glanbia nutritionals

Opportunities In Infant Nutrition

Providing Our Most Precious Consumers Nutritious Products

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INTRODUCTION

Infant Nutrition is a diverse market made up of two distinct subcategories: Baby Food and Infant Formula. The categories are similar in some aspects however both are driven by their own unique sets of trends and dynamics. The most relevant and influential trends in each segment have implications for the manufacturers of infant nutrition global products.

The most significant trends currently driving the Infant Formula (IF) Market is the regulatory and competitive tightening occurring in the Chinese market. Due to the size and rapid growth of this market, the changes in China are having profound ripple effects throughout the global IF market affecting the majority of global manufacturers. China's large base and rapidly growing volume of consumers with increasing purchasing power is very attractive to multinational brands; however, the 2008 melamine infant formula issues still overshadows the market and has created an environment where consumers are concerned with the health and safety of infant formula. In turn, government regulations continue to heighten. Although there is robust demand for infant formula in China, particularly imported brands perceived to be of higher quality compared to local brands, limitations on certificates issued to import products have been dramatically decreased from over 800 to less than 100. The majority of the certificates have been awarded to major global IF brands that can meet the stricter regulations. While this presents attractive opportunities, it nevertheless creates a challenge for international companies to meet the high demand and to become more efficient to increase capacity rapidly.

While meeting strict quality requirements is also important in the Baby Food Market, the most important trends in this market segment focus on benefits more than risk mitigation. Three key trends currently dominate the Baby Food Market: innovative package design, organic options and products that provide specific health benefits focused on children's physical and cognitive development. Today's parents require products that fit their busy lifestyle which are environmentally sustainable, convenient "on-the-go" packaging with clean labeling. Furthermore, health conscious parents seeking healthier options for the their babies prefer organic baby foods as well as choices that address focused health benefits such as cognitive or bone health.

These factors have had a global effect on brand manufacturers competing in the complex Infant Nutrition Market. Companies are required to have a deep understanding of the evolving global regulatory standards across regions as well as address consumer requirements for innovative packaging and organic certification. Partnering with the right vendors, from ingredient suppliers to premix manufacturers, is an important strategic option for companies to meet the demands of global production. Companies such as Glanbia Nutritionals are a knowledgeable partner with expertise in delivering safety-assured quality nutritional products that meet the demands of the infant nutrition market from ingredient sourcing to premix production.

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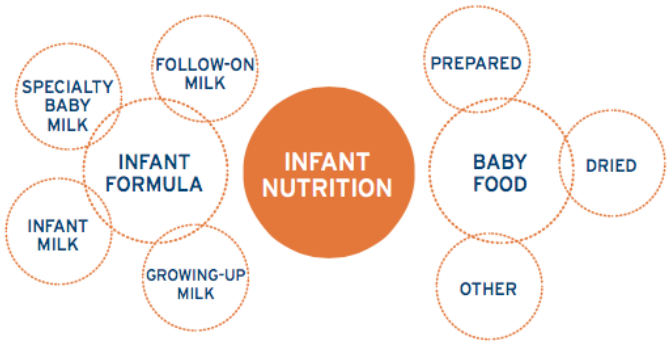
GLANBIA NUTRITIONALS

Glanbia Nutritionals is a global front-runner in micronutrient premix production for the Infant Nutrition Market, delivering nutritional fortification of infant formula and baby food products. As a leading formulator of premixes, Glanbia is uniquely positioned to globally scale production as well as provide a targeted portfolio of relevant ingredient and service solutions for infant nutrition and organic products. We bring together quality manufacturing processes and a comprehensive suite of quality assured tested ingredients and organic solutions that drive efficiency and safety for the infant nutrition industry creating a meaningful differentiation in the market. Glanbia Nutritionals can offer scientific support for claims substantiation and formulation support to both small and large scale producers. With a high level of expertise in infant nutrition production, testing procedures and a global barcode tracking system we ensure a high level of safety that allows manufacturers to obtain leadership in the market.

