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Connaître, évaluer, protéger

Pragmatic Approach for Risk Assessment Screening of Products Containing Manufactured Nanomaterials

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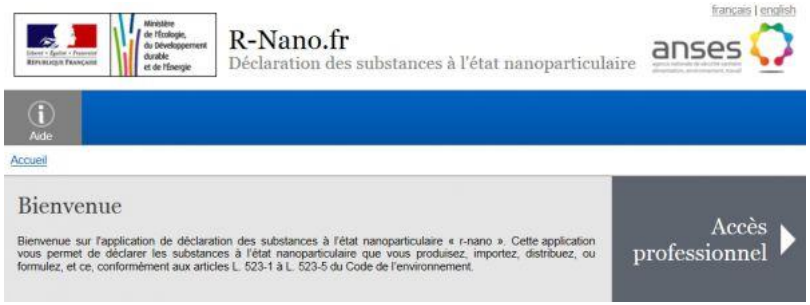
Manufactured nanomaterials:
What are we really talking about ?

Context

A well-aknowledged conceptual definition… but several technical definitions!

Some sectorial-specific definitions (cosmetics, novel food, *etc.*), controversial threshold (100 nm)

Some data from existing mandatory nanomaterial declaration



400 000 t NM produced or importated in France (2015)

- High diversity of materials: from very simple (ex: carbon black) to high-tech materials (ex: quantum dots)
- A recent tool (2013) progressively refined

Consumer products containing manufactured materials (nanoproducts)?

No specific nanoproduct declaration, some NM ingredient declaration in EU (cosmetics, novel food, *etc.*)
Some surveys (Woodrow Wilson Institute, RIVM, Anses 2010, *etc.*)

A higly diversified market
(examples of existing uses)

Context

« Smart » food packaging
(Ag – antibacterial
Quantum dots – quality tracers ?)

Salt, spices
(SiO_2 – anti-caking)

High-tech textile
(ZrO_2 –UV and IR filters)

Household appliances

Hair dryer
(Ag – antibacterial)

Fridge
(Ag - antibacterial)

Processor
(Si/CNT – electrical conductance)

Food - feed

Dietary supplement
(Ag – ??)

Candies
(TiO_2 – food coloring)

Textiles

Anti odour socks
(Ag – antibacterial)

Cement
(TiO_2 – air purifier, self cleaning)

Computers & electronics

Mousse
(Ag – antibacterial)

Health & cosmetics

Toothpaste
(SiO_2 - abrasive)

Sunscreen
(TiO_2 – UV filter)

Plaster
(Ag - antibacterial)

Tennis racket
(CNT – mechanical resistance)

Cleaning products

Glass cleaner
(?? – dispersant ?)

Construction & public works

Paints, dyes, stains, glazes
(TiO_2 – self cleaning)

Self cleaning glass
(polymer – self cleaning)

Transport

Tires
(SiO_2 – road adhérence and durability)

Bike
(CNT – mechanical resistance)

Hobbies

Toys
(Ag – antibacterial)

Surgery table
(Ag –antibacterial)

Others…

Risk assessment is blocked by uncertainties

Context

Main complexity factors:

Highly specific data required
(modified properties … inducing effects??)

Complexity for acccurate data production

Exposure quantification and expression (measurand?)

+ lifecycle issue,

+ market dynamic (new products roll-out) **vs research** (data production)

Illustration : Anses (2010)

Assessment for very different nanoproducts :

- Antibacterial socks (Ag)
- Photocatalytic cement (TiO_2)
- Sunscreen (TiO_2)
- Food ingredient (SAS)

Data interprétation with classical QHRA
(quantitative health risk assessment)

Identical results :

« risk cannot be assessed; it cannot therefore be dismissed »

Exploration of a methodological solution

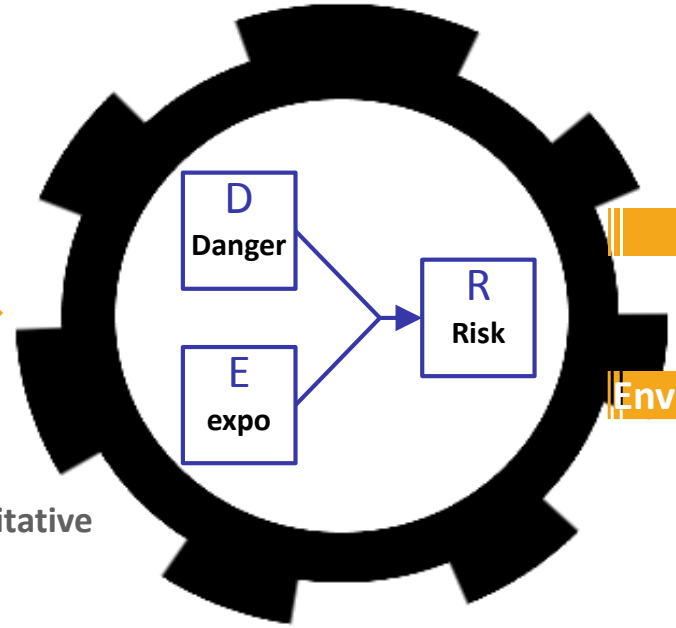
Anses 2015

General aim: structure for action guidance in a context of high uncertainty

Input

- Tox, ecotox data
- Physchem reactivity
- Exposure measure
- Usage scenario
- Product matrix
- *Etc.*

Using preferentially specific/quantitative data and, if unavailable, approached/qualitative data



Output

- Health
  - Risk level
  - Confidence score
- Environnement
  - Risk level
  - Confidence score

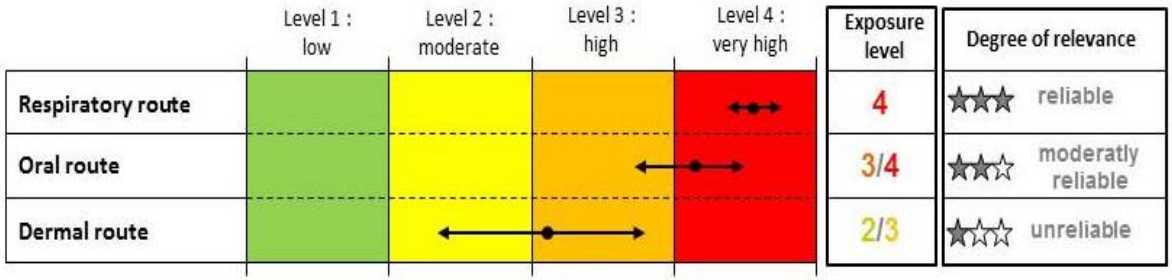
Objective and evolving framework for interpreting weak evidence available and qualifying uncertainty

Give risk manager relevant information toward risk assessment, on current knowledge

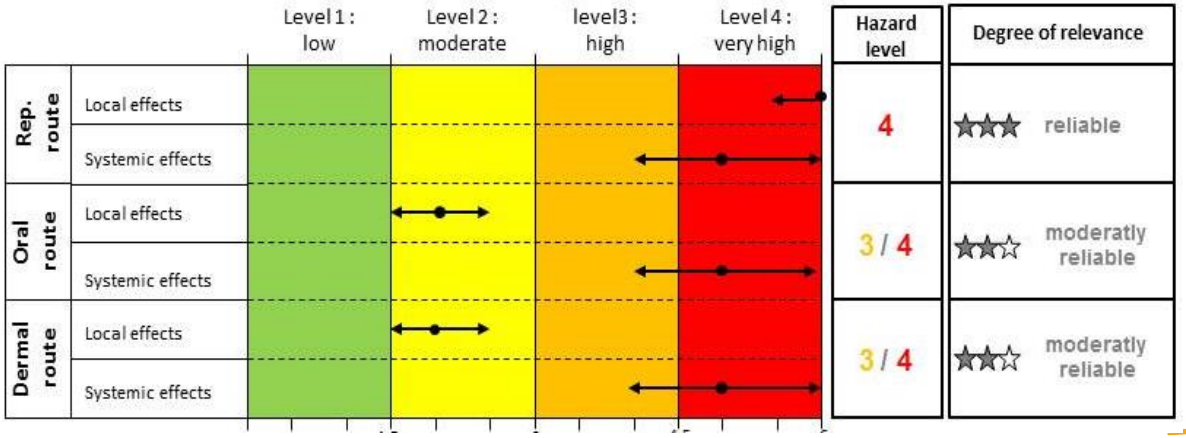
Illustration of final results
(for a couple use/product)

