



RIP-oN1: Industry Perspective



Morris Cole
Cristal Global





RIP-oN 1 – Industry Perspective

- **RIP-oN1 objective**
- **REACH text and existing technical guidance**
 - Substance definition / identification
- **Proposed potential identifiers for nanomaterials**
 - are they needed?
 - potential impacts
- **Pre-registration → pre-SIEF → SIEF → Registration**
 - Substance ID ≠ “sameness”
 - TiO₂ case example



RIP-oN 1 – Industry Perspective

Project objective:

Evaluate the applicability of the existing guidance to nanomaterials and, if needed, to develop specific advice on how to establish substance identification of nanomaterials.



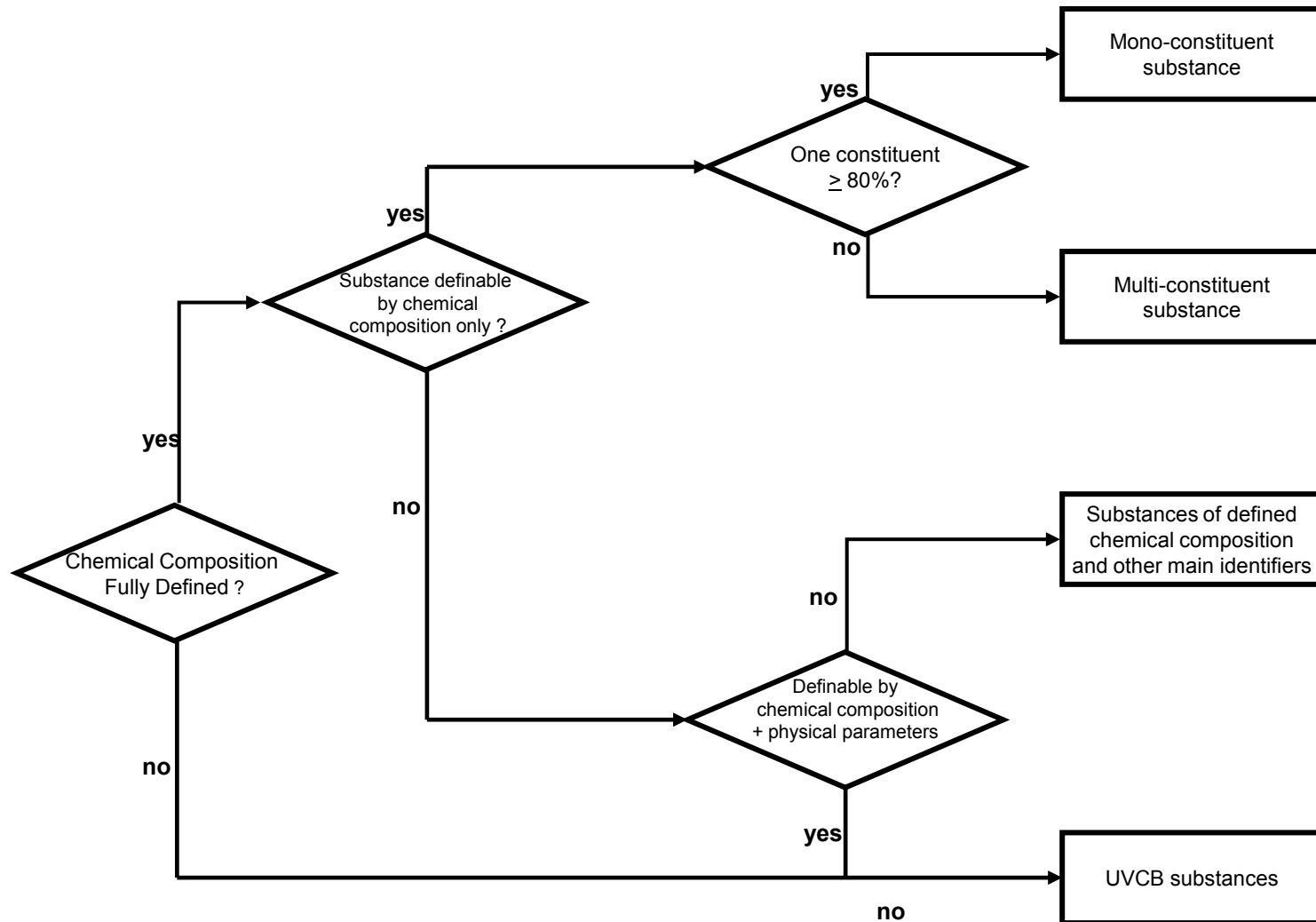
REACH Regulation

- The REACH text defines a substance as...

“A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition” (Art 3(1) of REACH regulation)
- ...and sets out in Annex VI(2) what has to be done to **identify** the substance based on:
 - Name or other identifiers
 - Molecular and structural formula
 - Composition



Chemical composition is the identifier





Chemical composition is the identifier

“A mono-constituent substance is identified by the chemical name and other identifiers (including the molecular and structural formula) of the main constituent and the chemical identity of the impurities and/or additives, and their typical concentration(s) and concentration range(s), which is proven by the spectroscopic and analytical information.”

“A multi-constituent substance is identified by the chemical name and identifiers of the substance as such, and the quantitative and qualitative chemical composition (chemical identity, including the molecular and structural formula) of the constituents, and is proven by analytical information.”

Guidance for identification and naming of substances, 4.2.1.2, p23 & 4.2.2.2, p25
http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

Potential identifiers proposed in RIP-oN1 project group



Potential identifier	Case study addressing a given property / parameter			
	TiO ₂	CaCO ₃	Ag	CNT
Physico-chemical properties				
Size	X	X	X	X
Solubility/dispersibility	X	X	X	X
Photo-catalytic and optical properties	X		X	
Surface energy / redox radical formation				
Density	X			X
Geometrical parameters				
Agglomeration/aggregation	X		X	X
Specific surface area	X	(X)	X	X
Shape	X		X	X
Other potential identifiers / issues discussed, but considered outside the scope of the RIP-oN1 project				
Purity	X			X
Crystal phase	X			
Lattice doping	X		X	
Surface treatment	(X)			

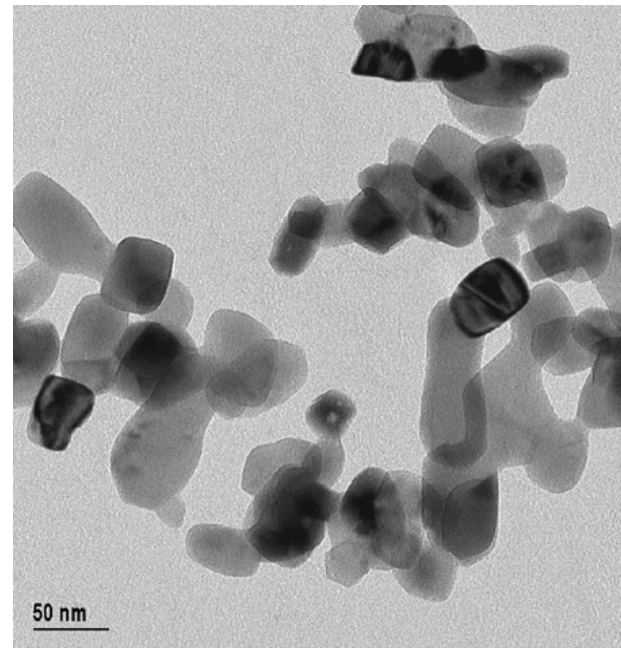
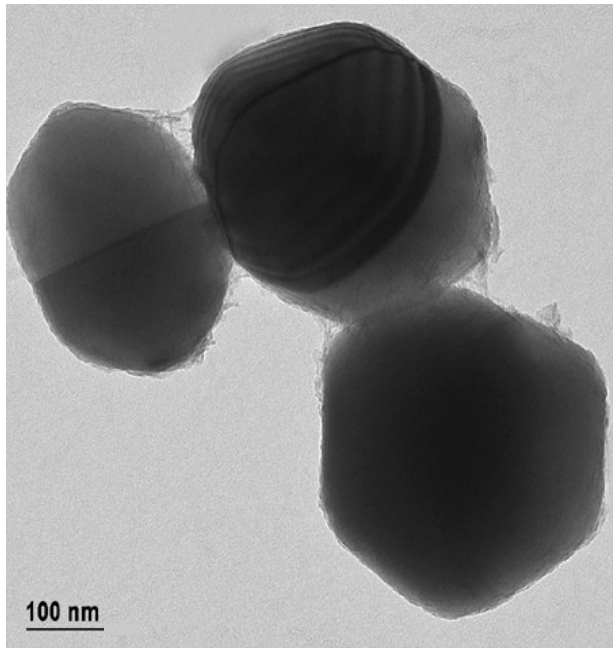


**Whatever we do to its physical form
it's still silver, Ag !**





And these TiO_2 examples are not different chemical substances!



Same molecule, same chemical identity, same substance



Is size an identifier?

- **Size is NOT an identifier**
- 'Substance' in REACH is defined as any chemical element and its compounds in the natural state or obtained by any manufacturing process.
- Size is not an intrinsic property but is a physical property which can be engineered and modified without affecting the chemical composition of a substance, i.e. its identity.
- CLP regulation does recognise that different physical forms of a substance could influence the hazard properties.
- Accordingly, size must be considered as part of the information requirements and when performing a safety assessment, and determining the appropriate classification under CLP.

And this is consistent with established chemicals management policy



Manual of Decisions¹ "*substances in nanoform which are in EINECS (e.g. titanium dioxide) shall be regarded as existing substances, and substances in nanoform which are not in EINECS (e.g. carbon allotropes other than those listed in EINECS) shall be regarded as new substances*".

US EPA² "TSCA Inventory Status of Nanoscale Substances - General Approach" : A nanomaterial will be deemed a new chemical only if the molecular identity of the nanoscale substance differs from the molecular identity of any of the substances already listed in the Inventory.

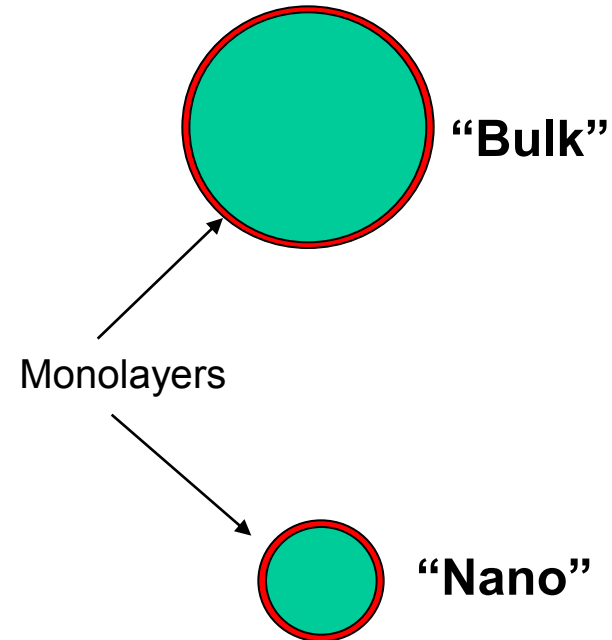
¹ http://ecb.jrc.ec.europa.eu/esis/doc/Manual_of_decisions.pdf

² <http://www.epa.gov/oppt/nano/nmsp-inventorypaper.pdf>



Surface treatment of nanoparticles

- The technique of surface treatment does not change the identity of the substance.
- Exemption made by ECHA in their FAQ 6.3.8 from registering surface treated substances separately under REACH.
- The example of the surface modification of silica with an organosilane was used as an illustration in early drafts of the ECHA FAQ 6.3.8.
 - *Surface treatment is a 2 dimensional modification of the surface of the particle. It is known that with decreasing particle size the surface of the particle increases, nevertheless, as long as the reaction (treatment) is of the surface-treating agent with the functional groups of the surface, the surface treatment remains a minor part of the particle.*





RIP-oN 1: Major impacts of new identifiers

- Cefic impact assessment underway
 - Number and cost of separate registration dossiers, in terms of fees, in particular for SMEs, compared to the current system;
 - Cost of additional testing requirements of identifying several distinct/new substances with the same CAS No.;
 - Increase in number of animal tests needed to comply with a distinct/new substance;
 - Consequences with regards to, for example, information to workers, added value to workplace safety and how to deal with reformulations;
 - Consequence for implementation of downstream regulations (Seveso, waste, air, water, soil) if volume changes due to identification of several distinct/new substances with the same CAS No. and
 - Comparison with the rest of the world.
- Target for report: October 2011

What does this mean for the REACH registration process?



- Purpose of REACH is to ensure that identified uses of a substance are safe.
- Multiple SIEFs and therefore registrations for different physical forms of the same substance are not required
 - The SIEF must address different information requirements, safety measures, Chemical Safety Assessments (RIP-oN2 and RIP-oN3) and CLP classification.
- For example: the SIEF may submit more than one classification if different size forms result in different hazards.



Substance ID \neq “Sameness”

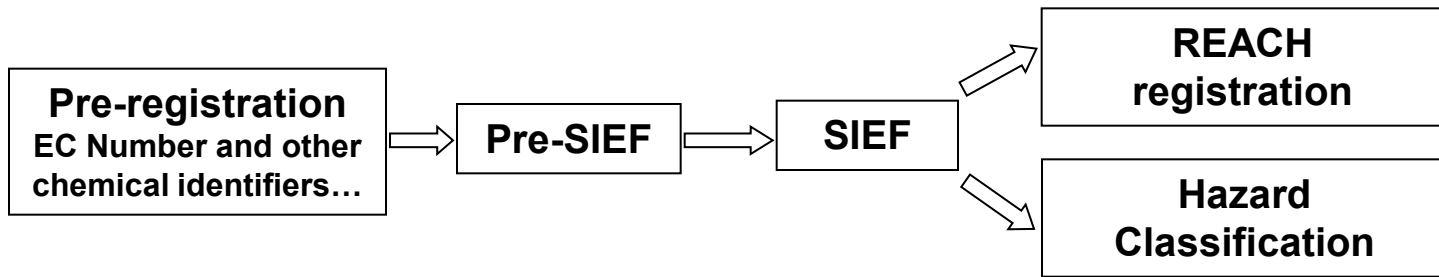
- “...the REACH Regulation does not define “sameness” and it does not foresee any formal step to confirm the establishment of sameness and the formation of a SIEF.”
- “The assessment of the exact nature of an EINECS entry and the different substances it may cover **can only be carried out by the Manufacturers or Importers who should be aware of the composition of the substance.** It is, therefore, up to them to take the responsibility of defining precisely the substance for which a SIEF will be formed.”
- “For substances with a well-defined composition (i.e. mono-constituent and multi-constituents substances) the sameness of the naming is in principle sufficient to be able to share data even though certain impurities might lead to a different classification/hazard profile. Only in cases where all data is clearly not suitable for the other substance these substances can be regarded as different (e.g. in case of very different physical properties which have essential impact on the hazard properties, like water solubility).”

Guidance on data sharing, 4.5, p34-5;

http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf

Registration process

Example: Titanium dioxide



4,483 pre-registrants

Name	EINECS no.	CAS no.
Titanium dioxide	236-675-5	13463-67-7
Rutile (TiO ₂)	215-282-2	1317-80-2
Anatase (TiO ₂)	215-280-1	1317-70-0
All sizes, surface treatments.....		

**TiO₂ dossier with
shared data and CLP
assessment covering
all forms.
(all non-hazardous)**



RIP-oN1: Industry Conclusions

- Substance identification = molecular identity
- REACH Annex VI (2) (*“Identification of the substance”*) already applies to nanomaterials: neither size nor other properties should be added
- Physico-chemical and other properties may differ for nano-scale forms of substances: these differences should be accounted for in information requirements, safety measures and Chemical Safety Assessments (RIPoN2 and 3), and CLP



RIP-oN1 – Industry Perspective

Thank you.