



Possible modifications of REACH Annexes concerning Nanomaterials (NMs) - subject to pending discussions -

This presentation does not necessarily represent the official position of the European Commission

Outline

- 1. Introduction**
- 2. State of Play**
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- 4. Procedural aspects**
- 5. Concluding remarks**

1. Introduction

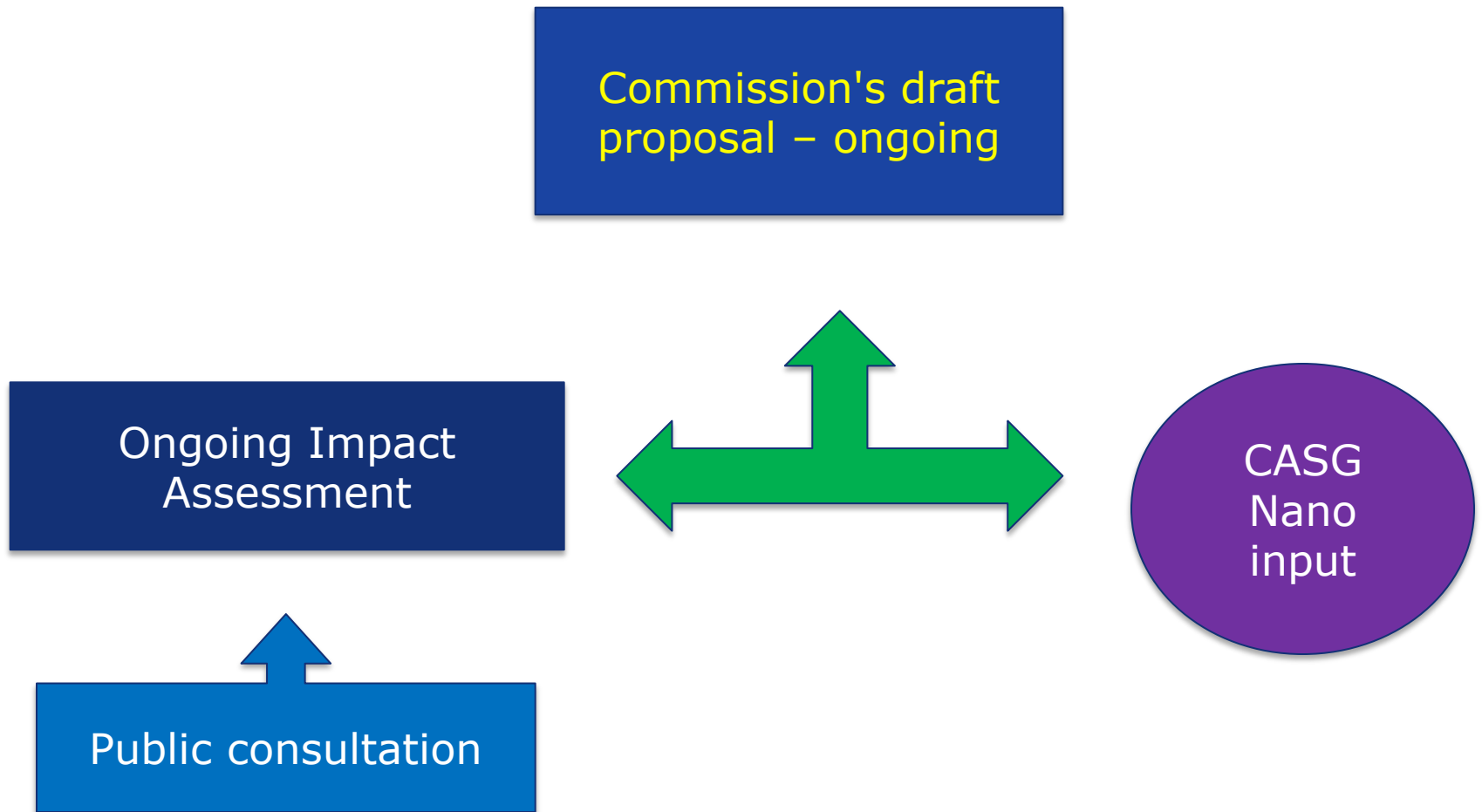
2nd Regulatory Review 2012 concluded:

- **REACH** sets the best possible framework for the risk management of NMs when they occur as substances or mixtures.
- *More specific requirements for NMs within REACH* have proven necessary.

REACH Review 2013 concluded:

- Commission will make an **IA** of relevant regulatory options – in particular **REACH Annexes** - to ensure further clarity on how NMs are addressed and safety demonstrated in registration dossiers.

2. State of Play



3. Possible modifications of REACH Annexes concerning NMs

The possible modifications of REACH Annexes must comply with REACH framework and EU law principles:

- Achieve the objectives of REACH:
 - Ensure high level of protection HH and ENV + promotion of alternative methods for the assessment of hazards
 - Free movement on the internal market
 - Enhance competitiveness & innovation
- The minimum standard information requirements set in accordance with Article 12 & REACH Annexes
- The information requirements must be tiered according to the volumes
- Proportionality

3. Possible modifications of REACH Annexes – pending COM discussions

Annex I

Annex II

Annex III

Annex IV

Annex V

Annex VI

Annex VII

Annex VIII

Annex IX

Annex X

Annex XI

Annex XII

further assessed



Cost & benefit analysis



3. Possible modifications of REACH Annexes – pending COM discussions

Modifications of REACH Annexes in COM non-paper discussed with CASG Nano – comments from MS-CA and stakeholder experts - **under further assessment & discussions:**

- *Annex I – clarifications of some provisions for Nanoforms (NFs)*
- *Annex III – additional criteria for certain NFs*
- *Annex VI – definition of NM included and identification of NFs*
- *Annex VII– adjusted waivers, tests and clarifications for NFs*
- *Annex VIII - adjusted waivers, tests and clarifications for NFs*
- *Annex IX - adjusted waivers, tests and clarifications for NFs*
- *Annex X - adjusted waivers, tests and clarifications for NFs*
- *Annex XI - clarifications of non-testing provisions for NFs*
- *Annex XII - clarifications of CSA/CSR provisions for NFs*



European
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3. Possible modifications of REACH Annexes – procedural aspects

*EP/Council
(3 months)*

Commission adoption

COM proposal
REACH Committee
(PRAC)

WTO (60 days)

IA - IAB

5. Conclusions

Questions & Answers

Thank you

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