Safe-by-design. Risk assessment and Risk governance

IMAGINENANO
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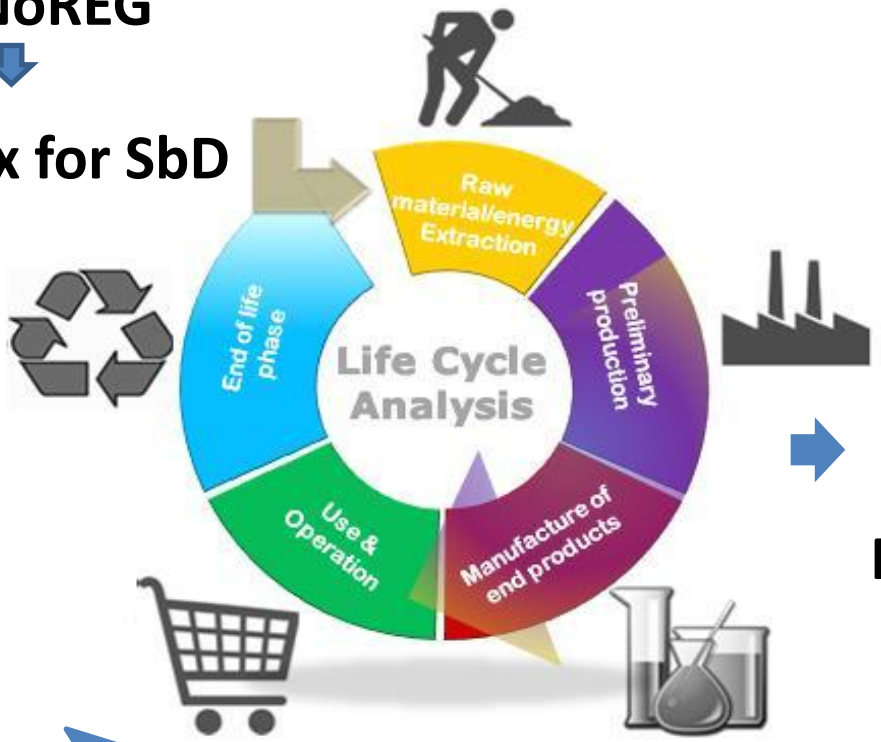
Safe-by-design. Risk assessment and Risk governance

NANoREG

Toolbox for SbD



CaLIBRAte

Risk governance framework

Nanoreg2

SbD implementation/Grouping of NM

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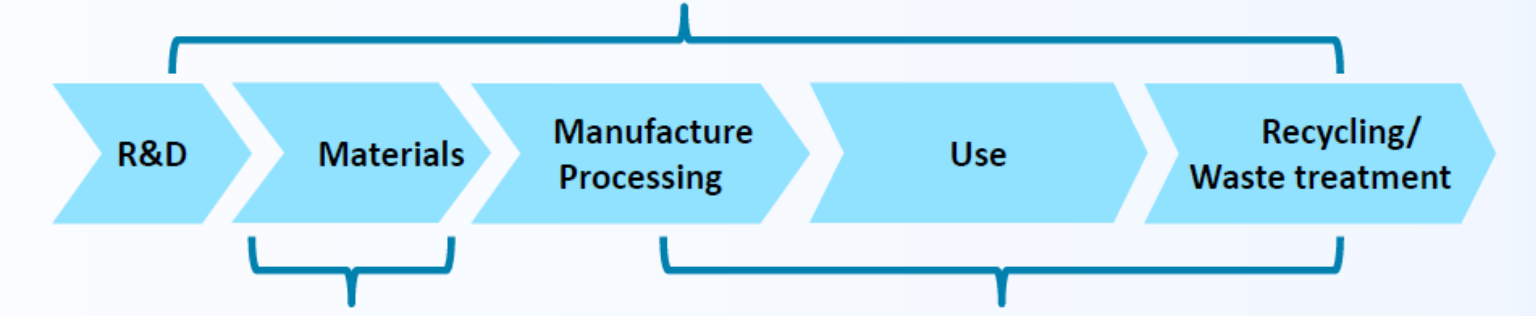
What is Safe-by-design. NanoReg2 concept.

To integrate knowledge of nanomaterials' potential adverse effects on human health, animals and the environment into the process of designing nanomaterials and nanoproducts and/or their production processes—and to engineer these undesirable effects out.



It covers:

- All the value chain. Three pillars Safe products, safe production, safe use.
- Reduces costs
- Flexible, it anticipates future nanosafety demands

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Safe-by-design

- Early identification of potential risks and uncertainties. Integrated Safety assessment.

- Actions to reduce or eliminate those uncertainties and risks **at the earliest stage** of development.

- Comparative safety assessment.

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Integrated safety assessment: RA, LCA, SEA

Risk Assessment (RA) in SbD

- Control banding tool for preliminary RA: identification of hot spots and lack of information.
- Comparative Risk assessment: before and after SbD, improvements in safety.

Life Cycle Assessment (LCA) in SbD

- Established & standardised method. Evaluates potential impacts on ecosystems, human health and resources.
- Limitations when applied to nanomaterials. Development needed: evaluation methodology & data on production.
- LCA can be applied even in the design stages to manage/ control the (out-coming-future) potential impacts.
- Different scenarios can be evaluated.