Overview

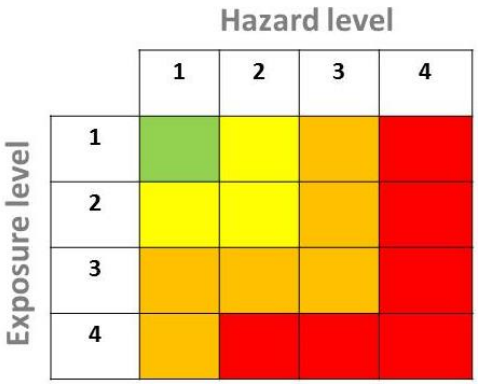
Exposure



Hazard

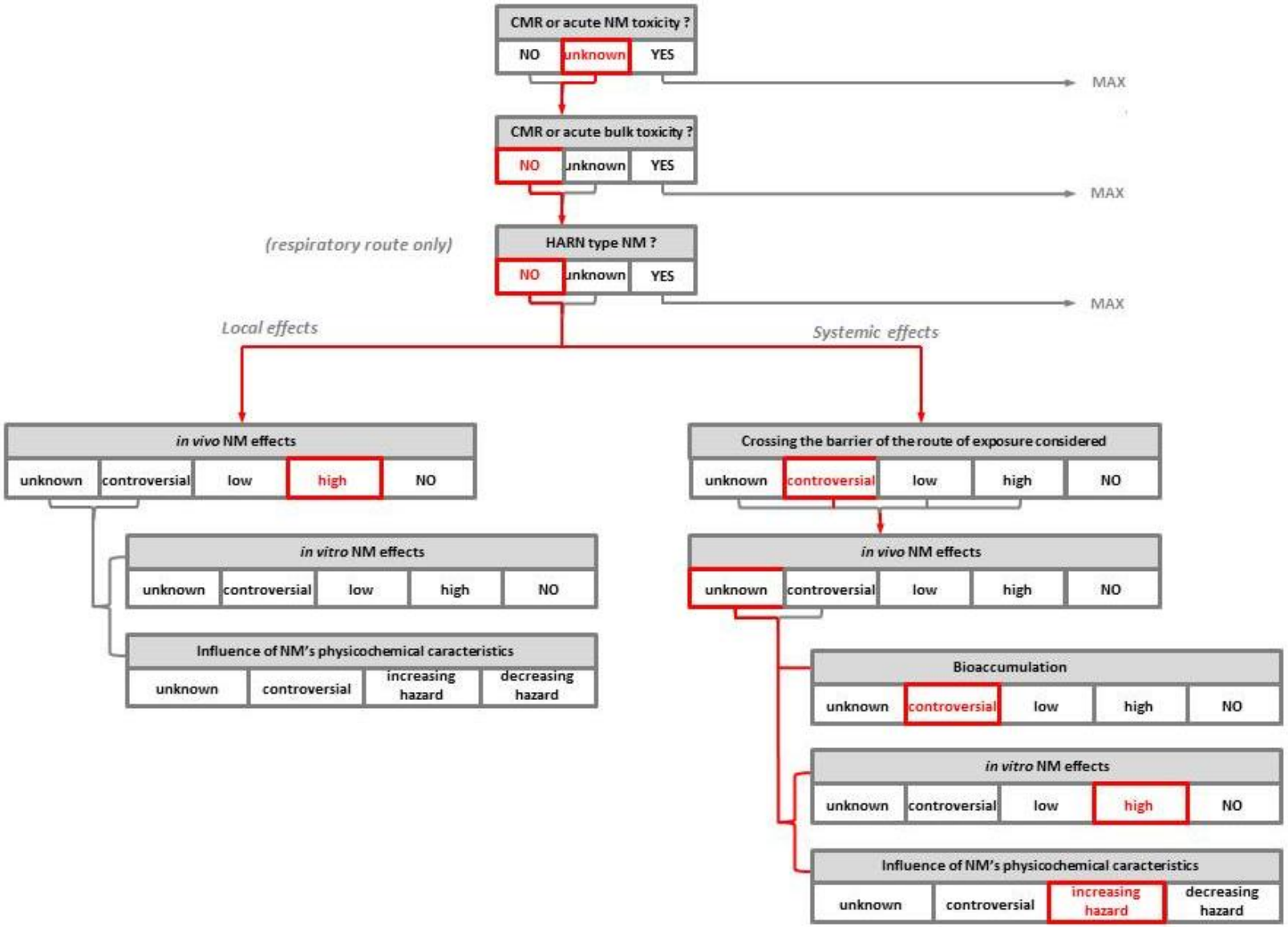


Risk level interpretation



+ intermediate data

Example of intermediate results
(Arguments for hazard level determination)



