## Executive Summary:

This application, on behalf of Fonterra Co-operative Group Limited, requests approval for a new Processing Aid, an **Agarose ion exchange resin,** which is intended for use by the applicant for the production of high purity Lactoferrin from bovine milk.

Lactoferrin is a glycoprotein, and a member of the transferrin family of proteins, thus belonging to those proteins which have the capability of binding and transferring iron. It is mainly found in human and bovine milk, and to a lesser extent in other external secretions. It has multiple physiological functions, and is therefore one of the most important proteins present in mammalian milk. Apart from its role in iron metabolism, lactoferrin exerts important protective roles against a wide variety of infectious agents and is considered to be part of the innate immune system. Since it was first isolated more than 50 years ago, Lactoferrin has become the focus of intense research to better understand its physiological effects. Other roles in human health that have been established for lactoferrin include antibacterial, antiviral, and antiparasitic activity, immunomodulatory and anti-inflammatory activity, anticarcinogenic activity, cell proliferation and differentiation, and antioxidant acivity. The multiple roles that lactoferrin has in human health and development has established it as the first, and potentially the most important biaoactive as yet isolated from mammalian milk. Hence the enormous interest in lactoferrin for use in dairy-based foods, as a nutriceutical and a potential pharmaceutical.

Lactoferrin has been produced commercially since 1986. The established commercial method utilizes ion exchange chromatography to extract Lactoferrin from pre-treated dairy streams such as skim milk and whey. The ion exchange resin used for this purpose requires certain specific characteristics, for example, strong cation exchange functionality, large pore size to bind Lactoferrin, suitable bead size and mechanical strength to allow loading at high flow rates, and the ability to process whey or milk without becoming blocked. None of the permitted ion exchange resins currently listed in Standard 1.3.3 have all of these characteristics and are therefore not suitable for efficient commercial production of Lactoferrin.

The processing aid has been fully evaluated for safety for the intended purpose and is approved by the U.S. Food and Drug Administration as a Food Contact Substance. It complies with Codex Guidelines on Substances used as Processing Aids. In the EU, the Processing Aid meets the regulatory requirements for substances that come in contact with food, and the substances used for the manufacture of the Processing Aid are included on the “list of substances used in the manufacture of ion exchange and adsorbent resins”. The matrix of the Processing Aid, agarose highly cross-linked with epichlorohydrin, is the same as for an ion exchange resin currently listed as a permitted processing aid in Standard 1.3.3.

Ongoing research has established Lactoferrin as a bioactive of major importance in human health, development and disease prevention. Its multiple physiological activities offer enormous potential for Lactoferrin use in food, and as a nutriceutical and a pharmaceutical. Approval of this application would provide the opportunity for innovation in development of value-adding new products and ingredients by the dairy industry in Australian and New Zealand for both the domestic and export markets.