Socio-Economic Analysis (SEA):

- Socio-Economic Analysis is a decision support approach for evaluation of regulation, regulatory proposals, projects…
- Methodological comparison of pros and cons of alternative situations
- Take into account : environmental, health and economic impacts

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RISK ASSESSMENT AND SbD

- **PRA dossier for each value chain demonstrator** (Description of the case studies in terms of RA):
  - Scope of the case study for the SbD implementation
  - Information about the nanomaterial: Available data
  - Information about the production process

- **Selection of RA tools. SIA Toolbox.**

Phase/Stage of the case study + Expected outcome: Risk, cost, benefit, all

Selection of models

The scope, input parameters and output of each model should be studied

- **Preliminary Risk Assessment**

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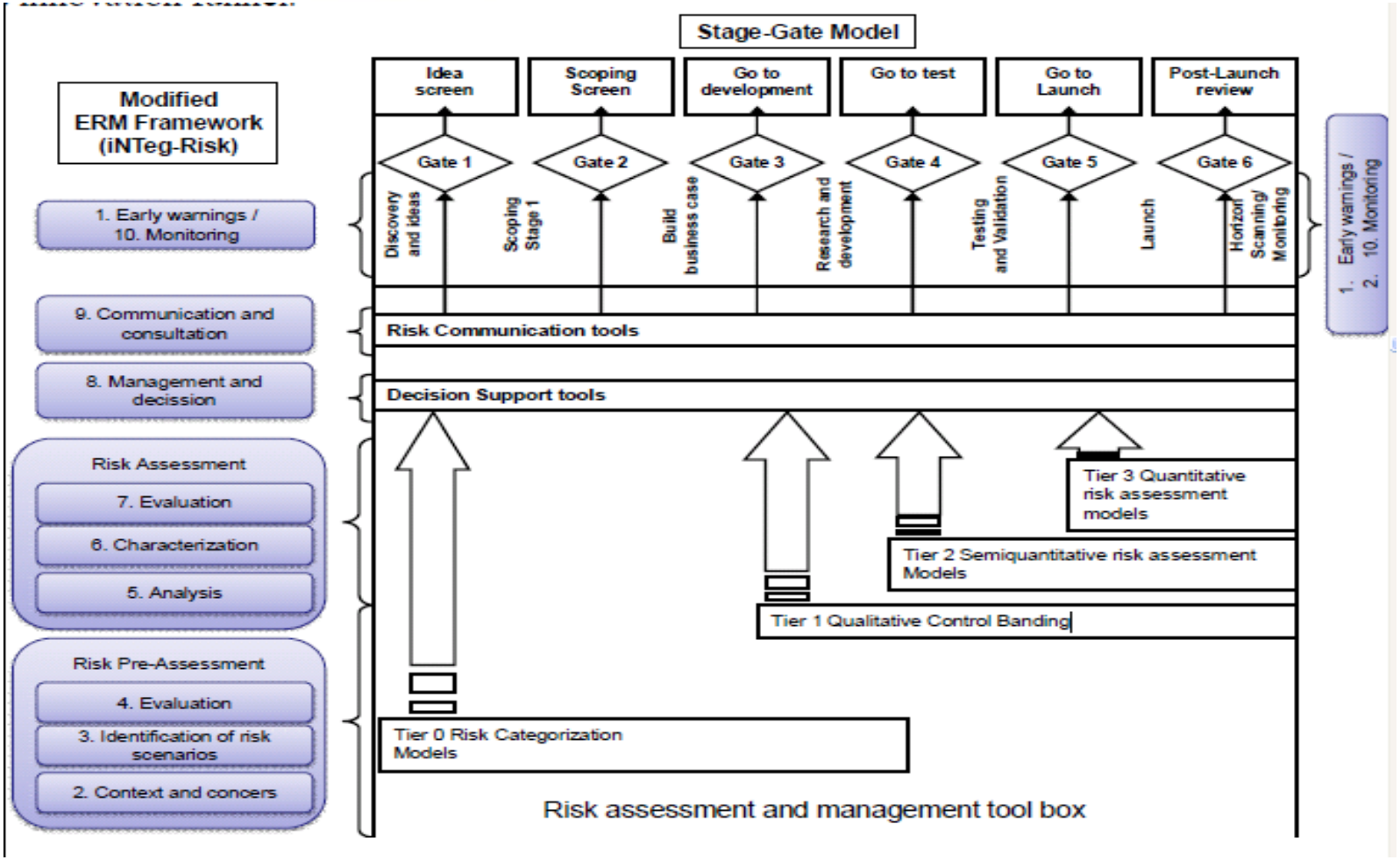
RISK ASSESSMENT



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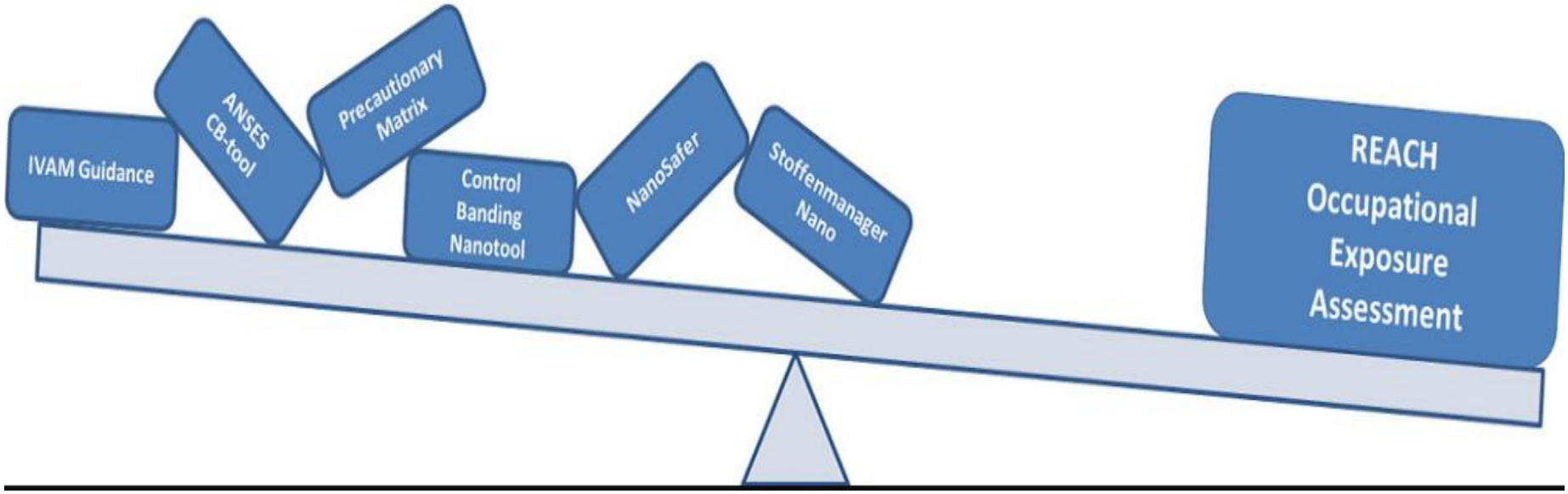
Control banding tools