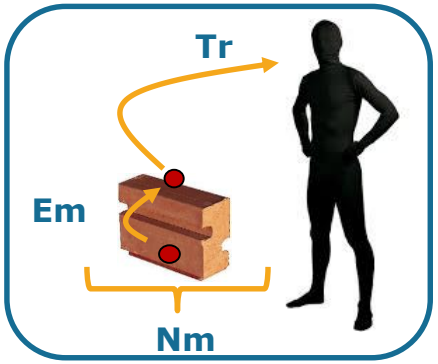
Exposure assessment general principle

Model principle

Semi-quantitative assessment based on a probabilist model

4 parameters to be considered:

- **Nm :** NM quantitity in product
- **Em :** NM containment by product matrix
- **Tr :** free NM ability to reach interface exposure pathway
- **Co :** context (use frequency, duration, *etc.*)



Exposure probability = $10^{Nm} .10^{Em} .10^{Tr} .10^{Co}$

Exposure score = Nm + Em + Tr + Co

+ uncertainty score (for each parameter)

(consolidated / controversial / approached data)

	Level 1 : low	Level 2 : moderate	Level 3 : high	Level 4 : very high
Respiratory route				↔
Oral route			↔	
Dermal route		↔		

Exposure level	Degree of relevance
4	★★★ reliable
3/4	★★☆ moderatly reliable
2/3	★☆☆ unreliable

Hazard assessment general principle

A semi-quantitative tool based upon a flow chart

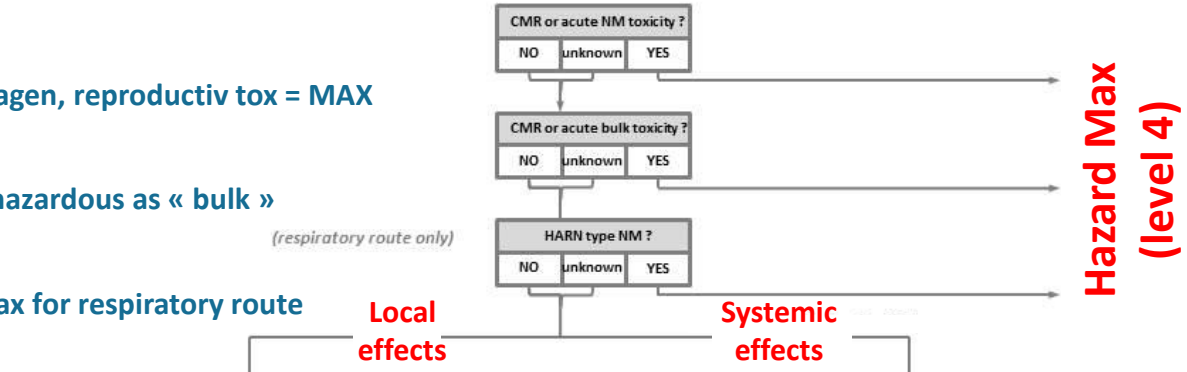
Model principle

Cancerogen, mutagen, reproductiv tox = MAX

MN is at least as hazardous as « bulk »

(respiratory route only)

