

21 February 2022

FSS/ENF/22/001

Sale of food supplement products containing an unauthorised novel food- Serratiopeptidase

Dear colleagues,

Food Standards Scotland (FSS) has become aware of the sale of a food supplement product containing Serratiopeptidase. Serratiopeptidase is an unauthorised novel food. It is also sold under the name Serrapeptase and marketed as SerraEnzyme capsules.

FSS is not aware of a significant history of consumption of Serratiopeptidase in the UK and EU prior to 15 May 1997. Unless evidence of a history of consumption can be provided, FSS consider it to be a novel food under the [Retained Regulation \(EU\) 2015/2283 on novel foods](#). As a novel food, it would need to undergo a mandatory pre-market safety assessment and obtain authorisation under the novel foods regulations before it can be legally placed on the market.

As Serratiopeptidase is considered an unauthorised novel food, FSS advise that products containing Serratiopeptidase be withdrawn from the market. Placing an unauthorised novel food on the market is an offence under regulation 4 of the novel foods regulations for failing to comply with Article 6(2) of [Retained Regulation \(EU\) 2015/2283](#).

When Serratiopeptidase is added to food for a technical purpose as a food enzyme it is permitted under [Retained Regulation \(EU\) 1332/2008](#). A food enzyme is a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms. Food enzymes can be added to foods for a number of reasons, such as catalyzing a specific biochemical reaction, at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage. Serratiopeptidase is one such enzyme.

However, any other uses, such as sale as a food supplement for direct consumption (commonly under the names 'Serratiopeptidase' 'Serrapeptase' and 'SerraEnzyme'), fall within novel food regulations. These products are commonly sold in tablet, capsule and powder form.

Each product should be considered on an individual basis to determine whether it is a novel food or a food enzyme. If local authorities (LAs) are unsure if the use of a product falls under use as an enzyme, or as a novel food, we recommend sending an enquiry to us at LabellingStandardsandRegulatedProducts@fss.scot

Where novel products are identified appropriate enforcement action would be expected i.e. request the business to withdraw the product from the market, in line with local enforcement policies, and advise them on the novel food [approval process](#).

LAs will also wish to be aware that there may also be issues regarding unauthorised health claims, labelling requirements and breaches under food supplements, which may require monitoring.

Yours sincerely,

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Enforcement Delivery

Food Standards Scotland