Both hazard and exposure are graded into two to five different levels, usually referred to as bands. The two sets of bands are combined, resulting into control or risk bands.
Simple, qualitative, few data available



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Control banding RA models

Model	Scope	Target group	# parameters	Outcput
CB Nanotool	Risk ass. and man.	Researchers	45	Risk Level + general recommendation
Swiss Precautionary Matrix	Source identification and risk reduction	Workers, consumers and the environment	28	Need for action/no action
Stoffenmanager Nano	Prioritize health risks implementation of control measures.	Workers	47	Risk priority bands. Ranking priority of needed actions
NanoSafer	Precautionary risk assessment	Workers	29	Risk Level (RL). Recommendation and actions to be taken into consideration
NanoRiskCat	Risk assesment	Professional end users, consumers, environment	16	Exposure and hazard potential
ISO/TS 12901-2:2014	Prioritize health risks and implementation of control measures.	Workers		Risk Level (RL). Recommendation and actions to be taken into consideration

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One Example: Swiss Precautionary Matrix

Potential effect	**Potential effect**	W
	Redox activity, catalytic activity, oxygen radical formation potential or induction potential for inflammatory reactions of the nanomaterial	W1
	Stability (half-life) of the nanomaterial in physiological conditions	$W2_{A,V}$
	Stability (half-life) of the nanomaterial under environmental conditions	$W2_{U}$
Potential human exposure / potential input into the environment	**Carrier material**	E1
	Potential for release related to human exposure	$E1_{A,V}$
	Potential for release related to the environment	$E1_{U}$
	Maximum possible human exposure	E2
	Amount of nanomaterials handled by an employee per day	E2.1
	Amount of nanomaterials with which an employee could come into contact in the worst case	E2.2
	Frequency with which an employee handles nanomaterials	E2.3
	Amount of nanomaterials handled by a consumer per day via the utility product	E2.4
	Frequency with which a consumer uses the utility product	E2.5
	Maximum possible input into the environment	E3
	Amount of nanomaterials reaching the environment from wastewater, exhaust gases, solid waste per year	E3.1
	Annual amount of nanomaterials in utility products	E3.2
	Amount of disposed nanomaterials per year	E3.3

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One Example: Swiss Precautionary Matrix

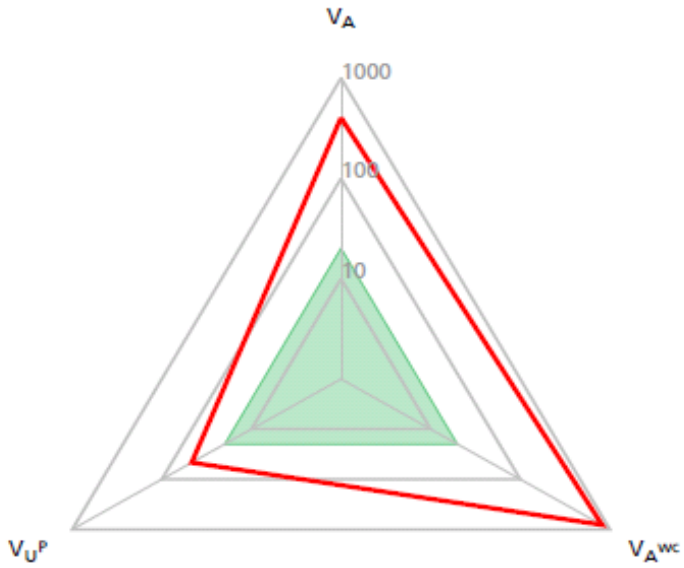
14/2/2018 Popup

for workers

Precautionary need for employees	V_A	408
Precautionary need for employees (Worst Case)	V_A^{wc}	813

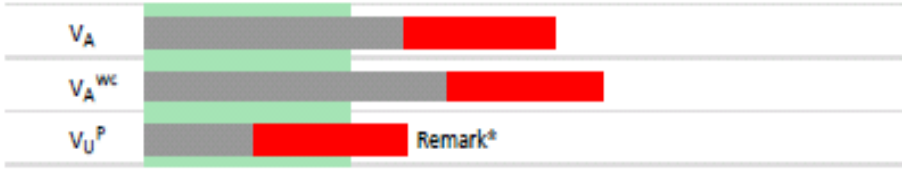
for environment

Precautionary need environment production	V_U^P	48



"Unknown" fraction

This diagram shows the unknown part of the result (red bar). If the unknown part is consequential, a few clarifications can lead to a significantly more favourable result.



* Further clarification can possibly allow these values to fall into the green zone.

