



DANONE

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EFSA opinion on the link between the consumption of Actimel and reduced risk of diarrhoea associated with the presence of *Clostridium difficile* (1) in hospital environments

In an opinion published today, EFSA concludes that the positive elements included in the application filed by Danone in August 2009 are not sufficient to establish a definite relationship of cause and effect between the consumption of Actimel, containing the *L. Casei* DN114 001, and a reduced risk of diarrhoea associated with the presence in the intestine of *Clostridium difficile* bacteria for older people undergoing antibiotic treatment in hospital environments (1).

EFSA's opinion does not concern current communications for Actimel addressing the public at large and consumers in general, and naturally does not concern the sale of Actimel.

Commenting on the opinion, Danone Co-Chief Operating Officer Emmanuel Faber stated:

“Danone contests this opinion, which is in contradiction with the findings of a series of clinical studies, of which the most significant was published in the British Medical Journal, a prestigious scientific review that is internationally known for its strict editorial policies (2).

That contradiction underscores the need, which Danone has pointed to on several occasions, for EFSA to amend evaluation processes and clarify the criteria for assessments of scientific evidence relating to specific products and drawing on the findings of recent clinical studies. These same observations were raised and reiterated by stakeholders attending the recent meeting on health claims related to gut and immune function organized by EFSA on December 2 this year.”

In accordance with the Regulation, Danone will thus be submitting arguments in support of its position to EFSA within 30 days.

1. *Clostridium difficile* is a bacterial pathogen causing serious nosocomial infections that can result in severe diarrhoea for hospitalized patients in weakened condition.

2. *The clinical study referred to was conducted in a hospital environment by a team of independent British researchers, at their own initiative. Published in the British Medical Journal on June 29, 2007, it shows significant reductions in the incidence of both diarrhoea in general and diarrhoea associated with the presence of Clostridium difficile when patients aged over 50 undergoing antibiotic treatment in hospital care take Actimel twice a day. In the control group for the study, 19 out of 56 patients undergoing antibiotic treatment suffered from diarrhoea, whereas this was the case for only 7 of the*

57 taking Actimel. The difference was even greater as regards diarrhoea relating to Clostridium difficile, since this affected 9 of the 53 patients in the control group but none of the 56 patients taking Actimel.

About Danone

Danone is a Fortune 500 company and one of the most successful healthy food companies in the world. Its mission is to bring health through food to as many people as possible. Fulfilling this mission is a major contributor to Danone's continuous strong growth. Danone, with 160 plants and around 80,000 employees, has a presence in all five continents and over 120 countries. In 2009, Danone recorded € 15 billion in sales. Danone enjoys leading positions on healthy food in four businesses: fresh dairy products (n°1 worldwide), water (n° 2 on the packaged water market), baby nutrition (n°2 worldwide) and medical nutrition. Listed on Euronext Paris, Danone is also ranked among the main indices of social responsibility: Dow Jones Sustainability Index Stoxx and World, ASPI Eurozone and Ethibel Sustainability index.