SAFER
CONSUMER
PRODUCTS

# California’s Safer Consumer Product Regulations:

## A Regulatory Framework That Includes Nanomaterials


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(Retired))

Department of Toxic Substances Control

Cal/EPA

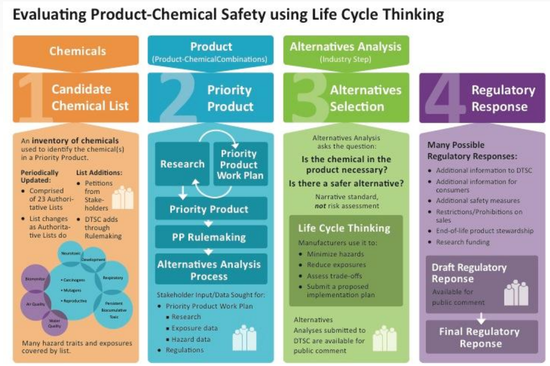
# Disclaimer


Opinions presented today are those of the presenter.

The policy approach of the California Green Chemistry Initiative, Safer Consumer Products Regulations & the California chemical data call-in continues to evolve through stakeholder input and constant policy review.

Therefore, what you hear today may not represent a final position, policy or approach of the Administration.

# Presentation Outline




- Overview: Safer Consumer Products Regulations (SCPR)
- Brief Description:
  - Candidate Chemical (focus on nanomaterials)
  - Priority Product Selection Process

# Prevention or Cure ?

Artwork by Jean Henri Gaston Giraud (1938-2012)

# Two Regulatory Tools

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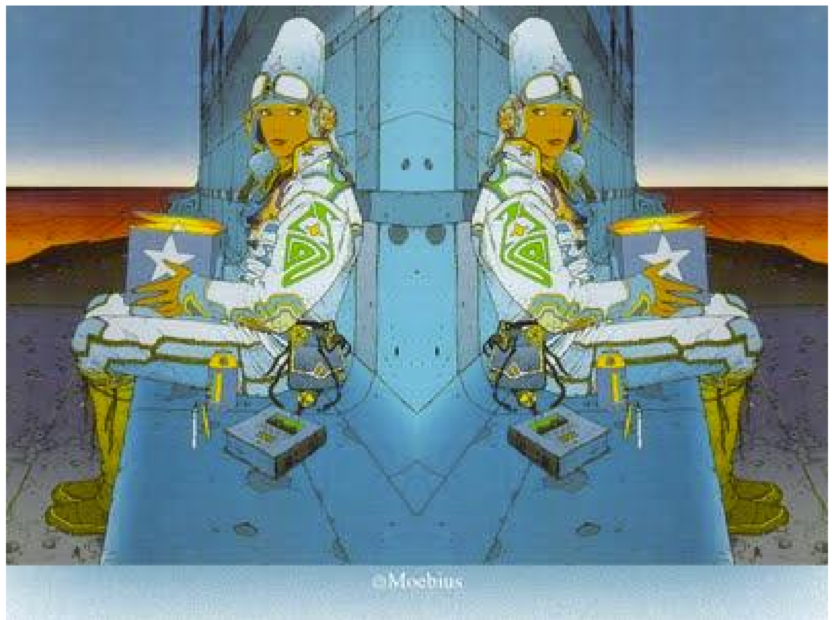
**California's Chemical Data Call-in (AB 289)**




Artwork by Jean Henri Gaston Giraud

**California's Safer Consumer Products Regulation (AB 1879 & SB 509)**


Neither process is nanomaterial focused or limited !

# The Goals

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## California's Safer Consumer Products Regulation


***Drive markets to make safe chemistry fundamental to product design.***

- *Reduce exposure*
- *Reduce or eliminate chemical hazards*
- *Look at full product lifecycle*
- *Encourage reformulation/innovation*
- *Avoid regrettable substitutes*