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Another example: Nanosafer

Material information	Safety data	Description of the work process and contextural information
Is the material labeled with a nano-specific word or term?	OEL for the comparable coventional material	Emission rate if constant source
Is the material coated or surface modified	Risk sentences: General toxicity; Carcinogenic effect Reprotoxicity Allergy and sensitization; Neurotoxicity	Activity handling energy factor
Dimensions of the primary particles		Total mass of material handled in each work cycle
Specific density		Duration of the work cycle
Solubility		Pause between work cycles
specific surface area		Number of work cycles per day
Powder dustiness		Amount of nanomaterial handled in each transfer
		Time required to add each transfer (spoon, bag, big-bag etc)
		Volume of the work room (width, length, height)
		General Far-field air exchange rate

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Another example: Nanosafer

Result of assessment

Estimated hazard level 0.741952 **The hazard level is estimated based on** **Potentially hazardous high aspect ratio nanomaterial** No A high volume specific surface area of 400.00 m2/cm3 **OEL of analogue bulk material:** 2 mg/m3 **Solubility:** Insoluble (< 1 g/L) **Presence of surface coating:** No **Known hazards of analogue bulk material** R22 Harmful if swallowed R36 Irritating to eyes R37 Irritating to respiratory system R38 Irritating to skin R43 May cause sensitization by skin contact		**Estimated time-resolved exposure potential**	
Near-field Acute 32.30 EB5: Very high exposure	**Near-field Daily** 20.44 EB5: Very high exposure	**Far-field Acute** 9.507 EB5: Very high exposure	**Far-field Daily** 18.76 EB5: Very high exposure
RL5: Very high toxicity suspected and/or moderate to very high exposure. The work should be conducted under strict dust release control, such as in a fume-hood, separate enclosure etc. Air-supplied respirators or highly efficient filter masks (PP3 or higher quality) may be used as a supplement and must be readily available in case of accidents. Expert advice is recommended.	RL5: Very high toxicity suspected and/or moderate to very high exposure. The work should be conducted under strict dust release control, such as in a fume-hood, separate enclosure etc. Air-supplied respirators or highly efficient filter masks (PP3 or higher quality) may be used as a supplement and must be readily available in case of accidents. Expert advice is recommended.	RL5: Very high toxicity suspected and/or moderate to very high exposure. The work should be conducted under strict dust release control, such as in a fume-hood, separate enclosure etc. Air-supplied respirators or highly efficient filter masks (PP3 or higher quality) may be used as a supplement and must be readily available in case of accidents. Expert advice is recommended.	RL5: Very high toxicity suspected and/or moderate to very high exposure. The work should be conducted under strict dust release control, such as in a fume-hood, separate enclosure etc. Air-supplied respirators or highly efficient filter masks (PP3 or higher quality) may be used as a supplement and must be readily available in case of accidents. Expert advice is recommended.
Based on the estimated hazard and exposure potential it is recommended to apply engineered protection equipment with a protection factor of 322.99			

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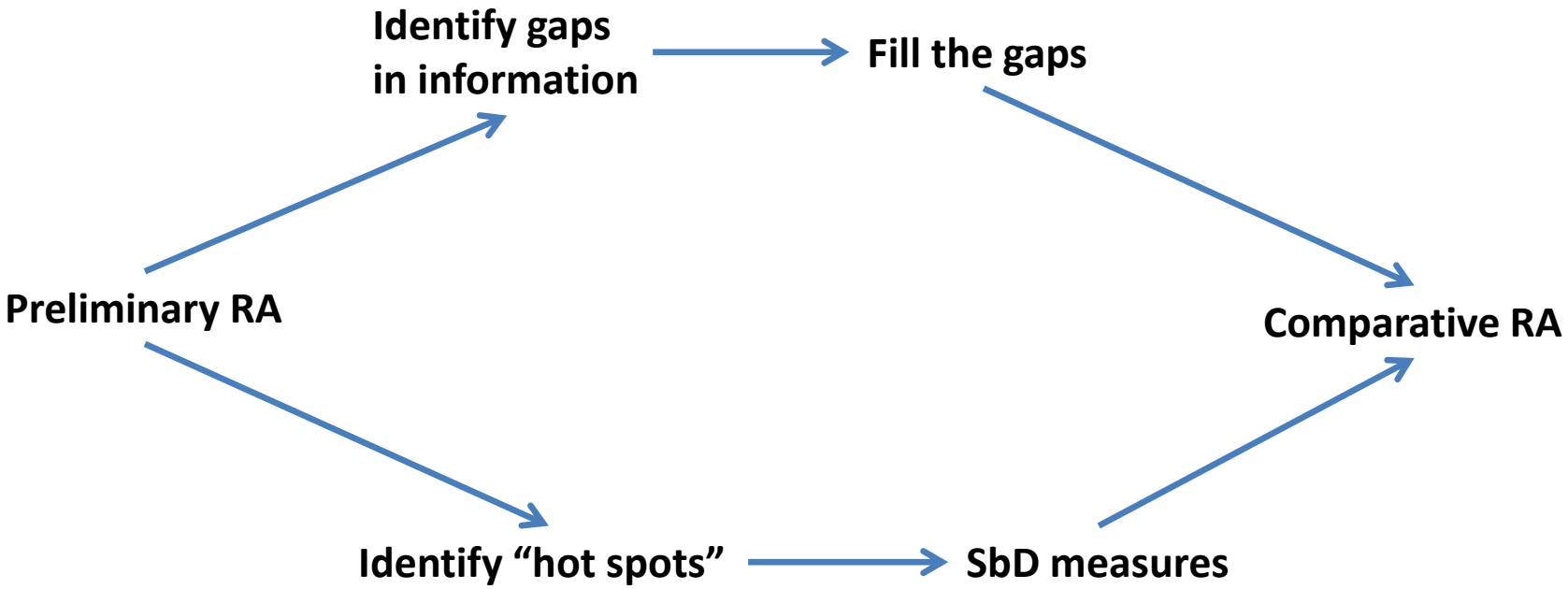
RISK ASSESSMENT AND SBD



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COMPARATIVE RA

i. Use of the control banding tools. Comparison with preliminary RA

ii. Use of a semiquantitative or qualitative models: ie SUNDS, Weigh of Evidence, Guidenano, etc.

