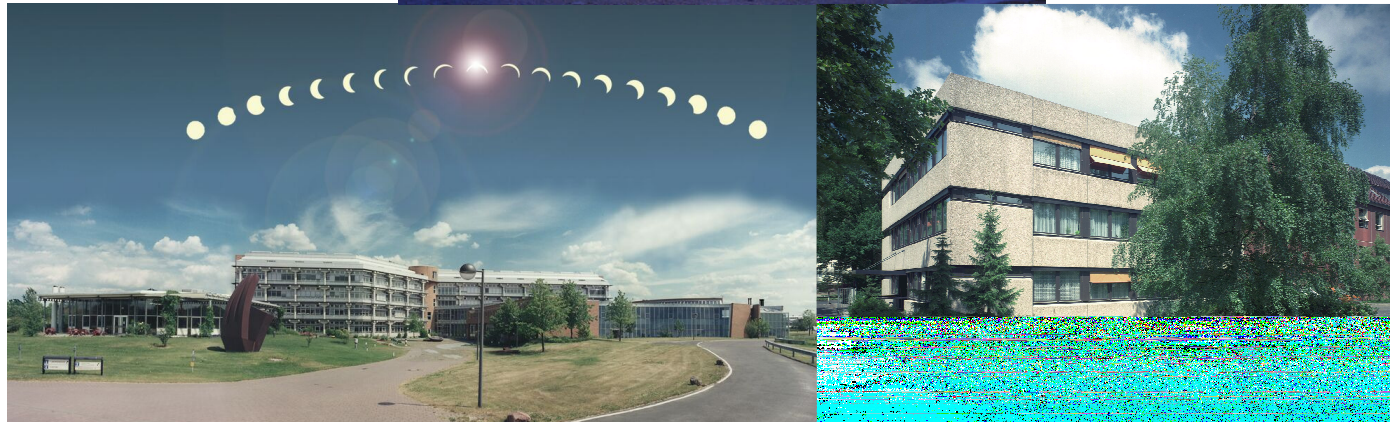


# German Federal Institute for Risk Assessment



**Nanosilver Conference @ BfR**

# History of BfR



Risiken erkennen – Gesundheit schützen

- Imperial Health Office (1876-1919)
- „Reich Health Office“ (1919-45)



Federal Health Office (1952-1994)



Federal Institute of Consumer Health  
Protection and Veterinary Medicine (1994-2002)



