



Austrias approach to nanosilver risk assessment and regulation

Dr. Aleksander Zilberszac
Federal Ministry of Health

Austrias approach to nanosilver risk governance

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Scientific basis

 <p>OAW ITA Institute of Technology Assessment of the Austrian Academy of Sciences</p>	 <p>nano trust dossiers No. 010en • November 2010</p>	
<p>René Fries, Sabine Greßler, Myrtill Simkó*, André Gazzó, Ulrich Fiedeler, Michael Nentwich</p>	<h2>Nanosilver</h2>	
<p>Summary</p> <p>Silver has a rich history of use in medicine and hygiene due to its broad-spectrum toxicity to bacteria, fungi and al-</p>	<p>Introduction</p> <p>Silver is perhaps second only to gold in its use since antiquity as a metal and material for jewelry. Silver has, due to its antibi-</p>	<p>Biocidal effects of silver</p> <p>Silver compounds and particles of elementary silver can release silver ions (Ag^+) – through oxidation or other processes – that</p>



BfR recommends that nano-silver is not used in foods and everyday products

BfR Opinion Nr. 024/2010, 28 December 2009

Manufacturers of foods, cosmetics or everyday products have long been taking advantage of the antimicrobial properties of silver ions. Lotions may contain silver salts as preservatives and refrigerators or athletic socks and other textiles are equipped with silver compounds in order to inhibit the growth of germs or avoid the development of odours. In recent times, nanoscale silver compounds have also increasingly been used for these purposes. The Fed-

Scientific basis

- Study „Nanosilver in cosmetics, hygiene articles and food contact materials“ (Gressler/Fries; Febr. 2010)
- **Main Conclusion →**
 - ... an extensive use of Nanosilver at low concentrations in consumer products might promote the development of allergies and multi-resistant bacteria. This might pose the risk that silver would be no longer an important weapon against pathogenic germs in medicine



Policy response

EntschlieÙung

des Nationalrates vom 8. Juli 2011

betreffend Nanosilber – antimikrobielle Wirksamkeit sichern

Die Bundesregierung wird aufgefordert, alle notwendigen Maßnahmen zu ergreifen damit die Wirksamkeit von Nanosilber und der damit verbundene hohe Stellenwert im medizinischen Bereich gesichert wird und nicht durch eine breitflächige, unkontrollierte Anwendung im Konsumgüterbereich konterkariert wird, deren Nutzen für die Konsumenten ohnehin mehr als zweifelhaft zu sein scheint.

Resolution of the Austrian Parliament of 8th July 2011 (adopted unanimously!)

The Federal Government is requested to take all necessary measures to ensure the therapeutic efficacy of nanosilver in human medicine. The high value of nanosilver for certain medical applications shall not be compromised by widespread and uncontrolled use in consumer products.

Facilitator for coherent implementation Austrian Nanotechnology Platform

Members are:

- Representatives from more than 20 different organisations
 - Authorities (5 Federal Ministries)
 - Research Institutions
 - Advocacy groups (economic chamber/ chamber of labour)
 - Environment and consumer protection NGOs
 - Industry

Aim: exchange of information, dialogue, discussion of relevant national activities

Members: qualified stakeholders

Nano – Platform: Leading Institution is the Federal Ministry of Agriculture, Forestry, Environment and Water Management

Implementation pathways

1. Enforcement of existing EU Legislation
2. Information of consumers
3. EHS research program
4. Voluntary initiatives/private standards



Enforcement of existing EU Legislation

Nano-relevant harmonised Legislation

1. Regulation on the provision of food information to consumers (EC) No 1169/2011
2. Regulation on cosmetic products (EC) No 1223/2009
3. Proposal for a Regulation concerning the making available on the market and use of biocidal products
4. Regulation on food additives (EC) No 1333/2008
5. Regulation on active and intelligent materials and articles intended to come into contact with food (EC) No 450/2009
6. Regulation on Novel food (EC) No 258/97
7. Directive on medicinal products (EC) No 2001/ 83
8. Directive on medical devices (EEC) No 93/42

REGULATION (EU) No 1169/2011 on the provision of food information to consumers

- Definition of Nanomaterials
- Labelling of Nano - Article 18 Nr. 3
 - All ingredients present in the form of engineered Nanomaterials shall be clearly indicated in the list of ingredients.
 - The names of such ingredients shall be followed by the word „**nano**” in brackets.