INFANT NUTRITION MARKET

The infant nutrition market encompasses a diverse set of products, from various infant formulas to an array of baby foods. The total global baby food and infant formula market is approximately $35B and is expected to grow at a compounded annual growth rate of 7.69% between 2015-2019.[1] In recent years, total sales of infant formula and baby food products in mature markets such as the US, EU, and Japanese markets reached $15.1B and a compound annual growth rate of 3.7% is forecast through 2017.[1] Increased growth will be moderate due to market saturation and low birth rates. In emerging markets, infant nutrition products are $17.1B in sales. As the population of these regions continue to expand and economies grow, strong compounded annual growth of 13.8% is expected.[1] Growth will be supported by high birth rates and rising consumer affluence. In the developed nations, as well as in the large emerging economies of China, Brazil, and Russia, birth rates are declining and are currently below the “replacement rate” at which a population replenishes itself, thereby intensifying competition among leading manufacturers to differentiate their products.[1]



INFANT FORMULA SUBCATEGORY MARKET

Infant Formula can be segmented to Infant Milk Formula, Growing-up Milk Formula, Follow-on Milk Formula, and Specialty Baby Milk Formula. The total global market for Infant Formula is estimated to be worth $18.1B, with annual growth of 9.9% expected through to 2017.1 Established markets such as the US, EU, and Japan represent large markets for infant formula products due to their relative affluence while the emerging markets, which include India and China, are 54% of the total global infant formula milk market.

The emerging markets account for infant formula sales of $9.9B, with 14.2% annual growth projected through 2017,[1] are the most important segment of the infant formula market and drive overall market growth. In these regions manufacturers increasingly focus their product development, promotional and manufacturing activities. Infant milk formula is the largest segment of the infant formula market with $10.5B in sales and 10.1% annual growth. Along with high birth rates in the emerging nations, this segment benefits from a lack of acceptable alternatives, as only breast milk can be viably substituted for infant formula.[1]

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Total global sales of follow-on formula are estimated at $6.3B with 9.4% growth through 2017. Sales of growing-up milk products (GUMPs) were just $1.3B, although relatively high annual growth of 10.8% is expected through 2017 due to increased product awareness, especially in emerging markets.[1] Sales will rise in the emerging markets as consumers embrace the new, convenient, nutrient rich products; rising consumer incomes will also boost affordability.

BABY FOOD SUBCATEGORY MARKET

Baby Food is segmented in the following categories: prepared Baby Food, Dried Baby Food, Other Baby Food. The total global market for baby food is estimated at $14.1B with annual growth of 9.0% expected through to 2017, driven mainly by growth in emerging markets, which already make up over half the value of the global baby food market. The mature US, EU, and Japan region accounted for baby food sales of $6.9B, with 3.8% annual growth expected through to 2017. Growth will be limited by high market saturation and low birth rates, although continued product innovation will contribute to sales gains.[1]

The emerging market region accounted for baby food sales of $7.2B, with 13.2% annual growth expected through 2017. This will be driven by high pent-up demand resulting from low market penetration, strong birth rates, expanding economies, and rising consumer purchasing power. Stage one baby food (four to six months) was the largest segment with $3.8B in sales and 9.4% annual growth. Market expansion will be greatest for early-stage baby foods. While nutrition is the key factor, with parents' main priority being the health value of new products, convenience is also a major influence of purchasing behavior. The value of the other baby food subcategories will rise on the back of emerging market growth, driven by rising birth rates. Sales of stage five baby food (24 months and up) are estimated at $1.4B with 9.3% annual growth through to 2017 from a relatively small base

INFANT FORMULA SAFETY CONCERNS

Safety concerns have played a significant role in driving the dynamics of international Infant Formula Markets, particularly those in the largest and fastest growing market – China. For example, in China quality issues have been an issue in the development of baby food and infant formula. In spite of climbing demand, customers are still cautious when choosing baby food brands. As a result, high-end products are becoming more popular, as most consumers believe their higher price guarantees higher quality. A growing number of mainland parents are also turning to Hong Kong, Macau and overseas regions such as the United States to purchase infant milk powders.[2] In an effort to improve quality standards and boost perception China has recently implemented more stringent quality and safety standards over the regulations put in place in 2013. The China Certification and Accreditation Administration (CNCA) stated that of the 800+ foreign brands distributing infant formula in China, only 94 have received approval to sell in China, and furthermore only two-thirds of the local Chinese infant formula manufactures have received production permit renewals. This extremely limits the competition for the high demand.[4]