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One example: SUNDS

It applies a two tiers approach which, on the basis of the supplied information, is able to generate qualitative or quantitative results.

- Risk for Health
- Risk for environment
- LCA
- SEA

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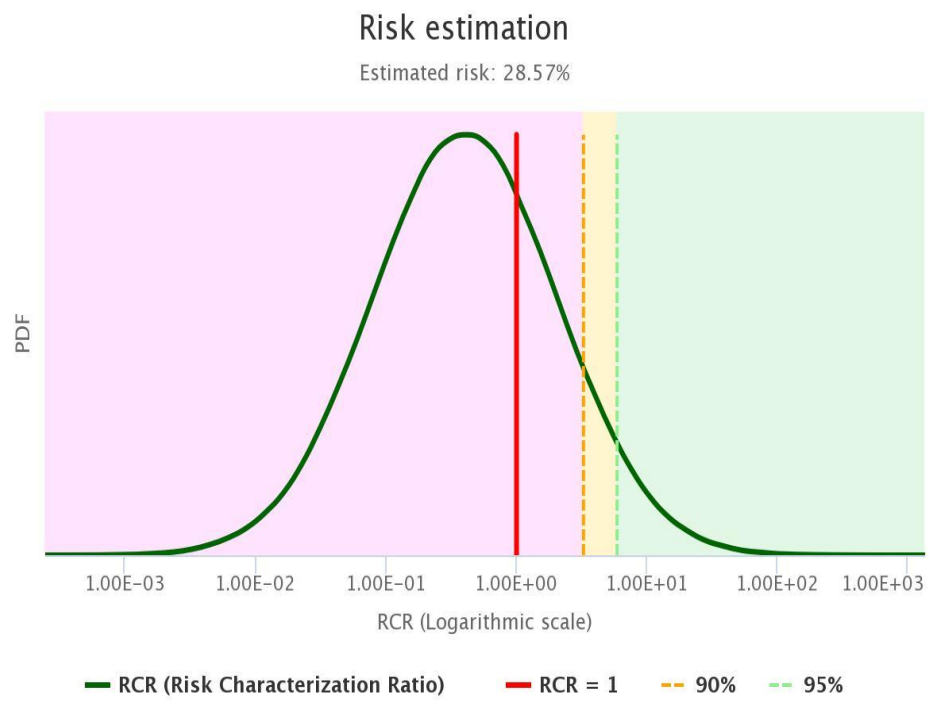
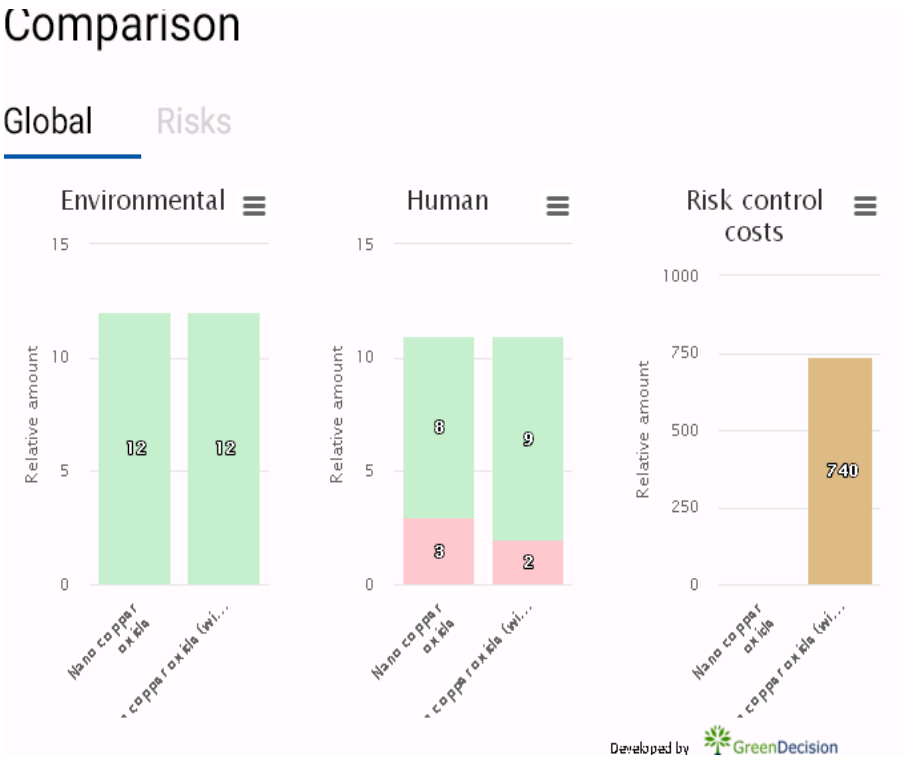
One example: SUNDS