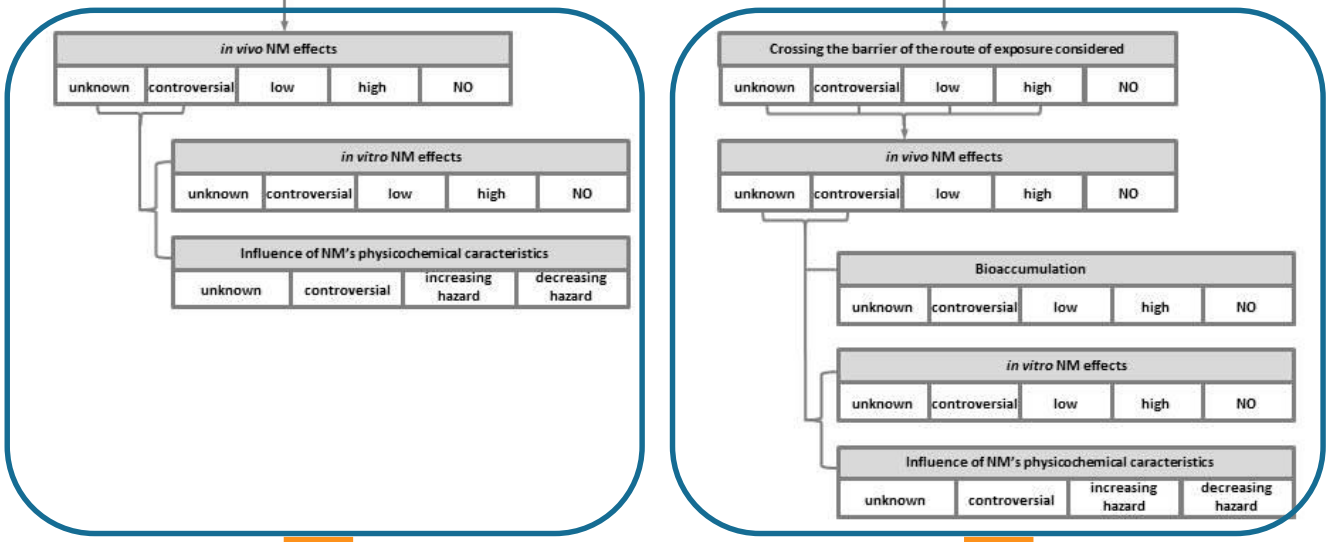
Fibre = Hazard max for respiratory route



Inconclusive *in vivo* data

Less robust data
(*in vitro* + physchem)

Uncertainty score (increased)