The globalization of the infant formula market is largely due the sellers' interest in the huge market for IF product in China. Like many other countries, China has a growing middle class with increased spending power. The high demand for formula in China has resulted in significant depletion of supplies elsewhere.[5] Via customs restrictions, regions such as Hong Kong are limiting the quantity of milk formula that individuals from China are able to purchase. A similar purchase limit was subsequently announced by the UK, the US and Germany, making it difficult for Chinese consumers to buy overseas. As a result, Chinese consumers are turning to foreign brands sold domestically and thus contributing to overall sales growth for foreign baby food brands.[4] In turn, multinational brands have increased their investment in China. Global companies need to develop sophisticated manufacturing processes to adhere to the stringent requirements necessary to produce infant nutrition.

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INFANT FORMULA QUALITY REQUIREMENTS

The rise in global demand for quality infant formula and baby foods creates the need for higher quality assured manufacturing processes that are critical for global brand companies to excel in the current environment. The need to partner with companies that understand the intricacies of global regulatory requirement around manufacturing and quality testing will play a major role in meeting the demand of international consumers.

Developing infant formula is a very complex and specific process due to the particular needs of growing babies - the safety requirements are stringent and it must match the physical and nutritional characteristic of mother's milk. It is critical to include all essential macro and micronutrients at the correct concentration.

Manufacturing sophistication in infant formula production is mission critical. Developing for the Infant Formula Market requires specific manufacturing capabilities and sophisticated quality assurance protocols. Infants are more susceptible to food related contaminants than adults, therefore, supplying ingredients and manufacturing for infant nutrition market requires higher quality controls than standard food. Issues in infant nutrition can have serious consequences, so each step of the process must be closely monitored and a systematic approach must be utilized for the testing and qualifying ingredients and the manufacturing procedures. Tests must be in place to ensure that no pathogens, foreign objects or toxins such as heavy metals are present. Many countries require Hazard Analysis and Critical Control Points (HACCP) to be in place to ensure safety from the beginning to the end of the process.[6] To ensure additional safety measures are in place many government organizations have implemented safety stringent regulations to ensure safe manufacturing procedures (e.g., EU Commission's Farm to Fork policy, the US Safety Modernization Act and China's Further Supervision of Baby Milk Formula Quality policy).

As an experienced partner in providing quality infant nutrition premixes to global businesses, Glanbia Nutritionals has made significant investments in implementing Key Quality Standards across their facilities in Asia, Europe and the US. These Key Quality Standards meet and in many cases exceeds the requirements for infant formula production regulations.

Glanbia Nutritionals has specific knowledge and leadership in the Infant Nutrition Market and meets the needs of infant formula manufacturing from sourcing and screening of ingredient to the production process. The high quality standards applied to infant formula are also applied to baby food manufacturing. In addition, Glanbia Nutritionals has expertise in developing formulations for the specific trends of the Baby Food Market.

KEY QUALITY STANDARDS:

> Supplier Qualification Program – This is a program to approve and qualify potential vendors, it can consist of a Quality Survey to gather pertinent information on suppliers as well as a request for documents proving certification and perform supplier audits

> Identity testing – Testing of all raw material upon receipt for economic adulterations to ensure "what is stated on the label is what is inside the container"

> Raw Material Testing – Critical test raw materials to meet strict infant food specifications

> Enterobacteria Testing Program – Constant and consistent testing to detect enterobacteria (including Cronobacter sakazakii) in raw materials, environment and finished product

> Hazard Analysis and Critical Control Points (HACCP) – HACCP tests for physical, chemical and biological contaminants

> Foreign Material Control Standards – capabilities in place to detect foreign material in ingredients and premixes, such as sieves, metal detectors, x-ray scanning, etc...