Regulation on cosmetic products (EC) No 1223/2009

- **Definition** of Nanomaterials
- Every cosmetic products containing Nanomaterials shall be **notified to the Commission**
- Nanomaterials shall be clearly indicated **of ingredients.**
- The names of such ingredients shall be followed by the word „**nano**” in brackets



Proposal for a EU Regulation concerning the making available on the market and use of biocidal products-Outcome of the European Parliament's second reading

- Definition of Nanomaterials
- Conditions for granting an authorization-
 - „where nanomaterials are used in that product, the risk to the environment and to health has been **assessed separately**”
- Eligibility for the simplified **authorization procedure**
 - „If the biocidal product does not contain a nanomaterial”
- The label provides the following information
 - „The name of all nanomaterials contained in biocidal products, followed by the word "**nano**" in brackets“



Proposal for a EU Regulation concerning the making available on the market and use of biocidal products-Outcome of the European Parliament's second reading

- The BP Regulation shall apply to biocidal products and **treated articles**
- ...”when a biocidal product falls within the scope of one of other legal instruments and is intended to be used for purposes ...(not covered by those instruments), this Regulation shall also apply to that biocidal product insofar as these purposes are not addressed by those instruments”:
 - antimicrobial coatings will fall within the scope of the new BPR!

Regulation on food additives (EC) No 1333/2008



- No specific Nano-Definition but →
- common Community assessment and authorisation procedure by European Food Safety Authority (EFSA) (No 1331/2008)
- „....when there is a change in **particle size, for example through nanotechnology**, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market”

Regulation on active and intelligent materials and articles intended to come into contact with food (EC) No 450/2009

- No specific Definition of Nanomaterials
- No specific provision on nanomaterials but :
only substances which are included in the **'Community list' of authorized substances** may be used in components of active and intelligent materials and articles.



Regulation concerning novel foods and novel food ingredients (EC) No 258/97

Food and food ingredients to which has been applied a production process not currently used, where that process gives rise to **significant changes in the composition or structure** of the food or food ingredients which affect their nutritional value, metabolism or level of undesirable substances

- **Authorisation procedure**
- **National notification system**



Directive for medicinal products

Directive for medical devices

Medicinal products

- No specific Nanodefinition
- Approval procedure -
 - centralised procedure for marketing authorization by the European Medicines Agency (EMA)
 - National procedure by AGES Pharmed

Medical devices

- No specific Nanodefinition
- conformity assessment procedure (CE)

2. Reading – regulation of the European Parliament and of the Council on novel foods, Article 3 Nr.(2) Zif. a Definition

- food containing or consisting of engineered nanomaterial
- engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.
- This includes also
 - those properties related to the large specific surface area of the materials considered; and/or
 - specific physico-chemical properties that are different from those of the non-nanoform of the same material; food containing or consisting of engineered nanomaterials;



Information of consumers on nanomaterials

NIP



Nano Information Platform

- Lead: Federal Ministry of Health
- Contributing organisations
Federal Ministries (BMG, BMLFUW, BMVIT, BMWF, BMASK), Austrian Agency for Health and Food Safety (AGES), BioNanoNet mbH, EU-Environmental Bureau, Institute of Technology Assessment of the Austrian Academy of Sciences (ITA), Austrian Research Promotion Agency (FFG), Environment Agency Austria, Austrian Federal Economic Chamber (WKO), NanoNet Styria
- Initial stage: development of an internal information platform
- Final stage: information portal for the general public



core tasks

- web-portal for information of interested general public
- Principle: Website offers basic information as well as scientific news, full text documents and studies as downloads, links to relevant stakeholders
- Objective: balanced and qualified information available to the public to facilitate forming of opinion

Website – preliminary version Main Page



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- Produkte
- Lebensmittel
- Gesundheit
- Umwelt
- Arbeitnehmer/innen-Schutz
- Wissenschaft & Forschung
- Rechtliches

Mit Lostuseffekt gegen Eis



Die Blätter der Lotuspflanze weisen Oberflächenstrukturen auf, die Wasser einfach abperlen lassen. Dieser Effekt wird bei sogenannten selbstreinigenden Oberflächen von Fassaden, Scheiben oder Autokarosserien eingesetzt. Nun soll er auch vor Eisbildung schützen.
Quelle/24.09.2009 > mehr

Fotoquelle

Nano für die Umwelt



Aus ökologischer Sicht bringen die Nanotechnologien im Umweltbereich einen grossen Nutzen. Nanotechnologien tragen dazu bei, dass herkömmliche oder erneuerbare Energiequellen wie die Sonne oder die Erdwärme effizienter genutzt und die daraus gewonnene Energie besser gespeichert werden kann.
Quelle/24.09.2009 > mehr

Fotoquelle

Nano im Alltag



Im Alltag sind wir bereits in vielerlei Hinsicht mit Nanotechnologien konfrontiert. Hinter vielen neuartigen oder auch hinter bereits vertrauten Eigenschaften von Alltagsgegenständen und Konsumprodukten stehen Nanomaterialien.
Quelle/24.09.2009 > mehr

