

The Good Oil

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New spray dryer contract in New Zealand expands manufacturing opportunities

Clover Corp has boosted its capacity to produce small batches of experimental and specialty products, following the signing of a 10-year contract for use of FoodWaikato's newly expanded spray dryer plant in New Zealand.

"We were facing a business challenge because we found it difficult to scale up new products from pilot to commercial size dryers without committing to larger, more costly batch quantities at our existing commercial facility in Australia," says Glenn Elliott, Nu-Mega Ingredients Research, Quality and Regulatory Manager.

"We identified that FoodWaikato had a small spray dryer in the Waikato Innovation Park that was comparable to the equipment we were using here. It allows us greater flexibility to do smaller batch sizes and be more experimental. This will in turn enable us to more easily commercialise new products in the future, thus opening up new sales opportunities."

The Waikato spray dryer can process batches as small as 300kg an hour, compared to the minimum throughput of 2 tonnes an hour in the Victorian spray dryer used by Clover Corp. If an experimental product is ultimately unsuccessful, the write-off will be minimised.

\$1 million capital investment

Under the 10-year agreement, Clover Corp has invested nearly \$1m in capital equipment which allows the company to produce its microencapsulated powder products. This move is significant, as Clover Corp has traditionally outsourced its manufacturing.

"Now we have taken a position in the value chain of the product and will be more involved in manufacturing," Mr Elliott says. "This is a key project which will enable us to vertically integrate our business."

"The New Zealand infant formula manufacturing industry is also growing significantly for us, so a manufacturing facility in that country is a good strategic step. We have already seen interest from existing and new customers."

The spray dryer will be used for about 10% of Nu-Mega's product capacity. All equipment has been commissioned and a series of product qualification trials has been run. Once a customer approves the product into their formulations, commercial batches can be produced for sale.

Mr Elliott says the customer qualification process can take from six to 12 months to complete.

"The team at Waikato have been very good to work with. They've been very flexible in their approach and understand what we do and where we need to get to with equipment requirements and quality standards."



Spray dryer in Waikato

Nu-Mega Ingredients is a wholly owned subsidiary of publicly-listed Australian company, Clover Corporation. It specialises in the manufacture and supply of Omega-3 DHA and Omega-6 ARA powders, the nutritional ingredients which are added to infant formulas, general foods and pharmaceuticals.

Clover Corp has a tuna oil refinery in Melbourne, where it takes crude tuna oil from various supply sources and converts it into a food and infant grade quality tuna oil.

Nu-Mega's spray dried microencapsulated powders use a CSIRO patented technology to stabilise the sensitive Omega 3 and 6 oils which can then be dry blended into a variety of foods, infant formulas and pharmaceutical products. The oils can be cooked, have no smell or taste, and have a shelf life of two years.



Peter Davey, Managing Director/CEO of Clover Corporation Limited (left); is pictured with New Zealand's Minister for Business, Innovation and Employment, Steven Joyce (centre); and MP David Bennett, whose electorate includes the Waikato region.

China's new 'two children' policy to ramp up demand for infant formula and DHA

China's new 'two children' policy is expected to have a significant long term impact on the global infant formula industry, which is already a major source of sales for Clover Corp's Nu-Mega DHA (Docosahexaenoic Acid) products.

DHA, an Omega-3 fatty acid which is essential for brain development in babies and children, is widely used to fortify infant formula. And if the recommendations of the European Food Safety Authority pass into law (see break-out), the amount of DHA contained in infant formula and children's milk is likely to increase.

"We believe the end of the one-child policy, which has been in place for 35 years, will ultimately have a huge impact on the global infant formula industry," says Mek Cheng, Innovation Analyst with Clover Corp's Nu-Mega Ingredients. "I see this happening over the longer term, with a gradual increase in the number of babies over the next five to 10 years."



China has ceased the one-child policy because its aging population and shrinking labour pool are contributing to the growing concerns about its economy. Couples may now legally have two children, although some commentators question how many in urban areas will have a second child because of the high cost of raising a family. The impact may be greater in some of the least affluent provinces where the rule has been strictly enforced.

The one-child policy was estimated to have prevented 400 million births, according to the Communist Party.

