

Regulatory Innovation Trial for NPs Selection Rules

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INTRODUCTION & MOTIVATION

The European Green Deal (EGD) [1] needs to be understood as a radical systemic change to transform the EU society and economy. It is built upon three interrelated pillars: policy, budget and regulation. In regulatory terms, the Commission presented a roadmap considered a real 'normative shock' [2]. But the need of transformational and innovative solutions imply that conventional (regulatory) approaches will not be sufficient. It is in this context where Experimental Regulation has acquired growing interest. We propose an experimental regulatory framework for innovative NPs and its applications, based on the progressive development of NPs engineering principles based on safe and sustainable guidelines and areas of application (NPs Selection Rules), geared towards its proactive introduction in Society.

AIMS

Within the framework of Experimental Regulation, we propose a Regulatory Innovation Trial (RIT) for NPs:

- Aligned with the EU policy directions included in the EGD and its implementing regulation and based on the Better Regulation System [3];
- Designed to be agile, innovation-friendly, future-proof, evidence-based and resilient [4]
- Focus on new generation NPs (smart nanomaterials) and tailored to capabilities and knowledge of SMEs, micro-enterprises and start-ups.
- Promoting precaution, safety, sustainability and innovation and not just avoiding risk.

HEADLINE

Regulatory Innovation Trial (RIT) for Nanomaterials can be defined as an alternative regulatory framework for NPs, enabling in a real-world environment the testing of innovative regulatory strategies, for a limited time and in a limited part of a sector or area under regulatory supervision. RITs focus on regulation itself as the main object of experimentation and learning (not in socio-technical experiments as is the case with *Regulatory Sandboxes*).

Key Features:

- For NPs excluded (>1Tn/year) or exempted from Registration and/or Authorisation and/or Restriction (Scientific Research and Development –SR&D–, Product Process Oriented Research and Development –PPORD–) from REACH Regulation.
- Focus on smart NPs and its applications (second and third generation NPs) that are currently outside chemical regulatory focus.
- Design based approach to regulation (NPs Selection Rules). SSbD NPs from the lab.
- Voluntary adherence linked to regulatory and non-regulatory incentives.
- Legal certainty for innovators, spotlight for investors, learning space for regulator.
- Fast track approval process after loosing the excluded or exempted status under REACH
- Linked to other non regulatory initiatives (innovation hubs, test beds, nano e-infrastructures).

NPs Selection Rules. As nanotechnology develops, the number of new NP entities may overwhelm the testing possibilities of nanotoxicity. Even more, it cannot be excluded that a seemingly minor variation in the NP characteristics may translate into a dramatically different effect. Thus, a more rational approach for nanotoxicity and nanosafety may consist of identifying and tracking common NP parameters related to their biological effects and describe them in such a way (Selection Rules) that nanoengineers can design safer NPs and NP uses. Knowledge development during last two decades, indicates that nanoparticles may induce unintended or unexpected biological effects. Therefore, it is essential to determine the compositional and morphological parameters of NPs toxicity to enable their safe design and use. After intense research efforts by the scientific community on the toxicity, safety and sustainability, biological and medical effects of NPs, a set of Selection Rules can be identified, indicating principles and ways to design safer NPs.

CONCLUSION

Experimenting an ex-ante approach to regulation centered in the design of innovative safe and sustainable NPs from the laboratory can help to overcome identified problems associated with ex-post risk regulation.

REFERENCES

- [1] COM(2019) 640 final
 [2] The main pillars being the Circular Economy Action Plan –COM(2020) 98 final–, the New Industrial Strategy –COM(2020) 102 final– and the Chemical strategy for Sustainability –COM(2020) 667 final–.
 [3] Better regulation: Joining forces to make better laws –COM(2021) 219 final–.
 [4] Council Conclusions 12683/1/20 REV 1 Brussels, 16 November 2020 (OR. en) 13026/20 BETREG 27