August 6, 2002



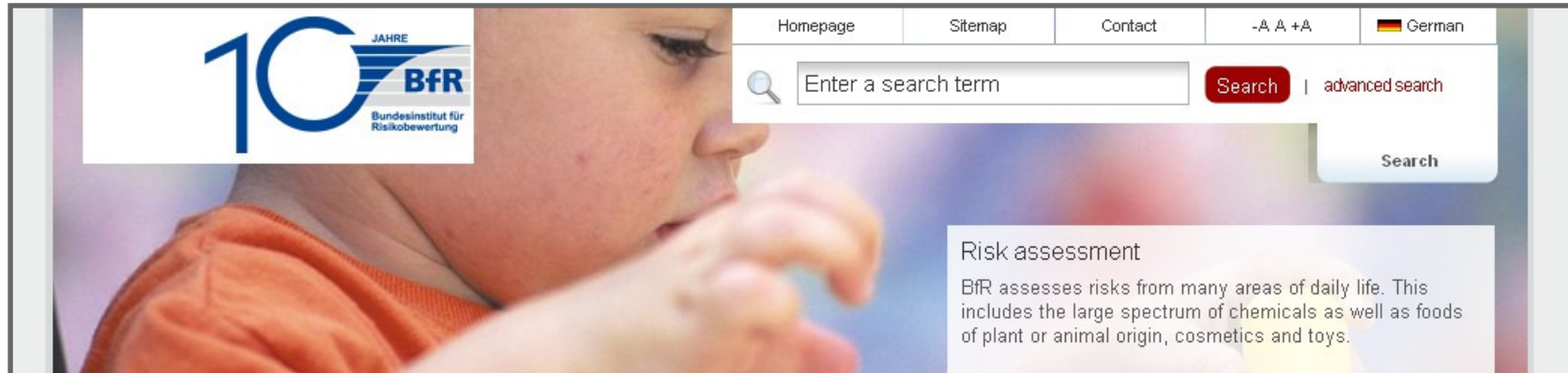
Risiken erkennen – Gesundheit schützen

**Risk Assessment**

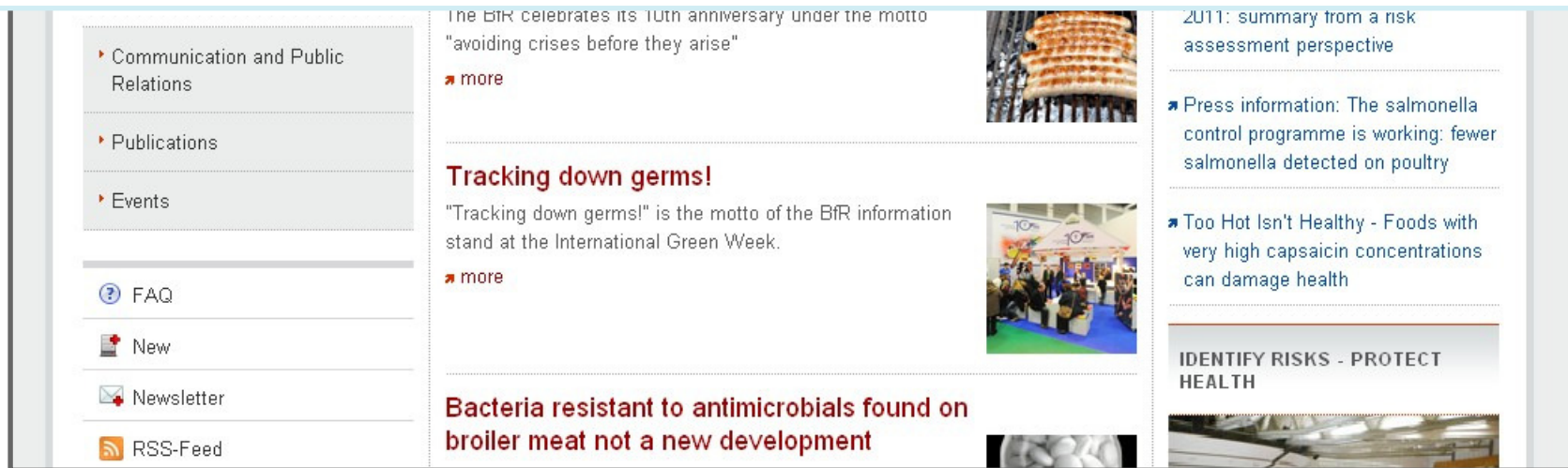


**Risk Management**





# ***Biological and Chemical Safety of Food, Feed & Consumer Products***



- **Assessment of risks ...**
- **Consideration of foreseeable misuse ...**
- **Recommending management measures ...**



**Core Paradigm:**

**Exposure-based  
Risk Assessment !**

# Organizational diagram

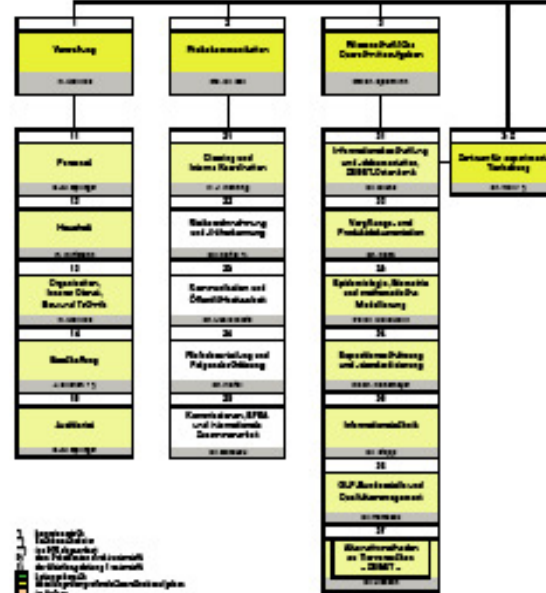
## Organigramm

### Bundesinstitut für Risikobewertung

**Standort:**  
 Berlin  
 Dudenstraße 48  
 10585 Berlin  
 Tel: 030 8947-0  
 Fax: 030 8947-3111  
 E-Mail: info@bfr.bund.de

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 10585 Berlin  
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 Fax: 030 8947-3111



## Executive Board

- Office of President
- Research Coordination
- Controlling/Audit



## Departments

- Department 1: Human Resources
- Department 2: Risk Communication
- Department 3: Scientific Services
- Department 4: Biological Safety
- Department 5: Food Safety
- Department 6: Chemical Safety
- Department 7: Safety of Consumer Products
- Department 8: Safety in the Food Chain
- Department 9: Experimental Toxicology and ZEBET



Risiken erkennen – Gesundheit schützen

# Fields of Competence

Biological Safety

Food Safety

Safety in the Food Chain

Safety of Consumer Products



Safety of Substances & Preparations

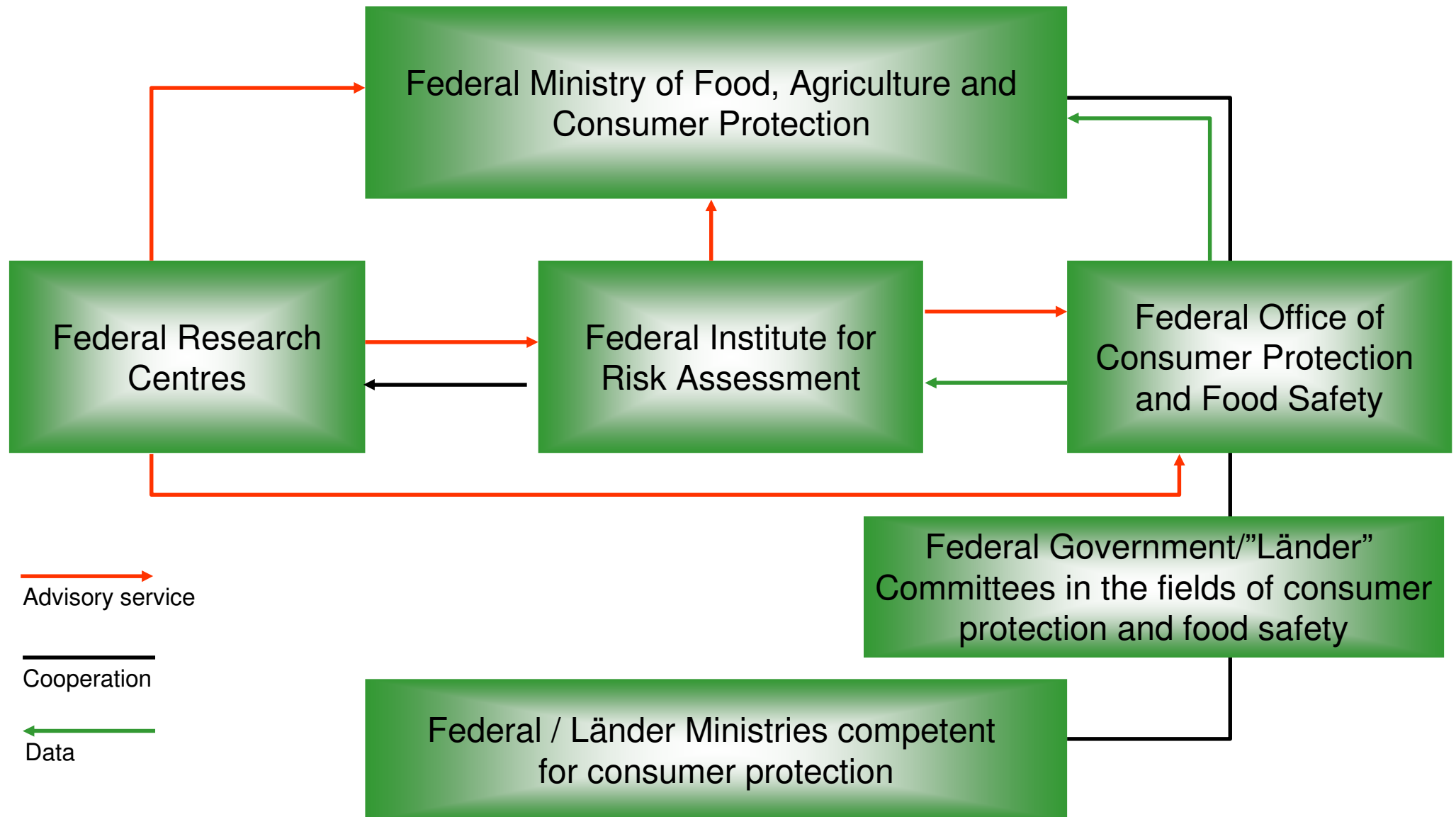


Risk Communication



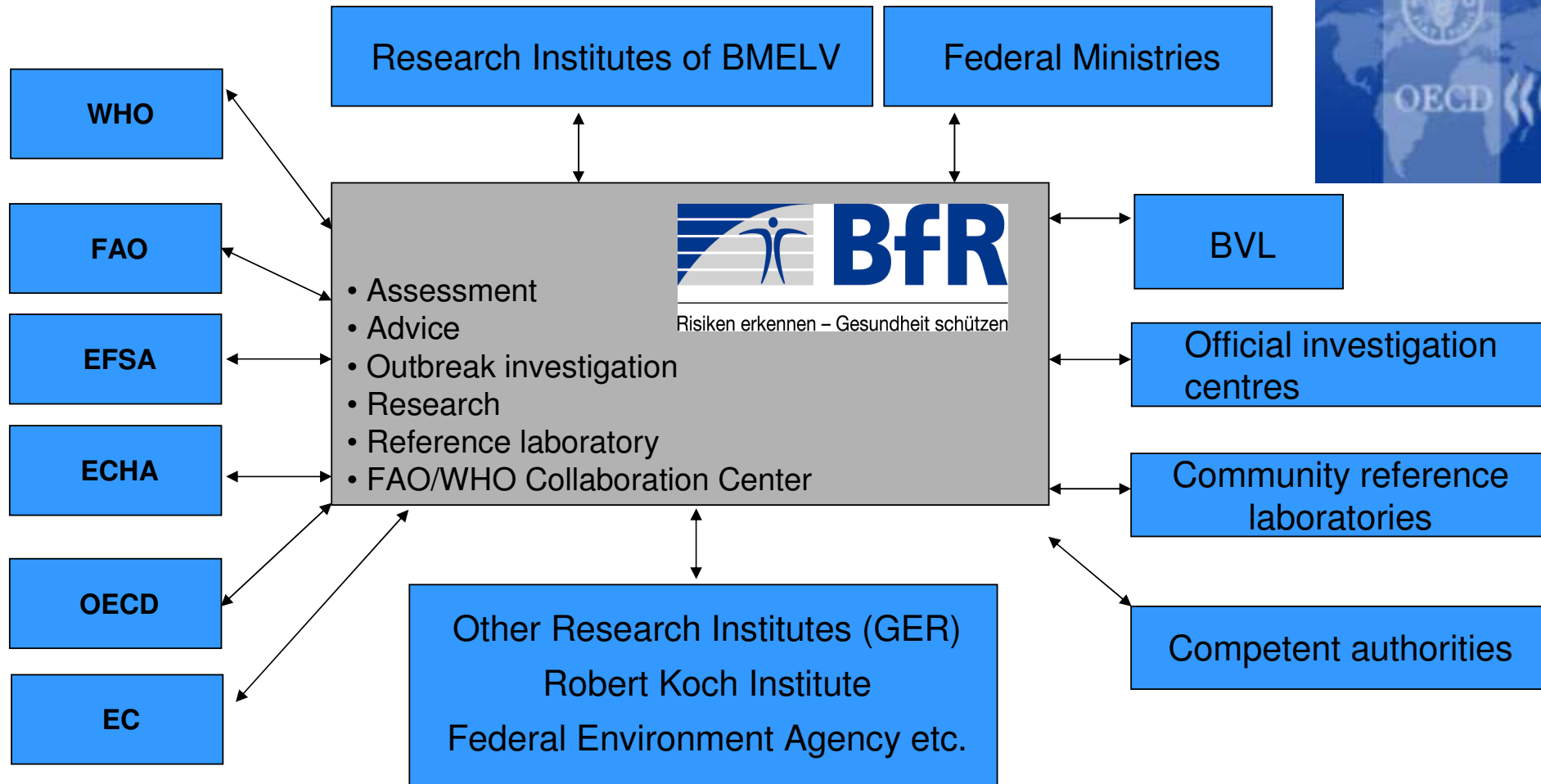
Experimental Toxicology & ZEBET

# Consumer Health Protection in Germany



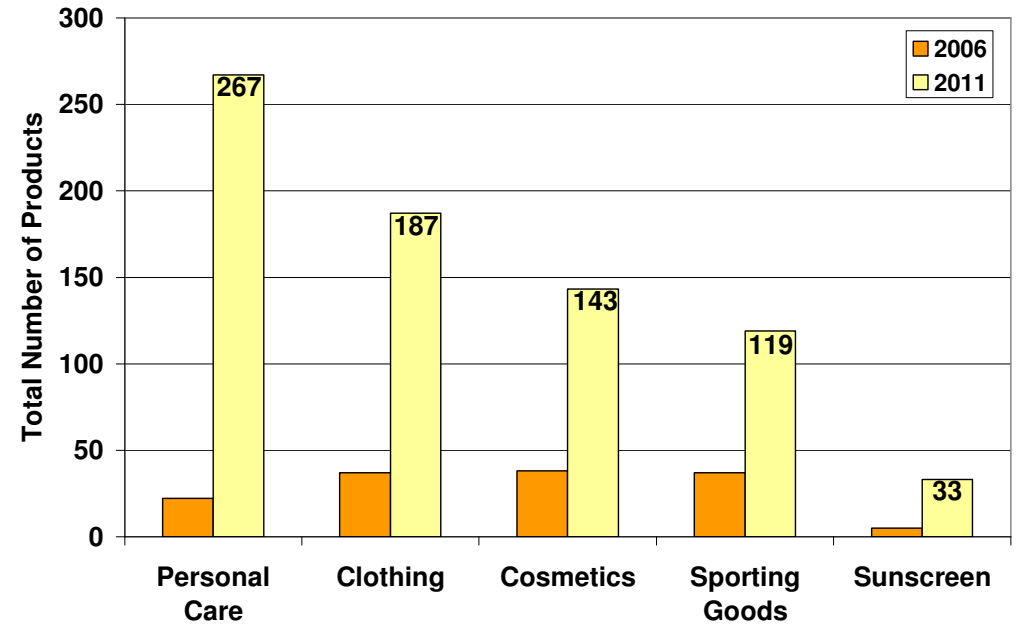
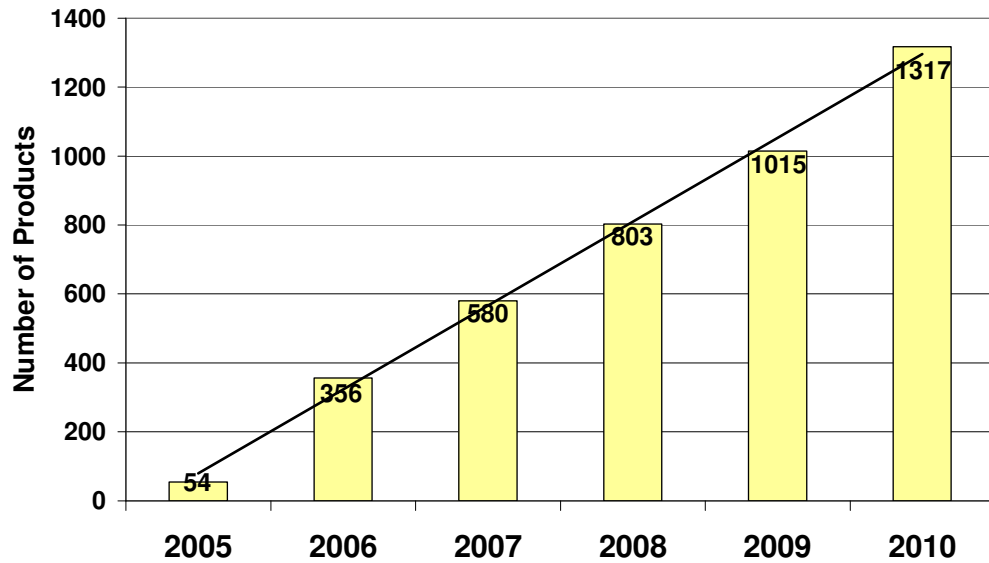


# International Cooperation



# Current prospects in the fields of nanotechnology

# Total number of products claiming to contain “nano”



Woodrow Wilson Inventory

