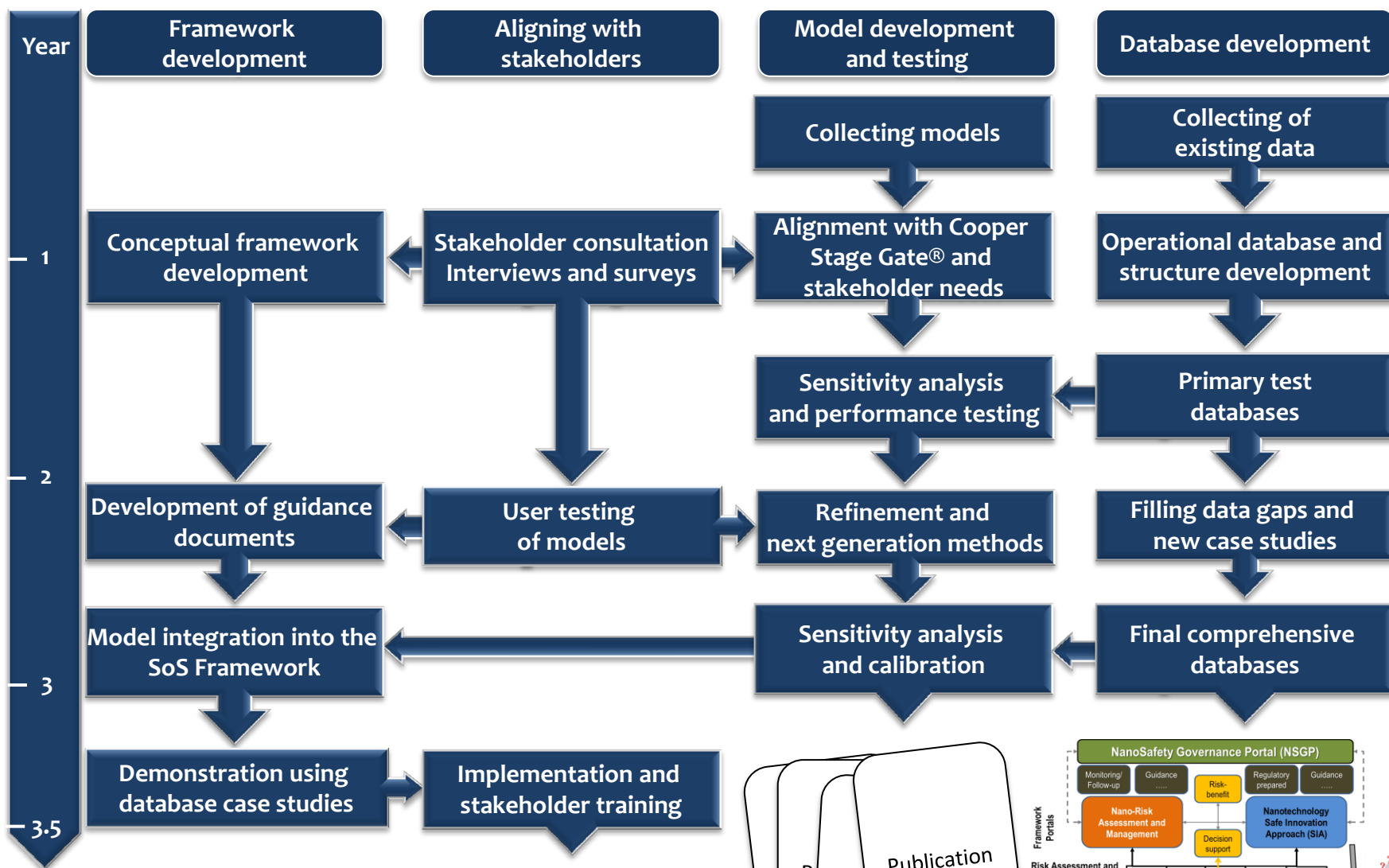
$$OEL_{nano} = OEL_{bulk} \cdot \frac{30}{SSA_{nano}}$$

