Precious Metals Consortium



Precious Metals & Rhenium Consortium

Nanos under REACH

31 May 2017 | Pforzheim, Germany

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Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.	Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.
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Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.	

Agenda…or discussion points

1/ What we have & know already

2/ Nanos – inclusion in existing dossier vs separate registration

3/ Consequences of approaches under 1/ for data requirements

4/ Data availability and potential way-forward regarding testing

Nano definition

- EC recommendation on nano definition (2011):
  - ≥ 50% of particles 1-100 nm

  OR

  - Surface area > 60 m^2

→ Number based = very small mass % of nanoparticles can make a material fall into the nano range!

→ Covers also non-intentionally manufactured particles

Nanos in PMC REACH dossiers

- PMC Scope:
  - nanoAg - included in ‘bulk’ Ag dossier (registered in 2010)
  - PMC scope frozen end 2015 – no other nano-forms required registration
  - Numerous discussions @ PMC level about nano-PGMs on the market:
    - nanoAu?
    - PGM blacks?
    - other PGMs?

What we know…

- NanoAg
  - REACH registration:
    - <10 tpa
    - n° registrants ↓↓ than bulk Ag
    - n° uses ↓↓ than bulk Ag
  - NanoAg included in ‘bulk’ Ag dossier
    - Different compositions & classification
    - No detailed phys-chem characterisation (↔ ECHA guidance)
    - Ecotox: nanoAg <= ‘bulk’ Ag
    - Tox: grouping of data nanoAg and ‘bulk’ Ag/Ag cmpds
  - SEv:
    - Dossier currently being updated
    - Data seem to confirm ecotox hypothesis

What we know…

- Earlier efforts to characterize/identify nanoPGMs:
  - Two questionnaires circulated (Sept. 2014 / Feb. 2015), but insufficient feedback received
  - Agreed at March 2015 PGM WG mtg. to conduct coordinated effort to generate data
    - Coordination by PMC
    - Analyses at Quantachrome
  - Formulation development for preparation of suspensions + Fractionation of particles < 200 nm, SSA via BET, Zeta Potenial (electroacoustic), PSD (via Dynamic Light Scattering,) Volume based PSD (via Static Light Scattering), SEM

19 Grades tested, at least 1 Grade considered nanomaterial (Rh cmpd)

What we know…

- Further information:
  - From members:
    - Intentional production of nanoAu
    - Intentional production of at least 1 additional nanoPGM
    - Unintentional production of at least 1 nanoPGM
  - Publications / presentations on nanoPGMs, nanoAu…
  - Use of nanomaterials in catalyst industry?

Strong indications (+ scientific evidence!) for additional nano-dossiers…but how to move on?

Inclusion in existing dossier vs separate registration

- ECHA's view:
  - 'Nano' = part of 'bulk' (cfr. Ag dossier)
  - Data requirements driven by tonnage band of 'bulk' registration dossier
  - Endpoint coverage should be applicable to 'nano' and 'bulk' (e.g. not 1-10 tpa data requirements for nano vs >1000 tpa for 'bulk')

    → via worst-case approach or testing different forms
- Approach questioned by Metals IND (differential data requirements depending on tonnage level nano vs bulk)

Key question: substance ID ?? (~ OSOR principle)

(cfr. PGM black = 'mixture' of metal/oxide/hydroxide)

Consequences of for data requirements

- PMC nanomaterials: kg/year…<10 tpa

  vs tonnage level of ‘bulk’ forms: up to 10-100 tpa

- REACH data requirements Annex VIII significantly higher than Annex VII:

  + short-term repeated dose toxicity (28-day)

  + screening for reproductive/developmental toxicity

  + additional in vitro genetox testing

  + short term fish tox testing / ASRIT

  …

- Depending on registration approach taken (or obligation by ECHA), data requirements for ‘nano’ might be significant!

Data availability and potential way-forward regarding testing

- New ECHA guidances (May 2017)
  - '*How to prepare registration dossiers that cover nanoforms: best practices'*

    […*aim of this document is to provide criteria for distinguishing between different nanoforms and to give a set of elements recommended to be reported on the characterization of nanoforms*.]
  - Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals
    - Grouping nanoforms & non-nanoforms possible if robust/conservative
    - Key parameters:
      - SID: composition + size/shape/surface chemistry/surface area
      - Behavior (e.g. solubility, dustiness, zeta potential…)
      - Reactivity (biological and/or photo(re)activity)
- 'Nano' dossier, or 'nano' as part of 'bulk' dossier?

  → What do we have for potential grouping / Read-Across?

  (cfr. next slides)

Data availability and potential way-forward regarding testing…bioelution testing @ CIMM

	% Solubility in Perspiration fluid	% Solubility in gastric juice
	168 h	2 h
Platinum powder	$1x10^{-4}$	$2x10^{-4}$
Platinum black	0.15	0.05
Palladium powder	0.003	0.32
Palladium black	0.22	18.3
Rhodium powder	$7x10^{-5}$	$7x10^{-4}$
Rhodium black	0.021	0.024
Ruthenium powder	$9x10^{-6}$	$5x10^{-5}$
Ruthenium black	0.005	0.011

Data availability and potential way-forward regarding testing…dustiness testing @ DMT

	Total dustiness	Inhalable fraction	Respirable fraction	MMAD
	(mg/g)	(mg/g)	(mg/g)	(µm)
Platinum sponge	73	42	0,5	31,4
Platinum black	206	157	61	7,4
Palladium powder	284	167	2	30,2
Palladium black	457	269	37	24,1
Palladium monoxide	567	336	6	29,8
Rhodium sponge	263	161	5	26,9
Rhodium black	515	316	16	28,1
Ruthenium powder	49	33	5	20,1
Ruthenium black	401	265	33	21,7

Data availability and potential way-forward regarding testing…TD testing @ Canmet

Loading	Target	Test	Conc				Measured total concentrations (µg/L)						
(mg/L)	pH	duration	at (h)	Pt	PtO2	Pd	PdO	PdO. 2H2O	Pd(OH)2	Rh	Rh2O3	Ru	RuO2
100	6	24-h scoping	24	0,1	107	0,06	0,06	7,6	0,1	0,03	3	0,0	0,9
100	8,5	24-h scoping	24	0,1	101	1,06	1,06	6,5	0,0	0,02	2	0,0	0,17
1	6	28-d definitive	168	/	/	/	/	0,0	0,01				
1	6	28-d definitive	672	0,0	1,3	0,0	0,0	0,0	0,13	0,0	0,0	0,0	0,0
10	6	7-d definitive	168	0,0	12,4	0,0	0,0	8,0	0,21	0,1	0,04	0,0	0,0
100	6	7-d definitive	168	0,08	112,7	0,0	0,0	98,9	0,4	0,0	0,52	0,02	0,08

Data availability and potential way-forward regarding testing

- There is already some evidence available, but significant further work is still required!
  - Investigate & agree on SID
  - Collect available data (if available at all)
  - Develop ITS
  - Perform testing
  - Collect information on uses (manuf – IND uses – others)
  - Include information in dossier

  …



THANK YOU

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