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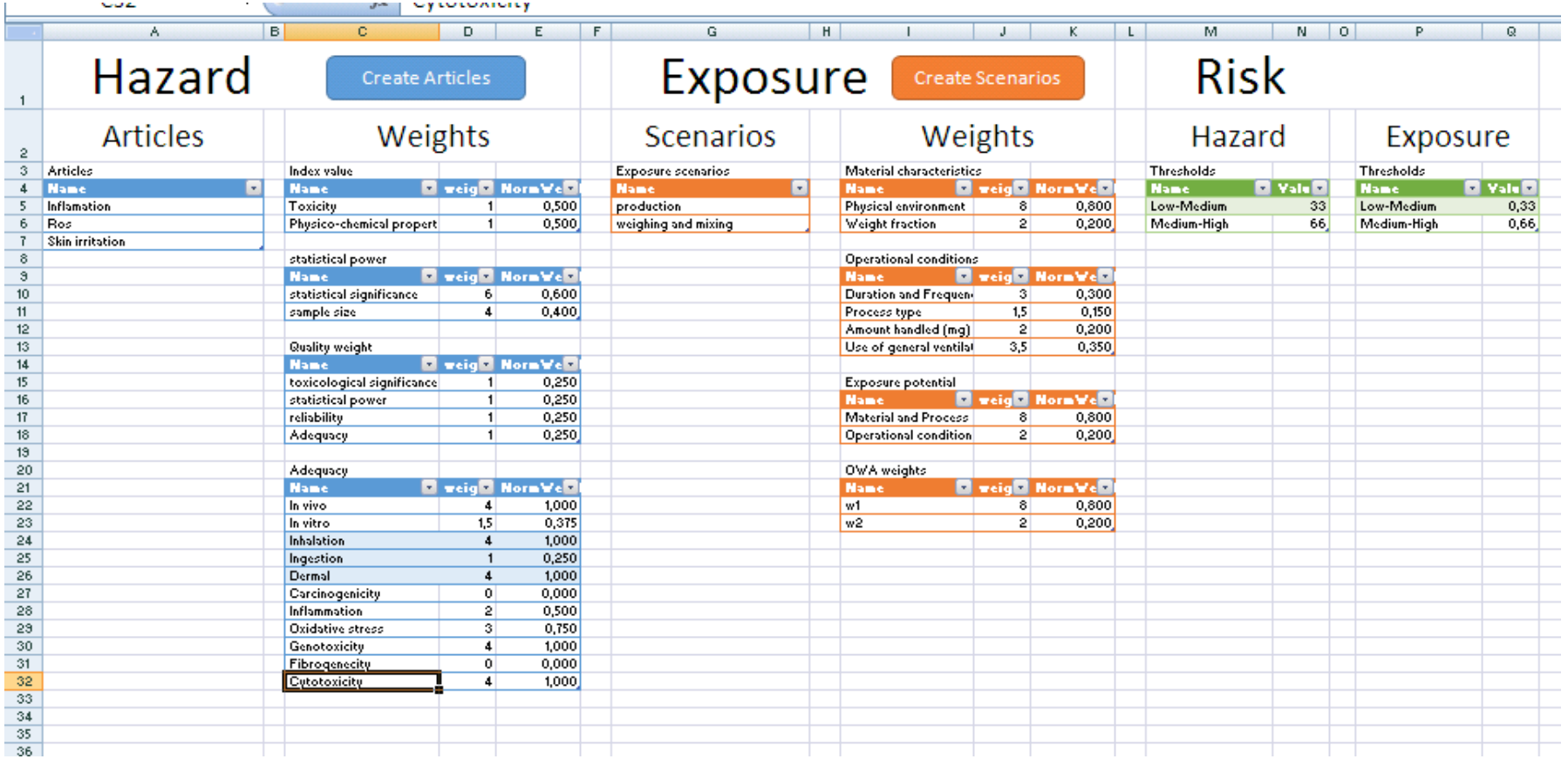
Weigh of Evidence

Combines the available data into hazard and exposure classes through a system of weights and algorithms. Relevance for the risk assessment and data quality are taken into account in the integration process.



Hazard | Create Articles | Exposure | Create Scenarios | Risk

Articles

Name
Inflamation
Ros
Skin irritation

Weights

Index value

Name	weig	NormWe
Toxicity	1	0,500
Physico-chemical propert	1	0,500

statistical power

Name	weig	NormWe
statistical significance	6	0,600
sample size	4	0,400

Quality weight

Name	weig	NormWe
toxicological significance	1	0,250
statistical power	1	0,250
reliability	1	0,250
Adequacy	1	0,250

Adequacy

Name	weig	NormWe
In vivo	4	1,000
In vitro	1,5	0,375
Inhalation	4	1,000
Ingestion	1	0,250
Dermal	4	1,000
Carcinogenicity	0	0,000
Inflammation	2	0,500
Oxidative stress	3	0,750
Genotoxicity	4	1,000
Fibrogenecity	0	0,000
Cytotoxicity	4	1,000

Scenarios

Exposure scenarios

Name
production
weighing and mixing

Weights

Material characteristics

Name	weig	NormWe
Physical environment	8	0,800
Weight fraction	2	0,200

Operational conditions

Name	weig	NormWe
Duration and Frequen	3	0,300
Process type	1,5	0,150
Amount handled (mg)	2	0,200
Use of general ventilat	3,5	0,350