***Asks questions?***

- ***Is this chemical necessary?***
- ***Is there a safer alternative?***

# Nothing is ever simple!

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Toxic Substances Control

## Evaluating Product-Chemical Safety using Life Cycle Thinking


**California's Safer Consumer Products Regulation**


# 1. Candidate Chemicals

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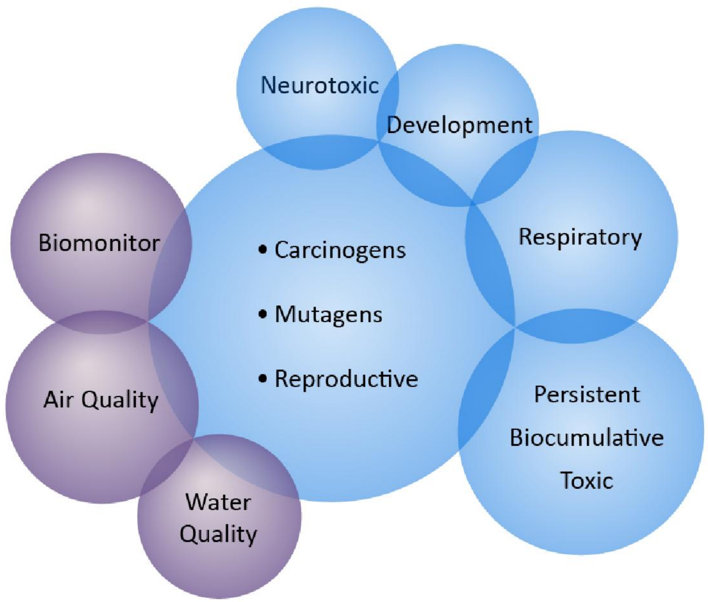
Toxic Substances Control




## 23 Authoritative Lists referenced

- 8 exposure potential lists (NHANES, CA Biomonitoring)
- 15 hazard trait lists (Prop 65, IARC)

## Exclusions

- Pesticides, prescription drugs, and their breakdown products
- Radioactive chemicals
- Natural toxins

~2,300 Chemicals http://www.dtsc.ca.gov/SCP/ChemList.cfm


# 2. Product Selection

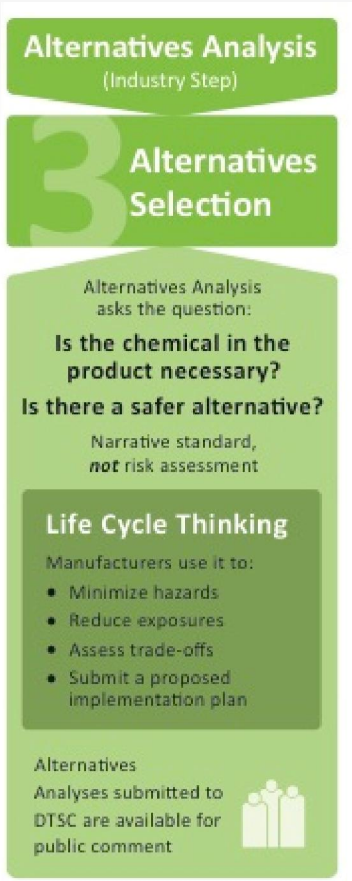
California Department of
Toxic Substances Control

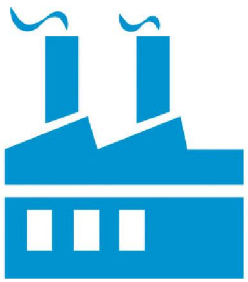
- **Prioritization Principles for Picking Products:**
  - Potential **exposure** to the Candidate Chemicals in the product

**plus**

  - Potential for exposures to contribute to or cause **significant or widespread adverse impacts**

# 3. Alternatives Analysis



## Answers key questions

- Is it necessary?
- Is there a safer alternative?
- Have regrettable substitutes been avoided?
- All relevant impacts throughout life cycle considered?

## Life cycle thinking informs

- Regulated entities' decisions
- DTSC's regulatory response

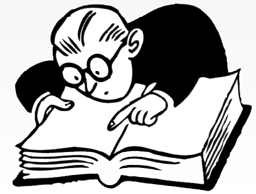
http://www.collierscanada.com/~/media/Images/Offices/Saskatoon/industrial-icon-2.ashx

# 4. Regulatory Responses

California Department of
Toxic Substances Control

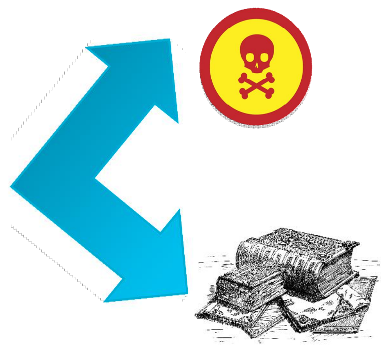

- No response
- Additional information to DTSC
- Additional information to consumer
- Additional safety measures
- Restrictions/Prohibitions on sales
- End-of-life product stewardship
- Research funding


# Define, Define, Define !



"Chemical"

**(Define)**



Hazard Trait ?

Authoritative List ?


approach was to include a definition of "nanomaterials" to be explicit about authority.

http://images.clipartpanda.com/definition-clipart-Look_It_Up_clip_art_hight.png

# Outrage about our thoughts on size !!!!!

IEEE SPECTRUM

## How Will Regulations on Nanomaterials Be Enacted?

By Dexter Johnson
Posted 8 Sep 2010 | 13:27 GMT

It is in California where the regulations look to be the most advanced. The most controversial bits of California’s regulatory project have been the definition of nanomaterials offered by California’s Department of Toxic Substances Control (DTSC), which considers “materials under 1,000 nm to be nanoscale rather than the more commonly accepted 100 nm.” When this definition is coupled with the view of California’s Office of Environmental Health Hazard Assessment (OEHHA) that “all nanomaterials will be considered hazardous” the broad range of regulations that could come forth is staggering.

