

Oral evidence – Dr. Ian White (Chairman SCC-NFP, Consultant Dermatologist, St. Thomas' Hospital, St. John's Institute of Dermatology, London.)

Taken in the presence of Dr. Andrew Dunn of the Royal Society Nanotechnology study secretariat, and Prof. Anthony Seaton, member of the Nanotechnology study working group on February 23rd 2004.

Dr. Ian White is currently Chairman of the scientific committee on cosmetic and non-food products (SCC-NFP), which is a risk assessment advisory committee of DG Sanco (Consumer Safety & Health Protection) at the European Commission.

Prof. Seaton began by giving a brief introduction to the study, and noted that the working group were keen to discuss the use and assessment of nanoparticles in cosmetics. He went on to note that the use of nanoparticulate titanium dioxide (TiO₂) was now widespread in cosmetics and sunscreens, and was aware that the SCC-NFP had given the expert opinion that this was safe. Prof. Seaton was keen to hear the methodology behind this opinion, the role of the SCC-NFP within the framework of regulation, and whether the size of particulates used in cosmetics was or is becoming a consideration in its own right for the SCC-NFP.

Dr. White began by noting that although he was not Chairman of the committee during the time that TiO₂ was under scrutiny, he was aware of the relevant information and was happy to give comments. Nanoparticulate TiO₂ is used in sunscreens due to its ability to absorb and reflect UV light whilst appearing transparent to visible light, and so is more acceptable to the consumer. However, nanoparticulate TiO₂ tends to agglomerate, and so the particles are coated hinder this effect. These coatings also reduce the formation of free-radicals. Uncoated nanoparticulate TiO₂ is photo-active and creates free radicals.

The issue then discussed was whether nanoparticles, due to their small size were able to penetrate the skin, and Dr. White was confident that studies on humans have clearly shown that nanoparticles of TiO₂ currently used in cosmetics do not penetrate through the stratum corneum (outermost layer of skin). It was noted that studies had not been done on diseased skin but some experiments had been done on skin that already had UV induced erythema. Dr. White also expressed the view that current methods of detection are sufficient when dealing with nanoparticles.

The role of the SCC-NFP within the regulatory framework was then discussed. Dr. White first made clear the fact that members of the committee are independent, with none coming from industry. The committee's advice is discussed by member states and other stakeholders, and once agreed, it may be adopted into EU directives. The SCC-NFP do not conduct testing of their own-this is done by the manufacturer under strict guidelines, and the onus is on industry to obtain the necessary information to demonstrate that a substance is safe for its intended use. As part of the procedure, manufacturers are required to sign a declaration that all relevant information has been obtained and submitted for consideration.

The divide between medicines and cosmetics was then discussed and it was noted that sunscreens in the USA are regulated as medicines, while in Europe they are classified as cosmetics. A medicine in the UK is defined as a substance for the treatment, prevention, investigation of disease or used to alter physiological function. It was then suggested that sunscreens might be considered as preventative medicines, and Dr. White was asked whether he felt that re-classification of these as medicines would present a significant

burden to industry. It was felt that as testing is already extremely rigorous, re-classification probably would not have a useful effect.

The discussion then turned to methods of testing ingredients of cosmetic ingredients. It was noted that the SCC-NFP do not examine formulations, only ingredients, and that most ingredients in cosmetics are not subject to rigorous testing, as their toxicity may be easily inferred. There are, however, a number of special annexes to the Cosmetics Directive which relate to prohibited substances and those for limited use and there are guidelines for testing issued by the SCC-NFP. There is also a specific annex relating to permitted UV filters in cosmetics (a 'positive' list). Dr. White felt it important to point out that a new EU regulation designed to limit, and ultimately end the use of animals in cosmetics testing, will severely restrict the level to which ingredients may be tested for safety, and he felt this to be a pressing issue. Certain toxicological endpoints for example could not be reached without the use of animals for testing. It was noted that the new EU regulations for chemicals (REACH) specify the use of animals for testing, however Dr. White felt that where chemicals would be used as ingredients for cosmetics, additional animal testing may be essential to ensure the safety of consumers; however this may not be permitted under forthcoming legislation.

For a cosmetic product on the market, it is the responsibility of the manufacturer to ensure that a complete safety evaluation of the product has been undertaken by a competent individual. This is required by the Cosmetics Directive.

The use of micronised zinc oxide in sunscreens was then discussed. Nanoparticulate zinc oxide is used as a UV filter, similar to titanium dioxide. Although currently on the market, the SCC-NFP has yet to receive an adequate dossier on the toxicology of this substance from industry, as opposed to zinc oxide of larger particulate size. The SCC-NFP has issued an opinion that more information is needed to enable a proper safety evaluation of micronised zinc oxide for use as a UV filter in cosmetic products.

Prof. Seaton then asked as to how the SCC-NFP were appointed and what their composition is. The committee is appointed by the European Commission, and is composed of individuals with particular expertise in the various fields of toxicology. No representatives of industry are on the committee, which is entirely independent. Dr. White noted that when required, outside experts are brought in. Assessments by the SCC NFP are rigorous, transparent and the full opinions are published.