Exposure potential

Name	weig	NormWe
Material and Process	8	0,800
Operational condition	2	0,200

OWA weights

Name	weig	NormWe
w1	8	0,800
w2	2	0,200

Hazard

Thresholds

Name	Valu
Low-Medium	33
Medium-High	66

Exposure

Thresholds

Name	Valu
Low-Medium	0,33
Medium-High	0,66

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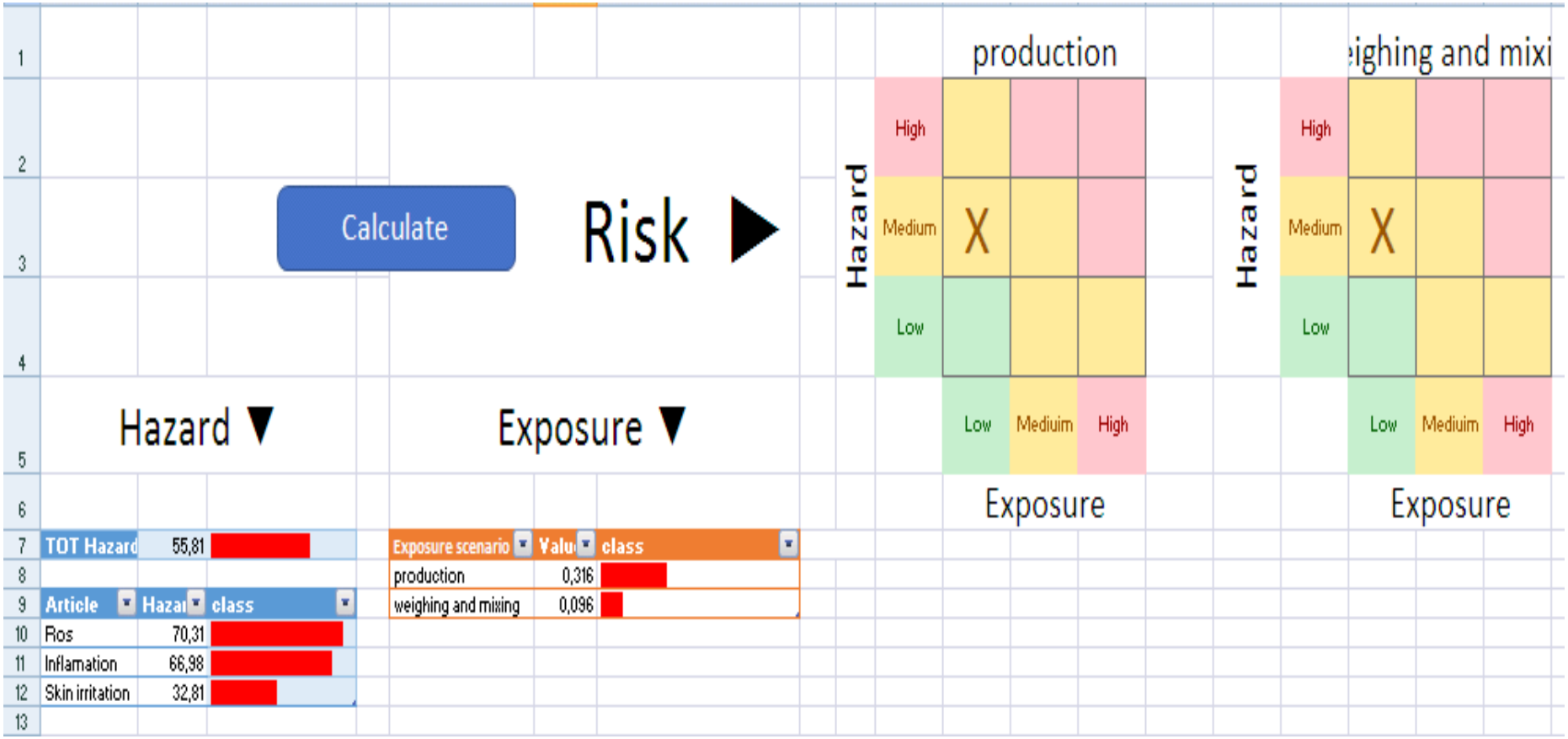
Weigh of Evidence. Results



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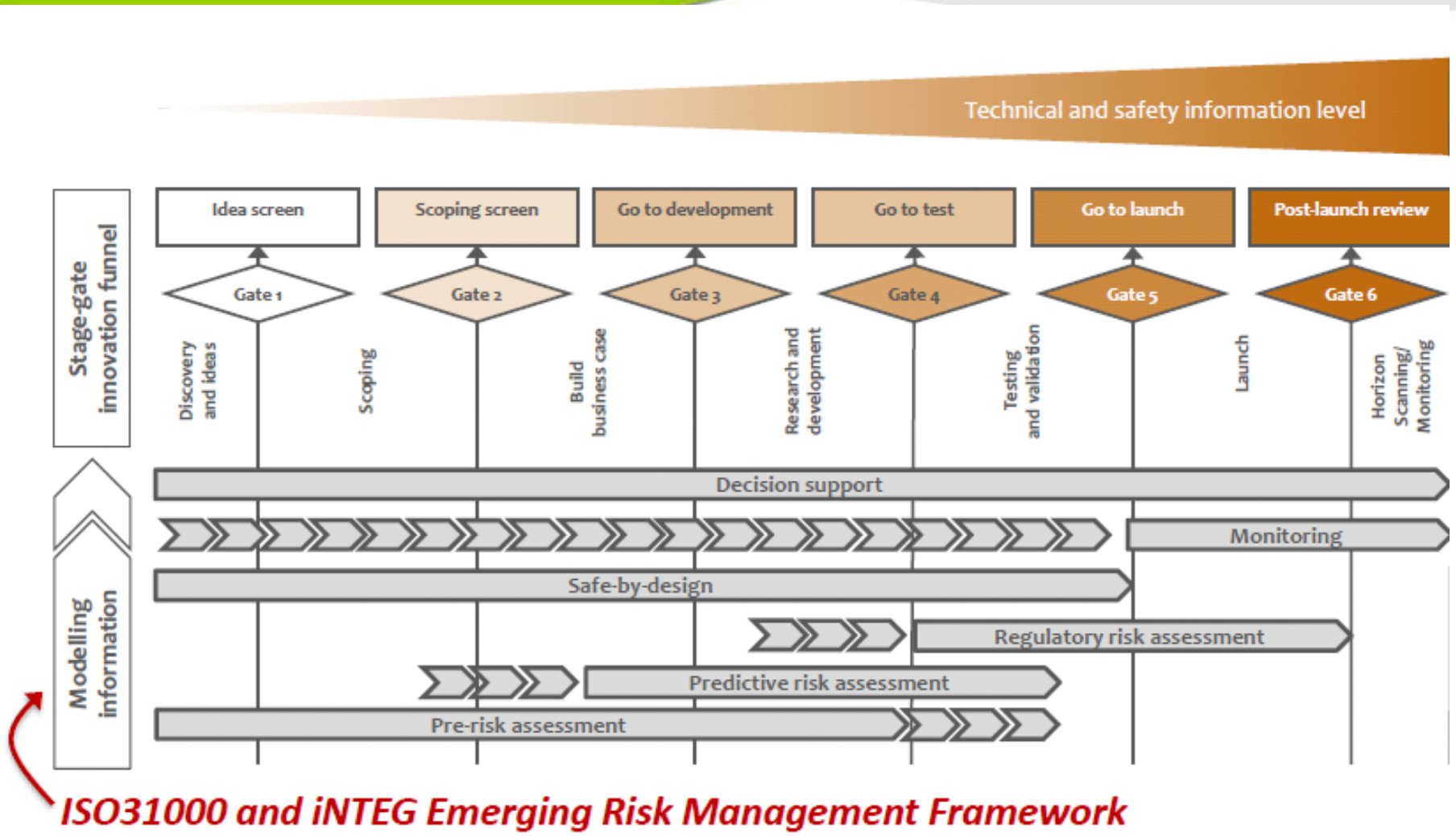