Headline eins

Blindtext – das ist eine Kurzmeldung mit max. 2 Zeilen
> mehr

Headline zwei

Gisteren gaf ze samen met Leontine Borsato, Nikkie Plessen,
> mehr

Headline drei

Liza Sips en Paulien kick-off voor de Mix & Match pop-up store by
> mehr

Headline vier

Haar bekende klanten kunnen in de winkel rustig een kijkje komen
> mehr

Headline fünf

De Nederlandse stylist lanceert deze winkel tegelijkertijd met haar
> mehr

Website – 1st Sub-Page

Kontakt Impressum Organisation Behörden FAQ Glossar



nan
NanoInformationsPortal



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Subebene Thema 3

Gesundheit

Umwelt

Arbeitnehmer/Innen-Schutz

Wissenschaft & Forschung

Rechtliches

Das ist die Headline eines kompletten Artikels



Fotoquelle

De reden van de breuk zou zijn dat Elisabetta Canalis kinderen helemaal niet ziet zitten en ze is dan ook niet van plan om de kinderwens van Clooney te vervullen. „Ik word al gek als Brad Pitt en Angelina Jolie op bezoek komen met hun kroost. Dan moet ik het huis uit. Ik ben geen moederfiguur en heb George al duidelijk gemaakt dat zoiets er nooit van zal komen”, aldus Canalis.

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Das ist eine Subline

Ook het huwelijk tussen de twee een ‚tijdje‘ uitgesteld: „te drukke agenda’s” liet Canalis weten. Clooney zelf zwijgt in alle toonaarden over zijn relatie met Elisabetta en heeft ook nog niet gereageerd op de vermeende breuk. Ook het huwelijk tussen de twee een ‚tijdje‘ uitgesteld: „te drukke agenda’s” liet Canalis weten. Clooney zelf zwijgt in alle toonaarden over zijn relatie met Elisabetta en heeft ook nog niet gereageerd op de vermeende breuk. George Clooney is weer single. De filmster en Elisabetta Canalis zouden al in januari een punt achter hun relatie hebben gezet, zo melden verschillende Italiaanse media. De reden van de breuk zou zijn dat.

Quelle/24.09.2009

[Blindtext.pdf \(254 kb\)](#)

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[> mehr](#)

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EHS research program

NANO Environment, Health and Safety Program (NANO EHS)



- Basis: Austrian Nanotechnology Action Plan
- Sponsoring Bodies: All federal ministries participating in the Action Plan and the economic chamber
- The Austrian Research Promotion Agency (FFG) is responsible for the project management

NANO Environment, Health FEDERAL MINISTRY OF HEALTH and Safety Program (NANO EHS)

Objectives:

1. Strategic

- To fill knowledge gaps in the safety assessment of nanotechnology, especially in the areas of environmental and health risks, and employee protection.
- Establishing necessary expertise in the research system

2. Operative

- Risk Assessment
- Safety measures

First Call for Tenders- Key aspects

Deadline 19 December 2011

1. Foundations for risk assessment

- a) Data / identification of relevant nanomaterials in consumer products
- b) Meta-analysis of existing occupational health, toxicological literature
Categorization of nanomaterials in risk categories
- c) Development and standardization of measurement and analytical methods
- d) Development of robust, simple and practical devices

2. Innovative and reliable protective measures

- a) Innovative and reliable materials for protective measures
- b) Analysis of the relevance and application of product design concepts for various consumer products



Voluntary initiatives/private standards

“ÖkoKauf Wien” - ecological criteria for public procurement

- the Vienna City Administration purchases its goods and services according to **ecological considerations**
- A central management tool for this is the **eco-criteria list**
- By executive decree, this criteria list is **binding for all departments** of the Vienna City Administration over the course of public **procurement and tendering**.
- **orientation for the economic operators as well as for private households**
- **Raising public awareness**

Products that are relevant in the City of Vienna's procurement processes and may contain nanosilver

- **Food/Drinks**
 - ...make sure to avoid buying cutting boards or packaging materials with anti-microbial nanosilver coatings
- **Paint for indoor use**
 - not to allow antimicrobial paint additives (e.g., nanosilver) for routine applications
- **Textiles**
 - Apart from very specialised applications (e. g. in hospitals' operating rooms), there is no reason to use nanosilver coatings in textiles or other products that are close to the human body
- **household appliances**
 - Anti-microbial nanosilver coatings, for example in refrigerators, dishwashers or washing machines while not providing any relevant benefits, cause additional silver to be released into the environment

eco-criteria for purchasing

- | | |
|---|--|
| <ul style="list-style-type: none">• Fax machines• Washing machines• Dish washers for households-• Laser printers• Coffee machines• Refrigerators and freezers• Laundry dryers | <ul style="list-style-type: none">• Mobile phones• Flat screens• Notebooks• Electric and electronic devices-• TV sets• Scanners• Vacuum cleaners |
|---|--|