The prospect of states determining the regulations of nanomaterials on a state-by-state basis, which in turn will decide the fate of nanomaterials’ commercial prospects, seems as though it should be a somewhat scarier proposition for producers.

# OK.. will not be based upon size!

European Commission (EC), *Public consultation document. Commission recommendation of (...) on the definition of the term "nanomaterial".* (2011).

"Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

**What about 100.1 nm?**

# Cannot rely upon CAS Numbers:

- Chemical Abstracts Service (CAS) leads to some confusion.

A division of the American Chemical Society

- Carbon black (1333-86-4) and fullerene (C60) (99685-96-8) each given different CAS #'s from that of elemental carbon (7440-44-0).

**BUT**

Nano-Ag, nano-TiO2, and nano ZnO given same CAS #'s as their macro-scale counterparts.

# Will the "new" TSCA help?

- U.S. EPA has traditionally interpreted TSCA definition of "chemical" to be about <u>chemical structure</u>.

- Unable to distinguish between nano-scale & macro-scale materials.

# "Nanomaterials…" are just "chemicals!"

http://img.izismile.com/img/img4/20110517/640/brilliant_wall_portraits_640_01.jpg

"Chemical" = any organic or inorganic substance of a particular <u>molecular identity</u>, including any combination of such substances occurring, in whole or part, as a result of a chemical reaction or occurring in nature, or any element, ion, or uncombined radical.

**Regulations Text**

**DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS**
**CHAPTER 55. SAFER CONSUMER PRODUCTS**

**DEPARTMENT OF TOXIC SUBSTANCES CONTROL REFERENCE NUMBER: R-2011-02**
**OFFICE OF ADMINISTRATIVE LAW NOTICE FILE NUMBER: Z-2012-0717-04**

No explicit inclusion or exclusion of nanomaterials..
So no need to define.. !


# "Molecular Identity"!

"Molecular identity" = the <u>physical and chemical characteristics of the substance</u>, including its chemical structure and composition, size and size distribution, shape and surface structure, reactivity, and any other properties that may be relevant to whether the substance is a potential chemical of concern.

- Goes beyond **SIZE**.

- Able to distinguish between macro-scale and nano-scale materials.

- In terms of regulatory approaches: useful beyond nano to other future novel materials in the marketplace.


# With “Molecular Identity” … no need to focus only on size.

“Chemical” means either of the following:

1. An organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity; or

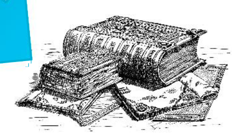
1. Agglomeration state;
2. Bulk density;
3. Chemical composition, including surface coating;
4. Crystal structure;
5. Dispersability;
6. Molecular structure;
7. Particle density;
8. Particle size, size distribution, and surface area;
9. Physical form and shape, at room temperature and pressure;
10. Physicochemical properties;
11. Porosity;
12. Solubility in water and biologically relevant fluids;
13. Surface charge; and
14. Surface reactivity.

http://dereksemmler.com/images/fingerprint06.jpg


# How does a "Chemical" get DTSC's interest (initially)?

**Hazard Trait**

"Chemical"



Authoritative List

Candidate Chemical List*

* Chemicals can also be added by new regulation


# What is a … "hazard trait?"

**DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS**
**CHAPTER 54. GREEN CHEMISTRY HAZARD TRAITS FOR CALIFORNIA'S TOXICS INFORMATION CLEARINGHOUSE**

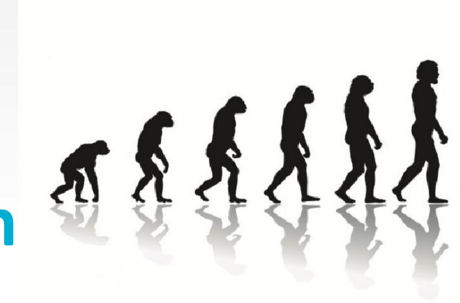
**Table of Contents**

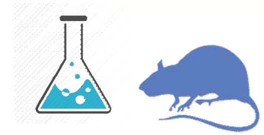
**Chapter 54. Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data**


# Hazard Traits

- Hazard Traits and Endpoints
  - 5 Major Hazard Trait Categories
    - *Toxicological: Carcinogen, Developmental & Reproductive*
    - *Other Toxicity: Organ, Tissues*
    - *Environmental: Domestic, Wild Life, Sewage Treatment*
    - *Exposure Potential: Ozone, Bioaccumulative, Mobility*
    - *Physical: Flammability*


# Evolution in Regulatory Approach
# Consideration of "Hazard"





**§ 69403.15 Reactivity in Biological Systems**

(a) The reactivity in biological systems hazard trait is defined as the occurrence of rapid reactions with molecules in the body that lead to alterations in critical molecular function and ultimately adverse health outcomes.