Specific density of the nanomaterial (g/cm³)

$$EXP_{Acute} = \frac{C_{Acute}}{2 \cdot OEL_{nano}}$$

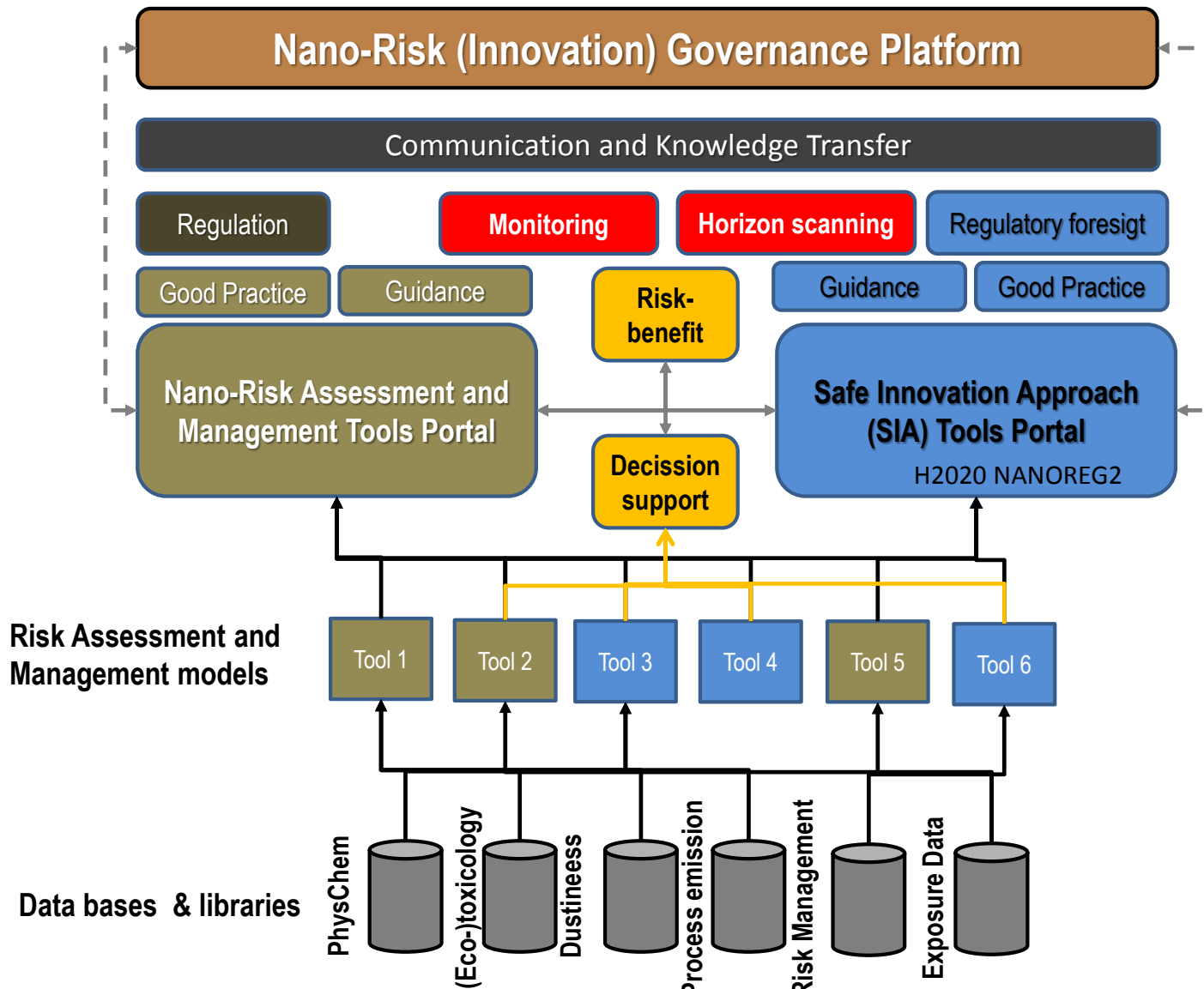
$$EXP_{8-hour} = \frac{C_{8-hour}}{OEL_{nano}}$$

