

Safety Assessment of Pasteurised Milk Treated with UV Light

Name of Applicant: Dairy Crest Ltd., UK

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Novel Food Classification: 6

Introduction

An application for the authorisation of pasteurised milk treated with UV light was submitted to the Food Safety Authority of Ireland (FSAI) by Dairy Crest (UK) in accordance with *Article 4* of the novel food Regulation (EC) No. 258/97. The application was accepted by the FSAI on September 26th, 2012.

The applicant intends applying a pre-determined dosage of UV-C (200-310 nm) light to pasteurised milk in order to further extend the shelf life of the product. Extended shelf life (ESL) milk with a reduced microbial load achieved through microfiltration is currently on the EU market, while other food and water products treated with UV are also on sale in the EU.

Vitamin D₃ is a nutrient that is naturally present in pasteurised milk at trace levels. However, vitamin D₃ levels are significantly elevated as a side effect of the exposure of pasteurised milk to UV-C light. UV-C light interacts with 7-dehydrocholesterol, a pre-vitamin in milk, resulting in the production of Vitamin D₃. Vitamin D is naturally produced by the interaction of UV-B from sunlight with the skin of humans. A vitamin D deficiency in humans is associated with defective bone mineralisation which is termed rickets in children, and often linked to insufficient sun exposure.

The applicant classifies the novel ingredient in line with *Article 1(2) (f)* of the novel food Regulation EC No 258/97: “foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances”. For the purposes of the safety assessment, the UV-treated milk product is placed in Class 6, as per Commission Recommendation 97/618/EC: “Foods produced using a novel process”. This assessment concerns the safety of milk and milk products treated with UV-C light, but it does not address any explicit or implicit nutrition or health claims.

I. Specification of the novel food

Bovine milk is well characterised and routinely consumed as milk or milk products such as cheese, butter, yoghurts etc. Milk or derived constituents (e.g. whey) are also used as ingredients in a large number of processed foods. The milk that is the subject of this application is essentially identical to regular pasteurised milk, with the

exceptions of a reduced microbial load and an increased level of vitamin D₃, both directly resulting from UV light exposure.

II. Production process

Production of the novel ingredient is detailed in the application dossier and involves the incorporation of a UV light source in a post-pasteurisation section of the normal processing line. The UV light source is termed the “SurePure unit” and is already used in South Africa for the UV treatment of liquids including milk, juice and wine. Pasteurised milk is pumped or gravity fed through the SurePure unit which results in a defined and monitored exposure of the pasteurised milk to UV-C light.

III. History of the source organism

Milk and milk products from a number of sources are available on the EU market, primarily from cows and to a less extent from goats and sheep. Cows’ (bovine) milk has a long and safe history of consumption in the EU and around the world. Milk is known to cause allergic responses in a subsection of the population while some people are intolerant to lactose, the primary sugar in milk.

IV. – VIII. GM aspects

Milk from GM cows is not available in the EU or indeed in any country, and therefore these sections are not applicable.

IX. Anticipated intake/extent of use of the novel food

The novel ingredient is not expected to impact on the consumption levels of milk but is expected to substitute at least for a portion of those existing products. The UV-treated milk will have general availability and, because of the increased vitamin D₃ content, may have more appeal to families with young children. Using UK consumption data relating to whole and semi-skimmed milk, and assuming a complete switch from pasteurised milk to milk that is pasteurised and UV treated, the applicant estimates that children between 1.5 and 3 years of age would have the highest average intake at 21 µg per day. This is within the tolerable upper limit of 25 µg per day of vitamin D set by EFSA for this age group. In other age groups, the applicant estimates that vitamin D₃ intakes from the novel ingredient would be considerably less than the tolerable upper limits set by EFSA and therefore not of concern.

X. Information from previous human exposure to the novel food or its source

Pasteurised bovine milk has a long history of safe consumption around the world, and while the applicant cites two other examples of extended shelf life milks, presumably on the UK market, neither has been treated with UV-C light. However, there are a few foods available that naturally contain vitamin D, with many others currently on the market, including infant formula, breakfast cereals and food supplements that are fortified with vitamin D.

XI. Nutritional information on the novel food

The applicant has identified vitamin D₃ as the only nutrient in pasteurised milk to be altered following exposure to UV light. Regular pasteurised milk contains trace levels of vitamin D₃, but this increases to 100 IU (2.5µg) per 100g of whole milk or 44 IU (1.1µg) per 100g of semi-skimmed milk upon UV-C light exposure.

The applicant does not specifically address vitamin D₃ intake from other foods (either natural or supplemented) and how this might impact on the overall vitamin D₃ intake, particularly at the higher 97.5th intakes in young children. However, evidence from the NDNS shows that 95% of children fail to meet the EU RDA of vitamin D₃ at 5 µg/d and therefore it is unlikely that the availability of vitamin D₃ from multiple sources would have a significant influence on overall intake.

XII. Microbiological information on the novel food

Pasteurisation of milk is a standard requirement in the EU (Regulation (EC) 863/2004 as amended by Regulation (EC) 2074/2005) and developed countries in general. This heat treatment process eliminates non-spore forming pathogens and reduces the levels of spoilage microorganisms with the dual purpose of enhancing food safety and establishing a stable shelf life. UV treatment is applied to pasteurised milk in order to reduce the microbial load even further and thereby extend its shelf life. The applicant provides data demonstrating the reduced microbial load resulting from UV treatment of pasteurised milk.

XIII. Toxicological information on the novel food

With the exceptions of reduced microbial load and increased vitamin D₃ content, the novel ingredient does not differ significantly from regular pasteurised milk in terms of composition or nutritional value. The applicant addresses possible protein and lipid breakdown resulting from the exposure of pasteurised milk to UV-C light, with no safety concerns being identified.

Allergenicity

Milk is a known allergen and is also associated with lactose intolerance. The use of milk or any of its derivatives must be indicated on the label when used as an ingredient, and these requirements will not change for pasteurised milk that has been exposed to UV-C light.

Conclusions

In addition to a few foods that naturally contain varying concentrations of vitamin D, a number of foods and beverages currently on the EU market have been fortified with vitamin D. The placing on the market of this novel ingredient is not likely to significantly affect the overall intake of vitamin D in a population but will provide an additional source of this nutrient in a product with an extended shelf life. The applicant has demonstrated that the UV treatment of pasteurised milk results in a

reduced microbial load and an increase in vitamin D₃ levels, but without undesirable effects on the final ingredient. The novel ingredient will remain subject to food legislation including that relating to allergen labelling and others, as appropriate for pasteurised milk.

Recommendation

The Food Safety Authority of Ireland has not identified any safety concerns with the consumption of pasteurised milk that has been treated with UV-C light as specified in this novel food application. Therefore, this novel ingredient meets the criteria for novel food set out in *Article 3.1.* of the novel food Regulation.