ISO31000 and iNTEG Emerging Risk Management Framework

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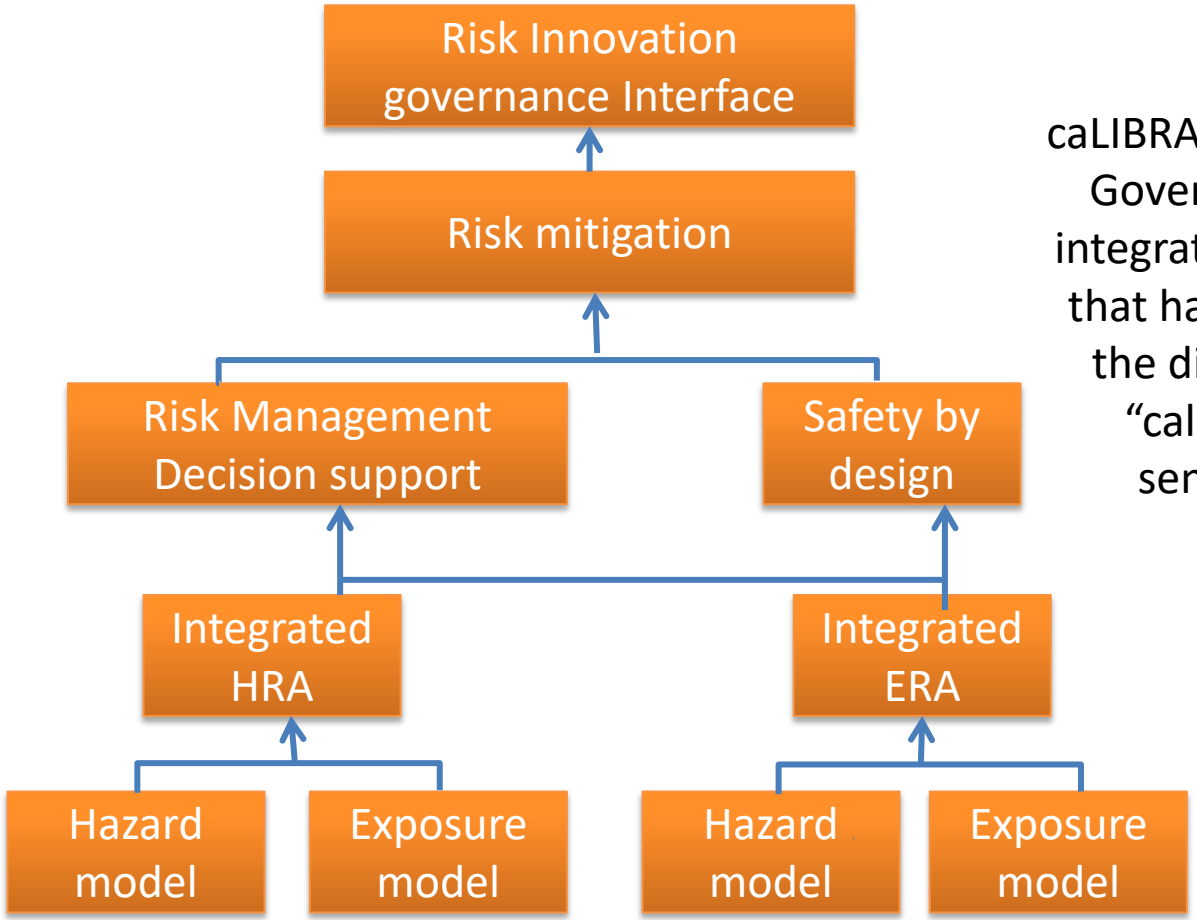

caLIBRAte will provide a Risk Governance Framework integrating SbD and models that have been chosen for the different stages and "calibrated" through sensitivity analysis.

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What will caLIBRAte deliver?

A framework to assist industries in developing ”safe” nanomaterials and nano-enabled products

EHS control banding, risk assessment and decision support tools tested and documented for nanomaterials

Ability to improved confidence and trust in risk communication between stakeholders and risk transfer

Key 4 Nano-Risk Innovation Governance!

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