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



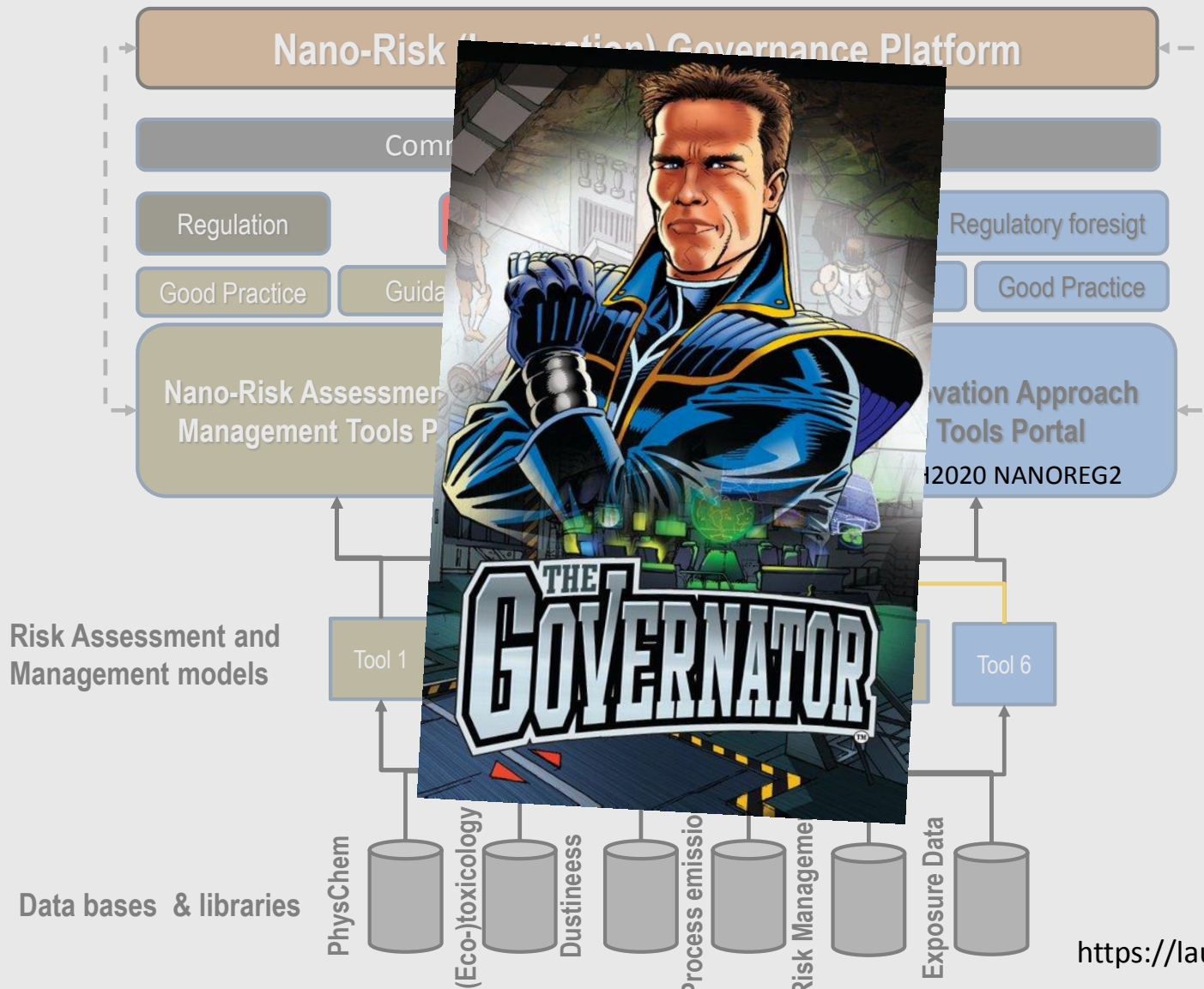


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service providers,
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<https://laughingsquid.com/>

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



Welcome

We are an 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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