Silver Nanotechnology Working Group
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SNWG comments on BfR & nanosilver

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Background

- In December 2009 the German Federal Institute for Risk Assessment (BfR) published an opinion advising against use of nanosilver in food and everyday products[1].
- Industry and other groups, including the Silver Nanotechnology Working Group (SNWG), repeatedly requested BfR to reconsider this extreme position and BfR subsequently organized a workshop ostensibly to consider alternative views on nanosilver[2].
- Despite BfR assurances that follow-up dialogue would occur after the workshop, BfR subsequently issued a press release[3] re-stating the original position of the initial opinion. This re-stating of the original opinion essentially ignores the facts presented to BfR during the workshop.

1. Key concerns of BfR

The concerns of BfR essentially come down to three issues:

1. BfR's belief that use of silver aims to replace normal hygiene measures
2. Concern over potential for bacterial resistance from silver
3. Claims of unusual effects of nanosilver compared to conventional silver

Concern 1: Replacing hygiene?

- Antimicrobial products bring benefit to millions of consumers every year. Products such as plastics, textiles, and cosmetics last longer and provide better value for money and increased utility to consumers.
- Benefits to the consumer include:
    - longer shelf life (eg. cosmetics) -- more safety, less waste and ultimately lower prices for consumers

[1] Opinion No. 024/2010 of BfR 28 December 2009. BfR "BfR rät von Nanosilber in Lebensmitteln und Produkten des täglichen Bedarfs ab", Bundesinstitut für Risikobewertung, Germany, Stellungnahme Nr. 024/2010 (Dez 2009). http://www.bfr.bund.de/cm/216/bfr_raet_von_nanosilber_in_lebensmitteln_und_produkten_des_taeglichen_bedarfs_ab.pdf

[2] 17 Feb 2011. BfR hosts workshop on nanosilver in Berlin.

[3] 12 April 2011. BfR press release, "Safety of nano silver in consumer products: many questions remain open" http://www.bfr.bund.de/en/press_information/2011/10/safety_of_nano_silver_in_consumer_products__many_questions_remain_open-70234.html

    - plastics protected against the degrading action of bacteria (eg. discoloration)
    - textiles protected against colonization of bacteria that can lead to odours (eg. sportsclothing), -- giving greater comfort and prolonged use. Additional benefits such as reduced washing frequency at lower temperatures can give significant water and energy savings.
- BfR's concern that antimicrobial treatments encourage the consumer to dispense with normal hygiene is based on a superficial understanding of the intended purpose of the treated goods as used in the marketplace.
- BfR singling out of nanosilver for the general concern of hygiene makes no sense when the antimicrobial market has been served by numerous other silver materials and synthetic chemical biocides in much higher volumes for decades.

Concern 2: Bacteria resistance?

- BfR's original opinion states concern regarding potential for bacterial resistance from widespread use of silver as a justification for recommending against the use of nanosilver in consumer goods.
- BfR's analysis disregards multiple publications that state the risk of resistance to silver in reality is low. e.g. Percival et al. who state that "*it is important to note that bacteria have been exposed to subinhibitory levels of* Ag^+ [silver ions] *for over four billion years and no widespread resistance has been evident to date*[4]".
- BfR's position reflects a failure to recognize that silver is a natural element that is by definition prevalent throughout the world at low, sub-inhibitory, concentrations, even in daily tap water, with no practical evidence to support a concern for widespread bacterial resistance.
- BfR wrongly singles out nanosilver in order to address a concern over silver resistance in general. To highlight nanosilver when other silver materials are used in often higher volumes makes no sense.

Concern 3: Unusual behavior of nanosilver?

- BfR's position reflects a conviction that small particle size must make nanosilver a new material and accordingly must behave differently to conventional silver.
- Contrary to BfR's assumptions, macro forms of silver ("macro" particles) that are cited as being 'conventional' silver materials are rarely employed in the market. Silver ion and silver salt materials (e.g silver glass, silver zeolite, and silver chloride) dominate the antimicrobial treatment market.
- Further contrary to BFR's assumptions "macro" silver has not informed the toxicological record for silver generally. Historical analysis reveals that the toxicological record is based on ionic and colloidal (nano) silver materials[5].
- Regardless of form, all silver antimicrobial materials function through the action of silver ions (Ag^+). The function of nanosilver is fundamentally no different from any other antimicrobial silver materials available in the marketplace. Furthermore, most commercial applications employ the silver embedded in a substrate (e.g. plastics, coatings and textiles) -- there is no other plausible mode of action other than via the release of silver ions.

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[4] SL.Percival, PG.Bowler, D. Russell, "Bacterial resistance to silver in wound care", Journal of Hospital Infection, 60(1) (2005) 1-7. http://dx.doi.org/10.1016/j.jhin.2004.11.014

[5] B.Nowack, HF.Krug, MJ.Height, "120 Years of Nanosilver History: Implications for Policy Makers", Environmental Science and Technology 45 (2011) 1177–1183. http://dx.doi.org/10.1021/es103316q

- BfR highlights a selective series of academic articles where silver nanoparticles interact with cells in superficially unusual mechanisms. On close inspection and critical analysis these studies do not definitively show that the antimicrobial effect derives from anything other than release of silver ions.
- The mode of action is therefore not unusual in comparison to other silver forms employed in the marketplace or used throughout history.

2. Questionable Analysis

There are a number of additional issues surrounding BfR's position on nanosilver that should bring concern to industry, consumers and the public in general.

Concerns are general yet BfR singles-out nanosilver

- The first two concerns of BfR as stated above clearly relate to silver materials in general yet BfR singles out nanosilver for special treatment. This position indicates an illogical bias and is without scientific basis.
- The BfR opinion gives implicit endorsement for using all other silver forms despite logically sharing the general concerns stated by BfR.