Result / local effects

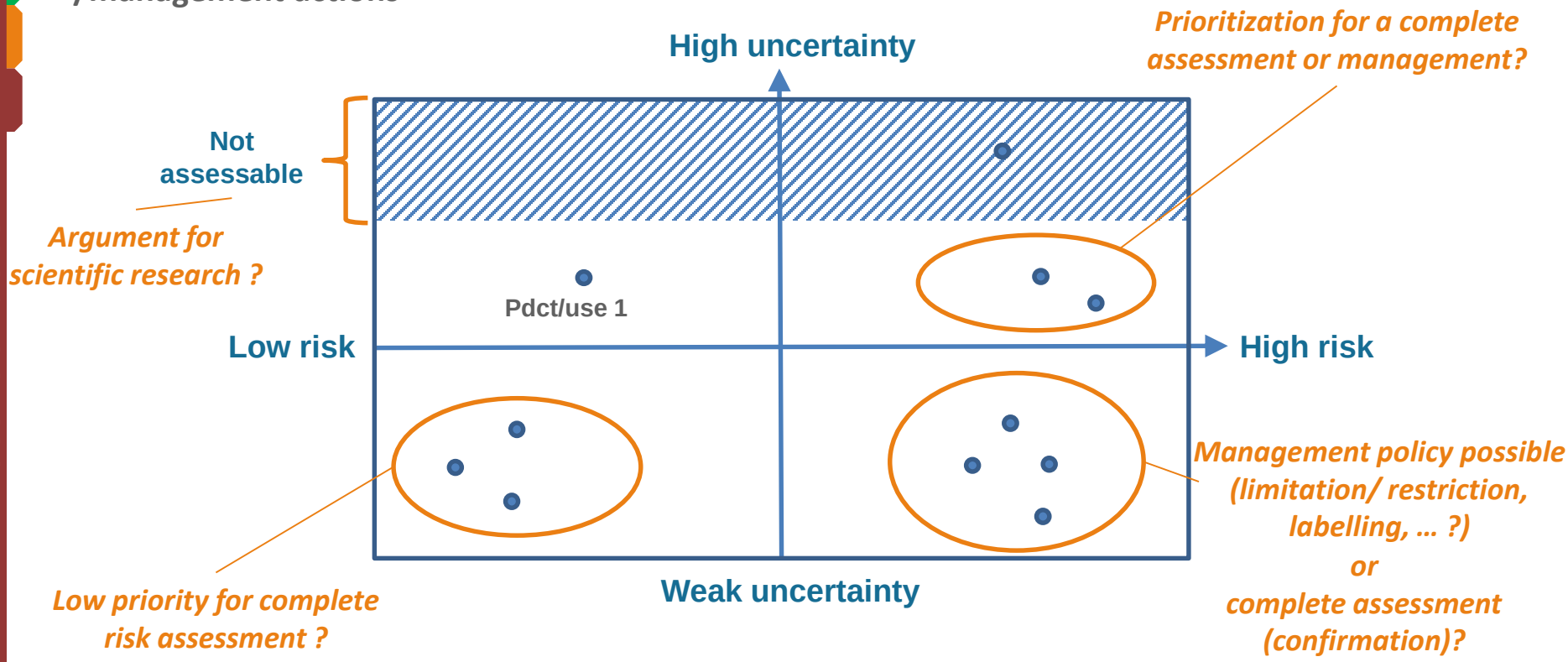
Result / systemic effect

Use example 1: Screening of nanoproducts

Potential uses

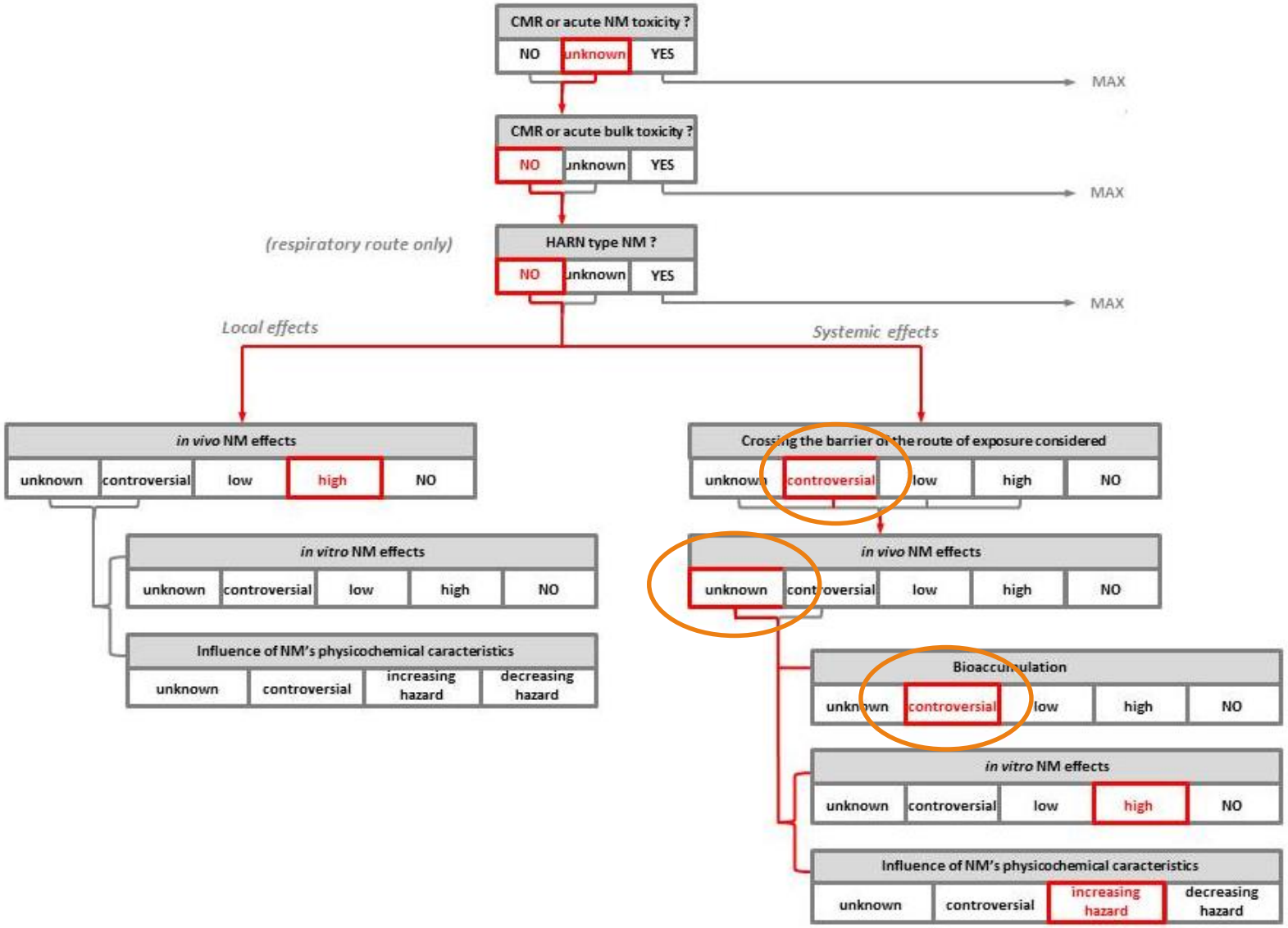
General principle:

