SCIENTIFIC OPINION

Inability to assess the safety of a silver hydrosol added for nutritional purposes as a source of silver in food supplements and the bioavailability of silver from this source based on the supporting dossier[1]

Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food (ANS)

(Question No EFSA-Q-2005-169)

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PANEL MEMBERS

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BACKGROUND AS PROVIDED BY THE COMMISSION

The European Community legislation lists nutritional substances that may be used for nutritional purposes in certain categories of foods as sources of certain nutrients.

The Commission has received a request for the evaluation of silver hydrosol added for nutritional purposes to food supplements. The relevant Community legislative measure is:

- Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements[2].

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion, based

[1] For citation purposes: Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on Silver hydrosol as a source of silver added for nutritional purposes to food supplements. *The EFSA Journal* (2008) 884, 1-3

[2] OJ L 183, 12.7.2002, p. 51.

on its consideration of the safety and bioavailability of silver hydrosol added for nutritional purposes in food supplements.

ASSESSMENT

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to provide a scientific opinion on the safety of silver hydrosol added for nutritional purposes as a source of silver in food supplements and on bioavailability of silver from this source.

1. Summary of available data on silver hydrosol

According to the petitioner silver hydrosol is an aqueous colloidal suspension of particles of silver with an average size of 0.8 nm at a concentration of 10 mg/kg or 23 mg/kg in purified water. Silver in silver hydrosol is a nanoparticulate material.

No data have been presented by the petitioner on the bioavailability of silver from silver hydrosol, toxicokinetics and repeated-dose toxicity of silver hydrosol. The petitioner has submitted toxicity data from an acute oral toxicity test in rats which used a single dose of 20 ml/kg bw of a 23 mg/kg solution administered by oral gavage (equivalent to 460 microg silver/kg bw), an *in vitro* cytotoxicity study which evaluated the effects of 24 hour exposures of three colloidal silver solutions (silver 23, 11 and 10 ppm, respectively), on mouse fibroblast cell viability, and from a bacterial mutagenicity assay and a chromosomal aberration test in Chinese Hamster Ovary cells to detect genotoxicity *in vitro*. No mammalian cell mutagenicity data were provided. Inadequate characterisation of the hydrosol was provided in these studies or evidence given for the form of silver to which cells or animals were exposed.

The petitioner provided additional information on the toxicity and bioavailability of ionic silver.

2. Assessment of nanomaterials

The Scientific Committee of EFSA has produced a draft opinion on the *Risks Arising from Nanoscience and Nanotechnologies on Food and Feed safety and the Environment*. EFSA launched a public consultation on this draft opinion on 17 October 2008. The Panel also noted that a number of national and international advisory committees have recommended strategies for the risk assessment of nanomaterials and that the implementation of these is ongoing. The Panel has taken these strategies into account and considered the following principles in undertaking this initial assessment of a nanomaterial:

- The currently used risk assessment paradigm (hazard identification, hazard characterisation, exposure assessment and risk characterisation) is considered applicable for nanomaterials. Conventional toxicological testing methods should be used as a starting point to identify hazards from nanomaterials. However, additional issues specific for the properties of nanomaterials must also be considered.
- The risk assessment of nanomaterials must be performed on a case-by-case basis as there are insufficient data to allow generic approaches for their risk assessment.

- The risk assessment of nanomaterials needs to include both nanospecific properties and those common to the equivalent non-nanoforms.
- Due to their physicochemical properties the toxicokinetic and toxicity profiles of nanomaterials cannot be inferred from data on their equivalent non-nanoforms.

Appropriate data for risk assessment of nanomaterials in the food and feed area should include comprehensive identification and characterisation of the nanomaterials. At the present time, the Panel considers that the following minimum characteristics and/or parameters should be provided: size (including its distribution), mass, surface area, specific surface area, number, shape, chemical composition (including impurities and processing chemicals), surface properties (e.g. coating, charge) and solubility (including hydrophilicity). For ingested nanomaterials, the Panel considers that the minimum requirements include data from repeated-dose toxicity studies and appropriate *in vitro* studies (e.g. for genotoxicity). The design and performance of these toxicity studies must be based on toxicokinetic information on the nanomaterial.

CONCLUSIONS

The Panel considers that the data provided by the petitioner are insufficient to adequately characterise silver hydrosol for risk assessment. The Panel considers that data on ionic silver cannot be used to establish the safety of silver hydrosol. The Panel considers that the toxicological data provided by the petitioner are insufficient to allow hazard characterisation of silver hydrosol. Therefore, the Panel concludes that due to the lack of an appropriate dossier supporting the use of silver hydrosol, the safety of silver hydrosol and the bioavailability of silver from silver hydrosol cannot be assessed.

Key words:

Food supplements, silver hydrosol, silver, CAS 7440-22-4, EINECS 231-131-3.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on silver hydrosol proposed for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council relating to Food Supplements. June 2005. Submitted by Natural-Immunogenics (UK) Ltd.

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