> Environmental Monitoring – Extensive environmental testing of production areas, packaging areas and surrounding areas

> Zone Concept - Highly hygienic zones separated by air locks

> Hygienic Areas – Ensures blending and packing in high hygiene areas

> Barcode System – Barcode system to provide traceability and to prevent errors

> Assurance of Homogeneity – Homogeneity testing assures even distribution across the entire batch

> Nutrient Level Tests – Ability to test for levels of nutrients

> Certifications/Registrations

- > SQF Level 3 Certified
- > FDA registered
- > Halal Certified by IFANCA
- > Kosher Certified by OU
- > SDA Organic Certified

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BABY FOOD MARKET TREND - CONVENIENT PACKAGING

The most important things in life often come in the smallest packages. In baby food, packaging, both in the form of convenience and clean label packaging, are key. Vendors are investing heavily in the development of innovative, eco- friendly, and recyclable alternatives to conventional packaging. Busy parents look for certain key aspects in powdered infant formula packaging, including product safety, convenience features for "no-fuss" packaging and re-sealability. According to report "Global Baby Food and Infant Formula Market 2015-2019" nowadays, baby food is often packaged in pouches manufactured from paper.

These pouches have a lower carbon footprint and better overall environmental ratings than plastic jars and bottles.[7]

BABY FOOD MARKET TREND - ORGANIC OPTIONS

Organic food is one of the fastest growing sectors in the food industry overall, experiencing double digit growth in most developed markets compared with a 1-2% growth rate for conventional food products.[7] The global demand is increasing due to the desire of parents to feed their babies healthier foods. Organic baby foods cost more than other non-organic baby food available in the market, but these foods have a "healthy" factor that, parents are willing to pay more. In addition, the market potential for organic products is likely to be greater in markets where demand for organic baby foods is being driven by:

> Growing consumer concern over chemicals in baby food

> Baby health consciousness

> Specific dietary and allergy conditions

> The perception of organic tasting better

> The desire to get back to "basics"

According to a new market research study from Innovative Research and Products (iRAP) titled "Branded Organic Baby Foods: New Developments, Global Industry & Market Analysis" the global market for organic infant food would have reached $760 million and will increase beyond $2.26B.[8] Of the seven types of organic baby foods analyzed, infant formula constituted around 38% of the organic baby food products, followed by organic fruits and vegetables. The report predicts a sharp increase in the total market for organic baby food products, with an annual average growth rate of around 23.8% and organic milk formula sales in the United States generated approximately USD 68.4 million.[9]

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BABY FOOD MARKET TREND - FOCUSED HEALTH BENEFITS

Nutrition for developing children is the key factor for baby food and fortified foods. Achieving good nutrition that supports the developmental needs of infants, all the way through to pre-pubertal children, begins from conception. Expectant mothers require increased levels of macronutrients and many essential micronutrients such as vitamin K2, folic acid and choline. Infants in the early stages of life are generally protected by the enhanced nutritional content of either breast or formula milk. Nature has evolved to ensure breast milk delivers the most of the necessary nutrients, and formula milk has been designed to closely mimic this. However, often when children are weaned from breast or formula milk to solid food, they begin to miss some of their essential nutrient RDI (Recommended Daily Intake) targets. As babies become toddlers, their levels of activity greatly increase, bringing about new demands on calorie and micronutrient intake. With rapid physical and cognitive growth, they also develop their personality and can strive to exert their independence by refusing to eat certain foods: an easy way for deficiencies to occur. Further, many commercial foods that adults rely on are quite inadequate for a child's specific needs. This is why fortified, baby focused foods are highly advantageous to ensure none of these nutrients are omitted.

NUTRIENTS FOR FORTIFYING CHILDHOOD DEVELOPMENT MENAQ7®

VITAMIN K2-MK7 (INFANT AND TODDLER)

The two types of Vitamin K (Vitamin K1 and K2) play important roles in the health of children, including support for coagulation, promoting cardiovascular health (through the inhibition of vascular calcification), and bone mineralization. Unfortunately, research shows that there is a high prevalence of vitamin K deficiency among infants and children. A low transfer of maternal vitamin K across the placental barrier and low vitamin K content in breast milk contribute to this deficiency. Studies indicate that maternal supplementation with vitamin K can help mitigate this problem,[10] however, it is well documented that there is widespread deficiency among adults who consume a Western-style diet.

In the United States, vitamin K deficiency without bleeding may occur in as many as 50% of infants younger than 5 days old.[11] Intramuscular vitamin K1 injections have been recommended for all newborns in the USA in order to prevent development of hemorrhagic syndrome. In addition, the average intake of vitamin K in infants who are exclusively breast-fed during the first 6 months of life has been reported to be less than 1 mcg/day; this is approximately 100- fold lower than the intake in infants fed a typical supplemented formula.[12] This is supportive in the argument for breast-feeding mothers to consider supplementation with vitamin K. Vitamin K2-MK7 (menoquinone) is a form of vitamin K that is even more frequently deficient, owing to its rare presence in the Western diet. It has a unique role that differentiates it from vitamin K1 (phylloquinone) in that it is responsible for the activation of two proteins responsible for regulating the allocation of calcium in the body. Matrix GLA protein (MGP) and osteocalcin are both present in the blood stream in an inactive (decarboxylated) state. High levels of inactive MGP are associated with calcification of the arteries: a leading contributor to the development of cardiovascular disease. In addition, high levels of inactive osteocalcin are associated with bone loss and osteoporosis. These proteins require K2-MK7 to become carboxylated and put in their active state. Once activated, these proteins gain a high affinity for calcium: latching onto it and shuttling it from the arterial walls toward the bones, where it is needed.

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Vitamin K2 is available for supplementation as MK-7 and MK-4. While the two might have comparable initial absorption rates, MK-7 lasts about 8 to 10 times longer in the circulation due to different transport mechanisms carrying MK-7 to distal parts of the body, as opposed to the same dose of MK-4. Supplementation with MK-7 only needs to be taken once a day at lower doses and is therefore more effective and convenient.[13] MenaQ7® is a highly pure, patented form of K2-MK7 based on solid clinical evidence. A prospective, 1-year pilot study14 investigated the effects of a dietary supplement with vitamin K2 (50 mcg MenaQ7®) and vitamin D3 on 20 children with thalassemic osteopathy or TOSP (a blood disorder that may result in osteopenia and osteoporosis). Results showed a significant improvement in the Bone Mineral Density (BMD) at the lumbar spine area of the patients at month 6 and month 12 of the treatment, especially in the prepubertal group. This pilot study demonstrated that vitamin K2 and vitamin D3 combination clearly has a positive effect on the BMD of the children with TOSP.

Further, in an 8-week, double-blind, randomized, placebo-controlled trial,[15] in which 45 mcg vitamin K2 (as MenaQ7®) was given to healthy prepubertal children, and undercarboxylated osteocalcin (ucOC) and carboxylated osteocalcin (cOC) were measured, as well as the the ucOC:cOC ratio (UCR) as an indicator of vitamin K status. Results showed that with increases in MK-7, the circulating concentration of inactive ucOC reduced and the UCR improved. There were no significant changes in the placebo group. Researchers concluded that supplementation with MenaQ7® vitamin K2 increases circulating concentrations of MK-7 and increases osteocalcin carboxylation in healthy, prepubertal children.

As children get older, their intake of vitamin K may continue to be inadequate. For example, a British study16 (Figure 1) compared dietary intake and sources of vitamin K in 4,599 4-year-old children born in the 1950s and 307 children in the 1990s. Results showed that dietary vitamin K intake was significantly higher (P<0.001) in the 1950s (39 mcg/day) compared with the 1990s (24 mcg/day). Further, food sources of vitamin K intake have changed significantly between the 1950s and the 1990s, with fats and oils typically associated with the Western diet con¬tributing more and vegetables less. With these general changes in food habits (i.e., emphasizing fast foods and processed foods), it is conceivable that children's vitamin K intakes have been on a significant decline since 1950, which the authors concluded may have implications for their bone and cardiovascular health in later adulthood.

Vitamin K Intake Among Children (µg/Kg/day)

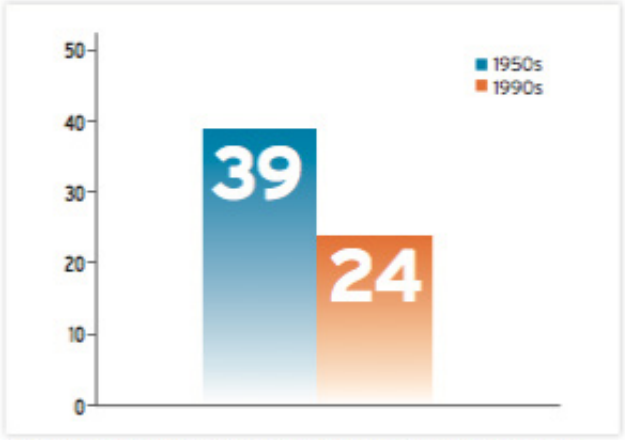

Figure 1 - *Source: A study of British children showed that vitamin K intake levels have dropped significantly p<0.001) from the 1950s to the 1990s"*

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Figure 2 - *TruCal® is a multi-mineral complex derived from milk*

TruCal® Milk Multi-Mineral Complex (toddler)

An ideal combination for optimizing bone health in growing children is a formulation consisting of MenaQ7® along with a calcium, magnesium, phosphorous and vitamin D3. Bones require a specific ratio of these minerals in order to achieve good density and strength. TruCal® is a multi-mineral complex derived from milk (Figure 2). It contains calcium, magnesium and phosphorus and other trace minerals at concentrations very similar to those found in bones.

The calcium in TruCal® is more easily absorbed than calcium from other sources. In studies using rats, TruCal® was compared with calcium carbonate and was shown to be significantly more effective for increasing bone density.[17] In a human study of females, TruCal® tended to decrease markers of bone resorption and turnover more effectively than calcium carbonate.[17]

Adding MenaQ7®, TruCal® and vitamin D3 to a toddler food formulation puts it at the forefront of the current scientific knowledge for promotion of optimal bone health in growing children. These ingredients are exclusively available from Glanbia Nutritionals globally.

Bioferrin® Lactoferrin (toddler in USA)

Lactoferrin is a small protein found in the whey portion of cow's milk and human breast milk. In newborns it plays an important role in enhancing the immune system. This immune-boosting mechanism is brought about by the lactoferrin molecule's structure, which maintains a high affinity for binding to iron. Gram-negative bacterial pathogens require iron from their host for their survival, therefore the presence of lactoferrin depletes levels of iron from the environment in which they are trying to proliferate. Lactoferrin also binds to bacterial endotoxins. These are substances such as lipopolysaccharide (LPS) that routinely cause low-grade inflammation. By binding to these, lactoferrin prevents some degree of aberrant inflammation. Furthermore, it promotes the production of anti- inflammatory cytokines while reducing pro-inflammatory cytokines.

A simultaneous function of lactoferrin's iron-binding ability is the improved delivery of iron for the healthy functioning of the child's hemoglobin. Iron supplements can induce gastro-intestinal discomfort and constipation, therefore using lactoferrin to improve delivery and absorption can warrant a reduced volume of iron supplements.

Bioferrin® is a mixture of iron-free apolactoferrin and iron-saturated hololactoferrin. Less bound iron is preferable as there will be more available capacity for iron-binding in the body and increasing the bacterial deprivation effect. Glanbia Nutritionals recently invested €60 million in its high-end whey and lactoferrin production facility in Twin Falls, Idaho. Bioferrin® presents a high quality form of lactoferrin that has a low level of pre-bound endotoxins meaning it is more readily effective than poorer-grade versions. Bioferrin® is available in EMEA and Asia Pacific regions for the fortification of infant formula.

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CONCLUSION

Nutrition is one of the most important factors that influence a child's growth and development. As the global demand for infant nutrition continues to grow, several notable trends can be highlighted. In the Infant Formula Market quality and safety are leading factors; in emerging markets such as China, regulation changes, import approvals for larger brands and brand consolidation drive increasing demand that companies will need to meet. In the Baby Food Market health benefiting, high-quality organic options in functional packaging is key to meet consumer demand. Meeting the fast growing demands of the market requires brand companies and their strategic partners to develop specific capabilities regarding adherence to stringent quality standards, product and packaging innovation and organic certification. All businesses involved in the supply chain must adhere to the high standards and regulatory requirements, *Providing Our Most Precious Consumers Nutritious Products.*

WHY GLANBIA NUTRITIONALS?

At Glanbia Nutritionals your success is our success. We partner with our customers to develop the right solution. Tested ingredients, precision premixes and sophisticated production processes that exceed stringent global regulations assure your products meets the highest quality standards. In the completive landscape of nutrition, working with Glanbia Nutritionals will give you peace of mind and your products a formula for success.

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