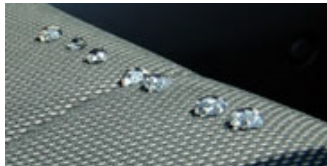
# Expectations and promises of nanotechnology

## Consumer Expectations

- More convenience (easier cleaning)



- Smarter products (functionalized textiles)

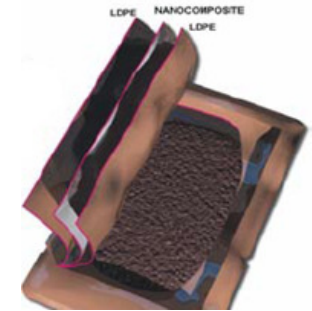


- Products with additional benefits (cosmetics)



## Scientific/Technical Expectations

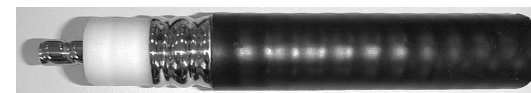
- New materials (doped plastics)



- Intelligent technologies (new surface coating techniques)

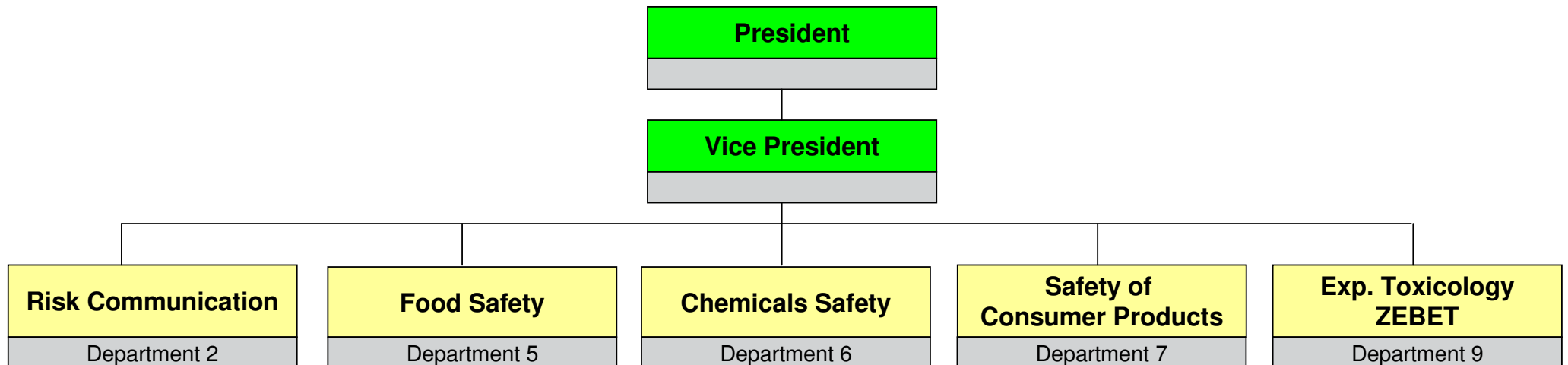


- Smarter products, sometimes functionality partly hidden (cabel, catalysts)





# BfR Departments involved in „nano activities“



## ➤ Risk Assessment

(expert reports, opinions according to internationally recognized scientific criteria)

## ➤ Work in National & International Bodies

(committees & panels, working groups)

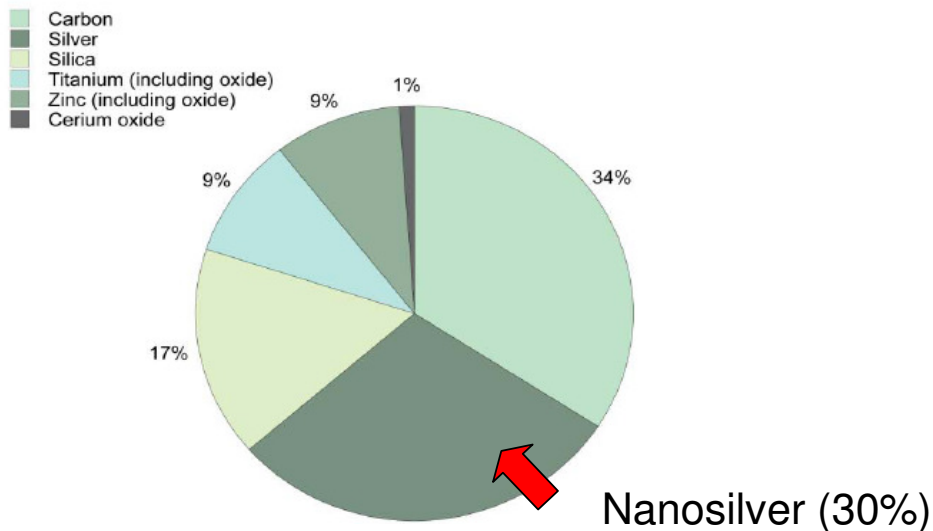
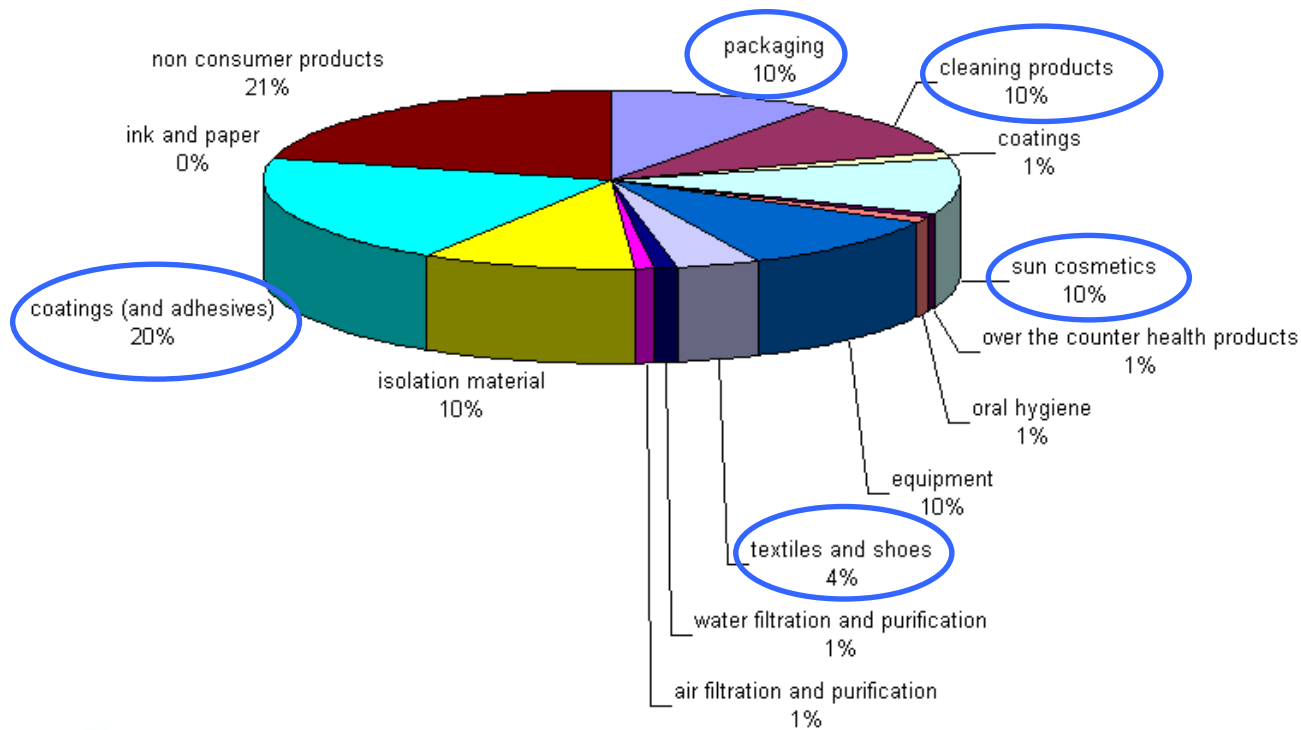
## ➤ Research Activities & Cooperations

(primarily to strengthen risk assessment processes)

## ➤ Risk Communication

(informing the public in a transparent, comprehensive way)

