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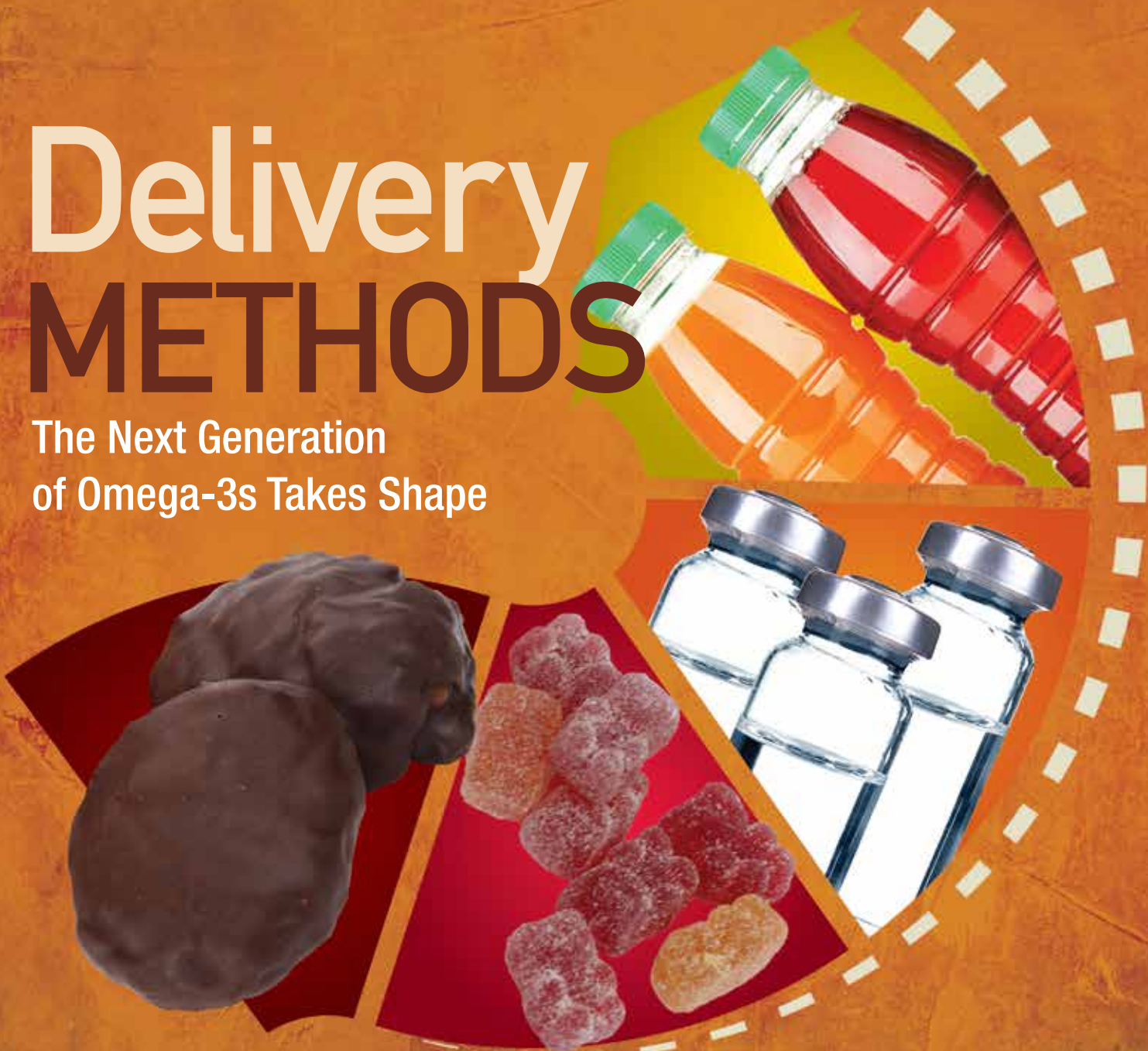
Omega-3 INSIGHTS

VOLUME 3 ISSUE 1

March 2014

Delivery METHODS

The Next Generation
of Omega-3s Takes Shape



- New Technologies
- History of the Softgel



JUNE 2-3, 2014
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CONTENTS

4



3 Viewpoint

4 New Technologies in Omega-3 Delivery by Joanna Cosgrove

Sensitive omega-3 oils must be handled with care, which increases the challenge of formulating new product delivery methods. Despite the obstacles, more palatable and versatile formats are leading to innovation in omega-3 supplements, foods and beverages.