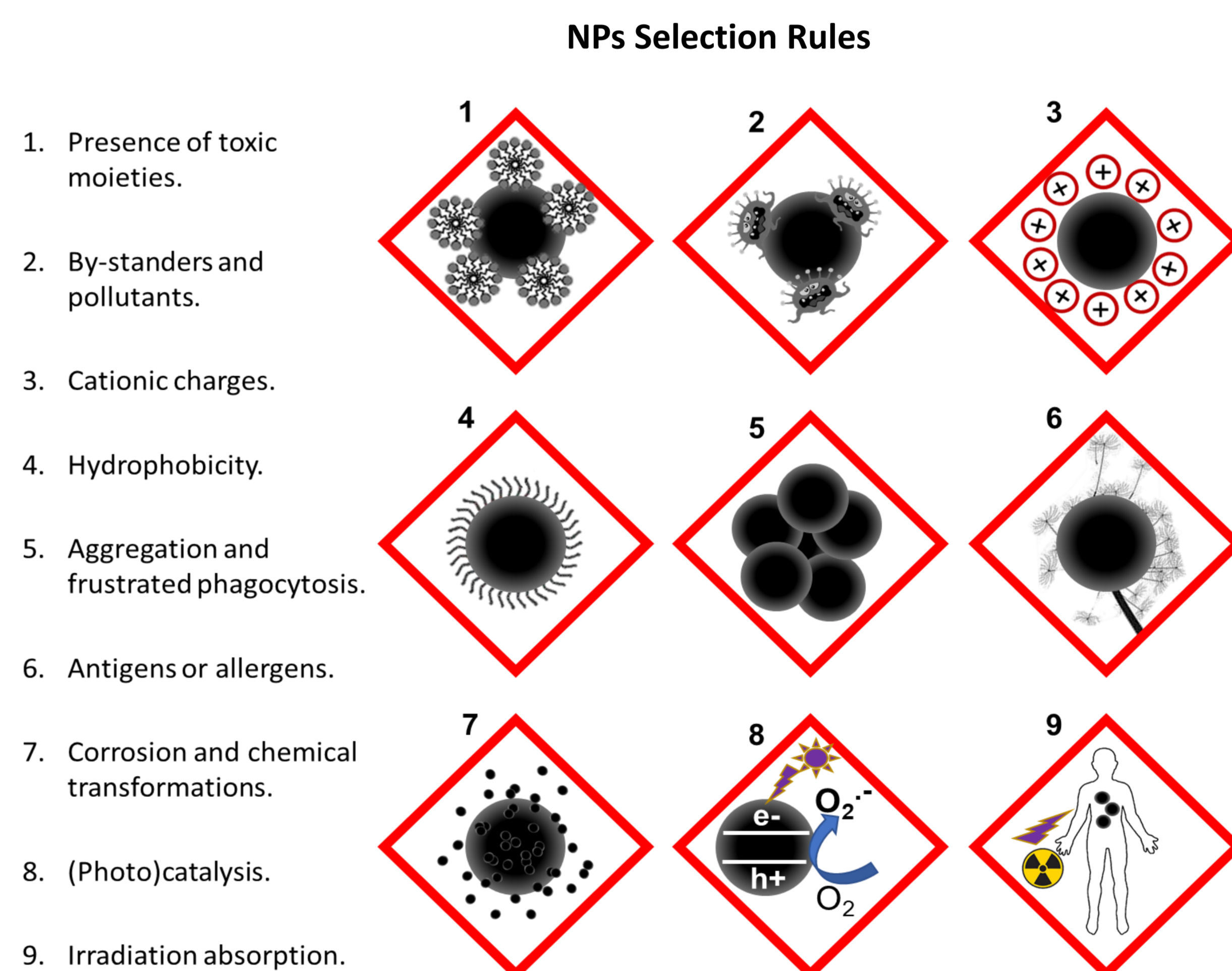


Figure 1. Warning signs for NP risks. A set of advice that can be proposed to NP engineers to produce safer NPs, such as to avoid the presence of toxic moieties (1) or pollutants (2) in the NPs preparation, storage and manipulation; to avoid surface cationic charges (3) and high hydrophobicity (4); to establish measures to prevent uncontrolled NP aggregation to micrometric sizes (5), NP association with allergens (6) and NP dissolution being the NP a reservoir of toxic ions (7); to avoid the interaction with UV radiation in the case of photocatalytic NPs (8) or the uncontrolled irradiation of metal and metal oxide NPs (9).