

ARTICLE 4 REQUEST

Regulation (EU) 2015/2283

Consultation request to determine the status of bovine colostrum immunoglobulin concentrate pursuant to Article 4(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

Recipient Member State: Denmark, Danish Veterinary and Food Administration (DVFA).

Name and description of the novel food:

The request concerns colostrum powder with increased amount of immunoglobulin. The product is produced from bovine colostrum through different processing steps. The content of immunoglobulin is increased from around 31 % in ordinary non novel colostrum powder to around 50-70 % in the processed colostrum powder.

The final product contains 75-95 % pure protein (hereof 50-70 % immunoglobulin, 10-40 % alpha-lactalbumin, and less than 1 % caseins and beta-lactoglobulin). The fat content is below 1 % and lactose content 0-20 %. The ingredient does not contain any engineered nanomaterials. The intended use is as food ingredient. In comparison, classic non novel colostrum powder contains around 56 % pure protein (hereof 31% immunoglobulin, 1 % alpha-lactalbumin, 11 % caseins, and 3 % beta-lactoglobulin), 25 % lipids and 11 % lactose.

In the process bovine colostrum, including transitional milkings, is mixed with hot water 1:1 and fat and caseins are removed. The resulting colostrum whey is ultrafiltrated to increase the protein concentration, upon which it is led through an ion exchange column in order to remove beta-lactoglobulins and soluble caseins. The resulting concentrate is further ultrafiltrated and diafiltrated, providing a concentrated colostrum powder reduced in lactose and devoid of beta-lactoglobulins and caseins. The degree of diafiltration controls the concentration of residual lactose and may be operated to produce a lactose-free product. This concentrate is dried to provide the final immunoglobulin concentrate.

Status –Novel food

Novel food category

Article 3(2)(a)(vii) *“food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.”*

Reasons statement

The content of immunoglobulin is increased from 31 % in classic colostrum to 50-70 % in the new product. The content of alpha-lactalbumin is increased from 1 % to 10-40 %. Casein content is lowered from 11 % to less than 1 %, beta-lactalbumin is lowered from 3 % to less than 1 %, fat content is lowered from 25 % to 1 %. Some of these changes are significant, but not likely to affect nutritional value, metabolism or level of undesirable substances of the product. However, the increased level of immunoglobulin constitutes a significant change, which is likely to affect nutritional value, metabolism or level of undesirable substances of the product. Therefore, the concentrate of bovine colostrum immunoglobulin is regarded as a novel food.

Conclusion

The production process used on colostrum is new, and results in significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances.