



# Nanomaterials & Scientific Committee on Consumer Safety: Overview with Focus on nano-hydroxyapatite and Silica

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# Background & Purpose

FDA-cosmetic*	SCCS
FDA-food	EFSA
FDA-drug	EMA
EPA-chemical	ECHA
EPA-pesticide	ECHA

## Talk Outline:

- Background
- 2013-2016 Overview
- Nano-HAP: SCCS & FSANZ
- Silica, Solubility & EU Research Project Input
- VSSA & EU Research Project Input
- Observations/Suggestions



Barnes Foundation

# Broader Context

- Epistemic Community
    - *a network of experts;*
    - *shared set of normative & principled beliefs;*
    - *shared causal beliefs*
    - *shared notions of validity ..; and*
    - *“a common policy enterprise”*
1. Is the SCCS an epistemic community for nanomaterials?
  2. If not, why not? (is there a role for us?)
  3. How do they ‘learn’?

# SCCS Role/Obligation/Responsibility

“nanomaterial” means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm’

- What is insoluble/soluble?
- What is biopersistent?
- Is there an exemption to testing & labeling?
- Is there only an exemption to labeling?

# SCCS

- Members:
  - 10 tox; 1 each from pathology; biochemistry; physics; chemistry + ***Secretariat***
  - Working Group on Nanomaterials
- Process
  - Mandate from the Commission
  - Template-based dialog with Submitters
  - Draft Opinion & conduct public commentary
  - Final Opinion to Regulators
  - EU Parliament approval to be in the Annex

# 2013-2016 Summary

Year	Hair Dye	Cosmetics	Fragrance	Nano-material	Other	Statements
2013	6	9	0	4	0	2
2014	5	9	1	1	1	2
2015	10	8	2	3	2	3
<b>Total</b>	<b>21</b>	<b>26</b>	<b>3</b>	<b>8</b>	<b>3</b>	<b>7</b>
# Minority	0	0	0	0	0	0
# Insufficient	4	2	2	3	n/a	n/a
# Inorganic	1	2	0	6	n/a	n/a

~22 actions/yr (16-23 Opinions)

40% of insufficient are inorganic

Never a minority report

27% of insufficient are nano

8 are nano (14% of 58 Opinions)

67% of inorganic insufficient are nano

# Hydroxyapatite (HAP-nano)

- Product uses considered by SCCS
  - Recalcification in Toothpaste (UltraDEX®<sup>®</sup>, Remin®) & Mouthwash
- FK Background
  - HAP as chromatographic material
  - HAP Deliberately formed in boilers
  - HAP inhibited in cooling tower corrosion (replaced chromate)
  - Hydrated silica in toothpaste

# Comments & Responses

## SCCS: Needles & Buccal Cells

Suggested Action	SCCS Response
1. Discontinue VSSA as a specification in light of recent analyses by the JRC and others	Your comments regarding the use of <u>VSSA</u> have ignored the fact that it was never proposed as the main ‘defining’ criterion for a nanomaterial.
2. Re-examine the use of zeta potential measurements in characterizing particles	Similarly, <u>zeta potential</u> provides important information on the surface characteristics of a material and hence this information is essentially required for safety assessments as recommended by numerous bodies dealing with safety of nanomaterials.
3. Consider biodurability rather than <u>biopersistence</u> as the concept coming closest to the Committee’s interests	..but their concerns have been over the possibility and the (yet unknown) extent of absorption of HAP in nanoparticle form through the mucous membrane in the oral area
4. Indicate that..there are pertinent issues regarding HAP chemistry in a physiological context... especially cellular and gastric solubility	Your suggestions about the potential dissolution/ <u>solubility</u> of HAP in the GI tract are appreciated. The SCCS is however <u>already aware</u> of these aspects..,
5. Acknowledge that HAP is a physiological particle.. ...ingested HAP poses a modest incremental risk.	Not addressed.

# Role & Responsibilities

- Proposed that the SCCS should take advantage of its ‘role’ to anticipate actions useful to RRI:
- *“As such it is the responsibility of the Applicants to provide (and they do provide) scientifically based evidence from all relevant angles in support of safety of their materials/products. Your suggestions should therefore be more appropriate to be directed to the industry who may find them helpful in preparing a better case for future assessments.”*

# Food Safety Australia New Zealand

- nano-HAP & needles found in infant formula by NGO citing SCCS & ‘pretense’ of past FSANZ assurances
- FSANZ responded on their ‘role’ and regarding SCCS “*the studies were specifically focused on dental applications, and don’t consider the solubility of the material in the gut*”
- SCCS concerns on buccal cells & needles is pertinent to infants feeding 4-5 times daily for ~20 min.
- FSANZ did not mention if they were notified by manufacturers of changes in raw materials; a form of regulatory capture.

# Amorphous Silica & EU Project Input

- Silica and HAP Opinions processed in 2015; in both solubility raised regarding >100 mg/L as “soluble”
- ASASP approached EC leading to a new mandate
  - NANOGENOTOX, PROSPEcT, NANoREG, ENPRA data mentioned in 2<sup>nd</sup> Opinion
  - ASASP had incorrectly calculated units in USP report
  - SCCS accepts <100 mg/l is ‘insoluble’; 100-1000 mg/L is ‘very slightly soluble’; and silica is not “soluble”
  - SCCS context is “the cosmetic formulation” not physiological conditions or the toxicity test’s medium.
- EU project results used when answering a p-chem question, probably introduced through JRC

# VSSA & EU Project Input

- From Kreyling, simple BET and density with a  $60 \text{ m}^2/\text{cm}^3$  “*universal cut off*”
- NanoDefine (9.3 million €): “*cut off*” not universal, need TEM & He-pycnometry, and porosity to achieve 70% reliability
- SCCS not citing NanoDefine in nano-Ag-Opinion until FK’s comments, not in 10/2019 Guidance; Kreyling is “*primary reference*”
- SCCS unaware of progress in EU projects; only regulator to use VSSA

# FK Opinion

- SCCS & HAP (nano) - Disagree
  - HAP not new to world, nature or humans;
  - Toothpaste exposure is episodic;
  - Silica (nano) used in toothpaste
- FSANZ & HAP (nano)
  - Agree on overall analysis for adults
  - Weak on supply chain oversight for infants
- SCCS & Silica (nano)
  - Deserved a Minority Report

# Observations

- SCCS is not a nanomaterial epistemic community
  - Not using discretion; not ‘pursuing a policy enterprise’
- If not, why not?
  - Chemistry through the lens of toxicologists and risk community (Society of Risk Analysis); disciplinary capture
  - Template-driven & using disputed p-chem parameters
  - Legal ‘standing’ narrows dialog to submitters’ knowledge
- Can we help?
  - Harmonize core tests, e.g. genotox, across all agencies
  - Initiate SCCS/SRA/EU research community dialog on general topics, e.g. solubility, GI tract, biodurability
  - Separate specifications used to assure product uniformity from parameters of interest to toxicology

# Labeling

*INGREDIENTS: Sorbitol, Aqua, Hydrated Silica, Sodium Lauryl Sulfate, PEG-12, Aroma, Cellulose Gum, Sodium Fluoride, Sodium Saccharin, Glycerin, Limonene, CI 42090.*

- No (nano) after hydrated silica
- UltraDEX® Recalcing toothpaste for sale at Dent-O-Care; no (nano) after hydrated silica or hydroxyapatite

# Citations I

Slide	References
2	<ul style="list-style-type: none"><li>• Haas PM (1992) Introduction: epistemic communities and international policy coordination. <i>International Organization</i> 46(1): 1-35. <a href="http://www.jstor.org/stable/2706951">http://www.jstor.org/stable/2706951</a></li></ul>
3	<ul style="list-style-type: none"><li>• European Commission (2009). Regulation (EC) No 1223/ 2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. <i>Off. J. Eur. Union (EN)</i> 52, 59–209. L342</li></ul>
6-8	<ul style="list-style-type: none"><li>• SCCS (2016) Opinion on hydroxyapatite (nano). Revision of 16 March 2016, SCCS/1566/15</li></ul>
9	<ul style="list-style-type: none"><li>• Lyons K, Smith N (2017) Governing with Ignorance: Understanding the Australian Food Regulator’s Response to Nano Food. <i>Nanoethics</i> (2018) 12:27–38. <a href="https://doi.org/10.1007/s11569-017-0309-2">https://doi.org/10.1007/s11569-017-0309-2</a></li><li>• Booth M (2018) Response to Article 309, <i>Nanoethics</i> 12(2):173. <a href="https://doi.org/10.1007/s11569-018-0320-2">https://doi.org/10.1007/s11569-018-0320-2</a></li><li>• Schoepf JJ, Bi Y, Kidd J, Herckes P, Hristovski K, Westerhoff P (2017) Detection and dissolution of needle-like hydroxyapatite nanomaterials in infant formula. <i>NanoImpact</i> 5: 22-28.</li></ul>
10	<ul style="list-style-type: none"><li>• SCCS (2015) Opinion on Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) 20 March 2015, SCCS/1545/15, revision of 29 September 2015.</li><li>• SCCS (2019) Opinion on solubility of Synthetic Amorphous Silica (SAS), 20-21 June 2019, SCCS/1606/19</li><li>• Klaessig, FC (2018) Dissolution as a paradigm in regulating nanomaterials. <i>Environ Sci Nano</i> 5: 1070–1077. DOI: 10.1039/c7en01130j.</li></ul>

# Citations II

Slide	References
11	<ul style="list-style-type: none"><li data-bbox="407 382 1715 448">• Kreyling WG, Semmler-Behnke M and Chaudhry Q (2010) A complementary definition of nanomaterial.</li><li data-bbox="407 454 768 488">• Nano Today 5:165–168</li><li data-bbox="407 494 1785 602">• Wohlleben W, Mielke J, Bianchin A, Ghanem A, Freiberger H, Rauscher H, Gemeinert M, Hodoroaba V, (2017) Reliable nanomaterial classification of powders using the volume-specific surface area method. J Nanopart Res, 19: 61</li><li data-bbox="407 608 1644 642">• SCCS (2018) Opinion on Colloidal Silver (nano), 21 February 2018, SCCS/1596/2018</li></ul>

# Thank You

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