Misunderstanding of materials and history

- BfR maintains that nanosilver is a new material with unique properties that have not been seen or characterized before.
- The origins of the modern nanosilver derive from historical colloidal silver materials which is a substance that has been in widespread use for well over a century[5].
- By failing to recognize historical colloidal silver as nanosilver, BfR incorrectly misallocates existing toxicological data that would otherwise directly inform the risk profile of nanosilver materials. This gives a false perception of data gaps.
- Where BfR does consider colloidal silver, the assumption is that these materials could not possibly have been adequately characterized to show they were nano. BfR has not adequately examined this assumption as prominent examples of historical colloidal nanosilver materials with demonstrated and thorough characterization are in the scientific record as early as 1969[6].
- BfR maintains the contradictory position of endorsing use of so-called conventional silver materials that share much of the same toxicological background derived from historical colloidal nanosilver data[7].

BfR analysis indicates nanosilver OK (as long as "nano" prefix is not used)

- The BfR opinion states that there is no issue for use of conventional silver products in cosmetics based on there being no evidence of adverse effects for a silver chloride based additive (page 3 of BfR opinion[1]).
- The silver chloride material endorsed by BfR is in fact a nanosilver material[8].
- BfR therefore appears to conclude that there is no evidence of adverse effects for a nanosilver material (provided that the material is not named "nano").

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[6] G.Frens, J.Th.G.Overbeek, "Carey Lea's colloidal silver", Kolloid-Zeitschrift und Zeitschrift für Polymere, 233(1-2) (1969) 922-929.

[7] LE.Gaul, AH.Staud, "Seventy cases of generalized argyria following organic and colloidal silver medication, including biospectrometric analysis of ten cases", J. Am. Med. Assoc. 104(16) (1935), pp.1387–1390.

[8] K.Kulthong, S.Srisung, K.Boonpavanitchakul, W.Kangwansupamonkon, R.Maniratanachote, "Determination of silver nanoparticle release from antibacterial fabrics into artificial sweat", Particle and Fibre Toxicology (2010) 7:8. http://dx.doi.org/10.1186/1743-8977-7-8

- This analysis appears to represent a double standard in risk assessment that shows a process driven more by nomenclature than materials science.

BfR selectively harming SMEs

- Nanosilver is a material produced primarily by small and medium size enterprises (SMEs) who have otherwise been encouraged by European governments to bring dynamism and employment opportunities to the European economy.
- Statements by BfR built on flawed analysis are directly impacting on the chances of SMEs to contribute to the economy and the employment prospects of Europeans.
- Even though BfRs concerns relate to silver materials in general, BfR has through its actions deliberately sought to restrict the commercial opportunities specifically for nanosilver materials provided by German and European SMEs.
- Many of these companies have been strongly supported by taxpayer money through numerous development initiatives. Efforts that are now put in danger by flawed analysis by BfR.

Ignoring benefits to the consumer and environment

- The BfR position shows a lack of consideration to the real-world purpose of why nanosilver materials are used in comparison to other materials.
- Nanosilver displaces far less efficient, more harmful and higher volume chemicals from numerous everyday applications.
- The position taken by BfR recommending against nanosilver in isolation of these facts amounts to an endorsement for greater volumes of synthetic chemicals and less efficient silver materials in consumer products – something that is ultimately not a benefit to the consumer and the environment.

Pre-empting EU regulatory processes

- BfR mistakenly believes that there is limited regulatory oversight for products containing nanosilver.
- In the latest press release BfR re-states that "*For consumer products such as textiles there is, however, no duty of notification or authorisation*[3]". Contrary to this statement the European Union Biocidal Product Directive[9] is the overarching regulatory framework that applies to the majority of consumer products where antimicrobial action is claimed.
- In particular it should be noted that the EU BPD explicitly applies to the protection of textiles and plastics, an application where BfR continues to claim that regulatory oversight is lacking.
- Under EU BPD regulations silver materials are undergoing comprehensive assessment including toxicology review and risk assessment, administered by the Swedish authorities who are the nominated responsible member state for this task. BfR appears to be pre-empting these efforts.

BfR opinion based on limited scope of analysis

- The BfR survey of toxicological data relating to nanosilver is prone to search term bias. Searching only for "nano"-specific data excludes the applicability of legacy colloidal silver data. Ignoring historical changes in nomenclature used to describe materials is not a valid basis for excluding data.

[9] European Biocidal Products Directive BPD 98/8/EC: http://ec.europa.eu/environment/biocides/index.htm

- BfR considers only studies that employ modern GLP protocols. For materials with a long historical record of safe use such as colloidal nanosilver, this approach inevitably identifies data gaps when studies are from an earlier era.
- Assessment of risk is a balance between potential for harm (toxicology) and exposure. BfR conspicuously makes no consideration of exposure in their analysis.
- Exposure analysis for nanosilver would reveal that most treated products employ miniscule amounts of nanosilver (tens of parts per million by weight of treated article) and most often this is employed in forms that are bound and secured in plastic matrices and/or coatings.
- Exposure analysis in comparison to conventional silver products and synthetic chemical antimicrobials would show significantly lower quantities of active substance are required for nanosilver to achieve an equivalent effect. Such analysis indicates a compelling potential for less chemicals to be used to treat consumer products and less pollution of the environment.
- The historical record of safe use must be taken into account when assessing the risk of colloidal nanosilver materials. BfR cannot simply proclaim a new risk from “new” nanosilver when the materials have clearly been in safe use by consumers and doctors for multiple decades.