Safety assessment of the active substance selenium nanoparticles, for use in active food contact materials

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Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) deals with the safety assessment of selenium nanoparticles, FCM substance No 1070, which is intended to be used as an antioxidant. Selenium nanoparticles are incorporated into the adhesive middle layer of multilayer laminates with an outside polyethylene terephthalate (PET) layer and an inner polyolefin (food contact) layer. The final materials are intended to be used for contact with all food types that are susceptible to oxidation. The specific migration of total selenium was tested using multilayer pouches containing selenium nanoparticles at 0.002 mg/dm^2 and filled with 3% acetic acid and 20%, 50% or 95% ethanol for 10 days at 60°C. In all tests, migration of selenium was not detectable. Taking into account current knowledge on the diffusional properties of nanoparticles in polymers, the CEF Panel concluded that there is no safety concern for the consumer if selenium nanoparticles are used in multilayer films and separated from the food by a polyolefin food contact layer for any type of food and under any food contact conditions.

Keywords: selenium nanoparticles, active and intelligent materials, multilayer, antioxidant

Requestor: Ministerio de Sanidad, Servicios Sociales e Igualdad, Spain

Question number: EFSA-Q-2017-00089

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 450/2009[1] of the Commission of European Communities is a specific measure that lays down specific rules for active and intelligent materials and articles intended for contact with foodstuffs in addition to the general requirements established in Regulation (EC) No 1935/2004[2] of the European Parliament and of the Council on materials and articles intended to come into contact with food. Active materials and articles are intended to extend the shelf life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.

The substance(s) responsible for the active and/or intelligent function of the material should be included in a positive list by the Commission following a safety evaluation by the European Food Safety Authority (EFSA) according to the procedure described in the above-mentioned regulations.

According to this procedure, the industry submits applications to the Member States competent authorities which transmit the applications to EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the EFSA 'Guidelines on submission of a dossier for safety evaluation by EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food' (EFSA, 2009b).

In this case, EFSA received an application from the Ministerio de Sanidad, Servicios Sociales e Igualdad, Spain, requesting the evaluation of the active substance Selenium nanoparticles, with the food contact material (FCM) substance No 1070.

According to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, EFSA is asked to carry out an assessment of the risks related to the intended use of the substance and to deliver a scientific opinion.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of their application for the authorisation of selenium nanoparticles (SeNPs) to be used in active FCM.

Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity
- Description of manufacturing process of substance/FCM
- Physical and chemical properties
- Intended use
- Existing authorisation(s)
- Migration of the substance
- Residual content of the substance.

Toxicological data

None.

2.2. Methodologies

In the context of the safety evaluation by EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food (EFSA, 2009b), the safety evaluation is conducted using the general methodological framework established for monomers and additives used to make plastics and published as the guidelines of the Scientific Committee on Food (SCF) (European Commission, 2001).

[1] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. OJ L 135, 30.5.2009, p. 3–11.

[2] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the guidelines of the SCF for the presentation of an application for safety assessment of a substance to be used in FCMs prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001).

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration, and the definition of minimum sets of toxicity data required for safety assessment. For active substances that are intended to be released themselves or to cause the release of other substances into foods, additional considerations apply with respect to their safety and status as direct food additives. These considerations are described in the EFSA guidelines on active or intelligent substances (EFSA, 2009b).

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently, there are three tiers with different thresholds triggering the need for more toxicological information as follows:

a) In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
b) In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
c) In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

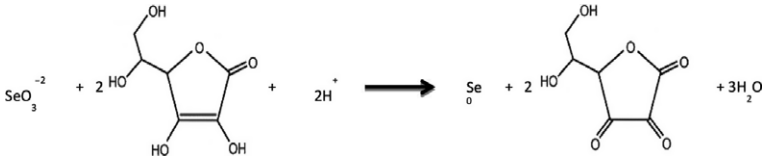
The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009a) and considering the relevant guidance from the EFSA Scientific Committee.

According to the general principles of the safety assessment of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food (EFSA, 2009b), this safety assessment focuses on the risks related to any dietary exposure to chemicals arising from the intended application. It should be noted that the EFSA evaluation cannot be considered as proof of the technical efficacy of an active and/or intelligent material and article.

3. Assessment

According to the petitioner, SeNPs are used as synthetic antioxidants incorporated into the adhesive middle layer of multilayer laminates consisting of an outer layer such as polyethylene terephthalate (PET) and a polyolefin layer such as low-density polyethylene (LDPE) as an inner food contact layer. This material is considered to be an antioxidant multilayer where the adhesive layer represents the active part which is not in direct contact with the food. The intention is to use this active packaging for all kind of food that is susceptible of oxidation. Some examples are meat, chips, dry fruit, fish and other. The conditions of use are in general under refrigeration or at room temperature but will depend on the particular application.

The SeNPs are synthesised in solution by reduction of sodium selenite with ascorbic acid in the presence of hydroxyethyl cellulose as a stabiliser agent.