Placing nanoproducts in a « risk/uncertainty » space in order to guide and prioritize assessment /management actions

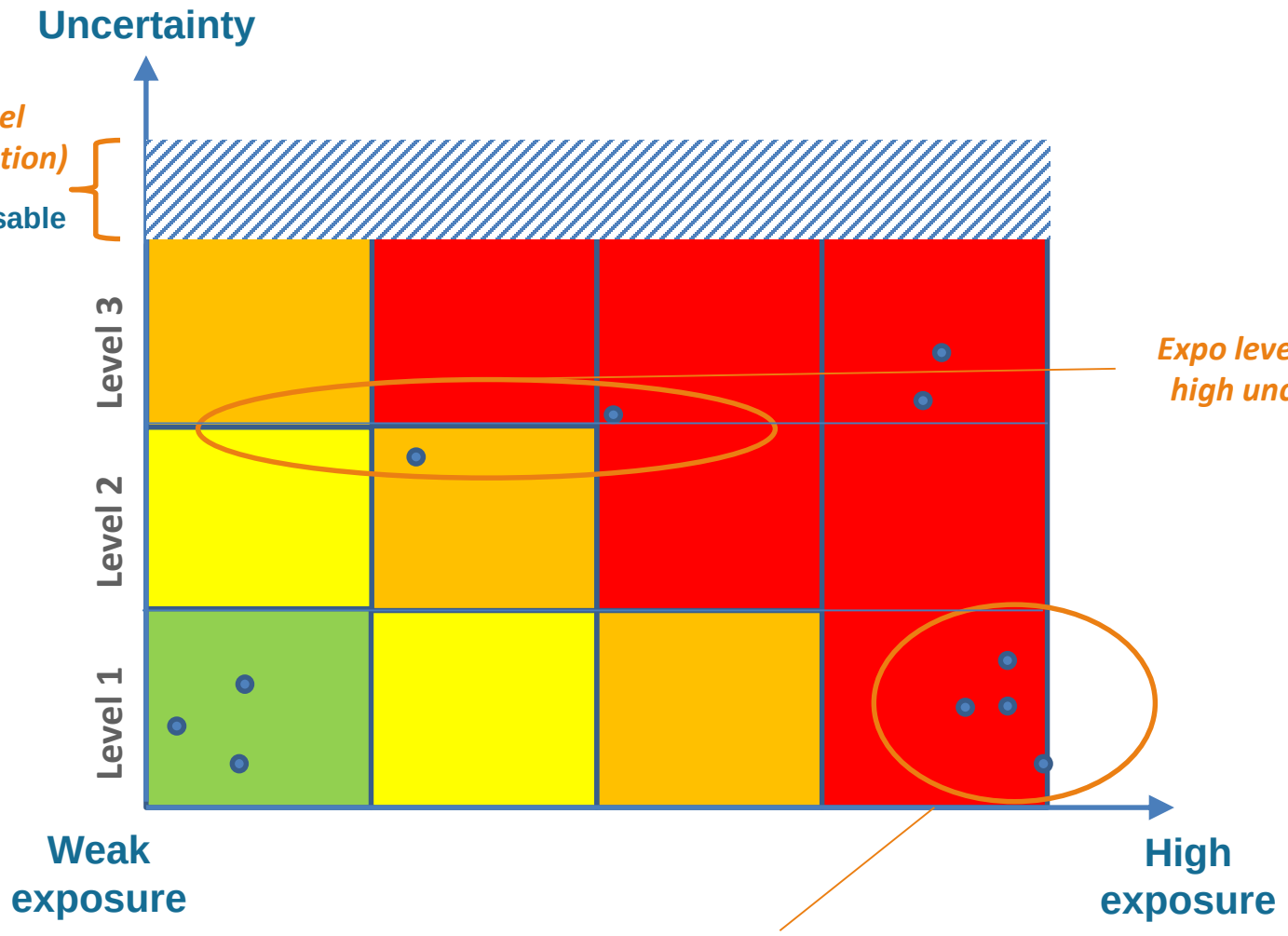


Key : which threshold for wich action?

Use example 2: Scientific research guidance



Use example 3: Exposure class determination



Potential uses

Thank you for your attention !

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