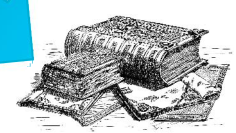
(b) Toxicological endpoints for reactivity in biological systems include, but are not limited to: covalent binding to or oxidation of cellular macromolecules; *in vivo* generation of reactive oxygen species or oxidative stress; catalytic generation of hydroxyl radicals *in vivo*.

(c) Other relevant data include, but are not limited to: *in vitro* measurements of covalent binding to or oxidation of DNA, lipids or proteins; detection of reactive species in cell culture; structural or mechanistic similarity to other chemical substances that are reactive in biological systems.


# How does a "Chemical" get DTSC's interest (today) ?

"Chemical"

Hazard Trait

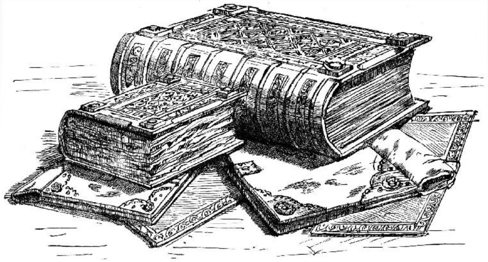


**Authoritative List**

Candidate Chemical List*

* Chemicals can also be added by new regulation


# Sources for Authoritative Lists (23)



**Hazard Trait Related**

- State: OEHHA
- Federal: ATSDR, IRIS, NTP
- International: EC CLP

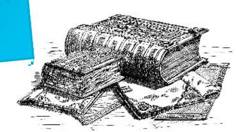
**Exposure Related**

- Biomonitoring
- Water
- Air


# List to include Nanomaterials (the future!)

“Chemical”

## Hazard Trait



## Authoritative List

1

## Candidate Chemical List*

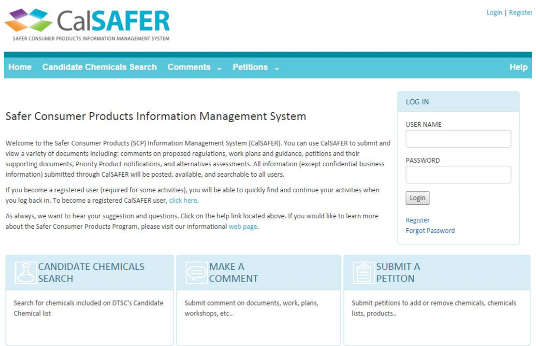
2

* Chemicals can also be added by new regulation

- Nominations through Petitions-Rule Making
- State added-Rule Making
- Changes in Dynamic List-No Rule Making
- Changes in Dated List-Rule Making
- Hazard only


# You can nominate Nanomaterials & Products !

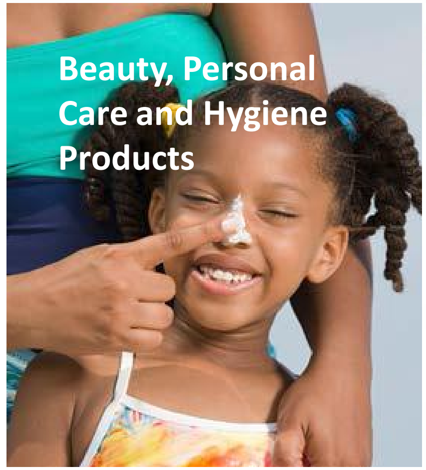
Petition:




- DTSC has Discretionary Authority
- Exclusions
  - Pesticides, prescription drugs, food
  - Non-chemicals

http://www.paramountfitness.co.uk/wp-content/uploads/2014/04/You.jpg


# Potential Product Classes



Beauty, Personal Care and Hygiene Products

usehold/Offic
e
Furniture/
Furnishings

Building Products – Paint Products, Adhesives, Sealants, Flooring

Fishing and Angling Equipment

Office Machinery Consumable Products

Clothing

Cleaning Products

# Current Policy Priorities for Product Selection



- Clear pathways for exposure to Candidate Chemicals
- Contain chemicals detected in biomonitoring studies
- Contain chemicals observed in indoor air/dust
- Impact children or workers
- Contain chemicals that may adversely impact aquatic resources or observed in water quality monitoring


