

Prepared by the New Zealand Embassy in Washington DC.

## Summary

- The New Zealand dairy industry is helping to alleviate infant formula shortages in the US.
- Two companies – Danone Nutricia New Zealand and a2 Milk (manufactured by Synlait) – gained access to the US infant formula market for the first time under temporary emergency measures put in place in May to address the shortages.
- These companies have the opportunity to continue to sell into the US as they demonstrate over time that they meet the US’ regulatory requirements to maintain long-term market access.
- The period for others to apply under these emergency measures has closed. However any New Zealand infant formula company can seek to meet US regulatory requirements through regular channels.
- Temporary tariff relief is also not expected to be extended beyond the end of 2022.

## Report

- Two New Zealand dairy exporters – Danone New Zealand and a2 Milk – have gained access to the United States’ infant formula market for the first time to help alleviate supply chain shortages that left many American parents facing empty store shelves.
- Widespread infant formula shortages in the US were triggered by the February shutdown of an Abbott factory in Sturgis, Michigan, which normally produces about 20 percent of the country’s infant formula supply. The shutdown followed US Food and Drug Administration (FDA) inspectors finding strains of the *cronobacter sakazakii* bacteria that can be deadly to infants in the manufacturing facility. The shortage was then exacerbated when the same facility suffered a further setback in June after being hit by severe storms and flooding.
- In response to the Abbott plant’s woes, in May the FDA enabled temporary “enforcement discretion” to be granted to interested foreign infant formula producers able to import into the US market if they met food safety and consumer product standards. This was supported by dozens of US organised flights to ensure infant formula stocks were replenished quickly to meet ongoing demand from US families. Congress also passed two bills in July and September that pause tariffs on imports of finished infant formula and the key base powder ingredient needed to produce infant formula through to 31 December 2022 to support this trade. Some of these tariffs were as high as 17.5%.
- While US infant formula supplies are beginning to stabilize again as these imports reach the market and the Abbott plant has reopened, the Infant Nutrition Council of America, which includes major US infant formula manufacturers as members, has sought to extend these relief measures. The Council called for “a continuation of both duty-free infant formula and bulk base infant formula powder bills as imports are still needed to get retail shelves back to normal levels”. But other US dairy stakeholders oppose an extension. The National Milk Producers Federation said they supported the original measure because of their “carefully tailored and time-limited nature” but that now that the “temporary production shortfall that

gripped American families in need of formula earlier this year has abated” they oppose “any effort to extend these preferential tariff benefits beyond the end of this year”.

- Overall, 19 foreign applicants were issued with “enforcement discretion” by the FDA before the window closed on 14 November 2022. This included two New Zealand applicants who were successful in being allowed to import, sell and distribute product in the US under the FDA’s temporary measures - Danone New Zealand in June 2022 and, more recently, a2 Milk in November 2022. It is likely that some New Zealand dairy manufacturers also supply some of the ingredients used by other successful applicants so are benefiting indirectly.
  - Exporters granted temporary enforcement discretion have been provided with the opportunity to maintain long-term access into the US market. They will be allowed to continue to sell their product into the US providing they are actively pursuing completion of all the standard regulatory requirements for infant formula access into the US market in line with guidance issued by the FDA. The pathway for other infant formula exporters, who have not obtained access under the time-limited “enforcement discretion” provision, remains unchanged.
  - New Zealand officials have been working with their US counterparts and exporters to help facilitate the efficient and timely delivery of the approved product to the US market. Officials also continue to seek more favorable US infant formula market access conditions for all New Zealand manufacturers. The high quality and enduring relationship shared between New Zealand and the United States’ food safety agencies stands us in good stead to continue to facilitate more smooth and efficient trade in food products for mutual benefit.
  - The infant formula crisis has prompted a rethink about e-commerce channels too. During the infant formula shortage, distribution channels and demographics played a role in who has the best access to supply. The federal nutrition programme through which infant formula can be purchased at a subsidised rate (via rebates) accounts for around half of all infant formula purchases in the US. Yet online purchasing restrictions for federal nutrition benefit programmes removed that option for many American families. The US Department of Agriculture announced it would use US\$50 million in the American Rescue Plan Act funds to test and launch online shopping so we expect to see the rollout of a pilot programme for online access to infant formula next year.
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## External links

- The following links may provide useful information to businesses:

[White House – Infant Formula Shortage page](#)

[US Food and Drug Administration – Infant Formula page](#)

[US Food and Drug Administration – Infant Formula Q&A](#)

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