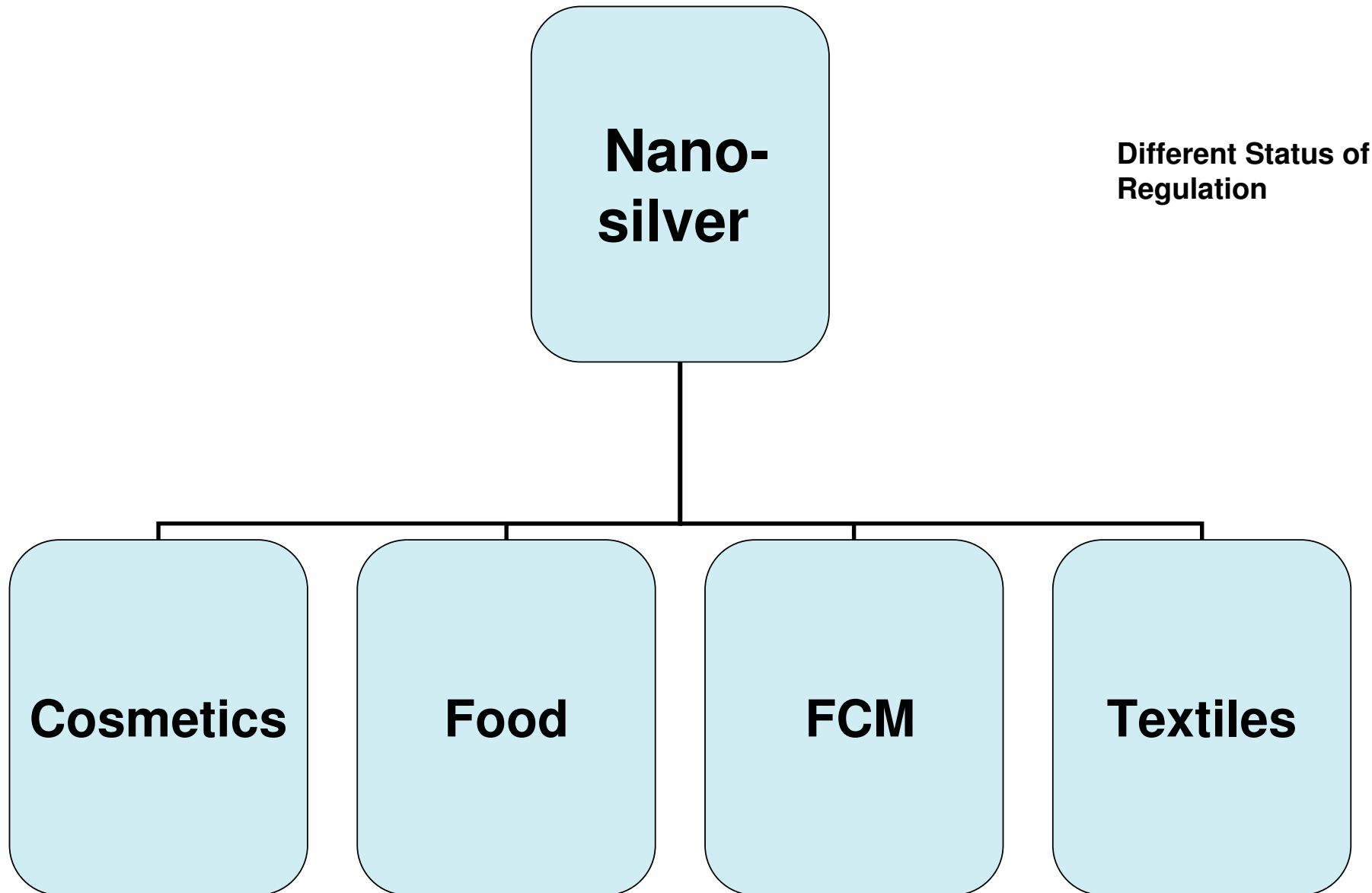
# Numbers of products claiming to contain “nano”



## Nanosilver (selection)

- tooth paste
- tooth brush
- shampoo
- soap
- disinfection spray
- T- shirts
- underwear
- medical products

# Main application areas of “nanosilver”



# Product categories



Cosmetic Products



Food Contact Materials



Food Additives

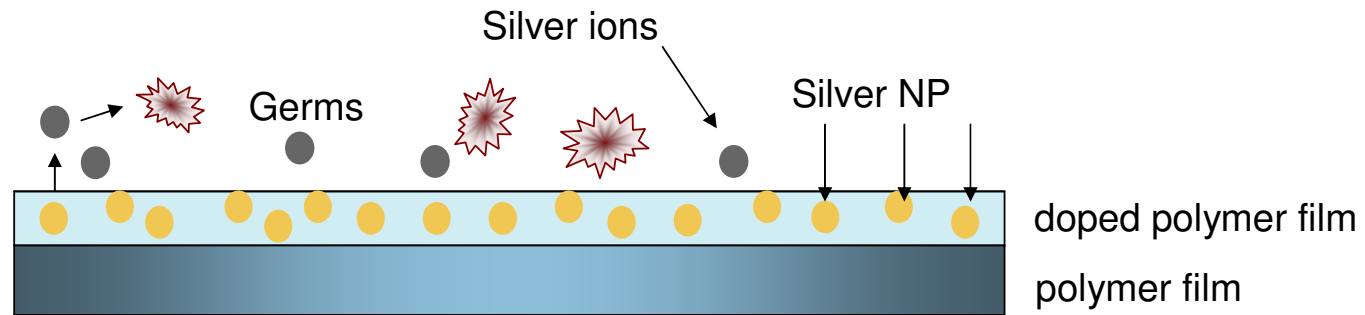


Textiles





# Example: FCM – Anti-microbial coating



without  
nanosilver

with  
nanosilver



Sources: Langowski, 2010;  
Bellucci, Nanodialog, 2008

# Example: FCM – Self-sterilizing polymer films

Generation of NP:  
plasma flame reaction:

$\text{Ca}_3(\text{PO}_4)_2$  NP, 20-50 nm

doped  
↓

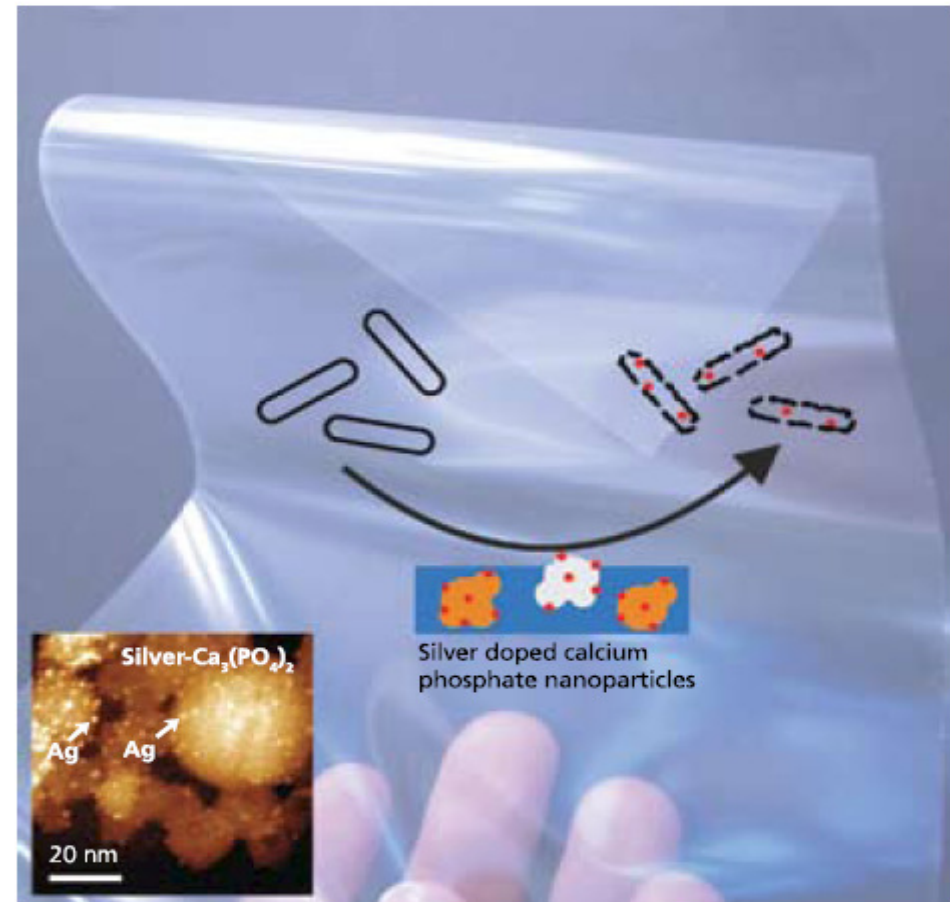
Nanosilver particles, 1-2 nm

**Metal salt complexes embedded in plastic film**

1000 x more effective against *E. coli* as conventional films using Ag as antimicrobial agent

Proposed mode of action:

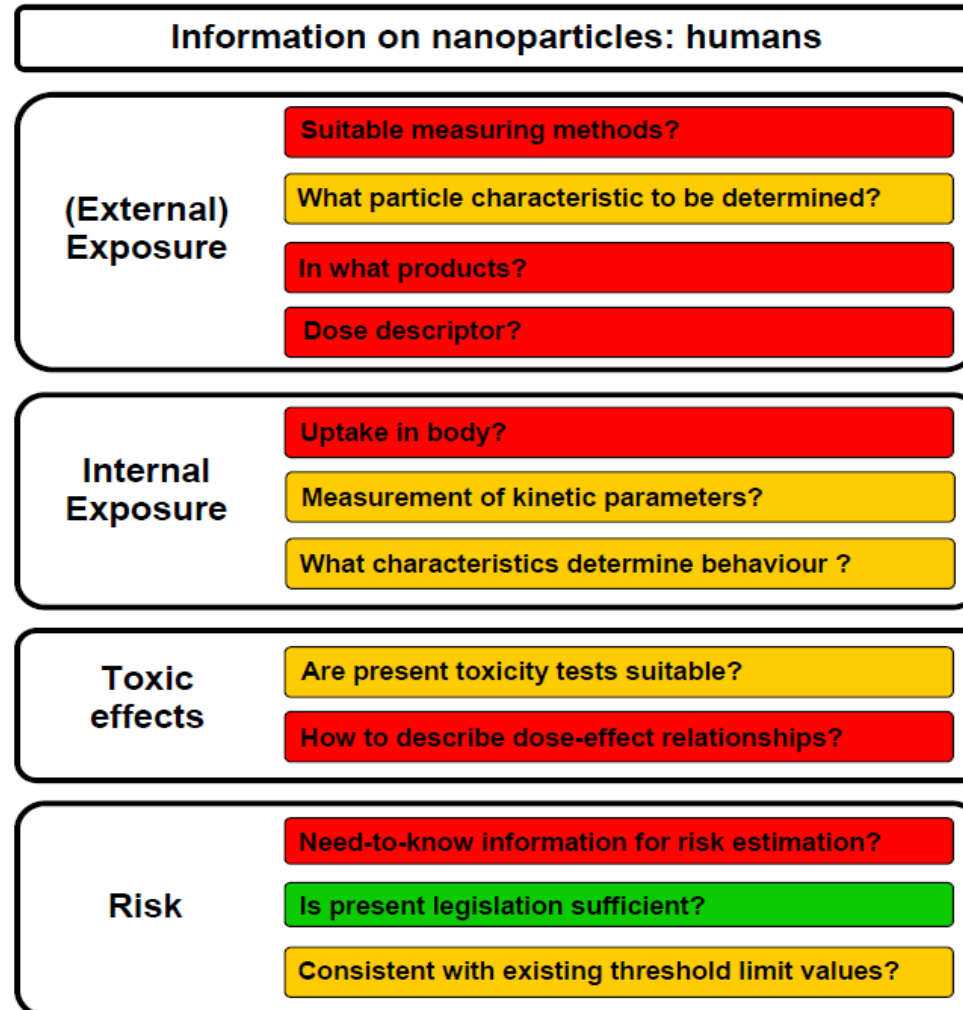
*E. coli*: ingestion of  $\text{Ca}_3(\text{PO}_4)_2$  during growth period, consumption of  $\text{Ca}_3(\text{PO}_4)_2$ , release of Ag NP



Loher et al. (2008) Microorganism-triggered release of silver nanoparticles from biodegradable oxide carriers allows preparation of self-sterilizing polymer surfaces. *Small* 4, 824 - 832

# Objective of this Conference?

# “Nanoproducts”: Most significant knowledge gaps



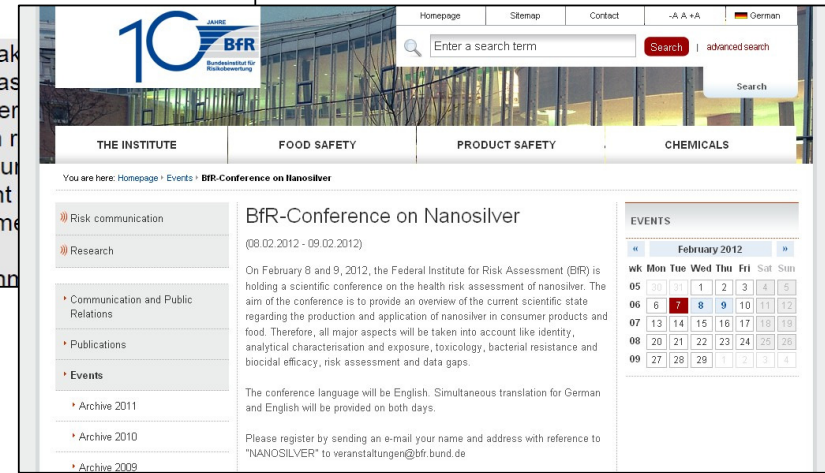


## BfR recommends that nano-silver is not used in foods and everyday products

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 and refrigerators or athletic socks and other textiles are equipped with silver ions in order to inhibit the growth of germs or avoid the development of odours. In recent years, nanoscale silver compounds have also increasingly been used for these purposes. The Federal Institute for Risk Assessment (BfR) finds that a conclusive assessment of the risks associated with the widespread use of nano-silver is not possible at this time.

Nanoparticles are particles with a diameter of less than 100 nanometres (nm).



The screenshot shows the BfR website interface. At the top, there is a navigation bar with links for 'Homepage', 'Site map', and 'Contact'. A search bar is also present. Below the navigation, there are tabs for 'THE INSTITUTE', 'FOOD SAFETY', 'PRODUCT SAFETY', and 'CHEMICALS'. The main content area features a sidebar with categories like 'Risk communication', 'Research', 'Communication and Public Relations', 'Publications', and 'Events'. The main text area is titled 'BfR-Conference on Nanosilver' and provides details about the conference dates (08.02.2012 - 09.02.2012) and its purpose. A calendar widget on the right shows the dates of the conference.



### Sicherheit von Nanosilber in Verbraucherprodukten: Viele Fragen sind noch offen

10/2011, 12.04.2011

BfR-Workshop bestätigt unvollständige Datenlage bei gesundheitlichen Risiken von nanoskaliger Silber

In seiner Stellungnahme zu Aspekten der Toxizität von Nanosilber hatte das Bundesinstitut für Risikobewertung (BfR) empfohlen, auf den Einsatz von Nanosilber in Lebensmitteln und Produkten des täglichen Bedarfs solange zu verzichten, bis die Datenlage eine abschließende Bewertung der gesundheitlichen Risiken erlaubt. Gegen diese Einschätzung des BfR wurde, insbesondere von Seiten der Industrie, eingewandt, dass zur Abschätzung des gesundheitlichen Risikos von Nanosilber in verbrauchernahen Produkten und in Lebensmitteln ausreichend Daten zur Verfügung stünden. Das BfR hat daher Experten aus Forschung und Wissenschaft sowie Vertreter von Verbänden und der Industrie zu einem Workshop eingeladen, um bestehende Risiken und mögliche Handlungsoptionen für einen umfassenden Schutz des Verbrauchers zu diskutieren. „Die Diskussion hat die Mahnung des BfR zur Vorsicht bestätigt“, sagte BfR-Präsident Professor Dr. Dr. Andreas Hensel, „denn es gibt nach wie vor zu wenig gesicherte wissenschaftliche Erkenntnisse über die spezifischen Wirkungen von Silberpartikeln in Nanogröße.“

## ENVIRONMENTAL Science & Technology

CORRESPONDENCE/REBUTTAL

pubs.acs.org/est

### Nanosilver in Consumer Products and Human Health: More Information Required!

**ABSTRACT:** Commenting on “120 Years of Nanosilver History: Implications for Policy Makers” (*Environ. Sci. Technol.* 2011, 45, 1177–1183). The title of the article seduces readers to the impression that we can look back at more than a century of safe use of nanosilver. In this context, colloidal silver and nanosilver have been sometimes used as synonyms. Historically, the term “colloidal silver” refers to dispersed silver particles encompassing a size range of 10–1000 nm. Following scientific definitions, “colloid” stands for freely dispersed particles in a fluid (heterogenic) phase irrespective of its size distribution, while the term “nanosilver” is used for categorization by size. Of course, just the labeling as such neither necessarily implies new hazard properties nor any specific risks; however, uncertainties and data gaps at many levels call for careful consideration and usually should take effect as alert signal for regulatory toxicologists all over the world. Within the frame of this short commentary, we would like to focus on some unclarified issues related to consumer products.

■ IS THE TOXIC POTENTIAL OF NANOSILVER IDENTICAL ... particle size, form and distribution were discussed, these effects

# BfR Opinion on Nanosilver

## Uncertainties:

- To what extent are consumers exposed to nanoscaled silver particles? Release, Uptake?
- What kind of effects of nanosilver in the human body?
- How great is the potential to develop resistance toward silver and the spread of resistance toward silver or antibiotics?

**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 Federal Institute for Risk Assessment (BfR) finds that a conclusive assessment of health risks associated with the widespread use of nano-silver is not possible at this time.

## **BfR Opinion # 024/2010**

**„BfR recommends manufacturers to avoid the use of nanoscaled silver or nanoscaled silver compounds in foods and everyday products until data are comprehensive enough to allow for conclusive risk assessment ensuring that products are safe for consumer health.“**

# Nanosilver in Consumer Products & Food

## Essential issues to be addressed:

- Analytics ?
- Exposure ?
- Toxicology ?
- Microbiology ?
- Current Concepts in RA ?



Risiken erkennen – Gesundheit schützen

**Thank you for your attention!**

Andreas Luch

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Andreas.Luch@bfr.bund.de • [www.bfr.bund.de](http://www.bfr.bund.de)