# Beauty, Personal Care and Hygiene

- Products are applied directly to body
- Volume and frequency of use
- Ingredients are not always disclosed
- Biomonitoring
- Potential impacts on aquatic environment
- Examples:
  - Body wash and soaps
  - Lotions
  - Deodorants
  - Nail care products


# TiO2:

# Potential Hazard Traits

Hougaard *et al. Particle and Fibre Toxicology* 2010, **7**:16
http://www.particleandfibretoxicology.com/content/7/1/16

PARTICLE AND FIBRE TOXICOLOGY

RESEARCH Open Access

## Effects of prenatal exposure to surface-coated nanosized titanium dioxide (UV-Titan). A study in mice

Karin S Hougaard*[1], Petra Jackson[1,4], Keld A Jensen[1], Jens J Sloth[2], Katrin Löschner[2], Erik H Larsen[2], Renie K Birkedal[1], Anni Vibenholt[1], Anne-Mette Z Boisen[1,2], Håkan Wallin[1,3] and Ulla Vogel[1,2,4]

**Abstract**

**Background:** Engineered nanoparticles are smaller than 100 nm and designed to improve or achieve new physico-chemical properties. Consequently, also toxicological properties may change compared to the parent compound. We examined developmental and neurobehavioral effects following maternal exposure to a nanoparticulate UV-filter (UV-titan L181).

**Methods:** Time-mated mice (C57BL/6BomTac) were exposed by inhalation 1h/day to 42 mg/m$^3$ aerosolized powder (1.7·10$^6$ n/cm$^3$; peak-size: 97 nm) on gestation days 8-18. Endpoints included: maternal lung inflammation; gestational and litter parameters; offspring neurofunction and fertility. Physicochemical particle properties were determined to provide information on specific exposure and deposition.

**Results:** Particles consisted of mainly elongated rutile titanium dioxide ($TiO_2$) with an average crystallite size of 21 nm, modified with Al, Si and Zr, and coated with polyalcohols. In exposed adult mice, 38 mg Ti/kg was detected in the lungs on day 5 and differential cell counts of bronchoalveolar lavage fluid revealed lung inflammation 5 and 26-27 days following exposure termination, relative to control mice. As young adults, prenatally exposed offspring tended to avoid the central zone of the open field and exposed female offspring displayed enhanced prepulse inhibition. Cognitive function was unaffected (Morris water maze test).

**Conclusion:** Inhalation exposure to nano-sized UV Titan dusts induced long term lung inflammation in time-mated adult female mice. Gestationally exposed offspring displayed moderate neurobehavioral alterations. The results are discussed in the light of the observed particle size distribution in the exposure atmosphere and the potential pathways by which nanoparticles may impart changes in fetal development.

ELSEVIER

Available online at www.sciencedirect.com
ScienceDirect

Chemosphere 67 (2007) 160–166

CHEMOSPHERE

www.elsevier.com/locate/chemosphere

## Enhanced bioaccumulation of cadmium in carp in the presence of titanium dioxide nanoparticles

Xuezhi Zhang [a], Hongwen Sun [a,*], Zhiyan Zhang [a], Qian Niu [a], Yongsheng Chen [b], John C. Crittenden [b]

[a] College of Environmental Science and Engineering, Nankai University, Tianjin 300071, China
[b] Department of Civil and Environmental Engineering, Arizona State University, Tempe, Arizona 85287, USA

Received 1 December 2005; received in revised form 31 July 2006; accepted 3 September 2006
Available online 12 December 2006

Abstract

In this study adsorption of Cd onto $TiO_2$ nanoparticles and natural sediment particles (SP) were studied and the facilitated transports of Cd into carp by $TiO_2$ nanoparticles and SP were assessed by bioaccumulation tests exposing carp (Cyprinus carpio) to Cd contaminated water in the presence of $TiO_2$ and SP respectively. The results show that $TiO_2$ nanoparticles had a significantly stronger adsorption capacity for Cd than SP. The presence of SP did not have significant influence on the accumulation of Cd in carp during the 25 d of exposure. However, the presence of $TiO_2$ nanoparticles greatly enhanced the accumulation of Cd in carp. After 25 d of exposure Cd concentration in carp increased by 146%, and the value was 22.3 and 9.07 l g/g, respectively. And there is a positive correlation between Cd and $TiO_2$ concentration. Considerable Cd and $TiO_2$ accumulated in viscera and gills of the fish.


Keywords: $TiO_2$; Facilitated transport; Nanotoxicology; Bioaccumulation

OPEN ACCESS Freely available online PLoS one

## $TiO_2$ Nanoparticles Are Phototoxic to Marine Phytoplankton

Robert J. Miller[1,2,3*], Samuel Bennett[1,3], Arturo A. Keller[1,3], Scott Pease[1,4], Hunter S. Lenihan[1,3]

1 Bren School of Environmental Science and Management, University of California Santa Barbara, Santa Barbara, California, United States of America, 2 Marine Science Institute, University of California Santa Barbara, Santa Barbara, California, United States of America, 3 University of California Center for Environmental Implications of Nanotechnology, University of California Santa Barbara, Santa Barbara, California, United States of America, 4 Department of Environmental and Occupational Health Sciences, University of Washington, Seattle, Washington, United States of America

Abstract

Nanoparticulate titanium dioxide ($TiO_2$) is highly photoactive, and its function as a photocatalyst drives much of the application demand for $TiO_2$. Because $TiO_2$ generates reactive oxygen species (ROS) when exposed to ultraviolet radiation (UVR), nanoparticulate $TiO_2$ has been used in antibacterial coatings and wastewater disinfection, and has been investigated as an anti-cancer agent. Oxidative stress mediated by photoactive $TiO_2$ is the likely mechanism of its toxicity, and experiments demonstrating cytotoxicity of $TiO_2$ have used exposure to strong artificial sources of ultraviolet radiation (UVR). In vivo tests of $TiO_2$ toxicity with aquatic organisms have typically shown low toxicity, and results across studies have been variable. No work has demonstrated that photoactivity causes environmental toxicity of $TiO_2$ under natural levels of UVR. Here we show that relatively low levels of ultraviolet light, consistent with those found in nature, can induce toxicity of $TiO_2$ nanoparticles to marine phytoplankton, the most important primary producers on Earth. No effect of $TiO_2$ on phytoplankton was found in treatments where UV light was blocked. Under low intensity UVR, ROS in seawater increased with increasing nano-$TiO_2$ concentration. These increases may lead to increased overall oxidative stress in seawater contaminated by $TiO_2$, and cause decreased resiliency of marine ecosystems. Phototoxicity must be considered when evaluating environmental impacts of nanomaterials, many of which are photoactive.

Citation: Miller RJ, Bennett S, Keller AA, Pease S, Lenihan HS (2012) $TiO_2$ Nanoparticles Are Phototoxic to Marine Phytoplankton. PLoS ONE 7(1): e30321. doi:10.1371/journal.pone.0030321

Editor: Jack Anthony Gilbert, Argonne National Laboratory, United States of America

Received November 15, 2011; Accepted December 19, 2011; Published January 20, 2012



Funding: This work was supported by the National Science Foundation and the United States Environmental Protection Agency under Cooperative Agreement # NSF-EF0830117, and by National Science Foundation grant EF-0742521. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: The authors have declared that no competing interests exist.

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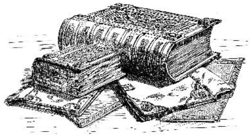
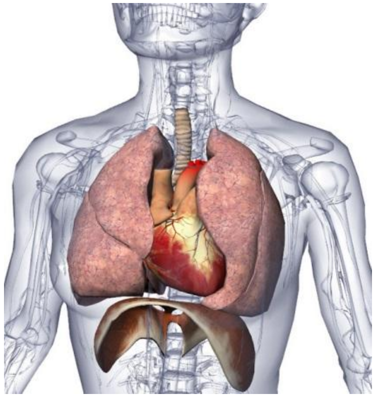
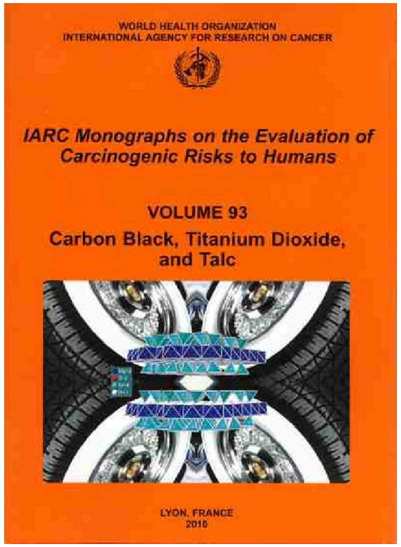
# Ultrafine TiO2 is a IARC 2B carcinogen

- Authoritative List
- Inhalation Route








# TiO2: Potential Exposure

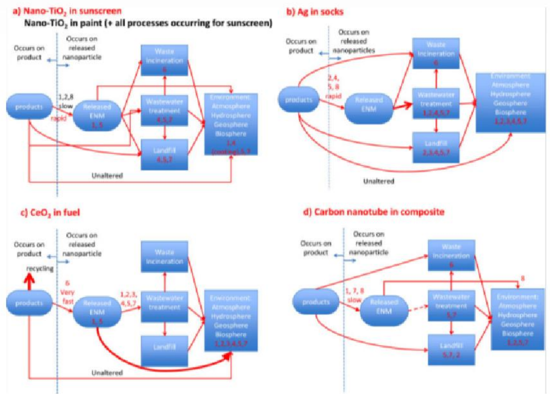



Fig. 4. (a–d) Material flow diagrams showing the release of engineered nanomaterials (ENM) from different products and the transformation reactions during transfer from one environmental compartment to another: $TiO_2$ release from sunscreen and paint, Ag release from textiles, $CeO_2$ release from fuels and carbon nanotubes release from composites. The numbers refer to the processes identified in the text. [Color figure can be seen in the online version of this article, available at wileyonlinelibrary.com]

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Environmental Toxicology and Chemistry, Vol. 31, No. 1, pp. 50–59, 2012

Printed in the USA
DOI: 10.1002/etc.726

*Critical Review*

## POTENTIAL SCENARIOS FOR NANOMATERIAL RELEASE AND SUBSEQUENT ALTERATION IN THE ENVIRONMENT

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#Environmental and Resource Studies and Institute for Freshwater Science, Trent University, Peterborough, Ontario, Canada
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(Received 2 September 2011; Revised 13 October 2011; Accepted 21 October 2011)

Colloids and Surfaces B: Biointerfaces 79 (2010) 5–18

Contents lists available at ScienceDirect

Colloids and Surfaces B: Biointerfaces

journal homepage: www.elsevier.com/locate/colsurfb

Review

## A review on the application of inorganic nano-structured materials in the modification of textiles: Focus on anti-microbial properties

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ARTICLE INFO

*Article history:*
Received 3 September 2009
Received in revised form 14 March 2010
Accepted 23 March 2010
Available online 30 March 2010

*Keywords:*
Anti-microbial
Inorganic nano-structured materials
Textile modification
Nano-particles
Nano-composite

ABSTRACT

Textiles can provide a suitable substrate to grow micro-organisms especially at appropriate humidity and temperature in contact to human body. Recently, increasing public concern about hygiene has been driving many investigations for anti-microbial modification of textiles. However, using many anti-microbial agents has been avoided because of their possible harmful or toxic effects. Application of inorganic nano-particles and their nano-composites would be a good alternative. This review paper has focused on the properties and applications of inorganic nano-structured materials with good anti-microbial activity potential for textile modification. The discussed nano-structured anti-microbial agents include $TiO_2$ nano-particles, metallic and non-metallic $TiO_2$ nano-composites, titania nanotubes (TNTs), silver nano-particles, silver-based nano-structured materials, gold nano-particles, zinc oxide nano-particles and nano-rods, copper nano-particles, carbon nanotubes (CNTs), nano-clay and its modified forms, gallium, liposomes loaded nano-particles, metallic and inorganic dendrimers nano-composite, nano-capsules and cyclodextrins containing nano-particles. This review is also concerned with the application methods for the modification of textiles using nano-structured materials.



Contents

# Titanium Dioxide ($TiO_2$)

## Potential Policy Considerations for Spray sunscreen, spray hair dye

- Pros
  - Inhalation (aerosols) most significant exposure pathway
  - Clear respiratory effects
  - Listed carcinogen
  - Enters WWTP, may not be fully removed
    - Found in high levels at downstream rivers
  - High exposure to children
  - High use of sunscreen every day

- Cons
  - Toxicity varies for fine particles versus nanoparticles
  - Coatings, size, shape of particles affect toxicity
  - Limited number of inhalation animal studies, scarce human data
  - FDA Approval
    - Sunscreen (limit 25%) Most are between 2-15%
    - Approved food additive

# Thinking about Current Policy Priorities

**(just speculation!)**

| | TiO2 |
|---|---|
| Clear pathways for exposure to Candidate Chemicals | ✓ |
| Contain chemicals detected in biomonitoring studies | 🚫 |
| Contain chemicals observed in indoor air/dust | 🚫 |
| Impact children or workers | ✓ |
| Contain chemicals that may adversely impact aquatic resources or observed in water quality monitoring | ? |


# Identification of Priority Products

- Process.
- Proximate.
- Policy.
- Politics.