<http://www.wien.gv.at/umweltschutz/oekokauf/ergebnisse.html#elektrische>

Consideration of Nanosilver in Öko-Kauf criteria

- It is intended to include the following text passage in all sets of criteria:

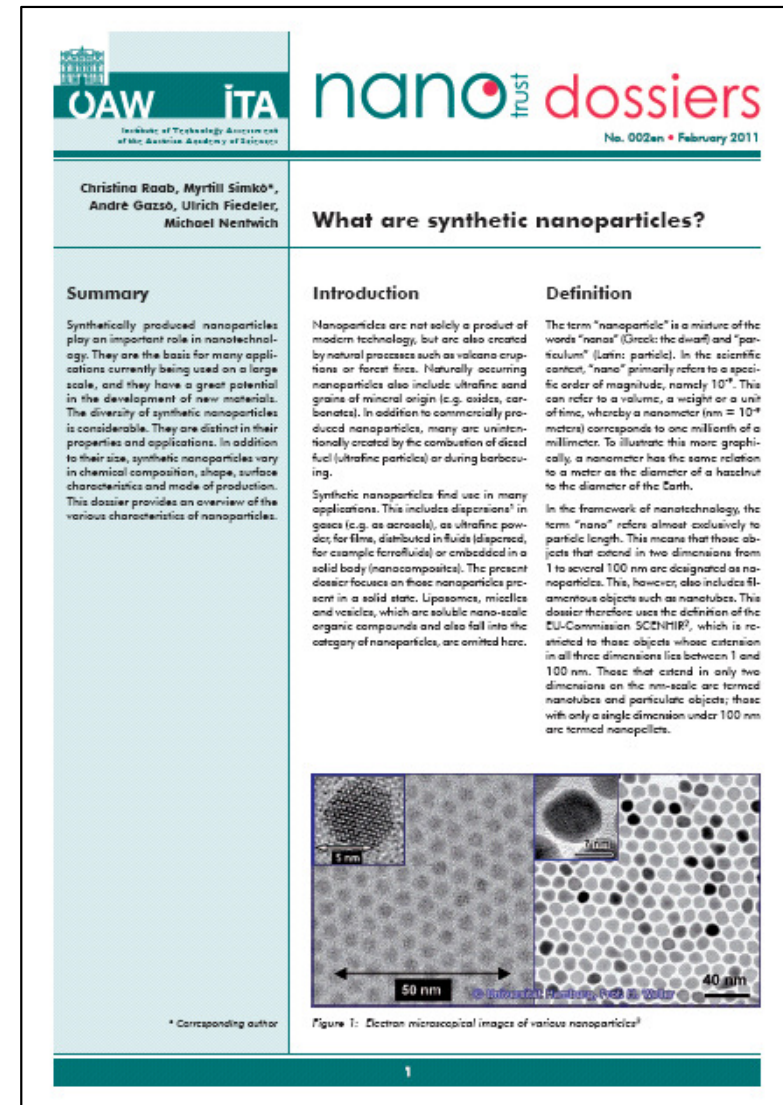
Antimicrobial coatings:

- The purchased devices shall not be equipped with antimicrobial coatings (e.g. nanosilver coatings)



ITA Nanotrust-Dossiers

- These dossiers summarize in an accessible language, but on a firm scientific base in texts of 3-6 pages the current state of knowledge regarding various aspects of nanotechnology.
- The NanoTrust team co-operates with external experts.
- 17 of the 24 already published NanoTrust dossiers are available in full text in English .



Nanotrust

- The NanoTrust project of the Institute of Technology Assessment of the Austrian Academy of Sciences is sponsored by the Federal Ministry for Transport, Technology and Innovation.
- the NanoTrust Team offers on an irregular basis „Dossiers”, = summaries of the state of knowledge on current issues in the developing nano debate
- Information about potential health and environmental risks, and societal aspects of nanotechnology

Workshop BMG/ITA

- **Workshop (round table)** on regulatory issues concerning nanomaterials in foods, food contact materials, cosmetics and hygiene products (23 March 2012).
- The **workshop** will focus on
 - the availability and applicability of instruments (methods for detection and identification/ risk assessment) for enforcement of existing and future legislation and
 - the need for a credible and transparent communication with the public in relation to existing uncertainties in the assessment of opportunities and risks of the use of nanomaterials

Workshop BMG/ITA

Key questions:

- Is the [definition for nanomaterials](#) as introduced by the Commission Recommendation of 18 October applicable?
- Are the analytic methods on hand sufficient for enforcement of the existing legislation?
- Are the scope and focus of current safety research related to nanomaterials sufficient?
- Do nanomaterials pose specific new risks?
- Which benefits can consumers expect from the use of nanomaterials (materials, applications, ...)?
Which benefits expects the industry ?



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