

Wissenschaftliche Posterausstellung: Poster 12

Nanotoxicological Classification System (NCS) – a rational approach to assess the safety & risk of nanoparticles

Rainer H. Müller (1), Cornelia M. Keck (1,2)

1: Department of Pharmaceutics, Biopharmaceutics and NutriCosmetics, Freie Universität Berlin, Kelchstr.31, 12169 Berlin, Germany

2: Applied Pharmacy Division, University of Applied Sciences Kaiserslautern, Campus Pirmasens, Carl-Schurz-Str. 10-16, 66953 Pirmasens, Germany

There is an increasing and by now almost uncontrolled use of nanomaterials in many different industrial areas, ranging from nanopigments in colours, via carbon nanotubes in cars to nanoparticles in cosmetics and pharma. In parallel there is an increasing concern by the consumers about the safety of these nanomaterials and potential risks for health and environment. Especially the popular press likes it to increase its circulation by lurid headlines about “dangerous nano”. As a consequence the public perception is getting more and more negative about nano, potentially impeding useful nanotechnology. The more it is necessary to put the safety and risk evaluation of nanomaterials on a scientific basis. This is done by the proposal of the nanotoxicological classification system (NCS) (1) for cosmetics and pharma, but it has also implications for other consumer products (e.g. personal care, nutrition).

The NCS places the nanomaterials in 4 groups of no or very little (I) via medium (groups II and III) to potential higher risk (IV). This is very important because it provides a guide on which nanomaterials toxicity studies should focus first. Meanwhile there are thousands of nanomaterials around, a safety evaluation for one material involves extensive different studies, but there is a limited capacity available to do these studies. Thus one should focus first on particles with potential highest risk, the NCS can be used as selection tool.

Toxicity determining parameters are size, degradability and biocompatibility. Depending on the size, the particles have different access to cells. Nanoparticles >100 nm to 1,000 nm have access to only a limited number of cells (macrophages), are therefore less risky, whereas nanoparticles < 100 nm can be internalized by any cell via endocytosis. Biodegradable particles will eventually disappear, most likely also a related undesired effect, non-biodegradable particles can stay forever in the body, thus being of higher risk. This results in 4 classes: I - >100 nm, biodegradable, II - > 100 nm, non-biodegradable, III - < 100 nm with easy cell access but still biodegradable, IV - < 100 nm and not biodegradable (= potentially highest risk, but not necessarily toxic!).

Another important point is the biocompatibility (B) or non-biocompatibility (NB). A non-biocompatible surface of a particle, even when the particle is of class I, might activate the immune system by opsonin adsorption. Therefore for a full picture each class needs to differentiate, resulting in a total of 8 classes from I-B, I-NB to IV-B and IV-NB. The classes can



also be shown in form of a traffic light system: green (I), yellow (II, III) and red (IV), easy to understand by politicians and the average consumer.

References

[1] Müller, R. H., Gohla, S., Keck, C. M., State of the Art of Nanocrystals - special features, production, nanotoxicology aspects & intracellular delivery, Eur. J. Pharm. Biopharm. 78 (1), 1-9 (doi:10.1016/j.ejpb.2011.01.007), 2011