11 Soft Gels Through The Years: **A Technological History** by Terri Albert

The softgel technology invented 80 years ago still serves as the industry standard, particularly for protecting and delivering oxygen-sensitive omega-3 oils. However, in recent years, advances in ingredients and encapsulation have yielded variations ranging from chewable softgels to time-release capabilities.



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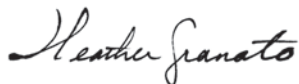
How Do You Omega?

As consumers buy into the health benefits of omega-3s, the next task is getting them to buy those omega-3s and make them a part of their daily wellness strategy. The challenge, however, can be ensuring that the products they select fit into their lifestyle and deliver the high-quality ingredients to bolster health.

Product formulators have not always had a great amount of flexibility in terms of the omega-3 category. Cod liver oil on a spoon gave way to softgels, which remain the delivery method of choice. And as one of the articles in this issue outlines, softgels have myriad benefits in the category. Our other article delves into some of the other opportunities in terms of delivery—not just for the finished product, but also how suppliers are optimizing ingredient profiles to improve bioavailability, fight oxidative degradation and much more.

Whatever your current position in the omega-3 category, I expect you'll find info of interest in this digital issue from SupplySide Omega-3 Insights. And if you're looking for even more, consider exploring the subject in person at Ingredient Marketplace, taking place in New York from June 1 to 3. As the show position underscores, "What's Inside Matters," and this focus on the ingredients in the products can be seen throughout the event. One new addition is the Trends In presentations—30-minute educational sessions right in the expo hall, exploring hot ingredients in the market, including long-chain omega-3s. More details on the Omega-3 Trends In **session are available online**; we hope you'll join us and GOED's Ellen Schutt to explore the category at the session, as well as around the expo hall.

Best regards,



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New TECHNOLOGIES in

Omega-3 Delivery


by Joanna Cosgrove

With global sales of omega-3 finished products expected to reach US\$34.5 billion by 2016, the omega-3 market is brimming with potential; however, its growth has been somewhat hampered by concerns about stability, bioavailability and delivery options. In recent years, omega-3 suppliers have been working hard to improve the heart-healthy ingredient's shortcomings, opening doors to new formulating opportunities with long-chain (LC) omega-3 eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

Technology has enabled omega-3 dosing to evolve beyond utilitarian softgel supplements into smaller pills, tablets and chews. Doses are more concentrated and formulations have become increasingly complex. According to Adam Ismail, executive director of the Global Organization for EPA and DHA Omega-3s (GOED), technological advances are helping ingredient suppliers and formulators overcome a variety of challenges. However these advances put shelf-life and stability burdens on the companies creating these technologies.

"Omega-3 oil refiners and concentrators understand the special care required when handling these oils, but many of these new entrants may not," he cautioned. "Even with simple softgels, we have heard reports of contract manufacturers opening barrels of oil for testing, but not nitrogen-blanketing them when they reseal the canisters, or storing them in warm temperatures."

Ismail said those issues can create a negative consumer experience and defeat the purpose of specialized delivery



GLOBAL SALES
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IN THIS ISSUE

Viewpoint p. 3

Softgel Through the Years p. 11

Table of Contents p. 2

technologies. He advised consumer product companies to work both with the technology providers and the ingredient manufacturers when launching products containing those types of technologies to avoid potential pitfalls.

To help circumvent the challenges of oxidation, Nutrasource Diagnostics Inc. (NDI) offers standard oxidation testing using peroxide and acid value measures. The company also developed a new True Anisidine Value (TAV) test method designed to negate false rancidity readings in plant, algal and marine oils. "TAV is based on high-performance liquid chromatography [HPLC] analysis developed to distinguish lipid oxidation from other factors that interfere with this measurement in finished omega-3 formulas," said William Rowe, president and CEO, NDI. "The TAV provides methodological sensitivity, robustness and accuracy to quantify the oxidative status of flavored oil products."



To avoid potential pitfalls, consumer product companies should work both with the technology providers and ingredient manufacturers when launching products containing those types of technologies

NDI also provides real-time and accelerated stability testing in its in-house laboratory, which holds both Health Canada and FDA accreditations. The company offers seven standard stability conditions, plus custom configurations, all conducted to ICH guidelines. The data can be used in support of GMPs (good manufacturing practices) and for market approvals as required in specific regions.

Alongside omega-3 safety and stability concerns is the issue of sustainability, which has prompted ingredient suppliers to branch out with their omega-3 ingredient sourcing. Sustainability was a driving factor in the partnership recently forged between DSM Nutritional Products and Monsanto, which, according to Laura King, DSM's marketing manager for life'sDHA®, would bring the first vegetarian stearidonate soybean oil (SDA) to market for use in food and beverage products in North America.

SDA is naturally converted by the body into EPA omega-3. "SDA soybean oil has a clean flavor, maintains shelf-life, is stable and can be incorporated into a variety of foods," King said. "SDA soybean oil could provide food and beverage manufacturers an additional choice to access heart healthy omega-3, while representing an additional sustainable supply of omega-3."

Federico Tripodi, Monsanto SDA program director, commented in a statement: "SDA omega-3 soybean oil would provide a sustainable way for consumers to increase

IN THIS ISSUE

[Viewpoint](#) p. 3

[Softgel Through the Years](#) p. 11

[Table of Contents](#) p. 2

their intake of omega-3 fatty acids that help maintain heart health. Food companies are looking for solutions to deliver the benefits of longer-chain omega-3s while maintaining flavor over the shelf-life of the product.”

Diversified Delivery Options

Technology is also helping extend omega-3 delivery options, especially as relates to formulating more consumer-friendly products. “The traditional 1- to 1.2-g softgels will always have a leading place in the market, but there is a portion of those consumers that wants to take their omega-3s in a new way, which may include wanting to take a small capsule, only taking one pill per day, not taking pills period, preferring a chewable form, or even a more solid tablet like their multis,” Ismail said. “These are all things that generally did not have solutions five to seven years ago.”

Bigger doesn't always equal better, and that is proving to be the case with omega-3 capsules and softgels. Smaller pills with more concentrated doses are continuing to find increased favor among consumers. For the last two decades, BASF has worked to perfect and deliver highly concentrated omega-3 and omega-6 oils that are marked by a high degree of purity. The company's Crystalpure™ technology is rooted in low-temperature fractionation technology that enables feedstock to be concentrated in its natural triglyceride (TG) form at up to 75-percent PUFA (polyunsaturated fatty acids) in botanicals and about 50-percent PUFA in fish oils.

“The process involves cooling the feedstock so that unwanted fractions, including most saturates and monosaturates, are greatly reduced, leaving a product rich in potent polyunsaturates,” said Nina Osten, global communications Nutrition & Health, BASF SE. “The TG [triglyceride] form is particularly suitable for food and nutritional applications, as it is very stable. Crystalpure oils hold cGMP [current GMP] accreditation and can therefore be used in pharma-grade products, including medical food.”

New and emerging dosing formats have made the well-publicized health benefits of omega-3 even more appealing to health-conscious consumers. “The delivery of omega-3 ingredients is increasingly moving away from traditional capsules toward more palatable and on-the-go formats, such as single-shot sachet servings and flavored gummies and chewables,” said Sarah Chisholm, marketing coordinator, Health Care, Croda Europe. “These delivery formats are popular thanks to improved taste and convenience,

The traditional
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place in the market.



IN THIS ISSUE

Viewpoint p. 3

Softgel Through the Years p. 11

Table of Contents p. 2



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resulting in demand for fish oil concentrates that provide a high dose of omega-3 while offering appealing organoleptic qualities.”

Chisholm said Croda’s proprietary PureMax™ technology not only results in fish oil concentrates with high organoleptic and stability profiles, it also takes into account the increasing concern surrounding the environmental impact of omega-3 ingredients. “PureMax uses Croda’s proprietary technology to concentrate and purify omega-3 fish oil concentrates to exacting standards by using multiple distillation steps,” she said. “PureMax technology provides ultra-high vacuum and short residence times in order to maintain the integrity of the oil [and minimize] a wide variety of contaminants including oxidative impurities, dioxins and furans, PCBs, dioxin-like PCBs, heavy metals and polyaromatic hydrocarbons.”

Developments in the super refining and steam deodorization steps that partly constitute the PureMax process have also enabled Croda to minimize the odor and taste associated with fish oils, making its Incromega™ fish oil concentrates suitable for a wide variety of applications beyond capsules, and also leading to increased shelf-life.

To meet the consumer need for an alternative to capsules, Croda developed Incromega 3mulsion DHA, a highly concentrated, natural, lemon-flavored emulsion that is convenient for sachet or syrup applications and ideal for delivering omega-3 to children because they can get a full recommended daily intake in just one sachet or spoon serving. “The new ‘all natural’ version of Incromega 3mulsion does not contain artificial colors, flavors or emulsifiers, and its great taste and lack of fish reflux improves compliance with children,” Chisholm said. Croda also carries Incromega DHA500TG, a DHA-rich fish oil concentrate that works well in chewable omega-3 product formats.

Beverages with Benefits

Among the most remarkable recent innovations in omega-3 formulating have been the processing advancements paving the way for their use in beverage applications, especially in clear beverages. “The lifetime of EPA and DHA is impacted dramatically by the presence of air and/or trace metals that can act as oxidizing agents,” said Bruce Lipshutz, Ph.D., co-founder and chief scientific officer,

Mycell Technologies and Oceans Omega. “Thus, while dissolution of omega-3s into water can follow several pathways (e.g., microencapsulation, nanoparticle emulsions, etc.), it is the stabilization of these solutions that dictate all of the features alluded to in this question: shelf-life, taste and cost. In other words, they all go together; solve the stability issue and reap the benefits from control of all.”



IN THIS ISSUE

Viewpoint p. 3

Softgel Through the Years p. 11

Table of Contents p. 2

Oceans Omega, a wholly-owned subsidiary of Mycell, created a patent-pending, aqueous-friendly omega-3 solution that delivers both solubilization and stabilization for formulators hoping to add omega-3s to stabilized liquid solutions. The nanoparticle technology also delivers maximum bioavailability and minimizes cost.

“The technology invokes an ‘inside-outside’ approach, where a cocktail of stabilizing agents positioned both within the nanoparticles, where the omega-3s are situated, as well as in the surrounding water, combine to protect the ingredient from oxidation, thereby allowing for production of a concentrated aqueous emulsion that can be added to beverages, or other water-based products, adding months of shelf-life to each,” Lipshutz explained.

Achieving omega-3 stabilization affords a wider berth to beverage applications that also require longer shelf-lives. “Never-before-seen products, such as enhanced waters that offer not only water-soluble ingredients such as vitamins, but now include omega-3s, have come to market,” Lipshutz said. “Product examples include omega-3 supplement shots and fortified gelatins that will augment the intake of omega-3s in ways that are appealing to the average consumer.”



Company Profile



Qualitas Health develops high-value vegetarian food supplements and pharmaceutical ingredients based on microalgae. With deep experience and expertise in algae cultivation and extraction gained from the biofuels sector, Qualitas has developed a unique and proprietary technology for strain selection, sustainable algae farming, harvesting and oil processing. This allows for the effective production of proprietary premium omega-3 algae oil for a wide range of applications.

Qualitas' flagship product is Almeqa PL™, a vegetarian, EPA-rich, polar lipid-structured omega-3 oil. Sourced from a researched strain of microalgae selected for its high level of EPA omega-3 and unique polar-lipid structure, Almeqa PL contains omega-3 fatty acids conjugated with phospholipids and glycolipids that provide superior absorption and digestibility. Almeqa PL's special molecular structure has been clinically shown on a gram-per-gram basis to offer better omega-3 bioavailability than krill oil.

Almeqa PL's attributes include:

Source — Almeqa PL is composed of a non-GMO strain of algae, providing a vegetarian source of omega-3 LC-PUFAs.

Composition — Almeqa PL contains polar lipids—phospholipids and glycolipids. This chemical structure improves bioavailability and provides a premium product.

Sustainability — Almeqa PL does not disrupt the delicate marine eco-system. The algae are grown in the deserts of Texas, where sunlight is the main energy input.

qualitas-health.com
432-242-4620 ext. 105

Oceans Omega's technology also plays well in combination products that couple omega-3s together with other healthy ingredients, such as coenzyme Q10 (CoQ10). The additional ingredients can be solubilized either within the same nanoparticles or in the water at room temperature.

Innovations on the Horizon

Despite all of the technological leaps and bounds achieved in recent years, industry insiders maintain the best is likely still yet to come.

Ismail said he was encouraged by a recent presentation he saw pertaining to a pharmaceutical that used monoglyceride forms of EPA, docosapentaenoic acid (DPA) and DHA to target specific types of cancers. "It is not really a traditional nutraceutical delivery, but I think technologies that help selectively deliver omega-3s to specific areas are really exciting," he said. "There are other technologies that are trying to do something similar, though, like using liposomes or nanoencapsulation to achieve a similar goal.

"These are really third- or fourth-generation technologies, so they may still be a few years from gaining a real foothold in the market, but are exciting nonetheless," he continued. "I also hope some of the technologies that are being used to solubilize omega-3s help the fortified food category gain more of a mainstream foothold."

While Ismail admitted he was underwhelmed by the current lack of "blockbuster" omega-3 foods on the market, he hoped advances in formulating and delivery technologies would stimulate new avenues of opportunity. "Having more technologies to deliver omega-3s in foods will help get consumers used to seeing omega-3s in beverages and other formats that [they] are not used to yet," he said.

NDI's Rowe specifically singled out encapsulation techniques, delivery mechanisms, antioxidant technologies, flavor profiles, and flavoring capabilities as the key contributors to future industry innovations.

"Companies continue to look for new technologies and innovative ways to formulate products so that they are both safe and efficacious for consumers and so that they are cost-effective," he said. "Advancements in encapsulation and antioxidant technologies assist companies in overcoming challenges with shelf-life and stability [while] the palatability of both encapsulated and liquid oils continues to improve and enables companies to offer unique product classes such as gummies and other chewables that are more appealing to consumers of all ages." □

Joanna Cosgrove is a freelance writer who has been covering the exciting and dynamic facets of the dietary supplement and functional food and beverage industries for more than 15 years. Her work has appeared in a variety of respected industry publications.

IN THIS ISSUE

[Viewpoint](#) p. 3

[Softgel Through the Years](#) p. 11

[Table of Contents](#) p. 2



Softgels Through the Years: A Technological History

by Terri Albert

Eighty years ago, Robert Pauli Scherer invented a process for making softgels that has since become the industry standard. Softgels serve as an ideal delivery format for omega-3 products, as softgels are designed to contain liquids, as well as protect them from the atmosphere. This is particularly important for oxidation-sensitive products such as omega-3 oils. Typically based on gelatin, many developments and improvements have been made to softgels through the years, with vegetarian alternatives now available, as well as versions with modified delivery profiles.

Softgels represent a significant improvement upon the traditional spoonful of cod liver oil, particularly in protecting the oil from the environment. These oils gradually go rancid with increased exposure to oxygen, imparting an undesirable fishy taste. Enclosing the oil within a protective casing, and adding an antioxidant such as alpha-tocopherol pre-encapsulation to further prevent oxidation, make a huge difference in palatability.

The capsules are made via a form–fill–seal process, with two flat ribbons of the gel material being made in situ [in their respective places]. These are brought together between two rotating dies with indentations that are the size and shape required for the capsules, and then cut, sealed and filled with the liquid contents by injection through a nozzle.



Cod liver oils gradually go rancid with increased exposure to oxygen, imparting an undesirable fishy taste.



IN THIS ISSUE

New Technologies p. 4

Contacts p. 16

Table of Contents p. 2

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Care must be taken in determining the best materials to create the softgels. The capsule should have an oxygen permeability below 5 ml/m²/d at room temperature and 30 percent humidity. The thickness of the ribbon used to make the capsules must be sufficiently thick to prevent oxygen permeation, but not so thick that the capsules are difficult to form, or material costs become excessive.

Historically, bovine gelatin was the basis of the ribbons used to make the softgels; but, in light of the BSE [bovine spongiform encephalopathy, or mad cow disease] scare a quarter of a century ago, alternatives were sought. Many countries now have restrictions on what parts of a cow can be used to make products for human consumption; the skin has become the predominant source of gelatin used in softgels because it does not contain any of the potentially risky tissue.

Another animal source of gelatin is pigskin, but it cannot be consumed by those requiring a kosher or halal diet. Fishskin is also used to make gelatin; however, it is substantially more expensive than gelatin sourced from either cows or pigs.

In the past couple of decades, softgels based on materials not derived from animals have been developed. The most common ingredient combination includes a seaweed-derived hydrocolloid, carrageenan, along with a starch from a vegetable source, such as potato or corn. Catalent's vegetarian softgels, for example, utilize iota-carrageenan and a corn starch.

These carrageenan-based omega-3 softgels are becoming more popular. Already widespread in southeast Asia, there is now a good deal of data about their long-term stability and performance. The shelf-life under correct storage conditions, for example, is more than three years, and they can be stored, handled, packaged and transported in exactly the same way as traditional gelatin capsules, with no detrimental effects.

Another development in the softgel field is the ability to modify delivery performance by adding an enteric coating. Applied around the outside of the capsule, this layer helps control in which area of the digestive system the coating will dissolve. Typically, the coating is stable in the highly acidic environment of the stomach, but at the higher alkaline environment in the small intestine, it will dissolve. This enables the capsule to pass through the stomach intact, not starting to disintegrate until it reaches the intestines.



SOFTGEL

technology invented
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However, in recent
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IN THIS ISSUE

New Technologies p. 4

Contacts p. 16

Table of Contents p. 2

Enteric coatings are advantageous for omega-3 softgels because if the oil is not released in the stomach, there is much less chance of reflux. Even modern deodorized fish-derived oils can result in a slight fishy aftertaste after consumption, which is unpleasant. Ensuring the aftertaste does not occur—by ensuring the oil does not emerge from the softgel until the intestine—will aid in increasing consumer acceptance of the product.

An alternative technique for preventing the taste and unpleasantness of reflux is to modify the contents of the softgel. One way to do this is by creating an emulsified oil dispersion system. This can also increase the speed of the oil's absorption. Emulsifiers such as lecithin and polysorbate are used to create emulsions with a particle size distribution below 100 μm .



The chewable softgel format was developed in response to published scientific studies suggesting DHA and EPA might be beneficial in brain development and behavior in children.

The colloidal particles have greater bioavailability than the unemulsified oil. Another advantage is the ability to pierce these capsules to release the contents. The emulsified oils can then be dispersed in food or drink, enabling the product to be taken by the very young, old or infirm who find swallowing large softgels difficult.

Another alternative for these consumers comes in the form of a novel softgel type—chewable softgels. Demand for omega-3s increased after scientific studies were published suggesting docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) might be beneficial in brain development and behavior in children. This format was developed in response, being particularly suitable for consumption by the young.

Chewability is conferred by mixing gelatin with starch from sources such as potato or corn, resulting in a shell that is less strong than a standard softgel. Palatability is ensured by mixing the omega-3 oils inside the softgel with oil-based flavoring and taste-masking agents, and carriers



IN THIS ISSUE

[New Technologies](#) p. 4

[Contacts](#) p. 16

[Table of Contents](#) p. 2

such as silica to confer a pleasant texture. The weaker shell starts to dissolve when it is chewed, releasing the oil. The thinner ribbon does pose manufacturing challenges in terms of achieving the optimum balance between robustness when being run through the machinery to make softgels, and the ability to disintegrate on chewing. Such capsules also require particularly careful packing and handling, as they are more delicate than their traditional cousins.

Softgels can also be printed, using a process originally developed to add identification marks in the manufacture of pharmaceutical products. Although this does not alter the softgels' delivery properties, it does offer potential in marketing. The ribbons can be printed in line using food-grade inks, whether with logos, pictures or identification codes. Pictures can make the products more appealing to children, while clear markings can be invaluable in creating more identifiable products for the elderly.

Although the original softgel manufacturing process is 80 years old, the field is far from static. New and improved forms continue to be researched and developed, many of which are applicable to consumer products such as omega-3s. By applying the latest technology, omega-3 suppliers can differentiate their products in a crowded market, offering consumers products that not only meet their dietary needs, but are easier and more pleasant to take. □

Terri Albert is director, global complementary medicines & technology, consumer softgel, for [Catalent Pharma Solutions](#).



IN THIS ISSUE

New Technologies p. 4

Contacts p. 16

Table of Contents p. 2

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