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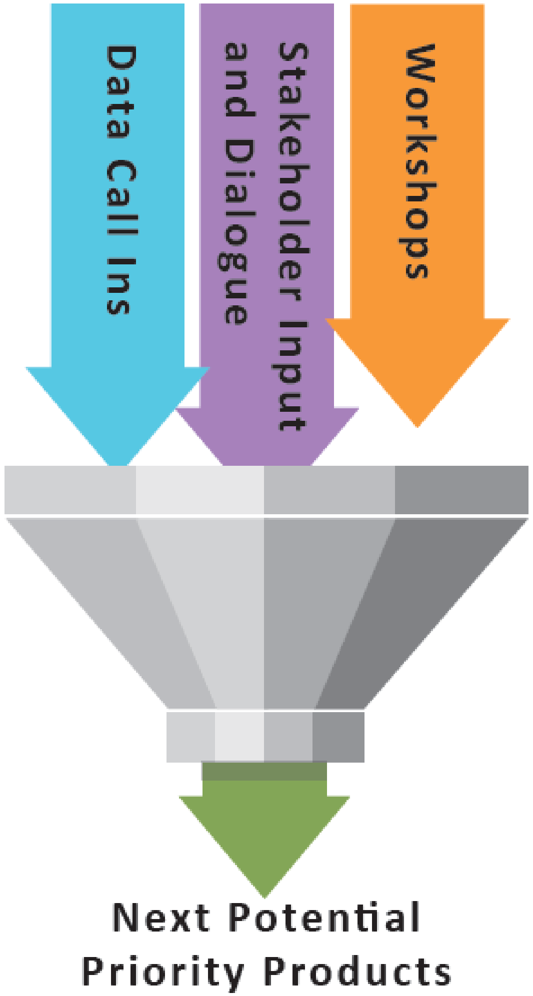
# Process of Priority Product Selection:
## Executing the Work Plan



# Key Prioritization Principles


- Potential **exposure** to the Candidate Chemical(s) in the product

plus

- Potential for exposures to contribute to or cause **significant or widespread adverse impacts***

*adverse environmental impacts alone are sufficient

# “Significant Adverse Impacts”


“Potential for exposures to contribute to or cause **significant or widespread adverse impacts”**

- Case-by-case basis
- Candidate chemical’s toxicity profile
- Adverse impacts on sensitive subpopulations
- Adverse impacts on sensitive environmental receptors

**ADVERSE ENVIRONMENTAL IMPACTS §69505.5(c)(1)(A)**

- **Adverse air quality impacts §69505.1(a)(3)**
  - CA Toxic Air Contaminants
  - Emissions of Greenhouse Gases
  - Emissions of nitrogen oxides
  - Emissions of particulate matter §69405.7
  - Emissions of stratospheric ozone depletion §69405.8
  - Emissions of sulfur oxides
  - Emissions of Tropospheric ozone-forming §69405.1
- **Adverse ecological impacts §69505.1(a)(7)**
  - Acute or chronic toxicity;
  - Changes in population size, reductions in biodiversity, or changes in ecological communities; and
  - The ability of an endangered or threatened species to survive or reproduce;
  - Deterioration or loss of environmentally sensitive habitats;
  - Impacts that contribute to or cause vegetation contamination or damage; and
  - Biological or chemical contamination of soils; or
  - Any other adverse effect in:#
  - Domesticated Animal Toxicity
  - **NOT COMPLETE LIST**
- **Adverse soil quality impacts §69505.1(a)(7)**
  - Compaction or other structural changes;
  - Erosion;
  - Loss of organic matter;
  - Soil sealing
- **Adverse water quality impacts §69505.1(a)(9)**
  - Increase in biological oxygen demand;
  - Increase in chemical oxygen demand;
  - Increase in temperature;
  - Increase in total dissolved solids;
  - CWA 303(c) & (d);
  - Safe Drinking Water Act Pollutants;
  - CA HSC 116455 with Notification Levels;
  - CA safe Drinking Water Act with Public; Health Goals

# Comparison of California, REACH & EPA

| | California SCPR | REACH | U.S. EPA TSCA | U.S. EPA Workplan |
|---|---|---|---|---|
| **Scope** | 1200 Chemicals | 30,000 chemicals | 82,000 Chemicals on TSCA Inventory | 86 Workplan Chemicals |
| **Priority** | 3-5 consumer products (initially) | Chemicals > 1 million tons | 1.Risk Assessments<br>2.Increasing Information<br>3.Safer Products | Conduct initial assessments on 23 chemicals |
| **Chemical or Product Safety Focus** | Both | Chemical Safety | Chemical Safety | Chemical Safety |



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# Conclusions


- **Nanomaterials** as chemicals or products are under the SCPR authority.
- The SCPR adds additional design features for nano-enabled products – performance **plus safety** throughout the lifecycle.
- Great opportunity for **partnerships** between stakeholders & regulators.

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# Acknowledgments

## to those on the leading edge…

# Thank you for your kind attention !

- DTSC staff scientists and engineers
- Professor Tim Malloy; UCLA Law
- Professors Andre Nel, Hillary Godwin, Arturo Keller; UCLA/UCSB
- Dr. Joseph Guth and Dr. Michael Wilson; UC Berkeley
- Dr. Richard Denison; EDF
- Terry Medley, J.D. & Thomas Jacob; DuPont

Thank you to IEEE for sponsoring this event !!