



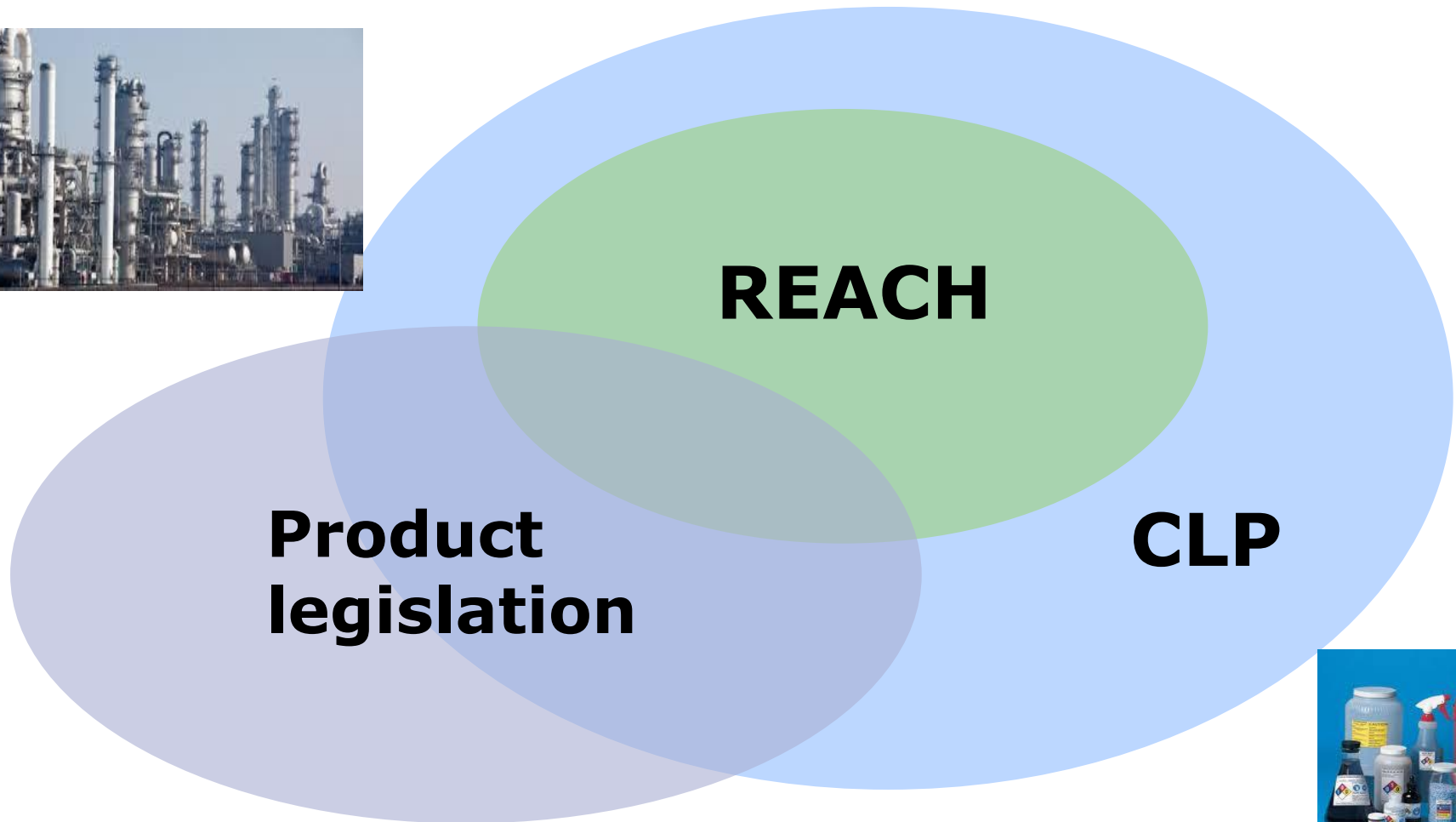
EU activities on Nanomaterials – REACH

-

***Danish 'Better control on nanomaterials'
Initiative, 2012-2015,
Copenhagen, 3 December 2015***

EU COM – M Puolamaa, DG Grow. D1

EU Regulatory Framework for Chemicals





IA on Possible amendment of REACH Annexes for NMs

COM 2nd Regulatory Review 2012

- **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

- 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.**

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 NF and characterisation 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*

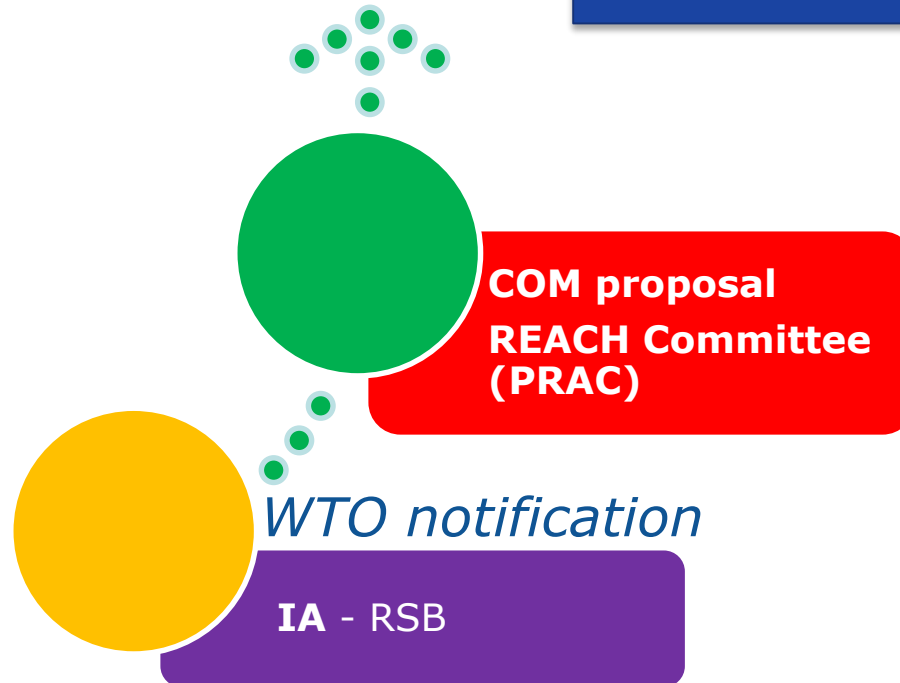


European
Commission

Possible modifications of REACH Annexes – procedural aspects

EP/Council
(3 months)

**Adoption by
Commission**



Key timelines

- **ECHA **Guidance update** on NMs in 2016**
- **Review of NM definition (EC No 696/2011)**
 - **Interservice discussions on-going**
 - **Public consultation, early 2016**
 - **Finalisation, mid 2016**
- **Impact Assessment of REACH Annexes for NMs**
 - **Results shortly**
 - **Implementation will take time**
- **Impact Assessment of Transparency measures**
 - **Results shortly**
 - **Implementation will take time**

Conclusions

REACH applies also to nanomaterials

REACH has a strong emphasis for the use of qualified alternative approaches and methods, also related to nanomaterials

ECHA activities on nanomaterials integrate the developments in science to regulatory risk assessment and guidance updates

OECD activities ensure global harmonisation of adaptation of OECD Test Guidelines and Guidance



European
Commission

Thank you for your attention!