DHA global clients

Clover Corp supplies DHA to many clients globally. International manufacturers of infant formula have enjoyed very significant sales in the Chinese market since the 2008 Chinese milk scandal which saw infant formula adulterated with melamine. About 300,000 babies were affected.

As a result, Chinese parents still prefer to buy imported formula, particularly from Europe, Australia and New Zealand.

"We have established good long term relationships with our customers in these countries and in the USA, so there is strong potential for growth," Ms Cheng says.

New EU Infant Formula legislation

On 2 February 2016, the European Union (EU) released new EU Infant Formula regulations (EU 2016/127) that will officially need to be adopted by 22 February 2020 by all EU infant formula manufacturers for infant formula marketed within the European Union (a 4-year transition period).

The new legislation includes changes that will directly impact the DHA (Omega 3) content of infant formula:

- DHA becomes a mandatory ingredient at a minimum of 20mg/100kcal and up to 50mg/100kcal for 0-12 month formula.
- ARA becomes an optional ingredient.

The majority of infant formula products marketed within Europe currently contain DHA levels that are below the new minimum requirement. Nu-Mega's Driphorm® DHA powders provide manufacturers with a viable solution for increasing the DHA dosage levels within their existing formula products without compromising the stability and flavour.

Health claims for DHA

In late 2014, the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies delivered a scientific opinion on DHA and its contribution to normal brain development. It noted the well-established role of DHA in brain function, and said it considered this applied to all ages, including brain development in infants and children.

It recommended that food manufacturers be able to include the health claim 'DHA contributes to normal brain development' on their infant formula packaging, provided that products for babies aged six to 24 months contained a daily intake of 100mg of DHA in one or more servings. Products for children aged from two to 18 years would need to provide a daily intake of 250mg of DHA. No health claims will be permitted on infant formulas for babies aged less than six months.

Mek Cheng says Clover Corp's Nu-Mega had analysed various infant formulas and children's milk products, and found that most were fortified at around 38 to 90 mg of DHA for daily intake.

"Only premium brand products were fortified at around 100mg, so we see the opportunity for increased sales if these recommendations are accepted by the European Union parliament," she says. "We are hopeful that the EU will make a decision in the near future."

Major international trade shows targeted to build global market share for Nu-Mega

A tray of muesli bars attracted an unusual level of interest when Clover Corp exhibited in the 2015 Food Ingredients Europe (FIE), one of the world's leading events for the food and beverage ingredients industry.

The muesli bars, which were made in the company's Brisbane test kitchen, were fortified with a high dose of Nu-Mega's Omega-3 fatty acid DHA (Docosahexaenoic Acid) derived from algal DHA oil powder. At that dose, the marine taste of the oil would normally be very apparent, but delegates could neither smell nor taste the oil.

"The muesli bars were a way of demonstrating the features that differentiate our DHA products from other manufacturers," says Bassam Hallak, Nu-Mega's Global Business Manager, who attended FIE in Paris last December.

"Our patented encapsulation technique, which was developed by the CSIRO, enables a higher potency of DHA to be captured in what is virtually a very robust shell. This allows us to get extremely high potency of DHA in our capsules.

"Because the encapsulation doesn't break up until it reaches the stomach, there is no smell or taste. It also provides stability from oxidation and doesn't impact on the fortified consumer product's shelf life."



Positive feedback to product demonstration

Feedback to this product demonstration was very positive, and the company is in discussions with infant formula manufacturers, food and beverage manufacturers and distributors from European countries.

"We did not attend FIE to make immediate sales," Mr Hallak says. "The goals were to expose the brand, make connections and then build on them. The reception from delegates from about 20 countries was fantastic, considering the attendance was affected by the Paris terrorist attacks."



He has found that infant formula and food manufacturers are being strongly influenced by EFSA's positive opinion regarding the recently submitted DHA health claim associated with normal brain function (see story on China's two-children policy for details). Mr Hallak says the European Union Parliament is expected to vote on the DHA claim in mid-2016.

"In order for manufacturers to use the pending DHA brain health claim on their labels, they will need to meet a minimum DHA fortification level. In many cases this will force them to double DHA dosage levels. Most are now readying themselves to use the DHA health claim when it is legislated, but if they double the dose using direct oil injection, they will increase the sensory risk of detecting the oil. This is making our encapsulated powder products far more attractive."

Mr Hallak will return to Europe in March, to follow up with existing and potential clients and meet with potential European distributors. Nu-Mega will also attend SupplySide West in the USA (see breakout) and is considering FIE in 2017.

"We are looking at doing both shows with strategic partners, which means a much larger stand and greater visibility," Mr Hallak says.

SupplySide West

SupplySide West, to be held from October 4 – 8, 2016 in Las Vegas, demonstrates the latest innovations for animal nutrition, beverages, cosmetics, dietary supplements, food and pharmaceutical products. It attracts up to 14,000 delegates.

While attendances at FIE in December 2015 were affected by the Paris terrorist attacks, visitors came from around 120 countries to meet with 1400 exhibitors. FIE will next be held in Frankfurt in November 2017.

Results expected mid-year of large international DHA clinical trial with premature babies

Results are expected shortly from a major international clinical trial which is testing the effectiveness of the company's proprietary DHA emulsion in reducing the incidence of bronchopulmonary dysplasia (BPD), a lung condition common in premature babies.

The N3RO trial (N-3 fatty acids for improvement in Respiratory Outcomes) commenced in 2013 and has involved more than 1200 babies in over 50 hospitals in Australia, New Zealand and Singapore. The study, one of the world's largest such trials involving preterm babies, has received funding from the National Health and Medical Research Council of Australia (NHMRC) and expects to deliver its results mid-year.



Clover Corp, which has supported strategic clinical studies for many years as a means of identifying new commercial opportunities, developed a DHA formulation specifically for hospital use in the trial. Babies born prematurely do not receive the necessary supply through the placenta of DHA (Docosahexaenoic Acid), an Omega-3 fatty acid which is important for normal brain development.

"This trial follows initial clinical studies called DINO conducted by the Women's and Children's Hospital in Adelaide, involving more than 600 preterm infants around Australia," says Peter Davey, Managing Director/CEO of Clover Corp.

"The outcomes of the DINO studies (Docosahexaenoic Acid for the Improvement of Neurodevelopmental Outcome) showed improved cognitive development in girls at 18 months, reduced oxygen requirement at 36 weeks in boys and a reduced incidence of hay fever."

In the DINO trials, Clover's DHA was fed to mothers, who then expressed breast milk for their babies. In the current N3RO trials, Clover's DHA emulsion was fed directly to babies via a nasogastric tube very soon after birth. Clover Corp's unique and patented encapsulation process and multi-dose delivery system, based on CSIRO technology for which Clover holds the exclusive global licence, ensures the DHA is not broken down until it reaches the stomach.

The product is therefore highly bioavailable, and no rejection has been evident in the trial.

Licence agreement accelerates product development

Clover Corp last October announced a licence agreement with Premneo Pharmaceuticals Pty Ltd to accelerate development of the DHA emulsion for preterm babies. Premneo's Executive Chairman is Dr Brian McNamee, former Managing Director and CEO of Australia's largest pharmaceutical company, CSL Limited.

"Dr McNamee is one of Australia's most internationally respected pharmaceutical leaders," Mr Davey says. "He was responsible for developing Australia's most successful pharmaceutical company, and his team has the specialised regulatory, manufacturing and marketing skills necessary to support us in rolling out our product to the global market."

The agreement gives Premneo an exclusive worldwide licence to develop and commercialise the emulsion product for use in preterm babies. Clover will earn milestone payments as product development advances, and royalties on future sales.

Key markets are neonatal hospitals with sophisticated facilities in the developed world, including Europe, the USA, Australia, Japan, Singapore and New Zealand. Premneo will work toward the approval processes for the European Union and the USA and will apply to Australia's TGA (Therapeutic Goods Administration).

Preterm snapshot

Approximately 13 million preterm births occur annually in the world, of which 4 million require tertiary care. Approximately 1.6 million of those births occur in countries which have critical care facilities. The Preterm DHA product is aimed at helping babies in this group that are less than 32 weeks old.

Medical issues that affect preterm infants include cognitive or mental impairment and respiratory impairment.

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