By this chemical reaction selenite is converted into SeNPs with a yield of 99.87%. The size of the obtained SeNPs ranges from 50 to 90 nm in diameter. The solution from this reaction is then added to a water based adhesive which is used in a conventional manufacturing process to bond two different polymer films together to make the antioxidant multilayer film. During this process, the applied wet

adhesive is dried under hot air injection at a temperature of 80°C for some 15 s. The maximum use level of SeNPs in the final multilayer film is intended to be 3 mg/m^2.

Although selenium itself or any other selenium-based chemical compounds are currently not listed and authorised in Regulation (EU) No 10/2011[3], the other two components used, ascorbic acid and hydroxyethyl cellulose, are both authorised without a restriction under FCM nos. 101 and 558, respectively.

3.1. Non-toxicological data

The active substance consists of SeNPs with a size range of 50–90 nm in diameter (determined by asymmetrical Flow Field-Flow Fractionation (AF4) analysis, transmission electron microscopy (TEM) and field emission scanning electron microscopy (FESEM) images) when incorporated into the adhesive middle layer of the multilayer film. The maximum intended use level of SeNPs is 3 mg/m^2 which corresponds to a total migration potential present in the multilayer film of 30 μg/dm^2. In such a multilayer film, the active substance is not in direct contact with the packed food and separated from the food by polyolefin layer, typically an LDPE film of 60 μm thickness. The multilayer film is manufactured by a co-lamination process of two polymer films in which the wet adhesive layer applied to one film is dried at a temperature of 80°C for a short time. Under these mild processing conditions, it cannot be expected that SeNPs would penetrate into and through the food contact polyolefin layer. Direct contact of SeNPs with food is therefore not to be expected when the multilayer is brought in contact with a food.

The petitioner performed specific migration tests by preparing pouches from multilayer test films and filling them with food simulants 10% ethanol (simulant A), 3% acetic acid (simulant B), 20% ethanol (simulant C), 50% ethanol (simulant D1) and 95% ethanol (alternative simulant D2). In addition, a migration test using hazelnuts as a real food was carried out. Three different multilayer test films, each with the same outer layer (12 μm PET) but three different food contact LDPE layers of 35 μm, 60 μm and 90 μm were used. The applied test condition was in all cases 10 days at 60°C using a surface/volume ratio of 0.5 dm^2/30 mL of food simulant. Inductively coupled plasma-mass spectrometry (ICP–MS) analysis was applied to measure selenium in the food simulants and in the hazelnuts. In all cases, migration of selenium was not detectable at a detection limit of 2.3 μg/kg food simulant or, in case of hazelnuts, 0.46 μg/kg. In these test films, the SeNPs level was determined to be 0.2 mg/m^2 corresponding to 0.002 mg/dm^2. The Panel noted that under these test conditions the maximum use level of 30 μg/dm^2 was not simulated. However, based on published data (Franz and Welle, 2017; Stoermer et al., 2017) on diffusion in and migration from polymers of nanoparticles, migration of SeNPs is not to be expected also at this higher use level. Due to the high conversion rate of selenite into SeNPs (99.87%) and taking inherently low diffusion characteristics of polyolefin polymers for inorganic species into account, also migration of ionic selenium such as residual selenite is not expected.

3.2. Toxicological data

Selenium is an essential trace element. In the human diet, selenium is present mainly in organic compounds, as L-selenomethionine and L-selenocysteine, with lower amounts in inorganic compounds, as selenate and selenite. The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) set in 2014, adequate intake (AI) values for selenium in the range of 15 μg/day for children aged one to three years up to 70 μg/day for adults. The SCF (2000) set tolerable upper intake levels (UL) in the range of 60 μg/day for children aged 1–3 years up to 300 μg/day for adults. The UL has not been reconsidered in the EFSA NDA Panel (2014) opinion.

Since no migration and therefore no exposure to selenium is to be expected for this multilayer application, the CEF Panel did not consider it necessary to propose restrictions or specifications on the particle size, the concentration of selenium in the plastic materials or on the thickness of the barrier layer.

4. Conclusions

The CEF Panel, after having considered the above-mentioned data, concluded that the active substance selenium nanoparticles does not raise a safety concern to the consumer if the active

[3] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance. OJ L 12, 15.1.2011, p. 1–89.

substance is used in multilayer films and separated from the food by a polyolefin food contact layer for any type of food and under any food contact conditions.

Documentation provided to EFSA

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Abbreviations

AF4	asymmetrical flow field-flow fractionation
AI	adequate intake
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
FCM	food contact materials
FESEM	field emission scanning electron microscopy
ICP-MS	inductively coupled plasma-mass spectrometry
LDPE	low density polyethylene
LOD	limit of detection
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
PET	polyethylene terephthalate
SCF	Scientific Committee on Food
SeNPs	selenium nanoparticles
TEM	transmission electron microscopy
UL	tolerable upper intake levels